



A Short Introduction to the WHO Guideline Development Process

(excerpts from: World Health Organization. (2014). *WHO handbook for guideline development*, 2nd ed. World Health Organization. <https://apps.who.int/iris/handle/10665/145714>)

1.1 What is a WHO guideline?

A WHO guideline is any document developed by the World Health Organization containing recommendations for clinical practice or public health policy. A recommendation tells the intended end-user of the guideline what he or she can or should do in specific situations to achieve the best health outcomes possible, individually or collectively. It offers a choice among different interventions or measures having an anticipated positive impact on health and implications for the use of resources. Recommendations help the user of the guideline to make informed decisions on whether to undertake specific interventions, clinical tests or public health measures, and on where and when to do so. Recommendations also help the user to select and prioritize across a range of potential interventions.

1.2 Why does WHO develop guidelines?

WHO develops guidelines whenever Member States, WHO country offices, external experts or other stakeholders ask for guidance on a clinical or public health problem or policy area. This generally happens when they are uncertain about what to do or how to choose among a range of potential policies or interventions. Uncertainty can be triggered by a new public health problem or emergency; the uncovering of new evidence; an absence of good-quality evidence (or of any evidence at all); or a change in resource availability or access to services.

1.3 What principles underlie WHO guidelines?

The Twelfth General Programme of Work (GPW) of WHO (2014) 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 the fundamental means through which the Organization fulfils its technical leadership in health, as identified in the GPW. The GPW states that “WHO’s legitimacy and technical authority lie in its rigorous adherence to the systematic use of evidence as the basis for all policies” (1). WHO has adopted internationally recognized methods and standards for guideline development to ensure that its guidelines are of the highest quality.

WHO guidelines must be developed in observance of the following principles:

- Guidelines address an area of uncertainty and an unmet need for guidance.
- Guidelines reflect the core WHO value of the “right to health” (2).
- 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.
- 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. (The audiences that WHO guidelines can target include public health policy-makers, health programme managers, health-care providers, patients, caregivers, the general public and other stakeholders.)

Table 1.1. The guideline development process at WHO

Stage/primary contributor	Step	Chapter
Planning		
WHO Member State, WHO country office or public/private entity	Request guidance on a topic	1
WHO technical unit	Determine if a guideline is needed; review existing WHO and external guidelines	2
	Obtain approval for guideline development from the director of the relevant technical unit at WHO	2
	Discuss the process with the GRC Secretariat and with other WHO staff with experience in developing guidelines	2
	Form the WHO guideline steering group	3
WHO guideline steering group	Identify sufficient resources; determine the timeline	2
	Draft the scope of the guideline; begin preparing the planning proposal	2,4
	Identify potential members of the GDG and its chair	3
	Obtain declaration of interests and manage any conflicts of interest among potential GDG members	6
WHO guideline steering group and GDG	Formulate key questions in PICO format; prioritize outcomes	5,7
WHO guideline steering group	Finalize the planning proposal and submit it to the GRC for review	4
GRC	Review and approve the planning proposal	4
Development		
Systematic review team	Perform systematic reviews of the evidence for each key question	8
	Evaluate the quality of the evidence for each important outcome, using GRADE as appropriate	9
WHO guideline steering group	Convene a meeting of the GDG	10,11
GDG	Formulate recommendations using the GRADE framework	10,11
WHO steering group	Draft the guideline document	10,11
External review group	Conduct external peer review	12
Publishing and updating		
WHO guideline steering group and editors	Finalize the guideline document; perform copy-editing and technical editing; submit the final guideline to the GRC for review and approval	12
GRC	Review and approve the final guideline	12
WHO guideline steering group and editors	Finalize the layout; proofread	12
	Publish (online and in print as appropriate)	12
WHO technical unit and programme manager	Disseminate, adapt, implement, evaluate	13
WHO technical unit	Update	12

GDG: guideline development group; GRADE: Grading of Recommendations Assessment, Development and Evaluation; GRC: Guideline Review Committee; PICO: population, intervention, comparator, and outcome.