British Thoracic Society

Standards of Care Committee

Guideline Production Manual

2025

Contents

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Guideline Production Process at a Glance

New guideline topic proposals

Topic selection with reference to BTS strategic objectives (Section 2.3 Process for identifying a topic for a Guideline)

Call for applications for co-chairs of new GDG

Open recruitment, led by SOCC (Item 3.1.1)

Open recruitment of all other GDG members

To include a minimum of 3 specialty trainees , 1 nurse, 1 allied health professional and 2 lay representatives (Item 3.1.3)

All members to complete BTS Declarations of Interest forms (Section 3.3 Declarations of interest (DoI)

Development of the scope

To be presented to SOCC for approval (Section 4.3 Defining the scope of the Guideline)

Development of the PICO questions

Clinical questions and outcomes defined for the guideline structure and literature search (4.4 Defining PICO questions; developing search strategies)

Comprehensive literature search

Completed by BTS Head Office

Initial screen of abstracts

Completed by co-chairs (Item 4.5.2)

Full systematic review of the literature

Group members work in small groups to critically appraise relevant papers (4.5 Reviewing the evidence)

Meta-analysis

Relevant study results statistically pooled into a single result (4.6 Meta-analysis)

Assessment of the quality of the evidence

Quality of the evidence graded using GRADE methodology (4.7 GRADE-ing the evidence)

Formulation and GRADE-ing of the recommendations

Recommendations graded as 'Strong' or 'Conditional' based on the GRADED quality of evidence assessment (4.8 Formulating and GRADE-ing recommendations)

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 (Appendix 14 BTS Guidelines and Thorax: Production Process)

Guideline development group to amend draft in light of public consultation

Amended draft to SOCC for final approval

Submission to *Thorax*

Submission to the *Thorax* Editor-in-chief (Appendix 14 BTS Guidelines and Thorax: Production Process)

Quality improvement activities

Communication across BTS Committees to ensure the key messages of the guideline are disseminated widely and supported by appropriate resources

1. Introduction

1.1 Background

1.1.1 The British Thoracic Society (BTS) has been at the forefront of the production of Guidelines for best clinical practice in respiratory medicine since the Society was established over 30 years ago. Over the past ten years, 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 for production and review.

1.1.2 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 the patient's condition, circumstances and wishes and the clinical judgement of the healthcare team.

1.1.3 This document has been developed to set out the policies, principles and processes that should be followed in the development of a BTS Guideline. 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 Head of Clinical Programmes, or the BTS Clinical Guideline and Quality Standards Programme Manager.

1.1.4 Guidelines published before early 2019 followed the SIGN methodology, as outlined in the 2016 BTS Manual for Guideline Production. In 2014, the BTS Board 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.

1.1.5 The 2025 Manual is an update of the 2024 Manual. The 2025 Manual cross refers to the comprehensive materials available for BTS Guideline Groups to support the development of BTS Guidelines.

1.2 Aims and objectives of the Society in relation to Guideline production

1.2.1 BTS' 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.

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

1.3 General principles for BTS Guidelines: AGREE Criteria

1.3.1 BTS Guidelines are produced by Guideline Groups selected, and approved, by the BTS SOCC, with advice from the BTS network of Specialist Advisory Groups (SAGs). The work of Guideline Groups is supported by BTS Head Office staff. The Society does not seek, or accept, external funding for the production of its guidance.

1.3.2 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 Appraisal of Guidelines for Research and Evaluation AGREE II).

2. Initiation of the Guideline production process

2.1 Role of the Standards of Care Committee

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

- 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.

- Production of **Clinical Statements**, which will be commissioned by the Committee and produced according to the agreed procedures.

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

2.1.2 The Constitution of the Committee (see Appendix 2 Standards of Care Committee Constitution) sets out the membership, remit and mode of operation of the Committee.

2.1.3 The Chair of the Committee is a Trustee of the Society and sits on the BTS Board.

2.1.4 The BTS Head of Clinical Programmes is the secretary to the Standards of Care Committee.

2.2 Definition of a Guideline

2.2.1 Guideline definition: "*Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.*" [2]

2.2.2 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. When developing guidance in areas where the evidence base is weak, it is important to ensure that robust methodology is used. Guidance on these topics is often much needed and can highlight areas where further research is required.

2.3 Process for identifying a topic for a Guideline

2.3.1 The SOCC is responsible for selecting topics for new BTS Guidelines. The commissioning process is led by the SOCC; and the Chair is able seek advice from the BTS Board on future Guideline topics as necessary to ensure alignment with the Society's overall strategic objectives.

2.3.2 Guideline topic proposals are welcomed from BTS members, chairs of BTS SAGs, stakeholder organisations and individuals at any point. Proposals can be put forward at any time and are considered by SOCC at one of its meetings during the year. The detailed process for generating and considering Guideline proposals is outlined in a separate document (see Appendix 3 BTS Guidelines – Topic Proposals).

2.3.3 For Guidelines concerning children, priorities for paediatric Guideline topics will be developed in consultation with the British Paediatric Respiratory Society (BPRS) via the BPRS representatives on the Standards of Care Committee.

2.3.4 All BTS Guidelines are marked as Valid/In Preparation/In Consultation/Withdrawn/Superseded/Archived on the BTS website. At five years after 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 (see Appendix 4 Information on BTS Guidelines). The SOCC may also consider whether a topic proposal is suited to the production of a Clinical Statement.

2.3.5 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)?

2.3.6 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

2.3.7 The SOCC will normally select one proposal at a time to go forward into production (when the timetable allows). Proposals that have not been selected may be resubmitted/reconsidered at a later date. Full details of the process are provided in Appendix 3 BTS Guidelines – Topic Proposals.

2.3.8 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 two years from the date that the Group is convened. Progress reports on the work of the group should be provided for each SOCC meeting and GDG co-chairs will be invited to attend SOCC meetings after completion of the draft Guideline.

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

2.3.9 The costs to be covered by BTS Head Office for the production of the Guideline should be agreed with the GDG chair/co-chairs 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
- Costs of literature searches (via BTS Head Office)
- Costs 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)
- Costs 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 Development Groups (GDG)

3.1 Process for selection of Guideline Development Group (GDG) members

3.1.1 Following SOCC approval of the proposed outline for the Guideline, a formal open invitation for applications for the posts of co-chairs of the GDG is issued via the BTS website and BTS member mailings. It is expected that at least one of the co-chairs would be an expert in the topic and skilled in managing a committee. Co-chairs would then be involved in the appointment of GDG members. A full role description for the co-chairs of the Guideline group is provided in Appendix 5 Role Description: Guideline Development Group co-chairs and members and would be provided to those considering applications for the role of GDG co-chairs.

3.1.2 The co-chairs would be expected to:

- Lead the Guideline development group with support from BTS Head Office
- 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 (see 3.3 Declarations of interest (DoI))
- Keep to the scope – manage the ambition of the GDG (noting that this is not a textbook)
- 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 and draft recommendations
- Ensure the Guideline production runs to timetable as far as possible
- Lead the write up of the draft document
- 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 one agreed SOCC meeting (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 with BTS policy

3.1.3 Following appointment of the co-chairs, an open selection process to recruit other members of the GDG will be conducted (via the BTS website/member mailings). Each GDG would be expected to have the following core members:

- Consultant members, including individuals working in a District General Hospital
- Specialty Trainees - this provides Specialty Trainees with an opportunity for valuable experience in Guideline preparation and brings the perspective of the Specialty Trainee to the Guideline. It is envisaged that a minimum of three members of the GDG will be trainees.
- Each group should also have a minimum of one specialist nurse and one allied health professional (recruited via liaison with appropriate organisations, e.g. the Association of Respiratory Nurse Specialists (ARNS), the Association of Chartered Physiotherapists in Respiratory Care (ACPRC), etc.)

3.1.4 In addition, the group will also include:

- Two Patient/carer representatives (see 3.2 Patient/carer representatives (patient/carer Guideline members))
- Representatives from other stakeholder organisations as required by the topic concerned.

3.2 Patient/carer representatives (patient/carer Guideline members)

3.2.1 In this context the phrase “patient/carer representative” is used to describe patients, carers, or lay representatives who represent and/or support patients in the voluntary sector. Patient/carer input into Guideline development is important to ensure that the Guideline reflects their needs and concerns and addresses issues that may be overlooked by health care professionals.

3.2.2 Each Guideline Group should include at least two patient/carer representatives. Patient/carer members of a 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 organisations that have patient involvement/representation as a main objective
- Via personal contacts of GDG members

3.2.3 Clear guidance is given to each patient/carer member of the Guideline Group regarding their role and responsibilities in the work of the Guideline Group. Briefing material for lay/patient members is available and it is likely that separate meetings with the lay/patient representatives, the BTS Lay trustee and one, or more, members of the Guideline group may be arranged, as required, to ensure that lay/patient involvement is ongoing throughout the Guideline production process. The Group will ensure that patient views and experiences inform its work through:

- The identification of key questions that are informed by issues that matter to patients
- Identification of areas where patients’ preferences and choices are of particular importance within the Guideline

- Assisting with the preparation of any Patient Information literature, which may be required, and identifying sources of further information.
- Helping to ensure that the Guideline is sensitively and appropriately worded

3.2.4 While it is not expected that patient/carer members will undertake the specific critical appraisal process for individual clinical questions, patient/carer members will be kept informed at all stages. Meetings involving the patient representatives and the co-chairs and members of the guideline group will be arranged to ensure the patient representatives have opportunity to discuss the content of the guideline as it develops.

3.3 Declarations of interest (DoI)

3.3.1 The proposed co-chairs of the GDG must complete a BTS Declaration of Interest (DoI) form. Any potential conflicts of interest will be considered by the BTS Honorary Secretary and the Chair of the SOCC before appointment to the role of co-chair 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 GDG must also complete a BTS DoI form before, or at, the first meeting of the GDG and on an annual basis thereafter for the period that the GDG is active. This is in line with the BTS Policy for Declarations of Interest. Information on the BTS Declaration of Interests can be found in Section 3.3. Declarations of Interest (DoIs) of the '*BTS and Biomedical Industries Policy 2021*' at https://www.brit-thoracic.org.uk/about-us/governance-documents-and-policies/

3.3.2 The Chair of the SOCC and the co-chairs of the GDG have responsibility for scrutinising Declarations submitted by GDG members. GDG 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 GDG will be available on the public area of the BTS website, and following publication of the Guideline, DoI forms for each GDG are held on file at BTS Head Office and can be provided on request.

3.3.3 DoI are a standing item at the beginning of each GDG meeting. Members will be asked if any new declarations have arisen, and forms can be unlocked by BTS Head Office staff if amendments are required. It is expected that the majority of the GDG 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.

3.3.4 A statement should be included in each Guideline when published to confirm that GDG members have adhered to the BTS policy for Declaration of Interests and, where appropriate, specific interests should be declared. An example of such a statement for inclusion in the final Guideline document is given below:

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

3.4 Stakeholder input

3.4.1 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 GDG is to identify potential stakeholders

of the final Guideline. BTS Head Office will invite these organisations to either nominate a representative to participate in the preparation of the Guideline as a formal member of the GDG or 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 will be undertaken by the BTS Clinical Guideline and Quality Standards Programme Manager on behalf of the GDG co-chairs.

3.4.2 BTS aims to ensure that GDG membership comprises all relevant stakeholders. It is important that some organisations (for example, the Royal College of Physicians (London)) have a representative on each GDG. 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 GDG.

3.4.3 Prior to its first meeting, the GDG 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. The 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. We will invite those who respond to the public consultation process to declare any relevant interests.

3.4.4 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.

3.5 Training for Guideline Development Group (GDG) members

3.5.1 It is important for all GDG members to be appropriately trained in the methods to be used for the production of an evidence-based Guideline.

3.5.2 Training sessions are organised by BTS Head Office and will usually take place as part of the first, second and third meeting of the GDG. BTS has developed a series of '*Guide to creating a BTS Guideline*' Handbooks, which are available to all GDG members.

3.6 Confirmation of authorship/membership of writing group

3.6.1 In general, all GDG members are usually 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 are usually named as first authors (or first and last authors). The proposed authorship of the Guideline should be discussed as early as possible after the GDG 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 names of the co-chairs are usually listed first alphabetically, followed by all members of the group in alphabetical order), e.g.:

Dr Brian Jones (co-chair), Dr Alan Smith (co-chair), Mr Clive Black, Dr Doreen Grey...

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

4. Guideline Production

4.1 Timetable

4.1.1 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 2.3 Process for identifying a topic for a Guideline, Item 2.3.8).

4.2 Methodology

4.2.1 BTS Guidelines are based on the best available evidence and use Review Manager (RevMan) (https://community.cochrane.org/help/tools-and-software/revman-5/revman-5-download) and GRADE (https://gradepro.org/) methodologies.

Although primarily designed for preparing Cochrane Reviews, RevMan facilitates the risk of bias assessment and data meta-analysis (pooling individual study data together to increase data power and precision), allowing Guideline evidence reviews and data to be stored together in individual RevMan files (one per clinical question).

GRADE is a method used to assess the quality of the evidence and decide whether to recommend an intervention. GRADE ensures that the process is systematic and transparent. GDGs will adopt clearly defined elements of the GRADE system (**G**rading of **R**ecommendations, **A**ssessment, **D**evelopment and **E**valuation) outlined in Section 4.7 GRADE-ing the evidence. GDGs should note that the system used should adhere to the AGREE II criteria (see Appendix 1 Appraisal of Guidelines for Research and Evaluation AGREE II).

Full training, instruction and support will be provided to all GDG members on all BTS Guideline methodologies.

4.2.2 The Guideline should include clear recommendations and include their GRADE category ('Strong recommendation' or 'Conditional recommendation'). A synopsis of the GRADE categories is included in Section 4.7 GRADE-ing the evidence and 4.8 Formulating and GRADE-ing recommendations. There should also be an explicit link between each recommendation and the supporting evidence.

4.3 Defining the scope of the Guideline

4.3.1 In line with the AGREE II criteria (see Appendix 1 Appraisal of Guidelines for Research and Evaluation AGREE II), each Guideline should explicitly state the objectives and clinical questions to be addressed and the patient population/target audience for the Guideline. Areas specifically excluded by the Guideline should also be itemised.

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

4.3.3 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.

4.4 Defining clinical questions; developing search strategies

4.4.1 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". [3]

4.4.2 The essential principles of a systematic review should be adhered to and the literature should be:

- Identified according to an explicit search strategy
- Selected according to defined inclusion and exclusion criteria; and
- Evaluated against consistent methodological standards

4.4.3 Where high quality, directly relevant Guidelines exist within the scope of a 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.

4.4.4 Guideline groups are required to break the Guideline remit down into a series of structured key questions. Each question must use one of question formats below:

Intervention (PICO)

- **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**omparator(s) to be used to compare the effect of the 'Intervention' against; and
- **O**utcome(s) to be used to establish the size of any effect caused by the 'Intervention'

Diagnostic (PInGO)

- **P**atients or population to which the question applies
- **In**dex test(s) being considered in relation to these patients
- **G**old standard being used to compare the effectiveness of the 'Index test(s)'; and
- **O**utcome (diagnostic accuracy outcome); or

Prognostic (PERO)

- **P**atients or population to which the question applies

- **E**xposure(s) (non-imposable characteristics) being considered in relation to these patients
- **R**eferent, which is/are the opposite of the 'Exposure(s)'; and
- **O**utcome(s) to be used to establish the prognostic effect of the 'Exposure(s)'

It is important that the scope, and all subsequent questions and identified outcomes, is 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 when published.

4.4.5 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 will be covered and which will be excluded (i.e. if the Guideline covers adults only, or children only, the age range should be specified, e.g. 16 years and over, or up to and including 16). The age range given will be agreed by the GDG for each specific guideline topic.

4.4.6 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.

4.4.7 The **Intervention(s)** (which in this context includes diagnostic tests, risk factors and risk exposure), **Index test(s)**, or **Exposure(s)** 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 focussing on a named agent.

4.4.8 For Intervention (PICO) questions, the GDG need to decide on the **Comparator(s)**, which will be used to compare the Intervention(s) against. Comparators are most often placebo/no treatment, comparison with other therapies, or the existing standard of care.

For Diagnostic (PInGO) questions, the **Gold standard** must be the best diagnostic test that is available for diagnosing the condition of interest (diagnostic accuracy **Outcome**).

For Prognostic (PERO) questions, the **Referent** is always the opposite of the **Exposure** (e.g. Smoking/ Non-smoking).

4.4.9 An **Outcome** is something that can be measured and the three question types have different types of outcomes:

A diagnostic (PInGO) outcome is always a 'Diagnosis of the disease of interest'

A prognostic (PERO) outcome is always measure of the prognostic effect of the **Exposure(s)** (e.g. the probability of developing a disease**,** the probability of responding to a treatment, etc.); and

An intervention (PICO) outcome is something that can be measured to show the effect of an Intervention. Intervention (PICO) outcomes should always be patient-important and should be GRADE-categorised according to their importance for decision-making (see Appendix 6 GRADE – relative importance of outcomes):

- Critical
- Important, but not critical
- Of limited importance

Only outcomes categorised as 'Critical' or 'Important, but not critical' should be used in a Guideline PICO question and the number of outcomes for each clinical question should be limited to about four. GDG members should agree on the outcomes for each PICO question when the PICO questions are being developed and before the literature review begins. Examples of patient-important PICO outcomes are reduced morbidity, improved quality of life, reduced infection, etc.

4.4.10 When each question has been defined, a protocol should be set for each question. The protocol is a very detailed version of the review question and includes the PICO, PInGO or PERO, the types of studies to be included in the review, the search plan and the analysis plan. The protocol should always be set before the literature review begins to avoid bias (please see Appendix 7 BTS Guideline Protocol Template).

4.4.11 The PICO/PInGO/PERO questions will then form the basis of the literature search. BTS Head Office will work with the Guideline group co-chairs to develop literature search strategies to address the clinical questions and will perform the literature search(es) using Medline, Embase (see Appendix 8 Literature search and literature management).

4.4.12 The literature search must focus on the best available evidence to address each PICO/PInGO/PERO question and should ensure maximum coverage of studies that include:

- Systematic reviews
- Randomised controlled trials
- Observational studies; and
- Diagnostic studies

4.4.13 Details of the search strategies, dates of searches, etc. will be included in the final document (and will be made available as an accompanying web appendix on publication).

4.5 Reviewing the evidence

4.5.1 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. GDG members should review the evidence (bearing in mind the AGREE II criteria). Guidance will be provided by BTS Head Office (see Appendix 8 Literature search and literature management).

4.5.2 An initial literature review should be performed to remove all references from the literature search list that are not relevant to the Guideline. This process should be performed by two GDG members (usually the co-chairs) and agreement should be reached on which references to include/exclude.

4.5.3 The abstracts on the revised literature list should then be allocated to each PICO/PInGO/PERO question and identification details of each abstract (per PICO/PInGO/PERO question)

4.5.4 At least two GDG members should be assigned to each PICO/PInGO/PERO question to ensure that each abstract is being reviewed by at least two people. An initial review of each allocated abstract should be performed to assess the relevance to the PICO/PInGO/PERO question, i.e. does the abstract:

- Include the PICO/PInGO/PERO population(s)

- Include the PICO intervention(s), the PInGO index test(s) or the PERO exposure(s)
- Include the PICO/PInGO/PERO comparator(s), the PInGO gold standard, or the PERO referent; or
- Include the PICO/PInGO/PERO outcome(s)

For this first review, if the abstract fulfils any of the above criteria, the reference should be included in the next step of the process. The list of included and excluded abstracts should then be agreed between GDG members assigned to the PICO/PInGO/PERO question and each 'included' abstract should be input into RevMan. Full training and support will be provided by BTS Head Office on inputting data into RevMan. The reason(s) for excluding an abstract at this stage should be recorded to ensure transparency of the process.

4.5.5 Abstracts should not be rejected on the basis of the journal of publication, location of research or location of publication.

4.5.6 Abstract should not be rejected on the date of publication (unless agreed by GDG members and detailed on the Protocol (see Appendix 7 BTS Guideline Protocol Template) before the literature review begins).

4.5.7 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. The GDG should consult with BTS Head Office if such an issue arises.

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

4.5.9 'Included abstract' papers should be divided between GDG members assigned to the PICO/PInGO/PERO question. Each full paper should be assessed using the following protocol:

Read the LAST section of the INTRODUCTION, this outlines the purpose of the study and outlines what has been done. [4]

ALL papers that address the PICO/PInGO/PERO question should be **ACCEPTED**

ALL papers that do not address the PICO/PInGO/PERO question should be **REJECTED**

An exception to this can be made if the literature available to answer the PICO/PInGO/PERO question is limited (i.e. a paper can be included if there is limited supporting literature and the paper addresses some of the PICO/PInGO/PERO criteria)

4.5.10 Each **ACCEPTED** paper should be critically appraised and a risk of bias assessment completed for each **ACCEPTED** paper in RevMan. Full training and support will be provided to all GDG members.

Each critical appraisal should be agreed by all GDG members assigned to the PICO/PInGO/PERO question, but where there is a difference of opinion on a paper, GDG reviewing groups should endeavour to reach a consensus, or refer to the GDG co-chairs for a final decision.

An **ACCEPTED** paper can become a **REJECTED** paper at any time during the critical appraisal process, but if a paper is later rejected, an explanation should be recorded in RevMan.

4.6 Meta-analysis

4.6.1 Meta-analysis is a statistical technique to summarise the results of several studies into a single overall result (a pooled estimate). This increases the power and precision of the estimate of the effect. If there is enough supporting evidence, GDG members should use RevMan to perform meta-analyses on the final **ACCEPTED** paper study (see Item 4.5.10). Individual meta-analyses should be performed for each PICO and PInGO outcome PERO question data can take different formats, so there is no defined method of performing meta-analyses for prognostic review questions. GDG members assigned to a PERO question should consult with the BTS Clinical Guideline and Quality Standards Programme Manager for advice on how to pool the data. Full training and support will be provided by BTS Head Office staff.

4.7 GRADE-ing the evidence

4.7.1 When all **ACCEPTED** papers (see Item 4.5.10) have been critically appraised for risk of bias and meta-analyses have been completed, GDG members are required to assess the quality of the evidence using GRADE methodology.

4.7.2 GDG reviewing groups who are assigned to PICO or PERO questions (as defined in Item 4.5.4) will use GRADEprofiler software (https://gradeprofiler.software.informer.com/3.6/) to assess the quality of the evidence. One GRADEprofiler file will be created per PICO/PERO question and the quality of the evidence will be assessed per outcome.

GDG reviewing groups who are assigned to a PInGO question (as defined in Item 4.5.4) will use GRADEpro (https://gradepro.org/) to assess the quality of the evidence. GRADEpro is an online program and one GRADEpro project will be created per PInGO question. The quality of the evidence will be assessed per outcome.

For PICO questions, and PERO questions that include meta-analyses, GDG reviewing groups should import their PICO/PERO question RevMan file (containing the risk of bias assessment (see Item 4.5.10) and outcome meta-analyses (see 4.6 Meta-analysis)) into GRADEprofiler to transfer the 'Summary of Findings' data from the outcome meta-analyses (see Appendix 9 Example Summary of Findings tables).

For PERO questions that do not include meta-analysis data, GDG members should consult with the BTS Clinical Guideline and Quality Standards Programme Manager for advice on inputting the 'Summary of Findings' data into GRADEprofiler.

For PInGO questions, the BTS Clinical Guideline and Quality Standards Programme Manager will input the 'Summary of Findings' data into GRADEpro.

Full training and support will be provided to all GDG members by BTS Head Office staff.

4.7.3 For each PICO/PInGO/PERO outcome, GDG reviewing groups should decide what the predominant study design is for the studies included in the evidence and input their decision into GRADEprofiler (PICO and PERO questions) or GRADEpro (PInGO questions). Different study types will give an intial GRADE-ing of the evidence (dependent on the question type):

PICO

Randomised controlled trial (RCT)	= high
Observational study	= low

PInGO

Cross-sectional (cohort type accuracy study)	= high
Cohort and case-control type studies	= moderate
Case-control type accuracy study	= low

PERO

Observational study	= high
Randomised controlled trial (RCT)	= low

4.7.4 GDG members should then GRADE the quality of the evidence. The quality of the evidence should be assessed per outcome (i.e. across the evidence for each PICO/PInGO/PERO outcome) and should consider the level of the following domains: **Risk of bias**, **Inconsistency**, **Indirectness**, **Imprecision** and **Publication Bias.** GDG reviewing groups should agree on the GRADE quality of evidence assessments and input the results into GRADEprofiler (PICO and PERO questions) or GRADEpro (PInGO questions). Footnote comments should be provided to ensure transparency and full training will be given to all GDG members.

If there is disagreement between members of a GDG reviewing group, the quality of evidence assessment should be referred to the GDG co-chairs for a final decision.

4.7.5 Full information on upgrading and downgrading Guideline evidence quality is available in the GRADE Handbook (http://gdt.guidelinedevelopment.org/app/handbook/handbook.html).

4.7.6 Following a full GRADE assessment of the PICO/PInGO/PERO question evidence (per outcome) and inputting all appraisal data into GRADEprofiler (PICO and PERO questions) or GRADEpro (PInGO questions), GRADEprofiler, or GRADEpro, will automatically GRADE the quality of the evidence as 'High', 'Moderate', 'Low', or 'Very Low' based on the information provided. A description of each GRADE is provided in the table below.

GRADE	Definition	Characteristics	Confidence
High ⊕⊕⊕⊕	High confidence that the true effect is close to the estimated effect	Based on consistent results from high-quality studies (see Item 4.7.3)	Further research is very unlikely to change the estimate of the effect
Moderate ⊕⊕⊕◯	Moderate confidence that the true effect is close to the estimated effect	Based on high-quality studies where there is evidence of bias, or from studies of moderate quality (see Item 4.7.3)	Further research is likely to have an impact on the estimate of the effect
Low ⊕⊕◯◯	Low confidence that the true effect is close to the estimated effect	Based on evidence from low-quality studies, or from high quality studies with several serious limitations (see Item 4.7.3)	Further research is likely to have an important impact
Very Low ⊕◯◯◯	Very low confidence that the true effect is close to the estimated effect	Based on low-quality studies, or expert opinion (see Item 4.7.3)	Estimates of effect are far from certain and more research is needed
Ungraded	A GRADE analysis cannot be performed	Evidence based on one study, or evidence presented in more than one format	Estimates of effect are uncertain and more research is needed

4.8 Formulating and GRADE-ing recommendations

4.8.1 When the quality of all evidence per PICO/PInGO/PERO question (i.e. the evidence across all outcomes) has been assessed, and all information has been input into GRADEprofiler (PICO and PERO questions) or GRADEpro (PInGO questions), this is the information should be used to formulate the recommendations.

GDG reviewing groups will make judgement via a series of questions e.g. is the problem a priority, are the anticipated effects desirable, how substantial are the undesirable effects, what is the certainty of the evidence, etc. and will include information on the research evidence (to be taken from the evidence review/'Support for judgement'). Examples of question formats are shown in Appendix 10 GRADEpro recommendations.

The judgements will be summarised in the 'SUMMARY OF JUDGEMENTS' table and will be the basis for deciding the 'TYPE OF RECOMMENDATION' (see Appendix 10 GRADEpro recommendations and Item 4.8.2 below).

4.8.2 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. The GRADE system assigns a recommendation 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

4.8.3 The body of evidence for each PICO/PInGO/PERO question will then be drawn together into a BTS Guideline Support for Judgement Template (see Appendix 11 BTS Guideline Support for Judgement Template) where a draft evidence review, evidence statements, recommendation and, where appropriate, good practice points (GPPs), will be produced

4.8.4 In GRADE-ing the recommendations the GDG 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 GPPs) 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/GPPs.

Recommendations by consensus

4.8.5 If the GDG feels strongly that they want to make a recommendation even though there is no significant evidence, this should be presented as a 'Conditional' recommendation (please see Item 4.8.2) and marked as 'Conditional – by consensus'. There should be some evidence of opinion supporting the recommendation from outside the GDG. 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 GDGs; and 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 GDG 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.

In some instances, where there is supporting evidence, but:

i) A GRADE analysis cannot be performed (e.g. when data across studies are reported in different formats and hence cannot undergo a meta-analysis); and

ii) A recommendation is important enough that it should be "offered", not "considered" (please see Item 4.8.2)

GDG members can choose to mark such recommendations as 'Strong – by consensus', when there is agreement by all GDG members to do so.

Good Practice Points

4.8.6 GPPs are intended to offer short pieces of advice, which may not have an evidence base, but are viewed as essential to good clinical practice. GPPs 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 GPPs will be arrived at by consensus, based on the clinical experience of the GDG members.

Financial considerations

4.8.7 While BTS Guidelines explicitly exclude consideration of cost-benefit analysis, GDGs 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 GDGs would discuss potential organisational and financial barriers, which may impact on the implementation of the recommendations.

4.9 Drafting the Guideline

4.9.1 When producing a draft of the Guideline the following structure is used:

- Title page listing authors
- Contents page
- Summary of recommendations (to be finalised on completion of the Guideline)
- Introduction (see Item 4.9.2)
- The body of the Guideline, divided into sections and PICO/PInGO/PERO questions 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

4.9.2 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 statement that environmental and sustainability impact of content has been considered
- A full list of the GDG 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)

4.9.3 The following sections are also associated with the Guideline, but are usually provided as web-based appendices rather than part of the published document (see Appendix 12 Supporting information):

- Research recommendations
- Audit criteria

- Patient information where appropriate
- Educational material
- Quality Standards (see Appendix 13 BTS Quality Standards and Audits).

4.9.4 GDGs 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 a recommendation should be clearly indicated against the recommendation when it appears in the Guideline (see Item 4.8.2). References should be included in the Vancouver format (the style used by *Thorax*) where references are numbered sequentially in the text.

4.9.5 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.

4.10 Public consultation and peer review/approval by SOCC

4.10.1 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 GDG 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.

4.10.2 The approved draft of the Guideline should usually be placed on the BTS website for open consultation. A consultation copy of the document should be sent to all stakeholders requesting their comments by the consultation deadline.

4.10.3 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 respondents to the public consultation exercise are asked to state their role/affiliation on the consultation form and declare any relevant interests. All comments are collated and sent to the co-chairs of the GDG. 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 GDG.

4.10.4 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. The consultation copy of the Guideline will be submitted to *Thorax* via Scholar One to allow the editors to invite peer review through the usual *Thorax* system. Comments from the *Thorax* reviewers will be passed through to BTS so that these comments can be addressed alongside all feedback from the consultation process. A separate document outlining the process for the

publication of BTS Guidelines in *Thorax* is available and kept under regular review with the editors in chief (see Appendix 14 BTS Guidelines and *Thorax*: Production Process). 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 placed as part of the public consultation stage (see Appendix 14 BTS Guidelines and *Thorax*: Production Process).

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

4.10.5 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.

4.10.6 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.

4.11 Publication/Dissemination

4.11.1 The principles and procedures for publication of the full Guideline/Executive Summary of the Guideline in *Thorax* are set out in Appendix 14 BTS Guidelines and *Thorax*: Production Process. 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.

4.11.2 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. *Thorax* appointed an Associate Editor (AE) with specific responsibility for BTS Guidelines and clinical statements in 2019. BTS Head Office will maintain close contact with the *Thorax* Guideline AE to ensure a smooth production process.

4.11.3 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 *Thorax* 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

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

4.11.5 Copies of the Guideline RevMan files, GRADEprofiler files, evidence tables, references and literature search records, together with notes of the GDG meetings, should be held at BTS Head Office.

4.11.6 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.

4.11.7 BTS Head Office will explore appropriate ways to support the dissemination of the key messages of each Guideline, e.g. the Society may provide open-access educational slides, eLearning modules, short courses and/or 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 five 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 (see Appendix 4 Information on BTS Guidelines).

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 five years, or have undergone an 'Exceptional Review' by the SOCC and have been deemed 'Valid'
In Preparation	Guidelines in development
In Consultation	Guidelines that are available for public consultation
Archived	Guidelines that have been published for more than five years. The following text will be included on the relevant webpage:

	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
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) (see Appendix 4 Information on BTS Guidelines)

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 "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.

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 Item 7.1 above).

BTS June 2025

References

[1] NHS Evidence Accreditation (http://www.evidence.nhs.uk/Accreditation/Pages/Accreditation.aspx)

[2] Field MJ, Lohr KN (Eds). Clinical Practice Guidelines: Directions for a New Program, Institute of Medicine, Washington, DC: National Academy Press, 1990

[3] Woolf S. Practice Guidelines, a new reality in medicine. II: Methods of developing Guidelines. Arch Intern Med 1992; 152:946-952

[4] Basu A. (2016) A tutorial on how to use Gradepro GDT Tool for writing reviews. Peer J Preprints 4:e2520v1 (https://doi.org/10.7287/peerj.preprints.2520v1)

Appendix 1 Appraisal of Guidelines for Research and Evaluation AGREE II

The purpose of the Appraisal of Guidelines Research & Evaluation (AGREE) II Instrument (http://www.agreetrust.org/agree-ii/) 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, i.e. 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 should be clearly defined.

Rigour of development

7. Systematic methods should be used to search for evidence
8. The criteria for selecting the evidence must be clearly described.
9. The strengths and limitations of the body of evidence should be clearly described.
10. The methods used for formulating the recommendations should also be clearly described.
11. The health benefits, side effects and risks should be considered in formulating the recommendations.
12. There should be an explicit link between the recommendations and the supporting evidence.
13. The guideline should be externally reviewed by experts prior to its publication.
14. A procedure for updating the guideline should be provided.

Clarity and Presentation

15. The recommendations should be specific and unambiguous.

16. The different options for management of the condition or health issue should be clearly presented.
17. Key recommendations should be easily identifiable.

Applicability

18. The guideline should describe facilitators and barriers to its application.
19. The guideline should provide advice and/or tools on how the recommendations can be put into practice.
20. The potential resource implications of applying the recommendations should be considered.
21. The guideline should present monitoring and/or audit criteria.

Editorial independence

22. The views of the funding body should not influence the content of the guideline.
23. Competing interest of guideline development members should be recorded and addressed.

Appendix 2 Standards of Care Committee Constitution

STANDARDS OF CARE COMMITTEE

CONSTITUTION 2025- 2028

TERMS OF REFERENCE

The BTS Standards of Care Committee has three major responsibilities:

- **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.

- Production of **Clinical Statements** which will be commissioned by the Committee and produced according to the agreed procedures.

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

MEMBERSHIP

The membership of the Committee comprises:

- Chair
- 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). One of these will serve additionally on the BTS Specialist Trainees Advisory Group (STAG) and will act as the link between the two.
- One Respiratory Nurse Specialist.
- Two lay members.
- Two representatives from the British Paediatric Respiratory Society (BPRS).
- A representative from the Association of Chartered Physiotherapists in Respiratory Care (ACPRC)
- A representative allied health professional, healthcare scientist or any other member of the respiratory team.
- The Chair of the BTS Board, and Chief Executive, ex-officio (standing invitations, although will not usually attend).

The Chair of the Committee may also be invited to attend other ad hoc meetings, for example the Steering Group for the production of the joint BTS/SIGN/NICE asthma guideline.

The terms of service and details of conduct of the Committee is contained in BTS Committee Constitutions Part B.

Appendix 3 BTS Guidelines – Topic Proposals

The British Thoracic Society has been at the forefront of the production of guidelines for best clinical practice in respiratory medicine since the Society was established over 40 years ago.

The BTS Standards of Care Committee (SOCC) oversees the Society's guideline production strategy and procedures, including the approval of new guideline topics.

The production of a BTS Guideline is a substantial undertaking, requiring significant time and commitment from the guideline group chair and members, as well as BTS Head Office and the Standards of Care Committee members. Details of the guideline production process are available in the BTS Guideline Manual: https://www.brit-thoracic.org.uk/quality-improvement/guidelines/

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

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

Each proposal should have the support of a BTS Specialist Advisory Group (SAG), if a relevant group exists.

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

Topic proposal form available from BTS Head Office.

BTS 2018

Appendix 4 Information on BTS Guidelines

The Society currently lists all published BTS guidelines on the BTS website at: https://www.brit-thoracic.org.uk/quality-improvement/guidelines/

The summary tables (BTS Guidelines, Other Guidance and Guideline Archive), 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:

Valid

In Preparation

In Consultation

Archived

Superseded

Withdrawn

A new category of 'Archived' was introduced in 2017 to indicate Guidelines that are more than five years old and where the content as not been checked/reviewed.

Guidelines marked as 'Withdrawn/Superseded' are still listed on the BTS website (on individual Guideline pages), but no longer appear in the BTS Guidelines summary table (see below).

BTS Guidelines summary table

The top table on the main BTS Guideline web page (https://www.brit-thoracic.org.uk/quality-improvement/guidelines/) includes:

Current BTS Guidelines; and

BTS Guidelines in development (BTS Guidelines that are currently 'In preparation')

Other Guidance summary table

This table provides links to 'Other Guidance' on particular issues, or disease areas. This includes links to BTS Recommendations, BTS Statements, BTS Clinical Statements and guidelines produced by other organisations (e.g. NICE), which are provided without endorsement.

Guideline Archive summary table

Guidelines that have been published more than five years ago should 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 a statement to say that the Guideline is provided for reference. This means that the list of BTS guidelines is current and that any Guidelines older than five years can still be found in the archive.

The status of "Under review" has now been removed. When using GRADE methodology, an existing Guideline cannot be updated without re-visiting the scope and clinical questions and hence all requested updates will now be considered as new topic proposals.

A disclaimer is added to each 'Archived' Guideline page:

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.

The disclaimer should make it clear that Guidelines will not automatically be updated after five years. Should the chair(s) of an existing Guideline wish to apply to update the Guideline, they should apply in the same way as those submitting a new topic proposal and identify the new scope and clinical questions according BTS GRADE methodology. BTS SAGs may also be a useful source of information should new literature be published in a certain area. It is not expected that Guideline chairs should undertake a top-level literature review after 3-5 years.

Links to Guidelines from other organisations

Archived Guidelines will include clear signposting to relevant guidance from other organisations (primarily NICE and ERS), which have superseded older BTS publications. This will provide useful links to other Guidelines that may be relevant to a give topic, but a clear statement will be included to confirm that inclusion does not constitute BTS endorsement.

New Guideline proposals

With the move to GRADE methodology, any new Guideline topic commissioned by BTS 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 to mark published Guidelines as 'Archived' after a given period and no update to the Guideline is undertaken. A new Guideline may be commissioned on the same, or related topics, but the scope and clinical questions will be new (see Appendix 3 BTS Guidelines – Topic Proposals).

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 will be 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.

Appendix 5 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 40 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) play a critical role in the development of the Guideline and have 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 textbook)
- 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 GDG members during and between meetings to identify key issues, formulate clinical questions, 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 with BTS policy

Guideline Group members would be expected to:

- Participate fully in the work of the GDG 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 and patient wishes to support the Guideline development.
- Input positively in meetings treating all as equals
- 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
- 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 (DoI) 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 GDG have responsibility for scrutinising Declarations submitted by GDG 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.

Guideline authorship

The co-chairs are responsible for drafting the scope and agreement will be reached by the full GDG. The co-chairs will take the lead in production of the full draft document for review by the group.

While it is expected that all GDG 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 GDG members to contribute as authors to the Guideline should be made clear at the first meeting of the Guideline group.

Appendix 6 GRADE – relative importance of outcomes

Figure 1: GRADE ranking of outcomes

rating scale:								
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
of **least** importance								of **most** importance
Of limited importance for making a decision (not included in evidence profile)			Important, but not critical for making a decision (included in evidence profile)			Critical for making a decision (included in evidence profile)		

Figure 2: Examples of GRADE-ranked outcomes

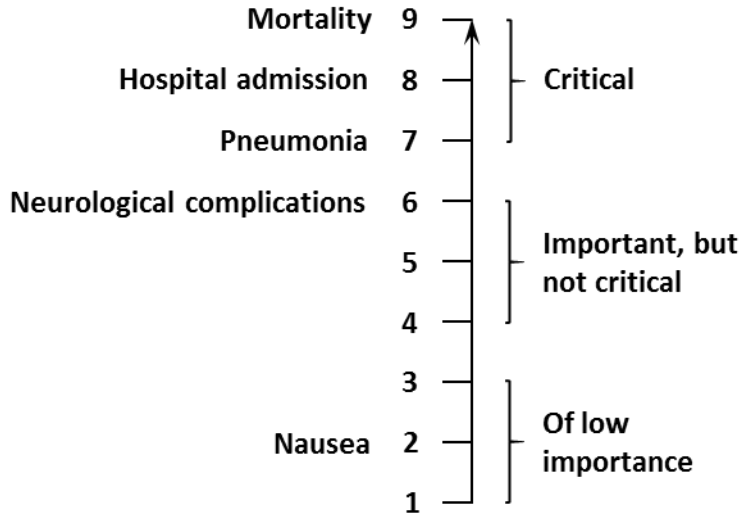

Figure 1 is taken from, and Figure 2 is adapted from, 'Section 3.1 Steps for considering the relative importance of outcomes' of the GRADE Handbook (https://gdt.gradepro.org/app/handbook/handbook.html).

GDGs should list all PICO outcomes and rank by their relative importance (see Figure 1 above), to determine if an outcome is 'Critical', 'Important', or 'Important, but not critical' (Figure 2 provides examples of GRADE-ranked outcomes). All outcomes should be patient focussed and only outcomes deemed as 'Critical' or 'Important' should be considered for the Guideline. It is recommended that GDGs use a maximum of four outcomes for each PICO question.

Appendix 7 BTS Guideline protocol template

BTS Guideline Protocol Template

Field	Content
Review Question	PICO question
Type of review question	Intervention
Objective of the review	Give background to the review question – what does the review aim to answer, what might the recommendations cover?
Eligibility criteria – population / disease / condition / issue / domain	e.g. Adults (16 years and older) with asthma
Eligibility criteria – intervention(s)	What is / are your intervention(s)?
Eligibility criteria – comparators(s)	What is / are your comparator(s)?
Outcomes and prioritisation	CRITICAL: e.g. mortality IMPORTANT: e.g. disease progression
Eligibility criteria – study design	e.g. Randomised controlled trials, systematic reviews of randomised controlled trials
Other inclusion /exclusion criteria	Non-English language Cross-over randomised controlled trials Studies comparing combinations of the interventions
Proposed sensitivity / subgroup analysis, or meta-regression	Subgroups: e.g. children
Selection process – duplicate screening / selection / analysis	If used, describe methods for duplicate screening, study selection or data extraction. What are thresholds for agreement and mechanisms to resolve disputes?

Data management (software)	RevMan: Pairwise meta-analyses Evidence review/considered judgement GRADEpro: Quality of evidence assessment for each outcome Endnote: Reference management
Information sources – databases and dates	Sources to be searched, limits applied to search, supplemental search techniques and rational. Other sources of evidence. Key papers if known. Cut-off dates?
Methods for assessing bias at outcome / study level	RevMan5 used to critically appraise individual studies. GRADEprofiler used to evaluate risk of bias across all available evidence. Document deviations/alternative approach if GRADE is not used, or if a modified GRADE approach has been used for non-intervention or non-comparative studies
Methods for quantitative analysis – combining studies and exploring (in)consistency	
Meta-bias assessment – publication bias, selective reporting bias	
Rationale / context – what is known	

August 2018

Appendix 8 Literature search and literature management

Literature searches

BTS Head Office will develop search strategies and provide literature searches for all BTS Guidelines. Further details of the services provided are available from BTS Head Office.

Managing data

BTS Head Office 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) will be exported into Excel from Endnote for checking by GDG members. BTS will hold the master copy of the Endnote file for referencing the Guideline document at final draft stage.

Obtaining copies of papers

GDG 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 GDG members
- Individual members' institutional library (or electronic library) subscriptions, e.g. via NHS or university Athens accounts.

BTS Head Office can assist where journal articles are particular difficult to locate.

Appendix 9 Example Summary of Findings tables

PICO question

For adults with malignant pleural effusion, is an indwelling pleural catheter better than talc slurry pleurodesis at improving clinical outcomes?

Population: Adults aged 18+ with malignant pleural effusion

Intervention: Indwelling pleural catheter (IPC)

Comparator: Talc slurry pleurodesis

Outcome	Number of participants (studies)	Estimate of effect	Quality of the Evidence (GRADE)
Quality of life	371 (4 studies)	No measured differences between the intervention and comparator	⨁⨁⨁◯ MODERATE [a]
Length of stay	2908 (7 studies)	Shorter median length of stay with IPC	⨁⨁◯◯ LOW [a,b]
Symptoms	522 (6 studies)	No measured differences between the intervention and comparator	⨁⨁⨁◯ MODERATE [a]

CI: Confidence interval

Explanations

a. Risk of selection bias and attrition bias in some studies
b. Imprecision in the data

PInGO question

What is the diagnostic accuracy of thoracic ultrasound for diagnosing pleural malignancy in adults?

Patient or population: Adults aged 18+ with pleural effusion and suspected pleural malignancy

New test: Thoracic ultrasound

Pooled sensitivity: 0.80 (95% CI: 0.71 to 0.87) | **Pooled specificity**: 0.90 (95% CI: 0.81 to 0.94)

Test result	Number of results per 1,000 patients tested (95% CI)	Number of participants (studies)	Certainty of the Evidence (GRADE)
	Prevalence 20% Typically seen in		
True positives	**160** (141 to 173)	99 (2)	⨁⨁⨁◯ MODERATE [a]
False negatives	**40** (27 to 59)		
True negatives	**716** (649 to 756)	86 (2)	⨁⨁⨁◯ MODERATE [a]
False positives	**84** (44 to 151)		
	Prevalence 70% Typically seen in		
True positives	**559** (495 to 606)	99 (2)	⨁⨁⨁◯ MODERATE [a]
False negatives	**141** (94 to 205)		
True negatives	**269** (243 to 284)	86 (2)	⨁⨁⨁◯ MODERATE [a]
False positives	**31** (16 to 57)		

CI: Confidence interval

Explanations

a. No risk of bias, indirectness, inconsistency, imprecision or publication bias, but data downgraded as based on two studies

Appendix 10 Recommendation tables

PICO question

Question Details

POPULATION:	
INTERVENTION:	
COMPARISON:	
OUTCOMES:	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	Conditional recommendation for the intervention	Strong recommendation for the intervention
☐	☐	☐	☐	☐

CONCLUSIONS

Recommendation
Justification
Subgroup considerations
Research priorities

PInGO question

Question Details

POPULATION:	
SUBGROUP POPULATION:	
INDEX TESTS:	
GOLD STANDARD:	
OUTCOME:	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
TEST ACCURACY	Very inaccurate	Inaccurate	Accurate	Very accurate		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	Conditional recommendation for the intervention	Strong recommendation for the intervention
☐	☐	☐	☐	☐

CONCLUSIONS

Recommendation
Justification
Subgroup considerations
Research priorities

Appendix 11 BTS Guideline Support for Judgement Template

TITLE

Introduction

Provide background on the PICO question – potential questions to address:

i) Description of the condition
ii) Description of the intervention
iii) How might the intervention work?
iv) Why it this important?

Outcomes

What are the PICO outcomes you are investigating?

Evidence Review

This is the main body of your literature review and evidence. Questions you should be asking:

i) Types of studies you are reviewing
    a. Which studies have you included?
    b. Have you excluded studies? Why?
ii) Types of participants
    a. Do they match your PICO question?
iii) Types of interventions
    a. Do the data interventions differ from your PICO intervention(s)?
iv) Types of outcome measures
    a. Are the outcomes different to your PICO outcomes?
    b. Are the data primary outcomes or secondary outcomes?
v) What are the effects of the interventions?
    a. Address each PICO outcome individually and review the literature per outcome.
vi) Side effects, mortality, etc.?

Evidence Statements

This section should consist of a set of statements (one per outcome) summarising the effect of the intervention against the comparison within the population (i.e. based on your PICO questions and outcomes) and include the GRADE quality of evidence score for each statement (High, Moderate or Low), e.g. Long term macrolide antibiotics are effective in reducing the acute exacerbation rate in patients with COPD with high exacerbation rates (i.e. three or more exacerbations per year). (High)

Recommendations

[

]

Good Practice Points

[

]

Research Recommendations

The above three sections should be based on the output of the GRADE recommendations.

Appendix 12 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* summary article

A separate (short – 1500 word) article is usually produced by BTS Head Office and submitted to *Thorax*. 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

GDGs 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 GDG 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, GDGs should provide a list of recommendations for further research. Research recommendations can be provided as an appendix to the main Guideline and will be passed to the BTS Science and Research Committee following publication of the Guideline.

Appendix 13 BTS Quality Standards and Audits

Quality Standards

A Quality Standard is a set of specific, concise statements that:

- Act as markers of high quality, cost-effective patient care across a pathway or clinical area, covering treatment or prevention
- Are derived from the best available evidence and are produced collaboratively with the NHS along with their partners and service users

A Quality Standards statement is a key part of the range of supporting materials that the Society produces to assist in the implementation of Guideline recommendations; and 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.

BTS Quality Standards are published in the BMJ Open Respiratory Research (since 2017) and are available from the BTS website (https://www.brit-thoracic.org.uk/quality-improvement/quality-standards/)

Audits

Currently, the BTS audit programme offers 11 national clinical audits, covering both adult and paediatric respiratory disease. 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.

March 2018

Appendix 14 BTS Guidelines and *Thorax*: Production Process

Introduction

BTS Guidelines are usually published as supplements to the journal *Thorax.* This document sets out the main elements of the process to be followed to ensure that the requirements of the BTS Guideline production process, and the peer review processes of Thorax are met.

The BTS Guideline process is documented in the Guideline manual (available on the BTS website and updated each year: https://www.brit-thoracic.org.uk/quality-improvement/guidelines/.

Guideline preparation

The BTS Standards of Care Committee (SOCC) oversees the commissioning and approval of Guidelines, and each Guideline is rigorously reviewed by the Committee before approval is given for the public/stakeholder consultation phase.

Following the selection of a Guideline topic, the SOCC will review and approve the scope of the Guideline and the draft clinical questions to be addressed.

The chair (or more usually co-chairs) of the Guideline group is required to make regular progress reports to the SOCC and will also present an early draft to the Committee for preliminary review well before the final draft is presented for approval for the consultation stage.

Public consultation

The Standards of Care Committee will review the final draft Guideline and make a decision on approval for the public consultation process.

The consultation draft is made available on the BTS website for at least four weeks and feedback is invited from stakeholder organisations and the wider BTS membership.

The consultation draft will be uploaded to Scholar One to ensure the manuscript is in the *Thorax* production process.

At this stage Thorax editors will be invited to nominate three reviewers to provide detailed peer review of the Guideline draft as part of the consultation process. EICs will also involve the appropriate Associate Editor in the selection of reviewers. The duty EIC may assign the manuscript to an associate editor. This will occur when the subject of the Guideline is an area where the sub-specialty expertise of an Associate Editor will be helpful.

The invitation to peer reviewers will be issued via Scholar One. Peer reviewers will be invited to complete their review within the timeframe of the consultation process. The Scholar One process required reviewers to declare any interest related to the paper concerned. The reviews provided by individuals nominated by Thorax editors will constitute the substantive peer review for the guideline. The reviewer comments will be sent to BTS head office (with a note of declared interests) to include in the public consultation feedback.

At the end of the consultation period BTS will:

- Produce a collated copy of comments from all respondents (including Thorax reviewers)
- Send all comments to the Guideline group with a request to address each comment and provide a response and produce an updated (tracked change) Guideline draft.
- Submit the revised draft and comment responses plus the original consultation draft to the Thorax EICs via Scholar One.
- Submit any comments from Thorax EICs to the SOCC for consideration with the revised draft
- Arrange for the SOCC to review all responses to the Guideline consultation and any comments from Thorax EICs and request final amendments to the draft from the Guideline group.
- Arrange for final approval of the updated draft for submission for publication by SOCC

Submission for publication

Following final approval by the SOCC, BTS will submit the following documents to *Thorax* via Scholar One:

- Final manuscript – clean
- Consultation copy of manuscript (R0)
- All consultation comments and responses (spreadsheet)
- Tracked change copy of manuscript showing all amendments to draft in relation to consultation comments (including *Thorax* reviewers) (R1)

On submission of the final clean copy of the manuscript via Scholar One the manuscript will be sent to the duty EIC/ hanging committee for final discussion and comments. At this point minor comments only (format/consistency/style) will be fed back to BTS for attention at either pre-proof or proof stage. No further detailed peer review is required at this stage. The comments provided at this point would be aimed at improving clarity rather than changes to content/substance.

BTS will work with the *Thorax* production team to check and correct proofs and agree the publication date.

Associated publications

Following acceptance of the Guideline on Scholar one BTS will:

- Arrange for a short "highlights article" to be produced and submitted to *Thorax* to accompany the publication of the Guideline supplement. This will be reviewed by *Thorax* editors for publication in the main journal (and should be submitted as an editorial). This document is likely to be authored by one or more members of the Guideline group.

- Submit the summary of the recommendations of the Guideline (with brief introduction) to Scholar One, for publication in *Thorax* to coincide with publication of the main Guideline.

Thorax editors may:

- Commission an editorial from independent authors on the content of the Guideline.

Other BTS publications

BTS has recently introduced a new series of publications "Clinical Statements, one of which has been published in *Thorax* in 2017 (BTS Clinical Statement on Pulmonary Arteriovenous Malformations).

For those **Clinical Statements** that may be appropriate for publication in *Thorax* in future, the Editors will be notified at an early stage in production that the document is in preparation, and the process for review and revision will be conducted as part of the public consultation process and subsequent approval by the SOCC as outlined above.

Future Guidelines and other publications

BTS will ensure that Thorax EIS and the production team are sent an update on Guidelines and clinical statements in progress every six months.

Review and approval

This statement was first developed in May 2018 and has been reviewed on an annual basis since then. The document is reviewed and approved by the Standards of Care Committee.