16. Decision-making for guideline development at WHO

16.1 Introduction

The process of developing guidelines at WHO involves decision-making on the part of all the groups and individuals described in Chapter 3 of the WHO handbook for guideline development (“the Handbook”) (1). It is therefore important that there be general agreement within and among these groups and individuals and a respectful, inclusive process for achieving it. General agreement is more readily attained when individuals are involved and empowered from the beginning of a process and the “ground rules” are transparent, perceived as just and fairly implemented. During guideline development, the contributors to the process need to understand and accept the basic principles, methods and processes underlying WHO guidelines, as outlined in the Handbook (1). The approaches for making group decisions are established at the very beginning of the guideline development process, long before groups meet to make key decisions. In addition, the preparatory work for effective decision-making has implications with respect to the dissemination, adaptation and implementation of WHO guidelines. If the contributors to a guideline development project are not familiar with these methods and principles or do not concur with or accept them, then a functional, collaborative process cannot be achieved and general agreement is not possible.

The present chapter focuses on group decision-making, primarily as conducted by guideline development groups at WHO. Such groups meet to define the scope and key questions for a planned guideline and formulate recommendations based on the balance of an intervention’s benefits and harms and other considerations (see Chapter 3 and Chapter 10 of the Handbook) (1). The in-person meetings at which recommendations are formulated are generally where group decision-making during guideline development becomes most challenging and complex and where guideline development group members make their most important contributions. The meetings, which are very time-limited, must therefore be run as efficiently and effectively as possible.
The approaches to decision-making discussed in this chapter apply mostly to these in-person meetings, although, with modifications, to virtual meetings as well. They may also extend to other parts of the guideline development process, including the tasks performed by the external review group and the WHO steering group.

### 16.2 Group decision-making and guideline development

#### 16.2.1 What is involved?

Group decision-making is a cognitive, collaborative process. In the context of guideline development, it results in the formulation of a recommendation for or against an intervention and in the determination of the recommendation’s strength, both on the basis of the available scientific evidence and of various other factors outlined in Chapter 10 of the *Handbook* (1). The decision-making process used to formulate recommendations relies heavily on logic and reasoning. It is informed by systematic reviews of the evidence and uses an explicit framework to delineate the various factors that should be considered (Chapter 10 of the *Handbook*). The process involves experts with diverse perspectives, experiences and knowledge. Decisions are never attributed to any one individual, but to the entire guideline development group.

#### 16.2.2 Why is guidance needed?

For every guideline development group, the decision-making approach to be followed during guideline development must be defined. This is a key process decision that must be carefully considered by the WHO steering group, transparently communicated to all guideline development group members and well documented. A clear, agreed-upon approach to decision-making allows guideline development group members to have explicit and reasonable expectations and to engage in a respectful and productive process. It also ensures that all members understand the procedures to be followed and are given the opportunity to participate so that the biases that may affect the decision-making process are avoided or minimized. Ultimately this will result in a high-quality, more credible guideline.

It is often difficult to reach agreement in a straightforward manner during group discussions. This is particularly true when issues are complex, when the evidence is conflicting or sparse, or when individuals have strong and diverse viewpoints. Furthermore, WHO has a mandate to formulate global guidelines representing the interests of Member States having diverse
needs and perspectives. Thus, explicit approaches are needed to organize, compare and contrast different perspectives and interpretations of the evidence and to incorporate different and evolving viewpoints in the process of formulating recommendations.

16.2.3 What guidance does this chapter provide?

There are many different approaches to group decision-making for guideline development. The methods that are desirable and feasible may differ across technical units, guideline topic areas and guideline development groups. This chapter provides an overview of the methods available to guideline development groups when determining how they will conduct their decision-making. It does not aim to be prescriptive with respect to the use of particular methods.

Specifically, the objectives of this chapter are to:
- provide guidance to WHO staff developing guidelines and organizing guideline development group meetings on the methods available for group decision-making;
- outline the relevant considerations when selecting an approach; and
- explain the minimum requirements for documenting the approach in the guideline planning proposal and in the final guideline.

16.3 Decision-making procedures among WHO advisory groups

Advisory groups convened by WHO can be classified into expert and non-expert groups, as described in Basic documents (2), depending on the legal framework regulating them. Expert groups, which include advisory panels and committees, study groups and scientific groups, must conform to their respective regulations in all aspects. For example, Rule 6 of the rules of procedure for expert advisory panels expressly prohibits voting (2):

*Scientific questions shall not be submitted to a vote. If the members of a committee cannot agree, each shall be entitled to have his personal opinion reflected in the report... This statement of opinion shall take the form of an individual or group report, stating the reasons why a divergent opinion is held.*

Non-expert groups – i.e. technical advisory committees, advisory groups, drafting groups, steering committees and strategic advisory groups
– do not have specific regulated rules of procedure and therefore have more flexibility. The section of Basic documents on “other mechanisms of collaboration”, which encompasses these non-expert groups, states that:

*The Director-General shall apply to these mechanisms the working procedures he deems most effective, even though these procedures may differ from those provided in the regulations and those pertaining to expert advisory panels and committees.*

It also states, however, that:

*These mechanisms (...) shall be in general conformity with the principles outlined in these regulations, especially concerning the adequate international and technical distribution of expertise.*

Guideline development groups are non-expert advisory groups to WHO. Thus, no formally prescribed rules of procedure are in place for these committees (2). However, as noted above, groups that are not subject to formal regulations should follow procedures in general conformity with those of expert groups, for which formal regulations are in place. In light of this, consensus is the approach to decision-making most strongly encouraged for WHO’s guideline development groups and its use is supported by the WHO Guidelines Review Committee. The following sections discuss what is meant by consensus, unanimity and decision rules; describe different methods for achieving consensus; and propose alternatives to consensus when this cannot be reached as defined.

### 16.4 What does consensus mean?

By dictionary definitions, the term *consensus* means “general agreement”. However, dictionaries do not clarify whether unanimity is required or whether agreement among a large majority suffices for consensus to be present. In some cases, consensus is interpreted to mean general acceptance by a group rather than agreement by all its members. These differences point to the fact that the process of reaching consensus, regardless of the definition used, always involves discussion and compromise to arrive at a decision that is acceptable to all parties.
In guideline development groups, consensus decision-making is a process whereby the consent of all committee members is pursued. When consensus has been reached, it generally means that every committee member finds the proposed resolution acceptable – or at least lends it support, even if less than wholeheartedly.

16.5 What is a decision rule?

The level of agreement necessary to finalize a decision is known as a decision rule. Decision rules for consensus vary across a broad range: unanimous agreement; unanimous consent; unanimous agreement minus one or two votes; unanimous consent minus one or two group members; supermajority or simple majority. The thresholds for defining supermajority can vary in themselves, with some of the most common being 90%, 80%, 75%, two thirds and 60%. A simple majority is reached when more than 50% of group members support a given decision.

16.6 What is unanimity?

In groups that require unanimous agreement or consent (unanimity) for a decision to be approved, objection on the part of any single participant can block consensus. Other groups follow a consensus process to generate as much agreement as possible but allow participants to finalize decisions with a decision rule not requiring unanimity. In this case, a group member who objects strongly to a decision can document his or her disagreement and the reasons for it. During appropriate consensus-based decision-making processes, efforts are usually made to address dissent early to maximize the chances of accommodating the views of all minorities.

Unanimity is desirable but may be difficult to achieve, especially in large and diverse groups. Hence, before starting their decision-making processes, all guideline development groups should have a plan as to how to move forward when unanimity cannot be achieved. This plan should encompass specific decision rules and should be discussed a priori to ensure that unanimity will be genuine and not the result of pressure, coercion, fear, undue influence, failure of group members to comprehend alternatives, or fatigue with the debate.
16.7 Defining when consensus has been reached

There are no firm or universally accepted decision rules for establishing when consensus has been reached. However, determining decision thresholds in advance is of paramount importance. A guideline development group may consider defining thresholds for consensus in support of a recommendation as well as against it, or it may decide on different levels of agreement for strong recommendations versus conditional ones. Furthermore, the stricter the decision thresholds, the more difficult it may be to obtain consensus (3). In such cases anodyne results that are of little interest are sometimes reached (4–6). A member of a guideline development group who does not support the agreement can register his or her concerns. If considerable reservations surround a given decision, the guideline development group may choose to modify or reword the recommendation.

16.8 Formal methods for achieving consensus

No matter how consensus is defined or what decision rules are applied, a variety of approaches may be used for reaching consensus within groups. These methods may be considered formal or informal, depending on the level of structure they involve. However, informal methods are not necessarily casual and unstructured. In fact, the distinction between formal and informal consensus methods may not always be clear. Formal consensus methods follow pre-defined, systematic procedures, but some of these methods may incorporate elements of informal interaction as well.

Three main formal methods are used in the health sector to achieve consensus: the Delphi method, the nominal group technique and the consensus development conference. There are also many variations of each of these methods and many examples of “hybrid” approaches that incorporate elements from more than one method.

16.8.1 The Delphi method

Developed in the early 1950s and named after the ancient Greek oracle at Delphi, the Delphi method is a process used to survey and collect the opinions of experts on a particular subject (7). A key characteristic of the Delphi method is that participants never meet or interact directly. Rather, the process involves the use of structured questionnaires to be filled out individually and anonymously. The goal is to incorporate a large number of viewpoints to
obtain, in general, a more reliable estimate of the “real” answer to a question (5, 8). The Delphi method is particularly useful whenever the judgments of experts are needed but time, distance and other factors make it unlikely or impossible for the group to convene in person (7).

Many modifications exist, but the general structure of the Delphi method is as follows:

- A questionnaire is sent (by post or email) to group participants, who individually rate or rank their agreement with specific statements.
- The organizers of the Delphi method collate and summarize the responses and document the preliminary level of group consensus for each item.
- A second questionnaire, displaying the summary response and consensus level, is sent back to the participants, who are then given the opportunity to rerank their initial judgment in light of the group’s response. Any respondent who holds an opinion that still differs substantially from that of the group should provide a brief explanation or reason for disagreeing.
- Steps 2 and 3 are repeated for a third time in light of the emerging pattern of group consensus and reasons for dissent.

This iterative procedure can continue for additional rounds, although experience has shown that the incremental gain usually diminishes rapidly after the third round (7).

16.8.2 The nominal group technique

The aim of a nominal group technique is to structure interactions within a group and encourage the generation of ideas (5). The process is similar to that of the Delphi method, with the difference that group discussions are held between the rounds in which individual judgments are recorded. These discussions require a competent facilitator. Again, many variations exist but the basic structure is as follows (5):

- Each individual records his or her opinion or ideas independently and privately.
- One idea from each participant is presented to the group for discussion until all unique ideas are listed.
- Similar ideas are grouped together and each idea is discussed by the group for clarification and evaluation.
- Individuals then privately record their judgments or decisions, or vote for options.
- Results are tabulated and summarized.
Finally, further rounds of group discussion on the direction and wording of the recommendation or its strength take place as needed.

### 16.8.3 The consensus development conference

Originally developed by the United States National Institutes of Health, the formal guidelines for running consensus development conferences have changed over time and have been adapted by many international organizations (5). This approach involves bringing together a selected group of people (as few as 10) to reach consensus about a particular issue during a two- to three-day meeting resembling a conference proceeding that is sometimes open to the public. Various interest groups or experts who are not on the decision-making panel present the evidence they have gathered on a particular issue. The panel then retreats to consider the evidence presented and attempts to reach a consensus. Both the open conference and the private group discussion are facilitated by a chair (4).

In the consensus development conference method, no formal guidance is given as to how consensus is ultimately reached. Thus, the method serves to exemplify the overlap between formal and informal consensus methods.

Note that voting can be a useful way to achieve consensus: A show of hands or an anonymous vote might be used during the consensus development process to assess progress and identify diverse viewpoints. This is different from using a vote to arrive at a specific decision, as described below.

### 16.9 Is there a “best” method for achieving consensus?

A variety of suitable approaches can be used to achieve consensus and there is no evidence in favour of one approach over another. The type of consensus development process best suited to a particular guideline development group sponsored by WHO will depend on several factors, including the geographical scope of the expertise required (national, regional or global); the focus and subject matter of the guideline under development; the population that will be affected by the recommendations; the users of the guideline; the quality of the available evidence; and the time and resource constraints involved (9). A summary of some of the strengths and limitations of different approaches to consensus development is found in Table 1.
Table 1. Summary of the strengths and weaknesses of various decision-making methods for guideline development groups

<table>
<thead>
<tr>
<th>Method</th>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unstructured, open discussion*</td>
<td>It allows for articulation of views and opinions.</td>
<td>The lack of structure and open forum may inhibit some members from speaking freely.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Strong individuals or “coalitions” can become dominant.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>It relies heavily on a good facilitator.</td>
</tr>
<tr>
<td>Delphi method</td>
<td>Anonymity helps to avoid undue influence by certain members.</td>
<td>There is no opportunity for clarification of ideas, discussion or other benefits of face-to-face interaction.</td>
</tr>
<tr>
<td></td>
<td>Groups can be larger and more geographically dispersed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>It is useful when a face-to-face meeting is not feasible.</td>
<td></td>
</tr>
<tr>
<td>Nominal group technique*</td>
<td>Participants come together face to face.</td>
<td>A small group may produce unrepresentative judgements.</td>
</tr>
<tr>
<td></td>
<td>Discussion sessions reduce the risk of misunderstandings and expose reasons for differences of opinion.</td>
<td></td>
</tr>
<tr>
<td>Consensus development</td>
<td>Open forum allows for incorporation of many views and opinions.</td>
<td>It is time-consuming, costly and hard to organize.</td>
</tr>
<tr>
<td>conference*</td>
<td></td>
<td>Decision rules must be developed a priori.</td>
</tr>
<tr>
<td>Voting</td>
<td>It is unambiguous.</td>
<td>The final recommendation may not actually represent group opinion.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Decision rules must be developed a priori.</td>
</tr>
</tbody>
</table>

* These approaches can incorporate informal voting.

Source: references 5, 7, 8, 10.

Certain studies have attempted to evaluate the reliability, validity and impact of different consensus development strategies, but they are limited and findings are mixed (3, 4, 8). Evidence suggests that in formal consensus processes, a convergence of opinion can be most effectively reached through iterations of feedback. However, little research has been conducted to determine what type of feedback is best. According to some studies, gathering information on the reasons for divergent views is more useful than simply feeding back the ratings to group members (4). Hybrid approaches that draw upon the advantages of various methods can also be used (11).
16.10 Alternatives to consensus

If a guideline development group cannot achieve consensus as it has defined it, then an alternative approach for achieving consensus is needed. Such an approach should have been agreed upon before the first guideline development group meeting. The alternative approach usually involves a vote, which gives each member of the group an equal say in the decision at stake. However, the disadvantage of this method is that the decision will reflect the majority viewpoint to the exclusion of the minority opinion. Although reports containing the minority viewpoint and its rationale can be presented in the final guideline document, such reports may be less than optimal and every effort should be made to achieve consensus. Sometimes a minority view on the strength of a recommendation or on contextual issues may be incorporated into a WHO guideline.

The specific methods for taking a vote should be drafted by the WHO steering group before the first guideline development group meeting. These methods should be included in the guideline planning proposal and agreed upon by the chair of the guideline development group. The following particulars need to be defined:

- Who exactly will be voting? Generally, only guideline development group members vote; the WHO steering group, the representatives of the funder and other observers do not participate in the voting – or in the consensus process used to formulate recommendations.
- How will the voting be executed? By the raising of hands? By using anonymous ballots or electronic means?
- What is the threshold for a decision? A 51% majority? A two-thirds majority?

A 51% majority is never ideal for a recommendation that will be issued by WHO, as it suggests that a large segment of the guideline development group is in disagreement. Terms such as majority or simple majority must always be accompanied by a definition, as they are meaningless otherwise.

16.11 What decision-making methods do guideline development groups not sponsored by WHO employ?

There is no single accepted international standard for guideline development (12), nor is there a recognized standard for group decision-making in this context.
According to an international survey of clinical guideline development programmes (13), seven of the 18 organizations examined used “formal” consensus methods to formulate their recommendations. A larger survey of organizations producing clinical practise guidelines or health technology assessments reported that 42% of the respondents used formal consensus methods when formulating recommendations (14). However, more detailed telephone interviews of a subset of this group revealed that only one of five organizations actually used a formal consensus method. Guideline programmes often provide a lot of information about the process they followed in developing a guideline, but very little about how group decisions were made (15).

16.11.1 The GRADE approach to decision-making

The Guideline Recommendations Assessment, Development and Evaluation (GRADE) Working Group has published case studies on approaches to decision-making in contentious situations, including voting with pre-specified thresholds (16) and the use of a GRADE “grid” (17). A grid of this kind provides a framework for members of the guideline development group to record their judgements on specific interventions on the basis of their analysis and interpretation of the evidence. In these studies, the grid was effectively used as a polling tool to gather votes on the strength of recommendations, and consensus was reached on topics that had previously proven difficult to resolve (16, 17). The concept behind a GRADE grid is similar to the concept underlying the use of evidence-to-recommendation decision tables, as outlined in Chapter 10 of the Handbook (1). The use of such decision tables helps to guide group discussions and to promote transparency with respect to the reasons for a group’s decisions. However, explicit approaches for reaching group decisions for each element in the table and, most importantly, on the wording and strength of the resulting recommendations, need to be established and clearly conveyed to all guideline development group members before deliberations begin.

16.12 What decision-making methods should be used by WHO guideline development groups?

WHO’s guideline development groups should try to achieve consensus on each recommendation that is formulated, including the direction, wording and strength of the recommendation. Because most guideline development
groups are not formally constituted WHO expert committees, they can use approaches such as voting, if deemed appropriate. This situation generally arises when consensus cannot be achieved.

The most important point for WHO staff developing guidelines is that the guideline development group must have defined a specific approach to decision-making before the process of formulating recommendations begins. The WHO steering group should consider this issue early in the planning stages and discuss and agree upon an approach with the chair of the guideline development group. The steering group may choose to involve the rest of the guideline development group in these discussions as well. The approach and processes should be presented in detail to the guideline development group before it begins discussing the evidence and formulating recommendations. The plan should include a definition for consensus, along with the approach to voting and decision rules in case consensus cannot be achieved. Decisions on how to make decisions should never have to be made once a problem or disagreement has arisen among group members.

In many cases, the guideline development group will elect to reach decisions through a process of informal consensus. This involves a group discussion process designed to allow all members of the group to voice their opinions and contribute equally to the decision-making. The goal of the consensus process is to bring the group to general agreement; ideally, the discussion will continue until consensus is achieved. Since informal processes may present challenges such as time constraints, group member fatigue and dominance by people with stronger personalities or intimidating reputations, the integrity of the process relies heavily on facilitation by a suitable chairperson. This individual usually closes the discussion and summarizes and restates the agreements reached. Some guideline development groups may choose to use more formal consensus methods, such as the nominal group technique, or to develop hybrid methods by combining different approaches.

16.12.1 The role of the chair of the guideline development group

The chair sees to it that the guideline development group functions effectively, in a collaborative way and with a balanced contribution from all members. For this reason, selecting an appropriate chair is a key part of the planning process. Chairs should have strong communication and group management skills, as well as experience in mediation and conflict resolution. To facilitate the process of group decision-making, the chair should:

- lay out the rules under which the guideline development group will operate (a member of the WHO steering group can also do this);
encourage all guideline development group members to contribute to the discussion;
be aware of and attentive to small group dynamics;
keep the discussion unified and avoid dominance by any single member or subgroup; and
encourage open and constructive debate without forcing agreement (18).

16.13 Documenting the decision-making process

Regardless of the approach to decision-making chosen by the guideline development group, the transparency of the decision-making process is essential. There should be a clear record of the proceedings and methods used to resolve areas of disagreement. Although unanimous consensus is ideal, in cases in which it cannot be reached dissenting opinions may be noted and included in the guideline, together with the decision rules agreed upon at the beginning of the process. The level of detail regarding disagreements included in the final guideline depends on the circumstances and may differ depending on the area of disagreement. Since the ultimate objective is to enhance transparency for the end user, the guiding principle should be to provide the information that a guideline user needs to interpret and implement each recommendation.

16.14 Acknowledgements

This chapter was prepared by Susan L. Norris and Stephanie Shendale and edited by Maria Luisa Clark. Sophie Guetaneh Aguettant performed design and layout and Myriam Felber provided technical support.

16.15 References


