Protocol for the production and revision of
IUSTI/WHO European sexually transmitted infection (STI) guidelines

1. Initiation of guideline production or revision

The proposal to produce a new guideline, or to revise an existing guideline, can be made by any member of the European Branch of the IUSTI (IUSTI-Europe), or by the European Office of the WHO (WHO-Europe).

The decision to produce a new European guideline, or to revise and update an existing one, will be made by the Editor-in-Chief.

2. Selection of authors and editors

- A guideline must be co-authored by at least two people, from different European[1] countries.
  Suggestions for authors can be obtained by contacting –
  - The other members of the Editorial Board (the representatives of the ECDC and WHO-Europe will also seek nominations through their own networks of contacts in Europe).
  - Members of the IUSTI Europe Council (via the Secretary, Dr Claudia Heller-Vitouch, e-mail: c.t.heller@chello.at).
- A lead author for the guideline will be identified. Authors will be invited to produce the guideline on behalf of IUSTI and WHO by the Editor-in-Chief.
- As the involvement of a large number of authors tends to lead to a delay in producing a guideline, the number of authors will be limited. In most cases it is expected that there will be two or three authors, each from a different European country.
- An editor will be appointed to oversee the production of each guideline. Editors will be appointed by the Editor-in-Chief.
- The guideline editor will place a brief announcement on the IUSTI website (www.iusti.org)[2] containing the following information: that the guideline is being produced/updated; the names of the authors; the name and e-mail address of the guideline editor, inviting interested parties to contact them if they wish to contribute to the process.

3. Review of the literature

- A thorough and systematic review of the literature must be undertaken to obtain the evidence base for the production of the guideline.

- Essential steps include:-

1) A search of Medline and Embase
2) A search of the Cochrane Library, including:
   - The Cochrane Database of Systematic Reviews

- The Database of Abstracts of Reviews of Effects
- The Cochrane Central Register of Controlled Trials

3) Review of relevant guidelines produced by the US Centers for Disease Control (www.cdc.gov/std/)
4) Review of related UK national guidelines (www.bashh.org)

- An optional step is the organisation of a workshop of invited experts to discuss and decide upon controversial issues pertaining to the diagnosis and management of a condition. The experts can be asked to prepare discussion (scientific background) papers in advance, using the format of key questions, review of data and proposed answers, as previously used in IUSTI/WHO Europe workshops for invited experts. These papers, with the comments given during the workshop, can be used to assist in the subsequent writing/updating of the guideline and can be used to inform all those interested in the field.
  The responsibility for organising such a workshop in the name of IUSTI Europe should be clearly delegated to a suitable individual by the Editor-in-Chief. Such a workshop should preferably be organised in cooperation with WHO Europe, which organisation may also help in organising the workshop and subsequent actions (report, translation and implementation).

4. Format

The main point to remember is that a guideline is intended to be used by a clinician in helping him or her to decide what to do in a clinical situation. Therefore it is very important that the guideline is concise and readable. It is not intended to be a monograph or a review article, and it is therefore undesirable to include substantial blocks of text explaining the details of studies underpinning the recommendations, and the thinking the authors went through in coming to their conclusions. Although it may be of interest to some users of the guidelines, such material would better be produced separately in the form of one or more supporting papers for the guideline.

The guideline should therefore be as brief as possible. An indicative word count would be between 1,500 and 3,000 words, excluding tables.

Recommendations must be clear and unequivocal. Where there is more than one acceptable option, then it should be made clear whether there is a clear order of preference, i.e. 1st line, 2nd line etc., or where the evidence does not allow a definite distinction to be made between the options (that is, they are to be regarded as equivalent) then this must also be made clear.

Recommendations must address all the key elements required for the management of a case, including diagnosis, treatment, partner notification and also what information should be given to the patient.

To ensure brevity and clarity, there should be logical use of sub-headings, and the use of bullet points is strongly encouraged to break up the text in a logical fashion.

A typical set of sub-headings to be used would be as follows:

- Title – e.g. "2007 European (IUSTI/WHO) guideline on …"
- Authors
- Lead editor (if published in a journal the lead editor's name should be included in the list of authors, in a position to be decided by the lead author.
- Aetiology and transmission
- Clinical features
    - Symptoms
    - Physical signs
    - Complications
- Diagnosis
- Management
    - Information, explanation and advice for the patient
    - Therapy
    - Partner notification
    - Follow-up
    - Prevention/health promotion
- Proposed review date
- Acknowledgements

  List (by alphabetic order of surname) persons, other than the authors or editorial board members, who have made a contribution to the guideline.
- Composition of editorial board (see appendix 2)
- References

  A full list of referenced source materials must be provided at the end of the guideline. All significant statements made in the guideline should be referenced with respect to these sources in the usual way.
- Appendices:
    - Search strategy
    - Tables of levels of evidence and grading of recommendations (see 5 below)
    - Statement on declarations of interest (see Appendix 1)

5. Levels of evidence and grading of recommendations

These must be provided for all key recommendations made for diagnosis and management. They should be inserted within the text, according to the following schemes[3]:

Levels 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 study without randomisation.
IIb	Evidence obtained from at least one other 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.

Grading of Recommendations

A (Evidence levels Ia, Ib)	Requires at least one randomised control 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 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.

6. Declarations of interests

Each author and editor involved in the production of a guideline will be asked to make a written declaration of interests utilising a standard form (see appendix 1). This information, or a summary of it, will form part of the guideline and will be published with it. Authors will return their declarations to the editor of their guideline; editors will return their declarations to the Editor-in-Chief.

7. Review

Each guideline to contain a suggested date for future review.

8. Consultation

Once the draft guideline has been produced by the authors, it will be sent to the editor who will undertake the formal review process including the following steps -

- The guideline to be placed on the IUSTI website for at least 3 months.
- The guideline to be sent to all members of the European STD Guidelines Editorial Board asking them to read and comment upon it.
- E-mails to be sent via the Secretary of IUSTI Europe to all members of the IUSTI Europe Council, and to the STD division of WHO-Europe, asking them to read the guideline themselves, and also to send the guideline to one or more experts in their respective countries. All comments to be sent to both the lead author and the editor by a given deadline.

- The authors to suggest to the editor two experts in the field who could be approached to give an independent opinion on the guideline (this step may be omitted if the guideline is to be submitted to a journal whose editor is going to send it out for peer-review).

9. Finalising the guideline

Any comments obtained through the consultation exercise to be discussed between the editor and the co-authors, and agreement reached by a process of consensus to produce the final version of the guideline.

The final version of the guideline can only be signed off as an accepted formal IUSTI/WHO European STD Guideline by the Editor-in-Chief.

Endorsement of the guidelines by the European Office of the World Health Organisation (WHO-Europe), the European Centres for Disease Prevention and Control (ECDC), the European Dermatology Forum (EDF) and by the Union of European Medical Specialists (UEMS) will be sought. The lead editor for the guideline will be responsible for seeking this by sending a copy to the WHO-Europe, ECDC, EDF and UEMS representatives on the Editorial Board.

10. Publication and dissemination

This is the responsibility of the lead editor. The guideline may be published solely in electronic form on the IUSTI and WHO websites, or paper publication in a journal may simultaneously be sought (it is particularly appropriate to publish in the *International Journal of STD & AIDS* as this is the official organ of the IUSTI). If published in a journal then the lead editor's name should be included in the list of authors, in a position to be decided by the lead author.

Scientific back-ground papers, if produced, may be published solely in electronic form on the IUSTI and WHO websites, but paper publication in a journal may also be sought.

Notes:
1. Europe as a geographic region is as defined by the WHO.
2. Contact: IUSTI webmaster (email: webmaster@iusti.org)
3. US Department of Health and Human Services 1997.

Dr Keith Radcliffe
Editor-in-Chief
IUSTI European Regional Director

Approved by IUSTI Europe at a meeting held on 12 October 2005

This version dated 29 September 2010

Appendix 1 : Declaration of interests for authors and editors of IUSTI / WHO European STD guidelines

Title of guideline: _____

Authors / editors to record possible interests in each of the categories listed below.

Interests need only be considered for inclusion if:-

- The total (cumulative) amount within the preceding 12 months exceeds 1,000 euros

and

- It is related to the remit of the particular guideline under consideration

Details of relevant employment/self-employment (including directorships, partnerships and work as an adviser or consultant).

Details of shares held in companies.

Details of gifts received or expenses paid (including to attend conferences or scientific meetings).

Details of research grants held (both by the individual and by his/her department).

Note: Amounts do not need to be specified.

Name of author / editor (delete as appropriate): _____

Signature: _____

Date: _____

Appendix 2 : European STI Guidelines Editorial Board

Dr Keith Radcliffe, UK – Editor-in-Chief

Dr Karen Babayan, Armenia (appointed 2009)
Dr Marco Cusini, Italy (app. 2010)
Prof Mikhail Gomberg, Russia (app. 2010)
Dr Michel Janier, France (app. 2006)
Dr Jorgen Skov Jensen, Denmark (app. 2006)
Prof. Harald Moi, Norway (app. 2007)
Dr Raj Patel, UK (app. 2006)
Prof Jonathan Ross, UK (app. 2006)
Dr Jackie Sherrard, UK (app. 2009)
Dr Magnus Unemo, Sweden (app. 2009)
Dr Willem van der Meijden, Netherlands (app. 2006)

Dr Simon Barton (UK) – UEMS representative, UK (app. 2010)
Dr Lali Khotenashvili – WHO European Office representative, Georgia (app. 2007)
Dr Marita van de Laar – ECDC representative, Netherlands (app. 2007)
Prof. Martino Neumann – EDF representative, Netherlands (app. 2007)
Dr Angela Robinson, - EADV representative, UK (app. 2009)

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