BSG Guideline and Guidance Development, Writing and Review Process

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Contents

Introduction

The Clinical Services committee (formerly CSSC) of the British Society of Gastroenterology (BSG) commissions guidelines on the management of a full range of gastrointestinal and liver disorders, in order to promote and improve the standard of practice of clinical gastroenterology.

NICE has ceased the accreditation of guidelines produced by the BSG and are in the process of deciding how they will interact with guidelines on the future. The Clinical Services committee intends that BSG guidelines will continue to meet the previously designated NICE standards. This document is intended as a guide to aid in the preparation of these guidelines.

The Clinical Services committee also commissions BSG Endorsed Guidance documents which are similar to full guidelines in some respects but are shorter in length and differ from full Guidelines in other respects as explained later in this document in Section I. The main part of this document relates to full guidelines only and section I specifies where guidance development differs from this. The term 'Position Statement', however, is no longer welcomed by either Gut or Frontline Gastroenterology journals as it implies opinion-based statements with limited supporting published peer reviewed evidence.

A. Commissioning

Most guidelines are commissioned by the Clinical Services committee or section committees. The BSG Council also sometimes suggest topics for BSG guidelines and invite the membership to suggest topics which would then be reviewed by the relevant section for a decision on commissioning.

Guidelines are usually commissioned because of a perceived need for greater clarity and consensus in the recommended management of a given condition. This need usually arises when there have been important recent advances in understanding and treatment, which should lead to improved patient outcomes but have not yet been incorporated into routine clinical practice.

BSG Guidelines should make an important and "state of the art" contribution to the published literature applicable both to UK, but increasingly importantly to an international audience. There may be circumstances, for example the recent appearance of guidelines on an identical topic from NICE or international specialist organisations that would make development of a BSG guideline on the same topic a duplication. In these circumstances, BSG Section Leads can request that Guidelines from other specialist bodies can be reviewed and the endorsed by the BSG (see "BSG endorsement of guidelines produced by other organisations" document). These BSG Endorsed Guidelines can be uploaded onto BSG Guidelines webpages with specific references given to the publishing Journal.

B. The Guideline Development Group (GDG) and Initial Submission

1. GDG Constitution

- Guidelines need to be the product of a specifically convened Guideline Development Group (GDG), which is composed of seven to twelve individuals who are recognised authorities in the field in addition to 2 GDG patient representatives. The maximum size of the GDG is 20, in the absence of exceptional circumstances (which would be judged by the guideline lead and Clinical Services committee chair). Self-elected single authors are not acceptable. The formulation of guidelines will be driven by the GDG which will include a writing group (typically at least four main authors) and others representing a range of relevant expertise, two patient representatives as well as clinicians whose everyday practice will be directed by the guidelines. The GDG should thus be multidisciplinary and should include a range of professionals who will be using the guideline in their day-to-day clinical practice. All members of the GDG should be listed as co-authors including the patient representatives.
- The guideline development group should aim to achieve balance in sex and diversity, and should seek to include representation from all four nations, as well as a trainee representative.
- A GDG Chairperson should be designated by the GDG. The Chairperson should also be one of the main authors and the majority of members of the GDG should be chosen by the relevant BSG section committee on the basis of having the relevant expertise. Further GDG members can then be invited according to the requirements of the Guideline topic and further interested applicants can be invited via an open call (via the BSG website) by submission of a CV. The final membership of the GDG must be approved by the Clinical Services committee Executive.
- GDG members are unpaid volunteers although reasonable travel expenses are anticipated from the GDG budget
- The BSG wishes to work in a collaborative and professional way and as such reserve the right to exclude people from roles within GDGs where there has been a failure to work in line with BSG process guidance or in a collaborative or responsive manner.

2. Patient Representation

- The BSG are committed to ensuring meaningful patient involvement in guideline development. The GDG should include 2 patient representatives, and they should play a full part in the clinical guidelines development process. Involvement will be influenced by guideline specific objectives, but could encompass three recognised strategies: *consultation* (collecting views on individual's needs, experiences and identification of topics that appear most important for the public), *participation* (direct involvement in GDG discussions), and *communication* (disseminating accessible guideline content to patients and the public). Although current evidence shows no standard approach to patient and public involvement (PPI) in guideline development, the BSG encourages engagement at all stages. This includes question identification, evidence review, draft guideline review, and patient summary development. The GDG should recognise that some clinical content and technical aspects of guideline development may be challenging for patient representatives and should provide additional support or preparation to enable meaningful participation. Patient input is most valuable in areas where their lived

experience provides unique expertise, such as the practical significance, acceptability, and implementation of evidence-based recommendations. Focusing on these areas could provide more meaningful contribution, rather than necessitating involvement in some of the complex clinical or methodological discussions.

- For some conditions there are well represented national patient organisations and it is recommended that these organisations be asked to nominate one or both patient representatives on the GDG. For clinical conditions where no such organisation may exist, other strategies to ensure patient and carer involvement would include:
  - Medical members of the GDG approaching individual patients under their care
  - An umbrella patient organisation such as the British Liver Trust or the Royal College of Physicians' Patient and Carer Network (PCN) approaching patients or carers with the condition
  - Advertising the position
- Patients / Carers views and preferences should be fully considered and incorporated into the guideline). Patient or carer members of GDGs will receive the same material support as do other members and will have technical language explained to them by other members of the GDG if necessary. They should be included in the authorship list and their contribution to the overall Guidelines process should be listed. In addition they should be particularly involved in writing the Patient Summary section to ensure accessibility to the lay person.

3. Conflict of Interests (see Appendix 1)

- All members of the GDG and any ad hoc groups or individuals having direct input into the guideline (including reviewers assigned by the BSG- see Section F2) must complete a Declaration of Conflict of Interests (COI) form (Appendix 1) before becoming involved in the process and provide an updated form should there be any change in circumstances during the guideline writing process.
- COIs must be declared in the final publication (this could be as supplementary material).
- The Chair must not have any direct COIs.
- Where an individual is felt to have a possible COI with a particular section of the guideline, the individual may continue to be involved in the overall process, but either withdraw their involvement from that area or be involved in discussions, but not in the recommendations or voting in that area. In some cases, a COI may preclude an individual's membership of the GDG. Decisions in regard to these issues will be made by the Chair of the GDG in consultation with the head of the relevant BSG Section and with the Clinical Services committee Executive.
- All such decisions should be documented and available for external review.
- An 'interest' is defined as any arrangement in the past 12 months, which constitutes a current significant benefit to the individual, partner of that individual or their immediate family. It includes: financial and non-financial benefits. See appendix 1 for full definition of conflict of interests defined by NICE.

4. The Submission Template (see Appendix 2)

An initial proposal should be submitted by the GDG Chairperson on the Submission Template available on the BSG website and submitted to the Guidelines Lead (cc the Clinical Services Support Officer), for consideration in consultation with the relevant

specialist section. The proposal should include:

- The overall objective of the guideline: this usually describes optimal management of specific gastrointestinal and liver conditions. The scope may include all or most aspects of the management of a specific condition e.g. IBD in adults, or it may focus on a specific management strategy e.g. liver transplantation or endoscopy, applied to one or more conditions.
- The target population of patients: this will usually be all patients with the condition in question or all patients undergoing the management strategy in question. Sometimes only specific age ranges, for example over 18 years, are included. Special patient groups, for example ethnic minorities, can be highlighted if appropriate.
- The target users: the guidelines are intended primarily to aid clinicians and so the target audience should include all healthcare professionals who contribute to clinical management of the condition. Some of these will be based in the primary care sector and therefore from the outset consideration should be given to which aspects of management can be primary care-based.
- The main clinical questions to be addressed.
- A stated adherence to the AGREE II criteria (see BSG website) is necessary for guideline development.
- All guidelines to have an agreed timeframe for completion, aiming for 18 months, with a view to setting up GDG meetings up to a year in advance with support from Clinical Services Support Officer.
- The proposal form needs to be submitted simultaneously with all COIs prior to review for approval.

5. Financial Support

Complete financial transparency is needed in the financial support of BSG Clinical Guidelines development process as well as of individual members of the GDG. All guidelines are BSG funded with no commercial funding. The scope of BSG funding relates to items such as organising meetings, booking video-conference facilities or meeting, essential refreshments, travel reimbursements, BSG recommended training for GDG members (please contact Clinical Services Support Officer if you require training for GDG members).

It should be clearly stated in all BSG Guidelines that there is no external funding in the development of guidelines. All funding of the process should be declared in the published work. This can require a considerable volume of time and work and in some circumstance requires external professional support. Prospective application can be made to the BSG to fund professional literature searches and agreement is needed prior to embarking on any financial commitments. In some cases, the Clinical Services executive may require the literature research to be undertake professionally. The BSG will also consider funding of training of members of the GDG in AGREE II methodology.

It should be borne in mind that Gut and Frontline Gastroenterology favour manuscripts of 150 - 200 references and that consideration should be given to limit the scope of the Guidelines when larger quantities of references are available in the published literature.

C. Non-Commissioned Guidelines

- Individuals who have a particular interest in a topic may also submit a proposal for a guideline on the Submission Template (Appendix 2) to the appropriate BSG section and the Clinical Services Guidelines Lead. These are termed non-commissioned guidelines.
- Criteria for approval will include a decision from the relevant BSG section that the guideline would make an essential contribution to the published literature not provided by other specialist organisations. As for commissioned guidelines (Section A) there may be circumstances which would make development of a BSG guideline a duplication and BSG Endorsement should be sought as the appropriate alternative
- The GDG Chairperson as lead author will usually be one of the individuals who proposed the guideline. The Chairperson must be approved by the relevant BSG section that, with the Clinical Services committee, may make proposals for membership of the GDG. The GDG may then choose other members of the GDG but the final membership must be approved by the Clinical Services Executive.
- Points 2 to 4 in Section B also apply to non-commissioned guidelines.

D. Development of Guidelines

1. AGREE II

Guidelines should be developed in accordance with the principles laid down by the AGREE II instrument (on the BSG website). A more detailed account of the several stages of guideline development can be found on the NICE website.

2. Stakeholder Views

- Guideline development must take account of all relevant stakeholder views and preferences including professional groups, patients and carers. The GDG should conduct a consultation exercise and prior to its first meeting should share the draft proposal with:
  - Relevant professional organisations (for example, Royal College of Nursing, British Association for Study of the Liver, Association of Coloproctologists Great Britain & Ireland or Association of Upper Gastrointestinal Surgeons, Primary Care Society for Gastroenterology) who might influence or be influenced by the guideline.
- The organisations and charities that represent and/or support patients and carers, asking them which issues they think the guideline should address. This can be done directly or via the BSG. All replies must be thoroughly considered by the GDG and incorporated into the initial guideline proposal when appropriate. The Submission Template should then be re-submitted to the Clinical Services Support Officer and Guidelines Lead and should include:
  - The final GDG member list with signed COI forms (Appendix 1).
  - The proposal modified and developed in the light of consultations with stakeholders and members of the GDG. Final approval by the Clinical Services may be dependent on modifications to the proposal.

3. Clinical Questions

- The GDG will develop the specific clinical questions to be addressed. These should be directed at specific questions relevant to optimal management of the condition in question. They should be set in the context of other recently published guidelines and

where specific areas can be adequately covered by reference to these published guidelines, they may not need to be re-addressed in detail.

- The clinical questions are usually best grouped into clinical sections. A useful and suggested process is the PICO (Patients, Interventions, Controls and Outcomes) system, in which these four critical components are pre-defined as precisely as possible. The largest section will usually relate directly to management and may be divided into sub groups (for example, first line and second-line treatments, management of acute and chronic disease, management of specific complications, specific drug treatments). Additional sections on epidemiology, clinical manifestations, diagnosis, health economics and health service organisation are encouraged. Usually, separate members of the GDG writing group are assigned responsibility for leading on the development of each section.

4. Evidence Search

- For each clinical section, there should be a systematic, comprehensive, transparent and reproducible strategy to search for evidence on which management recommendations will be based. The overall search strategy should be decided by the GDG as a whole and described in adequate detail, if necessary, in an appendix, including:
  - Electronic databases consulted (such as Ovid, Medline, Embase and US National Guideline Clearinghouse).
  - Time period covered and an indication of the reasons why, if this is limited (e.g. if an update on a previous guideline).
  - Search terms used: these should be key words derived from the clinical questions set by the GDG. Other sources of evidence may include hand-searching journals, viewing of references cited in relevant original papers, reviews and other guidelines. Most GDG members will be expected to have expertise in at least some aspects of the condition and so, will already be familiar with some of the published literature. Publications dealing with patient experience of the disease and their treatment preferences should be actively searched for.
  - Whether and under what circumstances conference abstracts can be used to help formulate recommendations.
- The GDG Chairperson is responsible for ensuring that all GDG members have adequate electronic access to relevant publications (via NHS Evidence, University sites, or other means).
- Libraries generated by keyword searches should be stored (e.g. in EndNote) to allow excluded references to be traced. One way to store references is to save a search by creating an account on PubMed and supplying a link for the search. Storage is essential because a transparent pathway from evidence searching to inclusion/exclusion is vital.
- A decision to include or exclude peer reviewed published studies identified by the search must be made. Initially, this is done on the basis of relevance to the clinical questions as suggested by the title and in cases of doubt by the abstract. When selecting and evaluating evidence the four PICO components should be borne in mind. Further consideration regarding inclusion or exclusion is based on assessment of methodological quality (based on the full publication).
- It may be necessary to include studies of suboptimal quality if they constitute the best available evidence to inform some clinical questions. Flaws and limitations need to be highlighted.

- When published evidence on a specific point is unavailable or incomplete, statements based on clinical experience and patient views may be incorporated. Areas of uncertainty should be acknowledged.
- Shortly before the guideline is finalised the search should repeated and any important studies published since the initial evidence search should be incorporated into the guideline.

5. Summary of Studies and Grading of Evidence

- The evidence for each clinical question, from all relevant individual studies, should be systematically reviewed and summarised. It is useful to categorise references as systemic reviews, randomised controlled trials, cohort studies, case-control studies and other studies.
- NICE and the Clinical Services now recommend https://www.gradeworkinggroup.org/.
- The strength and limitations of the body of evidence should be clearly described. There should be discussion of the risk of bias: consistency or disparity of evidence; applicability and relevance of study endpoints; the magnitude of the effect and any dose-response relationships.
- Construction of tables based on the PICO system is encouraged, incorporating the end points of several similar studies. If extensive, these tables may be incorporated into an appendix. The guideline should refer to any published work on relevant patient experiences.

6. Formulation of Recommendations

a) Recommendations should be specific to the topic and unambiguous. In general, they should allow for the flexibility of clinical decisions in the particular circumstances of an individual patient. They may be applicable to the whole of the topic in question or sometimes only to specific clinical healthcare or social circumstances, which should be stated explicitly.

b) Recommendations on specific clinical questions are drafted by the section leads. These should arise from and be explicitly linked to the corresponding evidence summary. The GDG as a whole must then discuss all recommendations in detail including their potential health benefits, side effects and risks. The strategy used by the GDG to arrive at decisions in regard to formulating the recommendations should be described either in the text or in an appendix.

c) Different grades of evidence may be available in response to different clinical questions. If the evidence is not conclusive, discussion with a view to reaching an informal consensus amongst the GDG should be tried. If this is not achievable, formal consensus techniques, such as Delphi may be useful. When disagreement persists, the GDG Chair should decide whether to seek resolution via (a) a formal voting system or (b) survey of relevant stakeholders. The GDG should categorise their recommendations into “strong” or “weak” as per the GRADE system. Where the GDG’s decision on the strength of the recommendation is unanimous and the recommendation is strong, then the wording ‘we recommend’ should be used. Where the decision is majority and the recommendation weak, the wording ‘we suggest’ should be used.

d) Strength of recommendation is different from and not automatically dictated by grade of evidence. Something which has only low quality or very low-quality evidence base might

be a “Strong” recommendation if it is clinically important and universally agreed by the GDG (for example timely referral for transplantation).

e) More than one management option may be recommended if the evidence suggests that these are of similar efficacy. In this case clinicians and patients' views might influence which option is recommended and further consultation with patient groups may be appropriate. GDGs are asked to document examples where patients’ views have directly influenced the final guideline. Alternatively, different options might be recommended as equally justifiable. If so, this must be clearly stated.

f) The GDG should consider which aspects of management can appropriately be performed by a range of healthcare professionals (e.g. nurses, specialist workers) in different healthcare settings (e.g. primary care). If possible, the GDG's conclusions should be incorporated into the recommendations.

7. Equality, Diversity and Inclusion

The recommendations should take into account the BSG’s Equality, Diversity and Inclusion policy, and ensure that no individual or group with a protected characteristic is negatively impacted.

8. Climate Change and Sustainability

The GDG should be aware of the BSG’s Climate Change and Sustainability strategy. Guideline recommendations should be assessed for their impact on climate change and incorporate sustainability strategies where appropriate.

9. Implementation of Guidelines

Where possible, tools to support implementation of the guideline should be included, if necessary, in an appendix. Examples of these might include; screening, diagnostic and management algorithms, and checklists, care bundles and key performance indicators.

10. Cost and Service Implications

The cost and service implications of implementing the guideline and the potential facilitators and organisational barriers to doing so should be considered. A full economic analysis is not expected but consideration should be given to the cost effectiveness of the recommendations, e.g. a particular intervention may require initial investment in staff or equipment but would result in healthcare benefits, thereby saving resources in the long term.

11. Assessment of Implementation

Guidelines should include a statement as to how the implementation of the guideline will be assessed. Specific criteria such as key performance indicators which can be audited or included in a quality improvement (QI) project should be specified and where possible, evidence-based and measurable standards of care should also be specified. In addition, QI/ audit and monitoring tools such as questionnaires or a request for feedback via an online survey, or via the BSG website should be included.

12. Patient Summary

A patient summary should be included which is expressed in non-technical terms to assist patients in understanding best clinical practice. This should be led by the patient representatives on the GDG with the support of the main authors. Where it would be helpful,

consultation with specialist patient groups can be utilised to obtain good uptake at a patient level.

13. Research Recommendations

A list of research recommendations should be included to resolve persisting uncertainties in regard to clinical questions.

14. Disclaimer

The Guideline must include the disclaimer below:

BSG guidelines (or guidance) represent a consensus of best practice based on the available evidence at the time of preparation. They may not apply in all situations and should be interpreted in the light of specific clinical situations and resource availability. Further controlled clinical studies may be needed to clarify aspects of these statements, and revision may be necessary as new data appear. Clinical consideration may justify a course of action at variance to these recommendations, but we suggest that reasons for this are documented in the medical record. BSG guidelines are intended to be an educational device to provide information that may assist in providing care to patients. They are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment.

E. Format of Guidelines

- Guidelines aimed at publication in 'Gut' will be up to 15,000 words in length and well referenced (usually 100-200 references in addition to the 15,000 word limit). Tables are encouraged (also in addition to the 15,000 words limit). The limit may exclude other additional data which may be submitted as a supplementary file, to be available online only.
- Guidelines should be written in a clear concise style with minimal repetition. They should be understandable by all healthcare professionals caring for the disease in question and also by informed patient representatives.
- The format of the guideline may be varied according to subject matter but should be based on the following outline structure:
  - Title.
  - Acknowledgments.
  - GDG: list of members, qualifications and currently held positions. The members assigned to lead on each clinical section should be highlighted.
  - Abstract.
  - Executive Summary: to include a concise summary of the recommendations of the guideline, its purpose, the patient group, the target users and any special features
  - Patient summary: this should be included where relevant to the guideline. It should inform patients of best practice in non-technical language as far as is possible.
  - Date of previous guideline and time period covered by previous literature search (if an update).
  - Background: why the guideline is necessary, how it arose, particular issues surrounding

the condition or its treatment.

- Objective: the objective of the guideline should be summarised in one sentence.
- Development process for the guideline: discussion of methodology with reference to search strategy and search terms used for evidence gathering, the criteria by which evidence was included/ excluded and the grading of evidence and recommendations. (See Section D).
- Evidence summary: divided into sections, for example epidemiology, prevention, clinical presentation, diagnosis, management (maybe several subsections here), and service organisation.
- Recommendations should be stated in bold. In the main text, they should also be divided into sections, with each recommendation close to and linked to the corresponding evidence summary. Management algorithms should be included when possible. In an additional duplicate one-page summary of the main points, the grade of evidence and strength of recommendation should be included (Section D6).
- Care bundles: these should be incorporated where applicable to the management of conditions to attempt to standardise best practice/ allow auditing/ QI projects.
- Key performance indicators- these should be incorporated where possible to allow for analysis/audit of standards and form the basis of QI projects.
- Cost-benefit analysis: This type of analysis is very useful for commissioners in considering new developments. In depth analysis can be complex but any level of cost-benefit analysis is encouraged (although not mandatory).
- Implications for the service organization; training and the desirability of implementation in specific settings.
- Research recommendations. Any declared conflicts of interests (see Appendix 1).
- References – numbered list, Vancouver style, comprehensive: 1-200.
- Planned review date.
- Appendices – should contain the final Submission Template (Appendix 2) and the grading system as well as tools for implementing the guideline, for example, algorithms, diagnostic tools, rating scales, screening tools etc.

F. Review of Guidelines prior to Publication

- The completed draft guideline should initially be forwarded to the relevant section chair for endorsement.
- The section-endorsed draft guideline, together with the COI forms), should be submitted to the Clinical Services Support Officer and the Guidelines Lead, who will circulate the document to the Clinical Services committee members, with feedback by a minimum of 3 reviewers. All reviewers providing feedback will need to declare any direct conflict of interest. The turnaround time should be three weeks.
- Feedback from the Clinical Services committee review is summarised by the Clinical Services Support Officer and reviewed by the Guidelines Lead. Anonymised feedback is then forwarded to the GDG Chair and Lead Author.
- The Lead Author returns appropriately amended manuscript to the BSG Guidelines Lead who checks that the suggested changes have been made. Amendments usually relate to clarity and emphasis rather than to content. When there is explicit disagreement in regard

to content, the peer reviewers' views might not be taken on board if, in the opinion of the GDG, they are not supported by the evidence. In rare situations of unresolved disagreement, it would be possible to seek opinions from further peer reviewers.

- Once the Guideline has been formally endorsed by the Guideline Lead on behalf of Clinical Services, the manuscript is returned to lead author to be considered for publication, either to submit to 'Gut', Frontline Gastroenterology, BMJ Open Gastroenterology. The BSG have an agreement with the BMJ journal group that our guidelines will be published, at the discretion of the Editor in Chief, as open access and all guidelines/guidance should be initially submitted for publication in a society affiliated journal.
- All associated papers that stem from the process of BSG guideline development must be reviewed and approved by the Guidelines Lead and Clinical Services Chair and submitted in the first instance to a partner BMJ journal (https://journals.bmj.com/our-journals/).
- It should be noted that there is no guarantee of publication by Gut (or other BMJ journal), and BSG Guidelines are subject to the same review process as other manuscripts submitted. This requires international review and subsequent adjustments of manuscripts by the senior authors which meet the requirements of the Gut reviewers before publication is agreed; the Editor in Chief of 'Gut' reserves the right to refuse publication. The current system allows for 5 – 6 BSG Guidelines to be published in Gut per year with the majority of these afforded open access status at the discretion of the Editor in Chief.
- Frontline Gastroenterology is the BSG Journal for Clinical Practice and has a wide UK readership. Clinically focused, concise papers that will directly improve clinical practice are welcome by the Frontline Editorial team. Manuscripts are subject to peer review and the Editor is keen to discuss potential options for papers where appropriate and the Editor is keen to support BSG endorsed publications. There has been an agreement recently that 5 -6 BSG Endorsed publications can be given open access status in FG.
- Joint publications in separate journals is increasingly difficult to co-ordinate due to specific Impact Factors issues which are now carefully monitored at an international level. When developing joint guidelines with other organisations, please discuss publication strategies with the Guidelines Lead at the earliest opportunity.

G. Promoting the Guidelines

- The GDG lead should inform the BSG prior to the publication of the guideline/ guidance so that it can be promoted in a timely manner.
- Once published, guidelines are uploaded on the BSG website, which is accessible to the public. If publication of a guideline or guidance is not planned, it will be uploaded to the BSG website once endorsed by Clinical Services. Guidelines may also be promoted by video blogs.
- New or updated guidelines on major clinical topics may be highlighted at national meetings of the BSG and associated organisations (BASL, Pancreatic Society, AUGIS, BAPEN etc). The GDG should liaise with the BSG who can utilise regional BSG leads to promote new guidelines in their areas.
- Guidelines/guidance should not be presented prior to endorsement by the Clinical Services committee and the first presentation should be at a BSG meeting.
- Promotional communications package - to include; a launch statement prior to publication

for the BSG website, recorded presentations, recorded interviews, Podcasts or webinars, social media and BSG newsletter. To liaise with the Clinical Services Support Officer and BSG Comms team.

H. Reviewing and Updating the Guidelines

On an annual basis, the BSG Guidelines co-ordinator will contact the Guidelines Lead for each BSG section for an update of their current and proposed Guidelines. A detailed spreadsheet is kept to record publication dates, review dates and current progress on each Guideline. Where Guidelines require updating an agreed timeframe is recorded and progress monitored. Due to new developments in a particular field, some Guidelines will become obsolete and are then removed from the BSG Guidelines webpage and archived with the archived date inserted in place of the review date.

- The date of search, publication or last update and the proposed date for review must be clearly stated within the guideline.
- For existing guidelines the date of completion of the current guideline is clearly displayed on the BSG website; if not already explicitly stated the proposed date for updating the guideline / guidance, which will usually be every five years, will be determined by the GDG and stated on the website. Every two years the research objectives identified in the guidelines would be reviewed for evidence of additional studies, contributing to resolving the objective.
- A full review of a guideline after a fixed time period is not always appropriate as new evidence is published at different rates in different fields. At Section committee meetings the Guidelines Section Lead is responsible for monitoring the progress and status of guidelines and undertakes discussions with the representatives from the GDG. The following factors will influence the decision whether and how to review a guideline on an unscheduled basis:
    - Emergence of new evidence that will change former recommendations.
    - Identification of any error in the guidelines after publication.
    - Emergence of any evidence of inequality in access to services between different social groups that can be addressed through guideline recommendations.
    - Emergence of any new technology or drugs or legislation that will change former recommendations.
- As a first step, the section commissions the GDG on this topic, who will carry out an update search looking for new studies, evidence-based guidelines, Health Technology Assessments and systematic reviews produced since publication of the last version of a guideline. These searches are based on the key questions and search strategies used in the original guideline but also include an element of horizon scanning to see if there are new treatments or technologies that should be considered as part of the update.
- Results are presented in the form of summaries of the findings of the studies that have been identified. The search results are incorporated into a report that summarises the new evidence and looks at how it will impact on the recommendations made in the existing guideline. This report will also note any new areas or key questions that have emerged since the previous publication and will be submitted to the Guideline lead and

relevant section lead who will decide if the guideline as it stands will be revalidated or will undergo a complete or partial review or will be withdrawn and archived.

- For guidelines which were developed jointly with partner organisations (e.g. ESGE, HIS) a consultation with these organisations will take place and members from these organisations will be recruited to the working party to assess the need for review.
- The guidelines are available on the BSG website which is accessible to the public.
- Updates can be published in Gut as a letter but will be subject to the journal's peer review process. They will also be published on the BSG website as stated above. Prior to submission to Gut, updates will be submitted to the Guideline lead who will arrange a peer review by the Clinical Services. A summary of the updates in a "What's new" section is encouraged as BSG members are often aware of previous version of the BSG Guidelines which require an update in clinical practice.

I. Guidance Documents

The BSG (usually via the section committees but sometimes via the Clinical Services committee, Council or the Executive) also commissions guidance documents on specific topics. These are significant and influential documents and, whilst usually not as comprehensive as guidelines, they are expected to be developed with a similar degree of rigour. In particular they have the same requirements as guidelines in regard to declaration of COIs (see Section B3). However, guidance documents differ from guidelines in regard to the following points:

- They usually address a topic which is removed from the direct patient interface (examples include staffing of endoscopy units or endoscopy decontamination). For this reason, patient representation on the GDG is not mandatory, although it may sometimes be desirable.
- The composition of the GDG is more flexible than for guidelines; its membership is often self-selected, although with the approval of the relevant section committee at least one of whose members should be on the GDG. Whilst the Clinical Services would wish to be informed regarding the membership it is unlikely to be prescriptive in this regard.
- Although they are expected to be evidence based where possible and developed in a rigorous manner, they are not currently subject to NICE quality standards. Often there is relatively little high-quality evidence to inform the questions addressed, and so recommendations are often based mainly on the informed opinions of GDG members.
- Guidance documents are submitted to the Clinical Services committee for approval just like guidelines.

The process for publication and uploading to the BSG website is identical to that of a Guideline.

This document is reviewed annually. The next review date is August 2026.

APPENDIX 1 - Declaration of Conflicts of Interests

GUIDELINE DEVELOPMENT GROUP
To be completed at the beginning and end of the guideline development process (refer to BSG guidelines advice document)

Title of guideline:

Do you, your partner (if applicable) or any member of your immediate family have any commercial interest (including personal shares, sponsorship or paid consultancy work) in any companies that are, or could be, involved in the above named guideline?

Company	Nature or purpose of support	Period of support From To

Does your department or unit receive financial support from any commercial organisations that are, or could be, involved in the above named guideline?

Company	Nature or purpose of support	Period of support From To

Are you a consultant to or a member of any national body, charity or pressure group whose work is related to the above named guideline?

Name of Group	Nature or purpose of support	Period of support From To

Do you receive editorial fees for commissioned articles for publication (in any format) or are you paid for editorial work for any publication related to the above named guideline?
If yes, please give details:

Do you or your department hold a patent (existing or pending) related to the above named guideline? If yes, please give details:

Please Note: 'nil' returns are required. Please update if new COIs develop during the guideline writing process.

Name: _____ (Please print)

Role in guideline development: _____

Signature: _____ Date: _____

Personal financial interest (from NICE documents)
Any consultancy, directorship, position in or work (which is specific to the product or matter being discussed) in the commercial sector that attracts regular or occasional payments or benefits in kind such as hospitality.

- Clinicians receiving payment from the commercial sector for undertaking a procedure while giving advice on that procedure to NICE
- Any fee-paid work commissioned by the commercial sector for which the individual receives payment or financial benefit in kind
- Any shareholdings in the commercial sector held by the individual
- A financial interest in a company's product that is, or may become, a competitor to the product under consideration
- Expenses or hospitality provided by the commercial sector beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences as set out in the NICE Hospitality Policy and Travel and Subsistence Policy
- Funds which include investments in the commercial sector that are held in a portfolio where the individual has the ability to instruct the fund manager as to the composition of the fund

Non-personal financial interest
- A grant from a company for the running of a unit or department where the individual is employed
- A grant or fellowship or other payment to sponsor a post or member of staff in the unit where the individual is employed
- The commissioning of research or other work by, or advice from, staff who work in a unit where the individual is employed
- Contracts with, or grants from, NICE

Personal non-financial interest
A clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review.

- A published statement in which the individual has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence.
- Authoring or co-authoring a document submitted as an evidence publication to a NICE advisory committee
- Holding office in a professional organisation (any organisation engaged in the medical, public health or social care sectors including the medical, nursing and midwifery Royal Colleges, NHS organisations, and universities), charity or advocacy group with a direct interest in the matter under consideration.
- Other reputational risks in relation to a matter under review

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APPENDIX 2- Proposal for guideline/guidance - Submission Template

(Refer to BSG guidelines advice document)

1. **Lead author / applicant:**

Name	Qualifications	Position

2. **Contact details:**

Address	Telephone / Fax	Email

3. **Co-authors:**

Name	Qualifications	Position

4. **Title of guideline:** (a provisional title may be provided at this stage)

5. **Brief outline of the area the guideline will be covering:**

6. **Clearly state the overall objective of guideline:**

7. **Clearly state the clinical questions to be answered by the guideline and reason why the guideline is being produced:** (e.g., health benefits arising from the guideline, absence of previous guidelines on this area or previous guidelines out of date)

8. **Scope of guideline:**

Who are the target users?	Describe the patient group / target population covered by the guideline

9. **Guideline Development Group (GDG):**

Name of group member:	Representing (group / discipline):

10. **Time scale:**

Start date:	(Anticipated) Finish date:

11. **Editorial independence:** Commercial sponsorship of the GDG members of process is discouraged and usually not acceptable. Any conflicts of interest for members of the GDG must be listed.

12. **Guideline methodology:**

Details of systematic methods that will be used to search for evidence:	
Databases to be searched	
Principal search terms	

Describe the criteria that will be used for including/excluding evidence: e.g. critical appraisal – methods used, who will appraise the evidence, grading scheme used

Describe the methods that will be used to formulate recommendations: Recommendations should arise from and be explicitly linked to the corresponding evidence summary. If recommendations are based on expert opinion describe any formal consensus technique and specify methods for resolving areas of disagreement e.g. the GDG will meet and vote on strength of recommendations using AGREE II Instrument.

How will the cost implications and/or cost effectiveness of the advice be assessed?

Describe how patient /user views will be incorporated other than by inclusion on the GDG:

13. **Is financial assistance likely to be required for the literature review?**

14. **Please indicate if the guideline might have implications for pharmaceutical/device manufacturers**

15. **Review of guideline:**

What are the planned procedures for updating the guideline? (The schedule for review is usually 5 years but may be sooner for rapidly developing topics, e.g. which Specialist Section committee will review the guideline and when.)

16. **Which BSG section has commissioned this guideline?**

Please state which section(s) have commissioned this guideline or, further information if this has not taken place.

I confirm that I understand that:

- BSG guidelines development should not receive external funding
- This work should not be presented until BSG endorsement has been given
- This work should first be presented at a BSG meeting
- That any spin of work from the guideline development process needs to be approved by the Clinical Services committee
- That the guideline should be submitted initially to a BSG-affiliated journal.

I confirm I have attached COI forms for all members of the GDG with this form and the GDG will adhere to the current BSG guidance on guideline production and if new conflict of interests arise in any of the members involved in the guideline production, this will be communicated to the BSG.

GDG Lead signature……
Date…….

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APPENDIX 3- Executive summary

BSG Guideline and Guidance Development, Writing and Review Process

Executive summary

A. Commissioning

- Guidelines are commissioned because of a perceived need for greater clarity and consensus in the recommended management of a given condition.
- BSG Guidelines should make an important and "state of the art" contribution to the published literature applicable both to UK and an international audience.

B. The Guideline Development Group (GDG) and Initial Submission

- The maximum size of the GDG is 20, in the absence of exceptional circumstances.
- The GDG should be multidisciplinary and should include a range of professionals who will be using the guideline in their day-to-day clinical practice.
- All members of the GDG should be listed as co-authors including patient representatives.
- The GDG should be balanced in gender and diversity; it should include representation from all four nations, as well as a Trainee representative.
- The majority of members of the GDG should be chosen by the relevant BSG section committee on the basis of relevant expertise.
- The final membership of the GDG must be approved by the Clinical Services Executive.
- The GDG should include 2 patient representatives
- All members of the GDG and any ad hoc groups or individuals having direct input into the must complete a Declaration of Conflict of Interests (COI) form
- In some cases, a COI may preclude an individual's membership of the GDG.
- Where an individual is felt to have a possible COI with a particular section of the guideline, the individual may continue to be involved in the overall process but either withdraw their involvement from that area or be involved in discussions but not in the recommendations or voting in that area.
- The GDG chair must not have any direct COIs.
- An initial proposal should be drafted by the GDG Chairperson on the Submission Template available on the BSG website
- All guidelines are BSG funded with no external funding.
- All guidelines to have an agreed timeframe for completion, aiming for 18 months.

C. Non-Commissioned Guidelines

- Individuals who have a particular interest in a topic may also submit a proposal for a guideline

D. Development of Guidelines

- Guidelines should be developed in accordance with the principles laid down by the AGREE II instrument.
- Guideline development must take account of all relevant stakeholder views.
- The GDG will develop the specific clinical questions to be addressed.
- Libraries generated by keyword searches should be stored (e.g. in EndNote) to allow

excluded references to be traced.

- When selecting and evaluating evidence the four PICO components should be borne in mind.
- The evidence for each clinical question, from all relevant individual studies, should be systematically reviewed and summarised.
- The strength and limitations of the body of evidence should be clearly described.
- Construction of tables based on the PICO system is encouraged.
- Recommendations should be specific to the topic and unambiguous.
- The GDG should categorise their recommendations into “strong” or “weak” as per the GRADE system.
- The recommendations should take into account the BSG’s Equality, Diversity and Inclusion policy, and ensure that no individual or group with a protected characteristic is negatively impacted.
- The GDG should be aware of the BSG’s Climate Change and Sustainability strategy. Guideline recommendations should be assessed for their impact on climate change and incorporate sustainability strategies where appropriate.
- Where possible, tools to support implementation of the guideline should be included.
- The cost and service implications of implementing the guideline should be considered.
- Guidelines should include a statement as to how the implementation of the guideline will be assessed.
- A patient summary should be included which is expressed in non-technical terms to assist patients in understanding best clinical practice. This should be primarily written by the patient representatives.
- The BSG disclaimer must be present on the published document.

E. Format of Guidelines

- For publications aimed at Gut please see current submission requirements.15,000 words is the usual maximum with additional 100-200 references.
- Outline structure is title, acknowledgements, GDG, abstract, executive summary, patient summary, background, objective, evidence summary, recommendations, care bundles, KPIs, cost benefit analysis, service implications, research recommendations, conflict of interests, references and appendices.

F. Review of Guidelines prior to Publication

- The completed draft guideline should initially be forwarded to the relevant section chair for endorsement.
- The section-endorsed draft guideline, together with the COI forms), should be submitted to the Clinical Services Support Officer and the Guidelines Lead, who will circulate the document to the Clinical Services committee members, with feedback by a minimum of 3 reviewers. All reviewers providing feedback will need to declare any direct conflict of interest.
- The Lead Author returns appropriately amended manuscript to the BSG Guidelines lead who checks that the suggested changes have been made.
- Once the Guideline has been formally endorsed by the Guideline Lead on behalf of the Clinical Services committee, the manuscript is returned to lead author to be

considered for publication, either to submit to 'Gut', Frontline Gastroenterology, BMJ Open Gastroenterology

G. Promoting the Guidelines

- The GDG lead should inform the BSG prior to the publication of the guideline/guidance so that it can be promoted in a timely manner.
- Once published, guidelines are uploaded on the BSG website.
- Guidelines/guidance should not be presented prior to endorsement by the Clinical Services committee and the first presentation should be at a BSG meeting.

H. Reviewing and Updating the Guidelines

- The BSG Guidelines co-ordinator will contact the Guidelines lead for each BSG section annually for an update of their current and proposed Guidelines.
- Some Guidelines will become obsolete and then be removed from the BSG Guidelines webpage and archived with the archived date inserted in place of the review date.
- For existing guidelines the date of completion of the current guideline is clearly displayed on the BSG website with the proposed date for updating the guideline / guidance. Where this is absent the section leads will decide which guidelines have become obsolete.

I. Guidance Documents

- They usually address a topic which is removed from the direct patient interface (examples include staffing of endoscopy units or endoscopy decontamination). For this reason, patient representation on the GDG is not mandatory, although it may sometimes be desirable.
- The composition of the GDG is more flexible than for guidelines.
- Although they are expected to be evidence based where possible and developed in a rigorous manner, they are not currently subject to NICE quality standards.
- Guidance documents are submitted to the Clinical Services committee for approval just like guidelines.

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APPENDIX 4 - BSG Guidelines Development, Writing and Review Process Flowchart