

# Specifications for the development of UK guidelines on the management of Sexually Transmitted Infections (STIs) and closely related conditions 2005

**Clinical Effectiveness Group  
British Association of Sexual Health and HIV**

## **Introduction**

The purpose of the guidelines are to make clear, explicit, and evidence based recommendations, to assist practitioner and patient in decisions about appropriate health care, with a definite intent to influence clinical practice. They should be systematically developed statements, where the quality of the guideline, and the process underlying its development, need to be both robust and reproducible.

To achieve this, the Royal College of Physicians (RCP) has approved and promoted a framework of guideline development and assessment, known as the 'Appraisal of Guideline Research & Evaluation (AGREE) Instrument' <sup>(1)</sup>. The Clinical Effectiveness Group (CEG) has adopted this instrument for the following guideline development specifications. In addition it will use it as a tool for the objective assessment of the quality of the reporting and the quality of some aspects of the recommendations (see appendix 1).

## **Structure and content of the guideline**

The guideline should be produced in the following format and style:

**Title** Initial capitals; bold; font size 14. Example:

***United Kingdom National Guideline on the Management of  
Gonorrhoea (YEAR)***

## **Recognition of CEG as Commissioning Body**

Immediately below the title separated by one clear line; same font size as the body of the text (12); bold. Example:

***Clinical Effectiveness Group  
British Association of Sexual Health and HIV***

## **Headings and Sub-Headings**

The headings to be used (underlined) are set out below. They may be omitted if there is nothing relevant. They should be the same font size as the body of the text (12).

### **Introduction and Methodology**

- scope and purpose (see explanatory notes 1-4)
- stake holder involvement (see explanatory notes 5-7)
- rigour of development (see explanatory notes 8-15)

## Aetiology

- causative agent; mode of transmission

## Clinical Features

- Use the following three sub-headings, which should be underlined and indented

### Symptoms

### Signs

### Complications

## Diagnosis

- Including:
- laboratory investigations (stating generic test types)
  - Sites sampled

## Management

- Use the following sub-headings, which should be underlined and indented

### General Advice

Give general advice as appropriate to the condition. Where indicated all guidelines should contain the following specific statements:

*"Patients should be advised to avoid sexual intercourse (including oral sex) until they and their partner(s) have completed treatment and follow-up."*

*"Patients should be given a detailed explanation of their condition with particular emphasis on the long-term implications for the health of themselves and their partner(s)."*

*This should be reinforced by giving them clear and accurate written information."*

### Further Investigation

In particular, a statement is required in all guidelines concerning the need for screening for other STIs. If additional investigations are recommended e.g. LFTs and liver biopsy for hepatitis B carriers, then it is important to make it clear whether these are to be done by GUM specialists or following referral elsewhere.

### Treatment

To include generic names, dosages, duration and indications for therapy. Where drugs are unlicensed, or licensed but are being recommended for unlicensed indications, then this must always be stated explicitly (remember that use in pregnancy is often an unlicensed indication). Where multiple regimens are recommended these should be sub-divided using the following two sub-headings which, should be underlined and double indented:

### Recommended Regimens

## Alternative Regimens

If multiple options are listed under these sub-headings, these should be given in a vertical list. They can be headed by the numbers 1,2,3, etc, if it is intended to convey that regimen 1 is superior to regimen 2, and 2 to 3 etc.; or by standard bullet points if it is intended to imply equivalence.

In addition the following two sub-sub-headings should be used; they should be underlined and double-indented

### Allergy

Recommendation should be given for patients believed to be allergic to the recommended first-line agents

### Pregnancy and Breastfeeding

#### HIV Infection

Where necessary, it may be important to highlight differences in the recommendations of the guideline if the individual is known to be HIV positive

#### Sexual Partners

Advice on partner notification must be given, including advice on epidemiological treatment.

As specific a statement as possible should be made as to the contact tracing period i.e. how far back should contacts be sought?

#### Children/parents/siblings

Document necessary action where relevant.

#### Follow-up

The need, timing and objectives of this should be stated explicitly.

## Qualifying statement

Generic statement to be applied to all guidelines:

*"The recommendations in this guideline may not be appropriate for use in all clinical situations. Decisions to follow these recommendations must be based on the professional judgement of the clinician and consideration of individual patient circumstances and available resources."*

*"All possible care has been undertaken to ensure the publication of the correct dosage of medication and route of administration. However, it remains the responsibility of the prescribing physician to ensure the accuracy and appropriateness of the medication they prescribe."*

## Applicability

See explanatory notes 16 – 18.

#### Auditable Outcome Measures

List using bullet points.

#### Acknowledgements

All those involved in the review process who contributed written comments, excepting CEG members, should be acknowledged alphabetically in the following way:

*“I (“We” if multiple authors) wish to thank the following for their valuable contributions to this Guideline: Fred Bloggs, Charles Frost etc.”*

#### Author(s) and Centre

All authors should be listed and the principle author noted.

The author(s) name should be given in the form of one forename and their surname without any title, followed by the name of their principal institution.

#### Membership of the CEG

This should be given as follows:

*“Clinical Effectiveness Group: Chairman Keith Radcliffe; Imtyaz Ahmed-Jushuf; David Daniels; Mark FitzGerald; Neil Lazaro; Guy Rooney”*

#### Editorial Independence

See explanatory notes 19 - 20 and appendix 2.

#### References

To be listed 1,2, 3 etc., in the Vancouver style, alphabetically.

Individual

statements in the body of the text should be referenced.

### **Revisions and further web based publication**

It is aimed that the primary publication of a guideline is in a peer reviewed journal. For revisions of publications originally published in the journals Sexually Transmitted Infections or the International Journal of STD and AIDS acknowledgement needs to be given to the source as well as a link to the respective website of the journal ([www.stijournal.com](http://www.stijournal.com) or [www.rsmprss.co.uk/std.htm](http://www.rsmprss.co.uk/std.htm)).

### **Style Points**

See appendix 3

# Explanatory notes to the specifications for the development of guidelines on the management of Sexually Transmitted Infections (STIs) and closely related conditions

## SCOPE AND PURPOSE

### Summary

1. The overall objective(s) of the guideline need to be described
2. Highlight the clinical question(s) covered by the guideline
3. Give a clear description of the target population
4. Give a clear description of the target users

### Notes

The example below represents a format that can be applied to most of the guidelines. Clearly some guidelines are not about the specific management of an STI, but relate to a condition or clinical practice that is common to the specialty. In those circumstances authors are still required to consider and document the above points (1-4).

Generic statement:

- (1) ***The main objective is to reduce the number of sexually transmitted infections (STIs) and the complications that can arise in people either presenting with signs and symptoms of an STI, or undergoing investigation for possible infection.***

Specifically:

- (2) ***This guideline offers recommendations on the diagnostic tests, treatment regimens and health promotion principles needed for the effective management of (insert main topic of guideline). Covering, the management of the initial presentation, as well as how to prevent transmission and future infection.***

- (3&4) ***It is aimed primarily at people aged 16 years or older (see specific guidelines for those under 16) presenting to health care professionals, working in departments offering level 3 care in STI management (see national strategy<sup>(2)</sup>) within the United Kingdom. However, the principles of the recommendations should be adopted across all levels (levels 1 and 2 may need to develop, where appropriate, local care pathways).***

## STAKEHOLDER INVOLVEMENT

The extent to which the guideline represents the views of the intended user(s) should be stated.

### Summary

5. Set out the involvement of appropriate professional groups.
6. Document patient input in the guideline development.

7. Prior to publication, a 'pilot' guideline should be made available to such 'stakeholders' and their input documented as part of the validation process.

## Notes

(5) Representation from the relevant professional groups may include doctors, nurses, health advisers, pharmacists etc. In most circumstances this will involve working with the relevant special interest group (SIG) of the BASHH. Their involvement may include the selection or review of the evidence, and/or the formulation of the final recommendations. Information will need to be provided about the composition, discipline, and relevant experience of the group, and how they were involved in the development of the guideline.

(6) There are various methods for ensuring that patients' perspectives inform guideline development. For example, direct patient representation, contacting patient associations or published work on patient experiences. Increased patient involvement is also a current aim of the Department of Health (DoH), and links are likely to emerge in the near future ([www.doh.gov.uk/involvingpatients](http://www.doh.gov.uk/involvingpatients))

Explicitly, the guideline should state:

- where and what form of patient involvement has been undertaken
- that published evidence has been
  - looked for (and how)
  - rated
  - and included if appropriate.

If no applicable information has been found this should also be documented.

(7) The guideline needs to be pre-tested for further validation amongst a sample of its intended end users prior to publication. This process should be documented.

Example:

***Prior to submission this guideline was distributed to 3 consultants in Genitourinary Medicine. They were asked to use the guideline as an aid to the management of patients presenting with (insert main topic of guideline). Their comments were noted and incorporated into the current document.***

## RIGOUR OF DEVELOPMENT

Relates to the process used to gather and synthesise the evidence, the methods to formulate the recommendations and to update them. To achieve this the guideline should be a systematically developed set of statements, and the process underlying its development needs to be transparent, robust and reproducible (8-14).

## Summary

8. Details of the search strategy used.
9. Details of the inclusion/exclusion of evidence criteria used
10. Formulation of recommendations
11. Consideration of harms as well of benefits of recommendations
12. The evidence base for the recommendations
13. The initial review process
14. Timescale for next revision
15. Dissemination process

## Notes

8) Details of the strategy used to search for evidence should be provided, including search terms, sources consulted, and dates of the literature covered. Sources may include electronic databases (e.g. Cochrane library, Medline, Embase), hand searching journals, conference proceedings and other guidelines (ensure compatibility or address areas of conflict).

9) Criteria for including/excluding evidence identified should be provided. These criteria should be explicitly described and reasons for including and excluding evidence clearly stated. For example, you may decide to only accept evidence from a systematic review or randomised control trial etc, or you may decide only to use articles published in the English language.

(10) There should be a description of the methods used to formulate the recommendations and how final decisions were arrived at. Again, this may involve documentation of the work undertaken within the SIG, other authors and/or expert opinion. Areas of disagreement and methods of resolving them should be specified.

(11) The guideline should consider health benefits, side effects and risks of the recommendations, with evidence that these issues have been addressed.

(12) There should be an explicit link between the recommendations and the evidence on which they are based (see appendix 4). These will need to be referenced as appropriate.

(13) Once the guideline has undergone formal assessment by the CEG (see appendix 1), and pre-test piloting (see 7), it will then be available to be reviewed externally for a period of three months.

This is undertaken by the CEG. A draft guideline will be placed on the BASHH ([www.bashh.org](http://www.bashh.org)) website and attention drawn to this through announcements in the newsletter and e-mail.

Generic statement: ***Prior to publication the final draft of the guideline was placed on the BASHH website, and circulated through the BASHH regional network. After a period of three months any comments received were reviewed by the guideline authors, and***

***acted on appropriately, before final authorisation by the CEG was given and publication was undertaken.***

Consideration of some of these comments may appear in the final draft as part of the documentation process.

(14) In order to remain up to date, and reflect advances in the field, the CEG will designate the timescale for the review and the revision of the guideline.

(15) Dissemination and application will be undertaken and documented by the CEG.

The CEG will support initial publication of the guideline in a peer-reviewed journal. Further updates will appear on the BASHH website. A letter highlighting the updates will be forwarded to the original journal where the guideline was first published.

The guidelines will also be available to other guideline databases: Royal College of Physicians [www.rcp.ac.uk](http://www.rcp.ac.uk); the USA National Guideline Clearinghouse [www.guideline.gov](http://www.guideline.gov).

Additional material produced in conjunction with or on behalf of the BASHH (e.g. leaflets or educational courses) will be expected to reflect the recommendations.

## **APPLICABILITY**

Pertains to the likely organisational, behavioural and cost implications of applying the guideline.

(16) Consideration needs to be given to the impact the guideline may have on the current organisation of care. For example, a statement recommending that testing for gonorrhoea may only be undertaken where immediate microscopy is available, could involve organisational changes for some services. Therefore, such statements will need to be discussed and validated with appropriate evidence.

(17) If the application of the recommendation is thought to involve additional resources, this should be discussed within the guideline.

(18) The guideline should offer clearly defined review criteria in order to facilitate audit. This may be in the form of explicit recommendations for audit.

## **EDITORIAL INDEPENDENCE**

(19) Generic statement:

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

(20) Specific:

In addition there should be an explicit statement that all authors and group members have declared, and provided details, on whether they have an actual or potential conflict of interest (see appendix 2). A list of any actual or potential conflict of interest must be included in the guideline, broken down by individual, including nil returns as appropriate.

## References

1. The Agree Collaboration. Appraisal of Guidelines for REsearch & Evaluation (AGREE) Instrument. [www.agreecollaboration.org](http://www.agreecollaboration.org)
2. The national strategy for sexual health and HIV; July 2001: [www.doh.gov.uk](http://www.doh.gov.uk)
3. Rockville, MD: AHCPR, 1993: 107. (Clinical practice guideline No 1, AHCPR publication No 92-0023)
4. Scottish Intercollegiate Guidelines Network. SIGN 50: a guideline developers' handbook. Edinburgh: SIGN, 2001.

This document is an update of the original article:

Rooney G, Daniels D, FitzGerald M, Ahmed-Jushuf 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.

It can be viewed on [www.rsmppress.co.uk/std.htm](http://www.rsmppress.co.uk/std.htm).

## **Appendix 1**

### **The assessment**

This will be undertaken formally and independently by at least 2 members of the CEG. It will follow the AGREE Instrument format <sup>(1)</sup>. Available on: [www.agreecollaboration.org](http://www.agreecollaboration.org) for individuals who may want to undertake their own assessment.

### **Documentation**

The CEG will need all the information about the guideline development before the formal assessment is undertaken. Some of this may already be included in the recommendations. The rest will need to be supplied separately.

These assessments will be formally undertaken by the CEG prior to publication for comment on the website. The process will involve two members of the CEG. They will score the guideline using the above assessment tool, and will provide the initial feedback to the authors. If major revisions are felt necessary, these will be undertaken by the authors prior to their being placed on the website for wider consultation.

## **Appendix 2      Editorial independence and potential conflicts of interest**

The CEG has determined that members of the CEG, its guideline development groups and any ad hoc groups or individuals having direct input into the guideline should provide a formal written declaration of personal interests. It is important that a declaration of interest form be completed before any policy decision involving the individual is taken.

In some instances, where an individual is felt to have a possible conflict of interest with a limited part of the guideline development or recommendations, that individual may continue to be involved in the overall process but elect to withdraw their involvement from the area of possible conflict. This should be documented and available for external review.

An 'interest' is defined as any arrangement in the past 12 months, which constitutes a current significant benefit to the individual, partner of that individual or their immediate family. It includes a financial benefit (starting at £750 or greater), to the person, practice or department in which they are employed and also membership of any organisation whose interests might conflict from time to time with the CEG sponsored guideline.

Generally, but not exclusively, the situation might include:

- Sponsorship or payment of expenses by commercial organisations
- Donations, sponsorship or similar from pharmaceutical firms and equipment manufacturers
- Consultancies and fees paid
- Patents (existing and pending) held by the individual or department
- Holding of shares in commercial organisations (pharmaceutical/equipment manufacturers for example), but excluding those held in pooled investment funds.
- Membership of any national body, charity or pressure group
- Editorial fees for publications (written or electronic)

Forms should be completed and returned to the CEG.

## 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:**

**title:**

**Role in guideline development:**

**Signature:**

**date:**

### Appendix 3 Style Points

- Use bullet-points (not numbers or letters – See section entitled “Treatment”\_below for exception) to put the text into note form as follows:

<ul style="list-style-type: none"> <li>• <i>Abcdefgh</i></li> <li>• <i>Ijklmnopq</i></li> <li>• <i>Rstuvwxyz</i></li> </ul>	<p>If second-level bullet-points are employed use as follows:</p> <ul style="list-style-type: none"> <li>• <i>Abcdefgh</i> <ul style="list-style-type: none"> <li>• <i>Ijklmnopq</i></li> <li>• <i>Rstuvwxyz</i></li> </ul> </li> </ul>
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- Always define abbreviations when first used e.g. Centres for Disease Control (CDC)
- Always put full microbiological names in italics e.g. *Chlamydia trachomatis*. Otherwise avoid use of underlining, bold or italics in the text.
- Both levels of evidence and recommendations (see appendix 2) should be graded in the text immediately following the statement to which it applies. The letter or number should be inserted in ordinary brackets e.g. (I).
- Reflecting the strength of the available evidence, recommendations need to be specific and unambiguous. They should provide a clear and precise description of which management is appropriate, in which situation and in what patient group. Where evidence is poor or lacking this should be stated in the guideline.
- The guideline should be concise (preferred maximum 2000 words, excluding references). To this end bullet-points, tables and flow charts may be used where required.
- Font type is Verdana. Font size is 14 for main title and 12 for the body of the text.
- In terms of spelling and use of grammar the BMJ house style is recommended: [www.bmj.com/advice](http://www.bmj.com/advice)
- Submission to CEG should be in Microsoft Word-for Windows format

## Appendix 4      Levels and grading of evidence

All major recommendations should be graded according to the level of evidence. The system to be used is that published by the US Department of Health and Human Services agency for Healthcare Policy and Research (AHPCR) <sup>(3)</sup>.

The relevant number/letter need to be placed at the end of the statement to which it refers. Where the evidence level = C (expert opinion), a footnote or reference is required (e.g. which expert body on which occasion).

**Table A**

Level	Type of evidence
Ia	Evidence obtained from meta-analysis of randomised controlled trials
Ib	Evidence obtained from at least one randomised controlled trial
IIa	Evidence obtained from at least one well-designed controlled study without randomisation
IIb	Evidence obtained from at least one type of well-designed quasi-experimental study
III	Evidence obtained from well-designed, non-experimental descriptive studies, such as comparative studies, correlation studies and case control studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

**Table B**

Grade	Recommendation
A (Evidence levels Ia, Ib)	Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation
B (Evidence levels IIa, IIb, III)	Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation
C (Evidence level IV)	Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates absence of directly applicable studies of good quality