

# Use of evidence in WHO recommendations



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## Summary

**Background** WHO regulations, dating back to 1951, emphasise the role of expert opinion in the development of recommendations. However, the organisation's guidelines, approved in 2003, emphasise the use of systematic reviews for evidence of effects, processes that allow for the explicit incorporation of other types of information (including values), and evidence-informed dissemination and implementation strategies. We examined the use of evidence, particularly evidence of effects, in recommendations developed by WHO departments.

**Methods** We interviewed department directors (or their delegates) at WHO headquarters in Geneva, Switzerland, and reviewed a sample of the recommendation-containing reports that were discussed in the interviews (as well as related background documentation). Two individuals independently analysed the interviews and reviewed key features of the reports and background documentation.

**Findings** Systematic reviews and concise summaries of findings are rarely used for developing recommendations. Instead, processes usually rely heavily on experts in a particular specialty, rather than representatives of those who will have to live with the recommendations or on experts in particular methodological areas.

**Interpretation** Progress in the development, adaptation, dissemination, and implementation of recommendations for member states will need leadership, the resources necessary for WHO to undertake these processes in a transparent and defensible way, and close attention to the current and emerging research literature related to these processes.

## Introduction

Every year, WHO develops a large number of recommendations aimed at many different target audiences, including the general public, healthcare professionals, managers working in health facilities (eg, hospitals) or regions (eg, districts), and public policymakers in member states. These recommendations address a wide range of clinical, public health, and health policy topics related to achieving health goals. WHO's regulations emphasise the role of expert opinion in the development of recommendations. In the 56 years since these regulations were initially developed, research has highlighted the limitations of expert opinion, which can differ both across subgroups and from the opinions of those who will have to live with the consequences.<sup>1-8</sup> Experts have also been known to use non-systematic methods when they review research, which frequently result in recommendations that do not reflect systematic summaries of the best available evidence.<sup>9,10</sup>

Evidence of the effects of alternative policies, programmes, and services is essential for well-informed decisions. Systematic reviews have several advantages over other approaches to amassing evidence of effects.<sup>11-13</sup> Firstly, systematic reviews reduce the risk of bias in selecting studies and interpreting their results. Secondly, they reduce the risk of being misled by the play of chance in identifying studies for inclusion, or the risk of focusing on a limited subset of relevant evidence. Thirdly, systematic reviews provide a critical appraisal of the available evidence and place individual studies or subgroups of studies in the context of all the relevant evidence. Finally, they allow others to critically appraise the judgments made in study selection and the

collection, analysis, and interpretation of the results. However, systematic reviews are only as good as the evidence that they summarise. There might be no evidence. When there is evidence, judgments are still needed about the quality and, especially for public health and health policy topics, its applicability in different contexts.<sup>12</sup>

Evidence of effects needs to be complemented by information about needs, factors that could affect whether effectiveness will be realised in the field, such as the available resources, costs, and the values of those who will be affected by the recommendations. Processes that allow for the explicit incorporation of these types of information, particularly values, have (like systematic reviews) emerged as central to the development of recommendations.<sup>14-18</sup> Moving from evidence to recommendations requires judgments, particularly judgments about goals and about the balance between the desirable and undesirable consequences of choosing one option over another to achieve these goals.

Evidence-informed dissemination and implementation strategies are increasingly recognised as a core part of the business of developing recommendations. Those charged with developing clinical practice guidelines can draw on a systematic review of randomised controlled trials of guideline dissemination and implementation strategies to inform their efforts.<sup>19,20</sup> Although there are no easy solutions and few strategies have been assessed in low-income and middle-income countries, such efforts clearly can have an effect.<sup>21</sup> Those charged with developing recommendations targeted at managers or public policymakers, on the other hand, have to deduce the attributes of the interventions from systematic reviews of observational studies and begin

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to build an evidence base about the effectiveness of these interventions.<sup>13,22</sup>

WHO has recognised the need to revise its approach to developing recommendations, in guidelines approved by the WHO Cabinet in 2003.<sup>23</sup> We sought to examine the use of evidence in WHO recommendations subsequent to this. We particularly wanted to explore the use of evidence of effects. Our hope was that such stock-taking would inform debates about how WHO could improve how it develops and disseminates recommendations and how WHO could better support member states in their efforts to adapt and implement recommendations.

### Methods

We interviewed department directors (or their delegates) at WHO headquarters and reviewed a sample of the recommendation-containing reports that were discussed in the interviews. We invited the participation of all department directors in five departmental clusters that had a content focus: non-communicable diseases and mental health (six departments); HIV/AIDS, TB, and malaria (four); family and community health (four); communicable diseases (three); and health technology and pharmaceuticals (two). We invited the participation of one department (of five) in the sustainable development and healthy environments cluster and three departments (of five) in the evidence and information for policy cluster. We did not invite the participation of the department directors in the two clusters—the external relations and governing bodies cluster and the general management cluster—that had a corporate focus. Although our written request for an interview was introduced by a WHO department director, we made clear that the study was independent of WHO and that we planned to publish the results after first making them available to WHO. We purposively sampled four of the reports identified by those interviewed on the basis of their focus on clinical treatment, centrality to major WHO initiatives, and relevance to the Millennium Development Goals. The first criterion was chosen to maximise the chances that evidence of effects would be available and that the reports could be expected to meet current standards for clinical practice guidelines.

Two individuals participated in each interview. One individual had main responsibility for doing the interview and the other for recording the interview on audiotape and taking notes. The brief structured part of each interview focused on the number and background of staff members and the number and type of recommendation-containing reports published in the past year. The semi-structured part of each interview focused mainly on the development of recommendations contained in one or two specific published guidelines or policies that were selected by interviewees from among those their department had developed or had a major responsibility in developing. For each guideline or policy, we asked about: why it was developed; the process used (including whether support was received from others within or outside WHO, whether

evidence of effects and other types of information were used, whether and how supporting documentation was made publicly available, and whether and how plans for updating were established); strengths of the processes used and elements that could have been improved; likely benefits, harms and costs of adhering to the recommendations; how the recommendations have been used and any plans for assessing the effects of adherence to the recommendations; and the availability of any background documentation.

Two individuals independently did a thematic analysis of the interviews and reviewed key features of the recommendation-containing reports (and related background documentation). We began the thematic analysis by using the notes taken during each interview (supplemented by the corresponding audiotape) to produce a summary of each interview, including the major themes that emerged. We then sent the summary to each interviewee with a request that they verify our interpretations and, if they wished, provide additional comments. We used the audiotapes to identify illustrative quotations for each major theme. We began the review by recording for each document its type, whether it included a section that described the methods used, the number of recommendations that were based on a systematic review, the number of systematic reviews cited, and the description provided of the development process. We then produced a summary for each recommendation-containing report. We presented our findings at various forums within WHO as an additional check on our interpretations.

The study was sponsored as part of a broader project—Pragmatic Randomised Controlled Trials In Health Care—funded by the European Commission's 5th Framework International Collaboration with Developing Countries. WHO was a formal partner in Practihc; however, WHO staff input was limited to commenting on the protocol and interview questions, and providing comments on the interview summaries (for those who were interviewed) and overall findings (for those who attended forums where these were presented).

We did 23 interviews with 29 people, and reviewed four recommendation containing reports and related background documentation. We interviewed the director in 15 departments and someone designated by the director in six departments. Three of the interviews were with more than one person. For two departments we did two separate interviews with different people from the department. We were unable to arrange interviews with the directors (or delegates) of two departments that had newly appointed directors who were not yet in post. The interviews, which lasted for up to an hour, were done between September, 2003, and February, 2004. Five of 21 participating departments did not produce formal recommendations and so their interviews were not included in the analysis, which is therefore based on 17 interviews with 21 people (across 16 departments). The four recommendation-containing reports that we selected for review were clinical

For Pragmatic randomised controlled trials in health care project see <http://www.practihc.org>

practice guidelines that addressed antiretroviral therapy for HIV, treatment of tuberculosis, treatment of malaria, and the integrated management of childhood illness.<sup>24-27</sup>

### Role of the funding source

The sponsors of the study had no role in the design (beyond commenting on the protocol and interview questions), data collection, data analysis, data interpretation (beyond commenting on the interview summaries and overall findings), writing or revising of the report. The corresponding author had full access to all data in the study and had final responsibility to submit the report for publication.

### Results

The directors or their delegates (hereafter directors) of the 16 departments that developed recommendations reported that their departments had between eight and 170 staff members each (median 55) and close to 1000 staff members in total. The directors estimated that between 20% and 80% of staff members had some background in research (median 30%). Many directors had difficulty quantifying the number of recommendation-containing reports that their department published each year because of the various formats of the recommendations. Their estimates ranged from one to 45 reports per department per year (median 8), with a total of almost 180 reports per year.

The reports varied widely in the nature of the topics they addressed. In addition to clinical treatment topics, the reports addressed topics such as malaria control with insecticide-treated bednets, promotion of mental health, helminthic guidelines for managers, human resources policy development, model list of essential medicines, tobacco legislation, and bioterrorism. The directors cited several reasons for developing recommendations, the most common of which were a perceived need for guidance, a perceived need for updating existing recommendations, and demand from member states. One report was developed to respond to criticisms of previous recommendations.

Expert committees or meetings of experts were almost always convened when developing recommendations whereas only a few directors mentioned having commissioned systematic reviews to inform the work of these expert groups. Some directors reported the use of a combination of work done in-house and an expert committee or the combination of a small task force to draft recommendations and either an expert committee or a review by external experts. Many directors reported a phase of external consultation or review. Only a few directors mentioned developing dissemination or implementation strategies. Most directors reported the involvement of one or more other WHO departments in the development process, and nearly all reported some form of external support. No directors mentioned drawing on any form of internal support in the methodological or technical aspects of developing

recommendations. The external support typically took the form of expert committee members, but sometimes involved expert advisors, writers of background reports and recommendation-containing reports, and reviewers.

When asked specifically about using evidence of effects, only a small number of directors reported using systematic reviews of such evidence and none reported using concise summaries of findings (eg, balance sheets) for the most important outcomes (benefits, harms, and costs) of each option being considered. Many directors instead reported using background documents, although there was little consistency in how the documents were prepared. For example, some background documents were prepared by the participating experts according to their own conventions. Other directors reported leaving the use of evidence up to the experts, feeling that evidence of effects was not relevant for some recommendations, and feeling that randomised trials were not appropriate for some types of interventions. Only one director reported grading the quality of the evidence.

When asked about the use of other types of information, several directors reporting using data about costs but only a couple mentioned using data about potential harms or explicitly considering values—ie, the relative importance or worth of the consequences (benefits, harms, and costs) of a decision.<sup>18</sup> Using data about potential harms was only mentioned in relation to clinical interventions, particularly pharmaceuticals, and not for public health or policy interventions. Explicitly considering values was undertaken in a general way. One director talked about the “weighing of values, which basically reflected the composition of the panel.” Another director commented: “Values were also brought into debate. For example, experience for high income countries suggest that encouraging more self efficacy and independency for young people could be effective in preventing mental health problems and substance use. However, this was by many considered as to be contrary to important values for people living in many low-income countries.”

Although directors were not asked specifically about group processes, many volunteered descriptions that suggested that these processes were not particularly structured with respect to group composition, format, or rules. These descriptions suggested that participants were implicitly weighing evidence of effects, harms, and costs along with values and many other types of information (eg, surveys, resistance patterns, other epidemiological data, availability of interventions, country experiences, political considerations, cultural differences, ethical considerations, and undocumented knowledge). One director clearly recognised the challenges associated with a lack of structured process: “There is a tendency to get people around the table and get consensus—everything they do has a scientific part and a political part. This usually means you go to the lowest common denominator or the views of a “strong” person at the table.”

Most directors reported that the information that was used by the committees was not published but was often made publicly available in some form. The format for the documentation varied widely, including a bibliography in the report, one or more published articles (such as a special edition of the *Bulletin of the World Health Organization*), one or more reports (eg, annual reports, multicountry assessment reports, and proceedings of meetings), a book, and an adaptation guide. The documentation was sometimes readily available (eg, on a website) and other

times required personal contact with those involved in developing the recommendations. Although one director reported updating recommendations every 2 years and some other directors reported that their recommendations were considered one-off initiatives that would not be updated, most directors reported ad hoc approaches to deciding whether and when to update recommendations. One director reported plans to update the recommendations using the guidelines for WHO guidelines.

The directors identified numerous strengths in the processes used for developing recommendations and in the recommendations themselves. The most commonly identified strength was bringing together or consulting with a wide range of people. Most other strengths were mentioned by only one director, although several of these strengths can be grouped together (panel 1).

Although most directors identified one or more ways in which the recommendation-development process could have been improved, four did not identify any way in which improvements could have been made. Directors singled out the use of evidence more commonly than any other area for improvement (panel 2).

Directors also frequently singled out the timeliness of recommendations as an area for improvement. Directors offered comments like “It could have happened earlier” and “It could have been done faster...perhaps better with one person being responsible for keeping up the momentum.” Recommendations were sometimes prepared as a “technical consultation” document as a way of reducing both the amount of time needed to produce recommendations and the level of expectations about the rigour of the process used. One director described a recommendation-containing report that was: “... prepared as a technical consultation document so it has a lower status. They should have been prepared by a study group and, even better, an expert committee. People have asked how can you say a technical consultation document is a WHO recommendation, but it has stood the test of time with other initiatives coming to similar conclusions. You can’t develop a guideline in less than a year, but this doesn’t work when there’s pressure. Should there be a guideline for urgent recommendations?”

Several directors identified the match between the resources available and the resources needed to develop recommendations, and attention to dissemination and implementation strategies, as other areas for improvement. Two directors identified a lack of resources as the problem. For example, one said: “We had inadequate time and resources. The recommendation was developed during about 10 months. I believe this is too short a time. Would like to be able to use a more systematic approach.” Two other directors indicated that the resources needed to develop recommendations was the problem. For example, one said: “It was a cumbersome and resource-demanding exercise.” Several directors noted that recommendations were not being implemented after they were published. One said: “We published it, but just left it there.... The

#### Panel 1: Strengths in WHO processes as identified by directors

- Usefulness of the recommendations, which included attributes like focusing on end users, ensuring usability, responding to the concerns of donors, and filling a gap
- Evidence-based process, which included attributes like obtaining evidence in a rigorous way, drawing on good data, basing recommendations on research, using cost-effectiveness analyses, testing the recommendations, and doing validation studies
- Experience-based process, which included attributes such as involving people with practical experience and, although this was also considered a weakness, developing instinct-based recommendations
- Expert-based process, which included attributes like working with knowledgeable experts and obtaining consensus among experts
- Systematic approach, which included attributes such as using a standardised method and adopting so-called “guideline logic” rather than “technocratic” approach
- Group members without conflicts of interest
- Good group process as a key element of the meeting structure
- Up-to-date recommendations

#### Panel 2: Comments by directors

Comments included:

- “I would have liked to have had more evidence to base recommendations on. We should have conducted a literature search.”
- “We never had the evidence base well documented. We should have reviewed evidence at a very early stage.”
- “The lack of resources does limit the ability to develop evidence-based recommendations.”
- “[Director General] Brundtland came in and said “evidence, evidence, evidence” but the approach to expert committees hasn’t changed since the 1950s—many see WHO as a technical agency and therefore we should have a comprehensive review of recommendation processes, including expert committees.”
- “Maybe what WHO needs is more work on the guidelines for guidelines.”

recommendations were never transformed into a programmatic approach. It is a common in-house failure to transform recommendations into action." Another said: "The marketing of it, making people aware, should have been thought of earlier."

Directors highlighted several other weaknesses with the processes used to develop recommendations, although most were mentioned by only one director. The weaknesses included a failure to involve key organisations, a failure to use evidence from other sectors, the creation of high expectations, a conflict over data, failure to use the guidelines for WHO guidelines (which were published after the process was started), the perceived need to choose between having a so-called mega-meeting or using a smaller group to develop recommendations, the failure to involve patients sufficiently, the failure to fit recommendations to health systems, not having had consultations earlier in the process, and not obtaining baseline data for an assessment.

The anticipated benefits, potential harms, and costs of adherence to the recommendations were unevenly considered. All directors could cite one or more anticipated benefits of adherence, such as simplification of treatment, improved quality of care, better management of technologies, and reduced morbidity and mortality. Fewer directors could cite one or more potential harms of adherence. Indeed, several directors reported that there were no potential harms in adhering to their departments' recommendations. For example, one director argued: "No harms are likely, since the recommendations were made by the top experts." Those directors who could cite potential harms provided general examples, such as side-effects and the consequences of misapplication or adaptation of the recommendations. One director reported that the potential harms were only considered implicitly in the discussion because it was feared that emphasising the risks might reduce the value of the recommendations, which were intended to help countries advocate for disease control programmes. Many directors identified both direct costs and opportunity costs associated with adhering to the recommendations.

When asked about how their department's recommendations have been used, directors provided examples such as educators using them in training programmes, WHO staff using them in their work in countries, and member states using them for development of policies. Several directors reported requests for reports, webpage hits, or translations of reports as indicators of the usefulness of the recommendations. Only a few directors reported any systematic monitoring of the uptake of their recommendations. Similarly, only a few reported completed or planned evaluations, which might partly be due to a lack of resources, as suggested by one director. "We would love to do it through a rigorous process. The problem is that this would require resources that we do not currently have and cannot reasonably expect in the foreseeable future." Another reported "no plans for evaluation because the

cycle of scientific developments is so quick that it isn't feasible." Most of the reported evaluations were not rigorous assessments of their effectiveness. They included the collection of indicators, case studies, site visits, and feedback at meetings.

The four clinical guidelines that we examined did not emphasise evidence about effectiveness or processes that would allow for the explicit incorporation of other types of information.<sup>24-27</sup> Two of the reports were called "guidelines", one a "technical consultation", and another a description of "the technical basis for the guidelines". Two of the reports stated that "This document is not a formal publication of WHO" on the page containing the publication information. Three reports (including the supporting documentation) did not contain a methods section. The fourth report contained a brief (less than one page) methods section. In all four reports the recommendations were neither itemised nor explicitly linked to evidence. All reports included references to primary studies or secondary sources. Three reports cited at least one systematic review as a reference (and at most four). The descriptions of the recommendation-development processes used in developing the recommendations were brief and provided little information about group processes (panel 3).

Several directors indicated that there was a growing recognition of the need for more systematic and transparent approaches to developing recommendations and that there was progress in this direction. One director observed: "There has been a culture change, but there is room for improvement." Another said: "It is improving, but slowly. Many departments are doing OK, while others are not doing so well. Some have been too close to industry, often because of lack of resources." A third director also provided a long-range view: "We are in the middle of a process, which needs time. There is increasing understanding of the need for evidence-based guidance and it is becoming part of the WHO culture."

## Discussion

The guidelines for developing WHO guidelines do not seem to be closely followed when WHO develops recommendations for member states. For example, systematic reviews and concise summaries of findings (eg, balance sheets) are rarely used, which means that evidence is generally not retrieved, appraised, synthesised, and interpreted using systematic and transparent methods. Processes for developing recommendations typically rely heavily on experts in a particular content area and not on representatives of those who will have to live with the recommendations or on experts in particular methodological areas (eg, information retrieval, systematic reviews, economic evaluations, and group facilitation). Although many people we spoke with viewed this as a problem, many others did not. Little attention seems to have been given by WHO to how to best help member states adapt global recommendations or take account of local needs,



**Panel 3: Recommendation-development processes used in four guidelines**

The following descriptions are taken from the four guidelines included in our document review.

- "...year-long process of international consultative meetings in 2001, in which more than 200 clinicians, scientists, government representatives, representatives of civil society and people living with...from more than 60 countries participated."  
"The recommendations included in this publication reflect the best current practices based on a review of existing evidence. When the body of evidence was not conclusive, expert consensus was used as a basis for recommendations."
- "This document was prepared for the WHO ...by.... The document was reviewed by the WHO Regional Advisors...and approved by the WHO Strategy and Technical Advisory Group..."
- "A WHO Technical Consultation on...was held in Geneva, Switzerland on 4 and 5 April 2001. Participants reflected a wide range of expertise in the document and use of...drugs. "The technical consultation took the form of presentations based on working papers and plenary discussions, on the basis of which specific conclusions and recommendations were agreed. The proceedings of the meeting and working papers form the basis of this report."
- "The guidelines...are based on both expert clinical opinion and research results. A technical review of existing programme guidelines was carried out with the cooperation of 12 WHO technical programmes through the WHO Working Group on.... Some modifications were required.... The draft guidelines were subsequently reviewed in several versions by clinicians and experts in specific diseases who had experience in clinical and public-health work in developing countries, then examined in research studies and by field-testing the training course."  
"Sufficient data were not available to make several guideline decisions.... Six studies were carried out..."  
"The case management charts and the modules were revised based on this experience and on the results of additional studies and analyses to help identify the best clinical indicators..."  
"The revised materials were made available to countries for closely monitored use..."

conditions, resources, costs, and values. Relatively little attention has also been given by WHO to roles and responsibilities related to effective dissemination and implementation strategies and their rigorous evaluation.

The strengths of our study include achieving a high response rate among the directors of a broad cross-section of WHO departments, interviews that probed the contexts for and processes used in developing specific guidelines or policies, and augmenting the interviews with document reviews in a domain that could be expected to be a best-case scenario (developing clinical practice guidelines as opposed to public health or policy recommendations), and undertaking two efforts to verify our interpretations (sharing our written summaries of each interview with directors and sharing our findings at various forums within WHO). The verification process yielded only minor corrections. The study's weaknesses include the potential for social desirability bias, particularly in terms of identifying the use of evidence as an area for improvement.

Although the WHO guideline recommendations are consistent with those developed by other organisations,<sup>28</sup> the actual processes used to develop recommendations at

WHO seem to be less rigorous than those of others. None of the directors reported using the guidelines for WHO guidelines and only two reported plans to use them. Few directors reported using processes that were consistent with the guidelines. An unpublished in-house review, which was done before our study using the Appraisal of Guidelines Research and Evaluation (AGREE) appraisal instrument for assessing clinical guidelines,<sup>14</sup> noted that most WHO guidelines did not meet most of the AGREE criteria (Robin Gray, personal communication, 2003). Reviews of clinical practice guidelines produced by other organisations also report that they often do not adhere to their own guideline recommendations.<sup>29-31</sup> WHO also is not alone in its failure to recognise the danger of inadequately assessed public health and policy interventions, which, like clinical interventions, can also have unintended consequences.<sup>32</sup> However, many organisations now report using systematic and transparent methods to develop clinical, public health, and policy recommendations, including a growing number of organisations funded by government.<sup>33-35</sup>

Progress in the way that WHO develops and disseminates recommendations for member states, and in how it supports member states in their efforts to adapt and implement recommendations, will require leadership. WHO's Cabinet recognised the need for using systematic and transparent methods to develop recommendations when it endorsed the guidelines for WHO guidelines in 2003.<sup>23</sup> Yet no mechanisms have been put in place to support and monitor adherence to the guidelines, and our study suggests that they are not being followed. Some directors reported a shift towards a culture that supports using systematic and transparent methods in developing recommendations, but this shift seemed to pertain more to clinical than policy recommendations. WHO has not clearly articulated whether and how it will support member states in their efforts to adapt and implement recommendations.

Progress will also require the resources for WHO to undertake recommendation-development processes in a transparent and defensible way, and will need close attention to the current and emerging research related to these processes. All of the directors we interviewed were highly motivated and trying hard to do a good job. Many were frustrated by a lack of resources and feelings of being pressured by a lack of time and perceptions of urgency. WHO relies heavily on external financial support, so resources will probably have to be sourced from outside the organisation. However, WHO could do much better with the resources it has, both by setting priorities and by adhering to its own guideline recommendations. Considering that these guidelines might be most relevant to the development of clinical practice guidelines and public health recommendations, future iterations of the guidelines will need to incorporate the emerging research literature about developing policy recommendations.<sup>12</sup>

**Contributors**

All authors contributed to the design of the study, participated in interviews, contributed to the analysis and drafting of the report, and have read and approved the final version of the report.

**Conflict of interest statement**

AO is a member of the WHO Advisory Committee on Health Research. JL is President of the PAHO/WHO Advisory Committee on Health Research, and a member of the Scientific and Technical Advisory Committee of the Alliance for Health Policy and Systems Research, which is co-sponsored by and housed within WHO.

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