

# Introduction and methods: British Thoracic Society pleural disease guideline 2010

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## CLINICAL CONTEXT

Pleural disease remains common, affecting over 3000 people per million population each year. They therefore represent a significant contribution to the workload of respiratory physicians. Pleural disease originates from a wide range of pathologies and a systematic approach to the investigation and management is therefore required. These guidelines attempt to summarise the available evidence to aid the healthcare professional in delivering good quality patient care.

## NEED FOR GUIDELINE

The Standards of Care Committee of the British Thoracic Society (BTS) established a Pleural Disease Guideline Group in December 2007. The objective was to produce an evidence-based update of the last pleural disease guidelines published in 2003. It was recognised that, since the last guideline, a number of good quality primary research papers have been published and the guidelines needed to reflect these new data. In addition, there was a need to develop new sections on local anaesthetic thoracoscopy and thoracic ultrasound to reflect changes in clinical practice.

## INTENDED USERS AND SCOPE OF THE GUIDELINE

This guideline is intended for use by all healthcare professionals who may be involved in pleural disease management. This will include doctors, nurses and other healthcare professionals.

## AREAS COVERED BY THIS GUIDELINE

The guideline addresses the investigation and medical management of pleural disease in adults. This is divided into the following sections:

1. Investigation of a unilateral pleural effusion in adults.
2. Management of spontaneous pneumothorax.
3. Management of a malignant pleural effusion.
4. Management of pleural infection in adults.
5. Local anaesthetic thoracoscopy.
6. Chest drain insertion and thoracic ultrasound.

The six sections can be downloaded individually from the website. Key points are repeated within sections to give users a full review of the individual documents without the need to cross reference repeatedly. In addition, at the end of this section (Annex 1) there is a list of good areas for audit and future research.

## AREAS NOT COVERED BY THIS GUIDELINE

The following areas fall outside the scope of this guideline:

1. Paediatric pleural disease
2. Detail on thoracic surgical techniques
3. Management of bilateral pleural effusions

## METHODOLOGY

### Establishment of guideline team

A Working Party was established with representation from a range of professionals with an interest in pleural disease together with a lay representative (see full list of Guideline Group members at the end of this section).

### Scope of the guideline, PICOT questions and literature search

The guidelines are based upon the best available evidence. The methodology followed the criteria as set out by the Appraisal of Guidelines Research and Evaluation (AGREE) collaboration in the document the AGREE instrument available online at <http://www.agreecollaboration.org/instrument/>.

The scope and purpose of the guideline had been agreed and defined in consultation with all potential stakeholders representing the medical and nursing professions, patient groups, health management and industry (see full list of stakeholders at the end of this section).

Guideline members identified and formulated a set of key clinical questions in Population, Intervention, Comparison, Outcome, and Time (PICOT) format to inform the search strategies for the literature search.

The BTS commissioned the Centre for Reviews and Dissemination at the University of York to undertake a bespoke literature search using the search strategies shown in detail on the BTS website (<http://www.brit-thoracic.org.uk>). The following databases were searched: Ovid MEDLINE (from 1960 onwards) (including MEDLINE In Process), Ovid EMBASE, Cochrane Database of Systematic Reviews (CDRS), the Database of Abstracts of Reviews of Effects (DARE) and the Cochrane Central Register of Controlled Trials. The initial searches were done in June 2008 and revised in September 2009. Searches were limited to English and adult literature; 19 425 potential papers were identified by the search. (see online appendix 1).

The Guideline Committee agreed on the following criteria to select relevant abstracts for the guideline:

1. Studies that addressed the clinical question.
2. Appropriate study types used to produce the best evidence to answer the clinical question.
3. Non-English abstracts were not evaluated.
4. Abstracts were not rejected on the basis of the journal of publication, the country in which the research was done or published or the date of publication.

A total of 17 393 abstracts were rejected through the criteria outlined above and 2032 full papers were ordered for critical appraisal.

**Critical appraisal of the literature**

A further 591 full papers were rejected because they fell outside the area of focus and scope of the guideline. Formal critical appraisal to assess the clinical relevance and scientific rigor of 1441 papers was performed independently by at least two guideline reviewers using the Scottish Intercollegiate Guidelines Network (SIGN) critical appraisal checklists (see online appendix 2). The guideline reviewers identified an additional 148 papers during the period of guideline development which were added and critically appraised. The evidence in each study was graded using the SIGN formulated levels of evidence (table 1).

**Considered judgement and grading of the evidence**

Evidence tables were produced to review the body of evidence and inform the considered judgements and grading of recommendations. Where there was a lack of evidence, consensus statements were derived by incorporating a number of individual non-biased expert opinions from experts in the field.

The following were considered in grading of the recommendations:

1. The available volume of evidence.
2. The applicability of the obtained evidence for making recommendations for the defined target audience of this guideline.
3. How generalisable the obtained evidence was to the target population for the guideline.
4. A clear consistency in the evidence obtained to support recommendations.
5. The implications of recommendations on clinical practice in terms of recourses and skilled expertise.
6. In-depth cost-effectiveness analysis falls outside the scope of this guideline.

Recommendations were graded from A+ to D as indicated by the strength of the evidence as listed in table 2.

**Drafting of the guideline**

The Guideline Group produced a draft guideline following regular email consultations and meetings held in December 2007, June 2008, November 2008, February 2009 and May 2009. The draft guideline was presented at the Summer BTS meeting in June 2009 and circulated to all the stakeholders identified (see below) for consultation and review.

The revised draft guideline was submitted to the BTS Standards of Care Committee for review and published online for a month (in August 2009) to allow for BTS member and public consultation. All the feedback was reviewed and discussed

**Table 1** Revised grading system for recommendations in evidence-based guidelines

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-analytical studies—for example, case reports, case series
4	Expert opinion

**Table 2** 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+
✓	Important practical points for which there is no—nor is there likely to be any—research evidence. The guideline committee wishes to emphasise these as Good Practice Points (GPP)

by the Guideline Committee and incorporated into the revised draft guideline. The literature search was repeated by the Centre for Reviews and Dissemination and Centre for Health Economics at the University of York and additional evidence appraised and included in the final draft of the guideline.

**PLANNED REVIEW OF THE GUIDELINE**

The guideline will be reviewed and updated in 4 years from publication.

**GUIDELINE GROUP MEMBERSHIP**

Guideline Group members: Dr Nick Maskell (Chair), Dr Nabeel Ali, Dr George Antunes, Dr Anthony Arnold, Professor Robert Davies, Dr Chris Davies, Dr Fergus Gleeson, Dr John Harvey, Dr Diane Laws, Professor YC Gary Lee, Dr Edmund Neville, Dr Gerrard Phillips, Dr Richard Teoh, Dr Naj Rahman, Dr Helen Davies, Dr Tom Havelock, Dr Clare Hooper, Dr Andrew MacDuff, Dr Mark Roberts.

Dr Edmund Neville represented the Royal College of Physicians, London. Dr Fergus Gleeson represented the Royal College of Radiologists. Thoracic surgical representatives: Mr Richard Berrisford, Mr Jim McGuigan (representing the Royal College of Surgeons), Mr Richard Page (representing the Royal College of Surgeons of Edinburgh).

Dr D L Evans (member of the BTS Standards of Care Committee) provided lay input during consultation phases of the production of the guideline.

**STAKEHOLDER ORGANISATIONS**

The following organisations were identified as stakeholders and given the opportunity to comment on the draft documents during the consultation period: Royal College of Physicians, London; Royal College of Surgeons of England; Royal College of Physicians of Edinburgh; Royal College of Surgeons of Edinburgh; Royal College of Radiologists; Royal College of Anaesthetists; Royal College of General Practitioners; Royal College of Nursing; Royal College of Obstetricians and Gynaecologists; Royal College of Pathologists; Joint Royal Colleges Ambulance Liaison Committee; College of Emergency Medicine; Society for Acute Medicine; Association for Palliative Medicine of GB and Ireland; British Geriatrics Society; Association for Clinical Biochemistry; Association of Medical Microbiologists; British Society for Immunology; British Society of Clinical Cytology; British Society for Rheumatology; Society for Cardiothoracic Surgery in Great Britain and Ireland.

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**Competing interests** No member of the Guideline Group is aware of any competing interests.

**Provenance and peer review** The draft guideline was available for online public consultation (July/August 2009) and presented to the BTS Winter Meeting (December 2009). Feedback was invited from a range of stakeholder institutions (see Introduction). The draft guideline was reviewed by the BTS Standards of Care Committee (September 2009).

## ANNEX 1 FUTURE RESEARCH DIRECTIONS AND AUDITS

Possible future areas that deserve further research:

1. Randomised controlled trial looking at the efficacy of talc poudrage versus talc slurry in controlling symptomatic malignant pleural effusions.
2. Optimal timing of drain removal post pleurodesis.
3. Thoracoscopic pleural biopsies — optimal size, number and distribution.
4. A large multi centre RCT comparing observation versus aspiration versus chest tube drainage in primary pneumothorax using patient centered outcomes.
5. Role of ambulatory catheters in treatment and management of primary and secondary pneumothorax.
6. Comparison of the efficacy and patient satisfaction between chest tube drainage with talc slurry and indwelling pleural catheter placement as first line treatment of malignant pleural effusions.
7. Safety of using indwelling pleural catheters in patients undergoing/about to undergo chemotherapy.
8. Value of serum and pleural fluid biomarkers in distinguishing underlying cause of pleural disease reducing the need for invasive procedures.
9. Studies on the detection of pneumothorax - comparing the newer ward-based digital technology with standard radiography.
10. Role of pleural irrigation in cases of pleural infection requiring simple chest tube drainage.

Possible pleural audits:

1. Consent documentation for chest drain insertion.
2. Chest drain iatrogenic infection rates.
3. Chest tube 'fall out' rate.
4. Availability of bedside ultrasound for pleural procedures.
5. Length of in-patient stay for new undiagnosed pleural effusions.
6. Pleurodesis success rates.
7. Trust adherence to the management algorithm for pneumothorax.
8. Documentation of discharge advice for patients with pneumothorax.
9. Local sensitivity of pleural fluid cytology
10. Documentation of pleural fluid pH in cases of pleural infection and use of heparinized syringes.
11. Appropriate antibiotic use/duration in cases of pleural infection. Are blood cultures always taken.
12. Diagnostic yields and complication rates of local anaesthetic thoracoscopy.
13. Is DVT prophylaxis prescribed (where no CI) for all cases of pleural infection and malignancy requiring a chest drain.
14. Size of chest tube used in cases of pneumothorax and length of time before surgical referral made.
15. CT/US guided pleural biopsy diagnostic sensitivity for malignancy.