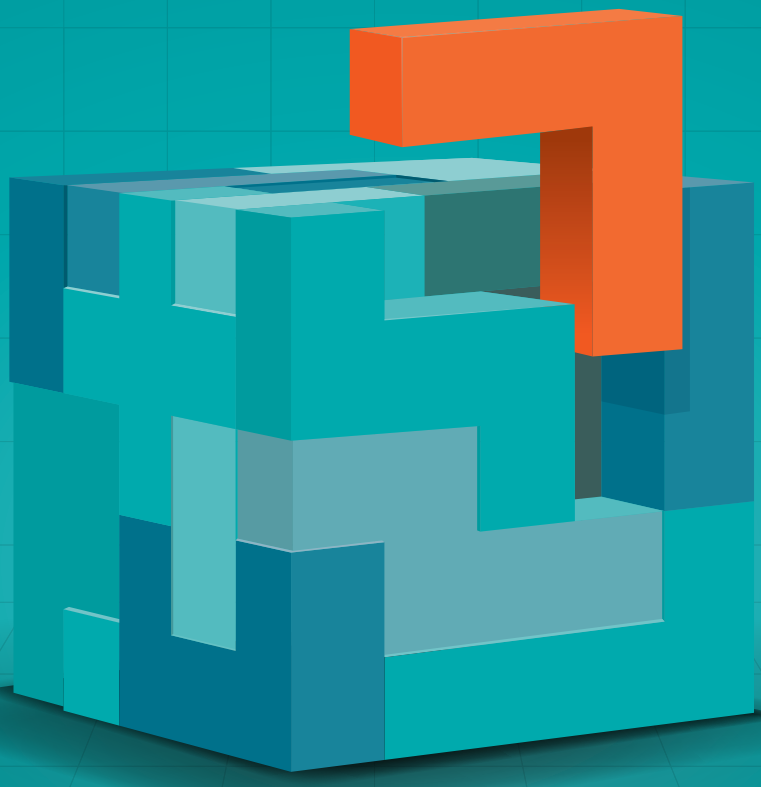
World Health Organization

European Region

Strengthening countries' capacities to adopt and adapt evidence-based guidelines

a handbook for guideline contextualization



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Abstract

Trustworthy guidelines are the cornerstone of giving evidence-informed advice in response to clinical, public health and health policy questions. Tools, validated methods and standards, as well as guidance, are available to support those involved in the creation and implementation of guidelines. In order to be most effective and have a chance to be implemented, guidelines also need to be fitted to available resources and organizational contexts. This cannot be achieved by a simple language translation of guidelines produced by others but requires considerations of context: guideline contextualization. This handbook provides a brief overview of main principles and approaches in guideline development and contextualization. It also describes 15 steps on how to apply GRADE-ADOLOPMENT for developing contextualized recommendations based on source guidelines and local relevant evidence. Reference is also made to other useful resources and tools. In addition to the adolopment process, brief information is provided about implementation and dissemination as well as about required quality assurance steps.

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Contents

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Abbreviations and acronyms

AGREE	Appraisal of Guidelines for Research and Evaluation
COI	conflict of interest
DOI	declaration of interest
EtD	evidence to decision (framework or table)
GIN	Guidelines International Network
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GRADE-ADOLOPMENT	Grading of Recommendations Assessment, Development and Evaluation Adaptation, adoption and de novo creation of recommendations of a guideline
PICO	patient/population, interventions, comparators, outcomes
RIGHT	Essential Reporting Items for Practice Guidelines in Healthcare
ROBIS	risk of bias in systematic reviews
SoF	summary of findings (table)

Executive summary

Trustworthy guidelines are the cornerstone of giving evidence-informed advice in response to clinical, public health and health policy questions. They address those questions by using the best available evidence and transparently integrating the judgements of experts and the input of stakeholders in the process.

Modern guidelines also provide the needed flexibility to individualize care for people with a condition of interest or to contextualize them to a policy context. Modern guidelines allow information to be shared with other decision-makers and harmonization of processes to avoid duplication and resource waste. While it is difficult to consistently demonstrate that the use of guidelines improves population outcomes and increases efficiency, there is no viable alternative to utilizing guideline recommendations and decisions based on the best available evidence. However, to be trustworthy and provide these gains, guidelines should:

- be developed by an informed, multidisciplinary panel of experts and representatives from key relevant or affected groups;
- be based on systematic reviews of the relevant evidence or on systematically and transparently extracted expert evidence if scientific evidence is missing;
- consider important population subgroups;
- consider people's values and preferences;
- be based on an explicit and transparent process that minimizes distortions and biases, and that appropriately manages any conflict of interest (COI);
- provide a clear explanation of the logical relationships between alternative care or policy options and health outcomes;
- be explicit about the certainty of the underlying evidence and how it links to the grade or strength of recommendations; and
- be reconsidered, updated and revised as appropriate when important new evidence warrants modifications of recommendations.

Tools, validated methods and standards, as well as guidance, are available to support those involved in the creation and implementation of guidelines.

In order to be most effective and have a chance to be implemented, guidelines also need to be fitting to available resources and organizational contexts. This cannot be achieved by a simple language translation of the guidelines produced by others but requires considerations of context: guideline contextualization.

This handbook for guideline contextualization can be used to support actual guideline contextualization processes and technical content in capacity-building workshops for Member States. It is also relevant for interested WHO staff to understand contextualization of guidelines to country needs through validated methods.

Guidelines can be developed by adopting existing recommendations, adapting existing recommendations to the specific context or creating new recommendations de novo. De novo recommendations are required in guideline efforts when the source guideline does not address all relevant questions. Monetary and

nonmonetary resources, credibility, maximization of uptake and logical arguments should guide the choice of the approach and processes. Ideally, the approach chosen will avoid wasting human and financial resources by utilizing what has already been achieved. This handbook will help to promote the use of global guidelines and their recommendations in the development of new guidelines. The approach utilized is based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology. GRADE is the most commonly used methodology for making guideline recommendations and is the method of choice for many organizations, including WHO. Adolopment is a neologism referring to the systematic and transparent approach to adoption, adaptation and/or de novo development of recommendations to fit the context of interest. The GRADE-ADOLOPMENT approach to guideline production, therefore, uses the adoption, adaptation and/or de novo creation of context-relevant recommendations with GRADE methodology. If the guideline is developed following the GRADE approach, existing summary of findings (SoF) tables and evidence to decisions (EtD) frameworks makes guideline adolopment and contextualization very efficient.

Fifteen steps are described that provide the conceptual underpinning of GRADE-ADOLOPMENT for recommendations based on source guidelines and local relevant evidence. Reference is also made to other resources and tools. In addition to the adolopment process, brief information is provided about implementation and dissemination as well as about required quality assurance steps.

Introduction

Background

National and international organizations are increasingly issuing their own guidelines, which can lead to multiple guidelines on the same topic. WHO defined a guideline as "a document that contains systematically developed evidence-based actionable statements that assist health professionals and recipients of care to make informed decisions" *(1)*. This 2003 document goes on to define health interventions as "broadly to include not only clinical procedures but also public health and policy actions".

Trustworthy guidelines are the cornerstone of giving evidence-based advice regarding clinical, public health and health policy issues and provide access to the best available evidence, experts' judgements and stakeholder input. This allows decision-makers to have wide-ranging gains from a single tool: a synthesis of the best available research evidence, access to experts and structured and transparent tools that can be discussed and revised as necessary. Guidelines following innovative processes also provide the needed flexibility to individualize care for people with a condition of interest[1] or to contextualize guidelines to a policy context. Modern guidelines allow for sharing of information with other decision-makers and can harmonize processes to avoid duplication and resource waste *(2)*. While it is difficult to consistently demonstrate that the use of guidelines improves population outcomes, increases efficiency and avoids duplication of effort, there is no viable alternative to making guideline recommendations and decisions based on the best available evidence.

A number of publications outline what guidelines should cover in order to be trustworthy and provide these gains *(3–14)*:

- be developed by an informed, multidisciplinary panel of experts and representatives from key relevant or affected groups;
- be based on systematic reviews of the relevant evidence or systematically and transparently extracted expert evidence if scientific evidence is missing;
- consider important population subgroups;
- consider people's values and preferences;
- be based on an explicit and transparent process that minimizes distortions and biases, and that appropriately manages COIs *(10)*;
- provide a clear explanation of the logical relationships between alternative care or policy options and health outcomes;
- be explicit about the certainty of the underlying evidence and how it links to the grade or strength of recommendations *(11–14)*; and
- be reconsidered, updated and revised as appropriate when important new evidence warrants modifications of recommendations.

Although developing guidelines that meet those criteria requires skills and resources, there are available tools that support guideline development (e.g. checklists or electronic tools). There also are validated methods and standards as well as guidance that can support the creators of guidelines. For example, the planning and

1 Condition of interest is a wide term to encompass both patients with a specific condition and also healthy individuals, such as those targeted with screening programmes.

production of guidelines is facilitated by tools produced by the partnership between the Guidelines International Network (GIN) and McMaster University (e.g. the GIN-McMaster Guideline Development Checklist *(6,15)*). This Checklist was developed in response to a demand to support WHO Member States with the planning and development of national guidelines *(6)* that can be integrated in advanced software applications. Guidelines developed according to these principles should also be reported according to modern standards, such as with the Essential Reporting Items for Practice Guidelines in Healthcare (RIGHT) standards for reporting of guidelines *(16)*. In addition, instruments exist to evaluate a guideline's trustworthiness or the processes for its development, such as the Appraisal of Guidelines for Research and Evaluation (AGREE) tool *(17)*, the United States Agency for Healthcare Research and Quality's National Guideline Clearinghouse Extent of Adherence to Trustworthy Standards instrument *(18)* and the PANELVIEW tool *(19)*.

In order for guidelines to be implemented, they need to be both easy to use and timely and must be relevant and responsive to the needs, values and preferences of the target populations or individuals affected by the recommendations and their individual risks for the outcomes of interest. In addition, guidelines also need to be suitable for the available resource and organizational contexts. On the one hand, it is obvious that this cannot be achieved by simply translating guidelines produced in one language to another; yet this approach is frequently used. Indeed, guideline recommendations usually change when they are adapted to other settings *(20)*. On the other hand, using guidelines developed by others saves resources and time required for conducting systematic reviews and producing de novo guidelines. Therefore, contextualization and not simple language translation is needed to achieve efficient implementation on different levels and to use existing guidelines developed by other organizations: that is, adopting and adapting existing recommendations from sources such as WHO, professional societies or national guideline developers. Two key reasons for contextualization of existing guidelines are to:

- assess the factors characterizing local circumstances compared with those in the setting of the source guideline in order to make the guideline more implementable in the setting of interest (contextualize the recommendations); and
- ensure optimal and economical use of the existing human and financial resources within a defined health system.

Fortunately, guideline developers are increasingly using transparent approaches in guideline development, laying out the criteria, the research evidence and additional considerations leading to judgements about the strength and direction of a recommendation *(21)*. This is done using GRADE EtD frameworks *(22,23)*. These frameworks help groups of people (guideline development groups or panels) making health-care recommendations or decisions to move from evidence to decisions (these major terms are defined and outlined in the next section). Using EtD frameworks can help to achieve the transparency needed to adapt or adopt recommendations developed by others.

Rationale for approach used

This document describes an approach to adopt and adapt evidence-based guidelines from WHO and other agencies, which are referred to here as source guidelines, to other jurisdictions, such as the regional or country level, through systematic, transparent and established means. This will allow scaling-up of implementing evidence-based measures and practices related to public health and clinical areas *(22,23)*. A commonly used and established approach to achieve this is the GRADE-ADOLOPMENT approach, which combines adoption, adaptation and, as needed, de novo development of recommendations (where adolopment is a neologism combining the terms).

This document aims to:

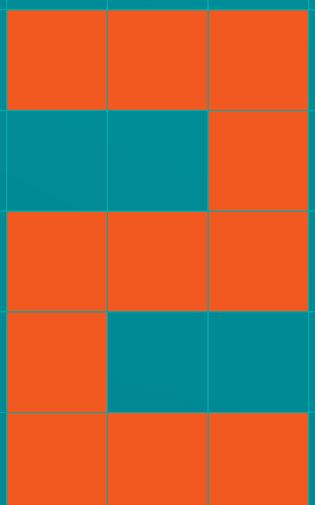
- provide a guide for contextualization of guidelines, with step-by-step guiding material and a list of resources, through the tailoring of available methods and tools for global use, such as GRADE-ADOLOPMENT *(24)*, to the context of the WHO European Region and its Member States; and
- provide a model institutional framework and list the minimum capacities, processes and functions needed for contextualization in specific situations (based on the GIN-McMaster Guideline Development Checklist *(6,15)* in line with WHO guideline methods).

The model framework can be evaluated by countries and will lead to enhanced iterations of the handbook. The handbook can be used to provide technical content for capacity-building workshops for Member States and for interested WHO staff to understand contextualization of guidelines to specific country situations through guideline adolopment. This, in turn, will help to promote the use of global guidelines and their recommendations through adoption, adaptation and/or de novo creation of context-relevant recommendations, thus avoiding waste of resources by repeating work that has already been done.

The approach in this document is based on GRADE *(8,12,13,22–24)* as this is the most commonly used methodology for making guideline recommendations and is the method of choice by many organizations, including WHO, the United Kingdom's National Institute for Health and Care Excellence, Cochrane and many professional organizations. GRADE is a highly operationalized approach creating transparent recommendations, with detailed guidance, handbooks and ongoing scientific development *(25)*. For example, GRADE is also the suggested approach in the WHO Region of the Americas for their national evidence-informed guidelines *(26)*.

The document was drafted and revised iteratively from November 2021 to June 2022 with incorporation of comments from external reviewers in July–August 2022. There are three sections that follow. The first provides an overview of key definitions and concepts in guideline development. The second describes the main organizational aspects of the guidelines, as well as main principles and steps for guidelines development and contextualization, and the third section provides a step-by-step guide on guideline adolopment.

Key definitions and concepts



The following section outlines the key terms and concepts utilized in this handbook.

Source guideline

A source guideline is one from another entity (such as WHO headquarters or a guideline-developing agency) that has been identified as a guideline that can be adapted or adopted to the context of interest (also see modules 7 and 8 in the OpenWHO course on understanding and using WHO guidelines on tuberculosis *(27)*).

Adoption

Adoption means the use of an existing recommendation either unmodified or with minimal changes. Ideally, this means that the source guidelines are reviewed and the judgements and decisions that led to a specific recommendation are still agreed with. For adoption, the source guideline must provide a clear, documented path to the recommendations: from the evaluation of the research to the preparation of the recommendation itself. If the path is credible and transparent, the entity responsible for implementation must assess the directness and timeliness of the recommendations. Directness refers to the concept that the recommendations are appropriate and applicable to the context of the health-care setting of interest, for example by addressing populations, interventions and outcomes of interest. To assess if the information is up to date, it is usually necessary to re-examine the incorporated evidence to ensure that no new or other essential evidence should be added, for example by updating the corresponding evidence synthesis performed in the original resource.

Adaptation

Adaptation of a recommendation means that reliable recommendations exist that meet the established criteria for credibility but that the judgements on the criteria that support the recommendation, or the recommendation itself, require updates or changes to be implemented for the health-care setting of interest. For example, the new recommendation may need to broaden the population of interest or may need to consider local costs that differ from the source guideline recommendation. Any change should be documented and the rationale for it transparently described. Because of international use of the term adaptation to refer to all processes summarized under adolopment (see GRADE-ADOLOPMENT below), the terms adolopment and adaptation are used as methods interchangeably when referring to guideline contextualization that reflects the process and concept of making recommendations relevant and implementable to the target setting (see the next section). Adaptation of a recommendation is used to specifically refer to a single recommendation.

Adolopment

Adolopment is a neologism referring to the systematic and transparent approach to adoption, adaptation and/or full development of recommendations to fit the context of interest, alongside and in accordance with the GRADE methodology. De novo recommendations are commonly required in guideline efforts as the source guideline is unlikely to address all relevant questions for a setting.

Contextualization

Contextualization of recommendations describes the process of:

- acknowledging the need for dialogue and formal consideration of local best available evidence and criteria for adopting, adapting or de novo creation of recommendations from an existing trustworthy source guideline to the national, local or other level;
- deciding whether the recommendations are right for that setting; and
- modifying or adding to the recommendations to optimize their implementation using structured and transparent processes.

This document focuses on GRADE-ADOLOPMENT as a method to contextualize guidelines *(24)*.

Expert evidence and opinion

Expert evidence is the observations or experience obtained from a person who is knowledgeable about or skilful in a particular area *(28)*. The expert evidence can be treated, if appropriately summarized, in the same way as case reports or case series. Expert evidence is not expert opinion *(28)*. The distinction between expert evidence and expert opinion is similar to the distinction between the results of a research study and the authors' conclusions, which include interpretation of the results or judgements about them. If an expert offers an opinion (a conclusion) and does not clearly describe the basis for that opinion – that is, the supporting evidence – it is not possible to know what the evidence is or how trustworthy the opinion is *(28)*. A description of expert evidence should, therefore, minimize interpretation of the extent to which the evidence does or does not support a conclusion.

The GIN–McMaster Guideline Development Checklist and Tool

Since its development in 2014, the GIN–McMaster Guideline Development Checklist and Tool has served as one of the most widely used tools to facilitate guideline development *(6,15)*. The Checklist provides guidance to countries, WHO and professional organizations about guideline development. It includes overarching areas, such as budgeting and planning, education of guideline developers, COI identification and management, and documentation. It also includes a publicly available toolbox that can be followed to create trustworthy guidelines *(15)*, as well as links to learning tools and training materials. The Checklist has undergone further development work since 2014, with extensions in key guideline development areas, such as the production of rapid guidelines, considerations of health equity, stakeholder engagement and the incorporation of quality indicators into recommendations.

After its original development under the leadership of scientists at McMaster University, the Checklist developed as a partnership between the GIN and McMaster University. GIN is the preeminent organization that brings together guideline developers, implementers and other stakeholders. The Checklist is intended for use by guideline developers to plan and track the process of guideline development and to help to ensure that no key steps are missed, in agreement with other international guideline development standards. It is publicly available, with links to learning tools and training materials. The Checklist, translated into many languages

and integrated in guideline development apps such as GRADEpro, is the blueprint for the first credentialling and certification programme for guideline developers and trainers in guideline development (INGUIDE) *(29)*.

The GRADE approach

The GRADE approach provides a transparent framework for assessing the certainty in evidence and for the development of recommendations according to transparently described criteria *(8,12,14,23)*. GRADE can be used in systematic reviews, health technology assessment and guidelines *(30)*. GRADE is the most commonly used methodology for guideline development and is used by over 110 organizations. It has been developed with the input of organizations such as WHO, which has developed thousands of recommendations using GRADE.

The GRADE Handbook is included in the GRADEpro website *(31)* and provides guidance for the writing, dissemination, adaptation and implementation tool. GRADE is extensively operationalized with detailed guidance, handbooks and tools through ongoing scientific development. GRADE resources are summarized by Cochrane Training *(32,33)*.

GRADE-ADOLOPMENT

GRADE-ADOLOPMENT is an approach that describes an efficient way for guideline contextualization allowing for local, national or regional input, as well as stakeholder involvement and ownership, which is critical in the uptake of recommendations *(20,24,34–38)*. The approach allows a systematic and transparent approach to adoption, adaptation and/or full development of recommendations to fit the context of interest, alongside and in accordance with the GRADE methodology. There are several frameworks for guideline adaptation but a recent systematic review judged GRADE-ADOLOPMENT to be most complete *(39)*.

Recommendations and small informative recommendation units

A formal recommendation is an actionable statement about the choice between two or more management or policy options (interventions) in a specific population and, if relevant, in a specific setting *(40)*. Alternative option(s) (i.e. comparator(s)) should be specified in the recommendation if they are not self-evident. GRADE offers standardized wording for the pragmatic completion of EtDs by guideline groups *(41)*. These statements are the results of a formal deliberation process and contain an explicit and direct link to the bodies of evidence, resulting from a systematic literature search and selection, appraisal and extraction processes. Recommendations should be made available in small informative recommendation units that cover a topic without causing confusion or important gaps *(42)*. Confusion and gaps can arise if single recommendations remain uninformative because they depend on other recommendations (e.g. recommendations for or against screening for breast cancer in different age groups should always be kept together in small informative recommendation units) *(42)*.

Remarks and good practice statements

Remarks are often an integral part of a recommendation *(40)*. They are defined as a support for interpretation covering the subdomains of the PICO model (patient/population, interventions, comparators, outcomes) and/or the conditions framing one or more specific recommendation(s) (e.g. guiding the user on the intervention options when the recommendation is conditional). They are not actionable in isolation.

Remarks should not include actionable suggestions. The recommendation or good practice statement and the actual accompanying remark should be seen as an inseparable unit *(40)*. Good practice statements are another form of actionable statements that typically should be applicable to all settings and contexts, which is why they are good or best practice statements *(40,43,44)*.

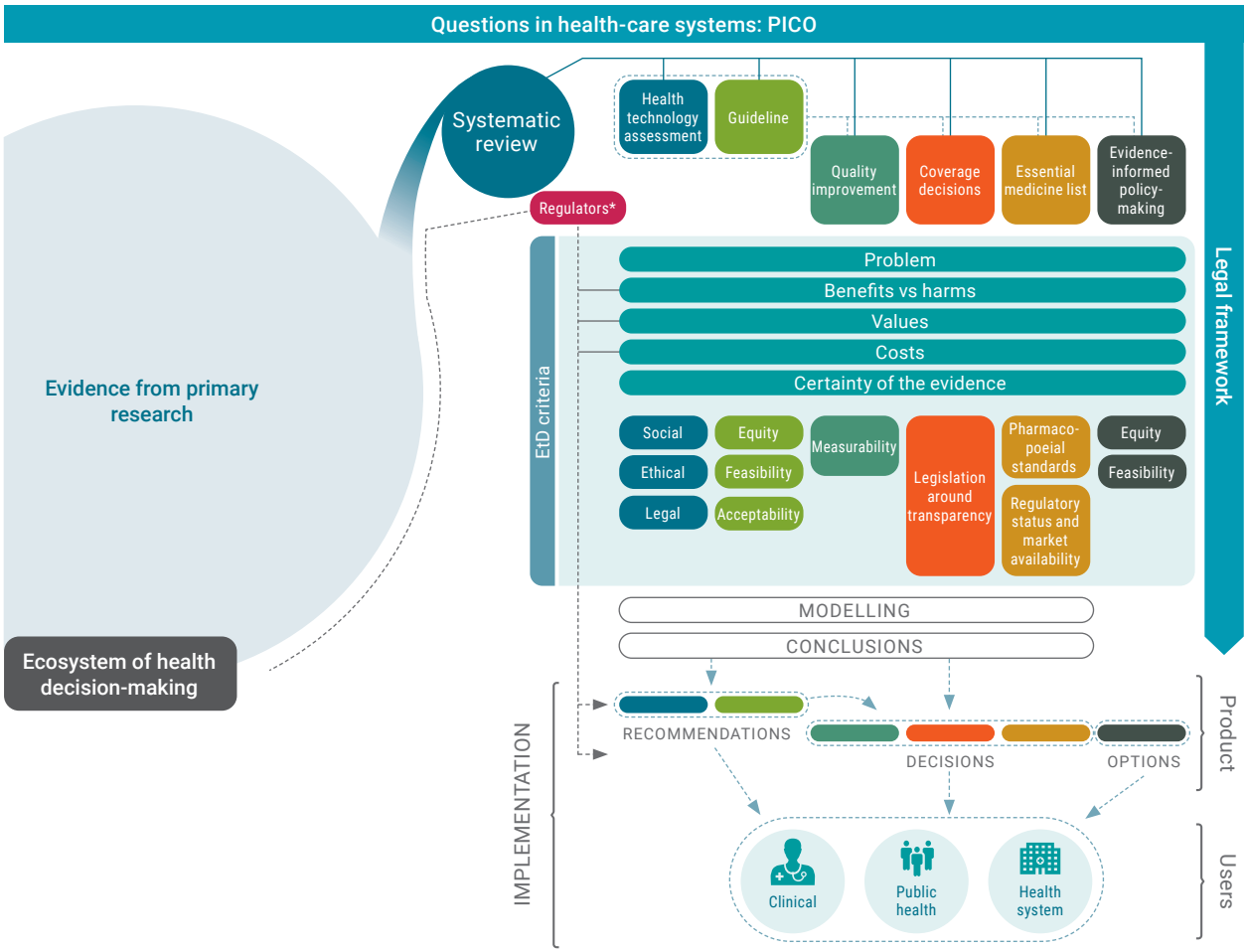
EtD frameworks

EtD frameworks help groups of people (guideline development groups or panels) to move from evidence to health-care recommendations and making decisions. The background includes details of the question addressed by the framework, and a summary of key background information. The assessment includes factors that should be considered (criteria) for making the decision, judgements that panels must make in relation to each criterion, research evidence to inform each of those judgements, and additional considerations that inform or justify each judgement. The conclusions that the panel must reach include the type of decision or recommendation (e.g. strength and direction of a recommendation), the recommendation, the justification for the recommendation, subgroup considerations, implementation considerations and research priorities. An example of practical guideline adolopment from the WHO tuberculosis programme is given in Annex 1.

The interactive EtD framework that allows for adolopment is a tool included in GRADEpro. EtD frameworks can create bridges across health decision-makers in the ecosystem of health decisions by linkage through the criteria that are used by different health-care actors in order to support recommendations and decisions (Fig. 1) *(2)*.

Fig. 1 illustrates the interconnectiveness of health decisions across disciplines. Although actors in the health decision-making ecosystem formulate questions, they often define outcomes differently and consider them with a specific perspective rather than refer to a common description that can facilitate communication and harmonization *(45)*. Evidence from primary research is synthesized using systematic review methods for health technology assessment, guidelines, quality assurance and improvement, coverage decisions, essential medicine list decisions and evidence-informed policy-making *(2)*.

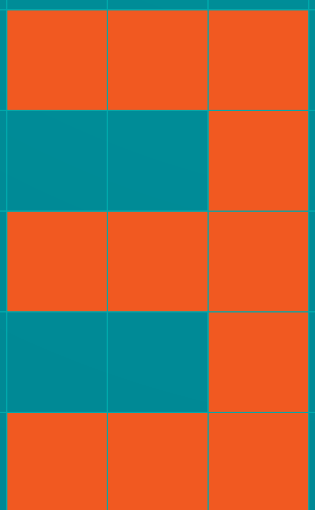
Fig. 1. Ecosystem of health decision-making



Source: Schünemann et al. *(2)*. Reproduced under CC BY 3.0 IGO (https://creativecommons.org/licenses/by/3.0/igo/).

Regulators, including those in the field of environmental health and risk assessment, often use single or a few studies (in the early phases of evidence assessment) but may rely on systematic reviews depending on the context and the available evidence. These disciplines have GRADE EtD criteria in common by focusing on the problem, health benefits and harms, values (or utilities in the health economy context), cost and the certainty that can be placed in the evidence for those criteria. Criteria that are more strongly linked to context often are overlapping within (e.g. cost and feasibility) and across (e.g. equity, ethics and acceptability) disciplines and may require emphasis depending on the decision-making actor and perspective. These criteria are broadly summarized under social, ethical, legal, feasibility, acceptability and equity headings. Legal frameworks may prescribe which criteria for decisions are relevant or must be considered in specific jurisdictions. Modelling to understand the consequences may be used. Groups or organizations then make recommendations or decisions or describe options. Recommendations from health technology assessment and guidelines may be directly used by decision-makers. Actors from other disciplines, such as for coverage decisions or the national essential medicine list, make decisions directly or based on the recommendations of health technology assessments and guidelines. Evidence-informed policy tools lay out contextualized options (rather than making specific recommendations). Implementation can take place in the context of research, which, together with new evidence, completes the evidence generation and synthesis cycle for revisions of recommendations and decisions.

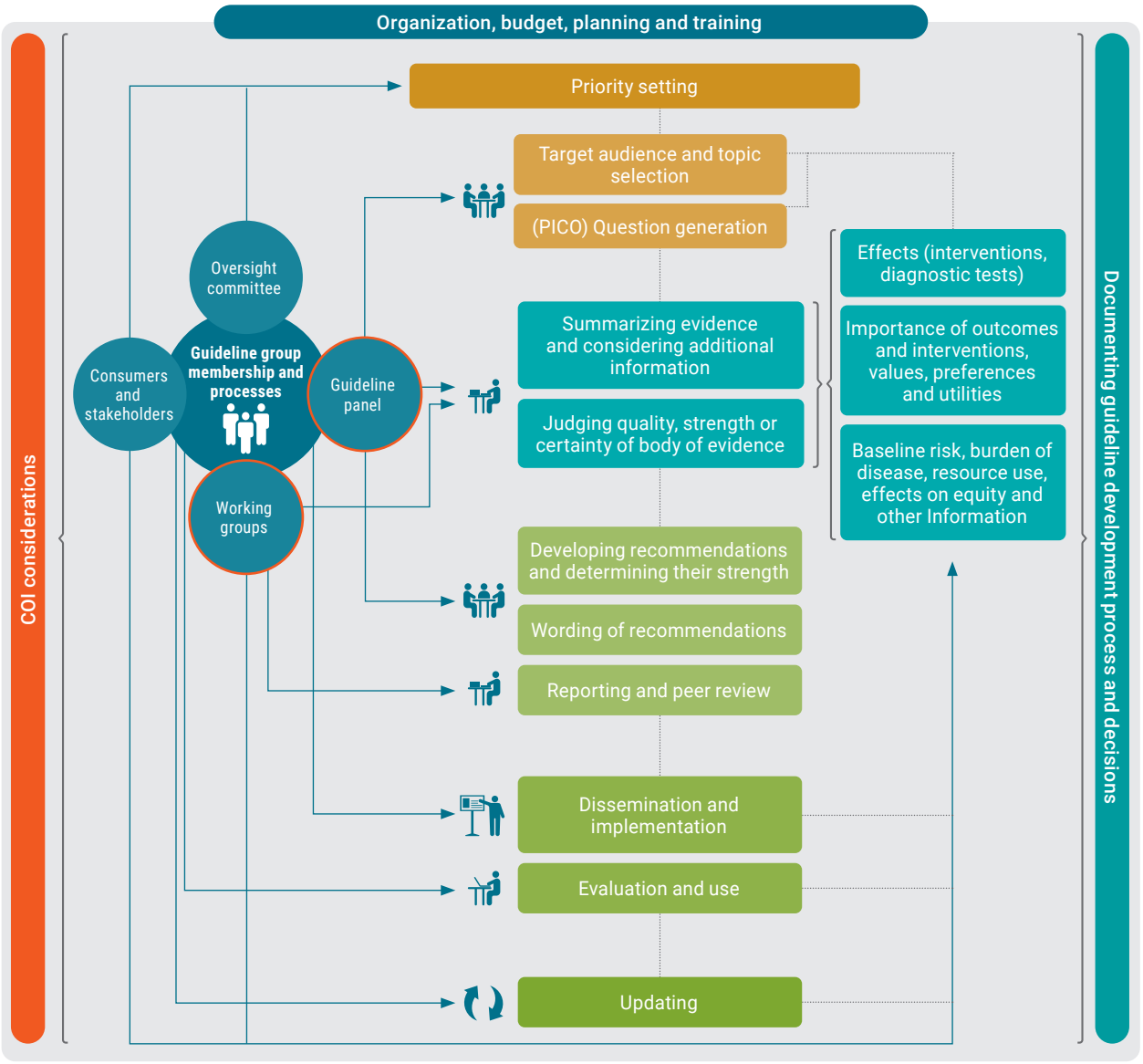
Organizational aspects, main principles and resources for guideline contextualization



Introduction

Guideline development and adaptation take place through the work of interconnected groups that participate in a structured process (not necessarily sequential), following agreed methodology (see the next section on the detailed steps for contextualization) and utilizing the best available global and local evidence supported by internationally recognized and widely used tools (Fig. 2).

Fig. 2. The guideline development process



Source: Schünemann et al. CMAJ. 2014;186(3):E123–42 *(6)*. (© 2014 Canadian Medical Association or its licensors.)

The process of guideline development should be transparent, well planned and carried out in close cooperation with all relevant stakeholders including the relevant health professionals, patients and the public. Furthermore, considerations for organization, planning and training encompass the entire guideline development project

and steps such as documenting the methodology used and decisions made, as well as considering any COI occurring during the entire process.

The guideline group comprises an oversight committee, a guideline panel and various working groups (which will include support staff, technical and content experts, evidence synthesis/systematic review groups and observers, among others). The oversight committee is tasked to manage and supervise priority setting, such as for a ministry of health or professional society, and the selection of a guideline panel. The guideline panel is responsible for making recommendations that start with defining the guideline or recommendation question that should be answered through the use of summarized evidence from systematic reviews complemented by contextual evidence (e.g. costs, acceptability and feasibility) to formulate the new recommendations. This evidence should be appraised and assessed for the level of certainty of the underlying evidence. The panel will pay careful attention to the formulation of recommendations before they are peer reviewed through processes such as submission for public consultation or for publication in a journal.

Guideline processes do not end with the approval or publication of the guidelines. The guideline developer is responsible for dissemination, evaluation and use in many scenarios but not all (e.g. a professional society may not be responsible for evaluation of the use of their guidelines). Consequently, every guideline should be accompanied by an implementation plan (including measurable outcomes, who is responsible for what in the implementation phase and when as well as how it is done) and be followed by monitoring and evaluation. Indeed, contextualization is not only a prerequisite but is also part of implementation and, therefore, these two aspects should be considered as equally important. There is no implementation without contextualization and there should be no contextualization without implementation.

This section describes the overarching principles and the following section gives the detailed steps for guideline adolopment.

Organization, budget, planning and training

Mandates, structure, organization and legitimization

The development of a guideline should start either with an assigned mandate or another documented reason that the guideline is required to address a health problem. The mandate may come from a ministry in charge of health, a government agency, another official entity or be the result of a priority setting by a professional society, a group of professionals or other health-care providers.

Guideline development and adoption requires setting up a structure for the guideline development groups with clear roles, tasks, reporting lines and relationships among the various involved groups (see below). It also requires that administrative and other logistic support is available and that someone is responsible and accountable for overseeing and facilitating the overall process and quality assurance of guidelines *(15)*.

It is strongly advised that, for guidelines to be accepted by stakeholders, a formal process, including approval of and access to official guidelines, is in place. This will also help with implementation as legitimization will increase the credibility of the produced guideline. This, in turn, requires a governance structure, not only for the initiation and development but also for approval and implementation efforts.

Budget and planning

As for any scientific or practical work done in health care, guideline development will require financial resources. Guideline developers should avoid the mistake of believing, or making others believe, that guidelines can be developed on small budgets. However, in countries with limited resources, using systematic adolopment approaches will save resources and is likely to produce guidelines of better quality. For example, resources are needed for many aspects, including support for the activity of the designated authority; remuneration for staff and members of the guideline development groups; for travel, organizing meetings and providing training; and for publishing and dissemination of conclusions. Therefore, securing funding, but with attention to COI considerations, is critical for success. Also, many countries already develop guidelines, albeit with unknown quality and implementation capability.

An operational and realistic workplan provides an overview during the process and keeps the guideline development group on track; it will include a timeline, milestones, task assignments, steps that require documentation of decisions, the proposed methodology for all steps and budget considerations *(6,15)*.

Budgeting and planning depend on the guideline development context. Defining the context refers to understanding and defining the guideline development programme, for example is this within an established guideline programme (which requires you to follow the guideline process of the organization) or is it an ad hoc group guideline being developed (e.g. applying a specific guideline development approach or one from a trusted source such as WHO)?

Additional resources

GIN–McMaster Guideline Development Checklist *(15)*
WHO Handbook for Guideline Development *(46)*

Human resources and training

Even more than the financial resources, human resources are a common challenge in groups that embark on guideline development or adolopment. Even if experience in guideline development is present, those who have been previously involved often need additional training and updating of their skills in methods and processes in order for the products to be trustworthy according to the criteria laid out in the Introduction to this document. In some countries, before embarking on guideline adaptation, awareness needs to be raised around the principles and criteria of evidence-based and trustworthy guidelines. This means that capacity-building in guideline development methodology is usually required in a country setting and should be part of the workplan and funding. This can take place before guideline development efforts are undertaken or with the help of an external guideline methodologist, who supports initial efforts and guides the process. Furthermore, standardized training, such as through the international guidelines development and certification programme INGUIDE *(29)*, an official programme by GIN and partners, should be considered by those in charge.

Additional resources

INGUIDE *(29)*
Introduction to WHO guidelines and GRADE, including training videos *(47)*

COI and confidentiality

Groups involved in guideline development should be impartial, independent and objective. When developing and adapting guidelines, it is essential to avoid situations where various interests can unduly influence the work and thus undermine the credibility of the guideline recommendations and jeopardize their implementation.

A COI is "a divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as direct financial, academic advancement, clinical revenue streams, or community standing" *(10)*, or more simply, "a financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open mind" *(10,48–50)*.

The process of managing COIs starts with the people involved in guideline work reporting any potential conflicts using a declaration of interest (DOI) (see Annex 2). A DOI according to WHO is the disclosure of any potential or actual COI, which includes financial, professional or other interests relevant to the subject of the work or meeting in which an expert may be involved and any possible interest that could be significantly affected by the outcome of the meeting or work. The DOI must also include any relevant interests of others who are related to the person making the declaration and who may, or may be perceived to, unduly influence the expert's judgement, such as immediate family members, employers, close professional associates or any others with whom the expert has a substantial common personal, financial, or professional interest *(50)*. A DOI indicates the participants' financial or nonfinancial interests in an external for-profit or non-profit-making organization. While there are no rules prohibiting financial or personal ties to companies or organizations, these ties may represent a COI if the company or organization has an interest in a product that is the subject of the guideline under development.

In addition to presenting DOIs prior to the meetings, during the meetings individuals who have direct input into the guideline should verbally report any potential COI. In managing the cases of (new) COI, several possibilities exist. First, the member may be invited to participate, but only if their conflict is publicly disclosed. Secondly, the member may be asked not to participate in a particular portion of the meeting, discussion or work that is directly related to their conflict, which will be publicly disclosed. Thirdly, the member may be asked to withdraw from the panel entirely (no DOI is necessary). The DOIs will be updated if any new interests emerge on an ongoing basis during the guideline development process. Any COI must be reflected in the guideline development documentation, with an explanation of what each conflict constituted and how it was managed *(51)*.

In addition, people involved in the guideline development process should commit to keep all information confidential unless permission has been obtained from the overseer of the process or the information disclosed is in the public domain. A commitment to confidentiality means typically to sign a confidentiality agreement with the organization that is developing the new guidelines *(51)*.

Additional resources

Chapter 6 on declaration and management of interests in the WHO Handbook for Guideline Development *(46)*
Preventing and Managing Conflicts of Interest in the Public Sector: Good Practices Guide *(52)*

Documenting the process and decisions

One of the main underlying principles contributing to the reliability of guidelines is transparency. In order to increase the transparency of the whole process, it is important to ensure that the decision process and judgements, as well as evidence used for decision-making, are made explicit and transparent to the reader through appropriate documentation, and making the guideline material and information available publicly.

Some of the tools to facilitate transparent and systematic decision-making as well as documentation are the GRADE evidence profiles or SoF tables, which provide a tabular format of the research evidence, and the GRADE EtD frameworks, which were specifically developed with WHO and other organizations to achieve proper documentation of research evidence, judgements and decisions *(22,23)*. Any changes to the original judgements as well as agreement with existing judgements should be documented (see step 9 in the next section).

A tool that facilitates the reporting of guideline development and guideline adaptation for peer-reviewed publications is the RIGHT checklist *(16)*, which together with other reporting tools is available from the EQUATOR Network *(53)*.

SoFs and EtDs, if they are available for those who adolop guidelines, are facilitators of effective contextualization with minimalization of research waste. Furthermore, registering and identifying registered evidence syntheses on the International Prospective Register of Systematic Reviews (PROSPERO) will support others in their efforts when using these products.

Additional resources

EQUATOR Network *(53)*
RIGHT-AD@PT Checklist: A Reporting Tool for Adapted Guidelines in Health Care *(54)*

Groups involved in guideline contextualization

The guideline developer (the organization or professional group in charge of developing a recommendation) and the working groups proceed collaboratively and are informed through public involvement. The guideline panel is the group of people responsible for agreeing on the recommendations. The guideline panel is a subgroup of the guideline development group, which often includes members of a technical team and other groups that assemble evidence syntheses or obtain evidence to inform recommendations (e.g. methodologist, health economist, evidence synthesis or systematic review team, administrative and coordination support). The panel typically reports to an oversight committee or board in the relevant government, national authority or body. While deciding how to involve stakeholders early for priority setting and topic selection, the guideline developer must also consider how developing formal relationships with stakeholders will enable effective dissemination and implementation to support uptake of the guideline. Table 1 shows an overview of the required human resources and the roles taken up for those involved (see also Fig. 2). The role of consumers and stakeholders is discussed subsequently.

Table 1. Human resources for guideline contextualization: guideline groups, their members and roles, qualifications and responsibilities

Participant role	Qualifications and specification	Responsibilities	Voting rights
Oversight committee	Individuals with training in guideline methodology and process evaluation; can be assembled by a ministry of health or a professional society	Oversees the process and ensures that established methods are followed according to set standards	No
Guideline panel and members			
Overview	Consists of experts (including people with the condition of interest) in the topic area and guideline methodology; composition should ensure broad multidisciplinary representation, including different levels of health care (primary, secondary level) and specialization (e.g. clinicians, nurses, laboratory specialists) as relevant for the topic Suggested size 10–15 depending on the topic (e.g. 6 health content experts, 2 guideline methods experts, 1 epidemiologist/public health/preventive medicine specialist with expertise in the topic area, 1 patient/public representative or other stakeholder programme manager, 1 health economist)	Ensures the quality of the guideline and quality assurance scheme; generates or agrees on the PICO questions; discusses the evidence; finalizes and agrees on guideline recommendations	All have voting rights unless there are direct COIs
Panel chairs	Co-chairs, one with methodological expertise and one with content expertise *Guideline methodologist co-chair* should have experience with chairing guideline panels as most of the process and group guidance will be through the methodology chair; have a good understanding of, and experience with, the guideline development and quality assurance process (e.g. INGUIDE certification level 3) and also, ideally, a background that allows understanding of the content area. *Content expertise co-chair* should be familiar with the content/subject matter of the guideline	Ensure the integrity of the process (methodologist co-chair) and the appropriateness of the content being discussed (content expert co-chair); in practice, responsible for meeting preparations and conduct, ensuring that there is full participation during meetings, that all relevant matters are discussed and that effective decisions are made and carried out	Chair(s) may choose only to cast votes when there is a tie among other panel members to stay as objective as possible and ensure the integrity of the process

Table 1. contd

Participant role	Qualifications and specification	Responsibilities	Voting rights
Guideline methodologists	Expertise in guideline development process, consensus-building approaches, health research methods (clinical) epidemiology, public health, health economics and/or qualitative methods	Contribute to the planning and conduct of the guideline development process	Yes, if no COI
Content experts	Expertise specific to the guideline content or relevant fields; recognized experts demonstrated by appropriate clinical (e.g. responsibility for care), public health (e.g. a prevention area), health policy (e.g. advancing a health systems intervention) or scientific (scientific contributions in the area of interest) expertise	Assist with ensuring relevance of the guideline recommendations, interpretation of research and other content the guideline group considers, in the context of their field of expertise	Yes, if no COI
Consumer or public representatives	May have a deeper understanding of people impacted by the guideline (for a specific condition of interest, which encompasses both patients with a specific condition and also healthy individuals, such as screening programmes)	Share perspectives and opinions based on their knowledge of consumer or personal experiences during the guideline discussions	Yes, if no COI
End-users	Health professionals or other consumers who will be expected to refer to or use the guideline; patients or public representatives (listed separately) are also a type of end-user	Provide input on priority questions, acceptability of interventions under consideration and implementation considerations through a formal stakeholder involvement process	Yes, if no COI
Working groups and their members			
Overview	Experts in specific areas, support and administration personnel, observers	Depending on the assigned tasks, these groups provide technical expertise and products, such as systematic review updates and/or complement with synthesis of locally relevant best available evidence for EtD tables, and logistic–administrative support	No
Scientific/technical support personnel	Scientific staff from the organization that produces the adoloped guideline (e.g. ministry of health) or technical support people to facilitate the process; individuals with relevant qualifications (e.g. scientific expertise in guidelines, project coordination, scientific writing)	Assist the guideline panel with research, methodological support and report/ recommendation writing as required	No

Table 1. contd

Participant role	Qualifications and specification	Responsibilities	Voting rights
Administrative–logistic personnel	Individuals with good organizational and administrative skills from the organization that produces the adoloped guideline	Assist the guideline panel with logistics and meeting arrangements	No
Technical experts	With varied qualifications as needed (either content or methodology related) depending on the guideline/ quality assurance process but not formal guideline panel members; brought into the guideline process as consultants on an ad-hoc basis for one or more PICO topics	Produce primary or secondary research or provide specific input for the guideline development group	No
Leads for evidence synthesis/ systematic review teams	Strong methodological expertise in evidence synthesis, coordination, writing and appropriate communication skills	Conduct of evidence synthesis/systematic reviews; deliver the draft GRADE evidence profiles and EtD frameworks in GRADEpro or similar; coordinate activities with guideline group and organizational staff; communicate with expert consultants as necessary	No
Members of an evidence synthesis/systematic review team	Methodological expertise, writing and appropriate communication skills; may be trainees in research methodology-related topics; skilled information specialist or librarian and biostatistician would be of added value to the team	Support evidence synthesis/ systematic review conduct	No
Content experts for evidence synthesis/systematic review team	Expertise specific to the content that the systematic review is addressing	Assist with ensuring relevance of the systematic review, the interpretation of research and other content the guideline group considers in the context of their field of expertise; may be recruited from the guideline group	No
Observers	Involved because of technical expertise or as representatives of stakeholder organizations	Have no formal role in the process but may provide specific input, when requested to do so by the chair(s)	No

Additional resource

Chapter 3.2 on the guideline development group in WHO Handbook for Guideline Development *(46)*

Public consultation and stakeholder engagement

Stakeholder engagement is a necessary component of guideline development and implementation and can help to ensure a guideline's feasibility and acceptability by the end-users. Engagement of appropriate stakeholders will also facilitate considerations about equity and human rights issues and will support the incorporation of guideline recommendations into broader policy and practice. However, while there are many stakeholder groups that can be affected by recommendations in guidelines (e.g. patients, consumers, providers, general public, researchers and policy-makers) there is as yet no global consensus on how best to involve all groups. An extension of the GIN-McMaster Guideline Development Checklist describing best practice and approaches to stakeholder involvement is being developed *(55)*. The broad principle is that there is little to be lost by including a wide range of stakeholders in the consultation process but a great deal to be lost by failing to consult an important stakeholder *(56)*.

Based on experience in national systems of guideline development, the following issues need to be considered and, ideally, documented in a handbook of methods so that they are available before a guideline effort starts *(34)*:

- how to select individual representatives of stakeholder groups
- what their input will be and how their COIs will be managed, and
- how the process will be transparently documented.

Another factor that needs to be considered is the availability and acceptability of different methods for stakeholder engagement, for example electronic or written input or face-to-face meetings, as well as the resources required and available to ensure meaningful input. It needs to be recognized that some stakeholders, such as patient groups, may not have the relevant resources or experience to provide input. Values about and preferences for available resources from patient groups from verbal, written and online or in-person input should be clarified, especially if a number of guidelines are being developed simultaneously in their area of interest *(56)*. Support may need to be provided by the government to allow poorly resourced stakeholders to have an effective voice while avoiding the risk of their resorting to funding from sources that raise issues of COI, such as the pharmaceutical or food industry.

Petkovic et al. described four levels of engagement *(55)*.

Level 1: communication. The stakeholders receive information; they may be present but have no role in contributing to the development of the guideline.

Level 2: consultation. Stakeholders provide their views, thoughts, feedback, opinions or experiences but without receiving any commitment that these will be acted upon.

Level 3: collaboration. Stakeholders are engaged to influence the production of guidelines (e.g. commenting, advising, ranking, voting, prioritizing, reaching consensus). Stakeholders provide information that directly influences the guideline process but without direct control over decisions.

Level 4: coproduction. Stakeholders are equal members of the guideline development team and participate in all steps of the guideline development process. Stakeholders work together in various roles throughout

the guideline development process and are involved in collaborative decisions to shape the guideline recommendations.

There are a number of different ways to define different relevant stakeholders (e.g. Petkovic et al. (55)); here they are considered as the 10Ps (Table 2).

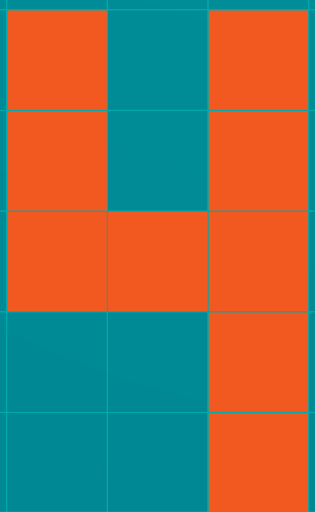
Table 2. Examples of potential stakeholders: the 10P groups

Stakeholder group	Possible non-state actor group	Description
Patients	–	Individuals and their family/carers who have experience with the condition/disease of interest
Payers of health research	Philanthropic foundations	Organizations or entities that fund research projects or programmes
Payers/purchasers of health services	Private sector entities	Private entities responsible for reimbursing the costs of health care
Peer-review editors	Academic institutions	Editors of peer-reviewed journals and those involved in peer review
Policy-makers	State actors	Individuals, organizations and entities that craft public or private policy (on health) at any level of government (national, provincial or state politicians, scientific advisers)
Product makers	Private sector entities	Entities that produce products such as pharmaceuticals, vaccines, diagnostic equipment, medical devices, assistive devices and medical procedures, and the international business associations that represent them
Programme managers	Nongovernmental organizations	Entities that deliver health-care programmes/interventions to patients or communities
Providers	Nongovernmental organizations	Professional medical staff (nurses, physicians, counsellors, pharmacists, midwives, community health workers); health-care organizations (hospitals, clinics, community health centres, community-based health organizations, pharmacies, emergency medical service agencies, nursing facilities, schools)
Principal investigators and researcher teams	Academic institutions	Researchers, research networks
Public	–	Members of the general population within a defined geographical area, excluding patients, caregivers and health professionals, living or working with the condition of interest

Additional resource

Factors to consider during identification and invitation of individuals in a multistakeholder research partnership *(57)*

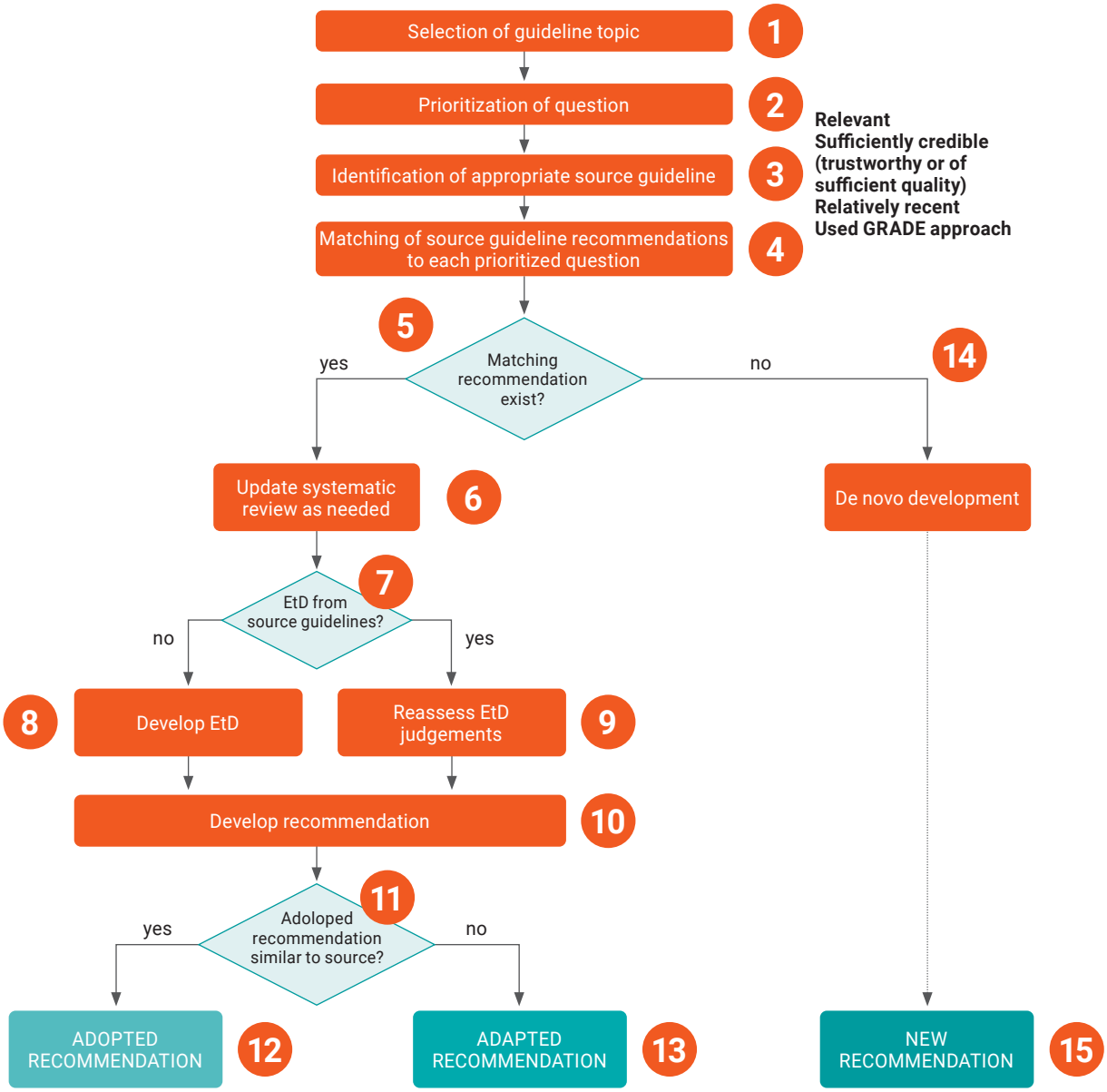
Detailed process and steps for contextualization



Introduction to the adolopment process

First, it is important to note that if at the end of the adolopment process a recommendation is adopted, adapted or de novo created this does not indicate a ranking of its importance or value. An adopted recommendation is not of less value than one that has undergone context-specific changes (adapted). This is because if a recommendation is relevant for the context without changes, it is as important as one that required extensive contextualization. Fig. 3 provides an overview of the general steps in the GRADE-ADOLOPMENT approach to contextualization of guidelines. These 15 steps are then outlined below.

Fig. 3. The GRADE-ADOLOPMENT approach



Generally, guideline developers should use the GIN-McMaster Guideline Development Checklist to plan and conduct the guideline effort (an extension specifically referring to adaptation is being developed *(55)*). The comprehensive checklist serves those creating guidelines to ensure that no steps are omitted.

Steps for the adolopment process

Step 1: selection of guideline topic

Step 1 can be considered in three stages.

Identify guideline topics. Several avenues exist to identify topics. Stakeholders can make requests for guidelines based on needs assessments or priority-setting exercises. Topics can also be identified by evaluating existing guidelines or evidence syntheses to understand the landscape of what is available before or after priorities are set by a guideline developer (e.g. a ministry of health), involving relevant stakeholders. This requires establishment of an oversight committee that can oversee the process (see Table 1).

Carry out scoping exercise. Such an exercise will identify what guidelines exist on the topic of interest and will involve conducting or contracting out the conduct of the exercise. It is helpful to keep in mind that a doable topic should be chosen that has a limited number of questions to ensure that those involved and asking for the guideline see products in a timely fashion. Therefore, in this step the topic can be narrowed down, for example from tuberculosis to screening for and diagnosis of tuberculosis but not treatment.

Create the organizational aspects required. This involves selecting a guideline group (see the previous section) that will be responsible for developing the recommendations (be they adopted, adapted or de novo). The selection of guideline group members follows established guideline processes (see above), such as identifying a multidisciplinary guideline panel with relevant representation.

Box 1 summarizes some useful sources and websites of specialist medical societies that are relevant to the choice of guideline topics (step 1). Databases such as PubMed can also be searched to identify existing information.

Step 2: prioritization of questions

Guideline questions should be identified and prioritized based on local needs and priorities. Generally, guideline questions should focus on areas of controversy that need to be answered by the guideline or on areas where changes in policy or practice are needed. For example, a formal process to prioritize key health questions can involve reviewing what questions are addressed in the preliminary search for guidelines, existing evidence syntheses, surveys of stakeholders or prospective guideline panel members.

In the original GRADE-ADOLOPMENT process, guideline panel members completed online surveys to rate the relative importance of health questions for a country health-care setting that were identified based on scoped guidelines (from step 1) using a 9-point Likert-type scale (1, least important; 9, most important), and through input of key health-care actors, such as the ministry of health *(24)*. Panellists were asked to consider the patient's perspective and the availability of the interventions but not to exclude questions for resource considerations (e.g. potential financial barriers for implementation of the proposed interventions). Mean and median importance ratings of questions across those who participated in the process decided inclusion in the guideline. To ensure that guidelines comprehensively addressed the topic with a complete set of recommendations, questions deemed complementary to those rated as important (e.g. questions that together addressed a complete diagnostic strategy; see Recommendations and small informative recommendation units in the Key definitions section) were also included. The selected questions were then sent to panellists for approval, with opportunity for further input before finalization. Similar approaches are used in other guideline adolopment processes *(20,58)*.

Box 1. Useful internet resources

The following selected sources and websites of specialist medical societies relevant to the topic, in addition to PubMed, can be searched to understand what information exists.

Sources of guidelines (databases)

- Database of WHO guidelines: WHO guidelines [website]. In: World Health Organization/Publications. Geneva: World Health Organization; 2023 (http://www.who.int/publications/guidelines/en/).
- International database of GRADE guidelines (BIGG): BIGG [website]. Washington: Pan American Health Organization; 2023 (http://sites.bvsalud.org/bigg/en/biblio/).
- National Guideline Clearinghouse: Guidelines and Measure [website]. In: Agency of Healthcare Research and Quality (AHRQ)/Programs. Rockville: Agency for Healthcare Research and Quality; 2023 (http://www.guideline.gov/).
- The GIN database: Resource [website]. In: Guidelines International Network (GIN). Pitlochry: Guidelines International Network; 2023 (http://www.g-i-n.net/get-involved/resources).
- ECRI Guideline Development Support: Guideline Development Support [website]. In: Emergency Care Research Institute/Solutions. Plymouth Meeting: ECRI; 2023 (https://www.ecri.org/solutions/guideline-development-support/).

Sources of general recommendations and EtD frameworks

- Database of GRADE EtDs and guidelines: Database of GRADE EtD's and Guidelines [website]. In: GRADEproGTD; Hamilton: McMaster University; 2023 (http://dbep.gradepro.org/).

Organizations producing guidelines and health technology assessments

- United Kingdom National Institute for Health and Care Excellence: NICE: National Institute for Health and Care Excellence [website]; 2023 (http://www.nice.org.uk).
- Canadian Medical Association: CPG Infobase: Clinical Practice Guidelines [website]. In: CMAjoule/Clinical tools; 2023 (https://joulecma.ca/cpg/homepage).
- United States Agency for Healthcare Research and Quality: Agency of Healthcare Research and Quality (AHRQ) [website]. Rockville: Agency for Healthcare Research and Quality; 2023 (http://www.ahrq.gov).
- Scottish Intercollegiate Guidelines Network: SIGN – Healthcare Improvement Scotland [website]; 2023 (http://www.sign.ac.uk/).
- GuíaSalud Spain http://www.guiasalud.es
- Canadian Agency for Drugs and Technologies in Health (CADTH): Canada's Drug and Health Technology Agency [website]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2023 (http://www.cadth.ca).
- EUnetHTA (restricted to members): Advancing cooperation on health technology assessment (HTA) and supporting the implementation of the new EU legal framework on HTA [website]. EUnetHTA; 2021 (https://www.eunethta.eu/). International Network of Agencies for Health Technology Assessment: International HTA database [website]. INHATA; 2023 (https://www.inahta.org/hta-database/).
- Regional Base of Health Technology Assessment Reports of the Americas: COVID-19 [website]. In: RedETSA/ BRISA; 2023 (https://sites.bvsalud.org/redetsa/en/brisa/).

The prioritization process for questions does not differ significantly between original guideline development and guideline adaptation projects *(24,59,60)*. However, what distinguishes GRADE-ADOLOPMENT from simple guideline adaptation is the fact that the former focuses on priorities for the context as opposed to being constrained by what is in one source guideline. In other words, in GRADE-ADOLOPMENT the selection of questions is driven by priorities of the local stakeholders (i.e. here are our questions, let us answer them through existing guidelines or evidence syntheses).

Alternatively, to adapt a single guideline into a country context the starting point should be the questions in the source guideline, and priority setting then takes place within those questions *(59)*. However, guideline panels can decide on whether there are other priority questions that need answering (from the PICO domains) and, therefore, require the scope to be broadened from the source guideline by adding additional questions,

which will be followed through the next steps *(59,60)*. On occasions, guideline panels may identify priorities not covered by the original guideline and, therefore, not available for adoption or adaptation. It is important for teams conducting GRADE-ADOLOPMENT to avoid dismissing such questions, not only to foster the local ownership in the guidelines but also to make them relevant. Rather, such questions can follow a traditional de novo development process (see step 15), within the same guideline development or as a follow-up update of the guideline.

Additional resources

Section 2.3 in Strengthening National Evidence-informed Guideline Programs *(26)*
Prioritization approaches in the development of health practice guidelines: a systematic review *(59)*
Methodology for the American Society of Hematology VTE guidelines: current best practice, innovations, and experience *(61)*
The implementation of prioritization exercises in the development and update of health practice guidelines: a scoping review *(62)*

Step 3: identification of appropriate source guidelines or systematic reviews

To ensure that all potential source guidelines are identified, a systematic search for existing guidelines needs to be conducted. This search should be carried out in consultation with an expert in information retrieval (e.g. a librarian, or information scientist) to ensure the use of a sound search strategy. The initial search should be broad and without limitation, as guidelines can be difficult to find through electronic databases. Guidelines, as identified in step 1 in the scoping exercise and through additional systematic searches, are evaluated with the AGREE tool to identify if they address the priority questions, defined in step 2 *(63)*.

Before a guideline can be used, it should be assessed to understand if it is relevant (i.e. addresses the topic of interest), credible (i.e. achieves high enough (>60%) AGREE II instrument scores on the key domains of editorial independence and rigour of development), recent (i.e. an update would be unreasonable or the guideline is up to date) and whether it is, ideally, based on GRADE. When relevant recommendations were developed using GRADE with freely accessible SoFs and EtDs, ideally in compatible electronic format, then it greatly reduces the effort and time required. All WHO guidelines are developed using GRADE and are publicly available.

In the assessment of credibility, for example, a source guideline should specify the methods used to conduct the systematic reviews supporting the recommendations. Research evidence to support the relative effects (as opposed to absolute effects) of interventions related to a particular recommendation is often globally applicable, whereas costs, values and preferences, and the equity, acceptability and feasibility aspects of recommendations are local considerations. Consequently, reviewing how these factors were considered in the source guideline should be the basis of adopting or adapting recommendations developed by others. Systematic reviews that have been carried out to support a recommendation in a source guideline can be assessed for risk of bias using the ROBIS (risk of bias in systematic reviews) checklist or AMSTAR 2 tool for methodological quality, which is sometimes required to complete the AGREE scoring of a source guideline *(64,65)*.

If no guideline is identified, groups conducting GRADE-ADOLOPMENT may decide to search for systematic reviews about the health effects of the interventions of interest. From the systematic reviews, teams can build the EtD framework by adding local evidence about costs, values and preferences, and the equity, acceptability and feasibility considerations.

If more than one systematic review is identified for a particular question, teams may decide to combine the data from the reviews by conducting their own meta-analysis. If there is limited time or expertise for conducting a new meta-analysis, teams may decide to use the results from the more comprehensive systematic review (i.e. the most current or the one which includes the greatest body of evidence).

It is important to emphasize that no trustworthy formal recommendation can be produced if the original guideline is not based on a systematic review or there is no independent systematic review available; if that is the case teams may be better off starting their own development process (step 15).

Additional resources

AGREE II: advancing guideline development, reporting and evaluation in health care *(63)*
AMSTAR 2: a critical appraisal tool for systematic reviews that include randomized or non-randomized studies of health care interventions, or both *(64)*
ROBIS checklist *(65)*

Step 4: matching source guideline recommendations to each prioritized question

Recommendations matching the prioritized questions are searched for within one or more guidelines; that is, the process follows a single recommendation as the unit of work.

To accomplish optimal adaptation, the PICO domains in the source guideline should be matched with the prioritized question. It is possible that more than one guideline will need to be used to match the prioritized questions or that a new recommendation is required because none of the identified source guidelines includes a matching recommendation; for example, two recommendations are from a guideline by WHO, two from a guideline by the United Kingdom's National Institute for Health and Care Excellence and one is created de novo. This approach maximizes usefulness for the context and distinguishes GRADE-ADOLOPMENT from other adaptation approaches that suggest using existing recommendations in a guideline and their adaption, as opposed to focusing on the priorities of the new recommendation, which may be contained in several guidelines or not be covered at all. However, it is possible that a guideline developer will choose one guideline to be adoloped based on an identified need (e.g. a WHO HIV guideline may be contextualized to maximize the uptake of a guideline developed at WHO headquarters). It is also possible that some published guidelines do not report on the prioritization or decision process for their questions. It is then advisable to contact the source guideline developer to see if source material (such as evidence profiles and EtDs) can be shared or if there are relevant proprietary issues that should be observed, such as a WHO technical unit. For some organizations, asking for permission to use material (including paying fees) may be required to use copyrighted material. Ideally, one or more informed individual(s) involved in developing the source guideline should be also involved in the adolopment process, even if just for checking information *(66)*.

Therefore, the main difference between typical guideline adaptation and guideline adolopment is that adolopment focuses on the questions that are relevant or important for a stakeholder, who is wanting to adapt and implement a guideline, whereas classic guideline adaptation focuses on a source guideline and how it can be applied in a particular new setting. Consequently, adolopment starts with identifying individual questions for which a recommendation is necessary and then moves on to look for source guidelines and evidence synthesis. Classic guideline adaptation looks for a source guideline for a topic and uses the recommendations therein without any prioritization of questions that are relevant for the implementer or the opportunity to search across guidelines and evidence syntheses.

Step 5: does a matching recommendation exist?

In this step, the question "is there a recommendation in the source guideline(s) that matches the prioritized question?" is asked. If a matching recommendation exists, it needs to be decided whether new or updated systematic reviews are required (see step 6). If a matching recommendation exists, the creators of the original guideline should be contacted with a request for adolopment of the source guideline, assuming that the AGREE scores and evaluation of the systematic reviews in the source guidelines are appropriate (see step 3). If no matching recommendation exists and this is still the case after checking or considering whether the prioritized recommendation could be slightly modified, the new recommendation will require a de novo development, which can, however, be based on existing evidence syntheses, such as a Cochrane review, if available (see steps 3 and 15).

Step 6: update systematic review(s) (as needed)

An existing systematic review may require updating or a new systematic review or other evidence synthesis may be required, particularly considering local contextual evidence.

Criteria for updating, expanding or conducting an evidence synthesis include:

- the reviews available are outdated (e.g. it is evident that research evidence exists that informs a criterion on the EtD but has not been included in the source guideline);
- the existing recommendation does not include all outcomes of interest for a prioritized question (e.g. the local guideline panel determines that quality of life is a critical outcome but the source guideline does not consider this outcome in its recommendation); or
- there is no evidence synthesis that includes evidence about the context of interest for important EtD criteria such as values, benefits and harms, feasibility, acceptability, equity and resource use.

Updated systematic reviews will require that SoFs and EtDs be updated. If SoFs or EtDs were not developed in the source guideline they should be developed with the systematic review update.

Contextualization requires focusing on relevant contextual evidence, including context-specific baseline risks, feasibility, acceptability, resource use and equity. This information may or may not have been included in the source guideline, but even if included will also be local in nature. For example, a search for evidence about how people with the condition of interest value the outcomes in the target setting may be needed, or a search for local cost information may be required. This can also include eliciting expert evidence to inform the context *(28)*. This step is usually the responsibility of the working group.

Additional resources

Section 2.14 in Strengthening National Evidence-informed Guideline Programs *(26)*

Step 7: EtD from source guideline

In this step, the question is asked, "Does the source guideline include a complete EtD framework?". If not, then an EtD should be developed (step 8). If there is one then the EtD will require a review of the judgements made in the source guideline (outlined in step 9) and integration of the contextual evidence. This step also includes

checking what EtD criteria are more important for the new setting (e.g. it may not be necessary to obtain information about cost–effectiveness if this criterion is not relevant for the destination setting).

Step 8: develop an EtD

If no EtD exists, one needs to be developed based on extracting information that explains the rationale for the recommendation in the source guideline (if a guideline is judged credible, this information should be available in the source guideline). For example, sections referring to equity or acceptability of an intervention may be included in the source guideline as narrative but not formally structured in an EtD. However, if not all information that is required for an EtD is available in the source guideline, it will lead to an incomplete EtD. In that case, a search for evidence supporting judgements of the guideline group on the missing EtD criteria is required (as opposed to using the contextual evidence if it was included in an evidence review informing the source guideline) *(67)*. It may also be necessary to use expert evidence to complete an EtD. See also step 6.

It should be recognized that local evidence must often be identified (possibly for updates) in order to contextualize and inform the recommendation best. Here, it must also be recognized that contextualization should be based on (local, regional, etc.) evidence and not on how things currently are being done; the latter is not contextualization and it would not allow for accepting new practice or policy (i.e. the direction and strength of a recommendation should be based on evidence from existing circumstances that may modify an existing recommendation).

Step 9: reassess EtD judgements

Steps 9 and 10 usually take place through a guideline panel meeting (in person but online is also possible) convened by the guideline panel chair. The chairs may use the Checklist for Guideline Panel Chairs as a guide for preparing, conducting and following up on the meeting *(68)*. The conduct of the meeting, such as COI management, documenting plans, necessary quorum, management of disagreements and voting, should be developed and agreed before the meeting.

If EtDs exist for the prioritized recommendations, then they need to be checked for completeness on all relevant EtD criteria. If EtDs are available, the judgements in the source recommendation should be reviewed and either agreed with or not. Reasons for disagreement should be indicated and documented (e.g. if there is new evidence). This process can be carried out in one of three ways.

1. The original guideline panel judgements are left in place, and the local panel decides whether they agree or not. This approach has the advantage of saving time. However, it may limit the discussion, especially if panellists are new to the process. Also, it may reduce the ownership of the final recommendation. This option may be the most efficient option if the changes to the EtD framework are minimal.
2. The original guideline panel judgements are hidden, and the local panel makes the judgements again. This approach usually takes more time since panellists are required to discuss and reach agreement. This is probably the best option if significant changes are made to the EtD framework.
3. A mixed approach combines options 1 and 2. For example, some judgements may be left in place while others may be open for discussion. The latter can be done for domains where significant changes were introduced to the EtD framework or for domains that are judged a priori very content dependent.

Whatever the approach used for one or for all the recommendations, the selection has to be reported explicitly on the adapted guideline.

Step 10: develop recommendations

Step 10, like step 9, usually takes place through a guideline panel meeting.

Steps 8 and 9 will lead to completed and contextualized EtDs that allow formulating a recommendation for the destination setting. During the panel meeting, the evidence presented in the EtDs will be discussed, judged and recommendations agreed on by the panel. During the deliberations, the research gaps and implementation considerations as well as the considerations for monitoring and evaluation may be documented. Monitoring and evaluation aspects will inform the drafting of the implementation plan. A search for evidence about existing decision thresholds that help to balance health benefits and harms may be helpful *(69)*.

Step 11: adoloped recommendation similar to source

If the recommendation is the same as the source recommendation *and* there are no changes to the judgements on the EtD, then the recommendation is an adopted recommendation (step 12). The recommendation is adapted (step 13) if the evidence differs because of an update, the recommendation is altered (a judgement is changed) or the recommendation is different (e.g. the population is narrower or broader).

Step 12: adopted recommendation

The recommendation is labelled as adopted from the source guideline (with reference) and left as is (of course it may be translated or may include the name of the organization developing it rather than the name of the original organization).

Step 13: adapted recommendation

The recommendation is labelled as adapted from the source guideline (with reference) and formulated to express the changes.

Step 14: de novo development

If step 5 determined that there is no source recommendation, a new recommendation is required (step 15) with a full recommendation development process to ensure the quality of the destination guideline. This can be based on an existing evidence synthesis from systematic reviews or guidelines. This includes developing an EtD for that recommendation if possible.

Step 15: new recommendation

By applying trustworthy recommendation development processes, a new recommendation can be developed. The process should be documented and reported appropriately, for example by using the RIGHT-AD@PT reporting tool *(54)*.

Feasibility of the 15-step approach

Following all steps explicitly will likely increase the credibility of the adoloped guideline. The approach has been used successfully in many cases and, therefore, can be followed *(35,37,70–73)*. However, it may not always be feasible to follow all the steps as described above. The key issue is to transparently describe what was done and what not.

Dissemination and implementation

To successfully implement guidelines, a systematic approach to dissemination and implementation is required with responsibilities assigned to stakeholders. Moreover, awareness and approval of the guidelines by relevant health professionals, people affected by the recommendations and other relevant stakeholders must be achieved, and the activities in this regard must be thoroughly considered and detailed in an implementation plan *(51)*. The panel should consider certain actions for implementation simultaneously with the development of the guideline.

An implementation plan should be prepared by the guideline developer and those with skills in implementation and approved by the relevant stakeholders. It should be added to the guideline after ensuring that responsible parties agree with the plan and the tasks assigned.

When developing an implementation plan, activities must be planned that take into consideration time constraints and requirements, along with the availability of the measurement, an evaluation system and the resources required for implementation. If necessary, the implementation process may be divided into several stages to accommodate local circumstances or for other reasons. A specific checklist can be developed for guideline implementation planning, and supporting literature exists to assist with the process *(74)*.

To prepare the implementation plan, the following steps will be helpful.

- Aims and target groups of the implementation activities should be determined with consideration for the challenges of current practice, new recommendations for the target setting and target groups with their characteristics/specifications, thus ensuring that the guideline is designed and disseminated in a way that is appropriate for the end-user.
- A dissemination strategy should be developed and followed to ensure the guidelines reach the target audience.
- Possible barriers for implementation should be identified and a plan prepared with strategies to overcome them. Criteria for adherence and success should be defined, along with the indicators that describe them.
- Linkages with other levers in the health-care system that support behaviour change should be identified and explored, including the benefits package (where such a system exists), the “positive list” of essential medicines and health products, the procurement system and a monitoring/quality improvement system aligned with the clinical guideline recommendations.
- The need for resources should be assessed. The resources required for implementation should be clearly indicated in the operational plan, including funding, staffing and time requirements.

- Milestones and a schedule should be set out for each implementation activity.
- Training should be provided to support implementation so that end-users know what the guidelines recommend. An education plan could be drafted.

Existing structures and networks should be used for implementation. Recommendations can be used to measure performance, which should be planned in advance *(75,76)*. The implementation process should be monitored by setting up a system for regular evaluation (including the above-mentioned criteria) and feedback.

A forward-looking plan should also ensure that the guidelines are reviewed and updated in a timely manner.

Quality assurance of adolopment

Five approaches to quality assurance of the adoloped recommendations are suggested:

- check the 15 steps of GRADE adolopment for completion
- report the guidelines using the RIGHT-AD@PT reporting checklist *(54)*
- check the group process and use of evidence in the adolopment using the PANELVIEW instrument *(17)*
- evaluate if it is possible to have an independent assessment of the credibility of the guidelines, and
- utilize external peer review.

Conclusion

Contextualization of guidelines is resource saving across settings if existing evidence synthesis and guidelines are credible. It avoids duplication but must be done rigorously. This handbook outlines the process for achieving optimized contextualization of guidelines. This process starts by identifying recommendations from source guidelines, using that information and complementing it with new or contextual evidence. It is followed by the description of a process of making a recommendation, following EtD frameworks. It will require training and capacity-building, some of which can take place during actual guideline development projects where guideline development group members can be trained. Capacity for guideline development projects may depend on how much capacity already exists in a country and on the extent of human and financial resources available for further capacity-building.

References

1. Guidelines for WHO guidelines. Geneva: World Health Organization; 2003 (EIP/GPE/EQC/2003.1; https://apps.who.int/iris/handle/10665/68925, accessed 11 January 2023).

2. Schünemann HJ, Reinap M, Piggott T, Laidmae E, Kohler K, Pold M et al. The ecosystem of health decision making: from fragmentation to synergy. Lancet Public Health. 2022;7(4):e378–e90. doi: 10.1016/S2468-2667(22)00057-3.

3. Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P, Board of Trustees of the Guidelines International Network. Guidelines International Network: toward international standards for clinical practice guidelines. Ann Intern Med. 2012;156(7):525–31. doi: 10.7326/0003-4819-156-7-201204030-00009.

4. Eccles MP, Grimshaw JM, Shekelle P, Schünemann HJ, Woolf S. Developing clinical practice guidelines: target audiences, identifying topics for guidelines, guideline group composition and functioning and conflicts of interest. Implement Sci. 2012;7:60. doi: 10.1186/1748-5908-7-60.

5. Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines. Clinical practice guidelines we can trust. Washington (DC): National Academies Press; 2011.

6. Schünemann HJ, Wiercioch W, Etxeandia I, Falavigna M, Santesso N, Mustafa R et al. Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise. CMAJ. 2014;186(3):E123–42. doi: 10.1503/cmaj.131237.

7. Woolf S, Schünemann HJ, Eccles MP, Grimshaw JM, Shekelle P. Developing clinical practice guidelines: types of evidence and outcomes; values and economics, synthesis, grading, and presentation and deriving recommendations. Implement Sci. 2012;7:61. doi: 10.1186/1748-5908-7-61.

8. Schünemann HJ, Best D, Vist G, Oxman AD, Group GW. Letters, numbers, symbols and words: how to communicate grades of evidence and recommendations. CMAJ. 2003;169(7):677–80. PMID: 14517128.

9. Oxman AD, Fretheim A, Schünemann HJ. Improving the use of research evidence in guideline development: introduction. Health Res Policy Syst. 2006;4:12. doi: 10.1186/1478-4505-4-12.

10. Schünemann HJ, Al-Ansary LA, Forland F, Kersten S, Komulainen J, Kopp IB et al. Guidelines International Network: principles for disclosure of interests and management of conflicts in guidelines. Ann Intern Med. 2015;163(7):548–53. doi: 10.7326/M14-1885.

11. Jaeschke R, O'Byrne PM, Mejza F, Nair P, Lesniak W, Brozek J et al. The safety of long-acting beta-agonists among patients with asthma using inhaled corticosteroids: systematic review and metaanalysis. Am J Respir Crit Care Med. 2008;178(10):1009–16. doi: 10.1164/rccm.200804-494OC.

12. Guyatt G, Oxman AD, Akl EA, Kunz R, Vist G, Brozek J et al. GRADE guidelines: 1. Introduction: GRADE evidence profiles and summary of findings tables. J Clin Epidemiol. 2011;64(4):383–94. doi: 10.1016/j.jclinepi.2010.04.026.

13. Brozek JL, Akl EA, Alonso-Coello P, Lang D, Jaeschke R, Williams JW et al. Grading quality of evidence and strength of recommendations in clinical practice guidelines. Part 1 of 3. An overview of the GRADE approach and grading quality of evidence about interventions. Allergy. 2009;64(5):669–77. doi: 10.1111/j.1398-9995.2010.02530.x.

14. Atkins D, Best D, Briss PA, Eccles M, Falck-Ytter Y, Flottorp S et al. Grading quality of evidence and strength of recommendations. BMJ. 2004;328(7454):1490. doi: 10.1136/bmj.328.7454.1490.

15. GIN-McMaster guideline development checklist [website]. Hamilton: Guidelines International Network, McMaster University; 2023 (https://heigrade.mcmaster.ca/guideline-development/using-checklist, accessed 11 January 2023).

16. Chen Y, Yang K, Marusic A, Qaseem A, Meerpohl JJ, Flottorp S et al. A reporting tool for practice guidelines in health care: the RIGHT statement. Ann Intern Med. 2017;166(2):128–32. doi: 10.7326/M16-1565.

17. Brouwers MC, Spithoff K, Lavis J, Kho ME, Makarski J, Florez ID. What to do with all the AGREEs? The AGREE portfolio of tools to support the guideline enterprise. J Clin Epidemiol. 2020;125:191–7. doi: 10.1016/j.jclinepi.2020.05.025.

18. Jue JJ, Cunningham S, Lohr K, Shekelle P, Shiffman R, Robbins C et al. Developing and testing the Agency for Healthcare Research and Quality's National Guideline Clearinghouse Extent of Adherence to Trustworthy Standards (NEATS) instrument. Ann Intern Med. 2019;170(7):480–7. doi: 10.7326/M18-2950.

19. Wiercioch W, Akl EA, Santesso N, Zhang Y, Morgan RL, Yepes-Nunez JJ et al. Assessing the process and outcome of the development of practice guidelines and recommendations: PANELVIEW instrument development. CMAJ. 2020;192(40):E1138–45. doi: 10.1503/cmaj.200193.

20. Neumann I, Izcovich A, Alexander KE, Castano J, Plovnick R, Kunkle R et al. Methodology for adaptation of the ASH guidelines for management of venous thromboembolism for the Latin American context. Blood Adv. 2021;5(15):3047–52. doi: 10.1182/bloodadvances.2021004268.

21. Meneses-Echavez JF, Bidonde J, Yepes-Nunez JJ, Poklepovic Pericic T, Puljak L, Bala MM et al. Evidence to decision frameworks enabled structured and explicit development of healthcare recommendations. J Clin Epidemiol. 2022;150:51–62. doi: 10.1016/j.jclinepi.2022.06.004.

22. Alonso-Coello P, Oxman AD, Moberg J, Brignardello-Petersen R, Akl EA, Davoli M et al. GRADE evidence to decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 2: Clinical practice guidelines. BMJ. 2016;353:i2089. doi: 10.1136/bmj.i2089.

23. Alonso-Coello P, Schünemann HJ, Moberg J, Brignardello-Petersen R, Akl EA, Davoli M et al. GRADE evidence to decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction. BMJ. 2016;353:i2016. doi: 10.1136/bmj.i2016.

24. Schünemann HJ, Wiercioch W, Brozek J, Etxeandia-Ikobaltzeta I, Mustafa RA, Manja V et al. GRADE evidence to decision (EtD) frameworks for adoption, adaptation, and de novo development of trustworthy recommendations: GRADE-ADOLOPMENT. J Clin Epidemiol. 2017;81:101–10. doi: 10.1016/j.jclinepi.2016.09.009.

25. McGowan J, Akl EA, Coello PA, Brennan S, Dahm P, Davoli M et al. Update on the JCE GRADE series and other GRADE article types. J Clin Epidemiol. 2021;140:163–4. doi: 10.1016/j.jclinepi.2021.05.023.

26. Strengthening national evidence-informed guideline programs: a tool for adapting and implementing guidelines in the Americas. Washington (DC): Pan American Health Organization; 2018 (https://iris.paho.org/bitstream/handle/10665.2/49145/9789275120163_eng.pdf?sequence=9&isAllowed=y, accessed 11 January 2023).

27. Understanding and using WHO guidelines on tuberculosis [website]. Geneva: World Health Organization; 2023 (https://openwho.org/courses/who-gtb-guidelines, accessed 11 January 2023).

28. Schünemann HJ, Zhang Y, Oxman AD for the Expert Evidence in Guidelines Group. Distinguishing opinion from evidence in guidelines. BMJ. 2019;366:l4606. doi: 10.1136/bmj.l4606.

29. INGUIDE. International guideline development credentialing & certification program [website]. Hamilton: Guidelines International Network, McMaster University; 2023 (inguide.org, accessed 11 January 2023).

30. GRADE Working Group [website]. Hamilton: McMaster University; 2023 (www.gradeworkinggroup.org, accessed 11 January 2023).

31. GRADEpro [website]. Hamilton: McMaster University; 2023 (https://www.gradepro.org/, accessed 11 January 2023).

32. GRADE approach [website]. London: Cochrane; 2023 (https://training.cochrane.org/grade-approach, accessed 11 January 2023).

33. McMaster GRADE Center. Hamilton: McMaster University; 2023 (https://heigrade.mcmaster.ca/, accessed 11 January 2023).

34. Garner P, Hill S, Schünemann H. Developing and implementing guidelines for health policy and clinical practice in Estonia: interim appraisal of progress. Copenhagen: WHO Regional Office for Europe; 2015 (https://apps.who.int/iris/handle/10665/350299, accessed 11 January 2023).

35. Darzi A, Harfouche M, Arayssi T, Alemadi S, Alnaqbi KA, Badsha H et al. Adaptation of the 2015 American College of Rheumatology treatment guideline for rheumatoid arthritis for the Eastern Mediterranean Region: an exemplar of the GRADE Adolopment. Health Qual Life Outcomes. 2017;15(1):183. doi: 10.1186/s12955-017-0791-9 [correction 15(1):214].

36. Kallenbach M, Conrad S, Hoffmann F, Matthias K, Gartlehner G, Langer G et al. GRADE Evidence-to-Decision-Tabellen für die Übernahme, Anpassung und De-novo-Entwicklung von vertrauenswürdigen [GRADE: Using evidence to decision frameworks for adoption, adaptation and de novo generation of trustworthy guideline recommendations – GRADE-ADOLOPMENT]. Z Evid Fortbild Qual Gesundhwes. 2019;144–145:90–9. doi: 10.1016/j.zefq.2019.06.001.

37. Reilly JJ, Hughes AR, Janssen X, Hesketh KR, Livingstone S, Hill C et al. GRADE-ADOLOPMENT process to develop 24-hour movement behavior recommendations and physical activity guidelines for the under 5s in the United Kingdom, 2019. J Phys Act Health. 2020;17(1):101–8. doi: 10.1123/jpah.2019-0139.

38. Tugwell P, Knottnerus JA. Adolopment: a new term added to the clinical epidemiology lexicon. J Clin Epidemiol. 2017;81:1–2. doi: 10.1016/j.jclinepi.2017.01.002.

39. Darzi A, Abou-Jaoude EA, Agarwal A, Lakis C, Wiercioch W, Santesso N et al. Frameworks for adaptation of health guidelines: a methodological survey. J Clin Epidemiol. 2017;86:3–10. doi: 10.1016/j.jclinepi.2017.01.016.

40. Lotfi T, Hajizadeh A, Moja L, Akl EA, Piggott T, Kredo T et al. A taxonomy and framework for identifying and developing actionable statements in guidelines suggests avoiding informal recommendations. J Clin Epidemiol. 2022;141:161–71. doi: 10.1016/j.jclinepi.2021.09.028.

41. Piggott T, Baldeh T, Dietl B, Wiercoch W, Nieuwlaat R, Santesso N et al. Standardized wording to improve efficiency and clarity of GRADE EtD frameworks in health guidelines. J Clin Epidemiol. 2022;146:106–22. doi: 10.1016/j.jclinepi.2022.01.004.

42. Schünemann HJ. Getting trustworthy guideline recommendations into practice. BMJ Opinion. 31 December 2018 (https://blogs.bmj.com/bmj/2018/12/31/holger-j-schunemann-getting-trustworthy-guideline-recommendations-into-practice/, accessed 11 January 2023).

43. Dewidar O, Lotfi T, Langendam MW, Parmelli E, Saz Parkinson Z, Solo K et al. Good or best practice statements: proposal for the operationalisation and implementation of GRADE guidance. BMJ Evid Based Med. 2022; bmjebm-2022-111962, online ahead of print. doi: 10.1136/bmjebm-2022-111962.

44. Dewidar O, Lotfi T, Langendam M, Parmelli E, Saz Parkinson Z, Solo K et al. Which actionable statements qualify as good practice statements In Covid-19 guidelines? A systematic appraisal. BMJ Evid Based Med. 2022;27(6):361–9. doi: 10.1136/bmjebm-2021-111866.

45. Schünemann HJ, Tunis S, Nieuwlaat R, Wiercioch W, Baldeh T. The SOLAR (Standardized Outcomes Linking Across StakeholdeRs) system and hub and spokes model for direct core outcome measures in health care and its relation to GRADE. J Clin Epidemiol. 2020;125:216–21. doi: 10.1016/j.jclinepi.2020.05.007.

46. WHO handbook for guideline development, 2nd edition. Geneva: World Health Organization; 2014 (https://apps.who.int/iris/handle/10665/145714, accessed 11 January 2023).

47. Introduction to WHO guidelines and GRADE. Hamilton: McMaster University; 2020 (https://heigrade.mcmaster.ca/learning/guideline-development-learning-modules, accessed 11 January 2023).

48. Schünemann HJ, Osborne M, Moss J, Manthous C, Wagner G, Sicilian L et al. An official American Thoracic Society policy statement: managing conflict of interest in professional societies. Am J Respir Crit Care Med. 2009;180(6):564–80. doi: 10.1164/rccm.200901-0126ST.

49. Traversy G, Barnieh L, Akl EA, Allan GM, Brouwers M, Ganache I et al. Managing conflicts of interest in the development of health guidelines. CMAJ. 2021;193(2):E49–54. doi: 10.1503/cmaj.200651.

50. Declaration of interests for WHO experts. Geneva: World Health Organization; 2023 (https://www.who.int/publications/m/item/declaration-of-interests-for-who-experts, accessed 11 January 2023).

51. Estonian handbook for guidelines development 2020. Tallinn: Estonian Health Insurance Fund; 2021 (https://tervis.ut.ee/sites/default/files/inline-files/estonian_handbook_for_guidelines_development_2020.pdf, accessed 10 January 2023).

52. World Bank, Organisation for Economic Co-operation and Development, United Nations Office on Drugs and Crime. Preventing and managing conflicts of interest in the public sector: good practices guide. Washington (DC): World Bank; 2020 (https://www.unodc.org/documents/corruption/Publications/2020/Preventing-and-Managing-Conflicts-of-Interest-in-the-Public-Sector-Good-Practices-Guide.pdf, accessed 11 January 2023).

53. Enhancing the quality and transparency of health research [website]. Oxford: UK EQUATOR Centre; 2023 (https://www.equator-network.org/, accessed 11 January 2023).

54. Song Y, Alonso-Coello P, Ballesteros M, Cluzeau F, Vernooij RWM, Arayssi T et al. A reporting tool for adapted guidelines in health care: the RIGHT-Ad@pt checklist. Ann Intern Med. 2022;175(5):710–19. doi: 10.7326/M21-4352.

55. Petkovic J, Riddle A, Akl EA, Khabsa J, Lytvyn L, Atwere P et al. Protocol for the development of guidance for stakeholder engagement in health and healthcare guideline development and implementation. Syst Rev. 2020;9(1):21. doi: 10.1186/s13643-020-1272-5.

56. Options for best practice clinical guideline development in Ukraine: policy brief. Geneva: WHO Regional Office for Europe; 2021 (https://apps.who.int/iris/handle/10665/341549, accessed 11 January 2023).

57. Parker R, Tomlinson E, Concannon TW, Akl E, Petkovic J, Welch VA et al. Factors to consider during identification and invitation of individuals in a multi-stakeholder research partnership. J Gen Intern Med. 2022;37(16):4047–53. doi: 10.1007/s11606-022-07411-w.

58. Neumann I, Izcovich A, Aguilar R, Basantes GL, Casais P, Colorio CC et al. ASH, ABHH, ACHO, Grupo CAHT, Grupo CLAHT, SAH, SBHH, SHU, SOCHIHEM, SOMETH, Sociedad Panameña de Hematología, SPH, and SVH 2021 guidelines for management of venous thromboembolism in Latin America. Blood Adv. 2021;5(15):3032–46. doi: 10.1182/bloodadvances.2021004267.

59. El-Harakeh A, Morsi RZ, Fadlallah R, Bou-Karroum L, Lotfi T, Akl EA. Prioritization approaches in the development of health practice guidelines: a systematic review. BMC Health Services Res. 2019;19(1):692. doi: 10.1186/s12913-019-4567-2.

60. Wiercioch W, Nieuwlaat R, Zhang Y, Alonso-Coello P, Dahm P, Iorio A et al. New methods facilitated the process of prioritizing questions and health outcomes in guideline development. J Clin Epidemiol. 2022;143:91–104. doi: 10.1016/j.jclinepi.2021.11.031.

61. Wiercioch W, Nieuwlaat R, Akl EA, Kunkle R, Alexander KE, Cuker A et al. Methodology for the American Society of Hematology VTE guidelines: current best practice, innovations, and experiences. Blood Adv. 2020;4(10):2351–65. doi: 10.1182/bloodadvances.2020001768.

62. El-Harakeh A, Lotfi T, Ahmad A, Morsi RZ, Fadlallah R, Bou-Karroum L et al. The implementation of prioritization exercises in the development and update of health practice guidelines: a scoping review. PLOS One. 2020;15(3):e0229249. doi: 10.1371/journal.pone.0229249.

63. Brouwers M, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G for the AGREE Next Steps Consortium. AGREE II: advancing guideline development, reporting and evaluation in healthcare. CMAJ. 2010;182(18):E839–42. doi: 10.1503/cmaj.090449.

64. Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017;358:j4008. doi: 10.1136/bmj.j4008.

65. Whiting P, Savovic J, Higgins JP, Caldwell DM, Reeves BC, Shea B et al. ROBIS: a new tool to assess risk of bias in systematic reviews was developed. J Clin Epidemiol. 2016;69:225–34. doi: 10.1016/j.jclinepi.2015.06.005.

66. He J, Chen WQ, Li N, Shen HB, Li J, Wang Y et al. 中国女性乳腺癌筛查与早诊早治指南(2021, 北京) [China guideline for the screening and early diagnosis and treatment of female breast cancer (2021 Beijing)]. Zhonghua Zhong Liu Za Zhi. 2021;43(4):357–82 [in Chinese]. doi: 10.3760/cma.j.cn112152-20210119-00061.

67. Lotfi T, Stevens A, Akl EA, Falavigna M, Kredo T, Mathew JL et al. Getting trustworthy guidelines into the hands of decision-makers and supporting their consideration of contextual factors for implementation globally: recommendation mapping of COVID-19 guidelines. J Clin Epidemiol. 2021;135:182–6. doi: 10.1016/j.jclinepi.2021.03.034.

68. Checklist for guideline panel chairs. Hamilton: McMaster University;2020 (https://heigrade.mcmaster.ca/guideline-development/chair-checklist, accessed 11 January 2023).

69. Morgano GP, Mbuagbaw L, Santesso N, Xie F, Brozek JL, Siebert U et al. Defining decision thresholds for judgments on health benefits and harms using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) evidence to decision (EtD) frameworks: a protocol for a randomised methodological study (GRADE-THRESHOLD). BMJ Open. 2022;12(3):e053246. doi: 10.1136/bmjopen-2021-053246.

70. Falavigna M, Belli KC, Barbosa AN, Zavascki AP, Nastri A, Santana CM et al. Brazilian guidelines for the treatment of outpatients with suspected or confirmed COVID-19. A joint guideline of the Brazilian Association of Emergency Medicine (ABRAMEDE), Brazilian Medical Association (AMB), Brazilian Society of Angiology and Vascular Surgery (SBACV), Brazilian Society of Geriatrics and Gerontology (SBGG), Brazilian Society of Infectious Diseases (SBI), Brazilian Society of Family and Community Medicine (SBFMC), and Brazilian Thoracic Society (SBPT). Braz J Infect Dis. 2022;26(2):102347. doi: 10.1016/j.bjid.2022.102347.

71. Falavigna M, Stein C, Amaral J, Azevedo LCP, Belli KC, Colpani V et al. Brazilian guidelines for the pharmacological treatment of patients hospitalized with COVID-19: joint guideline of Associacao Brasileira de Medicina de Emergencia, Associacao de Medicina Intensiva Brasileira, Associacao Medica Brasileira, Sociedade Brasileira de Angiologia e Cirurgia Vascular, Sociedade Brasileira de Infectologia, Sociedade Brasileira de Pneumologia e Tisiologia, Sociedade Brasileira de Reumatologia. Rev Bras Ter Intensiva. 2022;34(1):1–12. doi: 10.5935/0103-507X.20220001-pt.

72. Okely AD, Ghersi D, Loughran SP, Cliff DP, Shilton T, Jones RA et al. A collaborative approach to adopting/adapting guidelines. The Australian 24-hour movement guidelines for children (5–12 years) and young people (13–17 years): an integration of physical activity, sedentary behaviour, and sleep. Int J Behav Nutr Phys Act. 2022;19(1):2. doi: 10.1186/s12966-021-01236-2.

73. Okely AD, Ghersi D, Hesketh KD, Santos R, Loughran SP, Cliff DP et al. A collaborative approach to adopting/adapting guidelines. The Australian 24-hour movement guidelines for the early years (birth to 5 years): an integration of physical activity, sedentary behavior, and sleep. BMC Public Health. 2017;17(suppl 5):869. doi: 10.1186/s12889-017-4867-6.

74. Gagliardi AR, Marshall C, Huckson S, James R, Moore V. Developing a checklist for guideline implementation planning: review and synthesis of guideline development and implementation advice. Implement Sci. 2015;10:19. doi: 10.1186/s13012-015-0205-5.

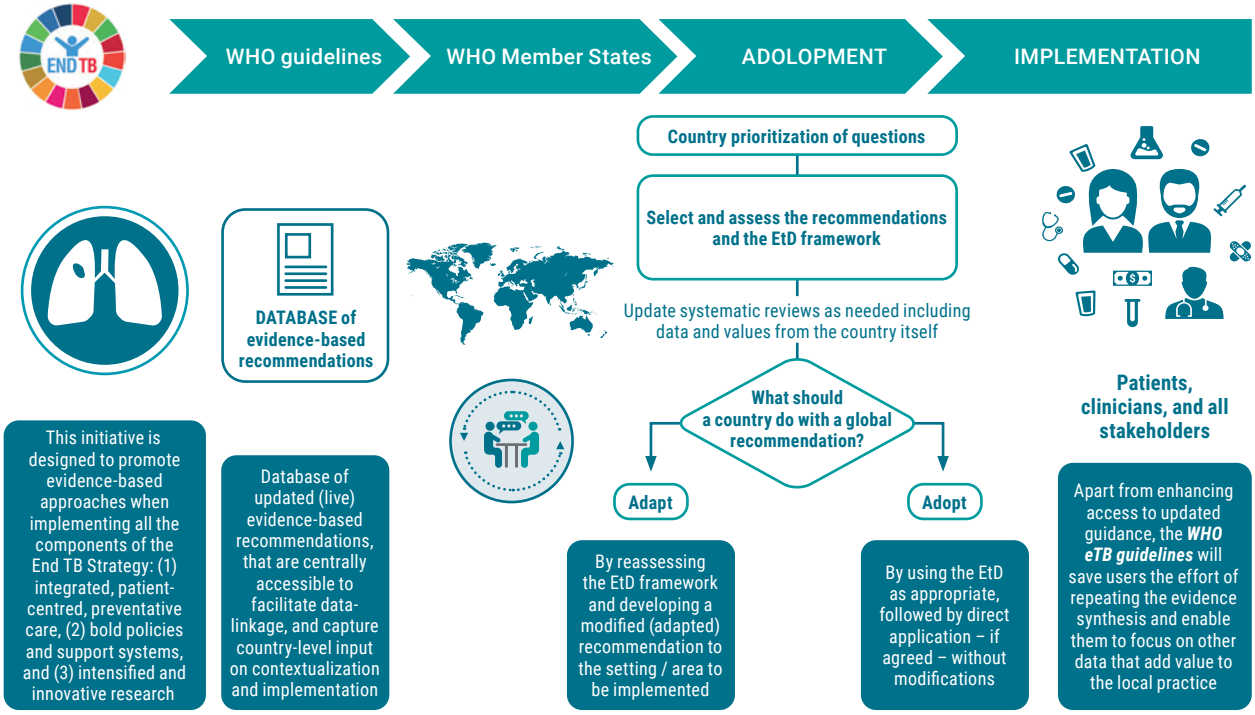
75. Piggott T, Langendam M, Parmelli E, Adolfsson J, Akl E, Armstrong D et al. The GIN-McMaster Guideline Tool Extension for the Integration of Quality Improvement and Quality Assurance in Guidelines: a description of the methods for its development. J Clin Epidemiol. 2022; S0895-4356(22)00085-3. doi: 10.1016/j.jclinepi.2022.04.002.

76. Piggott T, Langendam MW, Parmelli E, Adolfsson J, Akl EA, Armstrong D et al. Integrating quality assurance and quality improvement with guidelines: systematic stakeholder-driven development of an extension of the Guidelines International Network–McMaster guideline development checklist. Ann Intern Med. 2022;175(5):735–9. doi: 10.7326/M21-3977.

Annex. Practical example of guideline adolopment

The WHO eTB guidelines platform is a digital platform to promote adolopment of WHO recommendations by guideline development groups. Fig. A1.1 shows a conceptualization for how the adolopment process would work with the WHO eTB guidelines platform. The process begins with the WHO source guideline, which can be obtained from the database of evidence-based recommendations *(1)*. These recommendations are updated centrally and that facilitates data linkage to information at the country level to provide input on contextualization implementation.

Fig. A1.1. An example for practical guideline adolopment using the WHO eTB platform



WHO Member States or other entities adoloping recommendations would use the WHO source guideline and conduct a prioritization process of questions that are relevant for the context. Recommendations that are relevant are selected and assessed and the corresponding EtD framework created using tools such as GRADEpro. The guideline development group would review the judgments and the evidence within, and would update systematic reviews as needed to include contextual data such as data on values from the country itself.

The guideline development group either adapts or adopts a recommendation by assessing the EtD framework supporting a recommendation. A recommendation is adapted if judgments on the EtD change based on the context or it could be altered if, for example, different judgments or a different population are considered. If the new guideline development group agrees with all the judgments made by the guideline development group for the source guideline, the new group would adopt the recommendation without modifications.

This process also enhances implementation by engaging patients, people involved with the condition of interest and all other stakeholders relevant for a country setting in the guideline implementation process.

This approach will make the process more efficient by avoiding repeating the evidence synthesis and by enhancing the use of contextualized data while creating appropriate ownership of the recommendations that are relevant for a country or similar setting.

Reference

1. eTB guidelines [website]. Geneva: World Health Organization; 2023 (https://tuberculosis.evidenceprime.com/, accessed 10 January 2023).

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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