Full title:

British Association for Sexual Health and HIV:

2015 Framework for guideline development and assessment (2019 update)

Short title:

BASHH framework for guideline development

Key Words:

Treatment, screening

Abstract

The Clinical Effectiveness Group (CEG) of the British Association for Sexual Health (BASHH) has updated their methodology for the production of national guidelines for the management of sexually transmitted infections (STIs) and related conditions. The main changes are the adoption of the GRADE system for assessing evidence and making recommendations and the introduction of a specific Conflict of Interests policy for CEG members and guideline authors. This new methodology has been piloted during the production of the 2015 BASHH guideline on the management of syphilis.

Introduction

The Clinical Effectiveness Group (CEG) of the British Association for Sexual Health (BASHH) develops national guidelines for the management of sexually transmitted infections (STIs) and related conditions. The purpose of these

guidelines is to make clear and explicit recommendations for health care practitioners managing patients requiring diagnosis and management of these conditions. In 2011 BASHH achieved accreditation from the National Institute for Health and Care Excellence as a guideline producer.[1] The BASHH guidelines are systematically developed and assessed in a robust and reproducible manner using the widely accepted "Appraisal of Guideline Research and Evaluation" (AGREE) II instrument.[2] The purpose of this document is to specify the methodology BASHH requires for guideline development and the process of guideline evaluation by the CEG. This is a development of the previously published CEG document which gave specifications for the BASHH guidelines.[3]

Methods of guideline development

1. The CEG meets three times per year and at each meeting all current guidelines and their stage in the review cycle are discussed. All guidelines are reviewed every 5 years. New evidence which may require ad-hoc updates is discussed and an open dialogue regarding updates is encouraged between any interested parties, particularly the current guideline's lead authors, and the CEG. Annually the lead authors of current guidelines are asked to comment on whether there has been new evidence in the field and if they feel an ad-hoc update is required which the CEG review, and if considered appropriate will undertake. The BASHH public panel are invited to input into this process by suggesting new topic areas for guideline development, or when they consider an ad-hoc update is required.

2. Guideline development is undertaken by a multi-disciplinary writing committee, with a lead author and a CEG editor appointed by the CEG to lead and co-ordinate the process and report on progress to the CEG regularly. Writing committee membership is decided by the lead author and CEG editor and will include relevant professional groups (for example genitourinary medicine physicians, nurses, health advisors, pharmacists, microbiologists and other professionals from allied specialities as appropriate) and when relevant this will involve working with the appropriate BASHH Special Interest Group (SIG) and the BASHH National Audit Group. Writing committee and CEG members will follow the CEG conflict of interests (CoI) policy and sign the CoI form (appendix 1). This is available on request from the CEG chair.

3. Patients' views and preferences must be sought and considered and the process documented. This includes patient representatives involved in the writing committee, information obtained from patient interviews or surveys during the writing and/or piloting process, reviewing published work on patient experiences or involving patient associations. The BASHH process for establishing this involvement in each guideline, plus role description and person specifications for patient/lay members of the BASHH guideline writing committees are detailed in appendix 2. The BASHH Public Panel are invited to comment on the CEG's work and they regularly review both draft

guidelines and the accompanying patient information leaflets produced as guideline implementation tools.

4. Systematic, robust, reproducible and transparent strategies should be adopted to search for evidence with clear inclusion/exclusion strategies.

5. Recommendations should be formulated with consideration of their health benefits, side effects and risks, with evidence presented in the guideline that these issues have been addressed. Each recommendation should be linked to the supporting evidence with a list of relevant references. The GRADE system, adopted for use by BASHH as described in appendix 5, should be used to formulate and describe the strength of recommendation for intervention, treatment or tests. CEG and guideline development group members undergo training to use the GRADE system as described in appendix 3.

6. Consideration should be given to pragmatic and organisational issues relevant to the guideline. These may also be identified during the piloting of the guideline.

7. The authors should consider and state the cost implications of recommendations made as per the GRADE approach described in appendix 3.

8. Guidelines may recommend some drugs outside the terms of their UK licence or which have no licence for use in the UK if there is good evidence to support their use. Where recommendations have been made for this 'unlicensed medicine', this should be marked with a footnote in the recommendations. This is consistent with General Medical Council guidance.[4]

9. Where disagreement arises within the writing committee with regard to recommendations the writing committee should reach a consensus decision using the GRADE grid – see appendix 3. Members with a relevant declared CoI should be excluded from this process. If agreement cannot be reached the issue should be referred back to the CEG with supporting evidence and documents.

10. The particular needs of specific and possibly vulnerable patient groups such as gay people, young people and children, drug users, those from black and minority ethnic groups, commercial sex workers and those with learning/physical disabilities should be considered and the writing committee should complete the equality impact assessment tool in Appendix 4.

    Where appropriate and relevant the specific needs of non-binary individuals and those who have had gender-reassignment surgery should be considered and specific recommendations made.

11. BASHH produce patient information leaflets (PILs) to support the implementation of their guidelines by clinicians and this should be undertaken by a member of the guideline writing committee in parallel to the main guideline's development. The production process, structure and content is detailed in appendix 5.

12. The CEG will review the draft guideline using the AGREE II guideline appraisal tool,[5] and following any final revisions the guideline will be externally peer reviewed by posting it on the BASHH website for a two month period and informing all BASHH members of the posting and inviting comments to be submitted to the CEG. The Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Health will also be invited to comment as stakeholders. At the same time the guideline will be sent to the BASHH public panel for their views and the BASHH national audit group for specific input into the recommended auditable outcome measures. Following this period the CEG Editor will collate the comments and send them to the chair of the writing committee for comment and action, as required.

13. The post-consultation draft of the guideline should be piloted for validation by a sample of target users. This will be co-ordinated by the CEG using health care professionals independent from the writing committee who adopt the guideline into their clinical practice in a virtual fashion for a period of time and then provide an evaluation using a standard feedback form; appendix 6.

14. The final guideline will be approved by the CEG and a review date agreed which is usually 5 years from completion of the guideline, upon which the CEG will decide on the group to update the guideline and the above process will be re-visited. Should any interim evidence or comments be received which are thought to require a modification of the guideline by the CEG, the guideline may be amended prior to the agreed review date; this will be decided upon and action taken by the CEG.

15. The final guideline will be posted on the BASHH website with notification of BASHH members. Primary publication should be in a peer reviewed journal.

Format, structure and content of guidelines

1. *Format:* A template guideline which specifies the format required by the CEG is given in appendix 7.

2. *Specified content:* This is to be inserted into guidelines at points in the guidelines referenced in the template (appendix 7) and includes the following:
    a. The composition, discipline and relevant affiliation of members of the guideline development group, including CEG Editor/lead as final author on behalf of BASHH CEG.

b. The objectives of the guideline including the potential health benefits for patients, the target patient population and also the target users of the guideline.
c. Details of the search strategy including search terms, sources and dates of the literature reviewed, databases of systemic reviews, conference proceedings and other guidelines consulted.
d. The methods used to formulate recommendations and the final decision making process, as described by the GRADE system (appendix 3).
e. Details of any equality impact assessment should be stated.
f. Description of the initial piloting of the guideline, feedback received from this pre-testing process and the incorporation of this feedback into the final draft (feedback forms specified in appendix 6).
g. Auditable outcome measures. The BASHH National Audit Group should be invited to comment on these.
h. Recommendations for further research should be considered and stated.
i. The BASHH table of diagnostic tests should be updated as required.
j. Statement of editorial independence – see appendix 8.
k. Statement of conflict of interest. Members of BASHH guideline writing committees are required to complete the BASHH conflict of interest paperwork – see appendix 1.

l. The composition, discipline and affiliation of members of the BASHH CEG at the time the guideline was written – see appendix 9.

3. *Clarity of recommendations.*
    a. The clinical questions covered by the guideline should be clearly described (with particular reference to key recommendations), for example specific treatment regimens and recommendations for follow-up.
    b. Where evidence and clinical practice allow, recommendations should be clear and definite. If the evidence is lacking or where there is uncertainty about the best management strategy the guideline should make this clear.
    c. Authors should consider the use of different strategies for prevention, screening, diagnosis, treatment and other aspects of patient management with references to supporting evidence. These should be presented so that key recommendations addressing the most important clinical issues are easily identified by the guideline users. Authors may consider algorithms, flow charts, boxes or tables.

4. *Supporting materials.* These include tools for effective implementation of the guideline and may include the following:
    a. Patient information leaflets – are developed by the writing groups and the CEG to accompany clinical guidelines. The

standard format, processes for production, piloting and public panel input are described in appendix 5.

b. A quick reference guide of key recommendations.

c. Clinical care algorithms.

Summary

In producing this latest framework for guideline development the CEG has updated its previous specification to clarify the steps involved, further embed patient and public involvement in the process and also change the method for formulating recommendations. The CEG now require that the GRADE system for formulating and stating the strength of recommendations is adopted and this process for BASHH is described in appendix 3. This is in line with other NICE accredited guideline producers and so familiar with our target user group. The process summarising our guideline commissioning and producing processes are stated in appendices 9 -10 to further clarify the writing process for guideline producers and appraisers. By adopting the online guideline appraisal tool developed by the AGREE organisation[4] the CEG have a clear and consistent method for reviewing guidelines.

References

1. NICE Accreditation decisions: http://www.nice.org.uk/aboutnice/accreditation/AccreditationDecisions.jsp. Last accessed 3 May 2013
2. The AGREE Collaboration. Appraisal of Guideline Research and Evaluation" (AGREE) II Instrument. http://www.agreetrust.org/about-

the-agree-enterprise/agree-research-teams/agree-collaboration/last accessed 13th August 2015

3. British Association of Sexual Health and HIV: Framework for Guideline Development and Assessment. Clinical Effectiveness Group 2010; M Kingston, K Radcliffe, D Daniels, M FitzGerald, N Lazaro, G McCarthy, A Sullivan, FRCP. *Int J STD AIDS* 2010; **21**: 453-456.
4. Prescribing guidance: Prescribing unlicensed medicines. General Medical Council. http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp Last accessed 13th August 2015
5. AGREE. http://www.agreetrust.org/ Last accessed 13th August 2015
6. Developing NICE Guidelines: The Manual. https://www.nice.org.uk/media/default/about/what-we-do/our-programmes/developing-nice-guidelines-the-manual.pdf Last accessed 13th August 2015

Appendix 1: BASHH CEG conflict of interest declaration:

Editorial independence of the BASHH CEG:

The BASHH Clinical Effectiveness Group (CEG) receives funding exclusively from BASHH for room hire and refreshments and for travel from either BASHH or from member's employers. The professional activities of BASHH are funded by membership fees from the health care professionals subscribing to the organisation. The recommendations made in the clinical guidelines commissioned by the CEG are based on evidence from the medical literature synthesised according to the guideline production manual. The CEG functions independently of the BASHH board and so we believe that the no views or interests of the funding body influence the final guideline recommendations.

Ensuring editorial independence of the BASHH CEG members and guideline authors:

Whenever possible, members should not have CoI relevant to their role and members with CoI should represent not more than a minority of the group. The chair, co-chairs or CEG editor should not be a person(s) with a CoI.

For CEG members the guideline CoI form is completed at least every 3 years and for authors before they commence work on a guideline. If an individual's

circumstances regarding CoI change a new form should be submitted as soon as possible.

All CoI of each member should be reported and discussed openly by the prospective development group prior to the onset of the work. Each panel member should explain how their CoI could influence the guideline development process or specific recommendations. Chairs, vice chairs and the CEG editor should not have any personal professional financial interests that are relevant to guideline production.

Potential for bias should be taken into account through a combination of factors, for example, systematic literature review, critical appraisal, peer review, editorial independence and a conflicts-of-interest policy. Details on the credibility and any potential bias of the guidance in general, and the conclusions and recommendations in particular should be stated in the guideline in question.

As a current member of the CEG, or as an author involved in guideline production for the BASHH CEG I declare that:

 Prior to accepting the invitation to participate in the BASHH CEG or a guideline development group I declared all interests and activities potentially resulting in conflicts of interest (CoI) with development group activity, by written disclosure to those convening the group. This disclosure reflects all current and planned commercial, non-commercial, intellectual, institutional,

and patient/public activities pertinent to the potential scope of the guideline. If my circumstances with regard to this change during guideline production I will inform the BASHH CEG editor and lead guideline author.

□ Any CoIs have been clearly declared and the impact they may have on the guidance process and development of recommendations has been stated and considered by the CEG.

□ I have divested myself of financial investments I or my family members have in any organisations whose interests could be affected by the guideline recommendations.

Any relevant personal professional interests are declared here including personal professional financial interests:

Name:

Signature:

Guideline group:

Appendix 2: Public and Patient Involvement

2.1 Introduction

The involvement of patients and the public is integral to the development of BASHH clinical guidelines. This involvement includes, but is not limited to, patient members on writing committees, information obtained from patient interviews or surveys during the writing and/or piloting guidelines, reviewing published work on patient experiences and seeking the advice and involvement of patient associations and advocates.

The particular needs of specific and possibly vulnerable patient groups such as gay people, young people, drug users, those from black and minority ethnic groups, commercial sex workers and those with learning/physical disabilities are considered and, when appropriate, an equality impact assessment tool is used:

(http://www.nice.org.uk/media/4DC/76/Item62_NEquIATTopicSelectionSMTAppB221107.pdf).

We aim to include two patient representatives in each of our guideline writing groups.

2.2 Definition of Lay people

For the purposes of this guidance, we define lay people as:

- Patients, service users, members of the public and of specific client groups targeted by BASHH CEG guidelines, and patient/public

advocates.

- People from patient, carer, voluntary and non-governmental organisations that are run by, or directly reflect the perspectives of patients, service users, carers, or client groups targeted by BASHH CEG guidelines.

Guidelines for the management of particular sexually transmitted infections should, where possible, be written with the involvement of a patient with first-hand experience of that condition. When this is not possible, input and advice from other lay sources should be sought.

2.3 Generic Role Description

The role of the patient member of a guideline writing committee is:

- To help to identify and refine clinical questions for the guideline so that they cover issues important to patients.
- To help to identify knowledge gaps about the views and experience of patients.
- To assess whether the group's draft recommendations highlight areas where patient preferences and choice may need to be acknowledged.
- To address the needs for particular patient groups.
- To address patient and carer needs for information, education and support in relation to areas covered in the guideline.
- To ensure the use of wording which is respectful to patients and carers
- To lead the development of the patient information leaflet produced alongside the clinical guideline (if applicable).

When the continued involvement of patients with a particular guideline is simply not possible, then the following can be considered:

- Focused patient questionnaires on the guideline's main issues.
- Patient focus groups where the main patient issues relating to the guideline can be voiced. This may be particularly useful for gaining the thoughts and opinions of young people who would be difficult to retain in guideline writing groups.
- Patient involvement with the development of PICO questions which are then used during the development of the guideline.
- Using different patients at different times during the guideline-writing process. Ideally, however, the same patients would be involved throughout.

2.4 Documentation required for each guideline

For each guideline writing group, a role description, responsibilities and duties and person specification for a patient member need to be agreed. These documents are then used to recruit a patient to the guideline group.

Documents required for each guideline group:

1. Role/Job description
    - Information about BASHH and the CEG.
    - The membership of the guideline writing group.
    - The responsibilities of the role.
    - The time commitment required. This should include a timetable of

involvement. The times, dates and locations of face-to-face meetings should be specified. For a simple guideline (e.g. pediculosis, balanitis, scabies, SARA, candida, donovanosis, epididymo-orchitis),1 day (i.e. 2 half-days) may be sufficient. For a complex guideline (e.g. sexual health of HIV-infected persons, young people, PID, gonorrhoea), 2 days (i.e. 4 half-days) may be required. Milestones for a typical guideline:

- 6 months to draft
- 1 month for CEG review
- 2 months for consultation
- 2 months for writing group ro respond to consultation and piloting by CEG members in their clinics
- 1 month for final guideline and PIL to be produced, ratified and submitted for publication.

- The training and practical support which will be offered.
- The financial support which will be offered.
- How to apply for the role
- How to find our more about the role before applying.

2. Person Specification
    - This should list the personal experience and knowledge which are both essential and desirable for the role. It should also list other skills and abilities which are essential (e.g. ability to communicate via email).
3. Application Form

4. Conflicts of Interest Form

2.5 Recruitment

Patients / lay members can be sought in a number of ways:

- Through a direct approach from a professional member of the guideline writing group.
- Through advertisement on the public pages of the BASHH website, and dissemination of the advert through social media and other stakeholders.
- Through the BASHH public panel.
- Through a patient advice or advocacy organization (e.g. the herpes association).

2.6 Training, education and support

This should be tailored to the individual needs of the patient committee member. As a minimum, they should be:

1. Allocated a ‘buddy’ on the guideline group who is their first port of call for questions or concerns during the writing process.
2. Met by their buddy prior to the first meeting of the guideline group (this could be immediately prior to the meeting) to run through the composition of the group; the format of the guideline writing process
3. Given a glossary of terms
4. Given any previous version of the guideline being written.
5. Given a summary of GRADE and PICO methodology.

2.7 Payment for time, travel and subsistence

Payment should be offered to patient members of guideline writing groups to compensate their time, travel and subsistence costs.

Payment is offered at the following rates (subject to review from time to time):

1. Payment for time
    - £150 per full-day (four hours of longer) meeting or an equivalent amount of time spent working on the guideline at home.
    - £75 per half-day meeting (shorter than four) or an equivalent amount of time spent working on the guideline at home.

    N.B. These rates are fixed and are based on the planned duration of the meeting. Lay contributors will not receive less than the agreed amount if finishes early or more if it over-runs. The payments do not mean that NICE's lay contributors have a contract of employment with BASHH.

    All payments will be made directly to the individual. They may decline to accept the payment if they wish. If lay contributors accept any payments for contributing to BASHH's work, it is regarded, by Her Majesty's Revenue and Customs as part of their overall income. Each lay contributor is personally responsible for any liability with regard to Income Tax or National Insurance contributions. Lay contributors are asked to acknowledge this responsibility each time they claim the payment. BASHH does not deduct tax or National Insurance contributions from the payments at source.

2. Payments for subsistence

Maximum subsistence payment of £20 a day, which will not be considered as earnings.

- If away from home for 24 hours, a maximum of £20 should be paid if meals are not provided at the meeting of accommodation.
- If away for more than10 hours, £15 cn be claimed for a meal (after 7pm) provided they are staying away from home for more than 10 hours and returning home after 7pm OR are absent overnight but had a free lunch.
- If away from home for more than10 hours, but home before 7pm, then £10 can be claimed for a meal.
- If away for over 5 hours or overnight, but dinner was provided free, then £5 can be claimed for a meal.

3. Payments for travel and accommodation

The following travelling expenses will be reimbursed:-

- Rail travel (First class allowable for journeys over 100 miles; first class tickets bought on day of travel will not normally be reimbursed). Members should use advance purchase schemes wherever possible.
- Bus/coach/tube (economy class fare only). Use annual/season tickets where possible. Up to £8 for a return oyster journey allowable without receipt.
- Car mileage will be at the 2011-12 approved HMRC mileage rates of 45 pence per mile regardless of engine size. If you are using a

company car the mileage rate will be 15 pence per mile under 1400cc engines, 18p per mile for 1401 to 2000 cc and 26 pence per mile for over 2000cc engines.

- Taxi only outside central London or Manchester where public transport options more limited. Can be used in event of a strike or other disruption.
- Hotel accommodation: £125/night in London, £100 elsehwere. For early morning or late afternoon where travel on the day not appropriate. £25 if stay with a friend or relative. No additional expenses in hotel allowed (newspapers, rooms service etc).

3. Payment for Carer expenses

These are payable when the patient member would be unable to attend without carer costs covered. They can include:

- Payment of a carer to accompany the person to the meeting.
- Payment to replace the lay members caring duties.
- Childcare

These payments are subject to a maximum of £15 per hour. The hours are to be reasonable and 24 as a maximum. Carers travel and subsistence can be claimed if they accompany the patient.

2.8 Checklist for Patient involvement in a guideline group

Define level of patient involvement required (e.g. focus group, patient member on committee).	☐
Nominate a member of the writing group to lead patient recruitment. o Liaise with public panel as necessary o Liaise with webmaster and media team re advertising	☐
Nominate a member of the writing group as the patient 'buddy'.	☐
Set timetable/milestones for guideline o To include meeting dates and locations	☐
Assemble required documents: o Role description o Person Specification o Plan for education and training o Glossary of terms o Reading useful for the patient member of the committee	☐
Ensure all necessary paperwork complete o Application form o Conflict of interest form o Expense forms (as necessary)	☐

Appendix 3: Guidance for guideline authors and reviewer for adopting the GRADE system for assessing evidence during guideline development.

Introduction:

There has been a general move to using the GRADE system by many guideline producing bodies in recent years and the BMJ published a series of papers about the method in 2008:

1. Guyatt GH, Oxman AD, Vist G, Kunz R, Falck-Ytter Y, Alonso-Coello P, Schünemann HJ, for the GRADE Working Group. Rating quality of evidence and strength of recommendations GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008;336:924-926 or [pdf]

2. Guyatt GH, Oxman AD, Kunz R, Vist GE, Falck-Ytter Y, Schünemann HJ; GRADE Working Group. Rating quality of evidence and strength of recommendations: What is "quality of evidence" and why is it important to clinicians? BMJ. 2008 May 3;336(7651):995-8

3. Schünemann HJ, Oxman AD, Brozek J, Glasziou P, Jaeschke R, Vist GE, Williams JW Jr, Kunz R, Craig J, Montori VM, Bossuyt P, Guyatt GH; GRADE Working Group. Grading quality of evidence and strength of recommendations for diagnostic tests and strategies. BMJ. 2008 May 17;336(7653):1106-10

4. Guyatt GH, Oxman AD, Kunz R, Jaeschke R, Helfand M, Liberati A, Vist GE, Schünemann HJ; GRADE working group. Rating quality of evidence and strength of recommendations: Incorporating considerations

of resources use into grading recommendations. BMJ. 2008 May 24;336(7654):1170-3

5. Guyatt GH, Oxman AD, Kunz R, Falck-Ytter Y, Vist GE, Liberati A, Schünemann HJ; GRADE Working Group. Rating quality of evidence and strength of recommendations: Going from evidence to recommendations. BMJ. 2008 May 10;336(7652):1049-51

6. Jaeschke R, Guyatt GH, Dellinger P, Schünemann H, Levy MM, Kunz R, Norris S, Bion J; GRADE working group. Use of GRADE grid to reach decisions on clinical practice guidelines when consensus is elusive. BMJ. 2008 Jul 31;337:a744

The GRADE system applied in its purest form requires scientific analyses of evidence to produce “tables” from a series of “PICO” questions: Questions that identify the patient problem or population (P), intervention (I) (or aetiology/diagnosis/frequency/prognosis), comparison (C) and outcome(s) (O). Practically this is very labour intensive and requires someone very experienced in this area, and many large guideline writing bodies employ a scientist to do this for them. However, some bodies adapt the GRADE system according to their own needs, assess the evidence in the way they have done in the past, and then make strengths of recommendations according the GRADE system, which when applied in this way is actually quite simple to do and understand. BASHH have adopted GRADE to use in this manner.

The principles of GRADE:

1. Assessment of the evidence.

GRADE offers four levels of evidence quality: high, moderate, low, and very low, with randomised trials classed as high quality evidence and observational studies as low quality evidence. Quality may be downgraded as a result of limitations in study design or implementation, imprecision of estimates (wide confidence intervals), variability in results, indirectness of evidence, or publication bias. Quality may be upgraded because of a very large magnitude of effect, a dose-response gradient, and if all plausible biases would reduce an apparent treatment effect.

Summary of factors affecting quality of evidence:

- Study limitations
- Inconsistency of results
- Indirectness of evidence
- Imprecision
- Publication bias
- Factors that might increase quality of evidence
- Large magnitude of effect
- Plausible confounding, which would reduce a demonstrated effect
- Dose-response gradient

Based on the analysis of the evidence with these factors borne in mind the evidence should be graded as follows:

A: A body of evidence of high quality meta-analyses, systematic reviews of and RCTs directly applicable to the target population

B: As above but relating to high quality case control or cohort studies with low risk of bias or confounding and high probability that a relationship is causal

C: As B but trials may have some flaws

D: Non-analytic evidence eg. Case reports or series or expert opinion

However, when reviewing evidence graded A-D as above the grading can be altered follows:

- The strength of recommendation should be higher if the following apply:
- A large effect of an intervention is demonstrated
- Dose response/evidence of gradient
- All plausible confounding would reduce a demonstrated effect or would suggest a spurious effect when results show no effect

- Lower if there is evidence of:
- Serious/very serious study limitations
- Inconsistency
- Indirectness
- Imprecision
- Publication bias
- Study limitations
- Inconsistency of results
- Indirectness of evidence
- Imprecision
- Publication bias

2. Formulating recommendations

There are only two strengths of recommendation, which may be either for or against an intervention: 1 = strong or 2 = weak. Pragmatically this means the following:

Strong recommendation for intervention

For patients—Most people in this situation would want the recommended course of action and only a small proportion would not

For clinicians—Most people should receive the intervention

For quality monitors—Adherence to this recommendation could be used as a quality criterion or performance indicator. If clinicians choose not to follow such a recommendation, they should document their rationale

Weak recommendation for intervention

For patients—Most people in this situation would want the suggested course of action, but many would not

For clinicians—Examine the evidence or a summary of the evidence yourself and be prepared to discuss that evidence with patients, as well as their values and preferences

For quality monitors—Clinicians' discussion or consideration of the pros and cons of the intervention, and their documentation of the discussion, could be used as a quality criterion.

No specific recommendation

The advantages and disadvantages are equivalent

The target population has not been identified

Insufficient evidence on which to formulate a recommendation

3. Combining 1&2:

For example as described in the current BHIVA guidance manual:

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.

4. Consideration of using PICO

This may be helpful if guideline writing committee wish to utilise this method, this is explained in the NICE guideline manual; chapter 4:6

Patients/population: which patients or population of patients are we interested in? How can they be best described? Are there subgroups that need to be considered?

Intervention: which intervention, treatment or approach should be used?

Comparison: what is/are the main alternative/s to compare with the intervention?

Outcome: what is really important for the patient? Which outcomes should be considered, such as intermediate or short-term measures; mortality; morbidity and treatment complications; rates of relapse; late morbidity and readmission; return to work, physical and social functioning? Should other measures such as quality of life, general health status and costs be considered?

5. Consideration of costs

These may or may not legitimately be included in the GRADE system, but it would be sensible in the current climate to always consider these, and if they are not considered this should be stated and why – for example, there is no significant difference in cost between the recommended treatments. Generally speaking GRADE suggests a balance sheet should inform judgments about whether the net benefits are worth the incremental costs. Evidence profiles should always present resource use, not just monetary values.

6. Using the GRADE grid to resolve differences:

This supports the Delphi technique we already adopt, i.e. To develop a consensus within the group:

7. GRADE training for BASHH guideline authors

Authors need to be familiar and confident in using the GRADE system, and training for this is available as follows:

1. The papers from the BMJ series in 2008, as listed in the introduction to this appendix. The articles can be accessed through the grade working group web site at:
http://www.gradeworkinggroup.org/publications/index.htm
2. McMaster GRADE on line modules: these have been recommended by the GRADE working group and take about 20 minutes each to complete. The web address is: http://cebgrade.mcmaster.ca/
3. Journal of Clinical Epidemiology 2011: published a 20 part series that is available through the GRADE working group website (link above).

Summary

BASHH have now moved to the GRADE system for evaluating evidence and making recommendations by asking guideline authors and reviewers to apply the principles outlined in sections 1-3 above. Authors should consider structuring their analysis of evidence into PICO questions addressing Population / Intervention / Comparison / Outcome as stated in section 4. Costs should be included in the evaluation and formulation of recommendations as stated in section 5. When resolution of conflicting opinions is required the GRADE grid should be used. This appendix is a

brief summary of the GRADE system how it is to be adopted by BASHH guideline authors.

Appendix 4: Patient information leaflets (PILs)

1. PIL production process

PIL editor: Dr Cara Saxon

Guideline writing group (GWG) produces first draft of PIL which should:

- Be based on information in the guideline.
- Conform to the BASHH PIL template

PIL First draft reviewed by PIL editor (PILE).

When PILE is happy with draft he/she submits it to CEG and the BASHH Public Panel for review.

PILE modifies draft following CEG and Public Panel recommendations.

PIL is then sent to pilot GUM clinics. They will give the PIL (and patient questionnaire) to patients for approximately a month, or until at least 10 feedback forms have been received. The trial period can be extended when the PIL relates to less common infections or clinical scenarios.

Pilot GUM clinics send patient feedback summary to PILE who acts on this as required.

PILE sends final draft of PIL to graphic designer after CEG review.

Graphic designer sends web-ready draft to PILE, who sends it on to BASHH web master. PIL is posted on BASHH web site.

Note: In future BASHH intends to have all its PILs stamped with the 'Information Standard.' Conforming to the IS will alter this development template from its current form.

2. PIL Template

XX - the basics

How common is XX?

How do you catch xx?

What would I notice if I had xx?

How do I get tested for xx?

How is xx treated?

Important information about your treatment

What about my partner?

When can I have sex again?

What happens if my xx is left untreated?

Can I catch xx again?

xx in pregnancy

More information: http://www.bashh.org/guidelines

xxx 201x: Leaflet produced by the Clinical Effectiveness Group of the British Association for Sexual Health and HIV

Acknowledgement: CEG and writing group lead

3. Pilot PIL feedback form

PIL:

Dates for the period of PIL piloting:

Person undertaking the PIL piloting:

Name:

Affiliation:

Date:

Good points about the PIL:

Points for improvement:

Any other general comments?

Public panel review::

Date:

Good points about the PIL:

Points for improvement:

Any other general comments?

Appendix 4: EQI table

BASHH Guideline Equality Impact Assessment ***(based on NICE documentation shared with BASHH August 2019)***				
Guidance title: BASHH Guidelines for the Management		**Completed by:**		**Date:**
How relevant is the topic to equality?	**Inequalities in health impact of the condition or public health issue**	**Potential of guidance to add value**	**Priority for NHS or other government department**	**Topic relevance; conclusions and outcomes**
	• Prevalence and impact of condition or public health problem • Prevalence of risk factors	• Inequalities in access, uptake or impact • Timeliness • Equality issues identified by proposers of the topic • Equality issues identified by patient or lay organisations	• Department of Health or other centralised NHS bodies such as NHS England • Local authorities • Home Office • Other agencies	• If equality issues had impact on the guidance summarise these impacts
Sex/gender				
Race				
Disability				
Age				
Sexual orientation				
Gender reassignment				
Religion/belief				
Pregnancy & maternity				
Other definable characteristics & socioeconomic factors that may affected by protected characteristics, including: • Prisoners and young offenders • Refugees and asylum seekers • Migrant workers • Looked after children • Homeless people • Deprivation • Disadvantage associated with geographical distinctions				

Appendix 5: Pilot feedback form

Guideline:

Dates for the period of guideline piloting:

Person undertaking the guideline piloting:

Name:

Affiliation:

Date:

Good points about the guideline:

Points for improvement:

Any other general comments?

Appendix 6: Template guideline & specified content

Title

Clinical Effectiveness Group

British Association for Sexual Health and HIV

Where appropriate: New in the 20xx guidelines:

Introduction and Methodology

- Objectives
- Search strategy
- Methods
- Equality impact assessment
- Piloting & feedback

Aetiology

Clinical Features

Diagnosis

Management

- General advice
- Further Investigation

Treatments:

- Recommended & Alternative Regimens
- Pregnancy & Breastfeeding
- In HIV Positive Individuals
- Reactions to Treatment

Follow-up

Contact tracing & treatment

Auditable outcomes

Recommendations for further research

Acknowledgements (Pilot sites, consultation responders making a significant contribution)

References

Listed numerically in the Vancouver style.

Editorial independence

Conflicts of interest – sample statement

Membership of the Clinical Effectiveness Group

Appendix 7: Statement of Editorial Independence

This guideline was commissioned, edited and endorsed by the BASHH CEG without external funding being sought or obtained.

All members of the guideline writing committee completed the BASHH conflicts of interest declaration detailed below at the time the guideline's final draft was submitted to the CEG. The details of any actual or potential conflicts of interest will be documented by the CEG at this point in the guideline.

Appendix 8: CEG composition

From December 2019 the membership of the CEG is:

Dr Keith Radcliffe (Chair)

Dr Ade Apoola

Dr Darren Cousins

Dr Helen Fifer

Dr Sarah Flew

Dr Deepa Grover

Dr Sara Hardman

Dr Margaret Kingston

Dr Michael Rayment

Dr Cara Saxon

Dr Ann Sullivan

Dr Craig Tipple

Appendix 9: Pathway for guideline commissioning

1. The CEG decides to review an existing guideline or commission a new one with input from the BASHH Public Panel and wider membership.
2. Lead CEG author is appointed and guideline writing committee chair identified together with possible group members by the CEG.
3. The CEG lead author contacts the proposed guideline writing committee chair with the framework for guideline development and invites them to form a multi-disciplinary writing group.
4. The guideline writing committee, together overseen by the CEG lead, produce a draft guideline.
5. The draft guideline is reviewed by the CEG members using the AGREE II instrument and feedback given to the writing committee chair.
6. The second draft of the guideline is placed on the BASHH website for two months and publicised to members via the monthly newsletter and concurrently reviewed by the public panel. Comments are received by the CEG lead author and referred as necessary for consideration to the writing committee.
7. The third and final draft of the guideline is piloted by named peer reviewers in clinical practice. Any amendments required are made by the writing committee.
8. The finalised guideline is ratified by the CEG and adopted for use by BASHH, placed on the BASHH website and if appropriate submitted for publication.

Appendix 10: Pathway for guideline authors

1. The multi-disciplinary writing committee is formed by the chair and the CEG lead for the guideline. The people on the writing committee will depend on the guideline, but generally speaking consideration should be given to include the following:

    a. GUM physician

    b. GUM nurse

    c. Health advisor

    d. Pharmacist

    e. Virologist/microbiologist

    f. Patient representatives (ideally patient representatives will be involved from the outset and involved in every aspect and supported to optimise their input).

    g. Specialists from allied specialties, as appropriate, for example, gynaecology, urology, obstetrics, paediatrics).

2. Tasks for each member of the writing committee to be allocated by the chair of the writing committee with a time frame set for completion.

3. The writing committee should agree how the work will be carried out and whether they may choose to meet regularly, communicate by email or teleconference, or a combination of the two.

4. The BASHH framework for guideline development must be adhered to, with evidence reviewed, recommendations formulated and graded, and the layout of the guideline as specified in this document.

5. The first draft of the guideline to be reviewed by the CEG using the AGREE II instrument for guideline appraisal.

6. Comments from the CEG to be considered by the guideline writing committee, with required amendments made. This draft is then placed for consultation on the BASHH website for two months and concurrently sent to the BASHH Public Panel for review. Feedback from this process should be considered by the writing committee and the finalised guideline produced and approved by the CEG.

7. The final draft guideline then piloted by named clinicians in their GUM clinical practice.

8. The finalised guideline is placed on the BASHH website, and consideration should be given to submission for publication in a specialty journal.

Flow chart summarising the BASHH guideline development process