

British Association for Sexual Health and HIV:
Framework for Guideline Development and Assessment

Clinical Effectiveness Group 2010

BASHH Framework for Guideline Development

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SUMMARY

This article has been prepared by the Clinical Effectiveness Group (CEG) of the British Association for Sexual Health and HIV (BASHH) to specify the methodology BASHH requires for guideline development and the process of guideline evaluation by the CEG. This replaces the specifications for the development of UK guidelines on the management of Sexually Transmitted infections and closely related conditions previously published in this journal in 2004 and updated in 2005.

INTRODUCTION

The Clinical Effectiveness Group (CEG) of the British Association for Sexual Health and HIV (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 healthcare practitioners managing patients requiring testing for and management of these conditions. 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) instrument.¹ 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.² The UK Department of Health established NHS Evidence in 2009 which is run by the National Institute of Clinical Excellence (NICE),³ and this body also endorses the use of the AGREE instrument discussed above, making this review of CEG methodology timely and pertinent.

METHODS: METHOD OF GUIDELINE DEVELOPMENT

1. Guideline development is undertaken by a multi-disciplinary writing committee with membership determined in a transparent manner. The chair should be chosen by the CEG. The CEG lead should then discuss with the chair what suggestions they might have for members from other disciplines. The additional members of the group would then be invited by the CEG. Writing committee membership 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 audit group.

2. Timelines: Specific indication should be given, to help the chair of the writing group structure the work, an expected time frame would be 6 months.
3. Patients' views and preferences should be sought and considered and the process documented. This may include patient representative involvement in the writing committee, information obtained from patient interview or surveys during the writing and/or piloting process, reviewing published work on patient experiences or involving patient associations. The chair of the writing group should identify an appropriate member such as the Health Advisor to get patient feedback on the guideline. BASHH are currently developing a public panel to assist with its work and in the future this group could be approached to assist in guideline development.
4. Systematic, robust, reproducible and transparent strategies should be adopted to search for evidence with clear inclusion/exclusion dates and strategies documented.
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. Methods used to formulate recommendations should be described.

6. Consideration should be given to pragmatic and organisational issues relevant to the guideline. This should be sought during and may emerge from the piloting of the guideline.
7. The authors should consider the financial cost implications of recommendations made.
8. Where disagreement arises within the writing committee with regard to recommendations the chair should attempt to resolve these (for example by a voting system or formal consensus method). The process should be documented and reported to the CEG editor. When this is not possible the CEG will review the evidence themselves and invite the chair and possibly other members of the writing committee to a meeting to agree a resolution and final recommendations.
9. Initial drafts 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.
10. The CEG will review the final, piloted draft of the guideline using the AGREE instrument, and following any final revisions the guideline will be externally peer reviewed by posting it on the BASHH website for a 3 month period, informing all BASHH members of the posting and inviting comments to the CEG. Following this period the CEG will collate the

comments and send them to the chair of the writing committee for comment and action.

11. The final guideline will be approved by the CEG and a review date agreed, when 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.
12. The final guideline will be posted on the BASHH website with notification of BASHH members. Primary publication should be in a peer reviewed journal.

RESULTS: STRUCTURE AND CONTENT OF GUIDELINES

1. Format: A template guideline which specifies the format required by the CEG is given in appendix 1.
2. Generic content: This is outlined below :
 - a. The composition, discipline and affiliation of members of the guideline development group and lead editor from the CEG.
 - b. The objectives of the guideline including the potential health benefits for patients, the target patient population and 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.
 - e. Description of the initial piloting of the guideline, feedback received from the pilot process and the incorporation into the final draft (feedback form specified in appendix 2).
 - f. Auditable outcome measures. The BASHH audit group should be invited to comment on these.
 - g. Statement of editorial independence – see appendix 3.
 - h. Declarations of interest. Members of BASHH guideline writing committees are required to complete the BASHH conflict of interest paperwork – see appendix 4.
 - i. The composition, discipline and affiliation of members of the BASHH CEG at the time the guideline was written – see appendix 5.
 - j. Acknowledgements. For people who have contributed to guideline development but are not authors.
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 regimes 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. Different strategies for prevention, screening, diagnosis, treatment and other aspects of patient management should be clearly stated 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 leaflets to be linked via the website – see appendix 6.
 - b. A quick reference guide of key recommendations.
 - c. Clinical care algorithm.
 - d. Audit proformas to be linked via the website.

CONCLUSIONS

In producing this framework the CEG has updated its previous specification on guideline development, and hopes to make the guideline writing process a less daunting task for authors. We also hope to make the BASHH guideline development a more clearly defined and transparent process which is in line with that required by the recently established body NHS Evidence.³ We will implement this framework of guideline development and appraisal into the work of the CEG and aim to continue developing the well regarded guidelines within the field of sexual health.

REFERENCES

1. The AGREE Collaboration. Appraisal of Guideline Research and Evaluation” (AGREE) Instrument. www.agreecollaboration.org last accessed 1.12.2010
2. Rooney G, Daniels D, Fitzgerald M, Ahmed-Yushuf I, Radcliffe K, Welch J. Specifications for the development of guidelines on the management of sexually transmitted infections and closely related conditions. *Int J STD & AIDS*. 2004 May;15(5):299-305.
3. The National Institute for Health and Clinical Excellence. NHS Evidence. www.evidence.nhs.uk/default.aspx last accessed 1.12.2010

APPENDIX 1: TEMPLATE GUIDELINE

TITLE

DATE OF WRITING, DATE REVIEW DUE

Clinical Effectiveness Group

British Association for Sexual Health and HIV

GENERIC CONTENT 2a: Guideline development group membership and lead editor from the CEG.

*Where appropriate: **New in the 20xx guidelines:***

Introduction and Methodology

GENERIC CONTENT 2b: Objectives

GENERIC CONTENT 2c: Search strategy

GENERIC CONTENT 2d: Methods

GENERIC CONTENT 2e: Piloting & feedback

Aetiology

Clinical Features

Diagnosis

Management

General advice

Further Investigation

Treatments:

Recommended & Alternative Regimes

Pregnancy & Breastfeeding

In HIV Positive Individuals

Reactions to Treatment

Follow-up

Contact tracing & treatment

GENERIC CONTENT 2f: Auditable outcomes

GENERIC CONTENT 2g: Editorial independence

GENERIC CONTENT 2h: Declarations of interest

GENERIC CONTENT 2i: Membership of the Clinical Effectiveness Group

Acknowledgements

References

Listed numerically in the Vancouver style, authors alphabetically.

Appendices

APPENDIX 2: 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 3: 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 conflict 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 declarations of interest will be documented by the CEG at this point in the guideline.

APPENDIX 4: BASHH DECLARATION OF INTERESTS:

BASHH Declaration of interest forms completed, relevant answers summarised.

Declaration of Personal Interests

Name of guideline:

.....

1. Do you, your partner (if applicable) or any member of your immediate family have any commercial interest such as personal shares etc. with any companies that are, or could be, involved in the above named guideline?

No Yes (if yes please provide details)

2. Do you, your partner (if applicable) or any member of your immediate family receive sponsorship or paid consultancy work within commercial organisations that are, or could be, involved in the above named guideline?

No Yes (if yes please provide details)

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

No Yes (if yes please provide details)

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

No Yes (if yes please provide details)

5. Do you receive significant editorial fees for commissioned articles for publication (in any format) or are you paid editorial work for any publication related to the above named guideline?

No Yes (if yes please provide details)

6. Do you or your department hold a patent (existing or pending) related to the above named guideline?

No Yes (if yes please provide details)

Name:

.....

Role in guideline development:

.....

Signature:

.....

Date:

.....

APPENDIX 5: CEG COMPOSITION

From October 2009 the membership of the CEG is:

- Dr Keith Radcliffe (Chair); Consultant Physician in Genitourinary Medicine Whittall Street Clinic Whittall Street, Birmingham, B4 6DH
- Dr David Daniels, West Middlesex University Hospitals NHS Trust, Sexual Health Clinic West Middlesex Hospital Twickenham Road, Isleworth, TW7 6AF
- Dr Mark FitzGerald Consultant Physician in Genitourinary Medicine, Musgrove Park Hospital, Taunton, TA1 5DA
- Dr Margaret Kingston, Consultant Physician in GU Medicine, Manchester Centre for Sexual Health, The Hathersage Centre, 280 Upper Brook Street, Manchester M13 0FH
- Dr Neil Lazaro, Associate Specialist in GU Medicine, Royal Preston Hospital, Preston PR2 9HT
- Dr Gill McCarthy, Consultant Physician in GU Medicine, Kingston Hospital NHS Trust, Wolverton Centre for Sexual Health Galsworthy Road, Kingston Upon Thames, KT2 7QB
- Dr Ann Sullivan, Consultant Physician in Genitourinary Medicine, Chelsea & Westminster Hospital NHS Foundation Trust, John Hunter Clinic for Sexual Health, St Stephen's Centre 369 Fulham Road SW10 9NH

APPENDIX 6: PATIENT INFORMATION LEAFLETS

From 2010 BASHH will ask the guideline writing group to produce a patient information leaflet for each clinical guideline that will be suitable to use in GUM clinics. The chair of the writing group should identify someone to take responsibility for this. It may be helpful to ensure representation or input from all health professionals including doctors, health advisers, nurses and a local patient group if available.

Each patient information leaflet should conform to the following parameters:

No more than 2 sides A4 so that leaflet can be easily printed and photocopied in GUM clinics.

The leaflet will carry the BASHH logo and conform to a standard PDF style.

The leaflet will use the following headings:

1. X – the basics (key facts incl recommend a STI screen & HIV test)
2. How common is x?
3. How do you catch x?
4. What would I notice if I had x?
5. How do I get tested for x ?
6. How is x treated?
7. Important information about your treatment
8. What about my partner?
9. When can I have sex again?

10. What happens if my X is left untreated
11. X in pregnancy /HIV positive– if relevant
12. More information incl ref to BASHH website

The final patient information leaflet will be discussed by the Public Panel Forum of BASHH. Their comments and suggested amendments will be fed back to the CEG lead who will liaise with the guideline author re any changes.