World Health Organization

EXECUTIVE BOARD **EB137/5**
137th session **20 May 2015**
Provisional agenda item 7

WHO guidelines: development and governance

Report by the Secretariat

1. At its 136th session the Executive Board, having considered the proposal for a supplementary agenda item contained in document EB136/1 Add.1, requested the Secretariat to prepare a report for consideration by the Executive Board at its 137th session on the governance and development of WHO guidelines, with particular emphasis on the role of Member States.

2. Article 2(k) of the Constitution of WHO states that a function of the Organization is to "make recommendations with respect to international health matters". The Twelfth General Programme of Work of WHO specifies that in its normative and standard-setting work WHO is and will remain a science- and evidence-based organization with a focus on public health. Guidelines are one of the key means through which the Organization fulfils its technical leadership in health, as identified in the General Programme of Work.

3. For the purposes of this document, a WHO guideline refers to any document developed by WHO containing recommendations for clinical practice or public health policy.

4. Over the past decade, in response to substantial public criticism[1] of its previous approach to guideline development, WHO has developed stringent and state-of-the-art methods for ensuring that its guidelines are of the highest quality, are based on a comprehensive review of evidence and are independent, with appropriate management of conflict of interest. These methods are essential to ensure that the Organization's recommendations are independent, evidence-based and unbiased.

5. The principles on which guidelines are developed are:

- Guidelines address an area of uncertainty and an unmet need for guidance.
- Guidelines reflect the core WHO value of the "right to health".
- The process of developing recommendations is explicit and transparent: the user can see how and why a recommendation was developed, by whom, and on what basis.
- The process of developing guidelines is multidisciplinary and includes all relevant expertise and perspectives, including input from stakeholders.

[1] See, for instance, Oxman AD, Lavis JN, Fretheim A. Use of evidence in WHO recommendations. Lancet. 2007;369:1883-9.

- The processes and methods used in each step of guideline development aim to minimize the risk of bias in the recommendations.

- Recommendations are based on a systematic and comprehensive assessment of the balance of a policy's or intervention's potential benefits and harms and explicit consideration of other relevant factors.

- The evidence used to develop WHO guidelines is publicly available.

- Recommendations can be implemented in, and adapted to, local settings and contexts.

- Guidelines should be tailored to a specific audience, such as public health policy-makers, health programme managers, health care providers, patients, caregivers, the general public and other stakeholders.

6. Member States play an important role at two critical points in the guideline development process. First, though governing body resolutions, they provide direction and identify priorities for the selection of topics for WHO guideline development. Secondly, they have the sole authority to decide whether and how to implement WHO guidelines at a national or subnational level, and whether or not to include national or local values and preferences in any implementation programme.

7. Collaboration with leading international guideline methodologists, national guideline-producing organizations and other experts has ensured that the approach used by WHO is consistent with international best practice. In brief, this method includes: definition of priority questions for guideline development in response to Member States' requests for advice and guidance; preparation of a scientific protocol for each guideline developed; selection of independent experts for each guideline development group, with careful management of any conflict of interest; systematic reviews of all available evidence; and deliberative decision-making by the guideline development group in advising WHO on formulating recommendations.

8. The WHO Guideline Review Committee ensures the quality of the overall process for all guidelines. The Committee, established in 2007, has members drawn from both WHO staff (headquarters and regional offices) and external experts. The Guideline Review Committee reviews a planning proposal early in the process of development of each guideline, as well as the final draft guideline prior to publication, in order to ensure that WHO's methodological standards have been met, that processes have been complied with, and that the guideline is appropriately reported.

9. In 2007 the Guideline Review Committee published the *WHO Handbook for Guideline Development*, which described the processes and standards WHO used in developing WHO guidelines. The Handbook has been revised and updated regularly, most recently in December 2014,[1] both as a result of users' feedback and following a review of scientific research in guideline development. This ensures that the processes and standards described in the Handbook remain both practical and consistent with best practice. The Handbook is used as the basis for training both WHO staff and external experts who work on WHO guidelines, to ensure consistent application of the highest technical standards.

[1] WHO handbook for guideline development, second edition. Geneva: World Health Organization; 2014.

10. The Handbook provides guidance to guideline development groups on how to assess the quality of scientific evidence that is used as the basis for developing recommendations. It also provides guidance on how recommendations should be characterized. A "strong" recommendation can be made when the guideline development group, having evaluated the evidence, considers that the desirable effects (or benefits) of implementing the recommendation outweigh the potential undesirable effects (or harms). On the other hand, a "conditional" recommendation is formulated when the guideline development group is less certain about the balance between the harms and benefits of implementing a recommendation. Conditional recommendations generally include a description of the conditions under which the end-user should or should not implement the recommendation. Characterizing recommendations in this way assists Member States in prioritizing interventions.

11. In addition to the balance of benefits and harms, the guideline development group explicitly considers other factors when formulating recommendations, including the relative importance of the potential outcomes, the preferences of affected populations regarding intervention, the feasibility of implementation, the effect on equity across subpopulations, and resource implications. In the final guideline, the rationale for each recommendation must be presented in a clear and explicit statement, in order to maintain the integrity and independence of the guideline development process. Each rationale statement accordingly describes the elements that lead to a strong or conditional recommendation for or against an intervention.

12. The Handbook also provides advice on selection of members of guideline development groups. This guidance is based on the processes used for selecting experts to be members of WHO expert advisory panels. Members should have appropriate technical skills relevant to the guideline topic, they should provide diverse perspectives, and the overall composition of the guideline development group also needs to be balanced in terms of regional and gender representation. In the exercise of their functions, members of a guideline development group act as international experts serving the Organization only and may not receive or request instructions from any government or authority external to the Organization. Where relevant, members of WHO expert advisory panels can be selected for appointment as members of guideline development groups.

13. Each guideline is developed by the relevant guideline development group under the direction of a WHO steering group. This group consists of technical staff from the relevant departments. One of the key functions of each steering group is to assess disclosures of interests and manage them in a transparent way in accordance with WHO policy on conflicts of interest for experts, in consultation with the WHO Office for Compliance, Risk Management and Ethics.

14. The WHO "declaration of interests" form addresses both financial and non-financial (intellectual) interests that might interfere with the ability of an individual to objectively assess a body of evidence and provide independent advice to the Organization. To further enhance the transparency of the process of collecting and assessing disclosures of interests and managing conflicts, the revised guidelines for declaration of interests (for WHO experts) require that the names and brief biographies of individuals being considered for membership of a guideline development group must be published on the WHO website, together with a description of the objective of the guideline development group, for a period of at least two weeks and well ahead of the first planned meeting.

15. A centralized, up-to-date repository of WHO guidelines that have been approved by the Guideline Review Committee is maintained on the WHO website.[1] In addition, relevant WHO

[1] See http://www.who.int/publications/guidelines/en/.

departments publish on their own websites not only the guideline documents but also all background documents for any specific guideline (such as systematic reviews), except where they are constrained by copyright considerations (in which case a citation is provided for the source document).

16. One of the challenges in the guideline development process is to balance rigour, consultation with stakeholders and transparency with timeliness and efficiency. For a WHO "standard guideline", the timeline for development is currently some two years, which may be seen as slow in terms of responsiveness. Guidelines requested in response to a public health emergency need to be developed within weeks to months. Mandatory public consultation would significantly increase guideline development time.

17. Areas for further improvement in WHO's guidelines development process include continuing progress in how best to use scientific evidence, ensuring clarity of recommendations, and advice on implementation of interventions. Formal evaluation, including feedback from Member States, of the ease of implementing WHO guidelines, and of their language and clarity, as well as of barriers and facilitators to implementation would be desirable. Such evaluation should consider how best to communicate the basis for, and implications of, a strong recommendation as compared to a conditional one, as well as the meaning of high-, moderate-, low- and very low-quality scientific evidence. There is also a need to establish formal evaluation of the health impact of WHO guidelines.

18. In the past seven years, the processes for development and quality assurance of guidelines produced by WHO have substantially improved. To maintain this trend will require further investment. Priorities for development currently include: a centralized, public, web-based repository of all guidelines and background documents; effective processes for public consultation during guideline development; further elaboration of methods for preparing "emergency guidelines", so that they are produced rapidly and rigorously; continuing training for all WHO staff, including those from regional and country offices, in guideline development methods; and, as noted above, evaluation of the clarity and usefulness of WHO guidelines for Member States.

ACTION BY THE EXECUTIVE BOARD

19. The Board is invited to note the report.

= = =