British Thoracic Society

Clinical Statement Production Manual

1. Introduction

The British Thoracic Society has been at the forefront of the production of clinical guidance in respiratory medicine since the Society was established in 1982. The Society was awarded NICE Accreditation for its clinical guideline production process in November 2011, which has been renewed every five years since. Details of the guideline production process are set out in the BTS Guideline Manual.

In 2016/17 the Society identified the requirement for a further set of guidance documents in areas of clinical practice where the production of a full guideline is not appropriate or feasible; for example, where there is unlikely to be sufficient evidence to warrant a full literature review. Such documents are designated as a 'Clinical Statement.'

Clinical statements are not clinical guidelines, rather they seek to give a "snapshot in time" of knowledge and best practice in a particular clinical area and provide a series of good practice points.

It is likely that there will be clinical areas where it would be helpful for BTS to state a position, or provide a view, based on available evidence or expert opinion. This may be required in areas where new evidence for a specific condition has recently been published, or indeed where there is very little evidence.

This document sets out the process by which a Clinical Statement (CS) should be prepared for any topic approved by the BTS Board /Standards of Care Committee (SOCC). Proposals may also emanate from the Society's network of Specialist Advisory Groups (SAGs). Clinical Statements will be commissioned by the SOCC and generally there is not a regular call for topics.

The production of CS documents is the responsibility of the BTS Standards of Care Committee (SOCC). In instances where the statement has been proposed by the BTS Board directly, the final document will be shared with the Board for information before final approval for publication is given. Final sign off for all statements is the role of the SOCC.

2. Principles of Production

Topic approval

The SOCC will consider the following questions when reviewing a proposal:

- Is there a clinical need for the CS?
- Is this an area where there is limited published guidance or where published guidance has become outdated and does not reflect current practice?
- Does the proposal fit with the BTS strategy?
- Does the topic overlap with a BTS Guideline (either published or in process)?
- Does the topic overlap with a Guideline or statement from another Society/stakeholder (either published or in process)?
- Is this an area where practical guidance is needed and the evidence is difficult to assess?

2.1 Following confirmation of the topic for the CS, the following steps will be taken:

- The chair/co-chairs of the CS group will usually be identified by an open recruitment process and the SOCC Chair would usually be involved in the selection. It is expected that the chair/co-chair should be a published expert in the particular area that the CS is addressing, and would normally be a member of BTS. There is scope to have a non-BTS member as a co-chair, depending on the topic, however, the other co-chair must be an active BTS member.
- Members of the group will be selected via an open call for volunteers from across the BTS membership. Direct invitation is possible in the event that there are still gaps in expertise for the group, following the open call.. A CS Group will usually comprise no more than 10 members, all with a good knowledge of professional practice in the relevant field. It is expected that the group would be multidisciplinary and include at least one specialty trainee member.

2.2 It is expected that lay input into the development of the statement would be sought by the group. This could be achieved by different means including invitation of a lay representative onto the group, or sharing drafts of the CS guidance with patients and/or patient groups. Lay input would also be provided via the lay members of SOCC at:

- The initial SOCC review where the scope is agreed;
- At the public consultation stage; and
- At the final SOCC approval.

2.3 The CS group would be expected to identify relevant stakeholder organisations at an early stage in the process. BTS Head Office will make contact made with the relevant organisations to identify a contact for the peer review/public consultation stage (for example if the topic concerned has a bearing on thoracic radiology or haematology, contact would be made with the appropriate Royal College or professional society so that comments from a representative of that specialty could be sought). It is not anticipated that stakeholder organisations would hold a seat on the CS group unless there is a very specific case for direct involvement in the CS document production.

Declarations of Interest

2.4 The chair/co-chairs and group members are expected to adhere to the Society's policy for declarations of interest and the principles outlined below:

- The proposed chair/co-chairs of the group 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 chair/co-chair and any work on the CS is undertaken. The chair/co-chairs should not have any conflicts of interest in relation to the specific CS topic. Each member of the Clinical Statement Group (CS Group) must also complete a BTS DoI form before, or at, the first meeting of the CS and on an annual basis thereafter for the period that the CS Group 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/
- The Chair of the SOCC and chair/co-chairs of the CS Group have responsibility for scrutinising Declarations submitted by CS Group members. CS Group members are required to complete a DoI form as part of the annual BTS DoI scheme. Copies of DoI forms

for group members will be kept on file at BTS Head Office for the duration of the work of the CS Group (and then for the subsequent period of time that the Clinical Statement remains valid). Completed returns for active CS Group members will be available on the public area of the BTS website, and following publication of the Clinical Statement, DoI forms for each CS Group member are held on file at BTS Head Office and can be provided on request.

- DoI are a standing item at the beginning of each CS Group 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 CS Group will have no conflicts of interest. Should a consensus vote be required for any reason, those with conflicts of interest will be excluded from the process.
- A statement should be included in each Clinical Statement when published to confirm that CS group 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 Clinical Statement document is given below:

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

Support

2.5 BTS Head Office will provide project support for the Clinical Statement Group. All invitations to group members will be issued by BTS. BTS Head Office staff will make arrangements for meetings, ensure that accurate meeting notes are produced, and support the Group chairs/members in the timely production of the Clinical Statement. Administration of the public consultation process and liaison with the SOCC and with *Thorax*/BMJ Open Respiratory Research (BMJORR) takes place via BTS Head Office.

3. Production of the Clinical Statement

3.1 The CS group will be expected to:

- Develop a scope and clinical questions to address the topic of the CS;
- Conduct a review of the existing literature based on the scope/clinical questions. Please note this will not be the same as the full systematic literature search undertaken for a guideline, but some support will be available from BTS Head Office if needed;
- Draft an evidence review which will form the background to the Clinical Practice Points (it should be noted that the appraisal of evidence does not follow the same methodology as a BTS Guideline);
- Draft a series of Clinical Practice Points (based on the evidence review) to guide clinical practice (see definition below in 3.3).

3.2 The Clinical Statement Group will be expected to provide an outline scope and list of clinical questions for review by the Chair of the SOCC to ensure that the planned approach is appropriate. At this point an overall layout and approximate word count will be agreed. CS Groups should be aware that the final statement needs to be concise and easy to use for clinicians, so a maximum of 10,000 words is recommended. This limit is flexible according to the topic and the Committee will confirm the limit at an early stage in development.

Format of the Clinical Statement

3.3 The document will include the Society's evidence-based view/position on the given area and related good practice. The document should make clear that the guidance given is that of good practice, not recommendations. Clinical Practice Points (CPPs) are intended to offer short pieces of advice which may not have an evidence base but are viewed as essential to good clinical practice. CPPs may arise where the evidence is insufficient to be systematically reviewed, but where there may be a need to guide practice. All CPPs will be arrived at by consensus, based on the clinical experience of the group members. It is not anticipated that formal consensus methodology would be employed.

3.4 No grading systemwill be attached to the guidance but CPPs should be worded to assist with clinical decision making. Comprehensive references should be provided to support the discussion of evidence. Use of diagrams, flowcharts, tables and images is encouraged and can be in used in main document or in separate appendices referenced in the main document. Suggestions for future research, as well as for quality improvement/evaluation activities, may be included.

3.5 A CS document is be expected to include the following sections:

- Title
- Authors (on behalf of the British Thoracic Society)
- Remit/scope
- Process/methods
- Main text/review of literature
- Clinical Practice Points
- Suggestions for future research
- A statement in relation to the environment and sustainability
- A statement on declarations of interest
- Disclaimer
- References

Public consultation

3.6 After completion of the first draft, the document will be circulated to the SOCC for approval to proceed to the consultation stage. Following revision of the document to address any comments from the SOCC, the document will then be placed on the BTS website for a period of public consultation and comments invited from key experts/stakeholder organisations. Feedback from the peer review will be returned to the CS group for consideration and corresponding amendments to the draft. The purpose of the peer review stage is to ensure that the statement and good practice points are sound and achievable. If there is an intention to publish the final statement in *Thorax* (this may not apply to all CS documents) the editors of *Thorax* will be invited to nominate a limited number of peer reviewers at the public consultation stage.

3.7 It is expected that the CS would reach the public consultation stage within 6-9 months from the date the group was convened. At the consultation stage, the chair/co-chairs of the group will need to consider each comment received and document how each one has been addressed.

4. Approval by SOCC for publication

4.1 The final draft should be presented to a meeting of the SOCC for approval prior to publication. In some cases, the approved document will be submitted to the BTS Board (Officers' Group) for agreement for publication.

5. Publication/Dissemination/Review

5.1 Following approval, the document will be published on the BTS website and considered for submission for publication in *Thorax* or BMJ Open Respiratory Research, with an accompanying press statement. A copy will also be shared with relevant stakeholder organisations. Each statement would also be supported by a corresponding webinar, to help with dissemination.

5.2 The CS would be reviewed by the SOCC at 5 years following publication and a decision made on whether the document remains valid or whether it should be withdrawn or updated.

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