

British Thoracic Society

Standards of Care Committee

Guideline Production Manual

2018

**British Thoracic Society
Guideline Production Manual 2018**

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New guideline topic proposals Topic selection with reference to BTS strategic objectives – see section 2.7
Call for applications for co-chairs of new GDG Open recruitment, led by SOCC – see section 3.1/3.2
Open recruitment of all other GDG members To include trainees (50%), allied health professionals and lay representatives (see section 3.3) All members to complete BTS Declarations of Interest forms (see section 3.9).
Development of the scope To be presented to SOCC for approval (see section 4.4-4.6)
Development of PICOT framework Clear clinical questions and outcomes are defined for the guideline structure and literature search (see section 4.9)
Comprehensive literature search Completed by York
Initial screen of abstracts Completed by co-chairs (see section 4.20 onwards)
Full systematic review of literature using BTS GRADE methodology Group members work in small groups to appraise and grade all relevant papers.
Evidence identified as High, Moderate, Low or Very Low Evidence statements, recommendations and Good Practice Points drafted based on the appraisal of papers (see section 4.26)
Full group meeting to discuss findings from evidence review
Co-chairs to create first full draft
Presentation of draft to SOCC to seek permission for public consultation
4-6 week period of open public consultation on BTS website To include Thorax peer reviewers
GDG to amend draft in light of public consultation
Amended draft to SOCC for final approval
Submission to Thorax Executive summary submitted to BMJ ORR
Quality improvement activities Communication across BTS Committees to ensure the key messages of the guideline are disseminated widely and supported by appropriate resources

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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 and published before 2015 followed the SIGN methodology as outlined in the 2016 BTS Manual for Guideline Production. In 2014 the BTS Executive Committee and the Standards of Care Committee approved a proposal for the Society to move from SIGN to GRADE methodology for all new Guidelines commissioned from 2015.

1.5 The development of the 2017 Manual 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 from a range of experts in the field of Guideline development (NCGC, RCOT) and the BTS GRADE pilot guideline group. This advice 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, and the production of Guidelines that promote optimum standards of care is key to the achievement of this objective.

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

General principles for BTS Guidelines: AGREE Criteria

1.8 BTS guidelines are produced by Guideline Groups selected and approved by the BTS SOCC with advice from the BTS network of Specialist Advisory Groups. The work of Guideline Groups is supported by BTS Head Office staff who will make arrangements for meetings, ensure that accurate meeting notes are produced, and who will support the Group chairs/members in the timely production of the Guideline. The Society does not seek or accept external funding for the production of its guidance.

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1.9 BTS Guidelines are based on the best available evidence and should adhere to the AGREE II Instrument (<http://www.agreetrust.org/resource-centre/>) – 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 and describe specific, measurable aspects of care or service provision that people should expect to receive in a high-quality service.
- To ensure that all BTS Guidelines and Quality Standards follow the appropriate process, as detailed in the published production manual. The Committee will also ensure that the production manual is reviewed and updated where appropriate annually.
- 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 Board.

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 possible 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 can also serve to highlight areas where further research is required.

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Process for identifying a topic for a Guideline

2.7 The SOCC is responsible for selecting topics for new BTS Guidelines. The commissioning process is led by the SOCC and the Chair is able to seek advice from the BTS Board on future guideline topics as necessary.

2.8 Guideline topic proposals are welcomed from BTS members, chairs of BTS SAGs, stakeholder organisations and individuals at any point. Proposals are only considered at one specific SOCC meeting per year and the date of this meeting is advertised on the BTS website. 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.

2.10 In line with NICE Accreditation, all BTS guidelines are marked as valid/under review/in preparation/superseded/archived on the BTS website. At five years from publication a guideline will be marked as archived on the BTS website. The SOCC will regularly review the list of valid/archived guidelines. For topics where new guidance is required, the SOCC will consider whether a new guideline is commissioned. The SOCC may also consider whether a topic is suited to the production of a Clinical Statement.

2.11 The SOCC will consider the following factors in the approval process for 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 clear 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. Progress reports on the work of the group should be provided for each SOCC meeting. GDG co-chairs will be invited to attend SOCC meetings at the following specified points in the production process:

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- To present the PICO questions before the literature search is completed. At this meeting, the format, structure, word count and timescale will be discussed and agreed.
- A further meeting, approximately a year in, to discuss progress and allow the co-chairs to raise any potential issues or ask any questions of the Committee.

The SOCC will receive regular updates from Head Office staff at each meeting. These might highlight the need for additional advice and assistance. Such intervention may be initiated by the GDG itself, SOCC or Head Office.

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 open invitation for applications for the posts of co-chairs of the Guideline Development Group (GDG) is issued by the SOCC Chair via the BTS website and BTS member mailings. One of the co-chairs would be likely to be experts in the topic and skilled in managing a committee. They would be involved in the appointment of guideline group members. A full role description for the co-chairs of the guideline group is provided at Appendix 9 and would be provided to those considering applications for the role of Guideline Group co-chairs.

3.2 The 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 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.
- 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.

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- Ensure the guideline production runs to timetable as far as possible.
- 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 3 agreed SOCC meetings (at the start of the process, after 12 months and then to present the draft guideline before public consultation).
- 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 co-chairs, 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 Specialist Trainees with an opportunity for valuable experience in Guideline preparation and brings the perspective of the Specialist Trainee to the Guideline. It is envisaged that up to half of the members of the GDG will be trainees.
- 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 into 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 at least two lay/patient representatives. Lay/patient members of Guideline group can be sought from:

- The BTS Lay Trustees/other patient lay contacts
- The Patient Involvement Unit of the Royal College of Physicians (London).
- The British Lung Foundation, Asthma UK, Cystic Fibrosis Trust or other organisation that has patient involvement/representation as a main objective.
- Via personal contacts of guideline group members.

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3.7 Clear guidance is 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 important 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 co-chairs 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 co-chairs are confirmed and any work on the Guideline is undertaken. The co-chairs 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>

3.10 The Chair of the SOCC and the co-chairs 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:

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“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 co-chairs of the Guideline Group is to write to all potential stakeholders in the final Guideline (via BTS Head Office) 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 co-chairs.

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. This list of stakeholders will be published on the BTS website. 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 co-chairs 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 co-chairs would usually be named as first

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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 Production

Timetable

4.1 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 (including direct reports and presentations from the Guideline co-chairs at agreed intervals). (see section 2.14 for more detail).

Methodology

4.2 BTS Guidelines are based on the best available evidence. There is a range of Guideline methodology but BTS Guideline Development Groups will adopt clearly defined elements of the GRADE system (Grading of Recommendations Assessment, Development and Evaluation) outlined in this manual. In doing so Guideline Groups should note that the system used should adhere to the AGREE II criteria (<http://www.agreetrust.org/agree-ii/>) – see Appendix 1.

4.3 The Guideline should include clear recommendations with an indication of the grade of the recommendation. A synopsis of the grading categories is included at 4.28. There should be an explicit link between the recommendations and supporting evidence.

Defining the scope of the Guideline

4.4 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.

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

4.6 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.

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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:

- **P**atients or population to which the question applies
- **I**ntervention (or diagnostic test, exposure, risk factor, etc.) being considered in relation to these patients
- **C**omparison(s) to be made between those receiving the intervention and another group who do not receive the intervention
- **O**utcome(s) to be used to establish the size of any effect caused by the intervention.
- **T**imeframe (optional)

It is important that the scope and all subsequent questions and identified outcomes are tightly focused. The SOCC will provide advice on this to ensure that the guideline is achievable in the timescale and that it will be of practical use clinically once published.

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.

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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 and Grading the evidence, formulating and grading recommendations

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 specific outcomes being addressed by the guideline?
2. Has the appropriate study type been used to produce the best evidence to provide meaningful advice relating to the outcomes?

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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 BTS checklists). Each study should be evaluated for internal validity, external validity and generalisability using the BTS 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 co-chairs should first seek advice from the SOCC Chair and BTS Head Office.

4.28 The definitions for levels of evidence and grading of recommendations are included at Appendix 4.

4.29 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).

4.30 Guideline groups will use GRADEPro software to support the production process. This software allows all guideline group members to share their appraisal of papers and agree the evidence statements and subsequent recommendations. Training and support for GRADEPro is provided for all GDG members and a separate GRADEPro handbook is available.

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4.31 Quality of evidence for a given outcome should be given an initial grading:

Randomised controlled trial = high
Observational study = low
Any other evidence = very low

It is then important to look in more detail at any bias which may influence the outcome . It is possible to decrease or increase the initial grade. This process is based on the judgement of the guideline group members and must be transparent. The table below should be used to aid decisions about decreasing and increasing the grade of evidence.

Decrease* grade if	<ul style="list-style-type: none"> -Serious or very serious limitation to study quality - Important inconsistencies in results - Some or major uncertainty about directness of the evidence - Imprecise or sparse data (relatively few participants and/or events) - High probability of reporting bias
Increase grade if	<ul style="list-style-type: none"> - Magnitude of the treatment effect is very large and consistent - Evidence of a large dose-response relation - All plausible confounders/biases would have decreased the magnitude of an apparent treatment effect

*Each quality criterion can reduce the quality by one or, if very serious, by two levels.

4.32 Following a full appraisal the available evidence for each outcome per question will be assigned one of the following categories: (table is adapted from COT manual (ref no)):

Quality of evidence - level	Characteristics	Confidence
High	Based on consistent results from well-performed randomised controlled trials	Further research is very unlikely to change the estimate of the effect
Moderate	Based on randomised controlled trials where there is evidence of bias. Or from other well conducted study types (e.g. well executed observational studies)	Further research is likely to have an impact on the estimate of the effect.
Low	Based on observational evidence, or from controlled trials with several serious limitations	Further research is likely to have an important impact
Very low	Based on case studies or expert opinion	Estimates of effect are far from certain and more research is needed

Note: Only studies with no major threats to validity should be upgraded. (Based on GRADE Working Group 2004)

4.33 The body of evidence for each outcome per question will then be drawn together into a considered judgement form, and a draft evidence statement, recommendation and where appropriate, good practice point, will be produced.

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4.34 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) assessment 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. BTS has adopted the GRADE system of assigning recommendations as “strong” or “conditional”:

Strength	Benefits and risks	Implications
Strong. It is recommended and so “offer”	Benefits appear to outweigh the risks (or vice versa) for the majority of the target group	Most service users would want to or should receive this intervention
Conditional. It is suggested and so “consider”	Risks and benefits are more closely balanced, or there is more uncertainty in likely service users values and preferences	The service users should be supported to arrive at a decision based on their values and preferences

This table will be expanded, and more detail will be added on GRADEPro when the Macrolide guideline pilot has reported.

It should be noted that it is reasonable for GDGs to make strong recommendations based on weak evidence where appropriate. A strong recommendations need not exclusively come from a strong evidence base.

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

- The volume of the body of evidence for that particular outcome;
- 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 deliverability

The agreement on recommendations to be included in the guideline will be reached by consensus among the GDG members. Following production of the final draft guideline document, the GDG members will be invited to vote on each recommendation (and GPP) to indicate approval for each recommendation. The GDG will be expected to confirm at the outset of its work that agreement from 80% of the group would be the threshold for acceptance of any given recommendation/GPP.

4.36 If the Guideline group feels strongly that they want to make a recommendation even though there is no significant evidence, this should be presented as a Conditional recommendation (as noted in 4.36 above), making it clear it is based on very low quality evidence. There should be some evidence of opinion supporting the recommendation from outside the guideline group. If no such evidence exists, formal methods should be used to develop a consensus based recommendation and these methods will be clearly identified as such within the guideline. The methods used to reach consensus may vary between guideline groups. Whatever method is used, it is essential that it is described either in an Annex to the guideline or as a supporting document linked to the guideline on the BTS website. Where there is a lack of evidence on a particular outcome, 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 exist within the evidence, this should be highlighted as appropriate within the Guideline document.

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4.37 BTS guidelines can 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.

4.38 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

4.39 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)

4.40 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)

4.41 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

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- Quality Standards (this document is subject to a separate production process following preparation of the Guideline - see Appendix 7).

4.42 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.

4.43 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

4.44 The final draft Guideline should be submitted to the Chair of the SOCC for comment and discussion at a meeting of the SOCC. The co-chairs 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.

4.45 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.

4.46 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 co-chairs 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.

4.47 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.

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4.48 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.

4.49 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

4.50 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.

4.51 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.

4.52 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;
- 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.

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

4.54 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.

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4.55 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.

4.56 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 Guidelines are not routinely updated at a certain time point. Once a guideline has been published for 5 years, it will be automatically moved to the online archive on the BTS website with no specific review. Updates to existing topics are viewed as new projects and would not follow on from the original publication. The validity of the proposal would be considered alongside the other proposals.

5.2 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.
Under review	Guidelines that have been published over 5 years ago and are being considered by the SOCC for possible revision.
Update in progress	Guidelines that are in the process of being revised.
In preparation	Guidelines that are in the process of being produced.
Archived	Guidelines that have been published for more than 5 years. The following text will be included on the relevant webpage: <i>BTS Guidelines published more than five years ago are marked as archived. The Guideline content/recommendations have not been checked to confirm continued validity at the date of archival and readers should bear in mind that new evidence may have been published since the Guideline was produced.</i>
Superseded	Guidelines that are deemed to be no longer valid as a more recent version has been published.
Withdrawn	Guidelines that are deemed to no longer be valid but where a revision has not been published (with the date of withdrawal included).

5.3 It is recognised that there may be occasions where an ad-hoc update to a specific aspect of a published guideline may be required within a short timeframe. The need may arise for additional advice to be made available where a major new piece of evidence that impacts on a guideline recommendation is published. In instances such as these, the Society would take advice from its network of Specialist Advisory Groups (SAGs) on whether an immediate statement is required to be made available on the BTS website (and drawn to the attention of the relevant health care professionals via its communications networks). The Society may also commission and publish a

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“Clinical Statement “ which would provide a review of the current state of the art in a given area of respiratory medicine, together with advice on good practice. Such statements would be commissioned on the expert advice/intelligence gathered by the Society’s SAG network, and produced under the auspices of the Standards of Care Committee.

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).

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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.

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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 (ACPRC)
- 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)

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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.

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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.

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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.

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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

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Appendix 3: Procedure for Guidelines that are older than 5 years

The Society currently lists all published BTS guidelines on its website here:

<https://www.brit-thoracic.org.uk/standards-of-care/guidelines/>

The summary table, with publication date and status reflects the need to present this information to underpin the Society's NICE accreditation.

BTS guidelines are currently listed on the BTS website with a classification that marks each guideline as:

In preparation
Valid
In consultation
Under review
Withdrawn
Superseded
Archived

The status of "Under Review" is to indicate that a guideline is being reviewed (not updated) to establish:

- whether the content/recommendations are still valid
- if the document should be withdrawn completely, or marked as superseded
- or put forward for the production of a new updated version.
-

A new category of Archived was introduced in 2017 to indicate those guidelines that are more than 5 years old and where the content has not been checked/reviewed.

Those guidelines marked as Withdrawn/Superseded are still listed on the BTS website (on individual guideline pages) but no longer appear in the main Guideline summary table.

1. The BTS Guideline summary page includes the following sections:

- *Current BTS Guidelines* (all guidelines less than 5 years old)
- *Guidelines in Development* (list of BTS guidelines currently in preparation)
- *Other guidance*: To include links to guidelines produced by other organisations (but provided without endorsement of any kind).
- *Guideline Archive*: Guidelines that have been published more than 5 years ago would be moved to the archive section. In each case a brief explanatory statement will be associated with the guideline which may include links to more recent guidance or simply a statement to say that the guideline is provided for reference.

Rationale:

This means that the list of BTS guidelines is current and that any guidelines older than 5 years can still be found in the archive.

The status of "Under review" will be removed. With the new GRADE methodology it would not be possible to update an existing guideline without re-visiting the scope and clinical questions. It was always the case that updates to existing guidelines would be considered alongside new topic proposals and therefore it is considered clearer to remove the under review category.

This means that there are in effect three main categories: current/in preparation/archived.

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2. A disclaimer is added to each Archived guideline page, along the lines of:

This archive contains BTS guidelines that have been published five years ago or more. The guideline content/recommendations have not been checked to confirm continued validity at this point and readers should bear in mind that new evidence may have been published since the guideline was produced.

Rationale

This approach should make it clearer that guidelines will not automatically be updated after 5 years. There would be an expectation that chairs/co-chairs of guideline groups would remain champions for the publication (or nominate a replacement). BTS SAGs would also be a useful source of information should new literature be published in a certain area. It does not seem appropriate however to expect guideline chairs to undertake potentially lengthy top level literature reviews after 3-5 years. Should the chair(s) of an existing guideline wish to apply to update the guideline they would need to apply in the same way as those submitting a new topic proposal and identify the new scope and clinical questions according to BTS GRADE methodology.

- 3. A new section which includes links to guidelines from other organisations will be included.** Any guideline page will include clear signposting to relevant guidance from other organisations (primarily NICE and ERS) which may have superseded some of the older BTS publications.

Rationale

This will provide useful links to other guidelines that may be relevant to a given topic, but a clear statement will be included to confirm that inclusion does not constitute BTS endorsement. Some work on this has already been done in relation to physiotherapy guidance published since the BTS/ACPRC guideline.

4. New guideline proposals

As noted above, the move to GRADE methodology means that any new guideline topic commissioned by BTS in future will need an updated scope and set of clinical questions, regardless of whether a guideline on that topic has been published in the past.

This supports the arrangement at 1 above to mark published guidelines as archived after a given period, and no update to that guideline is undertaken. A new guideline may be commissioned on the same or related topics but the scope/clinical questions will be new.

5. Exceptional Review of selected guidelines

There may be instances where certain guidelines need to be checked and subsequently marked as valid so that they appear Current Guideline listing. The SOCC will advise on these each year as the need arises and a review/check done to provide advice on whether the recommendations remain valid. It is likely that this will be required only where a strategic need for review of a topic has been identified as part of the Society's QI strategy and framework.

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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 co-chairs 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.

Appendix 5

BTS Checklists and Templates

Checklists, notes, considered judgement form and evidence table example

GRADEPro guide

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Appendix 6 – to be updated to include information on GRADEpro tables

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Appendix 7

It is suggested that all guidelines include a listed of suggested audit criteria. Audits to be offered via the BTS audit system are usually produced following the publication of an appropriate Quality Standard document, but it is good practice to include audit points for local use in the Guideline document.

Quality Standards

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

The production of BTS Quality Standards is overseen by the Standards of Care Committee and the procedure is available as a separate document.

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Appendix 8

BTS Guidelines: Principles and procedures for publication in Thorax

BTS Guidelines are produced under the auspices 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 may be nominated by the editors at that point in the process (agreed June 2011).

Expert reviewers nominated by Thorax editors will be asked to complete a Declaration of Interest form.

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 may produce 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 BMJ Open Respiratory Research, the BTS website and may also be distributed as a paper copy to BTS members.

Please contact BTS Head Office for further information.

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Appendix 9

Role Description: Guideline Development Group co-chairs 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 co-chairs 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 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

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- 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 co-chairs, 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 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 co-chairs of the Guideline Development Group have responsibility for scrutinising Declarations submitted by Guideline Group members.

It is a requirement that guideline group co-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 co-chairs 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 co-chairs have responsibility for drafting the scope and agreement will be reached by the full Guideline Development Group. The 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 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.

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Appendix 10 – Supporting information

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

Summary of recommendations

Each guideline document will include a summary of the recommendations at the start of the guideline supplement.

Accompanying Thorax highlights article

A separate (short – 1500 word) article is usually produced by one or more guideline group members following completion of the main guideline document, and submitted to Thorax (via BTS Head Office). This article summarises the main points of the guideline and is published in the main Thorax journal to accompany publication of the guideline supplement.

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.

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.

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