



*National Institute for
Health and Clinical Excellence*

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Lung cancer

**The diagnosis and treatment of lung
cancer**

NICE clinical guideline 121

Developed by the National Collaborating Centre for Cancer

NICE clinical guideline 121

Lung cancer: the diagnosis and treatment of lung cancer

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You can download the following documents from

www.nice.org.uk/guidance/CG121

- The NICE guideline (this document) – all the recommendations.
- A quick reference guide – a summary of the recommendations for healthcare professionals.
- ‘Understanding NICE guidance’ – a summary for patients and carers.
- The full guideline – all the recommendations, details of how they were developed, and reviews of the evidence they were based on.

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- N2502 (quick reference guide)
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This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering.

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NHS Evidence has accredited the process used by the Centre for Clinical Practice at NICE to produce guidelines. Accreditation is valid for 3 years from April 2010 and is applicable to guidance produced using the processes described in NICE's 'The guidelines manual' (2009). More information on accreditation can be viewed at www.evidence.nhs.uk

This guidance updates and replaces NICE clinical guideline 24 (published February 2005).

New and updated recommendations are included on communication, diagnosis and staging, selection of patients with non-small-cell lung cancer (NSCLC) for treatment with curative intent, surgery with curative intent for NSCLC, smoking cessation, combination treatment for NSCLC, treatment for small-cell lung cancer (SCLC), managing endobronchial obstruction, managing brain metastases, and follow-up and patient perspectives.

Recommendations are marked as **[2005]**, **[2011]** or **[new 2011]**.

- **[2005]** indicates that the evidence has not been updated and reviewed since 2005.
- **[2011]** indicates that the evidence has been reviewed but no changes have been made to the recommendation.
- **[new 2011]** indicates that the evidence has been reviewed and the recommendation has been added or updated.

Since publication of NICE clinical guideline 24 in 2005, a number of new systemic therapies have been granted a marketing authorisation by the European Medicines Agency for use in people with NSCLC. NICE has published technology appraisals for pemetrexed, gefitinib and erlotinib. Other technology appraisals are in development.

The NHS has also commissioned a review of first-line therapy for NSCLC through the NIHR Health Technology Assessment Programme. This review is due to be published in 2011.

Introduction

There are more than 39,000 new cases of lung cancer in the UK each year and more than 35,000 people die from the condition; more than for breast cancer and colorectal cancer combined. Lung cancer is now the leading cause of cancer death in women.

About 90% of lung cancers are caused by smoking. Now that fewer men smoke, lung cancer deaths in men have decreased by more than a quarter in the UK (a 27% reduction between 1971 and 2006). However, the number of women who smoke has risen and deaths from lung cancer in women have increased.

Only about 5.5% of lung cancers are currently cured. Although the cure rate is rising slowly, the rate of improvement has been slower than for other common cancers. Outcomes in the UK are worse than those in some European countries and North America. There is evidence that outcomes vary within the UK, which – among other factors – may be explained by variations in the standard of care.

This updated guideline provides recommendations for good practice in the diagnosis and treatment of non-small-cell (NSCLC) and small-cell lung cancer (SCLC).

The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

Patient-centred care

This guideline offers best practice advice on the care of adults with lung cancer.

Treatment and care should take into account patients' needs and preferences. People with lung cancer should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If patients do not have the capacity to make decisions, healthcare professionals should follow the Department of Health's advice on consent (available from www.dh.gov.uk/consent) and the code of practice that accompanies the Mental Capacity Act (summary available from www.publicguardian.gov.uk). In Wales, healthcare professionals should follow advice on consent from the Welsh Assembly Government (available from www.wales.nhs.uk/consent).

Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's needs. Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

If the patient agrees, families and carers should have the opportunity to be involved in decisions about treatment and care.

Families and carers should also be given the information and support they need.

Key priorities for implementation

The following recommendations have been identified as priorities for implementation.

The importance of early diagnosis

- The public needs to be better informed of the symptoms and signs that are characteristic of lung cancer, through coordinated campaigning to raise awareness. **[2005]**

Communication

- Ensure that a lung cancer clinical nurse specialist is available at all stages of care to support patients and carers. **[new 2011]**

Diagnosis and staging

- Choose investigations that give the most information about diagnosis and staging with the least risk to the patient. Think carefully before performing a test that gives only diagnostic pathology when information on staging is also needed to guide treatment. **[new 2011]**
- Offer PET-CT, or EBUS-guided TBNA, or EUS-guided FNA, or non-ultrasound-guided TBNA as the first test for patients with an **intermediate probability of mediastinal malignancy** (lymph nodes between 10 and 20 mm maximum short axis on CT) who are potentially suitable for treatment with curative intent. **[new 2011]**

Surgery with curative intent for non-small-cell lung cancer

- Offer patients with NSCLC who are medically fit and suitable for treatment with curative intent, lobectomy (either open or thoracoscopic) as the treatment of first choice. For patients with borderline fitness and smaller tumours (T1a–b, N0, M0), consider lung parenchymal-sparing operations (segmentectomy or wedge resection) if a complete resection can be achieved. **[new 2011]**

Radiotherapy with curative intent for non-small-cell lung cancer

- Radical radiotherapy is indicated for patients with stage I, II or III NSCLC who have good performance status (WHO 0, 1) and whose disease can be

encompassed in a radiotherapy treatment volume without undue risk of normal tissue damage¹. **[2005]**

Combination treatment for non-small-cell lung cancer

- Ensure all patients potentially suitable for multimodality treatment (surgery, radiotherapy and chemotherapy in any combination) are assessed by a thoracic oncologist and by a thoracic surgeon. **[new 2011]**

Assessing patients with small-cell lung cancer

- Arrange for patients with small-cell lung cancer (SCLC) to have an assessment by a thoracic oncologist within 1 week of deciding to recommend treatment. **[new 2011]**

Managing endobronchial obstruction

- Every cancer network should ensure that patients have rapid access to a team capable of providing interventional endobronchial treatments. **[new 2011]**

Follow-up and patient perspectives

- Offer all patients an initial specialist follow-up appointment within 6 weeks of completing treatment to discuss ongoing care. Offer regular appointments thereafter, rather than relying on patients requesting appointments when they experience symptoms. **[new 2011]**

¹ The GDG recognised that radiotherapy techniques have advanced considerably since the 2005 guideline and centres would reasonably wish to offer these techniques (including SBRT and 4-D planning) to patients. These treatments have the advantage of reducing the risk of damage to normal tissue (estimated by using measurements such as V20).

1 Guidance

The following guidance is based on the best available evidence. The full guideline (www.nice.org.uk/guidance/CG121) gives details of the methods and the evidence used to develop the guidance.

Some of the abbreviations used in this guidance are defined below.

EBUS – endobronchial ultrasound

EUS – endoscopic ultrasound

FNA – fine needle aspiration

TBNA – transbronchial needle aspiration.

1.1 Access to services and referral

The importance of early diagnosis

- 1.1.1 The public needs to be better informed of the symptoms and signs that are characteristic of lung cancer, through coordinated campaigning to raise awareness. **[2005]**

Referral and indications for chest radiography

- 1.1.2 Urgent referral for a chest X-ray should be offered when a patient presents with:

- haemoptysis, or
- any of the following unexplained or **persistent** (that is, lasting more than 3 weeks) symptoms or signs:
 - cough
 - chest/shoulder pain
 - dyspnoea
 - weight loss
 - chest signs
 - hoarseness
 - finger clubbing
 - features suggestive of metastasis from a lung cancer (for example, in brain, bone, liver or skin)
 - cervical/supraclavicular lymphadenopathy. **[2005]**

- 1.1.3 If a chest X-ray or chest computed tomography (CT) scan suggests lung cancer (including pleural effusion and slowly resolving consolidation), patients should be offered an urgent referral to a member of the lung cancer multidisciplinary team (MDT), usually a chest physician. **[2005]**
- 1.1.4 If the chest X-ray is normal but there is a high suspicion of lung cancer, patients should be offered urgent referral to a member of the lung cancer MDT, usually the chest physician. **[2005]**
- 1.1.5 Patients should be offered an urgent referral to a member of the lung cancer MDT, usually the chest physician, while awaiting the result of a chest X-ray, if any of the following are present:
- persistent haemoptysis in smokers/ex-smokers older than 40 years
 - signs of superior vena cava obstruction (swelling of the face/neck with fixed elevation of jugular venous pressure)
 - stridor. **[2005]**
- 1.1.6 Where a chest X-ray has been requested in primary or secondary care and is incidentally suggestive of lung cancer, a second copy of the radiologist's report should be sent to a designated member of the lung cancer MDT, usually the chest physician. The MDT should have a mechanism in place to follow up these reports to enable the patient's GP to have a management plan in place. **[2005]**

1.2 ***Communication***

- 1.2.1 Find out what the patient knows about their condition without assuming a level of knowledge. Provide patients with the opportunity to discuss tests and treatment options in a private environment, with the support of carers, and time to make an informed choice. **[new 2011]**
- 1.2.2 Ensure that a lung cancer clinical nurse specialist is available at all stages of care to support patients and carers. **[new 2011]**

- 1.2.3 Offer accurate and easy-to-understand information to patients and their carers. Explain the tests and treatment options, including potential survival benefits, side effects and effect on symptoms. **[new 2011]**
- 1.2.4 Consider tailor-made decision aids to help patients to:
- understand the probable outcomes of treatment options
 - consider the personal value they place on benefits versus harms of treatment options
 - feel supported in decision-making
 - move through the steps towards making a decision
 - take part in decisions about their healthcare. **[new 2011]**
- 1.2.5 Offer patients a record of all discussions that have taken place with them and a copy of any correspondence with other healthcare professionals. Ensure all communications are worded in such a way to assist understanding. **[new 2011]**
- 1.2.6 Respect the patient's choice if they do not wish to confront future issues. **[new 2011]**
- 1.2.7 Avoid giving patients unexpected bad news by letter. Only give unexpected bad news by phone in exceptional circumstances. **[new 2011]**
- 1.2.8 Offer to discuss end-of-life care with the patient sensitively and when appropriate. Wherever possible, avoid leaving this discussion until the terminal stages of the illness. **[new 2011]**
- 1.2.9 Document discussions with the patient about end-of-life care. In particular, document:
- specific concerns of the patient
 - their understanding of their illness and its prognosis
 - important values or personal goals for care

- their preferences for the types of care or treatment that may be beneficial in the future and their availability. **[new 2011]**

1.2.10 Share information between healthcare professionals about:

- any problems the patient has
- the management plan
- what the patient has been told
- what the patient has understood (where possible)
- the involvement of other agencies
- any advance decision made by the patient. **[new 2011]**

1.3 *Diagnosis and staging*

Effectiveness of diagnostic and staging investigations

- 1.3.1 Sputum cytology is rarely indicated and should be reserved for the investigation of patients who have centrally placed nodules or masses and are unable to tolerate, or unwilling to undergo, bronchoscopy or other invasive tests. **[2005]**
- 1.3.2 Patients with known or suspected lung cancer should be offered a contrast-enhanced chest CT scan to further the diagnosis and stage the disease. The scan should also include the liver and adrenals². **[2005]**
- 1.3.3 In the assessment of mediastinal and chest wall invasion:
- CT alone may not be reliable
 - other techniques such as ultrasound should be considered where there is doubt
 - surgical assessment may be necessary if there are no contraindications to resection. **[2005]**

² This recommendation was outside the scope of the 2011 update but the GDG recognised that many centres include the lower neck when performing CT scans for the diagnosis of lung cancer. The GDG also recognised that contrast medium should only be given with caution to patients with known renal impairment.

- 1.3.4 Ensure all patients potentially suitable for treatment with curative intent are offered PET-CT before treatment. **[new 2011]**
- 1.3.5 Every cancer network should have a system of rapid access to PET-CT scanning for eligible patients. **[2005]**
- 1.3.6 Magnetic resonance imaging (MRI) should not routinely be performed to assess the stage of the primary tumour (T-stage) in NSCLC. **[2005]**
- 1.3.7 MRI should be performed, where necessary to assess the extent of disease, for patients with superior sulcus tumours. **[2005]**
- 1.3.8 Offer EBUS-guided TBNA for biopsy of paratracheal and peri-bronchial intra-parenchymal lung lesions. **[new 2011]**
- 1.3.9 Every cancer network should have at least one centre with EBUS and/or EUS to ensure timely access. **[new 2011]**
- 1.3.10 The local test performance of non-ultrasound-guided TBNA, EBUS and EUS-guided FNA should be the subject of audit. **[new 2011]**
- 1.3.11 Ensure adequate samples are taken without unacceptable risk to the patient to permit pathological diagnosis including tumour sub-typing and measurement of predictive markers. **[new 2011]**

Sequence of investigations

- 1.3.12 Choose investigations that give the most information about diagnosis and staging with least risk to the patient. Think carefully before performing a test that gives only diagnostic pathology when information on staging is also needed to guide treatment. **[new 2011]**
- 1.3.13 Chest CT should be performed before:
- an intended fiberoptic bronchoscopy
 - any other biopsy procedure. **[2005]**

Peripheral primary tumour

- 1.3.14 Offer CT- or ultrasound-guided transthoracic needle biopsy to patients with peripheral lung lesions when treatment can be planned on the basis of this test. **[new 2011]**
- 1.3.15 Biopsy any enlarged mediastinal nodes (≥ 10 mm maximum short axis on CT) or other lesions in preference to the primary lesion if determination of stage affects treatment³. **[new 2011]**

Central primary tumour

- 1.3.16 Offer fiberoptic bronchoscopy to patients with central lesions on CT where nodal staging does not influence treatment. Enlarged lymph nodes (≥ 10 mm maximum short axis on CT) may be simultaneously sampled with TBNA (non-ultrasound-guided) if required for diagnosis. **[new 2011]**

Mediastinal lymph node assessment

- 1.3.17 Offer PET-CT as the preferred first test after CT showing a **low probability of mediastinal malignancy** (lymph nodes < 10 mm maximum short axis on CT) for patients who are potentially suitable for treatment with curative intent. **[new 2011]**
- 1.3.18 Offer PET-CT, or EBUS-guided TBNA, or EUS-guided FNA, or non-ultrasound-guided TBNA as the first test for patients with an **intermediate probability of mediastinal malignancy** (lymph nodes between 10 and 20 mm maximum short axis on CT) who are potentially suitable for treatment with curative intent. **[new 2011]**
- 1.3.19 Offer neck ultrasound with sampling of visible lymph nodes or non-ultrasound-guided TBNA to patients with a **high probability of mediastinal malignancy** (lymph nodes > 20 mm maximum short axis on CT). If neck ultrasound is negative, follow with non-ultrasound-guided TBNA, EBUS-guided TBNA or EUS-guided

³ Many patients with lung cancer will not be fit for treatment with curative intent. This needs to be taken into account when choosing diagnostic and staging investigations.

FNA. If non-ultrasound-guided TBNA is negative follow with EBUS-guided TBNA or EUS-guided FNA. **[new 2011]**

- 1.3.20 Offer neck ultrasound with biopsy of visible lymph nodes to patients that have neck nodes detected by initial CT. If negative, follow with non-ultrasound-guided TBNA or EBUS-guided TBNA or EUS-guided FNA. **[new 2011]**
- 1.3.21 Evaluate PET-CT-positive mediastinal nodes by mediastinal sampling (except when there is definite distant metastatic disease or a high probability that N2/N3 disease is metastatic [for example, if there is a chain of lymph nodes with high ¹⁸F-deoxyglucose uptake]). **[new 2011]**
- 1.3.22 Consider combined EBUS and EUS for initial staging of the mediastinum as an alternative to surgical staging. **[new 2011]**
- 1.3.23 Confirm negative results obtained by non-ultrasound-guided TBNA using EBUS-guided TBNA, EUS-guided FNA or surgical staging. **[new 2011]**
- 1.3.24 Confirm negative results obtained by EBUS-guided TBNA and/or EUS-guided FNA using surgical staging if clinical suspicion of mediastinal malignancy is high. **[new 2011]**

Stage M1b

- 1.3.25 Confirm the presence of isolated distant metastases/synchronous tumours by biopsy or further imaging (for example, MRI or PET-CT) in patients being considered for treatment with curative intent. **[new 2011]**
- 1.3.26 Consider MRI or CT of the head in patients selected for treatment with curative intent, especially in stage III disease. **[new 2011]**
- 1.3.27 Offer patients with features suggestive of intracranial pathology, CT of the head followed by MRI if normal, or MRI as an initial test. **[new 2011]**

- 1.3.28 An X-ray should be performed in the first instance for patients with localised signs or symptoms of bone metastasis. If the results are negative or inconclusive, either a bone scan or an MRI scan should be offered. **[2005]**
- 1.3.29 Avoid bone scintigraphy when PET-CT has not shown bone metastases. **[new 2011]**

Organisational factors relevant to diagnosis and staging

- 1.3.30 Patients who have lung cancer suitable for radical treatment or chemotherapy, or need radiotherapy or ablative treatment for relief of symptoms, should be treated without undue delay, according to the Welsh Assembly Government and Department of Health recommendations (within 31 days of the decision to treat and within 62 days of their urgent referral). **[2005]**

Multidisciplinary teams

- 1.3.31 All patients with a likely diagnosis of lung cancer should be referred to a member of a lung cancer MDT (usually a chest physician). **[2005]**
- 1.3.32 The care of all patients with a working diagnosis of lung cancer should be discussed at a lung cancer MDT meeting. **[2005]**

Rapid access lung clinics

- 1.3.33 Rapid access clinics⁴ should be provided where possible for the investigation of patients with suspected lung cancer, because they are associated with faster diagnosis and less patient anxiety. **[2005]**

Cancer clinical nurse specialists

- 1.3.34 All cancer units/centres should have one or more trained lung cancer clinical nurse specialists to see patients before and after diagnosis, to provide continuing support, and to facilitate communication between the secondary care team (including the MDT), the patient's GP, the community team and the patient. Their

⁴ These were previously known as early diagnosis clinics.

role includes helping patients to access advice and support whenever they need it. **[2005]**

1.4 Treatment

Smoking cessation

- 1.4.1 Inform patients that smoking increases the risk of pulmonary complications after lung cancer surgery. **[new 2011]**
- 1.4.2 Advise patients to stop smoking as soon as the diagnosis of lung cancer is suspected and tell them why this is important. **[new 2011]**
- 1.4.3 Offer nicotine replacement therapy and other therapies to help patients to stop smoking in line with 'Smoking cessation services' (NICE public health guidance 10) and 'Varenicline for smoking cessation' (NICE technology appraisal guidance 123). **[new 2011]**
- 1.4.4 Do not postpone surgery for lung cancer to allow patients to stop smoking. **[new 2011]**

Selection of patients with non-small-cell lung cancer for treatment with curative intent

Perioperative mortality

- 1.4.5 When evaluating surgery as an option for patients with NSCLC, consider using a global risk score such as Thoracoscore to estimate the risk of death. Ensure the patient is aware of the risk before giving consent for surgery. **[new 2011]**

Cardiovascular function

- 1.4.6 Avoid surgery within 30 days of myocardial infarction. **[new 2011]**
- 1.4.7 Seek a cardiology review in patients with an active cardiac condition, or three or more risk factors, or poor cardiac functional capacity. **[new 2011]**
- 1.4.8 Offer surgery without further investigations to patients with two or fewer risk factors and good cardiac functional capacity. **[new 2011]**

- 1.4.9 Optimise any primary cardiac treatment and begin secondary prophylaxis for coronary disease as soon as possible. **[new 2011]**
- 1.4.10 Continue anti-ischaemic treatment in the perioperative period, including aspirin, statins and beta-blockers. **[new 2011]**
- 1.4.11 If a patient has a coronary stent, discuss perioperative anti-platelet treatment with a cardiologist. **[new 2011]**
- 1.4.12 Consider revascularisation (percutaneous intervention or coronary artery bypass grafting) before surgery for patients with chronic stable angina and conventional indications for revascularisation. **[new 2011]**

Lung function

- 1.4.13 Perform spirometry in all patients being considered for treatment with curative intent. Measure T_LCO if breathlessness is disproportionate or there is other lung pathology (for example, lung fibrosis). **[new 2011]**
- 1.4.14 Offer patients surgery if they have an FEV_1 within normal limits and good exercise tolerance. **[new 2011]**
- 1.4.15 Offer patients with predicted postoperative FEV_1 or T_LCO below the recommended limit of 30% the option of undergoing surgery if they accept the risks of dyspnoea and associated complications. **[new 2011]**
- 1.4.16 When considering surgery perform a segment count to predict postoperative lung function. **[new 2011]**
- 1.4.17 Consider using shuttle walk testing (using a distance walked of more than 400 m as a cut-off for good function) to assess fitness of patients with moderate to high risk of postoperative dyspnoea. **[new 2011]**

- 1.4.18 Consider cardiopulmonary exercise testing to measure VO_2 max and assess lung function in patients with moderate to high risk of postoperative dyspnoea, using more than 15 ml/kg/minute as a cut-off for good function. **[new 2011]**

Assessment before radiotherapy with curative intent

- 1.4.19 A clinical oncologist specialising in thoracic oncology should determine suitability for radiotherapy with curative intent, taking into account performance status and comorbidities. **[new 2011]**

Surgery with curative intent for non-small-cell lung cancer

- 1.4.20 Offer patients with NSCLC who are medically fit and suitable for treatment with curative intent, lobectomy (either open or thoracoscopic) as the treatment of first choice. For patients with borderline fitness and smaller tumours (T1a–b, N0, M0), consider lung parenchymal-sparing operations (segmentectomy or wedge resection) if a complete resection can be achieved. **[new 2011]**
- 1.4.21 Offer more extensive surgery (bronchoangioplastic surgery, bilobectomy, pneumonectomy) only when needed to obtain clear margins. **[new 2011]**
- 1.4.22 Perform hilar and mediastinal lymph node sampling or en bloc resection for all patients undergoing surgery with curative intent. **[new 2011]**
- 1.4.23 For patients with T3 NSCLC with chest wall involvement who are undergoing surgery, complete resection of the tumour should be the aim by either extrapleural or en bloc chest wall resection. **[2005]**

Radiotherapy with curative intent for non-small-cell lung cancer

- 1.4.24 Radical radiotherapy is indicated for patients with stage I, II or III NSCLC who have good performance status (WHO 0, 1) and whose disease can be encompassed in a radiotherapy treatment volume without undue risk of normal tissue damage⁵. **[2005]**
- 1.4.25 All patients should undergo pulmonary function tests (including lung volumes and transfer factor) before having radical radiotherapy for NSCLC. **[2005]**
- 1.4.26 Patients who have poor lung function but are otherwise suitable for radical radiotherapy should still be offered radiotherapy, provided the volume of irradiated lung is small. **[2005]**
- 1.4.27 Patients with stage I or II NSCLC who are medically inoperable but suitable for radical radiotherapy should be offered the CHART regimen. **[2005]**
- 1.4.28 Patients receiving radiotherapy with curative intent should be part of a national quality assurance programme⁵. **[new 2011]**
- 1.4.29 Patients with stages IIIA or IIIB NSCLC who are eligible for radical radiotherapy and who cannot tolerate or do not wish to have chemoradiotherapy should be offered the CHART regimen. **[2005]**
- 1.4.30 If CHART is not available, conventionally fractionated radiotherapy to a dose of 64–66 Gy in 32–33 fractions over 6½ weeks or 55 Gy in 20 fractions over 4 weeks should be offered. **[2005]**

Combination treatment for non-small-cell lung cancer

- 1.4.31 Offer patients with stage I–III NSCLC who are not suitable for surgery an assessment by a clinical oncologist specialising in thoracic oncology for radiotherapy with curative intent. **[new 2011]**

⁵ The GDG recognised that radiotherapy techniques have advanced considerably since the 2005 guideline and centres would reasonably wish to offer these techniques (including SBRT and 4-D planning) to patients. These treatments have the advantage of reducing the risk of damage to normal tissue (estimated by using measurements such as V20).

- 1.4.32 Consider chemoradiotherapy for patients with stage II or III NSCLC who are not suitable for surgery. Balance potential benefit in survival with the risk of additional toxicities. **[new 2011]**
- 1.4.33 Ensure all patients potentially suitable for multimodality treatment (surgery, radiotherapy and chemotherapy in any combination) are assessed by a thoracic oncologist and by a thoracic surgeon. **[new 2011]**
- 1.4.34 Offer postoperative chemotherapy to patients with good performance status (WHO 0 or 1) and T1–3 N1–2 M0 NSCLC. **[new 2011]**
- 1.4.35 Consider postoperative chemotherapy in patients with good performance status (WHO 0 or 1) and T2–3 N0 M0 NSCLC with tumours greater than 4 cm in diameter. **[new 2011]**
- 1.4.36 Offer a cisplatin-based combination chemotherapy regimen for adjuvant chemotherapy. **[new 2011]**
- 1.4.37 For patients with NSCLC who are suitable for surgery, do not offer neo-adjuvant chemotherapy outside a clinical trial. **[new 2011]**
- 1.4.38 Ensure eligible patients have the benefit of detailed discussion of the risks and benefits of adjuvant chemotherapy. **[new 2011]**
- 1.4.39 Treat Pancoast tumours in the same way as other types of NSCLC. Offer multimodality therapy according to resectability, stage of the tumour and performance status of the patient. **[new 2011]**

Chemotherapy for non-small-cell lung cancer

- 1.4.40 Chemotherapy should be offered to patients with stage III or IV NSCLC and good performance status (WHO 0, 1 or a Karnofsky score of 80–100), to improve survival, disease control and quality of life. **[2005]**

- 1.4.41 Chemotherapy for advanced NSCLC should be a combination of a single third-generation drug (docetaxel, gemcitabine, paclitaxel or vinorelbine) plus a platinum drug. Either carboplatin or cisplatin may be administered, taking account of their toxicities, efficacy and convenience. **[2005]**
- 1.4.42 Patients who are unable to tolerate a platinum combination may be offered single-agent chemotherapy with a third-generation drug. **[2005]**
- 1.4.43 Docetaxel monotherapy should be considered if second-line treatment is appropriate for patients with locally advanced or metastatic NSCLC in whom relapse has occurred after previous chemotherapy. **[2005]**

Gefitinib

Refer to 'Gefitinib for the first-line treatment of locally advanced or metastatic non-small-cell lung cancer' (NICE technology appraisal guidance 192 **[2010]**), available at www.nice.org.uk/guidance/TA192

Pemetrexed

Refer to 'Pemetrexed for the first-line treatment of non-small-cell lung cancer' (NICE technology appraisal guidance 181 **[2010]**), available at www.nice.org.uk/guidance/TA181

Erlotinib

Refer to 'Erlotinib for the treatment of non-small-cell lung cancer' (NICE technology appraisal guidance 162 **[2008]**), available at www.nice.org.uk/guidance/TA162

Assessing patients with small-cell lung cancer

- 1.4.44 Arrange for patients with small-cell lung cancer (SCLC) to have an assessment by a thoracic oncologist within 1 week of deciding to recommend treatment. **[new 2011]**

First-line treatment for limited-stage disease small-cell lung cancer

- 1.4.45 Offer patients with limited-stage disease SCLC (broadly corresponding to T1–4, N0–3, M0) four to six cycles of cisplatin-based combination chemotherapy. Consider substituting carboplatin in patients with impaired renal function, poor performance status (WHO 2 or more) or significant comorbidity. **[new 2011]**
- 1.4.46 Offer concurrent chemoradiotherapy to patients with limited-stage disease SCLC (broadly corresponding to T1–4, N0–3, M0) and a WHO performance status of 0 or 1 if they present with disease that can be encompassed in a radical thoracic radiotherapy volume. Start the radiotherapy during the first or second cycle of chemotherapy. **[new 2011]**
- 1.4.47 Offer sequential radical thoracic radiotherapy to patients with limited-stage disease SCLC (broadly corresponding to T1–4, N0–3, M0) who are unfit for concurrent chemoradiotherapy but who respond to chemotherapy. **[new 2011]**

Surgical treatment for patients with small-cell lung cancer

- 1.4.48 Consider surgery in patients with early-stage SCLC (T1–2a, N0, M0). **[new 2011]**

First-line treatment for extensive-stage disease small-cell lung cancer

- 1.4.49 Offer platinum-based combination chemotherapy to patients with extensive-stage disease SCLC (broadly corresponding to T1–4, N0–3, M1a/b – including cerebral metastases) if they are fit enough. **[new 2011]**
- 1.4.50 Assess the patient's condition before each cycle of chemotherapy for extensive-stage disease SCLC (broadly corresponding to T1–4, N0–3, M1a/b) and offer up to a maximum of six cycles, depending on response and toxicity. **[new 2011]**

- 1.4.51 For patients with extensive-stage disease SCLC, thoracic radiotherapy should be considered after chemotherapy if there has been a complete response at distant sites and at least a good partial response within the thorax. **[new 2011]**

Maintenance treatment for small-cell lung cancer

- 1.4.52 Offer maintenance treatment to patients with SCLC only in the context of a clinical trial. **[new 2011]**

Prophylactic cranial irradiation in small-cell lung cancer

- 1.4.53 Offer prophylactic cranial irradiation at a dose of 25 Gy in 10 fractions to patients with limited-stage disease SCLC and WHO performance status 2 or less, if their disease has not progressed on first-line treatment. **[new 2011]**
- 1.4.54 Offer prophylactic cranial irradiation to patients with extensive-stage disease SCLC and WHO performance status 2 or less, if their disease has not progressed on first-line treatment. **[new 2011]**

Second-line treatment for patients with small-cell lung cancer that has relapsed after first-line treatment

- 1.4.55 Offer patients with SCLC that has relapsed after first-line treatment assessment by a thoracic oncologist. **[new 2011]**
- 1.4.56 Inform patients whose disease has not responded to first-line treatment that there is very limited evidence that second-line chemotherapy will be of benefit. **[new 2011]**
- 1.4.57 Offer patients with relapsed SCLC, who are suitable for chemotherapy, treatment with an anthracycline-containing regimen or further treatment with a platinum-based regimen to a maximum of six cycles. **[new 2011]**
- 1.4.58 Offer radiotherapy for palliation of local symptoms to patients with SCLC that has relapsed after first-line treatment. **[new 2011]**

Topotecan

Refer to 'Topotecan for the treatment of small-cell lung cancer' (NICE technology appraisal guidance 184 [2009]), available at www.nice.org.uk/guidance/TA184

1.5 Palliative interventions and supportive and palliative care

Providing palliative care

- 1.5.1 Supportive and palliative care of the patient should be provided by general and specialist palliative care providers in accordance with the NICE guidance 'Improving supportive and palliative care for adults with cancer'. [2005]
- 1.5.2 Patients who may benefit from specialist palliative care services should be identified and referred without delay. [2005]

Palliative radiotherapy

- 1.5.3 Patients who cannot be offered curative treatment, and are candidates for palliative radiotherapy, may either be observed until symptoms arise and then treated, or be treated with palliative radiotherapy immediately. [2005]

Managing endobronchial obstruction

- 1.5.4 When patients have large airway involvement, monitor (clinically and radiologically) for endobronchial obstruction to ensure treatment is offered early. [new 2011]
- 1.5.5 Offer external beam radiotherapy and/or endobronchial debulking or stenting to patients with impending endobronchial obstruction. [new 2011]
- 1.5.6 Every cancer network should ensure that patients have rapid access to a team capable of providing interventional endobronchial treatments. [new 2011]

Other palliative treatments

- 1.5.7 Pleural aspiration or drainage should be performed in an attempt to relieve the symptoms of a pleural effusion. **[2005]**
- 1.5.8 Patients who benefit symptomatically from aspiration or drainage of fluid should be offered talc pleurodesis for longer-term benefit. **[2005]**
- 1.5.9 Non-drug interventions based on psychosocial support, breathing control and coping strategies should be considered for patients with breathlessness. **[2005]**
- 1.5.10 Non-drug interventions for breathlessness should be delivered by a multidisciplinary group, coordinated by a professional with an interest in breathlessness and expertise in the techniques (for example, a nurse, physiotherapist or occupational therapist). Although this support may be provided in a breathlessness clinic, patients should have access to it in all care settings. **[2005]**
- 1.5.11 Opioids, such as codeine or morphine, should be considered to reduce cough. **[2005]**
- 1.5.12 Patients with troublesome hoarseness due to recurrent laryngeal nerve palsy should be referred to an ear, nose and throat specialist for advice. **[2005]**
- 1.5.13 Patients who present with superior vena cava obstruction should be offered chemotherapy and radiotherapy according to the stage of disease and performance status. **[2005]**
- 1.5.14 Stent insertion should be considered for the immediate relief of severe symptoms of superior vena caval obstruction or following failure of earlier treatment. **[2005]**

Managing brain metastases

- 1.5.15 Offer dexamethasone to patients with symptomatic brain metastases and reduce to the minimum necessary maintenance dose for symptomatic response. **[new 2011]**

- 1.5.16 Consider palliative whole-brain radiotherapy for patients with symptomatic brain metastases with good performance status (WHO 0 or 1). **[new 2011]**

Hypercalcaemia, bone pain and pathological fractures

- 1.5.17 For patients with bone metastasis requiring palliation and for whom standard analgesic treatments are inadequate, single-fraction radiotherapy should be administered. **[2005]**

Managing other symptoms: weight loss, loss of appetite, difficulty swallowing, fatigue and depression

- 1.5.18 Other symptoms, including weight loss, loss of appetite, depression and difficulty swallowing, should be managed by multidisciplinary groups that include supportive and palliative care professionals. **[2005]**

1.6 *Follow-up and patient perspectives*

- 1.6.1 Offer all patients an initial specialist follow-up appointment within 6 weeks of completing treatment to discuss ongoing care. Offer regular appointments thereafter, rather than relying on patients requesting appointments when they experience symptoms. **[new 2011]**
- 1.6.2 Offer protocol-driven follow-up led by a lung cancer clinical nurse specialist as an option for patients with a life expectancy of more than 3 months. **[new 2011]**
- 1.6.3 Ensure that patients know how to contact the lung cancer clinical nurse specialist involved in their care between their scheduled hospital visits. **[new 2011]**
- 1.6.4 The opinions and experiences of lung cancer patients and carers should be collected and used to improve the delivery of lung cancer services. Patients should receive feedback on any action taken as a result of such surveys. **[2005]**

2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover. The scope of this guideline is available from www.nice.org.uk/guidance/CG121 – click on ‘How this guidance was produced’.

Groups that are covered

- Adults (18 years and older) with newly diagnosed non-small-cell lung cancer (NSCLC).
- Adults with newly diagnosed small-cell lung cancer (SCLC).
- Adults with relapsed NSCLC.
- Adults with relapsed SCLC.

Groups that are not covered

- Adults with mesothelioma.
- Adults with lung metastases arising from primary cancers originating outside the lung.
- Children (younger than 18) with lung cancer.
- Adults with rare lung tumours (for example, pulmonary blastoma).
- Adults with benign lung tumours (for example, bronchial adenoma).

How this guideline was developed

NICE commissioned the National Collaborating Centre for Cancer to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations. An independent Guideline Review Panel oversaw the development of the guideline (see appendix B).

There is more information about how NICE clinical guidelines are developed on the NICE website (www.nice.org.uk/HowWeWork). A booklet, 'How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS' (fourth edition, published 2009), is available from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1739).

3 Implementation

NICE has developed tools to help organisations implement this guidance (see www.nice.org.uk/guidance/CG121).

4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future.

4.1 *Selection of patients with NSCLC for treatment with curative intent*

Further studies should be performed into factors that predict successful outcome of treatment with curative intent. Studies should include fitness parameters and functional imaging.

Why this is important

Despite much research into factors that predict a successful outcome after treatment with curative intent it is still not clear how these relate to the patient

with borderline fitness. To ensure that fitness assessment is robust, consistent and meaningful, the place of exercise testing, lung function testing and functional imaging should be clearly defined by appropriately designed trials.

4.2 *Effectiveness of surgery with or without multimodality treatment in N2 disease*

Patients with non-bulky single zone N2 disease should be considered for trials of surgery with or without multimodality treatment. Outcomes should include mortality and 5-year survival.

Why this is important

A number of randomised controlled trials have been evaluated in this guideline that have shown that surgery, as part of multimodality treatment, does not worsen prognosis in patients with N2 disease. However, these studies did not distinguish between those patients who might intuitively benefit from surgery (a limited number of nodes involved and/or a single zone affected) and those with more extensive disease and potentially less favourable biology (many nodes involved and/or multiple zones affected). Further trials are needed to establish the role of surgery in this heterogeneous group.

4.3 *Pulmonary rehabilitation, optimisation of drug treatment and enhanced recovery programmes*

Research should be undertaken into the benefits of pulmonary rehabilitation, optimisation of drug treatment and enhanced recovery programmes before and after surgery. Outcomes should include mortality, survival, pulmonary complications, pulmonary function and quality of life (including assessment by EQ-5D).

Why this is important

There is some evidence that pulmonary rehabilitation, optimisation of drug treatment and enhanced recovery programmes are effective in patients undergoing surgery for some conditions but none for patients undergoing surgery for lung cancer. Fitness for surgery and the ability of the patient to

recover following surgery are key factors in the success of this treatment for lung cancer. The effectiveness of interventions to improve these factors should be evaluated.

4.4 *New regimens for radiotherapy with curative intent*

Research should be considered into dose escalation in radiotherapy with curative intent, including stereotactic body irradiation (SBRT). Outcomes should include mortality, pulmonary complications, pulmonary function and validated quality of life measures (including assessment by EQ-5D).

Why this is important

There have been considerable technological advances in radiotherapy equipment that has allowed radiotherapy to be more accurately delivered to the tumour and hence less damaging to normal tissues. This has allowed new regimens to be developed, including SBRT, which have not been evaluated adequately for their efficacy and toxicity.

4.5 *Imaging modalities for monitoring response and recurrent disease*

Randomised controlled trials should be conducted to examine the value of imaging modalities and other interventions in the monitoring of response and recurrent disease.

Why this is important

Patients with lung cancer have high recurrence rates even when treated with curative intent. It is not known whether imaging modalities and other interventions in the follow-up period can improve outcomes by detecting recurrence or relapse earlier. Therefore no firm recommendations can be made about their scheduling or use. This question should be addressed through properly designed clinical trials.

5 Other versions of this guideline

5.1 *Full guideline*

The full guideline, 'The diagnosis and treatment of lung cancer (update of NICE clinical guideline 24)', contains details of the methods and evidence used to develop the guideline. It is published by the National Collaborating Centre for Cancer, and is available from our website (www.nice.org.uk/guidance/CG121/Guidance).

5.2 *Quick reference guide*

A quick reference guide for healthcare professionals is available from www.nice.org.uk/guidance/CG121/QuickRefGuide

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N2502).

5.3 *'Understanding NICE guidance'*

A summary for patients and carers ('Understanding NICE guidance') is available from www.nice.org.uk/guidance/CG121/PublicInfo

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N2503).

We encourage NHS and voluntary sector organisations to use text from this booklet in their own information about lung cancer.

6 Related NICE guidance

Published

- Gefitinib for the first-line treatment of locally advanced or metastatic non-small-cell lung cancer. NICE technology appraisal guidance 192 (2010). Available from www.nice.org.uk/guidance/TA192
- Pemetrexed for the maintenance treatment of non-small-cell lung cancer. NICE technology appraisal guidance 190 (2010). Available from www.nice.org.uk/guidance/TA190

- Percutaneous radiofrequency ablation for primary and secondary lung cancers. NICE interventional procedure guidance 372 (2010). Available from www.nice.org.uk/guidance/IPG372
- Topotecan for the treatment of relapsed small-cell-lung cancer. NICE technology appraisal guidance 184 (2009). Available from www.nice.org.uk/guidance/TA184
- Pemetrexed for the first-line treatment of non-small cell-lung cancer. NICE technology appraisal guidance 181 (2009). Available from www.nice.org.uk/guidance/TA181
- Erlotinib for the treatment of non-small cell lung cancer. NICE technology appraisal guidance 162 (2008). Available from www.nice.org.uk/guidance/TA162
- Bevacizumab for the treatment of non-small-cell lung cancer (terminated appraisal). NICE technology appraisal 148 (2008). See www.nice.org.uk/guidance/TA148
- Endobronchial ultrasound-guided transbronchial needle aspiration for mediastinal masses. NICE interventional procedure guidance 254 (2008). Available from www.nice.org.uk/guidance/IPG254
- Smoking cessation services. NICE public health guidance 10 (2008). Available from www.nice.org.uk/guidance/PH10
- Pemetrexed for the treatment of non-small-cell lung cancer. NICE technology appraisal guidance 124 (2007). Available from www.nice.org.uk/guidance/TA124
- Varenicline for smoking cessation. NICE technology appraisal guidance 123 (2007). Available from www.nice.org.uk/guidance/TA123
- Workplace interventions to promote smoking cessation. NICE public health guidance 5 (2007). Available from www.nice.org.uk/guidance/PH5
- Brief interventions and referral for smoking cessation. NICE public health guidance 1 (2006). Available from www.nice.org.uk/guidance/PH1
- Referral guidelines for suspected cancer. NICE clinical guideline 27 (2005). Available from www.nice.org.uk/guidance/CG27

- Cryotherapy for malignant endobronchial obstruction. NICE interventional procedure guidance 142 (2005). Available from www.nice.org.uk/guidance/IPG142
- Photodynamic therapy for localised inoperable endobronchial cancer. NICE interventional procedure guidance 137 (2005). Available from www.nice.org.uk/guidance/IPG137
- Photodynamic therapy for advanced bronchial carcinoma. NICE interventional procedure guidance 87 (2004). Available from www.nice.org.uk/guidance/IPG87
- Improving supportive and palliative care for adults with cancer. NICE cancer service guidance (2004). Available from www.nice.org.uk/guidance/csgsp

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

- Erlotinib monotherapy for the maintenance treatment of non-small-cell lung cancer. NICE technology appraisal guidance. Publication date to be confirmed.
- Smoking cessation in secondary care. NICE public health guidance. Publication date to be confirmed.

7 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations. Please see our website for information about updating the guideline.

Appendix A: The Guideline Development Group, National Collaborating Centre and NICE project team

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Appendix B: The Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The panel includes members from the following perspectives: primary care, secondary care, lay, and public health.

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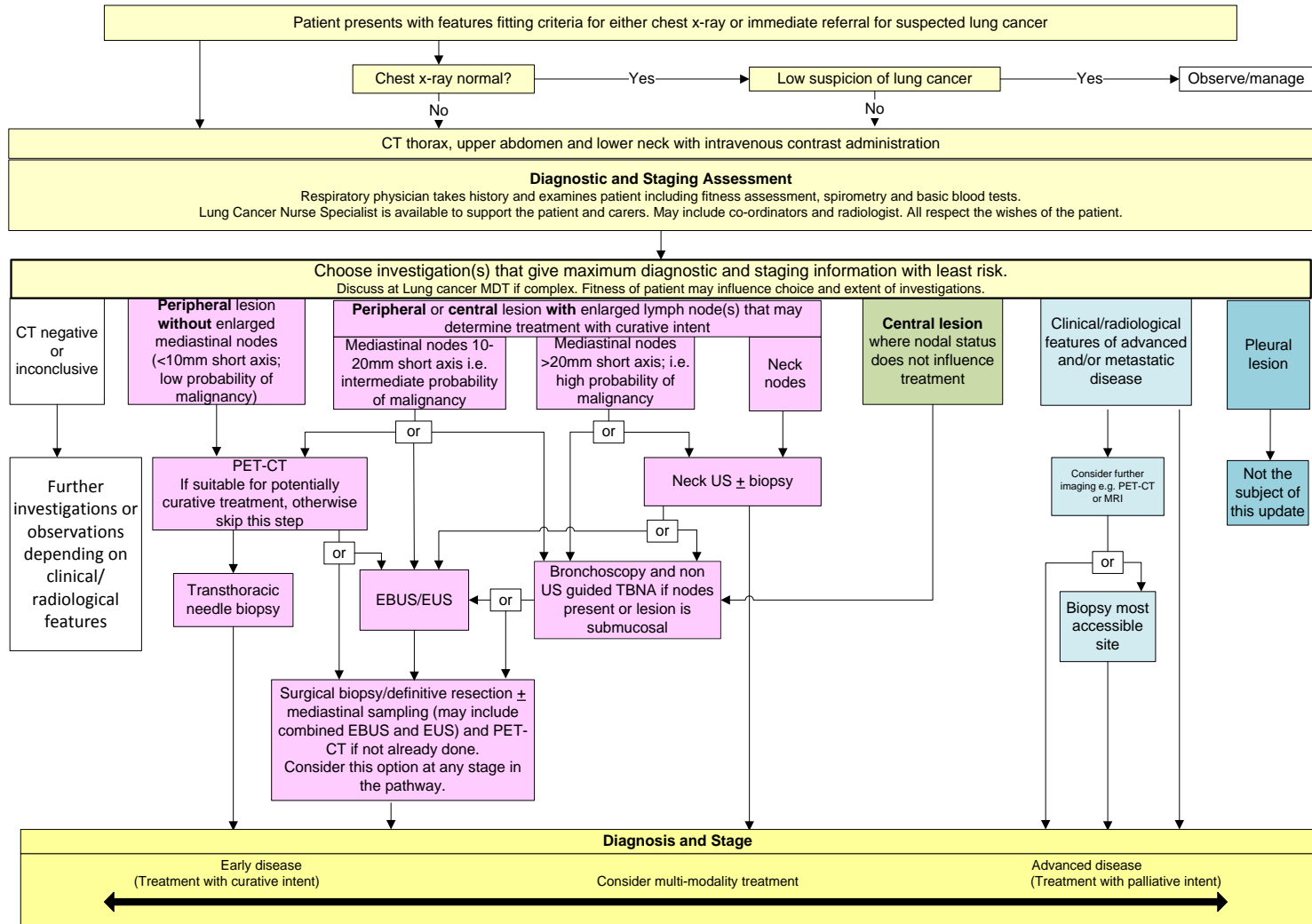
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Appendix C: The algorithms

Diagnostic and staging clinical pathway



Updated 2011

Detail of mediastinal diagnosis and staging

