BSH Guideline Development Process

Contents

1 Introduction

1.1 Background and aims of the BSH Guidelines Committee

The British Society for Haematology (BSH) develops up-to-date evidence-based guidance, on the diagnosis and treatment of haematological disease, for UK clinical and laboratory haematologists.

The guidance is written, according to the BSH process, by expert consultants, clinical scientists, nurses and other healthcare professionals, currently practicing in the UK. These may be supplemented by additional Writing Group Members from other specialties and by patient representatives as required; based on the subject under review.

The Guidelines Executive Committee was previously known as the British Committee for Standards in Haematology (BCSH). Following a consultation process on behalf of the Society, in 2016, the name was changed to the BSH Guidelines Executive Committee (GEC), when there was a revision of the guideline processes.

All BSH Guidelines commissioned after August 2016, should follow the revised processes; and the updates, covered in this document. Guideline publications that are not covered in this document should be brought to the attention of the Chair of the BSH GEC. This document is reviewed periodically at the BSH GEC Meetings.

The BSH GEC consists of:

- A Chair
- A Vice-Chair
- The Chairs of the four Task Forces - This group oversees all aspects of BSH Guideline development.
- BSH Board Representative(s)

Full details of the GEC Terms of Reference are in Appendix 1.

1.2 BSH Guidelines Task Forces

There are 4 BSH Task Forces; covering the main areas of haematological practice, as follows:

- Blood Transfusion Task Force
- General Haematology Task Force
- Haematology-Oncology Task Force
- Haemostasis & Thrombosis Task Force

Task Force membership selection is governed by:

- Membership to BSH;
- expertise;
- ensuring there remains geographical representation across the UK;
- ensuring representation in different hospital settings;
- ensuring representation from a broad range of practice.

Each Task Force reviews existing guidance produced by BSH and national and international professional groups; to identify areas of need; and where appropriate, commission guidance on a specific subject.

1.3 BSH Guidelines Administrative Team

The BSH Guidelines Administrative Team will assist you through the Guidelines development process and can be contacted, as follows:

- Guideline Executive Committee (GEC) Enquiries – Guidelines.Officer@b-s-h.org.uk and bshguidelines@b-s-h.org.uk
- Haemostasis & Thrombosis Task Force Enquiries - Guidelines.Officer@b-s-h.org.uk and bshguidelines@b-s-h.org.uk
- Blood Transfusion Task Force Enquiries- Guidelines.Officer@b-s-h.org.uk and bshguidelines@b-s-h.org.uk
- General Haematology Task Force Enquiries - Sarah@b-s-h.org.uk and bshguidelines@b-s-h.org.uk
- Haematology-Oncology Task Force Enquiries - Sarah@b-s-h.org.uk and bshguidelines@b-s-h.org.uk
- Guideline Literature Searches, Guideline Audits and podcast Enquiries - Rita@b-s-h.org.uk and bshguidelines@b-s-h.org.uk

2 Guideline Development Process:

2.1 General principles for BSH Guidelines and AGREE II criteria

BSH Guidelines should be developed based on the AGREE II criteria; for the assessment of Guidelines including: judgements about the methods used for developing the Guidelines; the content of the final recommendations; and the factors linked to their uptake. All guidance must have clear recommendations with evidence-based grading, as briefly summarised in Appendix 3; and in the GRADE Tutorial and summary videos, available on YouTube: https://www.youtube.com/@MacGRADECentre.

The AGREE criteria are summarised below:

Scope and Purpose

- 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.
- A detailed description of the health questions, covered by the Guideline, should be provided.
- There should be a clear description of the target population to be covered by the Guideline.

Stakeholder Involvement

- The Guideline development group should include individuals from all the relevant professional groups.
- The views and preferences of the target population (e.g. doctors, patients, allied health professionals and the general public); should be sought.
- The target users of the Guideline are clearly defined.

Rigour of Development

- Systematic methods were used to search for evidence.
- The criteria for selecting the evidence are clearly described.
- The strengths and limitations of the body of evidence are clearly described.

- The methods used for formulating the recommendations are clearly described.
- The health benefits, side effects and risks have been considered in formulating the recommendations.
- There is an explicit link between the recommendations and supporting evidence.
- The Guideline has been externally reviewed by experts prior to its publication.
- A procedure for updating the Guideline is provided.

Clarity and Presentation

- The recommendations are specific and unambiguous.
- The different options for management of the condition or health issue are clearly presented.
- Key recommendations are easily identifiable.

Applicability

- The Guideline describes facilitators and barriers to its application.
- The Guideline provides advice and/or tools on how the recommendations can be put into practice.
- The potential resource implications of applying the recommendations have been considered.
- The Guideline presents monitoring and and/or audit criteria.

Editorial independence

- The views of the funding body have not influenced the content of the Guideline.
- Competing interests of Guideline development members have been recorded and addressed.

2.2 BSH Guidance – Format

The BSH produces for following guidance formats:

- BSH Guideline (~5,000 words) - Evidence-based Guideline, developed following a professional literature search and a review of the evidence by the Writing Group. This is the formal “BSH Guideline”.

- BSH Good Practice Paper (GPP) (~2,000 words) - Used to recommend good practice in areas where there is a less robust evidence-based guidance, but for which a degree of consensus or uniformity is likely to be beneficial to patient care. A GPP is also an evidence-based Paper, developed following a professional literature search and a review of the evidence by the Writing Group.

- BSH Guideline Addendum – e.g. update of an existing BSH Guideline.

- BSH Guideline Supporting Paper – additional documents (e.g. charts and relative documents)

- BSH Position Paper – e.g. a brief Paper of BSH’s response to an external publication

2.3 Process for identifying a topic for BSH guidance

Each Task Force continually reviews areas of interest to identify where there is a requirement for evidence, to promote best practice in clinical and laboratory haematology. This is based on the Task Force members’ personal expertise, but also on suggestions from members of the haematological wider community. Anyone can suggest a topic via the BSH website and suggestions from the website will be passed to the relevant Task Force Chair. Joint Guidelines can be written with other professional bodies but will need to comply with the overall principles of the BSH Guidelines Development Process.

2.4 Determining the format and scope

The Task Force will agree which topics should proceed to the proposal stage. The format of the guidance and scope will be determined by the relevant Task Force, in conjunction with the proposed Writing Group Members (see writing group composition, below).

Areas to consider when scoping:

Is there any current guidance available?

This will involve a preliminary literature search to check what else is available. This includes an assessment as to whether a Guideline is relevant to the UK;

What type of guidance is appropriate?

A BSH Guideline with a professional literature search or, if there is known to be only poor-quality evidence, a brief BSH Guideline Addendum or Guideline Supporting document, based on expert consensus; and with suggested variations for UK practice.

Once a topic for potential guidance has been identified, it is the responsibility of the Task Force to identify an appropriate Writing Group Chair, with expertise in the topic under consideration; and to nominate a member, as the Writing Group Task Force Representative, who will be responsible, with the Writing Group Chair, for ensuring that the BSH Guidelines Development Process is followed. The Task Force Representative will also be part of the Writing Group.

2.5 Proposal and Approval Process

The proposal for the Guideline/GPP, must be denoted on the BSH Proposal Form, available on the BSH website. The Proposal Form should be completed by the Writing Group Chair, with the assistance of the Task Force Representative.

Once the Proposal Form has been completed, it should be submitted to the BSH Guidelines Administration Team. The BSH Guidelines Administration Team will forward the Proposal Form to the relative Task Force for their review/approval. Only when the Task Force has approved the Guideline Proposal, will the BSH Guidelines Administration Team forward it to the GEC, for their review/approval.

NB: The Writing Group should not commence work on the Guideline, until the GEC has approved the Proposal. This may include making Proposal revisions to the Guideline Writing Group Membership and/or the Scope of the Guideline; and ensuring that all Declarations of Interest (DoIs) have been received from all Writing Group members.

2.6 BSH Guideline Addendum & BSH Guideline Supporting Papers

BSH Guideline Addenda and BSH Guideline Supporting Papers do not follow all the formal BSH Guidelines Development Process, required, needed to write a Guideline. The relevant Task Force can decide to produce/commission a Guideline Addendum or Guideline Supporting Paper; and submit it to the BSH GEC for comment and/or approval. Once approved it will be placed on the BSH website with a separate link signposting it to the relative Guideline.

3. Composition of a Writing Group

3.1 Process for selection of Writing Group Members

The Task Force will discuss the composition of the Writing Group, to ensure that all areas of the guidance will be written by appropriate experts; and that relevant professional and patient bodies are represented or consulted, during the scoping/writing/review process. This may involve producing joint-guidance with other professional bodies.

There should be appropriate diversity in the members of a Writing Group, in terms of different professions and disciplines. A patient representative or patient group should be invited to be part of the Writing Group, where possible. The Guideline can be sent to additional patient representatives, as part of the BSH Guidelines Sounding Board process. An exception to this is Technical Laboratory Guidelines, where patient involvement may not be appropriate.

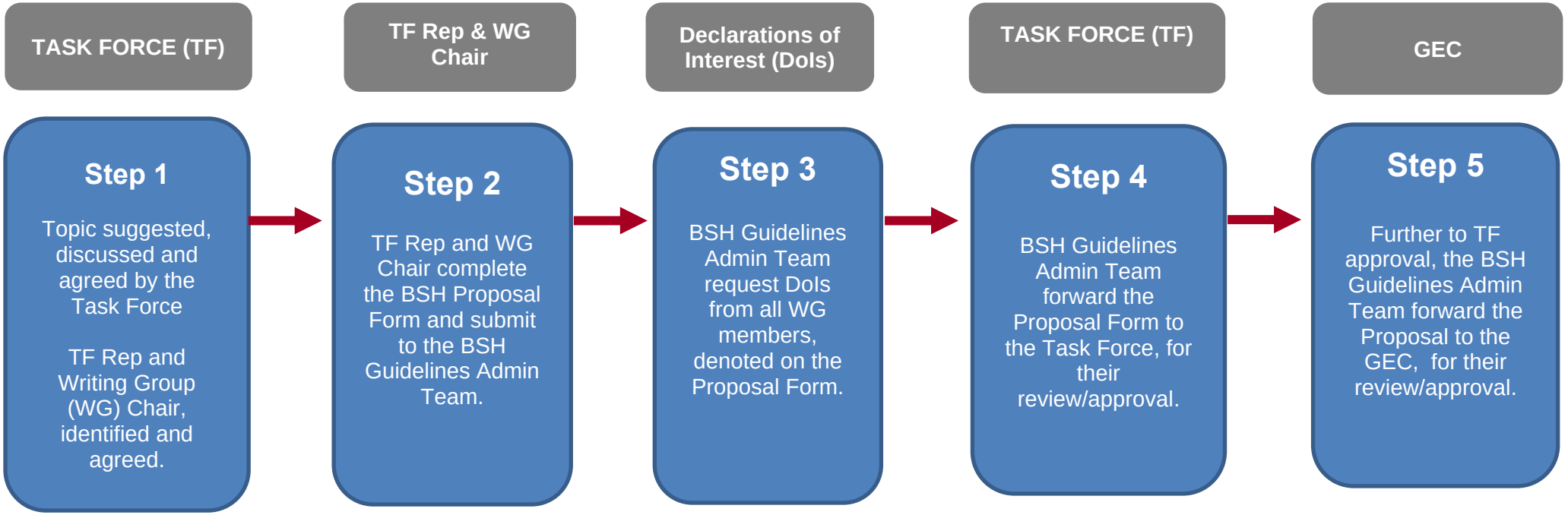
No Writing Group should be dominated by the views of any particular region or medical institution thus, there should be no more than two individuals from any institution. On occasion, where the Writing Group Chair feels that this cannot be complied, reasons must be documented in the BSH Proposal Form and discussed with the Task Force; prior to the Proposal Form being submitted to the Guidelines Executive Committee, for review and approval.

Each Writing Group must include a member of the Task Force (Writing Group Task Force Representative), who will work jointly with the Writing Group Chair, to ensure that the Guidance process is followed, and the Guidance layout is consistent with BSH procedure.

The BSH Guidelines Administration Team will assist the Writing Group Chair to move through the key review/approval stages, to ensure completion/publication of the Guideline.

Please find below, a summary flowchart of the BSH Proposal review/approval process:

BSH Proposal Review/Approval Process



3.2 Roles of Writing Group Chair, Writing Group Task Force Representative & Writing Group Members

Writing Group Chair:

- To decide, in conjunction with the Task Force Representative, the composition of the Writing Group and to identify and involve relevant stakeholders, including patient groups, where appropriate.

- To return a Declaration of Interest Form, review the BSH Guidelines Development Process and guidance on formulating recommendations based on GRADE; prior to starting work on the Guideline.

- To ensure that guidance is developed in accordance with the BSH Guidelines Development Process, writing should not start until the Proposal has been agreed by the BSH Task Force and GEC; and not until all members of the Writing Group have submitted a Declaration of Interest Form.

- The BSH Guidelines Administration Team will notify the Writing Group Chair when they have received all Writing Group member Declarations of Interest; and will send the Writing Group Chair and Task Force Representative a Declarations of Interest (DoI) Report, of which they will assess against any conflicts of interest. Should there be any conflicts of interest, the Writing Group Chair and Task Force Representative can refer the matter to the Task Force; and if the matter cannot be resolved at this level, it can be escalated to the GEC.

- To lead the scoping exercise and develop the PICO questions.

- To agree the parameters of the literature search and how the output will be presented to the Writing Group. The Writing Group Chair will contact Rita Gupta (Rita@b-s-h.org.uk), the Guidelines Programme Manager, who will arrange for a literature search to be carried-out.

- With the support of the BSH Guidelines Administration Team, the Writing Group Chair will oversee remote/hybrid/face-to-face meetings with the Writing Group.

- To delegate sections of the guidance to Writing Group members.

- To ensure a 1st Draft of the Guideline/GPP is submitted to the Task Force, within 6 months of receipt of the literature search.

- To ensure that relevant stakeholders review a draft of the guidance e.g. professional bodies, patient groups etc.

- To receive and respond to comments from the Task Force, BSH Sounding Board and the GEC; and modify the draft accordingly.

- To check the accuracy of the proof document before final submission for publication to Wiley.

- To inform BSH Guidelines Administration Team when the Guideline is submitted for publication.

- To inform the Task Force Representative if any new information makes the guidance obsolete, requiring updating and/or alteration.

Writing Group Task Force Representative:

- Assist the WG chair in the composition of the Writing Group; and to identify and involve relevant stakeholders, including patient groups, where appropriate.

- To submit a Declaration of Interest Form, review the BSH Guidelines Development Process and guidance on formulating recommendations based on GRADE; prior to starting work on the Guideline.

- To ensure that guidance is developed in accordance with the BSH Guidelines Development Process, writing should not start until the Proposal has been agreed by the BSH Task Force and GEC; and not until all members of the Writing Group have submitted a Declaration of Interest Form.

- Once Writing Group members have completed the Declaration of Interest Form, the BSH Guidelines Administration Team will send the Writing Group Chair and Task Force Representative a Declarations of Interest (DoI) Report, of which they will assess against any conflicts of interest. Should there be any conflicts of interest, the Writing Group Chair and Task Force Representative can refer the matter to the Task Force; and if the matter cannot be resolved at this level, it can be escalated to the GEC.

- Attend and support the WG Chair during remote/hybrid/face-to-face meetings with the Writing Group.

- To assist the WG Chair in the scoping exercise and their development of PICO questions.

- To agree the literature search criteria with the WG Chair; and where necessary, liaise with a medical writer who carry-out the literature searches; arranged by Rita Gupta (Rita@b-s-h.org.uk), the BSH Guidelines Programme Manager.

- To ensure a 1st Draft of the Guideline/GPP is submitted to the Task Force, within 6 months of receipt of the literature search.

- To report to the Task Force as to the progress of the guidance and to report any Task Force concerns are fed back to the Writing Group Chair and the Writing Group.

- To check accuracy of the proof document before final submission for publication to Wiley.

- To inform BSH Guidelines Administration Team when the Guideline is submitted for publication.
- To produce the guidance audit template.
- To produce a summary and key words for BSH website publication.
- To inform the Task Force Chair if any new information makes the guidance obsolete, requiring updating and/or alteration.

Writing Group Members:

- To submit a Declaration of Interest Form, review the BSH Guidelines Development Process and guidance on formulating recommendations based on GRADE; prior to starting work on the Guideline.
- To participate and support the WG Chair during remote/hybrid/face-to-face Writing Group meetings.
- To develop draft guidance, as agreed with the Writing Group Chair.
- To inform the Writing Group Chair if any new information makes the guidance obsolete or requires alteration (see guidance maintenance).

3.3 Declarations of Interest

Declarations of Interest (see: Appendix 2) must be completed by all members of the Writing Group. A Proposal cannot be approved by the GEC, without the receipt of all DoIs from the Writing Group. Once the Proposal has been approved and all DoIs have been received, the Writing Group can commence the writing of the guidance.

Declarations of Interest are fundamental criterion of a Guideline/GPP, which cannot be published until all Declarations of Interest have been received from the Writing Group; and audited for any conflicts of interest by the Writing Group Chair and/or the Task Force Representative. Any concerns about the Declaration of Interests will be referred to the Task Force, in the first instance; and if necessary, escalated to the GEC.

NB: Writing Group members who have not submitted a DoI, cannot be listed as an author of a Guideline/GPP.

GEC and Task Force DoIs will be valid for 1 year; and Writing Group DoIs are valid for 3 years.

3.4 Task Force & Writing Group Member eLearning

Task Force and Writing Group Members are urged to complete the following eLearning, prior to the onset of writing the guidance:

- GRADE Tutorial – Summary videos are also available on YouTube: https://www.youtube.com/@MacGRADECentre

3.5 Guidelines Funding

Members of Writing Groups, Task Forces and the BSH Guidelines Executive Committee, do not receive funding for Guideline production; except for covering costs for travel expenses.

4. BSH Guideline Preparation

4.1 PICO Question Development

As part of the Guideline preparation, clear structured questions should be developed. The PICO model is a valuable tool for this.

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

Assisted by the Writing Group Task Force Representative, the Writing Group Chair will develop the PICO questions for the Proposal.

4.2 Developing a Search Strategy & Literature Review

BSH will fund Information Scientists (Medical Writers) to undertake literature searches for new guidelines. This will be undertaken following advice from the Writing Group, with regards to keywords, databases, time periods, exclusion and inclusion criteria etc. The BSH Guidelines Programme Manager, Rita Gupta (Rita@b-s-h.org.uk) will assist in email correspondence between the Writing Group Chair and/or the Task Force Representative and the Medical Writer; to clarify the keywords.

The literature review should be completed within 12 weeks of the approved Proposal; and will be returned to the Writing Group Chair as an EndNote Library or Reference List. The search strategy will be sent as a separate document.

The search strategy must be included as an Appendix detailing, the following:

- Databases e.g. PubMed, Ovid, Cochrane
- Keywords used for search
- Time period covered
- Inclusion criteria e.g. Human, clinical trial
- Exclusion criteria e.g. no papers published in non-English journals, case reports, no abstract available.

The output from the literature search should be related to the key structured questions identified within the scope.

4.3 Producing the Draft Guideline

The literature search should be circulated to the Writing Group. The Writing Group may decide that they will review all the evidence, or it may be distributed among the authors according to PICO questions.

The Writing Group should decide which evidence is relevant and meets the inclusion criteria. This evidence should be used as the basis for developing recommendations for each PICO question and for subsequent GRADE evidence.

Each recommendation should be supported by an evidence-based discussion, including all relevant references. Authors may use additional evidence or references as part of their introduction and background discussion in the manuscript. Usually, sub-groups of authors will work on each PICO question and will develop the recommendations and background discussion. The Writing Group Chair should collate these sections, provide an overview and ensure consistency.

4.4 Grading the Evidence

All guidance must have clear recommendations with evidence-based grading, as briefly summarised in Appendix 3; and in the GRADE Tutorial and summary videos, available on YouTube: https://www.youtube.com/@MacGRADECentre. It is the role of the Writing Group Chair and Writing Group Task Force Representative to:

- Weigh-up and discuss the potential benefit and risk of a particular course of action, versus not carrying-out that action.
- Each recommendation and its evidence-based grading (GRADE) must be discussed by the entire Writing Group and a consensus agreed upon.
- The Writing Group should assess the quality of evidence for each recommendation (a-d) and based on this, should grade the recommendation as strong (GRADE 1) or weak (GRADE 2). If there is disagreement about the level of recommendation, all Writing Group Members should vote on the recommendation. This should be reflected in the guideline at the discretion of the Task Force Chair.
- When a recommendation is made, careful attention must be paid with regard to the use of wording; ‘recommend’, ‘offer’ and ‘should’, which are appropriate for GRADE 1 recommendations; and ‘suggest’ and ‘consider’ are more appropriate for GRADE 2 recommendations.
- Where an unlicensed agent or unlicensed indication (off label prescribing) for a licensed medicine is recommended (as per UK licensing), this should be clearly indicated.
- Where there are new diagnostic techniques or a requirement for particular skills, or equipment being recommended that the Writing Group know have limited availability in the UK, this should be identified and the risks versus benefit of accessing or not accessing this particular technique documented; to allow users of the guidance to have discussions about priorities of care within their institutions.

It is outside the remit of the BSH to do a cost-effectiveness analysis of each recommendation; and BSH feel that it is for Writing Groups to assess the guidance produced and assess the risks of implementing, or not, in the context of their own priorities and populations.

4.5 BSH Guideline Development Process

GUIDELINE RESEARCH & PREPARATION

Step 1
NB: Writing of a Guideline/GPP, cannot start, until the receipt of all DoIs from the WG.

The WG Chair and/or TF Rep requests will be sent a DoI Report from the BSH Guidelines Administration Team, to assess against conflicts of interest.

Step 2
WG Chair requests a Literature Search from the Guidelines Admin Team, providing search terms etc.
NB: A Literature Research is only valid for one year. If the Guideline is not completed within a year, a new Literature Research has to be undertaken.

Step 3
WG to write recommendations and background evidence for Guideline (GRADE)

Step 4
WGC collates each section of the Guideline and prepares the 1st Draft for submission.

1ST DRAFT GUIDELINE

Step 5
WG Chair sends the 1st Draft of the Guideline to the BSH Guidelines Admin Team, who will forward it to the TF for review/approval (usually, within 2 weeks).

Step 6
WG reviews TF comments; and compiles a 2nd Draft of the Guideline.

2nd DRAFT GUIDELINE

Step 7
WG Chair sends the 2nd Draft of the Guideline to BSH Guidelines Administration Team, who will upload it to the BSH website Sounding Board, for comments from BSH Members (usually, within 2 weeks).

Step 8
WG reviews Sounding Board comments; and prepares a Final Draft of the Guideline.

FINAL DRAFT GUIDELINE

Step 9
WG Chair sends the Final Draft of the Guideline to the BSH Guidelines Administration Team, who will forward it, simultaneously, to the TF and GEC , for their final review/approval.

Step 10
WG reviews the TF/GEC Final Draft comments; and updates the Final Draft, in preparation to be submitted to Wiley for publication.

SUBMISSION & PUBLICATION

Step 11
WGC submits the Final Draft of the Guideline to Wiley, for review/ approva/ publication. This process usually takes 2 months.

Step 12
WG responds to any Wiley Reviewer comments; and re-submits the updated Final Draft to Wiley.

Step 13
Guideline/GPP is approved and published by Wiley and uploaded to the BSH website.

4.6 Timelines

NB: The 1ST Draft of the Guideline should be submitted to the Task Force within 12 months of the literature search being completed.

NB: The Guideline should be submitted for publication within 18 months of the literature search being completed.

If the 1st Draft of a Guideline is not received by the Task Force, within 12 months, a new literature search will have to be undertaken. It is the responsibility of the Writing Group Task Force Representative to send a reminder of the deadline to the Writing Group Chair. If there is no response or the Writing Group Chair is unable to complete a 1st Draft of the Guideline within 12 months, the Task Force Representative should consider appointing another Writing Group Chair.

4.7 BSH Guidelines Style Template

BSH has a standard structure/style for writing Guidelines. The BSH Guidelines Structure Template, available on the BSH website, denotes the format; in Word document form.

4.8 Audit Tool

Guidelines should be accompanied by an Audit Tool, of which is completed by a Medical Writer. The Medical Writer, with the help of the lead author, will complete the Audit Template. This will not necessarily be a direct quote of the recommendations, but a practical tool to audit compliance with the principles of the guidance and demonstrate quality of care. The final Audit Tool will be uploaded to the RCPath website and will also be accessible via a link on the relative Guideline, published on the BSH website.

4.9 Wiley Submission & Publication

The BSH aims to publish all guidance in the Wiley peer reviewed journal, which includes: the British Journal of Haematology (BJHaem) and Transfusion Medicine. Thus, all guidance should be of a standard and length that is acceptable for Wiley publication.

To submit a Guideline/GPP to Wiley, for review, approval and publication, please undertake the following:

i. The Writing Group Chair will submit the approved final draft of the Guideline/GPP using this link: https://mc.manuscriptcentral.com/bjh.

ii. You will be asked to select either Open Access or 'Subscription based article'. Please ensure you choose Subscription based article.

NB: It is important that you select the subscription-based article and not open access, otherwise BSH will be incorrectly charged for the submission. It may seem counterintuitive, but that is the way Wiley's website is set-up.

iii. Please notify the BSH Guidelines Administration Team when you have submitted the Guideline/GPP to Wiley; and send a Word version of the Guideline/GPP, for our records.

iv. Notice of publication will be sent by Wiley to the Writing Group Chair and the BSH Guidelines Administration Team. The WG Chair should inform the Writing Group Members and the Task Force Representative of the publication. The BSH Guidelines Administration Team will then upload the Guideline to the BSH website.

NB: It takes approximately 2 months from the time the WG Chair submits the Guideline/GPP to Wiley, until the date Wiley publish the Guideline/GPP.

Additional Material
Writing Groups may also submit supplementary material. This may include appendices containing search strategy or supportive material for implementation.

4.10 Guideline/GPP Podcast

All Guidelines should have an audio podcast recording, which is usually undertaken by the Writing Group Chair. You will be contacted by the BSH Guidelines Administration Team, who will schedule a time/date for the audio recording. The actual podcast recording is usually for a duration of approximately, 15-20

minutes, but you will need to allow approximately 2 hours for the podcast recording meeting, which will include 15-20 minutes recording time and approximately 45 minutes for preparation/edits.

5. Guideline Review & Maintenance

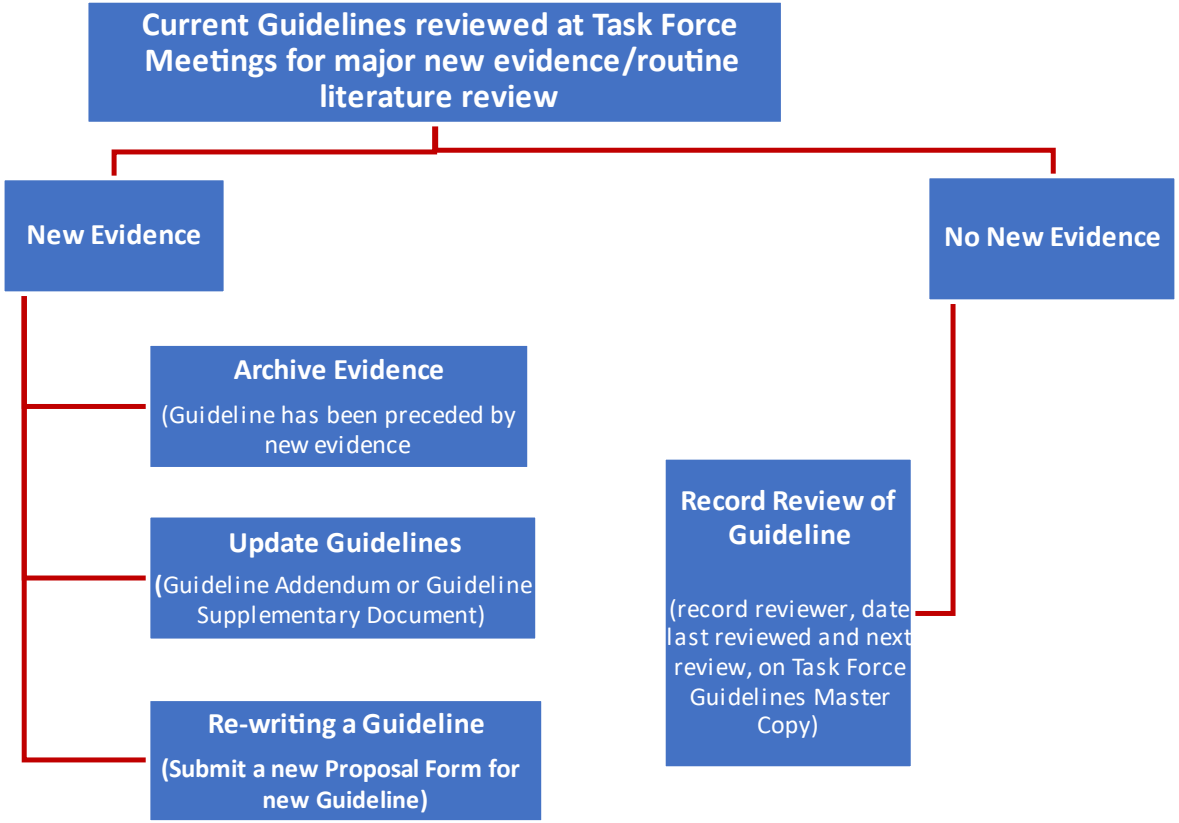
It is acknowledged that evidence for new important developments can appear at any time. At each Task Force meeting, members should consider whether any current Guideline needs an update. Every three years all BSH Guidelines must have a literature search re-run as a check for new evidence. If there is no substantial new evidence the Guideline should be approved by the Task Force and the BSH Guidelines Administration Team should note this on the website. If new evidence requires changes, the options for consideration, are:

- **Archive Guidance**: New evidence has become available requiring major changes or making a recommendation incorrect. The latter will be communicated to the BSH Guidelines Administration Team, who will immediately archive the current guidance. The Task Force will then review whether new guidance should be commissioned or can be updated.

- **Guideline Updates**: If there is additional information, but not to a degree to require archiving a Guideline, then this information can be denoted via a Guideline Addendum or Guideline Supplementary Document, which will be attached to the relevant Guideline, on the BSH website.

- **Re-writing a Guideline:** Further to a Task Force decision to re-write a Guideline, a Task Force Representative and Writing Group Chair will be assigned to develop a Proposal for the Guideline re-write.

Please find below a diagram summary of the above:


Current Guidelines reviewed at Task Force Meetings for major new evidence/routine literature review
New Evidence
No New Evidence
Archive Evidence
(Guideline has been preceded by new evidence
Update Guidelines
(Guideline Addendum or Guideline Supplementary Document)
Re-writing a Guideline
(Submit a new Proposal Form for new Guideline)
Record Review of Guideline
(record reviewer, date last reviewed and next review, on Task Force Guidelines Master Copy)

Appendix 1

British Society for Haematology Guidelines Executive Committee Terms of Reference

1. The Guidelines Executive Committee is established under Articles 79-84 of the Memorandum and Articles of Association of the British Society for Haematology (BSH) as a subcommittee of BSH. The Trustee Board will nominate a Trustee to be a member of the Guidelines Executive Committee.

2. The Officers responsible for the administration of the Guidelines Executive Committee will be a Chair and a Vice Chair, who will be appointed by the Trustee Board. The Chair of the Guidelines Executive Committee will be appointed for a period of two years and is not eligible for re-appointment. The post will normally be filled by the Vice Chair of the Guidelines Executive Committee subject to approval by the Trustee Board. The Vice Chair will be appointed by the Trustee Board and will normally have experience as a member of a Task Force. The appointment will be for a period of two years and is non-renewable.

   The Chair of the Guidelines Executive Committee is responsible for the efficient running of the Guidelines Executive Committee. The Chair's role is to define the style and contents of BSH Guidelines and to ensure that the Task Forces operate effectively. The Chair fulfils these functions with the help of the Vice Chair and BSH staff:

   - To implement the overall strategy of the Guidelines Executive Committee as agreed by the Trustee Board.
   - To chair the Guidelines Executive Committee Meetings.
   - To scrutinise Declarations of Interest.
   - To ensure that the Task Forces are operating effectively and are fulfilling their remit.
   - To provide a six-monthly report to the Trustees Board on the Guidelines Executive Committee activities
   - To compile the agenda and minutes of the Guidelines Executive Committee meetings in liaison with BSH Guidelines Team.

3. The Guidelines Executive Committee Vice Chair's role is:

   - To act as deputy to the Chair when required.
   - To co-ordinate Guideline production, providing clear guidance to Task Force Chairs to ensure due process and deadlines in liaison

with the BSH Programme Manager.

4. In addition to the Chair and Vice-Chair, the Guidelines Executive Committee shall consist of the Chairs of each Task Force (for whom the Task Force Deputy-Chair may deputise) and a Trustee.

The Guidelines Executive Committee will establish, with the approval of the Trustee Board, expert Task Forces of no more than eight members. Task Force Members must be members of BSH. The Task Forces may also be co-opt representatives from other organisations, provided that the Trustee Board approves (this is in addition to the ordinary members and therefore the total number on a Task Force may be greater than eight). No co-opted member should sit on the Task Force for more than six years, unless there is a particular reason to do so.

At present there are four Task Forces:

- General Haematology
- Haemato-Oncology
- Blood Transfusion
- Haemostasis & Thrombosis.

Each Task Force will have a Chair and Deputy-Chair:

a) The Chair will be nominated by the Task Force members and must have been a member of that Task Force; and a BSH Member. The appointment will be subject to approval by the Guidelines Executive Committee. The post shall be for a term of two years and is renewable once.

b) The Deputy-Chair will be nominated by the Task Force members and must have been a member of that Task Force; and a BSH Member. The appointment will be subject to approval by the Guidelines Executive Committee. The post shall be for a term of two years and is renewable once.

c) Should more than one person put themselves forward for the role of Chair or Deputy-Chair, the Task Force may decide to hold a secret ballot.

d) No individual shall sit on a Task Force for more than 12 years, including time as a co-opted member, ordinary member, Deputy-Chair and

Chair.

e) Task Force Members must hold a substantive post in the UK; and be a BSH Member. The appointment of Task Force Members shall be for a term of three years and shall be renewable once. Task Force membership should be spread geographically and in terms of hospital setting. Scheme Organisers of organisations such as NEQAS, NIBSC and SHOT may normally be expected to be co-opted members of the appropriate Task Force.

f) Upon the end of a Task Force Member's term, or at any other time when the membership of a Task Force falls below eight, a Task Force may decide to appoint new members. The new members will be a BSH Member that is chosen by the Task Force, with the Task Force Chair having the ultimate decision, and the appointments must be approved by the Guidelines Executive Committee.

g) The total length of time an ordinary member may sit on the Task Force is six years. An ordinary member who has sat on the Task Force for six years may not re-join as a co-opted member and vice versa.

h) The Chairman and Vice-Chair of the Guidelines Committee are ex-officio members of each Task Force.

5. The Task Force Chairs will set strategies for their Task Force and establish Writing Groups and monitor their performance.

The role of a Task Force member will include:
a) To attend quarterly meetings of their Taskforce.
b) To ensure they have completed appropriate training.
c) To return their Declaration of Interests on an annual basis.
d) To review all Task Force Proposals.
e) To review all Task Force Draft Guidelines.
f) To assist with the maintenance of Guidelines.

6. The office address of the Guidelines Executive Committee shall be the address of BSH, or such other address as stipulated by the Trustee Board.

7. Correspondence should be addressed to the BSH Guidelines Administration Team at the official address: The British Society for Haematology, 100 White Lion Street, London, N1 9PF.

8. Guideline publications by Task Forces must be approved by the Guidelines Executive Committee. When it is appropriate, the document may show the societies and organisations endorsing it.

9. Task Force Members and the Guidelines Executive Committee; societies and organisations invited to join a Task Force; and members of Writing Groups, shall have their reasonable expenses incurred on Task Force business; reimbursed by the BSH in line with the BSH expenses policy.

10. The Task Forces and the Guidelines Committee will meet quarterly in face-to-face meetings or via teleconference.

11. The Task Forces will review the Declarations of Interests and Training Log at each meeting.

12. The Declarations of Interest of all committee members will be updated at least annually (before the autumn meeting) or if there are substantial changes.

13. The Guidelines Committee will review the budget for the subsequent year, the Declarations of Interests and Training Logs in the autumn meeting.

14. The Guidelines Committee will review workload in the autumn meeting and will aim for a maximum of 12-16 new guidelines per year.

Appendix 2

DECLARATIONS OF INTEREST POLICY

The British Society for Haematology Guidelines Executive Committee require a Declaration of Interest (DoI) statement from the following individuals:

BSH GEC Members – Annually. To be reviewed by the BSH Trustees

BSH Task Force Members – Annually. To be reviewed by the BSH GEC.

Writing Group Members – Require for each Writing Group and reviewed annually. To be reviewed by the Task Force Chair.

Any concerns with conflict of interest which cannot be resolved, should be discussed with the BSH Task Force Chair and the Guidelines Executive Committee. The declarations from Writing Group Members must be outlined in the published Guideline and a broad outline of each individual DoI will be circulated to the Writing Group Chair, to ensure that all are aware of possible conflicts of interest during the writing of the guidance.

Explanation of Declarations of Interest

The healthcare industry includes companies which provide services for the health service, including those manufacturing pharmaceuticals, laboratory reagents of medical and laboratory equipment.

Personal Interests

A personal interest involves payment to the member personally. For example:

- Consultancies: any consultancy, directorship, position in or work for the healthcare industry which attracts regular or occasional payments in cash or kind.
- Fee-Paid Work: any work commissioned by the healthcare industry for which the member is paid in cash or kind.
- Shareholdings: any shareholding in or other beneficial interest in shares of the healthcare industry. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence or financial management.

Non-Personal Interests

A non-personal interest involves payment which benefits a department for which a member is responsible but is not received by the member personally. The main examples are:

- Fellowships: the holding of a fellowship endowed by the healthcare industry or any other grant funding organisation.
- Support by the healthcare industry: any payment, other support or sponsorship by the healthcare industry which does not convey any pecuniary or material benefits to a member personally, but which does benefit his/her position or department e.g. A grant from a company for the running of a unit or department for which a member is responsible.
- A grant or fellowship or other payment to sponsor a post or a member of staff in the unit for which the member is responsible. This does not include financial assistance for students.

The commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible.

Family Interests

'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

A personal family interest relates to the personal interests of a family member and involves a current payment to the family member of the employee or member. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as 'specific', or to the industry or sector from which the product or service comes, in which case it is regarded as 'non-specific'.

The main examples include the following:

- Any consultancy
- Directorship
- Position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.
- Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.
- Any shareholdings, or other beneficial interests, in a healthcare industry which is either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

- Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference).
- Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
- No personal family interest exists in the case of:
- Assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds), where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme).
- Accrued pension rights from earlier employment in the healthcare industry.

GUIDELINE WRITING GROUP MEMBERS

They should declare interests as per the following categories:

a. **Personal specific interest** if he or she has worked within the last two years on a project relevant to the guideline either for the healthcare industry and has personally received payment for that work, in any form or any non-financial interest. If the interest is no longer current, the member may declare it as a lapsed personal specific interest.

b. **Personal non-specific interest** if he or she has a current personal interest in the healthcare industry concerned which does not relate specifically to the guideline area under consideration.

c. **Non-personal specific interest** if he or she is aware that the department for which he or she is responsible has in the last 5 years worked in the area of the Guideline, but the member has not personally received payment in any form from the healthcare industry for the work done.

d. **Non-personal, non-specific interest** if he or she is aware that the department for which he or she is responsible is currently receiving payment from the healthcare industry concerned which does not relate specifically to the product under consideration.

e. **Non-personal, non-specific interest** if he or she is aware that the department for which he or she is responsible is currently receiving payment from the healthcare industry concerned which does not relate specifically to the product under consideration.

f. **Family interest.** In the last 12 months has a member of your family had any financial involvement with the healthcare industry, or are they planning to have such financial involvement? This could include:

- holding a directorship, or other paid position
- carrying out consultancy or fee paid work
- having shareholdings or other beneficial interests
- receiving expenses and hospitality over and above what would be reasonably expected to attend meetings and conferences.

TASK FORCE & BSHGC MEMBERS

They should declare interests as per the following categories:

- **Personal interest** if he or she has worked within the last 5 years either for the healthcare industry and has personally received payment for that work, in any form or non-financial interest. If the interest is no longer current, the member may declare it as a lapsed personal specific interest.
    -
- **Non-personal interest** if he or she is aware that the department for which he or she is responsible has at any time in the last 5 years worked with the healthcare industry but the member has not personally received payment in any form for the work done.
    -
- **Family Interests.** If members have interests not specified above but which they believe could be regarded as influencing their advice they should declare them.

If members have interests not specified in these notes but which they believe could be regarded as influencing their advice they should declare them.

Appendix 3 - GRADE

The BSH Guidelines Committee uses the GRADE nomenclature for evaluating levels of evidence and assessing the strength of recommendations in all Guidance. Details are available at: http://www.gradeworkinggroup.org/index.htm

Type of evidence	**Randomized trial = high (A) Observational study = low (C) Any other evidence = very low (D)**	
Decrease* grade if:	• Serious or very serious limitation to study quality • Important inconsistency • Some or major uncertainty about directness • Imprecise or sparse data • High probability of reporting bias	*Each quality criteria can reduce the quality by one or, if very serious, by two levels
Increase grade if:	• Strong evidence of association—significant relative risk of > 2 (< 0.5) based on consistent evidence from two or more observational studies, with no plausible confounders (+1) • Very strong evidence of association—significant relative risk of > 5 (< 0.2) based on direct evidence with no major threats to validity (+2) • Evidence of a dose response gradient (+1) • All plausible confounders would have reduced the effect (+1)	

Quality of Evidence and criteria for assigning the quality of evidence
The quality of evidence is graded as:
high (A), moderate (B), low (C) or very low (D).

In general:
(A) High: further research is very unlikely to change our confidence in the estimate of effect
(B) Moderate: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
(C) Low: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
(D) Very Low: any estimate of effect is very uncertain
Strength of Recommendation

Strong (grade 1): Strong recommendations are made if clinicians are certain that benefits do, or do not, outweigh risks and burdens. Grade 1 recommendations can be applied uniformly to most patients and words such as “recommend”, "offer” and “should” are appropriate.

Weak (grade 2): Weak recommendations are made if clinicians believe that benefits and risks and burdens are finely balanced, or appreciable uncertainty exists about the magnitude of benefits and risks. In addition, clinicians are becoming increasingly aware of the importance of patient values and preferences.