

**British Society for Haematology Guidelines Committee
BSH Guidelines Process 2016**

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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 guideline development 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 Committee and there was a revision of guideline processes.

All BSH guidelines commissioned after August 2016 should follow the revised processes as covered in this document. Issues that are not covered in this document should be brought to the attention of the Chair of the BSH Guidelines Committee.

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

1.2 BSH Guidelines Task Forces and Committee

There are four Task Forces, which cover the main areas of haematological practice; general haematology, haemostasis and thrombosis, blood transfusion and haemato- oncology. The membership of each Task Force is chosen for expertise, geographical spread across the UK and type of hospital the member works in, to provide a broad range of practice. Each Task Force reviews existing guidance produced by both BSH and other national and international professional groups to identify areas of need and, where appropriate, commission guidance on a specific subject.

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

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 23 criteria are summarised below:

Scope and Purpose

1. The overall objective(s) of the guideline should be described in detail and the expected health benefits from the guideline should be specific to the clinical problem.
2. A detailed description of the health questions covered by the guideline should be provided.
3. There should be a clear description of the target population to be covered by the guideline.

Stakeholder involvement

4. The guideline development group should include individuals from all the relevant professional groups.
5. The views and preferences of the target population (patients, public) should be sought.
6. The target users of the guideline are clearly defined.

Rigour of development

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

Clarity and Presentation

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

Applicability

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

Editorial independence

22. The views of the funding body have not influenced the content of the guideline.
23. Competing interests of guideline development members have been recorded and addressed.

2.2 BSH Guidance – Format

The BSH produces guidance in two distinct formats and also may formally endorse a non-UK guideline in a position paper as follows:

1. BSH Guideline (~5000 words) - Evidence-based guideline developed following a literature search and a systematic review of the evidence by the writing group. This is the formal “BSH Guideline”.
2. BSH Good Practice Paper (~2000 words) – used to recommend good practice in areas where there is a less robust evidence base but for which a degree of consensus or uniformity is likely to be beneficial to patient care. A preliminary literature search should be undertaken to confirm there is no high quality evidence.
3. BSH Position Paper (~1000 words) - adoption and adaptation of a non-UK evidence based guideline for use in the UK.

A Position Paper does not follow the formal development process for Guidelines and Good Practice Papers. The appropriate Task Force can decide to endorse a non-UK guideline rather than propose a BSH Guideline or Good Practice Paper. The Task Force will produce or commission the Position Paper and submit it to the BSH Guidelines Committee for approval. The Position Paper will then be placed on the BSH website in a separate section from the BSH Guidelines and Good Practice Papers.

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 and wider community. Anyone can suggest a topic via the BSH website and suggestions from the website will be passed to the relevant Task Force secretary. Joint guidelines can be written with other professional bodies, but will only be BSH guidelines if they comply with the process.

2.4 Determining the format and scope

The format of the guidance and scope will be determined by the relevant Task Force in conjunction with the proposed writing group members (see below for writing group composition).

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. If a guideline relevant to the UK is available this could either be signposted from the BSH Guidelines website or a BSH Position Paper could be produced to endorse it but with suggested variations for UK practice.

What type of guidance is appropriate?

A BSH Guideline with a literature search and a systematic review of the evidence or, if there is no high quality evidence, a BSH Good Practice Paper 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 of the Task Force to be responsible for ensuring that the BSH process is followed.

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

1. **P**atients or population to which the question applies - e.g. age range, gender, clinical description and co-morbidities
2. **I**ntervention (or diagnostic test, exposure, risk factor, etc.) being considered in relation to these patients
3. **C**omparison(s) to be made between those receiving the intervention and another group who do not receive the intervention
4. **O**utcome(s) to be used to establish the size of any effect caused by the intervention.

2.5 Proposal and Approval Process

A proposal for the guidance using the BSH Guidance Proposal Template available on the BSH guidelines as a word document must be completed in full by either the writing group chair or the Task Force representative and submitted for approval to the relevant Task Force. Only when the Task Force are happy with the proposal and recommend proceeding should it be forwarded to the BSH Guidelines committee for final approval. The writing group should not commence work until BSH Guidelines committee approval has been granted in case changes in the scope or changes in the writing group are requested.

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 in terms of different professions and disciplines. Involvement of a patient or a patient representative should be considered if appropriate. No writing group should be dominated by the views of any particular region or medical institution so there should be no more than two individuals from any institution. On occasions where the writing group Chair feels that this cannot be complied with the reasons must be documented in the Guidance Proposal, and discussed with the BSH Guidelines Committee.

Each writing group must include a member of the Task Force whose role is to ensure that the Guidance process is followed and the Guidance layout is consistent with BSH procedure. The BSH project manager and administrator will help support the Task Force member and writing group and will keep oversight of key milestones to help ensure completion within defined timelines.

3.2 Declarations of Interest

Declarations of Interest must be completed by all members of the writing group prior to commencing the writing of the guidance (appendix 2).

3.3 Training for writing group members

An eLearning module is available summarising BSH process for Task Force and writing

group members.

4. BSH guideline preparation

4.1 Developing a search strategy and literature review

BSH will fund information scientists to undertake literature searches for new guidelines. This should be done following advice from the writing group as to keywords, databases, time periods, exclusion and inclusion criteria etc. For good practice papers the authors must perform the literature search. The literature obtained should be discussed by the writing group and form the basis for making recommendations. The search strategy must be included in the methods section or as an appendix detailing

- 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.

It may be helpful to relate the output from the literature search to key structured questions identified within the scope.

4.2 Grading the evidence and formulating recommendations

All guidance must have clear recommendations with evidence based grading (GRADE) (<http://www.gradeworkinggroup.org/index.htm>) as briefly summarised in appendix 3.

It is the role of the writing group to weigh up and discuss the potential benefit and risk of a particular course of action versus not carrying out that action.

When a recommendation is made careful attention must be paid with regard to the use of wording; “recommend”, “offer” and “should” are appropriate for GRADE 1 recommendations, “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 institutions to assess the guidance produced and assess the risks of implementing or not in the context of their own priorities and populations.

4.3 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 Guideline 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.
- To return a completed Declaration of Interest form.
- To agree the parameters of the literature search and how the output will be presented to the writing group.
- To convene meetings of the Writing Group or agree on other means of communication either by tele or video conference.
- To delegate sections of the Guidance to Writing Group members.
- To ensure the initial draft is submitted within the agreed time scale to the Task Force.
- To ensure that relevant stakeholders review a draft of the Guidance e.g. professional bodies, patient groups
- To receive comments from the Task Force, Sounding Board and BSH members and modify the draft accordingly.
- 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 process.
- To report to the Task Force as to progress and to report any Task Force concerns back to the writing group members and chair.
- To submit the final draft Guidance to the Task Force Secretary.
- To produce the audit template.
- To produce the summary and key words for the website.

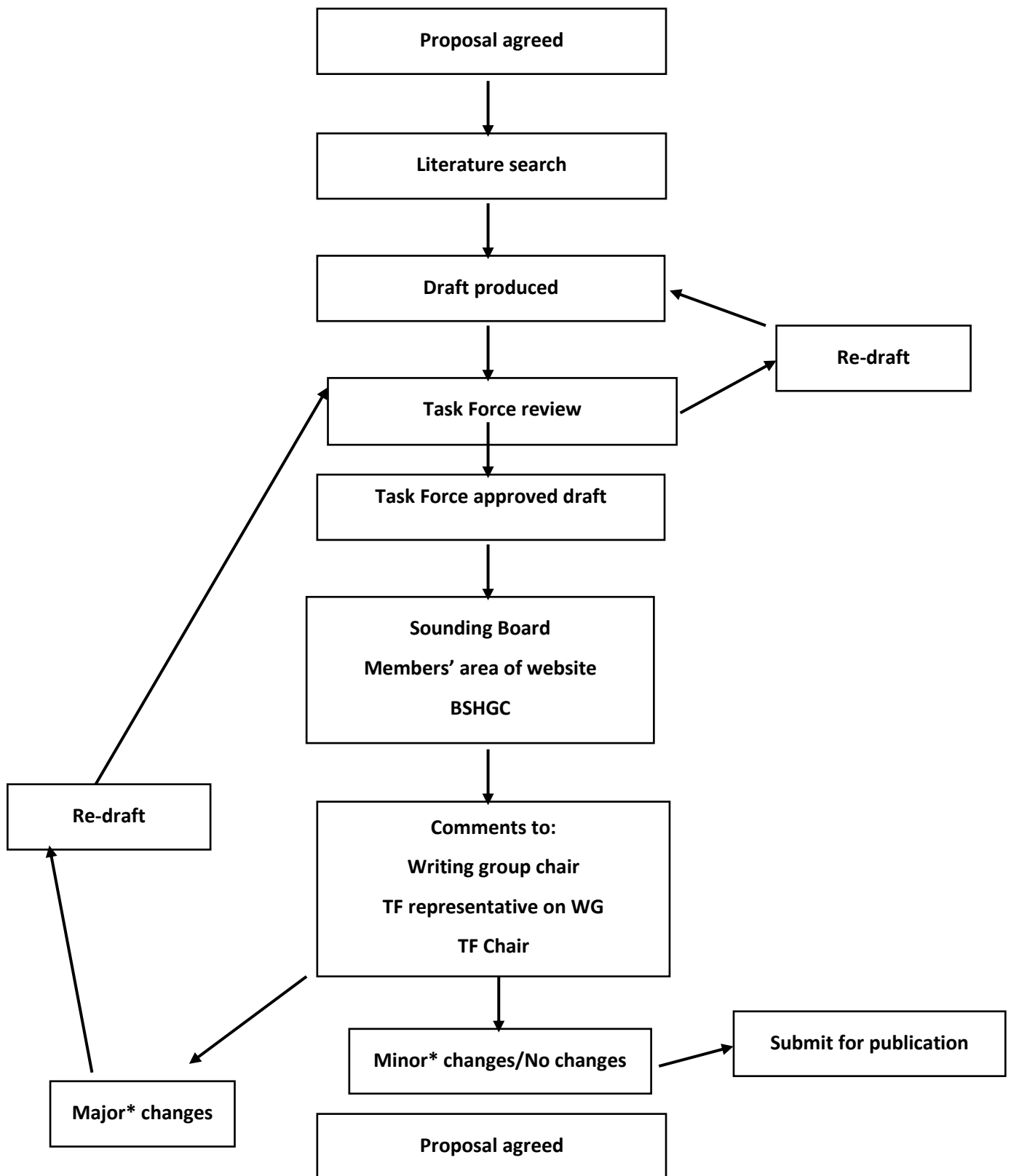
Writing Group Member:

- To return a Declaration of Interest form and complete the eLearning before starting work.
- To develop draft guidance as agreed with the Writing Group Chair.
- To formulate recommendations based on GRADE.
- To follow the BSH guideline process.
- To inform the writing group Chair if any new information makes the guidance obsolete or requiring alteration (see guidance maintenance).

4.4 Timelines

The guideline should be submitted for publication within 12 months of the literature search being completed.

4.5 Diagram of process to be followed



*Major v Minor changes at discretion of TF Chair

4.6 Style templates

Style templates for BSH Guidelines and Good Practice Papers are available on the BSH guidelines website as word documents.

4.7 Audit Tool

Guidelines must always be accompanied by an audit tool, a template for which is available on the BSH guidelines website as a word document. This should 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 audit tool can be submitted for publication as an appendix. The final draft of the guidance document must be submitted with an audit tool or it will not be reviewed by the Task Force or sent out to the sounding board. The final audit tool will be uploaded to the RCPATH website and will also be accessible from the BSH website

4.8 Publication

The BSH aims to publish all guidance in a peer reviewed journal (usually in the British Journal of Haematology (BJH) or an alternative Wiley journal) and, therefore, all guidance should be of a standard and length that is acceptable for publication.

5. Guideline 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 new evidence requires changes the options are:

Archive Guidance: New evidence has become available requiring major changes or making a recommendation incorrect. The current guidance will be archived immediately and this will be communicated to the BSH administrator. The Task Force will review whether new guidance should be commissioned or can be updated.

Update the guideline page on the BSH guideline website: If there is additional information but not of a degree to require archiving of the guideline then this can be indicated on the BSH Guideline website. It is not necessary to submit an addendum for publication, although this can also be done if preferred (e.g. as a letter to BJH).

British Society for Haematology Guidelines Committee

Terms of Reference

1. The Guidelines 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 Committee.
2. The Officers responsible for the administration of the Guidelines Committee will be a Chair and a Vice Chair, who will be appointed by the Trustee Board. The Chair of the Guidelines 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 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 Committee is responsible for the efficient running of the Guidelines 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 Committee as agreed by the Trustee Board.
 - To chair the Guidelines 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 Committee activities
 - To compile the agenda and minutes of the Guidelines Committee meetings in liaison with BSH administrator
3. The Guidelines Committee Vice Chair's role is:
 - To act as deputy for 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 Project Manager.
 4. In addition to the Chair and Vice-Chair, the Guidelines Committee shall consist of the Chair of each Task Force (for whom the Task Force Secretary may deputise) and a Trustee.
 5. The Guidelines Committee will establish, with the approval of the Trustee Board, expert Task Forces of no more than eight members. These Task Force members must be members of BSH. The Task Forces may also co-opt representatives from other organisations to be members of the Task Force, 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, and Haemostasis and Thrombosis. Each Task Force

will have a Chair and Secretary.

- 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 Committee. The post shall be for a term of two years and is renewable once.
 - B) The Secretary 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 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 Secretary 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, Secretary 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, 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 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.
6. The Task Force Chairs will set strategies for their Task Force and establish writing groups and monitor their performance.
8. The office address of the Guidelines Committee shall be the address of BSH or such other address as stipulated by the Trustee Board.
9. Publication by Task Forces must be approved by the Guidelines Committee. When it is appropriate the document may show the societies and organisations endorsing it. Correspondence should be addressed to the administrator (bshguidelines@b-s-h.org.uk) at the official address.
10. Members of Task Forces and the Guidelines 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.

Appendix 2

DECLARATION OF INTERESTS POLICY

The British Society for Haematology Guidelines Committee (BSHGC) requires a declaration of interest (DOI) statement from the following individuals:

BSHGC Executive Members – annually

BSHGC Task Force Members – annually

Writing Group Members – each time they are on a writing group

These are reviewed by the Task Force and the BSHGC Chair.

The declarations from the members of a writing group must be outlined in the published guideline and a broad outline of each individual DOI will be circulated to the members of the writing group 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, medical and laboratory equipment.

Personal Interests

A personal interest involves payment to the member personally. The main examples are:

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) and 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) **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:

- A) 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.
- B) 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.
- C) 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	<ul style="list-style-type: none"> • 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 <p>*Each quality criteria can reduce the quality by one or, if very serious, by two levels</p>
Increase grade if	<ul style="list-style-type: none"> • 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:

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 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.