GUIDELINES

Process of Development of WHO Guidelines

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Abstract

A WHO guideline is any document containing recommendations about health interventions, whether these are clinical, public health or policy recommendations. A recommendation provides information about what policy-makers, health-care providers or patients should do. It implies a choice between different interventions that have an impact on health and that have implications for the use of resources. The purpose of WHO guidelines is to improve the health and well-being of individuals and populations

To accomplish that, WHO guidelines need to be formulated, disseminated, adopted or adapted, and their recommendations implemented. Recommendations in WHO guidelines are based on a systematic review of the scientific literature guided by specific key questions about the intervention, exposure or approach under consideration. The science underpinning evidence identification and synthesis and the translation of a body of evidence into recommendations continues to evolve. Because of this, any manual on how to produce a guideline requires frequent reassessment and updating.

Introduction

The purpose of WHO guidelines is to improve the health and well-being of individuals and populations (1, 2). To accomplish that, WHO guidelines need to be formulated, disseminated, adopted or adapted, and their recommendations implemented. A WHO guideline is any document developed by the World Health Organization containing recommendations for clinical practice or public health policy. A WHO 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.

Recommendations also help the user to select and prioritize across a range of potential interventions or measures having an anticipated positive impact on health and implications for the use of resources in a particular setting.

WHO recommendations help the user of the guideline to make informed decisions on whether to undertake specific interventions, clinical tests or public health measures. These recommendations are formulated based on best available scientific evidence. All relevant evidence is identified, synthesized and presented in a comprehensive and unbiased manner. This is challenging, yet it is essential in developing valid recommendations and high-quality guidelines. Recommendations in WHO guidelines are based on a systematic review of the scientific literature guided by specific key questions about the intervention, exposure or approach under consideration (Figure 1 & Figure 2).

WHO guidelines were developed in observance of the following principles:

i. Guidelines address an area of uncertainty and an unmet need for guidance.
ii. Guidelines reflect the core WHO value of the "right to health".

iii. 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.
iv. The process of developing guidelines is multidisciplinary and includes all relevant expertise and perspectives, including input from stakeholders.
v. The processes and methods used in each step of guideline development aim to minimize the risk of bias in the recommendations.
vi. The evidence used to develop WHO guidelines is publicly available.
vii. Recommendations are based on a systematic and comprehensive assessment of the policy's or intervention's potential benefits and harms and explicit consideration of other relevant factors.
viii. Recommendations can be implemented in, and adapted to, local settings and contexts.
ix. Guidelines are 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).

WHO Standard guidelines

A "standard" guideline is produced in response to a request for guidance in relation to a change in practice or controversy in a single clinical or policy area – such as treatment of postpartum haemorrhage or avian influenza, or minimum requirements for safe delivery of HIV care. A standard guideline is not expected to cover the full scope of the condition or public health problem.

These guidelines are prepared after consultation on the scope of the guideline and the issue that it covers. It is supported by systematic evidence reviews (that could be commissioned externally) and one or two meetings of the guideline development group for consultation. A standard guideline may have a specified "use- by" date depending on the expected rate of change of evidence in the topic area. Most WHO guidelines fall into this category.

The Recommendations in a standard guideline are either developed de novo or by updating previous WHO guidelines.

WHO Standard guidelines generally focus on one or more of the following:

i. Clinical interventions (e.g. the management of severe acute malnutrition in infants and children);
ii. Health-care system or policy approaches (e.g. Country pharmaceutical pricing policies);
iii. Public health interventions or exposures (e.g. Optimal intake of dietary folate in pregnant women);
iv. Diagnostic tests (e.g. Fluorescent light-emitting diode [led] microscopy for the diagnosis of tuberculosis), or
v. Surveillance and monitoring (e.g. Surveillance guidelines for measles, rubella and congenital rubella syndrome in the WHO European Region).

Standard guidelines usually take between 9 and 24 months to complete, depending on their scope, and are prepared after wide consultation on their need, scope and rationale. They are supported by one or more systematic reviews of the evidence and finalized after one or two meetings of the GDG. A standard guideline is reviewed by a specified date depending on how fast the evidence in the topic area is expected to change.

The Guideline Review Committee (GRC)

The GRC has been established by WHO's Director-General to ensure that WHO guidelines are of high quality, developed using a transparent and explicit process, and that, to the extent possible, recommendations are based on available scientific evidence. The GRC is composed of approximately 30 individuals, including representatives from all WHO regions as well as external members, and meets monthly to review submitted documents. All WHO publications containing recommendations are to be to be approved by the GRC according to WHO policies and procedures. The GRC reviews every WHO guideline twice during its development – once at the initial planning stage and again after the recommendations have been developed and the guideline document has been finalized and edited.

Steps in Development Process of WHO Guidelines

i. Systematic review team: Perform systematic reviews of the evidence for each key question.
ii. Evaluate the quality of the evidence for each important outcome, using GRADE as appropriate

iii. WHO guideline steering group: Convene a meeting of the Guideline Development Group(GDG)
iv. Guideline Development Group: Formulate recommendations using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework
v. WHO steering group: Draft the guideline document
vi. External review group: Conducts external peer review

When developing WHO guidelines, four groups are established:

i. The steering group;
ii. The GDG;
iii. The external review group; and
iv. The systematic review team.

These groups have different skills, perspectives, roles, responsibilities and tasks. They are established at different times, but all work to produce a high-quality guideline.

The steering group

Once the technical unit has decided to proceed with developing a guideline, the steering group is formulated, led by the responsible technical officer. The steering group includes members from all WHO departments and regional offices whose work deals directly with the topic of the guideline. The group is limited to fewer than 8 or 10 members to maximize efficiency, although some guidelines require a larger steering group to encompass representatives from all relevant departments and regions.

Steering group members are prepared to allocate a lot of time to this work: senior WHO staff who cannot do so are not listed as members. Instead, they are consulted as appropriate during the development process. If the guideline is being developed jointly with another organization, individuals from that organization are also members of the steering group. Otherwise, the steering group is composed exclusively of WHO staff from headquarters and the regional offices.

The role of the steering group is to:

i. Provide administrative support for guideline development;
ii. Draft the scope of the guideline and key questions in PICO format;
iii. Identify the systematic review team and guideline methodologist(s);
iv. Develop and finalize the planning proposal for submission to the Guidelines Review Committee (GRC)
v. Oversee evidence retrieval, assessment and synthesis;
vi. Select members of the GDG and the external review group;
vii. Collect and assess disclosures of interest and manage conflicts in collaboration with the director of the technical unit and in consultation with the Office of Compliance, Risk Management and Ethics (CRE), as needed;
viii. Organize GDG meetings;
ix. Draft recommendations based on the decisions of the GDG;
x. Draft the final guideline, in collaboration with the technical writer;
xi. Oversee peer review, review comments and revise the draft guideline as appropriate;
xii. Submit the final guideline to the GRC and revise as indicated to meet GRC requirements;
xiii. Oversee publication and dissemination of the guideline; and
xiv. Monitor new information, user needs and requests that inform when an update may be needed.

The responsible technical officer is responsible for the efficient and effective function of this group and for liaising and consulting with departments and experts internal to WHO, and with the chair and members of the GDG as needed.

The guideline development group (GDG)

The GDG is made up of external experts whose central task is to develop evidence-based recommendations. The GDG also performs the important task of finalizing the scope and key questions of the guideline in PICO format. This group is established early in the guideline development process, once the steering group has defined the guideline's general scope and target audience and begun drafting the key questions.

Potential members of the GDG are identified by the steering group and are selected to encompass the technical skills, diverse perspectives and geographic representation needed. The group is small enough for effective group interaction and decision-making, but large enough to ensure that all relevant expertise and perspectives are represented. A group of 10 to 20 is usually feasible and effective, although some GDGs are larger if the scope of the guideline is broad. The group can hold online or teleconference

meetings but usually needs to have at least one face-to-face meeting to formulate the recommendations based on the systematic reviews of the evidence and other information.

The members of the GDG are not commissioned and do not receive any financial compensation other than for direct expenses associated with their work on the guideline. The responsible technical officer develops terms of reference so that potential GDG members clearly understand their roles and responsibilities before committing themselves. Members of the GDG participate in the guideline development process and at meetings as individuals and not as representatives of the institutions or organizations with which they are affiliated.

The role of the GDG is to:

i. Provide input into the scope of the guideline;
ii. Assist the steering group in developing the key questions in PICO format;
iii. Choose and rank priority outcomes that will guide the evidence reviews and focus the recommendations;
iv. Examine the Grading of Recommendations Assessment, Development and Evaluation (GRADE) evidence profiles or other assessments of the quality of the evidence used to inform the recommendations and provide input;
v. Interpret the evidence, with explicit consideration of the overall balance of benefits and harms;
vi. Formulate recommendations taking into account benefits, harms, values and preferences, feasibility, equity, acceptability, resource requirements and other factors, as appropriate; and
vii. Review and approve the final guideline document before submission to the GRC.

Composition of the guideline development group

The GDG is multidisciplinary and composed of individuals from all WHO regions likely to use the guideline, except for employees of WHO or other United Nations organizations. Its membership is balanced in terms of gender and geography. Possible conflict of interest is also an important consideration when selecting and confirming GDG members. There are several ways to identify, nominate and select members of the GDG. In addition to drawing members from established technical networks and WHO collaborating centres, publishing an open call for nominees is considered.

The aim is to have a diverse group that includes:

i. Relevant technical experts;
ii. End-users, such as programme managers and health professionals, who will adopt, adapt, and implement the guideline;
iii. Representatives of groups most affected by the recommendations in the guideline, such as service users and representatives of disadvantaged groups;
iv. Experts in assessing evidence and developing guidelines informed by evidence; and
v. Other technical experts as required (e.g. A health economist or an expert on equity, human rights and gender).

The chair of the guideline development group

The selection of the chair of the GDG is a key decision. The steering group usually selects the chair, but the choice is generally be agreed upon by members of the GDG. The chair is an expert in facilitating groups that reach decisions based on consensus; be experienced at critically appraising and interpreting evidence and developing evidence-informed and has no financial interests related to the guideline's topic. Although the chair has a general knowledge of the topic of the guideline, no one with strong views about the interventions under consideration chair the GDG. The chair has experience engaging in consensus-based processes involving people with different opinions. The chair can be a guideline methodologist with expertise in evidence synthesis and in formulating recommendations based on evidence. A vice-chair is also be identified by the steering group to stand in if the chair is absent and to share in the chair's tasks and responsibilities. The expertise of the chair and vice-chair is complementary, especially with regard to expertise in the content area versus guideline development methods or implementation. Complementary skills and perspectives also helps to balance the influence of a chair who is a content expert and has opinions on specific recommendations. Another acceptable option is to have two co-chairs with equal responsibilities and complementary expertise and perspectives. For instance, one co-chair might be a guideline methodologist and the other an expert on the subject at hand.

Technical experts

Individuals selected for their technical expertise in a guideline's subject area are critically important to GDGs but does not dominate the group. A balanced

group includes a range of expertise and institutional and professional affiliations.

End-users of the guideline

People with direct experience in managing the condition or problem addressed by the guideline and who have a role in implementing the new recommendations − members of governmental and nongovernmental organizations, programme managers, health-care workers and other end-users of the guideline − participate in the GDG. For example, palliative care nurses participate in developing a guideline about pain management; hospital administrators help to develop a guideline on infection prevention and control in health-care settings. The aim is to ensure that the final guideline document is useful to its end-users and readily understood by them.

Representatives of the people affected by the recommendations

Individuals who are likely to be affected by the intervention(s) or approach(es) under consideration in the guideline − or their representatives − bring invaluable perspectives to the guideline development process. They help to ensure that the guideline reflects the needs of its intended beneficiaries and can be effectively implemented, and they assist the GDG in understanding the impact of the recommendations in real life. For example, guidelines on the management of diabetes benefit from input by people with diabetes; similarly, guidelines on human resources for health benefit from input by labour union representatives. Although finding such individuals with the necessary background is not easy when developing global guidelines, an increasing number of groups are operating at the international level. Many countries have nongovernmental organizations whose members may be able to participate in the GDG in an individual capacity, or attend meetings as observers on behalf of their organization.

Involving service users in groups developing guidelines helps to ensure that:

I. The questions addressed are relevant to service users;
II. Important aspects of the experience of illness are considered;
III. Critical outcomes are identified and prioritized; and
IV. The balance of benefits and harms of the intervention is appropriately considered when recommendations are formulated.

Certain barriers can stand in the way of service user participation in guideline development. They include:

I. The lack of organized service-user groups, which makes it difficult to identify individuals able to participate in GDGs;
II. The fact that an individual cannot represent the varied perspectives and experiences of all persons affected by a disease or condition; and
III. The complex scientific terminology used by guideline developers and topic experts.

Experiences from organizations such as the United Kingdom's National Institute for Health and Care Excellence (NICE) suggest that service users make critical contributions to guideline development when provided with training and support.

Experts in guideline development

Ideally, at least one of the technical experts in the GDG has expertise in the processes and methods for developing evidence-based guidelines.

i) An economist

An economist is an important contributor to a GDG if resource-related issues are at play in the formulation of recommendations. This GDG member advise on matters of economic efficiency, such as cost–effectiveness, and on any other resource implications of the interventions under consideration. The economist also advise on how to search for and interpret relevant economic data and the evidence on resource use. If modelling of economic data is used to inform one or more recommendations, it is essential that the GDG includes one or more individuals with expertise in economic modelling or that an expert is commissioned to attend the GDG meeting.

ii) An expert on equity, human rights and gender

Depending on the topic of the guideline, a GDG member with expertise in matters of equity, gender and human rights contributes to the analysis and interpretation of evidence and determine how the intervention might affect certain subpopulations. For example, they bring insights into how women and men − in all of their diversity and across the life-course, subject to different gender norms, and belonging to different income and education groups − could be affected differently by the recommendations in the guideline.

iii) The external review group

The external review group is composed of persons interested in the subject of the guideline as well as

individuals who are affected by the recommendations (often referred to as "stakeholders"). Thus, the external review group include technical experts, end-users, programme managers, advocacy groups and individuals affected by the condition addressed in the guideline, among other stakeholders. This group is generally established by the steering group after the GDG is identified and once the guideline's scope and key questions have been drafted. Methods for recruitment vary. The steering group and GDG suggest names or issue an open call for interested persons and organizations. Like the GDG, the external review group is balanced in terms of geography and gender and provides diverse perspectives. If important perspectives and stakeholders are missing from the GDG, these are represented in the external review group.

Members of the external review group are asked to participate in different stages of the guideline development process, depending on the nature of the topic and the needs of the steering group. The external review group reviews the guideline's scope and key questions (in PICO format) in the early stages of the guideline development process, and the final guideline document at the end. When the external review group reviews the final guideline, its role is to identify any errors or missing data and to comment on clarity, setting-specific issues, and implications for implementation – not to change the recommendations formulated by the GDG. If external review group members have major concerns regarding one or more recommendations, the GDG meets to discuss and address them. Review of the final guideline by the external review group is often referred to as peer review.

The systematic review team

Systematic reviews of the evidence are the basis for most types of recommendations. Because WHO staff usually lack the time to perform these reviews, they normally commission them from external contractors. These contractors are identified very early in the guideline development process because they have expertise in the development of key questions and help the steering group to establish a reasonable scope that conforms to the available budget and timeline.

Systematic reviews are commissioned from any group with the necessary expertise and no financial conflicts of interest. The Cochrane Collaboration and the Campbell Collaboration have editorial teams whose expertise covers a broad range of topics relevant to WHO guidelines. These teams are interested in updating an existing review or in performing a review de novo. They are located via their organizational websites, or the GRC Secretariat helps to identify the appropriate contact person. Systematic review teams that are interested in working with WHO are listed on the GRC intranet site.

Important Note

SOURCE

1. World Health Organization. WHO handbook for guideline development. World Health Organization; 2012.
2. World Health Organization. WHO handbook for guideline development. World Health Organization; 2014.

Figures

Figure 1. WHO Guideline Approval Process

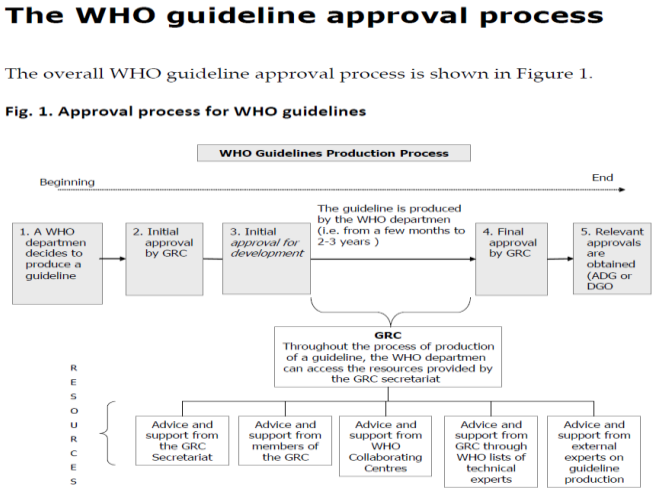

Figure 2. Flowchart Showing the Initial Process for Guideline Approval