Introduction

This document is one of a series that has been developed to help countries implement FCTC Article 14. It offers guidance on how to develop national guidelines for tobacco cessation support (as in the FCTC Article 14 guidelines the terms cessation support and tobacco dependence treatment are used interchangeably). It can also be used to update existing guidelines. The guidance contained in this document closely follows the recommendations of the FCTC Article 14 guidelines.

It is designed to be used with the National Situation Analysis (NSA) and the Effectiveness and Affordability Review (EAR).

The NSA has been designed to help develop or update a national cessation strategy.

The EAR summarises in a concise format the evidence for tobacco cessation support, with estimates of affordability. It is designed to be used as as the evidence base for national guidelines, and to help choose what interventions to prioritise with the resources available. This should speed up the process of guidelines development, help to keep them short and focused on what needs to be done, and help keep them affordable by removing the necessity of re-reviewing the evidence. The EAR includes a calculator into which you can input country data, in order to calculate the cost effectiveness and affordability of an intervention in your country.

It is recommended that these tools are used with the support of an independent specialist, who can offer an objective perspective, help collect and summarise information, and then suggest options for next steps. This can be especially valuable when governmental and nongovernmental organisations are working together.

These tools are freely available for anyone to use. However they will periodically updated and improved, in the light of our experience working with them, and so we recommend that you occasionally check for the latest versions with us (see on) and /or on www.treatobacco.net, where they will be posted.

Why produce national guidelines?

Firstly because it is an obligation of FCTC Article 14. In some countries guidelines are also important in legitimising the topic of tobacco cessation support, where, if guidelines do not exist, it is taken as implied that the topic is not important.
The FCTC Article 14 guidelines recommend that Parties develop and disseminate comprehensive tobacco dependence treatment guidelines, which include two major components:

1. A **national cessation strategy** to promote tobacco cessation and provide tobacco dependence treatment, aimed principally at those responsible for funding and implementing policies and programmes.

2. **National treatment guidelines** aimed principally at those who will provide and manage cessation support to tobacco users.

We recommend that these two components be produced as separate documents as their principal audiences are likely to be different. In many countries the national cessation strategy will be a section in a national tobacco control strategy. National treatment guidelines can then be focused on healthcare and other relevant workers.

**What are guidelines?**

The FCTC A14 guidelines (para 23 footnote) define treatment guidelines as: "systematically developed statements to help service managers, practitioners and patients to make decisions about appropriate treatment for tobacco dependence and cessation."

Guidelines usually contain a set of recommendations of actions for different sectors of the healthcare system and different healthcare workers, for example: "All smokers should be offered brief advice to quit." and "A system for identifying all smokers and documenting tobacco use should be used in every practice or healthcare service."

They sometimes contain (long) reviews of the evidence base; we recommend that you use the EAR as your evidence base and keep the guidelines themselves focused on what healthcare and other workers should do. You could, if there is some reason for doing so, include a summary of the evidence base as an appendix, or as a separate document posted online.

Guidelines should clearly state what should be done.

Guidelines can also be a used as a tool to persuade relevant authorities, including governments, to take action on cessation support. Some influential guidelines were developed by cessation specialists and professional bodies rather than by governments, and used to describe action needed at national level.

**How will your guidelines be disseminated and implemented?**

Plan how you will disseminate and implement your guidelines before you start writing them.

In this plan specify the objectives of the guidelines, the target audiences and how they will be reached, how the guidelines will be implemented, who will be responsible for ensuring they are implemented, how implementation will be funded if funding is needed, and how their impact will be assessed.

Dissemination options include publishing in scientific journals, publishing as a book or report which is sent to all healthcare workers, publishing online, and some combination of all
of these. The key points here are how will you ensure that the guidelines will reach all healthcare workers and will achieve their intended objectives?

**Questions to ask before starting (or updating) guidelines**

Answer these questions as you plan your guidelines, and preferably before you start writing:

1. What do you want to achieve with your guidelines? (what are their objectives)
2. Who do you want to read them? (which are their target audiences)
3. How will these people get them?
4. How will they change actual practice?

**Checklist: how to develop guidelines**

1. Identify a budget if needed.
2. Draw up a timetable.
3. Base the recommended interventions on their effectiveness and affordability using the EAR.
4. Select the lead author and if necessary secure funding for this person.
5. Select reviewers that will review the draft guidelines.
6. Set up the process of getting national professional associations and societies (doctors, GPs, nurses, community nurses, dentists, pharmacists, etc) to review and formally endorse the guidelines.
7. If the guidelines are not initiated by government ensure that the government formally endorse them; start liaising with the government as early as possible.
8. Keep your guidelines as short and action oriented as possible.
9. A library of existing national guidelines can be found at www.treatobacco.net.

**Notes on this checklist**

1. The budget may need to cover the time of the writer/project leader, and may be needed for design, printing, and dissemination. The FCTC and FCTC Article 14 guidelines emphasise that the process must be protected from actual and potential conflict of interest, including, obviously, with the pharmaceutical industry.

2. Using existing resources including the EAR and possibly experienced international experts to help, we believe a national guideline might be completed in about one year.

3. The project leader should be an experienced and respected cessation specialist, with good writing, communication and leadership skills.

5. This need not be a large number of people nor take too much time if planned in advance. There is so much experience around the world in writing guidelines that international as well as national experts may be able to help.

6. Experience in some countries suggests that endorsement of guidelines by influential national professional bodies greatly enhances their perceived authority. This process can take time so plan it in advance.

9. The www.treatobacco.net resource library offers access to more than 30 national treatment
guidelines; you may also find it helpful to talk to some guidelines authors.

**Main elements of national tobacco cessation guidelines**

In general keep guidelines as short as possible, focused on what you want done, and who you want to do it.

Consider having at the front an algorithm or flowchart showing the pathway for the healthcare worker, from raising the issue, to giving brief advice, offering support and referring to specialist support where it exists.

Examples of such flowcharts can be found in existing guidelines (Scotland 2004, Australia 2011) (see resources section below).

The headings below are not all essential but represent fairly traditional guidelines content. Much can be shortened, left out, or might be better placed in a technical appendix, or in a different document, possibly online.

**Introductory and 'procedural' pages:**
- Title page
- Contents page
- Authors with their institutional affiliations
- Reviewers with their institutional affiliations
- Endorsing organisations.
- There should be a clear description of the writing process, which explains who did what and how the guidelines will be kept up-to-date.

**Acknowledgements and funding:**
- There should be a prominent and clear description of funding sources, including any relevant relationships between funders and authors, and conflict-of-interest statements of all authors, at the front of the document. The Article 14 guidelines stress that national strategies and guidelines must be protected from vested interests.
- This includes the tobacco industry but also industries with clear conflicts of interest, the most obvious being the pharmaceutical industry. If pharmaceutical industry funding is used to produce national guidelines, it needs to be clearly shown that there was no connection at all between the funding and the writing process, and this needs to be clearly stated in the document.
- Even if these conditions are met pharmaceutical industry funding may be perceived as a conflict-of-interest. Our recommendation is not to use pharmaceutical industry support for treatment guidelines.
- Obviously national cessation guidelines should not display commercial logos.
- This section will include any other acknowledgements.

If a definition of terms section is desired it could be copied from the FCTC Article 14 guidelines, or you could refer to the Article 14 guidelines.

We suggest keeping the **introductory content** as brief as possible. In some countries knowledge of the dangers of tobacco use, and benefits of stopping, is so widespread that such a section is unnecessary. However in others such knowledge may not be widespread so it
may be important to emphasise the health risks.

Introductory content if needed:
- Tobacco use and the extent of the problem
- The health risks
- The benefits of stopping

Main recommendations:
- Evidence statements if desired but we recommend using the EAR.
- Set of recommendations, for example of the form:
  - All smokers should be offered brief advice to quit.
  - A system for identifying all smokers and documenting tobacco use in notes should be used in every practice or healthcare service
  - GPs should - - - - -
  - Hospitals should - - - - -
  - Etc

Technical appendices, for example (these headings are from the New Zealand guidelines):
- Benefits of stopping
- Assessing dependence
- Withdrawal symptoms
- Weight gain
- Prescribing information.
- Cost effectiveness evidence.

Cost effectiveness

Presenting the cost effectiveness evidence may be important in persuading some governments of the value of investing in providing tobacco cessation support, as was the case with the original English guidelines.

The EAR assesses affordability using WHO's definition and the cost effectiveness tables from Stapleton et al (see below). There is a considerable scientific literature showing tobacco cessation to be one of the most cost effective healthcare interventions; you can cite West et al and Stapleton & West on this.


Monitoring the impact of guidelines

Ideally in planning your guidelines you should plan how you are going to assess their impact, so that after a year or so you know:
Did they reach their target audience?
Did they achieve their objectives?

Resources

www.treatobacco.net contains a library of national treatment guidelines as well as links to other organisations and resources, including WHO, the FCTC Secretariat, Cochrane Library abstracts, and others. The authors are also happy to be contacted for advice and also, where relevant, refer to other specialists and organisations.

Origin, authorship and funding

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These documents have been produced working in close association with Robert West and Ann McNeill, all of whom are members of the UK Centre for Tobacco Control Studies, and authors of the Effectiveness and Affordability Review.

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Author interests statements

Martin Raw does not accept funding from the manufacturers of stop smoking medications and has not done so since 2008; Hayden McRobbie has received honoraria for speaking at research symposia and received benefits in kind and travel support from, and has provided consultancy to the manufacturers of smoking cessation medications.

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