

# British HIV Association (BHIVA) Guideline Development Manual

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**British HIV Association (BHIVA) Guideline Development Manual prepared by members  
of the BHIVA Working Group for NHS Evidence Accreditation of BHIVA guidelines**

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**Document dated 13 September 2011**

## 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 infection.

BHIVA has become the leading UK association representing professionals in HIV care. Now 16 years old, it is a well-established and highly respected organisation with national influence, committed to providing excellence in the care of those living with and affected by HIV.

BHIVA acts as a national advisory body to professions and other organisations on all aspects of HIV care. BHIVA also provides a national platform for HIV care and contributes representatives for international, national and local committees dealing with HIV care. In addition, BHIVA works to promote undergraduate, postgraduate and continuing medical education within HIV care.

The current membership of the Association is around 1,000 across a wide range of healthcare professionals and other HIV healthcare workers.

BHIVA produced its first treatment guidelines in 1997<sup>1</sup>, which were published in *The Lancet* and an update to the guidelines was published in the same journal the following year<sup>2</sup>.

The *HIV Medicine* journal was founded by the Association in 1999 and the majority of BHIVA guidelines have been published in *HIV Medicine* since that time (see Appendix 9)<sup>3-8</sup>. This journal is distributed to all BHIVA members and is incorporated into their subscription to the Association.

The BHIVA Guidelines Subcommittee is one of four subcommittees reporting to the BHIVA Executive Committee (see Appendices 1 and 2), the others being the Audit and Standards Subcommittee, the Conferences Subcommittee, and the Education and Scientific Subcommittee. The general purpose of the BHIVA Guidelines Subcommittee is to set standards for good clinical practice relating to various aspects of the treatment and care of persons infected with HIV. Guidelines are updated at appropriate time intervals to reflect the latest findings and are subject to scrutiny by consultative process. The terms of reference of the Subcommittee are determined by the BHIVA **Executive Committee**.

The BHIVA Guidelines Subcommittee is formed from nationally elected members of BHIVA who are elected to serve as trustees on the BHIVA Executive Committee for 3 years by the members of the Association. The trustees are representative of members working both in London and elsewhere in the UK. Members of the Executive Committee then elect to serve on two subcommittees of BHIVA on an annual basis. Additional members are then appointed onto the subcommittees in order to enhance any specific areas of expertise in accordance with the rules of the Association (see Appendix 3).

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 guidelines 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 good practice arising out of guidelines.

The original antiretroviral treatment guidelines and their subsequent revision were published as position statements in *The Lancet*<sup>1,2</sup>. Subsequent 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 Grades of Recommendation, Assessment, Development and Evaluation (GRADE) will be introduced to provide a transparent assessment of both the strength of recommendations and level of evidence for new guidance produced from 2011. **The use of GRADE has been adopted by other national and international guideline development groups.**

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

The main target audience for the BHIVA guidance is the entire HIV community caring for patients with HIV disease within the UK healthcare system; however, it is recognised that these guidelines have had considerable international influence. The key 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 patients with HIV disease (e.g. dietitians, HIV pharmacists, social workers).

## **1.2 Aims and structure of the guideline development manual**

This guidelines framework document replaces the previous Guidance for BHIVA Guidelines Development first agreed in 2007 and last updated in 2010.

The main aims of this framework document are:

- To combine the range of improvements introduced into the guideline development process in recent years into a single document
- To develop a reference tool for current and future co-authors of guidelines
- To summarise the guideline process for all users of the guidance but especially for members of BHIVA, stakeholders, patients and sister agencies

Based on the Appraisal of Guidelines for Research and Evaluation (AGREE) Instrument<sup>9</sup> the subsequent sections of this policy document demonstrate that BHIVA guidelines are:

- Produced to promote clinical care for those living with HIV and reduce the associated morbidity and mortality
- Produced by HIV specialists and other healthcare professionals caring for patients with HIV disease 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 and graded on the best available evidence
- Designed to provide recommendations – strong or weak – weighing up the cost, burden and benefits of treatment or intervention

- Designed to provide audit measures for the guideline recommendations
- Recognised by the US Department of Health and Human Services (DHHS), European AIDS Clinical Society (EACS) and other international HIV guideline development groups

### **1.3 Review and update of the guideline development manual**

It is planned that this manual will be updated every 3 years by the BHIVA Guidelines Subcommittee subject to ratification by the Executive Committee.

## **2. Selection and planning of guideline topics**

### **2.1 Selection criteria for guideline topics**

The *Standards for HIV Clinical Care, 2007*<sup>10</sup> highlights the need to identify markers of good practice to deliver equity of access, patient choice and a high quality of care to patients 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 guidance will be selected to cover all of the main areas of clinical management of patients with HIV disease. These topics are primarily proposed by the BHIVA Guidelines Subcommittee (see section 3.1). Additionally, topics identified by the Department of Health and NHS Scotland as well as any future NHS quality standards may inform guideline topic areas.

In addition, any member of the Association can suggest a topic for guidance to be formulated by the Association. This is submitted on a proposal form and considered by the BHIVA Guidelines Subcommittee and forwarded to the Executive Committee to be approved for development (Appendix 10).

The topics for guidance are submitted to and approved by the BHIVA Executive Committee before being placed on the BHIVA website: [www.bhiva.org](http://www.bhiva.org)

In addition, specialist areas of guidance that will require development in collaboration with other specialist societies 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.

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

### **2.2 Timelines for development of guidelines**

The dates of planned guidelines are published in the guidelines section of the BHIVA website.

Dates covered by the initial literature search performed in the preparation of the guidance should be recorded in the introduction section of the guideline. The timeline for the

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

If a writing group fails to 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.

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

For existing guidelines the date of completion of the current guideline is clearly displayed on the BHIVA website main guidelines page: <http://www.bhiva.org/PublishedandApproved.aspx>; if not already explicitly stated, the proposed date for updating the guidance will be determined by the BHIVA Guidelines Subcommittee and stated on the website.

In addition, the dates of the first and final drafts are recorded on the website in the archived PDF versions at the foot of the current guideline.

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

## **2.3 Composition and responsibilities of the BHIVA Guidelines Subcommittee and writing groups**

### 2.3a

Membership of the BHIVA Guidelines Subcommittee comprises a chair, vice-chair, ordinary members, a community representative, the Editor of *HIV Medicine* 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. Appointed 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.

### 2.3b

The chair and co-chair of each writing group are nominated by the BHIVA Guidelines Subcommittee, and one is usually from within the subcommittee membership; both should be recognised as experts within the chosen field. These act as the two lead authors for the guideline. The lead author has responsibility for timely preparation of the guideline. For most of the guidelines he/she will step down for the next planned update and the co-chair will prepare the next guidance with a new co-chair. This approach helps to maintain continuity whilst extending expert peer involvement and so assures the quality of future guidance. For some highly specialised areas (such as HIV-2 infection or pregnancy) there may be too few experts in the field for this approach to be possible for each successive guideline. In these situations, with successive versions of a set of guidelines, the lead author should certainly rotate within a specialist writing group, but may be required to remain within the group if it is felt that there are insufficient suitable alternatives. This will be determined by the BHIVA Guidelines Subcommittee.

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

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 and co-chair together with the guidelines writing group. The writing group will always contain at least one community representative elected and independently nominated by the UK Community Advisory Board (UK-CAB)\* and may also contain representatives from the nursing and pharmacy professional groups where relevant. All guideline writing groups should consider an open invitation to the membership to apply to join the writing group if they have the relevant experience, enthusiasm and time.

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 guidance, 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.

\*The UK-CAB is a network for community HIV treatment advocates across the UK: [www.ukcab.net](http://www.ukcab.net).

## **2.4 Declaration of conflicts of interest (see Appendix 5)**

The Association has had a policy on conflict of interest for members of its Executive Committee since 2005 and all guidelines published in *HIV Medicine* from 2000 should contain a full declaration of author's conflicts of interests.

From 2011 additionally all members of the writing groups 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 **guidelines writing group**. The conflict of interest statements 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.

## **2.5 Funding of guideline development**

BHIVA was founded in 1995 and was registered as a charity on 24 June 1996 in England and Wales with number 1056354.

BHIVA guidelines are not funded by any external organisation, commercial company or charity other than BHIVA itself. The BHIVA Guideline 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 costs of the BHIVA Secretariat for all administration as required).

## **3. Development process of the guidelines**

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

- Development is carried out by nationally representative experts in the field of HIV medicine who are free of overt conflicts of interest.
- The expert group commissions a systematic review to identify and critically appraise the evidence.
- Recommendations using the GRADE system are explicitly linked to the supporting evidence.



- 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.

### 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 patients with HIV disease.

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 which 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 in the guidance:

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

The definition of the target population and interventions is an essential component in the development of the guideline recommendations in the management of HIV disease and in the published data which provide the supporting evidence for the recommendations. Application of these principles is readily achieved using the Patient or Population/ Intervention or Indicator/ Comparison or Control/ Outcome (**PICO**) framework.

The **patients or population** of interest are patients with HIV infection on or off treatment. Within this population there are a number of groups such as those co-infected with hepatitis. BHIVA guidance applies to adolescents and adults with HIV disease; separate guidance for children with HIV disease is prepared by the Children's HIV Association (CHIVA). A link with the guidance on HIV treatment and care in children prepared by CHIVA is on the BHIVA website: [www.bhiva.org/ClinicalPractice.aspx](http://www.bhiva.org/ClinicalPractice.aspx).

The guidance is careful not to make recommendations which may prejudice clinical care based on gender, age, ethnicity or socio-economic status. No adult patients with HIV disease are excluded from the guidance.

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

The **comparisons** in the BHIVA guidance mainly involve comparison between different drug treatment options.



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

### **3.2 Systematic literature review**

It is recognised that there are ever-increasing demands on members' time, and BHIVA also recognises that the writing group 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 Co-ordinator to play a major role in performing the literature search and review and supporting the authors with appraisal of papers, grading of evidence and production of evidence tables (see Appendix 6).

The co-authors in 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 Co-ordinator 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 on PubMed, EMBASE and/or Medline using key search terms documenting the relevant literature for the search terms within the guideline topic agreed by the guideline writing group as well as a review of the Cochrane Library Database.

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 (as opposed to abstracts) from key international meetings, is considered and reviewed. This includes the British HIV Association annual conference, the Conference on Retroviruses and Opportunistic Infections (CROI), the European AIDS Clinical Society (EACS), the International AIDS Society conference (IAS), 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 such as DHHS, EACS or guidelines relevant to the topic.

### **3.3 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

In some areas in 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).

### **3.4 Grading the guideline recommendations**

In recent years, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group has developed a new 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<sup>11</sup>.

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 trade-offs between the benefits on the one hand, and 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 pregnant women be offered an HIV test at an early stage in pregnancy or as soon as possible if they present for antenatal care at a later stage."

- “We suggest that elective vaginal delivery should be an option for women with no detectable viraemia on HAART.”

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 randomised controlled trials, or overwhelming evidence of some other sort (such as well-executed observational studies with very strong effects).
  - Grade B evidence means moderate-quality evidence from randomized 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.
4. 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 study limitations, inconsistency between studies, surrogate outcome but no direct patient outcomes or bias
  - Raise grade if confounders would have reduced the observed effect, strong association without plausible confounders or large dose–response effect

For a summary of the modified GRADE system, see Appendix 7.

### **3.5 Consensus process for grading of the recommendations**

Based upon 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 the Table (see Appendix 7) and text in section 3.4. 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 amongst the co-authors in the guidelines writing group then this should be initially resolved in the first instance by reasoned discussion until unanimous consensus is achieved. If this is not possible then the lead author should organise a vote on the contentious issue with the lead author abstaining. If the vote is tied then the lead author can use a casting vote. The vote should be recorded in the writing group minutes.

Any issues of disagreement should be reviewed initially after the public consultation stage with comments specifically invited on any contentious issue. These issues should then be revisited by the guidelines writing group with the results of the consultation for preparation of

the final draft for peer review, and again after external peer review. If there is still disagreement within the writing group the process to achieve resolution detailed above should be repeated.

If the issue is not unanimously resolved this fact should be recorded as a majority decision in the guidance and the vote noted in the minutes of the writing group. These will be made public on the Association's website.

There will then be a review of the draft guideline by the BHIVA Guidelines Subcommittee using the proforma (Appendix 8). Comments made will be fed back to 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 guidance.

### **3.6 Consultation and peer review of the guideline modules**

Consultation of the recommendations within the guidelines is achieved by inviting feedback from the membership of BHIVA and any other interested party including the general public on the recommendations via the public section of the BHIVA website. An expert external peer review is undertaken simultaneously with nominated international experts in the field.

### **3.7 Public and peer review of the guideline**

The first draft of the guidance is subject to review by all of the membership of BHIVA invited stakeholders, service users and any member of the general public. The membership of BHIVA exceeds 900 people and includes almost all of the HIV consultants in the UK. The main steps in review of the first draft are:

1. The first draft of new or updated guideline is put on the guidelines page of the public access section of the BHIVA website with a request for comments to be sent by email to the lead authors within one month.
2. At the same time all BHIVA members (as well as committee members) are informed about this by email by the BHIVA Secretariat and via a notice on the BHIVA website.
3. Lead authors will also ask other key stakeholders, to comment on the first draft within 1 month.
4. The community representative on the writing group will circulate the draft to the community advisory board and will collate any responses from the community and patient representatives and send these to the lead author.
5. Lead authors will collate 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 lead authors should send the final draft and the summary of comments received and key changes to the Chair of the BHIVA Guidelines Subcommittee within 1 month of the deadline for receipt of comments on the first draft.

### **3.8 Peer review of the guideline**

During the public consultation period the chair and vice-chair of the writing group nominate 2–3 independent reviewers to the chair of the BHIVA Guidelines Subcommittee, who then arranges for the final draft of the guidance to undergo external peer review. These will be internationally acknowledged experts in the field 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.

### **3.9 Approval of the final version**

The writing group will meet to discuss the results of the public consultation and peer review and will amend the draft guidelines, if appropriate, in preparation for the final draft. The same processes for grading evidence and resolving differences in opinion will be used as detailed above. If the public consultation and peer review reveal significant areas of difference of opinion or controversy, consideration will be given to publication of the public consultation responses on the Association's website with the consent of the commenter.

The chair of the BHIVA Guidelines Subcommittee puts forward the final version for review and endorsement by the BHIVA Executive Committee at one of the meetings of the BHIVA Executive Committee or by email correspondence. Once approved, the final version is published and locked in the main guidelines page of the website with a notice of the dates of e-publication and planned review.

### **3.10 Updating existing guidelines**

The dates of planned updates of existing guidelines will be published on the main guidelines page of the website with each guideline with the intention that updates of existing guidelines should be available when the current guidance expires. The BHIVA Guidelines Subcommittee has the discretion to commission new or revised guidelines prior to the planned expiry of existing guidance, for example if new evidence becomes available to change practice.

If important new information from high quality studies becomes available prior to planned updates, the electronic website modular format permits selected recommendations to be made as an addendum or amendment to existing guidelines as a consensus statement, if this is deemed appropriate. This process would only be appropriate in extraordinary circumstances where the time taken for a formal revision of the guidelines would not be acceptable. This extraordinary addendum or amendment would need the support of both the BHIVA Guidelines Subcommittee and the BHIVA Executive Committee.

### **3.11 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).

### **3.12 Resource implications of the guideline recommendations**

Management of HIV disease 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 Added Life Years (QALYs) vs. 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 guidance will always make recommendations not to follow a specified form of treatment when the risks/harms exceed the assessed health gain.

## **4. Standard format of guidelines**

### **4.1 Layout of the guidelines**

There is a standard format for all modules of BHIVA guidelines as follows:

- Title page
- Contents page
- Introduction (including search methods)
- Scope and purpose
- Summary of all clinical practice recommendations
- Summary of all audit measures
- Rationale of each recommendation or group of recommendations followed by all of the references cited in the rationale
- Acknowledgements (including co-authors' conflicts of interest)
- Expiry date and date of review

### **4.2 Introduction**

In the introduction the guideline authors should indicate the background and rationale for the development of the guideline. Links to prior versions of the guideline and links with the guidelines of other international and national guideline development groups should be described when appropriate.

The search strategy with dates of search, search terminology and methods should be described in the introduction. Harmonisation with the recommendations from other international HIV guidelines should be acknowledged to provide clarity to the guidance user. The method of grading the strength of recommendations and level of supporting evidence should be described.

### **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 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.

#### **4.5 Supporting rationale and references for recommendations**

This section provides the rationale and chain of logic for the guidance 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.

#### **4.6 Summary of audit measures**

Each guideline contains a number of audit measures to assist with implementation of the guidance, promote an 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.

#### **4.7 Acknowledgements and declarations of interest**

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

All authors will provide declarations of interest in accordance with the conflicts of interest policy of the Association (see Appendix 5).

#### **4.8 Expiry date and date of review**

The expiry date of the guidelines will be stated on each guideline. This will usually be three (3) years subject to review by the BHIVA Guidelines Subcommittee but may be sooner where there is frequent change in data to inform practice, e.g. antiretroviral treatment.

### **5. Dissemination and implementation of the guidelines**

#### **5.1 Notification of e-publication of the final version**

The membership of BHIVA is notified by email when a final version of a clinical guideline is posted on the main guidelines page on the website: [www.bhiva.org](http://www.bhiva.org).

The previous versions of the guidance are published electronically rather than in print.

A patient-friendly version of the guidelines will be produced in conjunction with the community for dissemination to service users and will be included as an annexe to the main guidance. This will be available for free download on the Association's website.

Current and guidelines under review are published on the main guidelines page: <http://www.bhiva.org/PublishedandApproved.aspx>.

- Planned guidelines are published on the guidelines in development page.



- Guidelines produced in collaboration with other associations are published in the other guidelines page.
- Historical BHIVA guidelines are archived at:  
<http://www.bhiva.org/ArchivedGuidelines.aspx>

## **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 guidance. 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 all of the audit measures in each guideline is included before the rationale section of all of the recommendations.

The audit measures may be used for local and regional audit by individual HIV units and all of 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 that implementation of all of the recommendations covered by national audit is high. Some of the established audit measures have been used as performance indicators by BHIVA for many years and are utilised to compare the performance of HIV units across the UK. The latter is published online by BHIVA on [www.bhiva.org](http://www.bhiva.org).

## **5.3 Dissemination and implementation initiatives**

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

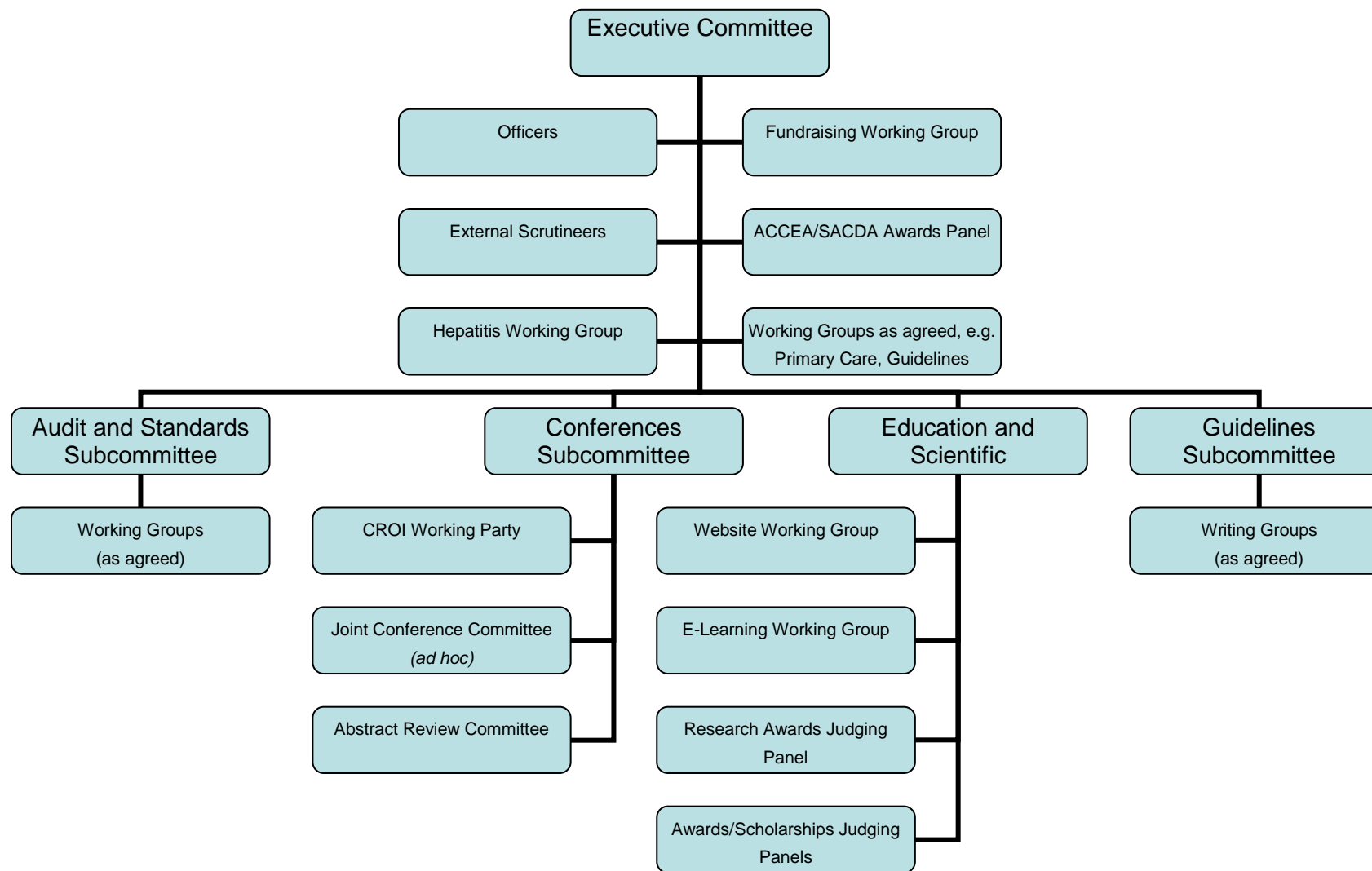
1. Each guideline has a summary of recommendations after the contents and introduction. This section of the guideline can be readily downloaded from the website as a concise summary of the recommendations without needing to read, download or print the entire guideline document.
2. The BHIVA Education and Scientific Subcommittee will liaise with the BHIVA Guidelines Subcommittee to produce educational CPD-accredited material to support the guidelines, including E-Learning material.
3. All of the 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 all 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. E-publication is planned on the BHIVA website and in *HIV Medicine* or other journal on completion of guidelines. The e-publications on the journal publisher's website will be cited by PubMed and Medline which should promote dissemination of the guidance.

## 6. References

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2. B Gazzard, G Moyle for the BHIVA Guidelines Writing Committee. 1998 revision to the British HIV Association guidelines for antiretroviral treatment of HIV seropositive individuals. *Lancet* 1998; **352**: 314–316.
3. BHIVA Writing Committee on behalf of the BHIVA Executive Committee. British HIV Association (BHIVA) guidelines for the treatment of HIV-infected adults with antiretroviral therapy. *HIV Medicine* 2000; **1**: 76–101.
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5. BHIVA Writing Committee on behalf of the BHIVA Executive Committee. British HIV Association (BHIVA) guidelines for the treatment of HIV-infected adults with antiretroviral therapy. *HIV Medicine* 2003; **4** (Suppl 1): 1–41.
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7. B Gazzard on behalf of the BHIVA Writing Committee. British HIV Association (BHIVA) guidelines for the treatment of HIV-infected adults with antiretroviral therapy (2006). *HIV Medicine* 2006; **7**: 487–503.
8. B Gazzard on behalf of the BHIVA Treatment Guidelines Writing Group. British HIV Association guidelines for the treatment of HIV-1-infected adults with antiretroviral therapy 2008. *HIV Medicine* 2008; **9**: 563–608.
9. The AGREE Collaboration. Appraisal of Guidelines Research and Evaluation. [www.agreecollaboration.org](http://www.agreecollaboration.org)
10. The British HIV Association, the Royal College of Physicians, London, the British Association of Sexual Health and HIV, and the British Infection Society. Standards for HIV Clinical Care, 2007. [www.bhiva.org/ClinicalStandards.aspx](http://www.bhiva.org/ClinicalStandards.aspx)
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## Appendix 1

### Structure of BHIVA as of 13 September 2011



## Appendix 2

### BHIVA Guidelines Subcommittee – Terms of Reference

#### CONTENTS

1. Structure
2. Purpose
3. Remit
4. Membership
5. Operational procedures

#### 1. Structure

BHIVA currently has four subcommittees – Audit and Standards, Conferences, Education and Scientific, and Guidelines. However, there are proposals to re-classify some of the Working Groups as subcommittees. Other groups are: Clinical Excellence Awards Nominating Panel, External Scrutineers, Hepatitis Working Group, Fundraising Working Group, CPD E-Learning Working Group, Research Awards Judging Panel, Awards and Scholarships Judging Panel, CROI Working Party, Abstract Review Committee (see Appendix 1 for chart of BHIVA structure).

#### 2. Purpose

The purpose of this subcommittee was last updated on 17 May 2011.

The general purpose of the Guidelines Subcommittee is to oversee the governance of the development of the guidelines to ensure that the guidelines produced are fit for purpose in setting the standards of best clinical practice and are consistent with the BHIVA process for guidelines development. To ensure that the guidelines produced cover the key areas of HIV medicine management in the UK.

#### 3. Remit

The remit of this subcommittee was last updated on 1 July 2011.

- 3.1. To agree and review every the guidelines development process manual every three years.
- 3.2. To set up and appoint the chair of writing groups whose purpose is to draw up national guidelines for best clinical practice for the care of persons infected with HIV infections and other topics as necessary.
- 3.3. To set up the purpose and remit of the writing groups and the timelines for guidelines production.
- 3.4. To review, make recommendations and approve guidelines for best clinical practice produced by the writing groups to be subsequently presented to the Executive Committee for ratification.
- 3.5. To agree which guidelines are appropriate and fit within the priorities of BHIVA, including nominations from members.
- 3.6. To confirm any endorsements or co-badging at the setup of any guidelines writing group and to agree which organisation is the lead organisation and therefore which guidelines development process should be followed.

- 3.7. To review the proposed membership of guidelines writing groups including:
  - i. To review conflict of interest declarations (Subcommittee chair and vice-chair
  - ii. To ensure the writing group membership is consistent with agreed guidelines development process.
  - iii. To ensure there is appropriate expertise.
  - iv. To ensure there is broad geographical representation where appropriate.
  - v. To ensure there is appropriate user involvement.
- 3.8. To monitor and oversee the progress of guidelines writing groups and to ensure that these are progressing according to the agreed process and timelines.
- 3.9. To provide advice and support to chairs and vice-chairs of writing groups and to assist with any problems that may arise with the process or timeline.
- 3.10. To review the first draft of every guideline to ensure it fulfils the requirements of the guidelines writing process.
- 3.11. To review the final guideline to ensure that adequate consideration has been given to input from consultation and peer review.
- 3.12. To review existing BHIVA guidelines and their timelines for review and to recommend if any interim statements or earlier update is required.
- 3.13. To liaise with the BHIVA Audit and Standards Subcommittee regarding audit issues.
- 3.14. To liaise with the BHIVA Education and Scientific Subcommittee regarding educational tools to assist guidelines implementation.
- 3.15. To liaise with the BHIVA Conferences Subcommittee regarding inclusion in the BHIVA scientific programmes.
- 3.16. To ensure the clinical guidelines section of the BHIVA website section is up to date, accurate and user friendly.
- 3.17. To liaise with the Editorial Board of *HIV Medicine* or other journals as necessary to ensure that guidelines are published to appropriate standards and timelines.
- 3.18. To help promote and disseminate best clinical practice guidelines to the Association's members and other clinical organisations and institutions that have a duty of care for people infected with HIV.
- 3.19. To carry out work as directed by the Executive Committee.
- 3.20. To suggest, or to receive a suggestion(s) from the Executive Committee for, the creation of a working group to undertake a particular project. The terms of reference of the parent subcommittee will apply.
- 3.21. To write a report on the work of the subcommittee on an annual basis by the chair of the subcommittee, for inclusion in the BHIVA Annual Report and Accounts.
- 3.22. To report to Executive Committee meetings as requested by the chair of BHIVA.
- 3.23. To make a detailed presentation to the Executive Committee on an annual basis.
- 3.24. To submit any requests for financial commitment to the BHIVA Honorary Treasurer and Executive Committee for approval.

#### **4. Membership**

The subcommittee should be appointed to best achieve the remit of the subcommittee and should be inclusive and properly representative of the BHIVA membership, including regional representation, level of expertise and community representation.

Each subcommittee must have the following:

#### 4.1. Chair

- To be appointed/ elected by the Executive Committee, with nominations and an election.
- Must be a member of the Executive Committee.
- Would be an advantage previously to have served on the relevant subcommittee.
- Tenure of chair will be two (2) years.

#### 4.2. Vice-Chair

- To be appointed/ elected by the chair of the subcommittee (approved by the Executive Committee).
- Tenure of vice-chair will be two (2) years, renewable.

#### 4.3. Community representative

- At least one Community Representative to be put forward by UK-CAB.

#### 4.4. Trustees on a self-select basis

- BHIVA Trustees are asked on an annual basis to select up to two subcommittees of their choice.
- It is recommended that each Trustee serves two consecutive years on a subcommittee.
- It is recommended that the BHIVA Officers review these selections and seeks to provide a good balance of numbers of BHIVA Trustees on each subcommittee.

4.5. Chair of subcommittee has the authority to appoint additional members taking into consideration the specific requirements of each subcommittee's specialty, skill, regional representation, stakeholders, etc.

4.6. Conflict of interest declaration to be completed by all members.

4.7. The subcommittee shall consist of 6 minimum and 20 maximum members.

4.8. Tenure of membership will be two (2) years.

4.9. Automatic resignation will ensue following non-attendance at three (3) consecutive meetings without reason.

4.10. Retention of former trustees – up to the individual member to consider if he/she wishes to remain on the subcommittee, subject to the agreement of the subcommittee chair.

### 5. Standard Operating Procedures

Each subcommittee is required to follow the following standard procedures:

5.1. Frequency of meetings (face to face or by telephone/video conference) will be as follows:

- Minimum three (3) per annum, excluding meetings of specific Guidelines Writing Groups

5.2. Quorum

- Must be one more than fifty (50) per cent of the membership. Must include chair or vice-chair

5.3. Voting

- Each member will have a single vote. In the case of a tie the chair (or whoever is chairing that meeting) will have a second and casting vote

#### 5.4. Documentation

- Agendas, minutes and other papers will be prepared by the Secretariat for approval by the chair before distribution.
- Members are asked to put forward any request for an agenda item (two (2) weeks before the scheduled date of the meeting).

5.5. The subcommittee group can recruit a suitably qualified co-ordinator to work as appropriate to carry out work over and above previously defined work of the subcommittee, e.g. a co-ordinator, subject to the approval by the Honorary Treasurer of any costs.

5.6. Subcommittees would not engage in activity that would be in contradiction to the BHIVA constitution.

5.7. Subcommittees would not engage in activity that could jeopardise the charitable status of BHIVA.

#### 5.8. Grievance procedure

- Any grievance by an individual member to be firstly addressed by the chair of the subcommittee. Should this fail to resolve the matter, it will be referred by the chair of the subcommittee to the BHIVA Executive Committee. If the Executive Committee recommendation should also fail to satisfy, the BHIVA External Scrutineers will be asked to review the case notes and provide the Executive Committee with a recommendation. The final decision to be taken by the BHIVA Executive Committee.

#### 5.9. Amendments

- Amendments to the terms of reference to be approved by the Executive Committee.



## Appendix 3

### Rules of the Association

#### 1. Name

The Association shall be known as the 'British HIV Association', hereinafter called BHIVA, and referred to as such or as 'the Association' or 'the Charity'.

#### 2. Objects

The objects of BHIVA are:

- (a) To relieve sickness and to protect and preserve health through the development and promotion of good practice in the treatment of HIV and HIV-related illnesses, and in such other charitable ways as BHIVA, through its Executive Committee, may from time to time decide;
- (b) to advance public education in the subjects of HIV and the symptoms, causes, treatment and prevention of HIV-related illnesses through the promotion of research and the dissemination of the useful results of such research, and in such other charitable ways as BHIVA, through its Executive Committee, may from time to time decide.

#### 3. Powers of the Association

In furtherance of the above objects BHIVA shall have the following powers:

- (a) to raise funds; but in such a way that the Association does not undertake any substantial, permanent trading activity;
- (b) to disseminate the results of research through scientific meetings and through the official publications of BHIVA;
- (c) to act as a national advisory body to professions and other organisations on all aspects of HIV care;
- (d) to provide a national platform for HIV care;
- (e) to provide representatives for international, national and local committees dealing with HIV care;
- (f) to promote undergraduate, postgraduate and continuing medical education within HIV care;
- (g) to promote and monitor high standards of care through advisory groups and the development and distribution of guidelines;
- (h) to set achievable targets and indicators of care against which success can be measured through national audit and other governance measures;
- (i) to publish and promote material related to the aims and objectives of BHIVA;
- (j) to do all such other things as shall further the objects of the Association.

#### **4. Membership**

- (a) Membership of BHIVA will be open to the following categories of personnel involved in HIV care:
  - (i) those working within professions or industry, or other appropriate HIV active healthcare workers, where a significant component of their work is directly or indirectly related to HIV care;
- (b) application for membership to the Association shall be made by completing a membership application in the form determined by the Executive Committee, periodically, and returning it to the secretariat with the appropriate fee;
- (c) the Executive Committee may only refuse an application for membership if, acting reasonably and properly, they consider it to be in the best interests of the Charity to refuse the application;
  - (i) the Executive Committee must inform the applicant in writing of the reasons for the refusal;
  - (ii) the Executive Committee must consider any written representations the applicant may make about the decision. The Executive Committee's decision following any written representation must be notified to the applicant in writing but shall be final;
- (d) membership is not transferable to any other person;
- (e) the Executive Committee must keep a register of names and addresses of the members;
- (f) the membership year runs from 1 January to 31 December, or as determined by the Executive Committee;
- (g) subject to any alteration to Rule 4(f), annual subscriptions paid by members joining BHIVA after 31 October shall be regarded as being in respect of the year ending 31 December the following year. The annual subscription is payable in advance on or before 1 January in each year and members whose subscriptions remain unpaid by 28 February following will be regarded as in arrears and, following a reminder, may cease to be a member of the Association.

#### **5. The Executive Committee**

- (a) BHIVA will be governed by an Executive Committee, which shall regulate the business of BHIVA, including annual subscription and the direction and management of its funds;
- (b) all members of the Executive Committee will be deemed to be 'Trustees' of the Association;
- (c) subject to Rule 5(d), the Executive Committee will consist of no more than twenty members including:
  - (i) 14 elected members; in the situation where the numbers of resigning elected members exceeds nominations, the Executive Committee may appoint additional members as under 5(d);

- (ii) 1 junior consultant doctor's representative, defined as a consultant within the first 5 years of his/her appointment as a consultant, to be elected by the membership;
  - (iii) the Editor of HIV Medicine or any successor publication; and
  - (iv) 1 community representative.
- (d) the Executive Committee may, from time to time, appoint additional members to the Executive Committee being members of BHIVA – but so that there will never be more than three such additional members serving at any one time – and any additional member appointed by the Executive Committee:
- (i) must retire at the next Annual General Meeting, but will be eligible to stand for election by the members of BHIVA, or for re-appointment by the Executive Committee; for a maximum of two consecutive years;
  - (ii) may only be appointed as an office holder if he or she has not just retired under the provision of Rule 5(d)(i); and
  - (iii) must not be taken into account in determining the members of the Executive Committee who are to retire by rotation.

*As far as possible, membership of the Executive Committee will provide a balance of disciplines and regional representation, and endeavour to achieve 50% representation of the London region and 50% outside London.*

## **6. Appointment and rotation of the members of the Executive Committee**

- (a) The elected members of the Executive Committee shall serve for three years;
- (b) at each Annual General Meeting the elected members of the Executive Committee who have completed a three year term or must retire from the committee. Officers continue to be members of the Executive Committee until the end of their tenure as an Officer;
- (c) any member of the Executive Committee retiring at the Annual General Meeting will be eligible for re-election;
- (d) if a member of the Executive Committee is required to retire at an Annual General Meeting by a provision of these Rules, the retirement shall take effect upon the conclusion of the meeting;
- (e) other than the appointment under Rule 5(c) (iii) and (iv) and Rule 5(d), appointments to the Executive Committee shall be by election by the members of BHIVA;
- (f) the request for nominations shall be sent out no less than 3 months before the Annual General Meeting each year to all paid up members having joined the Association no less than 5 months before the Annual General Meeting. Nominees, proposers and seconders must be current BHIVA members and must have been members for at least two consecutive years at the time of nomination;
- (g) any member of the Executive Committee intending to relinquish their positions on the Executive Committee of the Association before the normal retirement date should inform the Secretary as soon as possible, or in any event 4 months before the Annual General Meeting;

- (h) a list of nominees will be forwarded to all eligible members of the Association with a request for their selections to fill the vacancies;
- (i) the election scrutineer will normally be the immediate past Chair of the Association or another person nominated by the Executive Committee;
- (j) the results of the election shall be declared at the Annual General Meeting.

## **7. Disqualification and removal of Trustees**

A member of the Executive Committee shall cease to hold office if he or she:

- (a) is disqualified from acting as a Trustee by virtue of Section 72 of the Charities Act 1993 (or any statutory re-enactment or modification of said Section);
- (b) ceases to be a member of the Association;
- (c) becomes incapable by reason of mental disorder, illness or injury of managing and administering his or her own affairs;
- (d) resigns as a member of the Executive Committee by notice to the Secretary (but only if at least two members of the Executive Committee will remain in office when the notice of resignation is to take effect); or
- (e) is absent without the permission of the Executive Committee from 3 consecutive meetings and the Executive Committee resolves that his or her office be vacated.

## **8. Powers of the Executive Committee**

The Executive Committee shall have the following powers:

- (a) it shall appoint from amongst its number the office holders of Chair, Treasurer and Secretary to serve for three years (see Byelaws 2 and 4);
- (b) it may appoint a secretariat and conference organisers to assist the Association to carry out its day-to-day business in pursuance of the Charity's objects. The secretariat will report directly to the Executive Committee via the officers;
- (c) it may appoint and make Rules for sub-committees to assist it in the management of the Association; but so that all acts and proceedings of such sub-committees shall be reported fully to the Executive Committee;
- (d) it may appoint external scrutineers to consult on matters of importance to the Association, for such periods and subject to such terms of reference as the Executive Committee shall, from time to time, establish;
- (e) it will appoint Chairs for each sub-committee:
  - (i) Following nominations, an election will take place, unless the Executive Committee is unanimously agreed. In the absence of a simple majority, the Chair shall have a second or casting vote.
- (f) it may invite, as observers, to its meetings such persons as it considers appropriate to provide advice or information to the matters under discussion;
- (g) it may establish a consultative group consisting of such persons, for such purposes and on such terms of reference as the Executive Committee shall, from time to time, determine;

- (h) it may, from time to time, make, alter, add to or repeal bye-laws for the conduct of its business;
  - (i) the bye-laws may regulate the following matters but are not restricted to them:
    - (a) the admission of members of the Association (including the admission of organisations to membership), the rights and privileges of such members, the entrance fees, subscriptions and other fees or payments to be made by members;
    - (b) the conduct of members of the Association in relation to one another, and to the Association's employees and volunteers;
    - (c) the procedure at general meetings and meetings of the Executive Committee insofar as such procedure is not regulated by these Rules;
    - (d) the keeping and authenticating of records (if regulations made under this clause permit records of the Association to be kept in electronic form and require a member of the Executive Committee to sign the record, the regulations must specify a method of recording the signature that enables it to be properly authenticated);
    - (e) generally, all such matters as are commonly the subject matter of the bye-laws of an unincorporated Association;
  - (ii) the Trustees must adopt such means as they deem sufficient to bring the bye-laws to the notice of members of the Association;
  - (iii) the bye-laws shall be binding on all members of the Association;
  - (iv) no bye-law shall be inconsistent with, or shall affect or repeal anything contained in, these Rules.

## **9. Meetings and proceedings of the Executive Committee**

- (a) The Chair shall appoint another Officer to act as Chair at meetings in his or her absence;
- (b) the Executive Committee shall have meetings no fewer than four times a year;
- (c) a quorum for meetings of the Executive Committee shall be one third of the membership including one of the officeholders;
- (d) a vote will be carried by a simple majority. In the case of equality of votes, the Chair will have a second or casting vote;
- (e) for the purpose of this Rule, the expression 'meeting' includes, except where inconsistent with any legal obligation:
  - (i) a physical meeting;
  - (ii) a video conference, an internet video facility or similar electronic method allowing simultaneous visual and audio participation; and
  - (iii) telephone conferencing.

## **10. General meetings of the members of BHIVA**

- (a) An Annual General Meeting must be held in each year and not more than fifteen months may elapse between successive Annual General Meetings;

- (b) all general meetings other than Annual General Meetings shall be called special general meetings;
- (c) the Executive Committee may call a Special General Meeting at any time;
- (d) the Executive Committee must call a Special General Meeting if requested to do so in writing by at least eighty members or one tenth of the membership, whichever is the greater. The request must state the nature of the business that is to be discussed. If the Executive Committee fails to hold the meeting within twenty-eight days of the request, the members may proceed to call a Special General Meeting but in doing so they must comply with the provisions of this constitution;
- (e) the minimum period of notice required to hold any general meeting of the Association is twenty-one days from the date on which the notice is deemed to have been given;
- (f) a general meeting may be called by shorter notice, if it is so agreed by all the members entitled to attend and vote;
- (g) the notice must specify the date, time and place of the meeting and the general nature of the business to be transacted. If the meeting is to be an Annual General Meeting, the notice must say so;
- (h) the notice must be given to all the members of the Association and to the members of the Executive Committee.

#### **11. Quora at general meetings**

- (a) No business shall be transacted at any general meeting unless a quorum is present;
- (b) a quorum is:
  - (i) thirty of the members entitled to vote upon the business to be conducted at the meeting; or
  - (ii) 4 percent of the total membership at the time, whichever is the greater;
- (c) if:
  - (i) a quorum is not present within half an hour from the time appointed for the meeting; or
  - (ii) during a meeting a quorum ceases to be present;the meeting shall be adjourned to such time and place as the Executive Committee shall determine;
- (d) the Executive Committee must reconvene the meeting within 3 months and must give at least 7 clear days' notice of the reconvened meeting stating the date, time and place of the meeting;
- (e) if no quorum is present at the reconvened meeting within fifteen minutes of the time specified for the start of the meeting, the members present at that time shall constitute the quorum for that meeting.

## **12. Chairing general meetings**

- (a) General meetings shall be chaired by the person who is the Chair of the Executive Committee in office at the start of the general meeting;
- (b) if there is no such person, or he or she is not present within fifteen minutes of the time appointed for the meeting, a member of the Executive Committee nominated by the Executive Committee shall chair the meeting;
- (c) if there is only one member of the Executive Committee present and willing to act, he or she shall chair the meeting;
- (d) if no member of the Executive Committee is present and willing to chair the meeting within fifteen minutes after the time appointed for holding it, the members present, and entitled to vote, must choose one of their number to chair the meeting.

## **13. Adjournments of general meetings**

- (a) The members present at a meeting may resolve that the meeting shall be adjourned;
- (b) the person who is chairing the meeting must decide the date, time and place at which the meeting is to be reconvened unless those details are specified in the resolution;
- (c) no business shall be conducted at an adjourned meeting unless it could properly have been conducted at the meeting had the adjournment not taken place;
- (d) if a meeting is adjourned by a resolution of the members for more than 7 days, at least 7 clear days' notice shall be given of the reconvened meeting, stating the date, time and place of the meeting.

## **14. Votes at general meetings**

- (a) Each member shall have one vote, but if there is an equality of votes the person who is chairing the meeting shall have a second or casting vote in addition to any other vote he or she may have;
- (b) a resolution in writing signed by each member, who would have been entitled to vote upon it had it been proposed at a general meeting, shall be effective. It may comprise several copies, each signed by, or on behalf of, one or more members;
- (c) the election scrutineer will be appointed by the Executive Committee.

## **15. Representatives of other bodies at general meetings**

- (a) Any organisation that is a member of the Charity may nominate any person to act as its representative at any meeting of the Charity;
- (b) the organisation must give written notice to the Charity of the name of its representative. The nominee shall not be entitled to represent the organisation at any meeting unless the notice has been received by the Charity. The nominee may continue to represent the organisation until written notice to the contrary is received by the Charity;



- (c) any notice given to the Charity will be conclusive evidence that the nominee is entitled to represent the organisation or that his or her authority has been revoked. The Charity shall not be required to consider whether the nominee has been properly appointed by the organisation.

**16. Accounting year**

The accounting year of BHIVA runs from 1 January to 31 December.

**17. Amendments**

- (a) No alteration or addition to these Rules shall be made except by a resolution carried by a majority of at least two thirds of the members present and voting at a general meeting of BHIVA, notice of which shall have contained particulars of the proposed alteration or addition;
- (b) no alteration, amendment or addition to these Rules shall be made which would cause BHIVA to cease to be a Charity at law;
- (c) no amendment may be made to Rule 2 (Objects), Rule 18 (Dissolution) or this Rule 17 (Amendments) without the prior written approval of the Charity Commissioners.

**18. Dissolution**

In the event of BHIVA being dissolved, the property and assets of BHIVA remaining after the satisfaction of all debts and liabilities shall be paid or transferred to a charitable institution or institutions having similar objectives to those of BHIVA.

## Appendix 4

### Summary of steps involved in producing a guideline

1.	Title suggestion approved by the BHIVA Guidelines Subcommittee and agreed by the BHIVA Executive Committee.
2.	Lead author/chair and co-chair identified by BHIVA Guidelines Subcommittee and writing group members nominated by lead author and co-chair. Initial conflict of interest declaration.
3.	Initial meeting to identify questions, and to produce a scope, a search strategy and selection criteria. Allocation of sections/tasks to writing group members. Timeline and date of second meeting agreed.
4.	Scope and questions approved by the writing group.
5.	Data extraction: literature search performed by BHIVA Guidelines Co-ordinator (GC) and identified titles and abstracts forwarded to relevant section author.
6.	Authors, with assistance of GC, systematically sift and discard those that are irrelevant and scrutinize remaining papers to assess if they meet selection criteria. GC to document the selection process.
7.	Critical appraisal of the quality of remaining studies by members of writing group
8.	Section authors write draft review, concise guideline and identify potential audit points and educational tools.
9.	Second meeting to present a synthesis of data, review draft recommendations and establish consensus and implications for practice. GC will summarize recommendations.
10.	Draft documents collated by authors and GC and finalised.
11.	Review by BHIVA Guidelines Subcommittee using checklist (Appendix 8), comments fed back to authors and amendments made.
12.	Publication on BHIVA website for public consultation and sent for external peer review.
13.	Third meeting: consideration of consultation feedback and redrafting, if necessary, in light of received comments.
14.	Review of checklist (Appendix 8) by BHIVA Guidelines Subcommittee.
15.	Redrafting in light of received comments if necessary.
16.	Review by BHIVA Guidelines Subcommittee.
17.	Review by BHIVA Executive Committee.
18.	Publication on BHIVA website/ <i>HIV Medicine</i> or other journal with final conflict of interest statement.
19.	Periodic review: lead authors contacted by guidelines group prior to expiry of guidelines. Literature search re-run by GC. If needed, updated guideline subjected to usual peer review process. If no update needed, renew web-based document with new expiry date.

## Appendix 5

### Competing interest disclosure form: Membership of BHIVA Guidelines Writing Group

*Instructions:*

1. Executive Committee Trustees
  - a. BHIVA requires that all members of the Executive Committee, all members on the guidelines sub-committee and all members and co-opted members of guidelines writing groups as well as any expert external peer reviewers must declare all interests and membership of other committees retrospectively on an annual basis, to give protection to individuals working as BHIVA Trustees.
  - b. Declaration is required at the time of joining BHIVA as a Trustee and annually thereafter. Declaration is required retrospectively for the preceding 12 months from the beginning of membership of the Executive Committee and then annually thereafter until the conclusion of membership of the relevant guidelines writing group.
  - c. All members of guidelines writing groups must undertake a declaration of interests prior to serving on a writing group and this declaration is confirmed and repeated at the publication of each set of completed guidelines published.
  - d. The details given in this form will be retained on a register at the Secretariat and will be made available for publication, if required.
2. Please report all relationships with pharmaceutical, diagnostic, or such similar companies involved in HIV-related products in **[INSERT: year—year (CURRENT AND PRECEDING YEAR)]**. For the purposes of this disclosure, the term ‘member’ includes the BHIVA member and any spouse/partner/ family member.
3. Further information is likely to be requested if any positive responses are given in the sections below.
4. If undisclosed competing interest is later proven, BHIVA will follow Committee on Publication Ethics (COPE) guidelines.
5. If there is nothing to disclose, please so indicate.
6. This declaration covers the period **[INSERT: month/year—month/year (TO COVER 12 MONTHS RETROSPECTIVE TO START OF WRITING GROUP)]** for pecuniary and non-pecuniary interests.
7. A description is also included of the format for a competing interest in a presentation.
8. Please email your completed form by **[DEADLINE – INSERT AS APPROPRIATE]** to the BHIVA Secretariat at [jacqueline@mediscript.ltd.uk](mailto:jacqueline@mediscript.ltd.uk). Signed originals should also be posted to the address below.

<b>Name</b>	
<b>Signature</b>	
<b>Date</b>	

<b>1. Pecuniary interests</b>	<b>None</b>	<b>£<u>≥</u>1,000</b>
<p><b>Consultancy Work</b>            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.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p><b>Speaker fees</b>            This section 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.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p><b>Company shares</b>            This section would include any shares held by the member in the biomedical industry (e.g., pharmaceutical, diagnostic, or such similar companies).</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p><b>Grant support</b>            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 meetings.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p><b>Other paid income</b>            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.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p><b>Other relevant disclosure</b>            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.</p>	<input type="checkbox"/>	<input type="checkbox"/>

<p><b>2. Non-pecuniary interests</b>            You are required to declare any trusteeships in other organisations, other committee memberships or directorships, which have conflicting or competing interests.</p>
<p><b>Trusteeships</b>            Give full name of organisation(s) and information on term served to date and retirement date.</p>
<p><b>Committee memberships</b>            Give full name of organisation(s) and indicate your role on any committees, giving details of term served to date and retirement date.</p>
<p><b>Directorships</b>            Give full name of organisation(s) and information on term served to date and retirement date.</p>

Please email your completed form to [jacqueline@mediscript.ltd.uk](mailto:jacqueline@mediscript.ltd.uk), and post the signed original to:

**BHIVA Secretariat, Mediscript Ltd, 1 Mountview Court, 310 Friern Barnet Lane, London N20 0LD**

## Appendix 6

### **BHIVA Guidelines Co-ordinator: 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.

#### **Person specification**

- Experience of performing scientific literature searches, data extraction and analysis and preferably knowledge of the process of systematic reviews.
- Computer literate with accurate word processing skills and sound knowledge of Windows based applications, Word, Excel and Access.
- 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.
- Knowledge of and interest in HIV desirable.

## Appendix 7

### Summary of the modified GRADE system (grades 1A–2D)

#### 1A

Strong recommendation.

High-quality evidence.

Benefits clearly outweigh risk 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 our 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 risk 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 some other research design. Further research may impact on our confidence in the estimate of benefit and risk.

Strong recommendation and 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 risk 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, and applies to most patients. Some of the evidence base supporting the recommendation is, however, of low quality.

#### 1D

Strong recommendation.

Very low-quality evidence.

Benefits appear to outweigh risk 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 some other form. Further research is unlikely to change our 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 uncertainty 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 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 8

### Checklist for all BHIVA guidelines

	Yes	No	Unsure	Comments
Is the overall objective clear?				
Are the recommendations specific, unambiguous and clearly identifiable?				
Is the population and/or target audience defined?				
Is the language appropriate for the specified target audience?				
Are the clinical, healthcare or social questions covered?				
Are the recommendations in reference to specific clinical, healthcare or social circumstances clear?				
Has there been adequate involvement of patient and stakeholder groups in development e.g. via UK-CAB?				
Are the methods to search for evidence and data clearly defined and adequate?				
Are the criteria and reasons for inclusion or exclusion of evidence by documenting review methods clearly stated?				
Has the GRADE system been used to outline the strengths and limitations of the evidence and acknowledge any areas of uncertainty?				
Has the agreed BHIVA methodology been used to arrive at recommendations including methods to reach consensus?				
Have the health benefits, side effects and risks been considered in formulating recommendations?				
Have the different options for management of the condition been considered and stated?				
Are there auditable standards developed in liaison with BHIVA Audit and Standards Subcommittee?				
Are any potential organisational and financial barriers considered?				

## Appendix 9

### Previous BHIVA guidelines

- BG Gazzard, GJ Moyle, J Weber *et al.* for the BHIVA Guidelines Co-ordinating Committee. British HIV Association guidelines for antiretroviral treatment of HIV seropositive individuals. *Lancet* 1997; **349**: 1086–1092.
- B Gazzard, G Moyle for the BHIVA Guidelines Writing Committee. 1998 revision to the British HIV Association guidelines for antiretroviral treatment of HIV seropositive individuals. *Lancet* 1998; **352**: 314–316.
- BHIVA Writing Committee on behalf of the BHIVA Executive Committee. British HIV Association (BHIVA) guidelines for the treatment of HIV-infected adults with antiretroviral therapy. *HIV Medicine* 2000; **1**: 76–101.
- BHIVA Writing Committee on behalf of the BHIVA Executive Committee. British HIV Association (BHIVA) guidelines for the treatment of HIV-infected adults with antiretroviral therapy. *HIV Medicine* 2001; **2**: 276–313.
- British HIV Association. Guidelines for the management of HIV infection in pregnant women and the prevention of mother-to-child transmission. *HIV Medicine* 2001; **2**: 314–334.
- BHIVA Writing Committee on behalf of the BHIVA Executive Committee. British HIV Association (BHIVA) guidelines for the treatment of HIV-infected adults with antiretroviral therapy. *HIV Medicine* 2003; **4** (Suppl 1): 1–41.
- Poppa A, Davidson O, Deutsch *et al.*; British HIV Association (BHIVA) and British Association for Sexual Health and HIV (BASHH) guidelines on provision of adherence support to individuals receiving antiretroviral therapy (2003). *HIV Medicine* 2004; **5** (Suppl 2): 46–60.
- AL Pozniak, RF Miller, MCI Lipman, AR Freedman, LP Ormerod, MA Johnson, S Collins, SB Lucas on behalf of the BHIVA Guidelines Writing Committee. BHIVA treatment guidelines for tuberculosis (TB)/HIV infection (2005) *HIV Medicine* 2005; **6** (Suppl 2): 62–83.
- Brook MG, Gilson R, Wilkins E; BHIVA Hepatitis Coinfection Guidelines Committee. British HIV Association guidelines on HIV and chronic hepatitis: coinfection with HIV and hepatitis B virus infection (2005). *HIV Medicine* 2005; **6** (Suppl 2): 84–95.
- Nelson M, Matthews G, Brook MG, Main J; BHIVA Coinfection Guidelines Committee. British HIV Association guidelines on HIV and chronic hepatitis: coinfection with HIV and hepatitis C virus infection (2005). *HIV Medicine* 2005; **6** (Suppl 2): 96–106
- Hawkins D, Blott M, Clayden P *et al.*; BHIVA Guidelines Writing Committee. Guidelines for the management of HIV infection in pregnant women and the prevention of mother-to-child transmission of HIV. *HIV Medicine* 2005; **6** (Suppl 2): 107–148.
- S Bhagani, MG Brook, P Sweny on behalf of the British HIV Association and reviewed and endorsed by the British Transplantation Society Standards Committee. Guidelines for kidney transplantation in patients with HIV disease (2005). <http://www.bhiva.org/RenalTransplantation2005.aspx>.

- B Gazzard on behalf of the BHIVA Writing Committee. British HIV Association (BHIVA) guidelines for the treatment of HIV-infected adults with antiretroviral therapy (2005). *HIV Medicine* 2005; **6** (Suppl 2): 1–61.
- B Gazzard on behalf of the BHIVA Writing Committee. British HIV Association (BHIVA) guidelines for the treatment of HIV-infected adults with antiretroviral therapy (2006). *HIV Medicine* 2006; **7**: 487–503.
- M Bower, S Collins, C Cottrill *et al.* on behalf of the AIDS Malignancy Subcommittee. British HIV Association guidelines for HIV-associated malignancies 2008. *HIV Medicine* 2008; **9**: 336–388.
- A de Ruiter, D Mercey, J Anderson *et al.* British HIV Association and Children’s HIV Association guidelines for the management of HIV infection in pregnant women 2008. *HIV Medicine* 2008; **9**: 452–502.
- B Gazzard on behalf of the BHIVA Treatment Guidelines Writing Group. British HIV Association guidelines for the treatment of HIV-1-infected adults with antiretroviral therapy 2008. *HIV Medicine* 2008; **9**: 563–608.
- A Fakoya, H Lamba, N Mackie *et al.* British HIV Association, BASHH and FSRH guidelines for the management of the sexual and reproductive health of people living with HIV infection 2008. *HIV Medicine* 2008; **9**: 681–720.
- AM Geretti on behalf of the BHIVA Immunization Writing Committee. British HIV Association guidelines for immunization of HIV-infected adults 2008. *HIV Medicine* 2008; **9**: 795–848.
- British HIV Association, British Association for Sexual Health and HIV, British Infection Society, UK National Guidelines for HIV Testing 2008  
<http://www.bhiva.org/HIVTesting2008.aspx>
- G Brook, J Main, M Nelson *et al.* on behalf of the BHIVA Viral Hepatitis Working Group. British HIV Association guidelines for the management of coinfection with HIV-1 and hepatitis B or C virus 2010. *HIV Medicine* 2010; **11**: 1–30.
- Y Gilleece, DR Chadwick, J Breuer, D Hawkins, E Smit, LX McCrae, D Pillay, N Smith and J Anderson on behalf of the BHIVA Guidelines Subcommittee. British HIV Association guidelines for antiretroviral treatment of HIV-2-positive individuals 2010. *HIV Medicine* 2010; **11**: 611–619.

## Appendix 10

### Suggestion form for future BHIVA guidelines

If you have a suggestion for a future guideline, please submit it to the BHIVA Guidelines Subcommittee who will consider it and forward it, if agreed, to the BHIVA Executive Committee for consideration. Suggestions can be submitted by email to [bhiva@bhiva.org](mailto:bhiva@bhiva.org) or through the BHIVA website at: <http://www.bhiva.org/FutureGuidelinesSuggestion.aspx>.

We are particularly interested in:

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

<b>Suggestion for future guideline</b>	
<b>Which area(s) for prioritisation does this meet?</b>	<ul style="list-style-type: none"> <li>▪ Areas of variation in clinical practice</li> <li>▪ Areas of variation in patient outcomes</li> <li>▪ Resources to provide high-quality patient care</li> <li>▪ Interventions, procedures and drug management which influence patient morbidity and/or mortality</li> <li>▪ Patient safety and avoidance of preventable complications</li> </ul>
<b>Name</b>	
<b>Institution</b>	
<b>Address for correspondence</b>	
<b>Email address</b>	