BSH Guideline Development Process

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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 a team of expert Consultants and other allied 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, when there was a revision of guideline processes.

All BSH Guidelines commissioned after August 2016, should follow the revised processes as 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 Guidelines Executive Committee. This document will be reviewed periodically at the BSH Guidelines Executive Committee Meetings.

The BSH Guidelines Executive Committee consists of a Chair and Vice-Chair, in addition to the Chairs of the four Task Forces. This group oversees all aspects of BSH Guideline development.

The Terms of Reference of the BSH Guidelines Committee are in Appendix 1.

1.2 BSH Guidelines Task Forces

There are four Task Forces, which cover the main areas of haematological practice, as follows:

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

The membership of each Task Force is chosen, as follows:

- For their expertise;
- To ensure geographical representation across the UK;
- To ensure representation in different hospital settings;

- To ensure 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.

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 (http://www.agreetrust.org/agree-ii/). A checklist is available at http://www.agreetrust.org/resource-centre/agree-reporting-checklist/. 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 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 (patients, 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 guidance in distinct formats:

- BSH Guideline (~5000 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).
- BSH Guideline Addendum.
- BSH Guideline Supporting Paper.

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 expert knowledge, 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 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 should include the following:

Is there any current guidance available?

This will involve a preliminary literature search to check what else is available. This include an assessment as to whether a guideline is relevant to the UK; and whether a BSH Guideline Addendum or a BSH Guideline Supporting document could be produced with suggested variations for UK practice.

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.

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 process is followed. The Task Force Representative will 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 template, 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 for approval to the Guidelines Programme Manager, Rita Gupta (Rita@b-s-h.org.uk), who will forward the Form to the relevant Task Force, for their approval. Only when the Task Force has approved the Guideline Proposal, will the Guidelines Programme Manager forward it to the Guidelines Executive Committee, for their review and approval.

The Writing Group should not commence work on the Guideline, until the Guidelines Executive Committee has approved the Proposal. This may include making Proposal revisions to the Guideline Writing Group Membership and/or the Scope of the Guideline.

2.6 BSH Guideline Addendum & BSH Guideline Supporting Papers

BSH Guideline Addenda and BSH Guideline Supporting Papers do not follow all the formal development procedures, needed to write a Guideline.

The relevant Task Force can decide to produce or commission a Guideline Addendum or Guideline Supporting Paper; and submit it to the BSH Guidelines Executive Committee 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 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 an appropriate expert; 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 Sounding Board exercise. 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 Team (Guidelines.Officer@b-s-h.org.uk) will assist the Writing Group Chair to move through the key review and approval stages, to ensure completion/publication of the Guideline. A summary flowchart of the BSH Proposal Approval Process and the BSH Guidelines Development Process, is available below (4.5 and 4.6, respectively).

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

Writing Group Chair:

- To ensure that Guidance is developed in accordance with the BSH process (note that writing should not start until the proposal and participation of all members has been agreed by the BSH Guidelines Executive Committee).
- To decide, in conjunction with the Task Force Chair, the composition of the Writing Group and to identify and involve relevant stakeholders, including patient groups, where appropriate.

- To lead the scoping exercise and develop the PICO questions.
- To return a completed Declaration of Interest Form. Once Writing Group members have completed the Declaration of Interest Form, the Writing Group Chair should undertake an audit of Declarations of Interest submitted; ensuring that there are no conflicts of interest, prior to the Guideline submission for publication. The Writing Group should request the Declarations of Interest Report from the Guidelines Team (guidelines.officer@b-s-h.org).
- To agree the parameters of the literature search and how the output will be presented to the writing group.
- With the support of the BSH Guidelines Team (guidelines.officer@b-s-h.org), the Writing Group Chair will oversee remote meetings, with the Writing Group, via video conferencing.
- To delegate sections of the Guidance to Writing Group members.
- To ensure the initial draft is submitted within 6 months of receipt of the literature review to the Task Force.
- To ensure that relevant stakeholders review a draft of the Guidance e.g. professional bodies, patient groups etc.
- To receive comments from the Task Force, Sounding Board, BSH members and the Guidelines Executive Committee; and modify the draft accordingly.
- To check the accuracy of the proof document before final submission for publication to Wiley.
- To inform BSH Guidelines Team (Rita@b-s-h.org.uk / guidelines.officer@b-s-h.org) when the Guideline is published.
- To inform the Task Force Chair if any new information makes the Guidance obsolete/ requiring updating/ alteration.

Task Force Representative: (will be a member of the Writing Group)

- To ensure that the BSH process is followed at all times; and that all Writing Group Members are aware of the BSH Guidelines Development Process, including formulating recommendations based on GRADE.
- 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 Members and Writing Group Chair.
- To check accuracy of the proof document before final submission for publication to Wiley.
- To produce the guidance audit template.
- To produce a summary and key words for the website.

Writing Group Member:

- To return a Declaration of Interest form and complete the eLearning before starting work; including the BSH Guidelines Development Process and formulating recommendations based on GRADE.
- 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, once the Guideline Proposal has been approved; and prior to commencing the writing of the guidance. Declarations of Interest are fundamental criterion of a Guideline, 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. Any concerns about the Declaration of Interests will be referred to the Task Force and BSH Guidelines Executive Committee, for review.

Declarations of Interest will be reviewed on an annual basis, by the BSH Guidelines Team; and audited by the Writing Group Chair, prior to publication.

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:

- BSH Guidelines Induction Tutorial – This is a brief overview of the BSH Guidelines Development Process and is currently only accessible to BSH Members.
- 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 of travel.

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.

Lead by the Writing Group Chair and 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 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 Information Scientist (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 review 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.

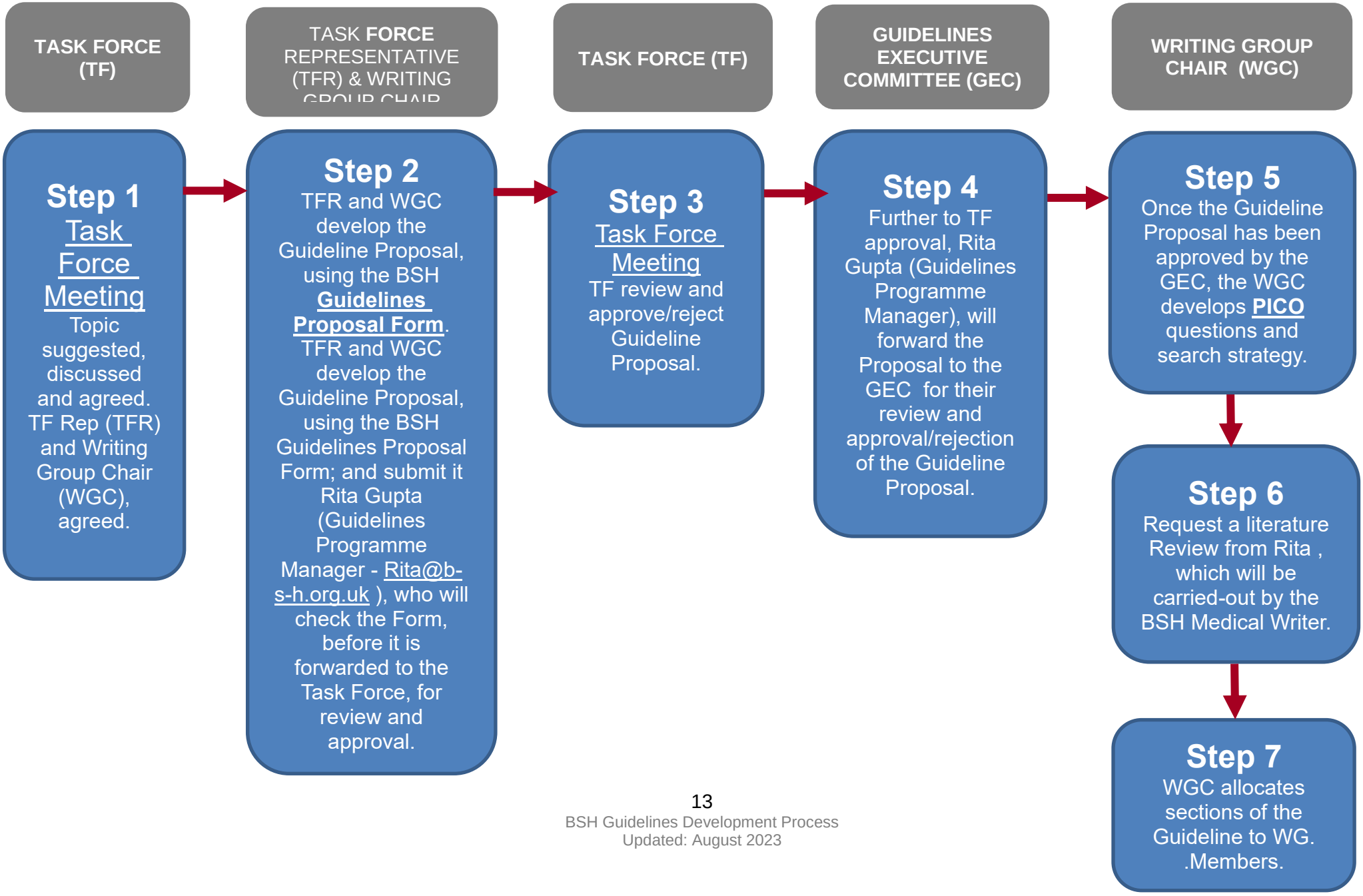
4.4 Grading the Evidence

All guidance must have clear recommendations with evidence-based grading, as briefly summarised in Appendix 3; and in the following 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 Guidelines – Proposal Approval Process



4.6 BSH Guideline Development Process

GUIDELINE RESEARCH, PREPARATION & DEVELOPMENT

Step 1
WG review literature.
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 2
WG complete the Declarations of Interest Form, on the BSH website. An email request will be sent by the Guidelines Team.

Step 3
WG to write recommendations and background evidence for Guideline.

Step 4
WG to GRADE all recommendations.

Step 5
WGC collates each section of the Guideline and prepares the 1st Draft for submission.

1ST DRAFT GUIDELINE

Step 6
WGC send the 1st Draft Guideline to the Guidelines Team (Guidelines.Officer@b-s-h.org.uk), who will forward it to TF for comments (usually, within 2 weeks).
Dependent on the TF, this process may be undertaken during a TF Meeting, where a 1St Draft review and comments would be undertaken Live. A WGC would be invited to discuss the 1st Draft with the TF.

Step 7
WGC reviews TF comments with the WG; and updates the 1ST Draft.

Step 8
WGC reviews TF comments with the WG; and updates the 1ST Draft.

Step 9
WGC sends the updated 1st Draft to the Guidelines Team (Guidelines.Officer@b-s-h.org.uk), who will forward it to the GEC for comments (usually, within 2 weeks).

Step 10
WGC reviews GEC comments with the WG; and prepares the 2nd Draft of the Guideline.

2nd DRAFT GUIDELINE

Step 11
WGC sends the 2nd Draft of the Guideline to Guideline sent to the Guidelines Team (Guidelines.Officer@b-s-h.org.uk), who will upload it to the BSH Sounding Board for comments (usually, within 3 weeks).

Step 12
WGC reviews Sounding Board comments with the WG; and prepares a Final Draft of the Guideline.

FINAL DRAFT GUIDELINE

Step 13
WGC sends the 2nd Draft of the Guideline to Guideline sent to the Guidelines Team (Guidelines.Officer@b-s-h.org.uk), who will forward it to the TF and GEC , for final review and approval.

Step 14
WGC requests Declaration of Interest Report from the Guidelines Team (Guidelines.Officer@b-s-h.org.uk), to assess any conflicts of interest.

PUBLICATION

Step 15
WGC submits the Final Draft of the Guideline to Wiley, for review, approval and publication. This process usually takes 2 months.

Step 16
Final Draft Guideline approved and published by Wiley; and published on the BSH website.

4.7 Timelines

The first draft of the guideline should be submitted to the Task Force within 12 months of the literature search being completed.

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

If the first draft Guidelines are not received by the Task Force, within 12 months, a new literature search will have to be undertaken. It is the responsibility of the 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.

4.8 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.

4.9 Audit Tool

Guidelines must always be accompanied by an Audit Tool, of which is completed by a Medical Writer. The Medical Writer 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.

4.10 Publication

The BSH aims to publish all guidance in a peer reviewed journal (usually in the British Journal of Haematology (BJH) or Wiley); thus, all guidance

should be of a standard and length that is acceptable for publication. Notice of publication will be sent by the Journal to the Writing Group Chair and they should inform the Writing Group Members, Task Force Representative and BSH Guidelines Team. The BSH Guidelines Team will then upload the Guideline to the BSH website.

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

5. Guideline Review & Maintenance

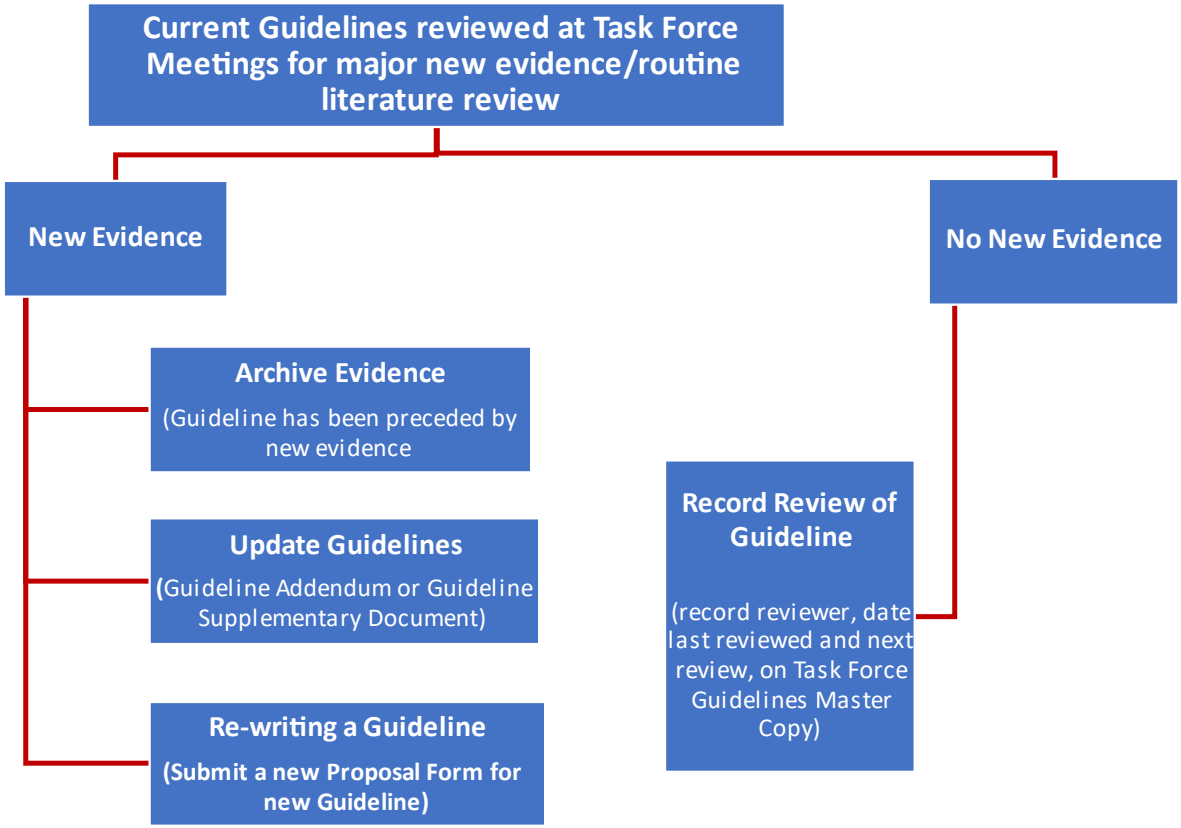
It is acknowledged that evidence for new important developments can appear at any time. At each Task Force meeting members should consider whether any current guideline needs an update. Every three years all BSH Guidelines must have the literature search re-run as a check for new evidence. If there is no substantial new evidence the guideline should be approved by the task force and the BSH administrator should note this on the website. If new evidence requires changes the options 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 Team (guidelines.officer@b-s-h.org), 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:



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. 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. 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. 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 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 Team (bshguidelines@b-s- h.org.uk) at the official address.

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

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).

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)

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	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.
Strength of Recommendation Strong (grade 1): Strong recommendations are made if clinicians are certain that	**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 in clinical decision making. When, across the range of patient values, fully informed patients are liable to make different choices, guideline panels should offer weak recommendations. Grade 2 recommendations require judicious application to individual patients and words such as “suggest” and “consider” are appropriate.