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Date of Production: March 2009
Due for next review: July 2017
1. Introduction

Background

1.1 The British Thoracic Society has been at the forefront of the production of Guidelines for best clinical practice in respiratory medicine since the Society was established over 25 years ago. Over the past 5 years especially, the methodology for the production of evidence-based Guidelines has evolved considerably and the purpose of the current document is to set out in detail the policy for BTS Guidelines and the procedures by which they are produced and reviewed.

1.2 It is important to emphasise that BTS Guidelines are intended as an aid to clinical judgement. Guidelines cannot provide the answers to every clinical question and the ultimate decision about a particular clinical procedure or treatment will always depend on each individual patient’s condition, circumstances and wishes, and the clinical judgement of the healthcare team.

1.3 This document has been developed to set out the policies, principles and processes that should be followed in the development of BTS Guidelines. While the document aims to be as instructive as possible it cannot cover, in detail, every possible issue that may arise during the course of BTS Guideline development. Issues that may arise during the work of a Guideline Group, that are not covered in this document, should be brought to the attention of the Chair of Standards of Care Committee for advice and guidance, via the BTS Deputy Chief Executive.

1.4 Guidelines commissioned before the end of 2015 will have followed SIGN methodology as outlined in this Manual, and in previous editions. Guidelines commissioned from 2016 onwards will use GRADE methodology and a revised Manual will be produced in 2016 to support this process.

1.5 The development of the BTS Manual for Guideline Production has been informed by a number of sources of information including the SIGN 50 Guideline Developer’s Handbook (1), the NICE Accreditation (2) process and as well as informal advice from a range of experts in the field of Guideline development and respiratory medicine. This advice and assistance is gratefully acknowledged.

Aims and objectives of the Society in relation to Guideline production

1.6 The British Thoracic Society’s main charitable objective is to improve the care of people with respiratory and associated disorders. The production of Guidelines that promote optimum standards of care is key to the achievement of this objective.

1.7 Guideline production is the responsibility of the BTS Standards of Care Committee (SOCC).

General principles for BTS Guidelines: AGREE Criteria

1.8 BTS guidance is produced by Guideline Groups selected and approved by the BTS Standards of Care Committee with advice from the BTS network of Specialist Advisory Groups. The work of Guideline Groups is supported by BTS Head Office staff. The Society does not seek or accept external funding for the production of its guidance.
1.9 BTS Guidelines are based on the best available evidence and should adhere to the AGREE II criteria (http://www.agreetrust.org/agree-ii/) – see Appendix 1.

2. Initiation of the Guideline production process

Role of the Standards of Care Committee

2.1 The Standards of Care Committee (SOCC) is one of the standing Committees of the Society and has the following remit:

- **Guideline development.** This involves the development of robust systems for the production of the Society’s own Guidelines, from assessing the need for a Guideline to the submission for publication. The scope of this work will involve Guidelines on specific diseases, specific procedures and on processes of care, plus advice about key messages for dissemination, associated audit tool(s) and patient information.
- **Quality Standards.** A quality standard is made up of quality statements and associated quality measures. A set of quality statements is drafted based on the agreed prioritised areas for quality improvement and derived from the source guidance. The statements describe specific, measureable aspects of care or service provision that people should expect to receive in a high-quality service.
- **A research responsibility** which will involve identifying gaps in knowledge exposed by the Guideline development process and advising on priority areas for research.

2.2 The Constitution of the Committee (at Appendix 2), sets out the membership, remit and mode of operation of the Committee.

2.3 The Chair of the Committee is a Trustee of the Society and sits on the BTS Executive Committee.

2.4 The BTS Deputy Chief Executive is the secretary to the Standards of Care Committee and the main point of contact for all Guideline Group members and Guideline-related matters at BTS Head Office.

Definition of a Guideline

2.5 The definition of a **Guideline** is as follows: "Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." (3)

2.6 The Society requires that its Guidelines are based on the best available evidence, but it recognises that in some areas, evidence may be sparse or of poor quality. It is important to ensure that robust methodology is used to develop guidance even in areas where the evidence base is weak. Guidance for good practice for these topics is often much needed, and its development can also serve to highlight areas where further research is required.

Process for identifying a topic for a Guideline

2.7 The SOCC is responsible for approving topics for new BTS Guidelines. Proposals for new Guidelines are submitted to the SOCC through the following channels:

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• Through the Society’s network of Specialist Advisory Groups (SAGs). The Specialist Advisory Groups provide an annual report to the BTS Executive Committee and as part of their report, the Groups are required to list any areas where it is felt that there is a need for guidance;

• Through organisations associated with the Society such as the British Paediatric Respiratory Society (BPRS), and the Association for Chartered Physiotherapists in Respiratory Care (ACPRC), via their representatives on the SOCC, as well as other organisations such as the Primary Care Respiratory Society (PCRS-UK) and the Association for Respiratory Technology and Physiology (ARTP);

• Through the BTS Science and Research Committee, through the work of other BTS Committees, or directly from the BTS membership.

2.8 A call for proposals for new Guidelines is made via the BTS website and in communications to the Society’s membership on one occasion each year. An announcement is placed on the BTS website, with appropriate forms and supporting information included. Proposals are welcomed from BTS members, chairs of BTS SAGs, stakeholder organisations and individuals. The detailed process for generating and considering Guideline proposals is outlined in a separate document (see Appendix 3).

2.9 In relation to guidelines concerning children, priorities for paediatric guideline topics would be developed in consultation with the British Paediatric Respiratory Society (BPRS) via the BPRS representatives on the Standards of Care Committee, with the intention that at least one paediatric guideline would be in preparation at any one time, bearing in mind the overall guideline work programme.

2.10 In line with NICE Accreditation, all BTS guidelines are marked as valid/under review/in preparation/supersede on the BTS website. When a guideline is due for review (at the specified period following publication, the relevant SAG will be asked to suggest 2 or 3 individuals to review the document (and individuals may include members of the original guideline group) and prepare a report for the SOCC, using a standard proforma. A literature search may be commissioned to establish the extent of new published evidence. Where the outcome of this exercise indicates that a published guideline requires revision/updating, the proposal for that topic would be considered along with all new guideline proposals for a final decision at the September SOCC meeting taking account of the relative priority of each case assessed. The Standards of Care Committee will receive a report on the review of published guidelines each year and confirm continued validity/withdrawal as appropriate bearing in mind advice from the SAG/guideline group members.

2.11 The SOCC will consider the following factors in the process for commissioning a new Guideline:

• Are there areas of clinical uncertainty as evidenced by wide variation in practice or outcomes?
• Is this a condition where effective treatment is proven and where mortality and/or morbidity can be reduced significantly?
• Is this a clinical priority area for BTS where clinical guidance is lacking (and with a perceived need for guidance) and the area is unlikely to be covered by other Guideline producers (such as NICE)?
2.12 The Guideline proposal outline should explicitly include:
- the aim of the Guideline
- a description of the intended users of the Guideline
- a clear description of which areas are to be included and excluded from the guidance.

2.13 The SOCC will normally select up to two proposals at a time to go forward into production (when the timetable allows). The proposals that have not been selected may be resubmitted for consideration the following year. Full details of the process provided in Appendix 3.

2.14 The timetable for the production of the Guideline should be set out at the start of the group’s work. In general production of a full Guideline should be completed within 2 years from the date that the Group is convened, and updates to existing Guidelines should be completed within 12-18 months. Progress reports on the work of the group should be provided for SOCC meetings (3 or 4 times a year).

2.15 The budget for the production of the Guideline should be agreed with BTS Head Office before work begins. In general the following items are included within the budget for Guideline production (in line with BTS policies for reimbursement of expenses):
- Guideline group meeting costs (room hire, refreshments etc)
- Travel costs for group members to attend meetings
- Cost of literature searches undertaken by the Centre for Reviews and Dissemination in York
- Cost of obtaining copies of papers that cannot otherwise be acquired through group members’ own library access (including reimbursement of librarian costs where agreed in advance with BTS Head Office)
- Cost of production of drawings/figures for inclusion in the final Guideline document.
- Training costs
- Dissemination/publicity costs (arrangements to be agreed with BTS Head Office)

3. Composition of Guideline Group

Process for selection of Guideline Group members

3.1 Following SOCC approval of the proposed outline for the Guideline, a formal invitation for applications for the post of Chair or co-Chairs of the Guideline Development Group (GDG) is issued by the SOCC Chair via the BTS website and BTS member mailings. Co-chairs may be appointed. The Chair(s) would be likely to be experts in the topic and skilled in managing a committee. They would be involved in the appointment of any Co-Chair and guideline group members. A full role description for the Chair(s) of the guideline group is provided at Appendix 9 and would be provided to those considering applications for the role of Guideline Group chairs.

3.2 The Chair(s) would be expected to:
- Lead the guideline development group with support from BTS.
- Facilitate the process of the development within the framework of agreed BTS methodology following the AGREE II criteria.
- Ensure equality of input from all GDG members.
- Adhere to the Society’s policy for declarations of interest and manage declarations of interest and potential conflicts of interest of group members in line with the stated policy.
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- Keep to the scope – manage the ambition of the GDG (noting that this is not a text book).
- Attend all committee meetings and read meeting papers in advance of meetings.
- Encourage constructive debate among all group members during meetings.
- Participate in guideline development training as appropriate.
- Work with BTS Head office staff and group members as required during and between meetings to identify key issues, formulate clinical questions for review, review evidence tables, and draft recommendations.
- Lead the write up of the draft document (in line with BTS template)
- Work with group members and BTS Head Office staff to write and edit drafts of the guideline.
- Lead the group in considering and addressing stakeholder comments on the draft guideline.
- Provide progress reports to the BTS SOCC as required
- Attend an agreed SOCC meeting to present the draft guideline.
- Support the dissemination and implementation of the guideline - be a champion for the guideline after publication and undertake activities to promote its implementation, such as talking at professional conferences and participation in the production of publishing guideline-related articles in accordance BTS policy.

3.3 Following appointment of the Chair/Co-Chair, an open selection process to recruit other members of the Guideline Development Group would be conducted (again via the BTS website/member mailings). Each Guideline Group would be likely to have the following core members:
- Consultant members, to include individuals working in a District General Hospital;
- Specialty Trainees. This provides Specialty Trainees with an opportunity for valuable experience in Guideline preparation and brings the perspective of the Specialty Trainee to the Guideline.
- Allied health professionals (recruited via liaison with the appropriate organisation, eg ARNS/ACPRC etc)

3.4 In addition, the group would also include:
- A current (or recently demitted) member of the SOCC (to provide insight and guidance into the overall standards to be applied to meet SOCC approval)
- Patient/lay member (see section 3.4 – 3.6)

Lay/patient input

3.5 In this context the phrase “lay/patient” is used as a generic term to describe patients, carers, lay representatives and those who represent and/or support patients in the voluntary sector. Lay/patient input in Guideline development is important to ensure that the Guideline reflects their needs and concerns, and to ensure that the Guideline addresses issues that may be overlooked by health professionals.

3.6 Each Guideline Group should include 2 lay/patient representatives at the start of the guideline development process. Lay/patient members of Guideline group can be sought from:
- The BTS Public Liaison Committee (or equivalent).
- The Patient Involvement Unit of the Royal College of Physicians (London).
- The British Lung Foundation, Asthma UK, Cystic Fibrosis Trust or other organisation that considers patient involvement/representation as its main objective.
3.7 Clear guidance should be given to each lay/patient member of the Guideline Group regarding their role and responsibilities in the work of the Guideline Group. The Group will ensure that patient views and experiences inform its work through:

- The identification of key questions that are informed by issues that matter to patients.
- Identification of areas where patients’ preferences and choices are of particular importance within the Guideline.
- Assisting with the preparation of any Patient Information literature which may be required, and identifying sources of further information.
- Helping to ensure that the Guideline is sensitively and appropriately worded.

3.8 While it is not expected that lay/patient members will undertake the specific critical appraisal process for individual clinical questions, lay/patient members will be kept informed at all stages and invited to every meeting of the guideline development group. While much of the discussion at the meetings will be very clinically focussed, all members of the guideline development group are expected to use appropriate and where possible accessible language.

Declarations of interest

3.9 As noted above, the proposed Chair(s) of the Guideline Group must complete a BTS Declaration of Interest form and any potential conflicts of interest considered by the BTS Honorary Secretary and the Chair of the SOCC before the appointment to the role of Chair is confirmed and any work on the Guideline is undertaken. The Chair should not have any conflicts of interest in relation to the specific guideline topic. Each member of the Guideline Group must complete a BTS Declaration of Interest (DoI) form at or before the first meeting of the Guideline group and on an annual basis thereafter for the period that the Guideline group is active in line with the BTS Policy for Declarations of Interest. Full details of the BTS Declaration of Interest scheme can be found at [http://www.brit-thoracic.org.uk/about-bts/governance.aspx](http://www.brit-thoracic.org.uk/about-bts/governance.aspx)

3.10 The Chair of the SOCC and the Chair of the Guideline Group have responsibility for scrutinising Declarations submitted by Guideline Group members. Guideline Group members are required to complete a DoI form as part of the annual BTS DoI scheme. Copies of DoI forms for group members will be kept on file at BTS Head Office for the duration of the work of the Guideline Group (and then for the subsequent period of time that the Guideline remains valid). Completed returns for active Guideline Groups will be available on the public area of the BTS website, and following publication of the guideline, declarations of interest forms for each group are held on file at BTS Head Office and can be provided on request.

3.11 Declarations of interest are a standing item at the beginning of each guideline group meeting. Members will be asked if any new declarations have arisen and forms can be unlocked by BTS staff should amendments be required. It is expected that the majority of the guideline development group will have no conflicts of interest. Should a consensus vote be required for any reason, those with conflicts of interest will be excluded from the process.
3.12 A statement should be included in each Guideline when published to confirm that the Guideline Group members adhered to the BTS policy for the Declaration of Interests, and where appropriate specific interests should be declared. An example of such a statement for inclusion in the final Guideline document is given below:

“All members of the Guideline Group made declarations of interest in line with the BTS Policy and further details can be obtained on request from BTS.”

Stakeholder input

3.13 The identification and involvement of stakeholders in the development of BTS Guidelines is crucial. One of the initial tasks for the Chair of the Guideline Group is to write to all potential stakeholders in the final Guideline to invite that organisation to either nominate a representative to participate in the preparation of the Guideline as a formal member of the Group, or to nominate a contact to whom information on the draft Guideline can be directed as work progresses. BTS Head Office holds a list of stakeholder organisations and contact with each stakeholder organisation is made through BTS. Correspondence with stakeholder organisations is usually undertaken by the BTS Deputy Chief Executive on behalf of the Guideline Group Chair.

3.14 The aim is to ensure that the Guideline Group membership comprises all relevant stakeholders. It is important that some organisations (for example, the Royal College of Physicians (London)) have a representative on each Guideline Group. In other cases, it may be sufficient for the organisation to have the opportunity to comment on the draft Guideline at an early stage (or to provide specialist input when required) rather than for the organisation to have a representative on the Group itself.

3.15 Prior to its first meeting, the Guideline Group will have the opportunity to confirm the list of relevant stakeholder organisations that will be invited to endorse the Guideline at an early stage in the Guideline development process. Stakeholders include patient, professional, commercial, commissioner and government organisations as well as individual patients and members of the public. All respondents to the public consultation exercise will be required to declare their role/affiliation on the consultation form.

3.16 All stakeholders will be sent a copy of the draft Guideline at or before the public consultation stage. All stakeholder organisations will then be sent a copy of the final draft Guideline, prior to publication, with a request to confirm their endorsement of the document.

Training for Guideline Group members

3.17 It is important for all Guideline Group members to be appropriately trained in the methods to be used for the production of an evidence-based Guideline. Where possible the Chair of the Guideline Group should receive training in advance of the other members of the Group.

3.18 Training sessions are organised by BTS Head Office, and will usually take place as part of the first and second meeting of the Guideline Group. BTS has developed an online training module for Guideline Groups as part of the BTS Learning Hub and is made available to Guideline Group members.
Confirmation of authorship/membership of writing group

3.19 In general all guideline group members would usually be named as authors (and would contribute appropriately to the authorship of the guideline – fulfilling the stated criteria for authorship as appears on the Thorax website). The Chair/co-chairs would usually be named as first authors. The proposed authorship of the guideline should be discussed as early as possible after the Guideline group starts work, to ensure that all group members are aware of the contribution required.

The authorship of a BTS Guideline should be given in the following form (the name of the chair are usually listed first, followed by all members of the group in alphabetical order):

A Smith, B Jones, C Black, D Grey, ........ on behalf of the British Thoracic Society Pleural Disease Guideline Group

The full membership of the Guideline group should also be listed in a section at the start of the Guideline.

4. Guideline preparation

Selecting the methodology

4.1 BTS Guidelines are based on the best available evidence. While is a range of Guideline methodology available, the Guideline group would normally use the SIGN methodology (Appendix see Appendix 4). The system used has been selected to adhere to the AGREE II criteria (http://www.agreetrust.org/agree-ii/) – see Appendix 1.

4.2 The Guideline should include clear recommendations with an indication of the grade of the recommendation (appropriate to the methodology used in consideration of the evidence). There should be an explicit link between the recommendations and supporting evidence.

Defining the scope of the Guideline

4.3 In line with the AGREE II criteria, each Guideline should explicitly state the clinical questions to be addressed, and the patient population/target audience for the Guideline. Areas specifically excluded by the Guideline should also be itemised.

4.4 Consideration should be given to palliative care issues and where appropriate the document should include a section on end of life issues.

4.5 Studies often record side effects, harmful effects and risks of effects of interventions under scrutiny but these are rarely primary outcome measures. Where evidence permits, these will be balanced against beneficial effects with a view to informing recommendations.

Defining key questions and developing search strategies

4.6 BTS Guidelines should be based on a systematic review of the evidence. Systematic review is defined as “an efficient scientific technique to identify and summarise evidence on the effectiveness of interventions and to allow the generalisability and consistency of research findings to be assessed and data inconsistencies to be explored” (4).
4.7 The essential principles of systematic review should be adhered to as set out below:

- the literature is identified according to an explicit search strategy
- selected according to defined inclusion and exclusion criteria
- evaluated against consistent methodological standards.

4.8 Where high quality, directly relevant Guidelines exist within the scope of the new Guideline, reference can be made to the existing Guidelines rather than repeating work that has already been completed. However all such existing Guidelines must be evaluated using the AGREE II instrument and be shown to have followed an acceptable methodology before they can be considered for use in this way.

4.9 Guideline groups are encouraged to break down the Guideline remit into a series of structured key questions using the PICOT format:

- Patients or population to which the question applies
- Intervention (or diagnostic test, exposure, risk factor, etc.) being considered in relation to these patients
- Comparison(s) to be made between those receiving the intervention and another group who do not receive the intervention
- Outcome(s) to be used to establish the size of any effect caused by the intervention.
- Timeframe (optional)

4.10 The Patients or population to be covered by the literature searches is largely defined by the presence of the particular condition that the Guideline will cover. It should be made clear at this stage, however, which age groups are to be covered and which are excluded (for example, if the Guideline covers adults only or children only, the age range should be specified (for example, 16 years and over, or up to and including 16). The age range given will be agreed by the guideline group for each specific guideline topic.

4.11 Consideration should also be given as to whether any ethnic or social groups have particular needs in relation to the topic under review. Exclusion of any group from the population covered by the Guideline should be identified when setting the key questions, and reasons given for their exclusion.

4.12 The Interventions (which in this context includes diagnostic tests, risk factors, risk exposure) must be specified clearly and precisely. The only exception is in drug therapy where drug classes should be used in preference to specific agents unless there is a clear reason for focusing on a named agent.

4.13 The decision on Comparisons is mostly between placebo / no treatment, or comparison with other therapies or the existing standard of care.

4.14 Outcomes should be identified in advance in relation to what will influence the views of Guideline group members as to how effective a particular intervention is. For some questions there will be a wide range of outcomes used in the literature, and if useful comparisons are to be made across studies it must be made clear which of these outcomes are important. Outcomes should be objective and directly related to patient outcomes (eg length of time to next cardiovascular incident...
or survival time, rather than just reductions in blood pressure). It is also important to include outcomes that are important to patients, rather than focusing entirely on clinical outcomes. Outcomes should include potential serious untoward effects of interventions.

4.15 The **Timeframe** covered by the question, where long term efficacy and safety data of interventions are important.

4.16 The questions identified in this way will then form the basis of the literature search. Guideline groups are encouraged to draw up as concise a list of key questions as possible. The Society has a service level agreement with information specialists in York who are able to provide assistance with literature searches and guidance on formulating search strategies including advice on search terms and sources to be consulted such as Medline/US National Guideline Clearing House/Embase/Psychinfo (see Appendix 4).

4.17 The literature search must focus on the best available evidence to address each key question, and should ensure maximum coverage of studies that include:

- Systematic reviews.
- Randomised controlled trials.
- Observational studies
- Diagnostic studies

4.18 A useful summary of the systematic literature review procedure is given in the Figure in Appendix 4, taken from the SIGN 50 Handbook.

4.19 The details of the search strategies, dates of searches etc should be included in the final document (and can also be made available as an accompanying web appendix on publication).

**Reviewing the evidence**

4.20 The literature search will produce a long list of potential sources of evidence. Each reference must then be assessed to ensure its relevance and validity. The Guideline Group members should review the evidence (bearing in mind the AGREE II criteria). Detailed instructions for each step in this process are provided by the Society (Appendix 10).

4.21 It is suggested that this is best performed by dividing the literature into sections and allocating at least two Guideline group members to each section/set of literature to ensure that each paper is read by at least two people. Criteria should be formulated to ensure that this process is carried out uniformly across the Guideline group, and could include, for example:

1. Does this study address the clinical question?
2. Has the appropriate study type been used to produce the best evidence to answer the clinical question?

The chosen inclusion and exclusion criteria should be stated in the Guideline document.

4.22 Non-English abstracts should be considered, provided there is an English translation available. It would not be usual to provide translations of non-English papers unless a compelling case could be made. Guideline group should consult BTS Head Office if such an issue arises.
4.23 Abstracts should not be rejected on the basis of the Journal of publication, location of research or publication nor the date of publication.

4.24 For each section of the Guideline, two Group members should scrutinise the title and abstract of each article retrieved by the literature searches to decide whether the paper is relevant. Where there is a difference of opinion on a paper, the group members should endeavour to reach a consensus, and refer to other members of the group for a final decision. A note should be made of the decision for each reference (relevant/possibly relevant/not relevant). When a consensus has been reached on the list of relevant abstracts, full copies of papers of all relevant and possibly relevant articles should be obtained.

4.25 Guideline Group members are encouraged to make full use of their NHS/university library resources to obtain full copies of the papers remaining within copyright rules at all times. Where Guideline groups encounter difficulty in obtaining copies of papers, BTS Head Office can offer advice and assistance.

Grading the evidence, formulating and grading recommendations

4.26 When all relevant papers have been obtained (and any non-relevant papers excluded), Guideline group members are required to grade the evidence.

4.27 The quality of the evidence should be appraised using existing appraisal tools (eg SIGN checklists). Each study should be evaluated for internal validity, external validity and generalisability using the SIGN checklists and other documentation (2). If a Guideline Group wishes to use an alternative system in the production of the Guideline concerned, the Guideline Group Chair should first seek advice from the SOCC Chair and BTS Head Office.

4.28 BTS is aware that GRADE methodology (5) is being used by some Guideline producers (for example NICE). BTS is planning to incorporate GRADE methodology into its own system for guidelines commissioned from 2016 onwards and a new Manual will be produced to support that process. The details outlined in this Manual apply to BTS guidelines commissioned before the end of 2015.

4.29 The current SIGN definitions for levels of evidence and grading of recommendations are included at Appendix 4.

4.30 For those studies that are deemed relevant to a particular key question, a checklist is prepared and the data relevant to the evidence review and guideline development is extracted into evidence tables (template evidence tables may be obtained from the SIGN website or BTS Head Office). This data commonly includes: the study author, year, design, quality, objective, population, setting, sample size, follow-up, and definitions and results of clinically relevant outcomes. Evidence tables are developed for each key question. Data are extracted by one or more authors, and disagreements are resolved by the remaining authors. Systematic reviews may also be included in a guideline if there are a large number of relevant reviews available in the literature. A level of evidence should be assigned to each paper (according to the table included in Appendix 4).

4.31 Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgement is made on the basis of an (objective)
assessments of the design and quality of each study and a considered judgement on the consistency, clinical relevance and external validity of the whole body of evidence.

4.32 Where there is a lack of evidence on a particular key question, the Guideline group should be clear about how a consensus has been reached in formulating a recommendation (for example using the Delphi process). Where areas of uncertainty within the evidence, this should be highlighted as appropriate within the Guideline document.

4.33 In grading the recommendations the guideline group should consider the following aspects for considered judgement:

- The volume of the body of evidence;
- The applicability of the obtained evidence to the defined target audience of the guideline.
- The generalisability of the evidence to the target population of the guideline.
- The level of consistency in the evidence obtained to support recommendations.
- The implications of recommendations on clinical practice in terms of resources and skilled expertise.

4.34 While BTS Guidelines explicitly exclude consideration of cost-benefit analysis, Guideline Groups may include a consideration of cost implications and cost-effectiveness issues where literature exists that is appropriate to the topic. It is expected that the guideline development group would discuss potential organisational and financial barriers which may impact on the implementation of the recommendations.

Drafting the Guideline

4.35 When producing a draft of the Guideline the following structure is suggested:

- Title page listing authors
- Contents page
- Summary of recommendations (to be finalised on completion of the Guideline)
- Introduction (see above)
- The body of the Guideline, divided into sections as appropriate, with each recommendation clearly identified in bold type and numbered consecutively throughout the document
- Conclusion
- Appendices and list of web appendices
- Figures/Tables
- References (see at 4.38 below)

4.36 The introduction should include:

- the aim of the Guideline
- a description of the intended users of the Guideline
- a description of the target patient population
- a clear description of which areas are included and excluded from the guidance.
- A description of the methodology used
- A description of the search methodology, the dates of the literature searches and how many papers were considered. The detailed search terms should be included in a Web Appendix
- A statement on when the Guideline should be reviewed/revised – this is normally within 5 years from the date of publication
- A description of the inclusion and exclusion criteria for evidence selection
• A statement on declarations of interest
• A full list of the Guideline Group members and the contributors to each section of the Guideline, noting where individual members have represented other organisations
• A list of stakeholders/endorsing organisations (to be finalised prior to publication)

4.37 The following sections are also associated with the Guideline, but are usually provided as web based appendices rather than part of the published document:
- Research recommendations
- Audit criteria
- Patient information where appropriate
- Educational material
- Quality Standards (this document is subject to a separate production process following preparation of the Guideline - see Appendix 7).

4.38 Guideline groups should ensure that the level of evidence is clearly indicated against each evidence statement and that individual references that are included in the evidence summary appear in the accompanying evidence table (as well as in the bibliography). The grade of recommendation should be clearly indicated against the recommendation when it appears in the Guideline. Reference should be included in the Vancouver format (the style used by Thorax) where references are numbered sequentially in the text.

4.39 BTS guidelines should include Good Practice Points (GPP) which are intended to offer short pieces of advice which may not have an evidence base, but are viewed as essential to good clinical practice. GPP may arise in a Guideline where the evidence is insufficient to be systematically reviewed, but where there may be a need to guide practice. All GPP will be arrived at by consensus, based on the clinical experience of the guideline group members.

4.40 The following paragraph should be inserted at final draft stage:

*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 presented 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.*

**Public consultation and peer review/approval by SOCC**

4.41 The final draft Guideline should be submitted to the Chair of the SOCC for comment and discussion at a meeting of the SOCC. The Chair of the Guideline Group will be invited to be present at that meeting. Peer review will be undertaken by SOCC members, who may also invite key expert reviewers to provide comments. The public consultation period takes place immediately after the SOCC meeting provided the Committee has given approval that the draft guideline is suitable for the consultation process to take place.

4.42 The approved draft of the Guideline should usually be placed on the BTS website for open consultation, and if the timing allows, an open meeting should be held at a BTS Summer/Winter meeting. A consultation copy of the document should be sent to all stakeholders requesting their comments by the consultation deadline.

Date of Production: March 2009
Due for next review: July 2017
4.43 A standard form is used to collect the comments from respondents who are asked to specify if the comments are submitted on behalf of an individual or an organisation. All comments are collated and sent to the chair(s) of the guideline development group. The actions for each comment are recorded, even if there is no change/action required. All amendments to the draft must have the agreement of the guideline development group.

4.44 At this stage, the editors of Thorax are invited to propose expert reviewers to comment on the draft Guideline as part of the public consultation process. This satisfies the external peer review process for the journal and means that a further peer review process is not required following final approval of the guideline by the Standards of Care Committee. It should be noted that when the guideline is published it is noted as subject to internal Thorax review as the external peer review process has taken place as part of the public consultation stage.

The spreadsheet of comments and associated actions is included in the submission for publication to Thorax to provide evidence of external peer review.

4.45 Following the incorporation of comments from the SOCC meeting and the open consultation, the final draft document should be returned to the SOCC for approval. At this point the SOCC may request a further review of the document before approval is given.

4.46 When the final draft has been approved, the document should be sent to stakeholders (relevant organisations/Royal Colleges) to request confirmation of endorsement, if applicable.

Publication/Dissemination

4.47 The principles and procedures for publication of the full Guideline/Executive Summary of the Guideline in *Thorax* are set out at Appendix 8. An online copy of the full Guideline (and associated web appendices) will be available on the BTS website following publication. Options for alternative publication arrangements should be discussed with the SOCC Chair and BTS Head Office.

4.48 BTS Head Office is responsible for liaising with the Thorax Production team regarding the likely timing of publication. BTS Head Office will submit the final manuscript to Thorax via Scholar One and will be the main point of contact with *Thorax* for production issues. The corresponding authors will be responsible for checking the proofs of the Guideline.

4.49 The sequence of events for the publication process is as follows:

- Final draft is considered by the SOCC (at this point a copy of the draft is sent to the *Thorax* editors for information with an estimate of when the final document is likely to be formally submitted to Thorax);
- When the final draft is approved by the SOCC Chair, BTS Head Office takes responsibility for checking its content (to confirm that all figures/tables and associated documents are available), and confirming with the corresponding authors;
- BTS Head Office submits the required documents to *Thorax* via Scholar One (the Thorax manuscript submission system);
- *Thorax* will communicate with the designated corresponding authors for checking of proofs;
- BTS Head Office will provide *Thorax* with instructions such as authorisation for production of colour figures etc;
- Final proofs signed off by the corresponding author;
British Thoracic Society  
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- BTS Head Office will produce the Full Guideline/Quick Reference Guide/Summary of Recommendations document (as required) for download from the BTS website to coincide with publication (published under BTS ISSN report series);
- A summary of Guideline recommendations will be submitted to BMJ Open Respiratory Research for simultaneous publication on the open access journal website.
- *Thorax* confirms the likely publication date;
- On publication, *Thorax* provides a pdf copy of the document which is placed on the BTS website with the associated full Guideline/Quick Reference Guide/additional documentation.

4.50 BTS Head Office, in consultation with the chair of the Guideline group and the SOCC chair, will oversee the press and media coverage associated with the publication of the Guideline.

4.51 Copies of the Guideline evidence tables, references and literature search records together with notes of the Guideline group meetings should be held at BTS Head Office.

4.52 BTS Head Office will arrange for relevant associated materials (educational documentation, audit tools and patient information) to appear on the BTS website to coincide with the guideline publication.

4.53 BTS Head Office will explore appropriate ways to support the dissemination of the key messages of each guideline. For example, the Society may provide open-access educational slides, eLearning modules, short courses/symposia at the BTS Winter or Summer Meetings, examples of template documents which support the guideline recommendations etc.

5. Process for Review/Updating of Existing Guidelines

5.1 Updates/revisions to existing Guidelines are considered by the SOCC (and SAG Chair) on a regular basis with the intention that existing Guidelines are reviewed within 5 years of the publication date to confirm whether a revision is required (or sooner if the evidence base for the Guideline is known to have changed). The Chair of the Guideline group (or another nominated individual) will be asked to review a Guideline that is over 5 years old, and to advise the SOCC on the need for an update. If no significant additional evidence is available, the SOCC may decide to confirm the validity of the existing Guideline for a further specified period, and review the Guideline again subsequently. Cross check previous section....

5.2 In cases where it is known that new evidence is likely to become available within 5 years of publication of a Guideline, the Guideline Group may advise that a revision is required within the normal 5 year period.

5.3 The BTS website includes a list of published Guidelines with an indication of the status of the document as follows:

- **Valid** Guidelines that have been published within the past 5 years, or that have been reviewed and confirmed to still be current (with the date of last and next review included).

- **Under review** Guidelines that have been published over 5 years ago and are being considered by the SOCC for possible revision.
6. **Production of Joint Guidelines**

6.1 The Society may be approached by other organisations or group with an invitation to produce a joint Guideline.

6.2 The SOCC will consider proposals for the production of joint Guidelines, and will require that the methodology used in the Guideline production process meets the standards required for the production of BTS Guidelines. In such circumstances the Society would expect to nominate an appropriate proportion of members of the Guideline group (and this could include nomination of a co-chair), and the draft Guideline would be submitted for comment and approval by the BTS Standards of Care Committee in the normal way.

6.3 The British Thoracic Society has a formal agreement with SIGN to produce the British Guideline on the Management of Asthma and, in the case of this Guideline, the SIGN Guideline production procedure is used.

7. **BTS representation and endorsement of externally produced Guidelines**

7.1 The Society may be invited to nominate a BTS representative to act as a member of another organisation’s guideline group. The Standards of Care Committee will approve an individual as a BTS representative on a Guideline group provided that:

- The Guideline topic and outline is deemed appropriate;
- The Guideline methodology and production process is in line with that used by the Society;
- That the nominated representative agrees to provide a brief written report to each meeting of the Standards of Care Committee.
- That the final draft guideline is presented to the SOCC (with the BTS representative in attendance) for approval.

7.2 In the case of requests for formal endorsement of another institution’s Guideline, the Society would expect to nominate at least one representative member of the Guideline group, and the draft Guideline would be submitted for comment and approval by the BTS Standards of Care Committee in the normal way, before a decision on whether to endorse the Guideline is made (see 7.1 above).

**BTS June 2016**

Date of Production: March 2009
Due for next review: July 2017
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References

1. SIGN 50: A Guideline Developer’s Handbook
   http://www.sign.ac.uk/Guidelines/fulltext/50/index.html

2. NHS Evidence Accreditation
   http://www.evidence.nhs.uk/Accreditation/Pages/Accreditation.aspx


5. GRADE  http://www.gradeworkinggroup.org/
Appendix 1

Appraisal of Guidelines for Research and Evaluation AGREE II
http://www.agreetrust.org/agree-ii/

The purpose of the Appraisal of Guidelines Research & Evaluation (AGREE) II Instrument is to provide a framework for assessing the quality of clinical practice guidelines.

The AGREE II criteria for assessment of guidelines includes judgements about the methods used for developing the guidelines, the content of the final recommendations, and the factors linked to their uptake. The AGREE Instrument assesses both the quality of the reporting, and the quality of some aspects of recommendations. It provides an assessment of the predicted validity of a guideline, that is, the likelihood that it will achieve its intended outcome. It does not assess the impact of a guideline on patients’ outcomes.

The 23 criteria are summarised below:

Scope and Purpose
1. The overall objective(s) of the guideline should be described in detail and the expected health benefits from the guideline should be specific to the clinical problem.
2. A detailed description of the health questions covered by the guideline should be provided.
3. There should be a clear description of the target population to be covered by the guideline.

Stakeholder involvement
4. The guideline development group should include individuals from all the relevant professional groups.
5. The views and preferences of the target population (patients, public) should be sought.
6. The target users of the guideline are clearly defined.

Rigour of development
7. Systematic methods were used to search for evidence.
8. The criteria for selecting the evidence are clearly described.
9. The strengths and limitations of the body of evidence are clearly described.
10. The methods used for formulating the recommendations are clearly described.
11. The health benefits, Side effects and risks have been considered in formulating the recommendations.
12. There is an explicit link between the recommendations and supporting evidence.
13. The guideline has been externally reviewed by experts prior to its publication.
14. A procedure for updating the guideline is provided.

Clarity and Presentation
15. The recommendations are specific and unambiguous.
16. The different options for management of the condition or health issue are clearly presented.
17. Key recommendations are easily identifiable.

Applicability
18. The guideline described facilitators and barriers to its application.
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.
20. The potential resource implications of applying the recommendations have been considered.
21. The guideline presents monitoring and and/or audit criteria.

Editorial independence
22. The views of the funding body have not influenced the content of the guideline.
23. Competing interest of guideline development members have been recorded and addressed.
Appendix 2

BRITISH THORACIC SOCIETY

STANDARDS OF CARE COMMITTEE

1. TERMS OF REFERENCE

The BTS Standards of Care Committee has two major responsibilities:

- Primarily, Guideline development. This involves the development and maintenance of robust systems for the production of the Society's own Guidelines, from assessing the need for a Guideline to the submission for publication, in line with NHS Evidence Accreditation criteria. The scope of this work will involve Guidelines on specific diseases, specific procedures and on processes of care, plus advice about key messages for dissemination, associated audit tool(s) and patient information.

- Production of Quality Standards, based on BTS Guidelines, which aim to provide clinicians, commissioners, planners and patients with a guide to the standards of care that patients with a particular disease/condition should expect, together with measurable markers of good practice.

Additionally the Committee will identify research questions arising from Guideline development work and refer these directly to the NIHR Respiratory Specialty Group.

2. MEMBERSHIP

- Chair
- Chair-elect (in the third year of the Chair’s period of service, to allow handover
- Council member(s), who may select to serve on the Committee while serving on Council. A maximum of 4 Council members to be on this Committee at any one time.
- Three consultant physicians who will be selected from those who come forward following the annual call for volunteers (in succession-one per year).
- Three Specialist Trainees who will be selected from those who come forward following the annual call for volunteers (in succession-one per year). Two of these will serve additionally on the BTS Specialist Trainees Advisory Group (STAG) and will act as the link between the two.
- Two nurse representatives, at least one of whom will be selected from the BTS Nurse Advisory Group. This person will be nominated by the Group and will act as the link between the two.
- Up to 2 members of the BTS Public Liaison Committee or equivalent
- Two representatives from the British Paediatric Respiratory Society (BPRS).
- A representative from the Association of Chartered Physiotherapists in Respiratory Care (ACPAC)
- Chair of the BTS Executive Committee, and Chief Executive, ex-officio (standing invitation to the former, although will not usually attend)

(NB Committee cannot have their own Deputy; Honorary Secretary or other nominal post)
2.2 All members, however selected and in whatever capacity, will normally serve for a maximum of 3 years from the date of taking up membership. The term of service is usually effective from the date of Society’s Annual General Meeting in December each year. The only exception is the Chair-elect. S/he will be appointed in the third year of the Chair’s period of service, to allow handover, and will therefore expect to serve for no longer than 4 years, but exceptionally for 5 or 6 years. This will only occur if the Chair-elect is already serving on the Committee at the time of the election (see item 3.6, below).

2.3 Members can join Committees in one of 3 ways:-

- By volunteering annually in response to a call for volunteers. This is circulated in the early summer each year to all BTS members. The call for volunteers will clearly state the vacancies that are available; the experience and special interests sought (if any) and the arrangements for selection. If there are more volunteers than places available, selection will be undertaken by a ballot involving all members of the current Committee based on the provision by volunteers of a short CV and supporting statement.

- When elected to serve on Council, each Council member is asked to select a Standing Committee on which to serve. There is generally no barrier to a Council member joining their Committee of choice, although it may from time to time be necessary to negotiate filling a gap where one exists and the Society has need of additional Council input, and therefore first choice of Committee cannot always be guaranteed.

- By being the nominated representative of one of the bodies mentioned above in the membership list. In this event, the “three year rule” will still apply

2.4 All members of BTS Committees must be members of the Society unless they have been nominated by an external organisation.

2.5 If a Committee wishes to involve a member with specific skills, and that person is not therefore likely to be a BTS member; or, if a Committee wishes to vary the membership as outlined above, this MUST be discussed first by the Chair with the Executive Committee (the Society’s Trustees), and agreement of Trustees obtained.

2.6 Every effort is taken to agree dates of meetings one year in advance and notify these to all members as soon as they have been agreed. Dates agreed in advance will only be changed if there are exceptional circumstances, and then at least 8 weeks’ notice will normally be given. If a member misses more than 2 meetings in succession, and there are no extenuating circumstances (in relation to sickness absence, for example), then the Society will ask that member to stand down.

2.7 All members are required to conduct themselves in accordance to the Society’s policies and general procedures (e.g. for travel expenses), and in particular in relation to the policy about relationships with the bio-medical and tobacco industries, and the associated Declarations of Interest Scheme (DoI) (see section 4 following). Members are especially asked to note that efforts should be made to return a completed DoI form before the end of January each year, or prior to the first meeting of the Committee in every calendar year, whichever is earlier. If a form has not been completed after a reminder has been given at that meeting, the member concerned will be asked to withdraw until the information has been provided.
3.  STANDING ORDERS

3.1  Role of the Chair of the Committee
The Chair of the Committee also serves as a Trustee of the Society during the time s/he is in post. S/he is therefore the main link between the development and execution of the Society’s strategic objectives (as summarised in the Strategic Plan) and the detailed work of the Committee.

3.2  The Chair is responsible for the direction, conduct, moving forward and completion of Committee business, both during Committee meetings and between the meetings. In this task s/he is supported by the Society’s staff (who provide a full secretariat service) and other members. A Deputy Chair post is not required.

3.3  The Chair will approve the Committee agenda and draft minutes, which are prepared by BTS staff. S/he will also prepare and/or commission papers from other and will chair the formal meetings of the Committee and any ad-hoc meetings and teleconferences.

3.4  While BTS staff can draft follow up correspondence and deal with queries arising from the work of the Committee on an operational level from day to day, it is anticipated that the Chair will provide advice on content and professional issues involved and, in particular, deal with peers and external organisations in relation to all areas where clinical leadership is required.

3.5  The Chair has an important role in ensuring that Declaration of Interest forms from all Committee members are scrutinised and any issue of concern discussed with the individual concerned and/or the Honorary Secretary. S/he must also ensure that at the beginning of each meeting members are asked to declare any additional recently-acquired interests, and is expected to exercise judgement in the conduct of Committee business in the event of any potential conflicts of interest.

3.6  Succession planning for the Chair of the Committee will take place as follows. In the spring of the year when the Chair’s 3 year term in office is due to end, the Society will advertise that a vacancy for the Chair of that Committee will be coming up. Members of the Committee plus any other member of the Society will be invited to apply by submitting a short CV and statement of interest. The Committee will then vote (secret ballot, based on information supplied) and the outcome of that vote made known to the Executive Committee at its December meeting. The Executive Committee is responsible for confirming the appointment of the new Chair of the Committee, taking into account the result of the ballot. Trustees reserve the right not to accept the outcome of a ballot, although the circumstances under which this right might be exercised would be exceptional. The Executive Committee’s decision will be made known to the successful candidate so that the Chair-elect can spend the year before taking up post shadowing the incumbent and receiving information about being a Trustee of the Society.

3.7  Before a Chair is appointed, s/he will be asked to submit an updated Declaration of Interest form, if this is not already available. This will be submitted to the Chair of the Executive Committee (the Trustees) and Honorary Secretary for approval before the appointment is confirmed.

3.8  Frequency and conduct of meetings of the Committee
The Committee will normally meet no more than 4 times a year, at the Society’s headquarters building in London.
3.9 Trustees recognise that it may be necessary from time to time to plan an additional meeting in any year when anticipated business demands this. This would not normally be a problem, except that short notice may result in poor attendance, and it is now important to give at least 8 weeks’ notice. For urgent/timing dependent issues that might arise which do not justify a full agenda, the Society’s constitution allows business to be conducted by teleconference. This can be organised at no cost to Committee members or their employers. This paragraph does not contradict the restriction in paragraph 2.6, above.

3.10 Because some members have to travel some distance to attend meetings in London, and to maximise the amount of business that can be achieved and also opportunities for “off peak” travel (in at least the return portion) meetings are normally held between 10.30 and 3.00pm and lunch is provided.

3.11 It is not usually acceptable to conduct a Committee meeting at BTS headquarters with one or more members attending for all or part of the meeting via teleconference or web-cam, as this impedes progress of business. The Society recognises that in exceptional circumstances it may be necessary for a Committee member to participate for specific items of business, but this should be arranged on a case-by-case basis.

3.12 The Committee secretary (BTS staff member) will draft an agenda and discuss with the Chair no later than 3 weeks before the date of the meeting. The agenda and papers will be sent by post to all members no later than 7 days (and preferably) 10 days before the meeting takes place. It is not good practice, and will not normally be possible, to table papers at meetings, especially those that contain detailed information except at the discretion of the Chair, and taking into account circumstances involved. Authors of papers are therefore asked to submit in time according to the date given by the secretariat, so that copying can take place.

3.13 A draft minute, including named action points, will normally be produced within 7-10 days of the meeting to be agreed by the Chair and then sent to members as an aide-memoire for those who may have been asked to carry out actions, or for the information of those who were not able to attend.

3.14 The nature of the work of this Committee requires that individual members may be called upon to review documentation and provide comments in advance of Committee meetings or in between meetings. Guidance on the work required is provided and the workload shared across the Committee as equitably as possible.

3.15 Sub-Committees and ad-hoc groups
Because the Society has a comprehensive network of Specialist Advisory Groups which act as expert advisors in specific disease/therapy areas, it is not generally permitted for Standing Committees to establish any sub-Committees and/or working parties and ad-hoc groupings. Any proposals that this ruling is relaxed must be discussed and agreed by the Executive Committee in advance.

4. CODE OF CONDUCT

4.1 The Society values the contribution of those members who serve on its various Committees and Advisory Groups and Working Parties. Without this service, it would not be possible to carry out the great variety of work that is undertaken which contributes to the raising of standards of care of
people with respiratory disease. BTS has a justifiably high reputation for the quality of its activities and the advice it gives to external bodies.

4.2 The Society is also proud to have been a pioneer in a number of areas, including its Declarations of Interest scheme, which has been replicated by a number of other Societies in recent years. The probity of our actions is underpinned by a number of policies and procedures which are kept under regular (annual) review.

4.3 To ensure effective functioning of the Declarations of Interest process the Chair should proactively manage declarations from SAG members. This will include:
  - Having declarations of interest as a standing item on all meeting agendas;
  - Formally asking members whether anything has changed since they submitted their last declaration;
  - Formally asking members at the start of each meeting whether there are any agenda items which may cause conflict or in which they have an interest;
  - Seeking advice when required from the Honorary Secretary or Chief Executive if there are any concerns about new items mentioned under declaration of interest.

4.4 Consequently, we ask all members of Committees, Advisory Groups and Working Parties to note and abide by the following policy and procedures documents:-

  - BTS Policy on Biomedical Industries & Commercial Sponsorship and associated Declarations of Interest Scheme. This is reviewed annually by BTS Council and Trustees.
  - Endorsement Policy (reviewed in June 2015 by Executive Committee and BTS Council)
  - Media policy (to be reviewed in October 2015)
  - Travel and subsistence policy (reviewed annually by Honorary Treasurer and Chief Executive)

These documents can all be found on the BTS website in the “governance” pages of the section entitled “About BTS”

Date of production/revision: June 2015
By: BTS Governance Review group/Executive Committee

Review date – June 2019
Appendix 3

Call for Guideline proposals

The British Thoracic Society has been at the forefront of the production of guidelines for best clinical practice in respiratory medicine since the Society was established over 25 years ago. The BTS Standards of Care Committee (SOCC) oversees the Society’s guideline production strategy and procedures, including the approval of new guideline topics. The production of a BTS guideline is a substantial undertaking, requiring significant time and commitment from the guideline group chair and members, as well as BTS Head Office and the Standards of Care Committee members. Details of the guideline production process are available in the BTS Guideline Manual: https://www.brit-thoracic.org.uk/guidelines-and-quality-standards/

From 2016, proposals for new guideline topics will be invited on one occasion each year. The SOCC will review all proposals for new guideline topics and proposals for the revision of published BTS guidelines and select up to two topics to go into production.

The SOCC will consider the following factors in the approval process for a new guideline – please address these points in the topic proposal form below.

- Are there areas of clinical uncertainty as evidenced by wide variation in practice or outcomes?
- Is this a condition where effective treatment is proven and where mortality or morbidity can be reduced?
- Is this a clinical priority area for BTS where clinical guidance is lacking (and with a perceived need for guidance) and the area is unlikely to be produced by other Guideline producers (such as NICE)?

Each proposal should have the support of a BTS Specialist Advisory Group (SAG), if a relevant group exists. A full list of SAGs can be viewed at https://www.brit-thoracic.org.uk/about-bts/bts-committees-and-advisory-groups/.

Please note that BTS is not currently seeking formal nominations for potential Chairs and Guideline Group members but suggestions for individuals with a particular interest in the proposed topic are welcome.

Please complete the following form and return to BTS Head Office (sara.flemming@brit-thoracic.org.uk) by 11 May 2016.

Please see the ‘Important Information for Guideline Proposers’ for further points to consider in your application.

All proposals will be considered by the BTS Standards of Care Committee and a decision confirmed before the end of November 2016.

BTS 17 March 2016
British Thoracic Society
Guideline Production Manual 2016

BTS Guideline Proposal Form

<table>
<thead>
<tr>
<th>Guideline title</th>
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<tbody>
<tr>
<td>Name(s) of proposer(s)</td>
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<tr>
<td>Organisation</td>
<td></td>
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<tr>
<td>Email address(es)</td>
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</tr>
<tr>
<td>Name of the BTS SAG supporting the proposal (if applicable)</td>
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</tbody>
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Is this a proposal for a new topic or for update of part/all of a previously published guideline?

If you are proposing a new guideline: Please complete sections 1 and 3 below.

If you are proposing an updated guideline: Please complete all sections below.

Please note that a new form must be completed for each proposal.

Section 1 – Guideline details

Aim of the guideline

Who are the intended users of the guideline?

Description of the scope of the guideline - which areas and patients groups are to be included and excluded from the guidance?
## Justification for a BTS guideline
- Please provide evidence for the need for the guideline, include reference to other available guidance (if any).

## Section 2 – Updated Guideline
- Date of the latest literature search/bibliography content in the previously published document.

- Please give details of any evidence published since the date of the last literature search e.g. have any high quality RCTs or other research studies been published?

- Please provide information on any safety issues or announcements that relate to the guideline topic.

- Is it likely that evidence published since the date of the last literature search would alter (change or strengthen) the recommendations made in the existing guideline?

## Section 3 – All Proposed Guidelines
- Any other comments in support of the proposal.

- Optional: Suggestions for potential Guideline Group members and/or stakeholder organisations (for information only – members will be formally recruited by BTS when and if topic is approved).
Procedure for review of published BTS Guidelines

The BTS Guideline Production Manual includes a commitment to review and, if necessary, update or withdraw existing guidelines.

This document outlines the procedure for each Guideline that has reached its stated date of review. Proposals to update an existing guideline will be considered alongside other new topic proposals at the September SOCC meeting.

At the March Standards of Care Committee meeting each year, a list of all BTS published guidelines will be presented, noting where the date of review has been reached or falls within that year. The Committee will review the listed guidelines together with the label that appears on the website: valid, under review, in preparation or superseded.

The following steps will be taken for each guideline which is due for review:

- A high level literature search will be commissioned by BTS Head office to identify any RCTs/systematic reviews that have been published since the date of the original search or the date of the last review search.
- The results of the literature search will be reviewed by BTS head office and a summary prepared as background information for the guideline author/clinical lead.
- A lead person for each guideline topic will be identified - this may be the lead author, other member of the guideline group, a relevant SAG chair or another person identified as active in the topic area. Lead contacts will be asked to prepare a brief report on the guideline regarding its ongoing validity, whether any evidence has been published that would alter key recommendations or whether the guideline has been superseded by another publication.
- A recommendation for the SOCC about whether the guideline should remain valid, be updated or removed as superseded will be presented to the SOCC at the June meeting, to be considered alongside new guideline topic proposals.
- If a Guideline is considered to remain valid, the date of next review (in a further 2 or 3 years) will be recorded on the website.

May 2016
Appendix 4

Support for literature searches.

Guideline groups are able to call upon the services of the Centre for Reviews and Dissemination (CRD) at the University of York for assistance with the development of search strategies, literature searches, the provision of lists of abstracts as well as acquisition of papers. The chair of the guideline group should consult the CRD as early as possible to ensure that maximum benefit is obtained from the services provided by the team in York. Further details of the services provided are available from Sally Welham.

Managing data

The CRD will provide the results of literature searches as Endnote files (Endnote is a reference management software programme). The results of the searches (references and abstracts) can be exported into Word from Endnote for checking by guideline group members. It is suggested that one member of the guideline group is nominated to hold the central Endnote files for the searches. BTS will provide a copy of the Endnote software for one member of the group to allow them to manage the literature searches.

BTS can also arrange to make available the Word files containing the abstracts as downloads on a section of the BTS website. This allows all guideline group members to access what are often very large files that may be difficult to email.

BTS can also provide a copy of the database used by SIGN which has been developed to hold references, record results of checklists and produce evidence tables.

Obtaining copies of papers

Guideline group members will sift through abstracts provided by the literature searches and will generate a list of references for which the full papers are required. Copies of papers may be obtained from:

- Journals/books held as personal copies by guideline group members
- Individual members’ institutional library (or electronic library) subscriptions, eg via NHS or university Athens accounts.

The CRD can assist with ordering copies of journal articles that are otherwise difficult to locate.
The systematic literature review procedure
Appendix 5

A proposal document for the development of audits to be offered as national or local audit via the BTS Audit system has been produced by the Quality Improvement Committee and is available on request from BTS Head Office.
Appendix 6 – Supporting information

Each Guideline should include the following information which may be most appropriately included as web-based appendices to the published document:

Patient Information

Guideline groups should provide examples of patient information leaflets as appropriate to the topic of the guideline, where these are not provided by other patient groups or lung charities. BTS Head Office will provide advice in relation to the development of patient information.

Executive Summary

Consideration should be given to the production of a summary of the guideline which would set out how the guideline was developed and would include a description of the main points for a non-specialist audience. Such a summary document may be produced in addition to the editorial/article that is usually published in Thorax to accompany the guideline supplement.

Education materials

The Guideline Group will be asked to develop educational materials to assist with the dissemination and implementation of the Guideline recommendations. Educational materials may be produced in one or more of the following formats:

As the topic of a session at the BTS Summer or Winter Meeting following (or just prior to) Guideline publication;
As the subject of a BTS Short Course
As the subject for the development of a module as part of the BTS Learning Hub
As a series of supplementary documents or powerpoint files made available to accompany the published guideline;

BTS Head Office will provide advice and assistance for the production of this supporting material.

Research recommendations

As part of the Guideline production process, Guideline Groups should provide a list of recommendations for further research. Research recommendations can be provided as an appendix to the main Guideline and will be passed to the BTS Science and Research Committee following publication of the Guideline.
Appendix 7

Quality Standards

The Society aims to produce a Quality Standards document based on the recommendations of each BTS Guideline.

The procedure for the production of BTS Quality Standards can be obtained from BTS Head Office.

May 2016
Appendix 8

BTS Guidelines: Principles and procedures for publication in Thorax

BTS Guidelines are produced under the auspicies of the BTS Standards of Care Committee, in line with the policies and processes contained in the BTS Guideline Production Manual (2011).

BTS Guidelines are subject to a rigorous review and public consultation process as part of their development and are submitted to Thorax only after final approval by the BTS Standards of Care Committee. Following the agreement with the previous two sets of Thorax editors, BTS Guidelines are not subject to the Thorax peer review process and the content cannot be amended following submission (other than for journal style issues). The draft Guideline will be sent to Thorax editors as part of the formal consultation process and additional expert reviewers will be nominated by the editors at that point in the process (agreed June 2011). This satisfies the journal’s requirement for peer review. It is common for the published guideline to include the words “internally peer reviewed” on publication in Thorax – which refers to the fact that the document is not peer reviewed following submission for publication (the peer review process having been undertaken as part of the consultation process).

Guidelines are submitted to Thorax through the journal’s manuscript submission system and undergo the copy-editing and typesetting process. Where appropriate, appendices and other supporting information are provided as web-only documents. The full Guideline is published as a citable supplement to the main journal, published online via the Thorax website, and distributed as a paper copy to journal subscribers.

When published, a pdf of the Guideline supplement is provided to BTS by the Thorax production team and is made available to download from the BTS website. The Guideline is not made available via the BTS website until the Thorax supplement is published. Thorax editors will normally invite the Guideline authors to produce a one page summary of key points from the guideline to be published in the main Thorax journal.

BTS produces an Executive Summary or Quick Reference Guide which contains the key recommendations from the Guideline as well as important figures and tables. This is made available via the BTS website and may also be distributed as a paper copy to BTS members.

Please contact BTS Head Office for further information.

February 2016
Appendix 9

Role Description: Guideline Development Group Chair and members

The British Thoracic Society has been at the forefront of the production of Guidelines for best clinical practice in respiratory medicine since the Society was established over 25 years ago. BTS Guidelines are produced by multidisciplinary groups drawn from those working in respiratory medicine and allied specialties and professions, and are aimed at providing pragmatic evidence based guidance for the management of respiratory conditions.

The Chair of a Guideline Development Group (GDG) plays a critical role in the development of the guideline, and has a key responsibility in ensuring that the guideline production process is conducted appropriately to an agreed timetable.

The chair (co-chairs) would be expected to:

- Lead the guideline development group with support from BTS
- Facilitate the process of the development within the framework of agreed BTS methodology following the AGREE criteria
- Ensure equality of input from all GDG members
- Manage declarations of interest and potential conflicts of interest
- Keep to the scope – manage the ambition of the GDG (noting that this is not a text book)
- Attend all committee meetings and read meeting papers in advance of meetings.
- Encourage constructive debate among all group members during meetings.
- Participate in guideline development training as appropriate.
- Work with BTS Head office staff and group members as required during and between meetings to identify key issues, formulate clinical questions for review, review evidence tables, and draft recommendations.
- Lead the write up of the draft document (in line with BTS template)
- Work with group members and BTS Head Office staff to write and edit drafts of the guideline.
- Lead the group in considering and addressing stakeholder comments on the draft guideline.
- Provide progress reports to the BTS SOCC as required
- Attend an agreed SOCC meeting to present the draft guideline.
- Support the dissemination and implementation of the guideline - be a champion for the guideline after publication and undertake activities to promote its implementation, such as talking at professional conferences and participation in the production of publishing guideline-related articles in accordance BTS policy.

Guideline Group members would be expected to:

- Participate fully in the work of the guideline development group with support from BTS
- Adhere to the process of the development within the framework of agreed BTS methodology following the AGREE criteria
- Submit and update declarations of interest and potential conflicts of interest on a regular basis
- Participate in guideline development training as appropriate.
- Attend all committee meetings and read meeting papers in advance of meetings.
- Use their clinical expertise + research evidence + patient wishes to support the guideline development.
- Input positively in meetings treating all as equals

Date of Production: March 2009
Due for next review: July 2017
• Work with BTS Head office staff and other group members as required during and between meetings to produce clinical questions for review, review evidence tables, and draft recommendations.
• Participate in the preparation and review of the draft document (in line with BTS template)
• Work with the chair, other group members and BTS Head Office staff to write and edit draft sections of the guideline.
• Work with other group members to consider and address stakeholder comments on the draft guideline.
• Support the dissemination and implementation of the guideline - be a champion for the guideline after publication and undertake activities to promote its implementation, such as talking at professional conferences and participation in the production of publishing guideline-related articles in accordance with BTS policy.

Declarations of Interest
The Chair (co-chairs) of the proposed group must complete a BTS Declaration of Interest form and any potential conflicts of interest considered by the BTS Honorary Secretary and the Chair of the SOCC before work on the Guideline is undertaken. The Chair of the SOCC and the Chair of the Guideline Development Group have responsibility for scrutinising Declarations submitted by Guideline Group members. It is a requirement that guideline group chairs would not have conflicts/declarations of interest in the subject area of the guideline concerned. It is also expected that at least 50% of the members of a guideline group would have no declarations/conflicts of interest.

Training
Where possible the Chair of the Guideline Group should receive training in advance of the other members of the Group. This may take the form of one or more individual sessions with the BTS SOCC Chair and BTS Head office team.

Guideline authorship
The Chair (co-chairs) have responsibility for drafting the scope and agreement will be reached by the full Guideline Development Group. The Chair (co-chairs) would take the lead in production of the full draft document for review by the group. While it is expected that all guideline group members would usually be named as authors (and would contribute appropriately to the authorship of the guideline – fulfilling the stated criteria for authorship as appears on the Thorax website) it is expected that the Chair (co-chairs) of the guideline group would be the first named author(s). The expectations and requirements for all guideline group members to contribute as authors to the guideline should be made clear at the first meeting of the guideline group.
Example of Instructions for Guideline Group members

BTS xx Guideline
Instructions for review of full papers

Following the literature search, the abstracts identified have been screened to identify those that are relevant to the key questions/guideline sections.

The full literature search (3848 abstracts) were subject to initial screen to remove:
- Abstracts deemed by the steering group to be not relevant/outside the guideline scope
- Abstracts for review papers/conference abstracts/letters/comments/case reports

The full list of abstracts (including those marked as not relevant) will be retained for the archive.

Abstracts deemed to be relevant and appropriate to the guideline are allocated to each key questions - one abstract may be allocated to more than one key question depending on the subject of the paper. 1022 abstracts were allocated to individual clinical questions.

See the accompanying spreadsheet for the abstracts allocated to individual questions.
See the accompanying documents for the allocation of group members to key questions (group members are assigned to questions to work in pairs and for larger questions, more than one pair is allocated to a question).

Next steps:
For each section/key question, group members have been assigned to work in pairs and progress as follows:

1. **Review abstracts assigned to the given key questions and remove any that are not relevant to the question.** Divide the list of abstracts between the two (or more) individuals assigned to the question and taking each abstract in turn decide whether on closer reading, the abstract is relevant to the question concerned and mark this in the spreadsheet column. Although the initial screen aimed to remove review papers/comments etc if any still remain these should also be excluded at this point. Those abstracts marked not relevant should be agreed between the pair by cross checking each other’s screened list. The steering group have been careful not to over-exclude papers in the initial screening process so non-relevant papers will remain and can be removed at this stage.

Papers should also be excluded if the following apply:
- If the paper does not answer the clinical question concerned
- If it is a case report of less than 10 patients
- If the language of the full paper is not English

2. **For those abstracts considered relevant – obtain the full paper.** For those abstracts that you consider relevant to the question, obtain full copy of paper (using own NHS/academic library resources, requesting assistance from other group members as necessary). If there are problems with obtaining specific papers, contact SW in first instance. Use Dropbox
3. Assign each full paper to one member of the reviewing pair for detailed reading and completion of the checklist/evidence table.

4. Select the appropriate SIGN checklist to use by referring to the algorithm at http://www.sign.ac.uk/pdf/studydesign.pdf to assist with classifying study design and deciding on which checklist to use.

5. Each paper should be critically reviewed by one person, and the appropriate SIGN checklist completed. The paper and checklist should then be shared and agreed with the other partner. It is up to each pair to decide the allocation of papers between them for their section.

Question 2.1 in the checklists requests a rating of the methodological quality of the study, based on responses in Section 1 and using the following coding system:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>++</td>
<td>All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought very unlikely to alter.</td>
</tr>
<tr>
<td>+</td>
<td>Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.</td>
</tr>
<tr>
<td>-</td>
<td>Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.</td>
</tr>
</tbody>
</table>

The code allocated here, coupled with the study type, will decide the level of evidence that this study provides. The rating should be included in the evidence table (see point 6). See flow chart at Annex 1.

6. An evidence table should be completed for each paper used to support a recommendation/good practice point (see template/example provided). Complete the sections of the evidence table for a given paper at the time the checklist is being completed to avoid having to return to the paper at a later point.

7. Summarise the evidence for the key question by populating the considered judgment form. When all papers for the question concerned have been reviewed, a considered judgement form (Annex 2) should be completed which summarises the evidence, and if possible a draft evidence statement/recommendation should be included (this document should be agreed by both members of the reviewing pair). This documentation will form the basis of discussion at the next guideline group meeting and contribute directly to the first draft of the guideline.

The following point should be considered when formulating recommendations: “Recommendations cannot be based purely on minus rated studies. If this is the best available evidence, it should be discussed but not recommendations drawn from it. If findings are consistent with other body of evidence, then include and may reinforce the weight of evidence”.

Copies of the checklists/considered judgement forms and evidence table template are provided separately.

Deadline for completion of checklists/evidence tables/considered judgement forms:

Date of Production: March 2009
Due for next review: July 2017
Additional information regarding critical appraisal can be obtained from Sally. When complete, the checklists and evidence tables should be returned to: sally.welham@brit-thoracic.org.uk for the archive. Any queries – please contact sally.welham@brit-thoracic.org.uk

Annex 1
Considered Judgement Form

<table>
<thead>
<tr>
<th>Key question:</th>
<th>Evidence table ref/Abstract numbers:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Volume of evidence</td>
<td></td>
</tr>
<tr>
<td>Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality.</td>
<td></td>
</tr>
<tr>
<td>2. Applicability</td>
<td></td>
</tr>
<tr>
<td>Comment here on the extent to which the evidence is directly applicable to the NHS.</td>
<td></td>
</tr>
<tr>
<td>3. Generalisability</td>
<td></td>
</tr>
<tr>
<td>Comment here on how reasonable it is to generalise from the results of the studies used as evidence to the target population for this guideline.</td>
<td></td>
</tr>
<tr>
<td>4. Consistency</td>
<td></td>
</tr>
<tr>
<td>Comment here on the degree of consistency demonstrated by the available of evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.</td>
<td></td>
</tr>
<tr>
<td>5. Clinical impact</td>
<td></td>
</tr>
<tr>
<td>Comment here on the potential clinical impact that the intervention in question might have – e.g. size of patient population; magnitude of effect; relative benefit over other management options; resource implications; balance of risk and benefit.</td>
<td></td>
</tr>
<tr>
<td>6. Other factors</td>
<td></td>
</tr>
<tr>
<td>Indicate here any other factors that you took into account when assessing the evidence base.</td>
<td></td>
</tr>
<tr>
<td>7. Evidence statement</td>
<td>Evidence level</td>
</tr>
<tr>
<td>Please summarise the development group's synthesis of the evidence relating to this key question, taking all the above factors into account, and indicate the evidence level which applies.</td>
<td></td>
</tr>
</tbody>
</table>
### 8. Recommendation

What recommendation(s) does the guideline development group draw from this evidence? Please indicate the grade of recommendation(s) and any dissenting opinion within the group.

<table>
<thead>
<tr>
<th>Grade of recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SIGN LEVELS OF EVIDENCE</strong></td>
</tr>
<tr>
<td>1++</td>
</tr>
<tr>
<td>1+</td>
</tr>
<tr>
<td>1-</td>
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<tr>
<td>2++</td>
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<td></td>
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<td>2+</td>
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<tr>
<td>2-</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
</tbody>
</table>

### GRADES OF RECOMMENDATIONS

**A** At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; 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+

**Good practice points**

☑ Recommended best practice based on the clinical experience of the guideline development group