British HIV Association (BHIVA) Guideline Development Manual

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The first British HIV Association (BHIVA) guideline development manual was prepared by members of the BHIVA Working Group for NHS Evidence Accreditation of BHIVA guidelines in 2007.

First edition 2007
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Updated August 2020 by Dr Nadi Gupta and Dr Clare van Halsema
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1. Introduction

1.1. Guidelines and the British HIV Association

The British HIV Association (BHIVA) was established in 1995 as a specialist society for clinicians caring for people living with HIV.

BHIVA has become the leading UK association representing professionals in HIV care. It is a well-established and highly respected organisation with national influence, committed to promoting excellence in the care of those living with and affected by HIV.

BHIVA acts as a national advisory body to professionals and organisations involved in all aspects of HIV care. BHIVA also provides a national platform and contributes representatives for international, national and local committees concerned with HIV care. In addition, BHIVA works to promote undergraduate, postgraduate and continuing medical education within this area.

The current membership of the Association comprises a wide range of healthcare professionals, academic researchers and community members.

BHIVA produced its first antiretroviral treatment guidelines in *The Lancet* in 1997 and an update to the guidelines was published in the same journal the following year (see Appendix 1). The journal *HIV Medicine* was founded by the Association in 1999 and the majority of BHIVA guidelines have been published in *HIV Medicine* since that time (see Appendix 1). This journal is distributed to all BHIVA members and is incorporated into their subscription to the Association.

The BHIVA Guidelines Subcommittee is one of five subcommittees reporting to the BHIVA Executive Committee, the others being the Audit and Standards Subcommittee, the Conferences Subcommittee, the Education and Scientific Subcommittee and the External Relations Subcommittee. The general purpose of the BHIVA Guidelines Subcommittee is to set standards for evidence-based, good clinical practice relating to various aspects of the treatment and care of people living with HIV. Guidelines are updated at appropriate time intervals to reflect the latest findings and are subject to scrutiny through a consultative process. The terms of reference of the Subcommittee are determined by the BHIVA Executive Committee and can be found on the BHIVA website.

The BHIVA Guidelines Subcommittee is formed primarily from nationally elected members of BHIVA who are elected to serve as Trustees on the BHIVA Executive Committee for 3-year terms by the members of the Association. The Trustees are representative of members working across the UK. Members of the Executive Committee then choose to serve on at least one BHIVA subcommittee on an annual basis. Community representatives are nominated by the UK Community Advisory Board (UK-CAB)* and there are two representatives as members of the Guidelines Subcommittee. Additional members are then appointed onto the Subcommittee in order to enhance any specific areas of expertise in accordance with the rules of the Association.

*The UK-CAB is a network for community HIV treatment advocates across the UK: www.ukcab.net.

The structure of the BHIVA Executive Committee ensures good communication between the BHIVA Guidelines Subcommittee and other relevant subcommittees. Close links with the BHIVA Audit and Standards Subcommittee promote implementation of the guideline recommendations and the achievement of performance indicators. In parallel with this, the Education and Scientific Subcommittee ensures that educational materials, including e-learning packages, are provided to promote dissemination of recommendations in guidelines.

The original antiretroviral treatment guidelines and their subsequent revision were published as position statements. Subsequent antiretroviral treatment guidelines were supported by emerging evidence. However, much of the evidence to support the recommendations in HIV clinical guidelines has come not from randomised controlled trials (RCTs) with clinical endpoints but from studies with surrogate marker endpoints such as viral load, so a grading system was used to evaluate these as guidance. The modified Grading of Recommendation, Assessment, Development and Evaluation (GRADE) was introduced to provide a transparent assessment of both the strength of recommendations and level of evidence for new guidance produced. The use of GRADE has been adopted by other national and international guideline development groups.

BHIVA attempts to harmonise its guidance with other international HIV guideline development groups, whenever appropriate to the UK healthcare system.

The target audience for the BHIVA guidelines is the entire HIV community caring for people living with HIV within the UK healthcare system as well as people living with HIV; however, it is recognised that these guidelines have had considerable international influence. The key target professional groups include medical staff (consultants, associate specialists, specialty doctors and specialty trainees), nursing staff (especially specialist nurses) and all other health professionals caring for people living with HIV (e.g. dietitians, HIV pharmacists and social workers). For those who are not used to medical terminology, for example people living with HIV who are accessing care or community groups, non-technical summaries are produced to aid understanding of guideline content and recommendations.

1.2. Aims and structure of the guideline development manual

This guideline development manual replaces the previous Guidance for BHIVA Guidelines Development, first agreed in 2007.

The main aims of this manual are:

- To combine the range of improvements introduced into the guideline development process over time into a single document.
- To serve as a reference tool for current and future authors of guidelines.
- To summarise the guideline development process for all users of the manual but especially for members of BHIVA, stakeholders, people accessing HIV care and partner organisations.

Based on the Appraisal of Guidelines for Research and Evaluation (AGREE) Instrument [1] the subsequent sections of this policy document demonstrate that BHIVA guidelines are:

- Produced to promote excellence in clinical care for people living with HIV and reduce the associated morbidity and mortality, as well as improve quality of life.

- Produced by HIV specialists, academic researchers and other healthcare professionals caring for people living with HIV, in collaboration with lay representatives, for the benefit of peer healthcare professionals, patients and the public.
- Produced using a transparent, consistent and reliable development process.
- Designed to provide recommendations based on and graded according to the best available evidence.
- Designed to provide recommendations, strong or weak, as well as clear indication of the strength of evidence underpinning the recommendations, weighing up the cost, burden and benefits of treatment or intervention.
- Designed to provide audit measures for the guideline recommendations.

1.3. Review and update of the guideline development manual

It is planned that this manual will be updated at least every 3 years by the BHIVA Guidelines Subcommittee subject to ratification by the Executive Committee, as led by agreed changes in processes. The updated manual is circulated to the full Guidelines Subcommittee and the Executive Committee for approval before publication.

2. Selection and planning of guideline topics

2.1. Selection criteria for guideline topics

The *Standards of Care for People Living with HIV, 2018* [2] highlight the need to identify markers of good practice to deliver equity of access, patient choice and a high quality of care to people living with HIV, particularly with regard to access to treatments, management of co-infection and morbidity, and earlier diagnosis and prevention of complications associated with late presentation.

Topics for guidelines will be selected to cover all the main areas of clinical management of people living with HIV and HIV prevention. These topics are primarily proposed by the BHIVA Guidelines Subcommittee (see section 3.1). Additionally, topics identified by the Department of Health, NHS England and NHS Scotland as well as any future NHS quality standards may inform guideline areas.

In addition, any member of the Association can suggest a guideline topic to be considered by the Association. This is submitted electronically on a proposal form (available on the BHIVA website) and considered by the BHIVA Guidelines Subcommittee and forwarded to the Executive Committee to be approved for development (Appendix 2).

Areas of guidance that will require development in collaboration with other specialist organisations undergo approval by the BHIVA Executive Committee and should then proceed through the agreed process of guideline development and peer review of the lead organisation. BHIVA will be involved in consultation of the co-badged guidance through the BHIVA member(s) of the writing group ensuring that the consultation draft is sent to the BHIVA Guidelines Subcommittee and that BHIVA members are invited to participate in consultation (see section 3.7).

The guidance contained within the full range of HIV clinical guidelines provides an up-to-date template for the management and prevention of HIV within the UK healthcare system and with the use of audit measures serves to provide data for local and regional audit, informing improvement measures.

For some topics, a short position statement, rapid guidance or best practice policy statement is required. These statements are approved (see section 6 for approval process) before being placed on the BHIVA website: www.bhiva.org/PositionStatements or www.bhiva.org/rapid-guidance.

2.2. Timelines for development of guidelines

The timeline for the completion of each guideline will be approved by the BHIVA Guidelines Subcommittee and this may vary between guidelines dependent on their scope and complexity.

Role of the Chair of a guideline writing group

The Chair of each individual guideline writing group must ensure that the following are complete prior to the commencement of the guideline writing process (see proforma Appendix 3):

- Appoint members of the writing group. This may include a Vice-chair if required.
- Ensure that each member of the guideline writing group has provided a conflict of interest declaration at the start of the process covering the preceding 12 months (see section 2.4) and that these have been reviewed by the Guidelines Subcommittee Chair and Vice-chair.
- Ensure that each member of the guideline writing group has completed GRADE training within the last 3 years as described in section 2.5.
- Estimate the number of guideline group meetings required (both face to face and virtual) to produce the guideline (in order for approval to be sought from the BHIVA Treasurer to allocate the appropriate level of funding for the production of each guideline).
- Detail the scale of the literature search required (in order to estimate how much time the BHIVA Guidelines Coordinator will require to complete it, and seek approval from the BHIVA Treasurer to allocate the appropriate level of funding).
- Provide a clear timescale to the Guidelines Subcommittee Chair of the anticipated date of completion of the public consultation draft and the final draft of the guideline. A copy of the proposed timelines for completion of each individual guideline will be held by the BHIVA Guidelines Coordinator and these will be reviewed at each Guidelines Subcommittee meeting. The Guidelines Coordinator will take an active role in encouraging timely completion of each guideline by liaising with the relevant members of each guideline writing group.

Each guideline may require in excess of 6 months for completion after the first draft is prepared to allow 1 month for public consultation and peer review and time for preparation of the revised draft to take account of feedback from the public consultation and expert peer reviewers prior to endorsement of the final version by the BHIVA Guidelines Subcommittee and BHIVA Executive Committee.

If a writing group does not complete its work within the specified period, the BHIVA Guidelines Subcommittee will have the discretion to either extend the timeline or replace some or all of the members of the writing group.

Role of each writing group Chair post-publication of the guideline

- The Chair of each guideline writing group is responsible for ensuring the production of an abridged version of the guideline within 1 month of publication to be used for the BHIVA guidelines app. Assistance is provided by the Guidelines Subcommittee.
- The Chair of each guideline writing group is also responsible for producing a non-technical summary in collaboration with the UK-CAB members of the writing group and the Guidelines Subcommittee.

- The Chair of the writing group, in collaboration with the Chair of the Guidelines Subcommittee, will decide whether to seek publication in *HIV Medicine* (online only) or another journal if appropriate.

For current guidelines, the date of completion is clearly displayed on the BHIVA website main guidelines page: www.bhiva.org/guidelines.

For a table summarising the timeline and process, see Appendix 4.

2.3. Composition and responsibilities of the BHIVA Guidelines Subcommittee and writing groups

Guidelines Subcommittee

Membership of the BHIVA Guidelines Subcommittee comprises a Chair, Vice-chair, ordinary members, two community representatives, a doctor in training and appointed members. The Chair is elected by the BHIVA Executive Committee and ordinary members are self-appointed from the membership of the BHIVA Executive Committee. Members can be appointed from the BHIVA membership to ensure the Subcommittee has the appropriate level of expertise and representation to fulfil its duties and responsibilities. The community representative(s) can nominate a deputy if they are unable to attend a meeting of the Guidelines Subcommittee. For the role of community representatives on the Guidelines Subcommittee, see Appendix 5.

Guidelines writing groups

The Chair of each writing group is nominated by the BHIVA Guidelines Subcommittee, and is often recognised as an expert within the field but may be a skilled chair nominated to lead the group**.** The Chair or another member of the writing group should also be a member of the Guidelines Subcommittee. The Chair has responsibility for timely preparation of the guideline according to agreed processes set out in this manual. In ideal circumstances, the Chair will step down for the next planned full update. This approach helps to maintain continuity while extending expert peer involvement and so assures the quality of future guidance. For some highly specialised areas there may be too few experts in the field for this approach to be possible for each successive guideline. In these situations, for each full update of a guideline, rotation of the Chair within a writing group and refreshing the membership may be desirable. This will be determined by the BHIVA Guidelines Subcommittee.

The other members of each guideline writing group are then selected, on the basis of their expertise and track record of interest in the sub-specialty area as well as freedom from overt conflict of interest, by the Chair of each guideline writing group. The writing group will always include at least one community representative (ideally two and where there is only one, the two community representatives on the Guidelines Subcommittee will support so that at least two community representatives have had input into each guideline) elected and independently nominated by the UK-CAB and may also include a doctor in training in a relevant specialty and representatives from nursing, pharmacy or other professional groups where relevant. For the role of community representatives in the guideline writing groups, see Appendix 5.

If the Chair of the writing group requires more writing group members, the BHIVA Secretariat will also send an open invitation, via email (usually in the monthly 'BHIVA Members Matters'), to the membership to apply to join the writing group. Subsequently applicants will be invited to join by the writing group Chair, based on whether they have the relevant experience, enthusiasm and time.

Prior to the first group meeting a full declaration of interests in line with BHIVA policy is solicited for all prospective members of the writing group and this is recorded by the BHIVA Guidelines Coordinator.

The involvement of a significant proportion of the UK HIV specialists in the production of the guidelines promotes wider acceptance and credibility for the guidance issued to peer professionals. In the preparation and publication of the guideline, the writing group is responsible to the Chair of the writing group who in turn is responsible to the BHIVA Guidelines Subcommittee and the BHIVA Executive Committee.

A full list of all authors and their affiliations will be published with each guideline.

The procedures for authorship in BHIVA guideline writing groups are summarised in Appendix 6.

2.4. Declaration of conflicts of interest

The Association has had a policy on conflict of interest for members of its Executive Committee since 2005 and all guidelines published should have a full declaration of authors' conflicts of interest accompanying the version on the BHIVA website (see Appendix 7).

The Chair of the writing group should ideally be appointed 12 months in advance of taking on the role to ensure freedom from conflict of interest, unless a new Chair is required due to unforeseen events (e.g. illness) in which case the conflict of interest policy will apply for the 12 months preceding the date of appointment. The Chair must be free of specific conflict of interest, i.e. relating to the topic of the guideline. All members of the writing group will be required to declare their potential conflicts of interest in line with the Association's policy on conflict of interest prior to the first meeting of the guideline writing group. This process is repeated when the guideline is prepared for public consultation and peer review, and the declarations are published with both the public consultation draft and the final version of the guideline. The conflict of interest declarations of the writing group members will be reviewed by the Chair and Vice-chair of the BHIVA Guidelines Subcommittee. If there are any concerns, these will be referred to the BHIVA External Scrutineers. Individuals who have a potential conflict may be disqualified from voting on any decisions or contributing to relevant discussions. Significant conflict as judged by the Scrutineers would disqualify the conflicted individual from membership of a writing group. None of the co-authors may have, or will acquire, any financial gain from developing the recommendations in their guideline. The names and conflict of interest declarations of the peer reviewers are also published with the conflict of interest declarations of the writing group and are available to download with the guideline.

2.5. GRADE training

A new writing group member who has not completed GRADE training before should, as a minimum, watch the recorded lecture by Dr Ian Williams on the BHIVA website (https://www.bhiva.org/guideline-development) and read the following three short *BMJ* papers:

1. Guyatt GH, Oxman AD, Vist GE *et al*.; GRADE Working Group. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ* 2008; **336**: 924–926.
2. Guyatt GH, Oxman AD, Kunz R *et al*.; GRADE Working Group. GRADE: what is "quality of evidence" and why is it important to clinicians? *BMJ* 2008; **336**: 995–998.
3. Guyatt GH, Oxman AD, Kunz R *et al*.; GRADE Working Group. Going from evidence to recommendations. *BMJ* 2008; **336**: 1049–1051.

At 3 years, refresher training consists, as a minimum, of watching the presentation by Dr Ian Williams again, and re-reading the third paper above (Going from evidence to recommendations).

Two additional papers will be of interest to some writing group members, depending on the topic of the guideline:

4. Schünemann HJ, Oxman AD, Brozek J *et al*.; GRADE Working Group. Grading quality of evidence and strength of recommendations for diagnostic tests and strategies. *BMJ* 2008; **336**: 1106–1110.
5. Guyatt GH, Oxman AD, Kunz R *et al*.; GRADE Working Group. Incorporating considerations of resources use into grading recommendations. *BMJ* 2008; **336**: 1170–1173.

2.6. Funding of guideline development

After being established in 1995, BHIVA was registered as a charity on 24 June 1996 in England and Wales (current no. 1170707).

BHIVA guidelines are not funded by any external organisation, commercial company or charity other than BHIVA itself. The BHIVA Guidelines Subcommittee receives no funding apart from expenses from the BHIVA Executive Committee to cover the cost of assistance with gathering and grading evidence, meetings, incidental travel expenses and the BHIVA Guidelines Coordinator for all administration as required.

3. Development process of the guidelines

BHIVA guidelines are developed using an explicit methodology based on seven core principles:

- Development is carried out by nationally representative experts in the field of HIV medicine relevant to the guideline, led by a chair who is free of specific conflict of interest.
- The expert group commissions a systematic review to identify and critically appraise the evidence to address selected PICO (patient or population/intervention or indicator/comparison or control/outcome) questions.
- Recommendations are explicitly linked to the supporting evidence using the GRADE system.
- The language/terminology used in all BHIVA guidelines should be in accordance with the recommendations in the recent NHIVNA Best Practice article [4]: https://www.nhivna.org/file/5dcbdcb83254e/BP-19-2.pdf.
- Recommendations take account of equality issues, financial and resource implications, and patient choice and lifestyle.
- Recommendations are open to public review including the full membership of BHIVA, stakeholders, patients and interested members of the public.
- The guidelines are person-centred and, in line with the BHIVA standards, should consider the practical, emotional and psychological aspects of living with HIV, where appropriate.

3.1. Selection criteria of topics within guidelines

Each proposed new guideline is approved by the BHIVA Guidelines Subcommittee prior to beginning the process of producing the guidance. The current guidelines cover the main areas in HIV treatment and care with the main aims of reducing morbidity and mortality in people living with HIV.

The selection of key issues for each guideline is based on clinical priorities, the expert co-authors' knowledge of the available literature, the range of treatment and interventions in this field and outcomes that are important to patients. On this basis several criteria are used by the expert co-authors of each guideline to decide which topic areas within each module merit inclusion:

- Areas of variation in clinical practice
- Areas of variation in patient outcomes
- Resources to provide high-quality patient care
- Interventions, procedures and drug management that influence patient morbidity and/or mortality
- Patient safety and avoidance of preventable complications.

3.2. The PICO framework

The definition of the target population and interventions is an essential component in the development of the guideline recommendations in the management of HIV and in the published data which provide the supporting evidence for the recommendations. Application of these principles is readily achieved using the **PICO** framework.

The **patients or population** of interest will vary for different guidelines (e.g. people living with HIV on or off treatment, or with a CD4 count in a given range; people at risk of acquiring HIV). BHIVA guidance applies to adolescents and adults with HIV; separate guidance for children with HIV is prepared by the Children's HIV Association (CHIVA: https://www.chiva.org.uk/infoprofessionals/guidelines/).

The writing group should not make recommendations which may prejudice clinical care based on gender, age, sexuality, ethnicity or socioeconomic status. No adults living with HIV are excluded from the guidance.

The **interventions or indicators** of relevance to guidance on the management of HIV are readily identified in the literature to generate intervention-specific recommendations: for initiating drug treatments for clinical conditions or complications secondary to HIV (e.g. treatment of opportunistic infections) and for initiating antiretroviral treatment.

The **comparisons or controls** used in developing the BHIVA guidance mainly involve comparison between different drug treatment options, but may involve testing strategies or investigations.

Hard **outcomes** such as mortality, morbidity, hospitalisation and complication rates are preferred in developing recommendations within BHIVA guidelines and these are more frequently available in some areas such as pregnancy and treatment of opportunistic infection; however, as survival has improved markedly since the introduction of effective antiretroviral medication, most studies involving antiretroviral medication only report surrogate marker outcomes, for example viral load.

3.3. Systematic literature review

It is recognised that there are ever-increasing demands on members' time, and BHIVA also recognises that the writing group members provide their time and expertise free of charge and should be supported as much as possible. The BHIVA Guidelines Subcommittee will therefore provide a Guidelines Coordinator to attend the meetings and subsequently play a major role in performing the literature search and review and in supporting the authors with appraisal of papers and, if necessary, grading of evidence and production of evidence tables (see Appendix 8).

The co-authors of each writing group will have followed the literature in their field for many years prior to reviewing the evidence to prepare their guideline module. The Chair of the writing group will commission the Guidelines Coordinator to conduct a systematic search of the literature published in English. The dates covered by the systematic literature search should be stated clearly in the introduction of each guideline along with specific details of the search strategy and search terms used. This will involve, as a minimum, a search using Medline, Embase and the Cochrane Library databases with key search terms according to the search strategy for each guideline topic agreed by the guideline writing group.

HIV medicine is a rapidly evolving field and therefore developments in treatment and care often change practice rapidly. For this reason, 'grey' literature, namely conference presentations and abstracts from key international meetings, is considered and reviewed. This includes the BHIVA annual conference, the Conference on Retroviruses and Opportunistic Infections (CROI), the European AIDS Clinical Society (EACS) and the International AIDS Society conferences, and the International Congress on Drug Therapy in HIV Infection, Glasgow. These will be given less weight in consideration than peer-reviewed published work but should not be excluded from consideration in formulation of guidelines. Articles not available in English or only available as letters, case reports, editorials or review articles are excluded.

The co-authors also review other HIV guidelines, such as clinical practice guidelines issued by other national and international societies (e.g. US Department of Health and Human Services and EACS).

3.4. Selection and evaluation of the evidence

The expert co-authors assess articles for relevance to the guideline topic, eligibility for inclusion in the evidence base for that guideline and methodological quality. Articles are considered of particular relevance if they are describing:

- Prospective randomised or quasi-randomised trials
- Controlled trials
- Meta-analyses of several trials
- Cochrane systematic reviews
- Systematic reviews
- Large cohort studies.

The co-authors include all relevant RCTs, prospective cohort studies, systematic reviews and meta-analyses in preparing recommendations and the supporting evidence for the rationale of the recommendations. In some areas within HIV medicine the number of such high-quality publications is, however, relatively low compared with other areas and much of the supporting evidence is based on observational studies. In general the co-authors do not exclude this evidence from the literature

given that the GRADE system provides an informative and transparent means of providing strong or weak recommendations for best practice even if the available supporting evidence is limited to low-level evidence such as observational and case–control studies or case reports. In such circumstances the recommendations are qualified explicitly by an appropriate low grading of the level of evidence (Grade C or D).

3.5. Grading the guideline recommendations

The GRADE Working Group developed an approach to grading evidence that moves away from initial reliance on study design to consider the overall quality of evidence across outcomes. The GRADE system was developed by an international group of guideline developers and methodologists to maximise the usefulness of clinical practice guidelines in the management of typical patients [3].

The advantages of the modified GRADE system are:

1. The grading system provides an informative, transparent summary for clinicians, patients and policy makers by combining an explicit evaluation of the strength of the recommendation with a judgment of the quality of the evidence for each recommendation.
2. The two-level grading system of recommendations has the merit of simplicity.
    - A Grade 1 recommendation is a strong recommendation to do (or not do) something, where the benefits clearly outweigh the risks (or vice versa) for most if not all patients.
    - A Grade 2 recommendation is a weaker recommendation, where the risks and benefits are more closely balanced or are more uncertain.

    Two levels facilitate a clear interpretation of the implications of strong and weak recommendations by clinicians. Explicit recommendations are made on the basis of the balance between the benefits on the one hand and the risks, burden and costs on the other.
3. Standard wording is used to indicate the strength of each recommendation.
    - It is desirable to provide clinicians with a standard terminology to aid interpreting the strength of recommendations.
    - When making a strong recommendation guideline authors are encouraged to use 'We recommend…' and when making a weak recommendation authors should use 'We suggest…'. The use of the active voice attributes responsibility for the recommendations to the guideline authors and their supporting organisation. For example:
        - We recommend that all individuals with tuberculosis should start antiretroviral treatment as soon as is practicable, and within 8–12 weeks of the diagnosis (Grade 1A).
        - We suggest that raltegravir can be used for individuals in whom efavirenz is contraindicated (Grade 2B).
4. Explicit methodology is used to describe the quality of evidence.
    - Grade A evidence means high-quality evidence that comes from consistent results from well-performed RCTs, or other overwhelming evidence (such as from well-executed observational studies with very strong effects).
    - Grade B evidence means moderate-quality evidence from randomised trials that suffer from serious flaws in conduct, inconsistency, indirectness, imprecise estimates,

reporting bias, or some combination of these limitations, or from other study designs with special strength.

- Grade C evidence means low-quality evidence from observational evidence, or from controlled trials with several very serious limitations.
- Grade D evidence is based only on case studies or expert opinion.

5. Ability to upgrade and downgrade the quality of evidence.
    - GRADE can appraise all relevant study data to upgrade or downgrade the overall quality of evidence.
    - RCTs = high initial grade.
    - Observational studies = low initial grade.
    - Other evidence = very low initial grade.
    - Reduce grade if there are study limitations, inconsistency between studies, surrogate outcomes but no direct patient outcomes or bias.
    - Raise grade if confounders would have reduced the observed effect, there is strong association without plausible confounders or a large dose–response effect.

Good practice points (GPPs) are recommendations based on the clinical judgment and experience of the working group. GPPs emphasise an area of important clinical practice for which there is not, nor is there likely to be, any significant research evidence, but where the aspect of care is regarded as such sound clinical practice that healthcare professionals are unlikely to question it and where the alternative recommendation is deemed unacceptable.

For a summary of the modified GRADE system, see Appendix 9.

3.6. Consensus process for grading of the recommendations

Based on the GRADE instrument the co-authors of each guideline aim to reach a consensus on the strength of recommendation (1 or 2) and level of supporting evidence (A–D) as described in detail in Appendix 9 and in section 3.5. The recommendations for the first draft result from a collective decision reached after discussion by the expert co-authors within the writing group and whenever necessary with input from the Chair of the BHIVA Guidelines Subcommittee.

Where consensus is not reached among the co-authors in the guideline writing group, this should be resolved initially by reasoned discussion until unanimous consensus is achieved. If this is not possible, the Chair should organise a vote on the contentious issue with the Chair abstaining. If the vote is tied, the Chair can use a casting vote. The vote should be recorded in the discussion minutes.

Any issues of disagreement should be reviewed initially after the public consultation and external peer review with comments specifically invited on any contentious matter. These issues should then be revisited by the guideline writing group with the results of the consultation/peer review for preparation of the final draft for publication. If there is still disagreement within the writing group, the process to achieve resolution detailed above should be repeated.

If any issues are not unanimously resolved, this fact should be recorded as a majority decision in the guideline and the vote noted in the minutes of the discussion. This will be made public on the BHIVA website.

There will then be a review of the draft guideline by the BHIVA Guidelines Subcommittee using a checklist (Appendix 10) and by the Executive Committee. Comments will be communicated to the authors and any necessary amendments made.

Changes to the grading of the recommendations may be considered after feedback from the first and final drafts of the guideline.

3.7. Consultation and peer review of the guideline

Consultation is achieved by inviting feedback on the guideline from the membership of BHIVA and any other interested party including the general public via the public section of the BHIVA website. Additionally, an external peer review is undertaken with nominated international experts in the field. These external reviewers will be subject to the same rules on conflict of interest as the writing group and their names and affiliations will be published on the BHIVA website with the guideline.

3.8. Public review of the guideline

The first draft of the guideline is subject to review by BHIVA members, all BHIVA-invited stakeholders, service users and any member of the general public. Before consultation, the writing group will share the document with the Chair of the Audit and Standards Subcommittee for review of the auditable standards included. The main steps in review of the first draft are:

1. The first draft of a new or updated guideline, together with a declaration of conflicts of interest for each writing group member, is posted on the guidelines page of the public access section of the BHIVA website with a request for comments within 1 month. A watermark is added to this consultation version with ‘draft’ on every page.
2. At the same time all BHIVA members (as well as any non-BHIVA members of the writing group or Guidelines Subcommittee) are informed about this by email from the BHIVA Secretariat, via a notice on the BHIVA website and/or in the next BHIVA Members Matters e-newsletter.
3. The Chair of the writing group may also ask other key stakeholders to comment on the first draft within 1 month.
4. The community representative(s) on the writing group will circulate the draft to the UK-CAB and will collate any responses from the community and patient representatives and send these to the Chair.
5. The Chair of the writing group will review the comments from BHIVA members and other stakeholders and provide a brief summary of the amendments to be included in the final draft.
6. The final draft with the summary of comments received and key changes should be sent to the BHIVA Guidelines Subcommittee and Executive Committee within 1 month of the deadline for receipt of comments on the consultation draft.
7. Where another organisation is the lead, the BHIVA Guidelines Subcommittee will coordinate communication to BHIVA members so that they can respond to the consultation led by the lead organisation. The consultation draft should be viewed by members of the Guidelines Subcommittee, who may respond with comments.

3.9. Peer review of the guideline

The Chair of the writing group invites two or three independent experts to review the guideline, with a request for comments to be sent by email to the Chair within 1 month.

These reviewers will be internationally acknowledged experts in the field and free from any overt conflict of interest. They will be subject to the same policy on disclosure of conflict of interest as the writing group in accordance with the rules of the Association. Peer reviewers' names and affiliations are published with the guideline on the website.

3.10. Approval of the final version

The writing group will discuss the results of the public consultation and peer review and will amend the draft guideline, if appropriate, in preparation for the final draft. The writing group will use the guideline checklist (Appendix 10) to ensure that all essential content is included. The same process for grading evidence and resolving differences in opinion will be used as detailed above. The public consultation responses will be published with the guideline on the BHIVA website.

The final draft and summary of comments/key changes to the consultation draft are circulated to all members of the BHIVA Guidelines Subcommittee and the Executive Committee for final review and endorsement. However, in some cases to improve efficiency, the Chair may delegate two members of the Subcommittee to review the final draft in detail and provide feedback to the writing group and other members of the Subcommittee.

After incorporating feedback and comments on the final draft, the co-authors of the guideline should submit the final version to the BHIVA Guidelines Subcommittee and the Executive Committee for final review and endorsement. Once approved, the final version is published on the main guidelines page of the BHIVA website with the date of publication.

3.11. Updating existing guidelines

- It is recommended that, following publication of each guideline, the guideline writing group Chair should hold at least one virtual or face-to-face meeting per year with the rest of their guideline writing group, in order to ascertain whether there has been any new evidence that would change practice and therefore require an interim update to the guideline. Alternatively, Chairs can discuss this with the group by email.

- The BHIVA Guidelines Coordinator will organise an additional annual virtual meeting with the Chairs of each guideline writing group in order to ascertain whether an interim guideline update is required because of new evidence that is likely to require change in published recommendations for clinical practice. Alternatively, Chairs can send an email to advise whether they consider that an interim update is required. Short minutes will be circulated for this meeting and arrangements made for any necessary interim updates. Interim updates will be published on the BHIVA website only.

- Each guideline must undergo the full guideline development/review process (i.e. full literature review) **at least** every 5 years. These full updates will be published in *HIV Medicine* and on the BHIVA website.

Full review process versus interim updates

In order to facilitate timely production of the guidance, every year Chairs of the guideline writing groups will ascertain whether a full or an interim guideline update (or no update) is required.

For full updates of the guidelines (at least every 5 years), the full review process will be required, including setting PICO questions, conducting literature searches and use of GRADE criteria.

For interim updates, PICO questions will be identified (which may be one/some of those used for full update) and literature searches carried out only for the recommendations that have been identified as needing an update. A 'top up' literature search from the date of the last search to the present will be done. When the guideline is then due for full review, a further 'top up' literature search should be carried out, to bring it to the agreed (present) time.

The BHIVA Guidelines Subcommittee has the discretion to commission new or updated guidelines (full or interim updates) prior to the planned expiry of existing guidelines, for example if new evidence becomes available to change practice. Funding should be approved at the outset by the BHIVA Treasurer.

The usual method is outlined above for interim updates, which are prompted by new evidence presented or published and include a 'top up' literature search relevant to those recommendations. Interim updates should be initiated only if new evidence is thought significant enough to change the recommendations made and not just to update the text.

3.12. Forming the guideline recommendations audit measures and implementation tools

Close liaison with the BHIVA Audit and Standards Subcommittee enables identification of appropriate audit standards and liaison with the BHIVA Education and Scientific Subcommittee enables preparation of supportive educational materials to coincide with the launch of the guidelines (see sections 5.2 and 5.3).

3.13. Resource implications of the guideline recommendations

Management of HIV demands a relatively high level of healthcare resource and finance. The provision of HIV services has been limited by resource allocation in the past and resources are finite. The co-authors of each guideline should draft and agree the recommendations within each guideline based primarily on clinical effectiveness, but the use of resources and cost-effectiveness should also be taken into account.

There are limited data on the relative cost-effectiveness of various treatments in this field; however, the available data strongly support the case that HIV treatment is cost-effective in terms of quality-adjusted life years versus many other health interventions.

The co-authors should produce recommendations to follow any specified management which on balance favours health gain/patient benefit over risk/harm where there is evidence of clinical effectiveness.

At the same time the co-authors may produce no recommendations, or recommendations not to follow a specified management if clinical and cost-effectiveness is in doubt. The co-authors will always make recommendations not to follow a specified form of treatment when the risks/harms exceed the assessed health gain.

4. Format of guidelines

4.1. Layout of guidelines

All BHIVA guidelines should include the following:

- Title page (including writing group details)
- Contents
- Introduction
- Scope and purpose
- Methods (including search strategy)
- Supporting patients
- Summary of recommendations
- Summary of audit measures
- Rationale for recommendations
- References
- Acknowledgements
- Expiry date and date of review (minimum every 5 years)

4.2. Introduction

In the introduction, the guideline authors should indicate the background and rationale for the development of the guideline. Harmonisation with the recommendations from other international HIV guidelines should be acknowledged to provide clarity to the user. Links to prior versions of the guideline and to the guidelines of other international and national guideline development groups should be provided when appropriate.

4.3. Scope and purpose

Each guideline should clearly indicate its overall objective, the clinical question(s) addressed, any particular patient groups included or excluded and the audience for which the guidance is intended.

4.4. Methods

The search strategy with search dates, terminology and method of reviewing evidence should be outlined here. The method of grading the strength of recommendations and level of supporting evidence should be described, as well as any methods of particular relevance to the topic of the guideline.

4.5. Supporting patients

This section, to be written in close collaboration with community representatives on guideline writing groups, focuses on key aspects of support and information required for the patients to whom recommendations apply.

4.6. Summary of recommendations

A summary of the guideline recommendations is collated to provide a list of all recommendations for ease of review by the user. This section is readily available for printing separately from the full guideline and serves as a quick reference guide.

4.7. Summary of audit measures

Each guideline contains a number of audit measures to assist with implementation of the guidance, promote improvement in the quality of care and allow comparative audit. The audit measures should be measurable, achievable and serve as evidence-based criteria for continuing quality improvement.

4.8. Supporting rationale for recommendations

This section provides the rationale and chain of logic for the guideline recommendations. The rationale and references are described separately after each recommendation or subgroup of recommendations to allow for ease of updating and editing. The rationale should provide support for the grading of the recommendations.

4.9. Acknowledgements

Significant contributions to the guideline from HIV physicians, clinical scientists, patients and other stakeholders should be acknowledged.

Authors will be listed as such when the guideline is published online in *HIV Medicine*, and will thus appear as authors on PubMed.

4.10. Expiry date and date of review

The expiry date will be stated on each guideline. This will usually be 5 years subject to review by the BHIVA Guidelines Subcommittee but may be sooner where there is frequent change in data to inform practice.

5. Dissemination and implementation of the guidelines

5.1. Notification of publication of the final version on the BHIVA website

The membership of BHIVA (as well as any non-BHIVA members of the writing group or Guidelines Subcommittee) is notified by email when the final version of a clinical guideline is posted on the main guidelines page on the website: www.bhiva.org/guidelines. Members are also notified in the next BHIVA Members Matters e-newsletter.

A non-technical version of the guideline will be produced in conjunction with the community representative(s) in the writing group as soon as possible after publication of the guideline for dissemination to service users. After approval by the UK-CAB, this will be available for free download on the BHIVA website.

The Chair of each guideline writing group will also be responsible for ensuring the production of an abridged version of the guideline to be used for the BHIVA guidelines app.

Both the non-technical summary and the app version can be drafted at the stage of public consultation.

Current guidelines and those under review are published on the main guidelines page:

- Guidelines produced in collaboration with other associations are also published on the main guidelines page.
- Historical BHIVA guidelines are archived at www.bhiva.org/ArchivedGuidelines.

5.2. Use of audit measures for national audit by the BHIVA Audit and Standards Subcommittee

Implementation of the BHIVA guidelines is promoted by audit on performance measures related to key recommendations within the guideline. The co-authors of each guideline should identify several audit measures, in collaboration with the BHIVA Audit and Standards Subcommittee, to serve as evidence-based useful criteria for continuing quality improvement. A summary of the audit measures in is included each guideline.

The audit measures may be used for local and regional audit by individual HIV units and all the HIV units within a region. Some of the audit measures are used as performance indicators in national audit performed annually by BHIVA. This approach helps ensure a high level of implementation of all the recommendations covered by national audit. Some of the established audit measures have been used as performance indicators by BHIVA for many years and are utilised to demonstrate the performance of HIV units across the UK. National audit reports are published online by BHIVA at www.bhiva.org/NationalAuditReports.

5.3. Dissemination and implementation initiatives

Several strategies and initiatives have been introduced to improve dissemination and implementation of the BHIVA guidance:

1. Each guideline has a summary of recommendations after the contents and introduction. This section of the guideline can be readily downloaded from the website as a concise summary of the recommendations without needing to read, download or print the entire guideline document.
2. The BHIVA Education and Scientific Subcommittee will liaise with the BHIVA Guidelines Subcommittee to produce educational material to support the guidelines, including e-learning material.
3. All BHIVA guidelines published to date have been formatted as PDF files on the BHIVA website providing printable copies of each guideline ready for download from the website at no cost to users.
4. Liaison with the BHIVA Conferences Subcommittee has ensured that presentations on new BHIVA guidance at one of the BHIVA conferences have been used to launch and promote the awareness and uptake of guideline recommendations.
5. On completion, e-publication is planned on the BHIVA website of all full guideline updates and any interim updates. In addition, completed guidelines (full updates) will be published online in *HIV Medicine* (or any successor publication); this will be cited by PubMed which should promote dissemination of the guidance.

6. A non-technical version of the guidelines will be produced in collaboration with the UK-CAB members of the writing group or Guidelines Subcommittee.

6. BHIVA guidance for developing position statements and rapid guidance

For position statements and rapid guidance on issues and events of immediate concern to members and/or people living with HIV, the following principles apply:

1. The need for a statement, and a document lead author, should be agreed by the Executive Committee or, for very rapid decisions (within 7 days), the BHIVA Officers and Guidelines Subcommittee Chair or Vice-chair.
2. The following should be agreed, and documented, at the start:
    a. Timelines
    b. Writing group membership
    c. Any support required (e.g. literature searches)
    d. The need, or not, to list authors and affiliations on the final publication (if not, a record of authorship and reviewers should be available on request)
    e. The need, or not, for consultation and the scope (e.g. public, members and other stakeholders).
3. All documents should be reviewed by the community Trustee, Guidelines Subcommittee community representatives or another nominated representative from the UK-CAB.
4. For statements based on the definition of ‘very rapid' given above, approval is required by the BHIVA Chair, one other Officer and the Chair or Vice-chair of the Guidelines Subcommittee; ideally the whole Executive Committee will have the opportunity to comment.
5. For statements not deemed ‘very rapid’ the Executive Committee will have the opportunity to comment before final approval.
6. Rapid updates to existing guidance can be approved by two of: the BHIVA Chair, one other Officer or the Guidelines Subcommittee Chair/Vice-chair plus a community representative if possible within 7 days.
7. For governance purposes, all correspondence related to the development of position statements or rapid guidance should be copied to the BHIVA Secretariat.
8. Position statements and rapid guidance will be accessible on the BHIVA website, clearly differentiated from formal guidance that has been through a NICE-approved development process; documents should be clearly identified as:
    a. Clinical guidelines (that have been through the formal guideline process)
    b. Position statements
    c. Rapid guidance (that has not been through the formal guideline process).
9. At the time of completion and if considered necessary by the lead author, Chair of the Guidelines Subcommittee and community representative(s), a non-technical summary will be produced by the writing group in collaboration with community representative(s).
10. To mitigate the lack of full consultation for rapid guidance without consultation, a feedback form is included on the webpage so that members and other stakeholders may comment. Comments should be reviewed within a reasonable timeframe (1 month) after receipt, by the Guidelines Subcommittee Chair or Vice-chair and, if needed, authors of the rapid guidance or position statement.
11. All rapid guidance and position statements should include a date for review which will vary according to the event or issue they are produced in response to. This review will be undertaken by the Guidelines Subcommittee and archiving or updating initiated as appropriate.

7. References

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Appendix 2. Suggestions for future BHIVA guidelines

Suggestions can be submitted by email to bhiva@bhiva.org or through the BHIVA website: https://www.bhiva.org/FutureGuidelinesSuggestion.

The BHIVA Guidelines Subcommittee will consider all suggestions and forward them, if accepted, to the BHIVA Executive Committee for consideration.

Appendix 3. Proforma for starting a new guideline or full update of an existing guideline

To be completed by the guideline writing group Chair, with support from the Guidelines Coordinator and Chair of the Guidelines Subcommittee, at the start of the process.

	Stage	Date/comment
1	Agree title of new or fully updated guideline	
2	Nominate Chair, and Vice-chair if needed	
3	Agree writing group members	
4	Community representative(s) nominated	
5	Number of face-to-face meetings needed	
6	Number of virtual meetings needed	
7	Details of the scale of literature search required	
8	Estimate of length of guideline, e.g. number of sections	
9	Estimate of time commitment for Guidelines Coordinator	
10	Cost approved by Treasurer	
11	Estimated date of first scheduled writing group meeting	
12	Estimated date of first draft to Guidelines Coordinator	
13	Estimated date for consultation	
14	Estimated date for publication	
15	Proforma completed	

Appendix 4. Summary of steps involved in producing or fully updating a guideline

1.	Title suggestion approved by the BHIVA Guidelines Subcommittee and agreed by the BHIVA Executive Committee.
2.	The Chair of each writing group is to be identified by the BHIVA Guidelines Subcommittee, and writing group members nominated by the writing group Chair (including a Vice-chair if required). Initial conflict of interest declaration and GRADE training completed.
3.	The Chair of each writing group must inform the Chair of the BHIVA Guidelines Subcommittee of the anticipated timeline for completion of the guideline and number of meetings required (face to face and virtual) and provide an estimation of the scale of the literature review required. Initial meeting to identify questions, and to produce a scope, a search strategy and selection criteria. Allocation of sections/tasks to writing group members. Proforma for starting a guideline (Appendix 3) is completed and filed.
4.	The PICO search strategy must be utilised to construct appropriate research questions in order to inform the literature search. Scope and questions approved by the writing group.
5.	Data extraction: literature search performed by the BHIVA Guidelines Coordinator and identified titles and abstracts forwarded to relevant section author(s).
6.	Authors, with assistance of the Guidelines Coordinator, systematically sift and discard those that are irrelevant and scrutinise remaining papers to assess whether they meet selection criteria. Guidelines Coordinator to document the selection process.
7.	Critical appraisal of the quality of remaining studies by members of the writing group.
8.	Guidelines Coordinator to synthesise the data from eligible studies and produce evidence tables with quantitative pooling of data if appropriate.
9.	From synthesis of evidence to producing a recommendation is not a straightforward process. There needs to be a dialogue between writing group members at this stage. The process should take into account the body of evidence, i.e. not just one paper.
10.	Guideline authors draft recommendations and identify potential audit points and educational tools.
11.	Meeting to present a synthesis of data, review draft recommendations and establish consensus and implications for practice. Recommendations summarised.
12.	Draft documents collated by authors and Guidelines Coordinator and finalised.
13.	Review by BHIVA Guidelines Subcommittee and Executive Committee using checklist (Appendix 10), and comments communicated to authors and amendments made.
14.	Publication on BHIVA website for public consultation (with all author declarations of conflict of interest) and commission external peer review. The community representative(s) on the writing group will circulate the draft to the UK-CAB and will collate any responses from the community and patient representatives.
15.	Consideration of consultation feedback and redrafting, if necessary, in light of received comments.
16.	Review by BHIVA Guidelines Subcommittee using checklist (Appendix 10).
17.	Review of auditable standards by Audit and Standards Subcommittee (Chair's action or circulation outside of meeting if no imminent meeting).
18.	Review by BHIVA Executive Committee.
19.	Publication on BHIVA website with final conflict of interest statements (full and interim guideline updates), and with comments received during the public consultation with writing group responses (full updates).

20	For full updates, production of a non-technical version of the guideline in collaboration with the community representative(s) in the writing group, and an abridged version of the guideline for the BHIVA guidelines app.
21.	Publication in *HIV Medicine* online or other journal (full guideline updates).
22.	Annual review of all guidelines: the Guidelines Coordinator will arrange an annual virtual meeting, after the CROI meeting, with the Chairs of each guideline writing group to ascertain whether a guideline update (full or interim) is required. All guidelines will require a full review at least every 5 years.

Appendix 5. Role of community representatives on BHIVA Guidelines Subcommittee and writing groups

The involvement of people living with HIV and stakeholder groups in the development of guidelines is greatly valued by BHIVA. Community representatives should have experience and/or knowledge of issues that are important to patients and carers, to ensure that such issues, as well as the views of healthcare professionals, inform the guideline development process. In general, community representatives will have direct experience of HIV as a patient, or in exceptional circumstances (e.g. where community organisations are involved in delivery) as a member of a patient or carer organisation or support group but only in addition to a representative living with HIV. They should be willing to reflect the experiences of a wide network of patients, rather than basing their views on their own experience alone. They should not represent the views of any organisation.

Role on BHIVA Guidelines Subcommittee

The BHIVA Guidelines Subcommittee membership must include at least two community representatives. The community representatives on the Subcommittee should:

- Provide a view from lived experience for all new guideline suggestions to the Subcommittee.
- Ensure that appropriate topics are addressed by the writing groups. As such, the community representatives can influence which topics are the subject of guidelines and oversee how these guidelines are produced.
- Be responsible for ensuring recruitment and adequate representation of at least one and ideally two community representatives in each guideline writing group (where only one is possible, additional input to a guideline will be provided by the representatives from the Guidelines Subcommittee).
- Ensure that the views of community representatives in the writing groups are heard and any issues raised are considered.
- Offer support to the community representatives in all writing groups and receive feedback from them, in particular prior to each Guidelines Subcommittee meeting.

Role on writing groups

All guideline writing groups will always include at least one community representative. Two representatives are required to be involved in each guideline and so if there is only one representative in the writing group, the representatives on the Guidelines Subcommittee will support. The representative(s) will be responsible for ensuring that review questions embrace patient as well as clinical issues, that recommendations address patient issues and concerns, and that the language of guidelines is appropriate (e.g. person-first language and treating patients as people, not as recipients of tests or treatments). The community representative(s) will also be able to raise awareness of literature (such as patient surveys) that highlights patient issues, consider the extent to which published evidence has taken into account outcome measures that patients consider important, and highlight areas where patient preferences and choice may need to be acknowledged in the guidelines.

In circumstances in which a representative has not been identified for a guideline, or where a representative who has been part of a writing group is no longer able to contribute, the community representative members of the Guidelines Subcommittee will support the writing group and provide input.

As a member of a BHIVA guideline writing group, together with all other members of the group, community representatives will be required to:

- Complete a conflict of interest declaration form

- Complete training in the grading of scientific evidence (by watching a 50-minute video presentation and reading a series of scientific publications; liaise with the writing group Chair if further training is required)
- Attend face-to-face and/or virtual meetings.

In addition:

- When the final draft of the guideline has been prepared, it will be available for public consultation. The community representative(s) will circulate the draft to the UK-CAB and then collate any responses and send these to the Chair of the writing group.
- Once a guideline is ready for publication, the Chair of the writing group will be responsible for ensuring the production of a non-technical summary in collaboration with the community representative(s).

Appendix 6. Procedures for authorship in BHIVA guideline writing groups

At the BHIVA Guidelines Subcommittee meeting on 14 November 2013, it was agreed that BHIVA would use as its definition for authorship the *BMJ* Group Editorial Policy on Authorship, which is as follows:

Authorship
Based on the International Committee of Medical Journal Editors requirements for manuscripts submitted to medical journals, authorship credit should be based on the following four criteria:

- Substantial contribution to the conception or design of the work, or acquisition, analysis or interpretation of data.
- Drafting the article or revising it critically for important intellectual content.
- Final approval of the version published.
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All four of these conditions must be met. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Participation solely in the acquisition of funding, the collection of data or general supervision of the research group does not justify authorship. We wish writing group Chairs to assure us that all authors included on a paper fulfil the criteria of authorship. Conversely, we also ask for assurance that there is no one else who fulfils the criteria who has not been included as an author.

Order of authorship
The Chair should be the first or last author and others listed alphabetically, unless a disproportionate contribution has been made by any member(s), who may then be second or third authors, and this is agreed within the writing group.

Alteration to authorship
Any change in authors after initial submission must be approved by all authors. This applies to additions, deletions, change of order to the authors or contributions being attributed differently. Any alterations should conform to the *BMJ* Group Editorial Policy on Authorship.

Contributors should be acknowledged
All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help or writing assistance, or a department chair who provided only general support. Financial and material support should also be acknowledged. Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under a heading such as ‘clinical investigators’ or ‘participating investigators’, and their contribution should be described clearly: for example, ‘served as scientific advisors’, ‘critically reviewed the study proposal’, ‘collected data’ or ‘provided and cared for study patients’.

Because readers may infer their endorsement of the data and conclusions, all persons must give written permission to be acknowledged.

Appendix 7. Competing interest disclosure form

Instructions

1. Requirements for declaration
    a. BHIVA requires that all members of BHIVA guideline writing groups as well as any expert external peer reviewers and literature searchers must declare all interests and membership of other committees.
    b. Declaration is required to be made prior to the commencement of service on the relevant guideline writing group retrospectively for the 12 months preceding the beginning of membership of the guideline writing group.
    c. All members of guideline writing groups must undertake a declaration of interests prior to serving on a writing group and this declaration is confirmed and repeated on the publication of the completed guideline.
    d. This form will be retained by the Guidelines Coordinator and the details will be made available for publication.
2. Please report all relationships with pharmaceutical, diagnostic or similar companies involved in HIV-related products, or other products relevant to the guideline you are working on, during the period given below. For the purposes of this disclosure, the term 'member' includes the writing group member and any spouse/partner/family member.
3. If any positive responses are given in the sections below, please provide further information. Chairs of guidelines writing groups must be free of specific conflicts of interest relating to the topic of the guideline.
4. If undisclosed competing interest is later proven, the writing group will follow Committee on Publication Ethics (COPE) guidelines.
5. Please also indicate If there is nothing to disclose.
6. This declaration covers the period **DATE to DATE** for pecuniary and non-pecuniary interests.
7. Please email your completed form by **DATE** to the BHIVA Guidelines Coordinator at: cniemansims@bhiva.org

Title and full name **Affiliation**	
Signature	
Date	

1. Pecuniary interests	None	≥£10
Consultancy work This refers to any paid retainer or agreement between the member and a company usually with a contract for a specific period and includes payment for attending Advisory Board meetings.	☐	☐
Speaker fees This mainly concerns fees (e.g. for lectures, commissioned articles or other suchlike paid activity) received from a commercial sponsor and where the member has benefited personally.	☐	☐
Company shares This includes any shares held by the member in the biomedical industry (e.g. pharmaceutical, diagnostic or similar companies).	☐	☐
Grant support This refers to fees and grants paid to the member which have been used for research, education, equipment, salaries (including fellowships) in your department and for personal travel/hospitality for conferences and meetings.	☐	☐
Other paid income This refers to patents or royalties, serving as an expert witness, or performing other activities for an entity with a financial interest in this area undertaken by the member.	☐	☐
Other relevant disclosure This refers to any other relationship which is financial or with an organisation that, if not disclosed by the member, could compromise the member or BHIVA as a charitable organisation.	☐	☐
Detail where ≥£10 declared including date(s), payment(s), source(s) of funds		

2. Non-pecuniary interests
You are required to declare any trusteeships in non-BHIVA organisations and non-BHIVA committee memberships or directorships, which have conflicting or competing interests. Please ensure that you give full information regarding dates and length of term.
Trusteeships Give full name of organisation(s), plus term served to date and retirement date.
Committee memberships Give full name of organisation(s) and indicate your role on any committees, plus term served to date and retirement date.
Directorships Give full name of organisation(s), plus term served to date and retirement date.

Appendix 8. BHIVA Guidelines Coordinator: job description and person specification

Responsibilities

1. To lead in supporting systematic reviews to inform guideline development and updating including performing literature searches, assessing scientific papers against set criteria, data extraction and analysis, as directed by the BHIVA Guidelines Subcommittee and any writing groups.
2. To include the preparation of agendas and minutes, circulation of papers, correspondence, publications, reports and other items on behalf of the Chair of the BHIVA Guidelines Subcommittee and individual guideline writing groups, in liaison with the BHIVA Secretariat.
3. To liaise with the BHIVA Secretariat to ensure that external enquiries are considered by the BHIVA Guidelines Subcommittee and appropriate responses submitted. To provide research assistance, drafting of documents and liaison with external organisations.
4. To provide content for the guidelines section of the BHIVA website in liaison with the BHIVA Secretariat.
5. To liaise with the BHIVA Secretariat in the production of guidelines for publication in *HIV Medicine* and on the BHIVA website.
6. To attend BHIVA conferences (5 days p.a. maximum), if necessary.

Person specification

- Medical writer with editorial experience essential.
- Knowledge of and interest in HIV desirable.
- Experience of performing scientific literature searches, data extraction and analysis and preferably knowledge of the process of systematic reviews.
- Excellent organisational skills.
- Ability to follow established procedures and policy.
- Ability to work as part of a team.
- Ability to work well under pressure, meet deadlines and pay accurate attention to detail.
- Ability to prioritise a range of tasks.
- Flexible.
- Computer literate with accurate word processing skills and sound knowledge of Windows-based applications, Word, Excel and Access.
- Excellent communication and interpersonal skills.
- Previous administrative experience desirable.

Appendix 9. Summary of the modified GRADE system (Grades 1A–2D)

1A **Strong recommendation** **High-quality evidence** Benefits clearly outweigh risks and burdens, or vice versa. Consistent evidence from well-performed, randomised controlled trials or overwhelming evidence of some other form. Further research is unlikely to change confidence in the estimate of benefit and risk. Strong recommendations can apply to most patients in most circumstances without reservation. Clinicians should follow a strong recommendation unless there is a clear rationale for an alternative approach.
1B **Strong recommendation** **Moderate-quality evidence** Benefits clearly outweigh risks and burdens, or vice versa. Evidence from randomised controlled trials with important limitations (inconsistent results, methods flaws, indirect or imprecise), or very strong evidence of other research design. Further research may impact on confidence in the estimate of benefit and risk. Strong recommendation; applies to most patients. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
1C **Strong recommendation** **Low-quality evidence** Benefits appear to outweigh risks and burdens, or vice versa. Evidence from observational studies, unsystematic clinical experience or from randomised controlled trials with serious flaws. Any estimate of effect is uncertain. Strong recommendation; applies to most patients. However, some of the evidence base supporting the recommendation is of low quality.
1D **Strong recommendation** **Very low-quality evidence** Benefits appear to outweigh risks and burdens, or vice versa. Evidence limited to case studies. Strong recommendation based mainly on case studies and expert judgment.

2A

Weak recommendation

High-quality evidence

Benefits closely balanced with risks and burdens.

Consistent evidence from well-performed, randomised controlled trials or overwhelming evidence of other form. Further research is unlikely to change confidence in the estimate of benefit and risk.

Weak recommendation; best action may differ depending on circumstances or patients' or societal values.

2B

Weak recommendation

Moderate-quality evidence

Benefits closely balanced with risks and burdens, some uncertainly in the estimates of benefits, risks and burdens.

Evidence from randomised controlled trials with important limitations (inconsistent results, methods flaws, indirect or imprecise). Further research may change the estimate of benefit and risk.

Weak recommendation; alternative approaches are likely to be better for some patients under some circumstances.

2C

Weak recommendation

Low-quality evidence

Uncertainty in the estimates of benefits, risks and burdens; benefits may be closely balanced with risks and burdens.

Evidence from observational studies, unsystematic clinical experience or from randomised controlled trials with serious flaws. Any estimate of effect is uncertain.

Weak recommendation; other alternatives may be reasonable.

2D

Weak recommendation

Very low-quality evidence

Uncertainty in the estimates of benefits, risks and burdens; benefits may be closely balanced with risks and burdens.

Evidence limited to case studies and expert judgment.

Very weak recommendation; other alternatives may be equally reasonable.

Appendix 10. Checklist for all BHIVA guidelines

1. Is the overall objective clear?
2. Are the recommendations specific, unambiguous and clearly identifiable?
3. Has the PICO strategy been utilised to formulate questions?
4. Is the language appropriate for the specified target audience?
5. Are the clinical, healthcare or social questions covered?
6. Are the recommendations in reference to specific clinical, healthcare or social circumstances clear?
7. Has there been adequate involvement of patient and stakeholder groups in development, e.g. at least two members of the UK-CAB, including assistance from the UK-CAB members of the Guidelines Subcommittee?
8. Are the methods to search for evidence and data clearly defined and adequate?
9. Are the criteria and reasons for inclusion or exclusion of evidence clearly stated?
10. Has the GRADE system been used to outline the strengths and limitations of the evidence and acknowledge any areas of uncertainty?
11. Has the agreed BHIVA methodology been used to make recommendations including methods to reach consensus?
12. Have the health benefits, side effects and risks been considered in formulating recommendations?
13. Have the different options for management of the condition been considered and stated?
14. Have auditable standards been developed in liaison with the BHIVA Audit and Standards Subcommittee?
15. Have any potential organisational and financial barriers been considered?
16. Has a non-technical summary of the guidelines been produced in conjunction with the community for dissemination to service users?
17. Has an abridged version of the guideline been submitted to be used for the BHIVA guidelines app?
18. Are the details of the guideline writing group clearly stated?
19. Are all author and peer reviewer conflicts of interest available with the final version of the guideline?
20. Are comments received during the public consultation with writing group responses available with the final version of the guideline?
21. Is the proposed date for review included in the guideline?