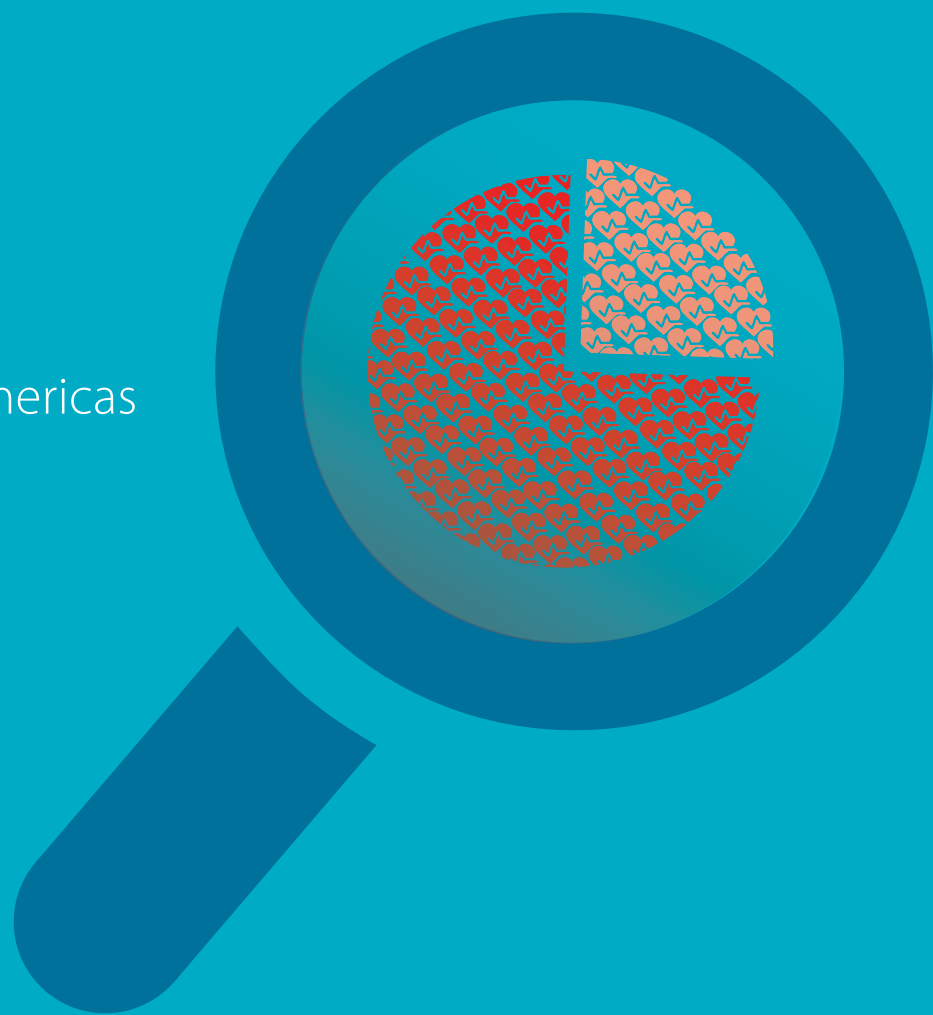


Strengthening national evidence-informed guideline programs

A tool for adapting
and implementing
guidelines in the Americas



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**Pan American
Health
Organization**



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Organization**
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Preface

Evidence-informed guidelines are currently one of the most useful tools; they improve public health and clinical practice, offer interventions with solid efficacy tests, avoid unnecessary risks, promote reasonable use of resources, and decrease practice variability in order to improve health and ensure quality of care in health systems and services.

The development of guidelines, as proposed by the GRADE Working Group (Grading of Recommendations Assessment, Development and Evaluation), is based on rigorous systematic reviews, evidence profiles, and a summary of findings tables. The purpose of the GRADE system is to provide detailed information on the quality of the evidence used to support each health recommendation, the effectiveness of the intervention, the balance between desirable and undesirable outcomes, and the confidence in values and preferences of the target populations, among others. Additionally, guidelines incorporate best practices, particularly when solid evidence is not available.

In addition to their methodological rigor, evidence-informed guidelines should consider not only the best results of research, but also the social and organizational environment in which recommendations are to be implemented and evaluated. This poses a formidable challenge when taking into account the countless variables that affect and modify the settings in which the guidelines are used. These variables are specific to factors such as the area of practice, resources available, organizational and governance aspects of health systems, cultural implications, settlement patterns of the communities, the priorities and hierarchy of unmet needs, and collective appropriation of health as a value.

Thus, it is not enough to have evidence-informed recommendations with a favorable net risk-benefit ratio for each one. It is fundamental that these recommendations can be implemented at the different health-care levels with a broad sense of equity, while offering quality and timely care.

The adaptation of guidelines or the development of new ones should be based on methods that follow strict methodological rigor. This will ensure the validity of their content and utilization of guidelines as a quality tool. By capitalizing on existing available knowledge when adapting guidelines, the time and cost involved in the development of documentation with a local or regional scope can be reduced, allowing the focus to be on a detailed analysis of the variables in the context in which they will be used and the adoption of efficient implementation strategies. A transfer of knowledge does not, in itself, guarantee useful and practical recommendations. That is why, to achieve effective implementation, multimodal strategies are required (system and process improvements, education and training, follow-up, monitoring, organizational culture, etc.).

The Region of the Americas is moving forward to offer quality universal health care, with high standards and with safety, efficiency, and equity, recognizing developments in science, technology, and services with solid evidence regarding their benefits and risks. In this way, while recognizing differences in the level of development of our countries, we will be able to share knowledge and both successful and unsuccessful experiences and offer quality care despite our limitations.

The Pan American Health Organization offers public health authorities, administrators and decision-makers, health professionals, patients, and other users this document as a tool to advance this process. It focuses on strengthening of national programs in charge of developing public health and practice guidelines, with an emphasis on the adaptation of high-quality guidelines and the use of rapid adaptation methods as an efficient and rigorous strategy for formulating recommendations on prevention, diagnosis, treatment, and rehabilitation, to be used for the different diseases or health conditions that are of concern to the countries in the Region.

This document on strengthening guideline programs is presented in three chapters. Chapter 1 presents general information and the components of national guideline programs, with a description of the activities to be carried out. Chapter 2 provides an overview of the guideline adaptation process, which includes operational information and facilitates the use of the methodology. Chapter 2 is based on the use of the GRADE developed by the GRADE working group, which acts as the general framework for producing guides known as “adoption.” Additionally, this chapter reflects the experience of the Pan American Health Organization through its technical assistance of developing guidelines in the region and the experience of the national guideline programs in the region. Chapter 3 provides information on implementation to help guide managers, institutions, and decision-makers as they move forward in implementing the recommendations.

We hope that the countries of the Region find this document useful in supporting the mission of creating better health conditions for their populations.

Scope and objectives

The purpose of this document is to present policy-oriented and methodological strategies for developing and/or strengthening national guideline programs, focusing on the adaptation of evidence-informed guidelines in the Americas.

The information presented in this document includes considerations to be taken into account in national guideline programs in order to facilitate their implementation and sustainability. It presents methodologies and tools for adapting the guidelines, as well as general information on the implementation of guidelines to help governmental agencies, stakeholders in the health care system, and civil society use evidence-informed guidelines in decision-making processes at the individual, organizational, and health system level.

This document seeks to support the development and implementation of guidelines while providing a general map of the requirements. It also presents the different resources and regional manuals that discuss in greater detail the methodological process. In general, this document takes elements of different methods of adaptation as “Adolopment” (Schünemann et al., 2017) and operationalize them to support the adaptation processes of guidelines.

Methodology

This document was developed following the planning guidelines used by health services, which recognize the importance of an evidence-based, participatory process for formulating guidelines adapted to the context where they will be implemented (WHO, 2014).

Overall, the methodology consists of three steps:

1. Review of the literature

The literature was reviewed to learn about global experiences in the strengthening of evidence-informed guideline programs and decision-making, as well as guideline adaptation methodologies. We consulted databases, technical reports of ministries of health around the world and reference organizations on the subject, such as the World Health Organization (WHO, 2014) and the Pan American Health Organization, as well as manuals on the development, adaptation, and implementation of guidelines. In general, the review identified information developed by institutions of Canada, Colombia, England, the European Union, France, Mexico, and the United States.

In addition, rapid systematic reviews for decision-making were identified (Haby, 2016a; Tricco, 2017), along with methodological manuals in Spain (GuíaSalud, 2016), USA (AFFP, 2016), England (NICE, 2014), Colombia (MSPS, 2013), Chile (MSC, 2014), Peru (Ministry of Health/DGSP, 2015), and Brazil (Brazilian Ministry of Health (MSB), 2014).

2. Development of the manual

Based on the information from the previous step and the experiences of the development group, a document was created with instructions for strengthening national guideline programs or institutional adaptation and implementation processes targeted to health systems stakeholders in the Americas, with the aim of making an impact on the health outcomes of the population and the quality of the health care services provided.

3. Validation

The document was reviewed by experts from the ministries of health and other institutions responsible for the development and implementation of guidelines at the national level, as well as by reference organizations or academic institutions in the Region, in order to receive their contributions and comments. A consultation process was used to receive feedback on the content of this document and make the required adjustments.

Chapter 1: Strengthening national guideline programs

1.1. Introduction

To move forward in the health system strengthening process, evidence-based medicine (EBM) has been introduced as part of health sector reform strategies (Rossof, 2012). EBM is described as an approach to a clinical problem that uses the best and most relevant evidence available to answer a clinical question. This concept has been transferred to health policies, where public health professionals, administrators, and decision-makers apply these precepts as tools in the decision-making process. Systematically developed information is used to inform decisions related to reforms or changes in health systems and services, as well as policy research (Lohr, Eleazer and Mauskopf, 1998; Coleman, 2001).

The recognition of EBM as input for public policy-making facilitates having continuous information that provides the basis for making decisions in the health field. As a result, governments are required to develop sustainable strategies on the use of valid, objective, and reliable evidence (Stirman et al., 2012) to enhance the quality of health care, support innovation, and optimize costs (Bonfill et al., 2013).

One of the evidence-informed strategies to strengthen health systems is the development of guidelines aimed at reducing unjustified variability in clinical practice, from early detection, prevention, diagnosis, treatment, and rehabilitation, to palliative care and health cost containment, in order to achieve the highest attainable standard of health for the people (WHO, 2016).

The guidelines offer each country recommendations to define treatment models and to support health programs at the national level. In addition, they facilitate the selection of cost-effective technologies that should be covered by the health system and generate policies on the rational use of resources and self-regulation by system stakeholders. To inform and regulate the use of guidelines in the health systems, national evidence-informed guideline programs must be created and strengthened (Novotná, Dobbins and Henderson, 2012).

1.2. Evidence-informed guidelines

During the 1990s in the United States, the Institute of Medicine (IOM) of the National Academy of Sciences defined clinical practice guidelines as “systematically developed statements to assist practitioners and patient decisions” (IOM, 1990). The guidelines were initially directed to clinicians, but the recommended practices were of interest to decision-makers, payers, health care providers, and patients (Lohr, 1998).

According to WHO, the guidelines are a set of recommendations that “help the user of the guideline to make informed decisions on whether to undertake specific interventions, clinical tests or public health measures, and on where and when to do so. Recommendations also help the user to select and prioritize across a range of potential interventions” (WHO, 2014).

The term **guideline** is often interchangeable with the term **protocol** or **standard**. Table 1 illustrates the main differences. There are different types of guidelines, but the ones used to support decision-making are known as **evidence-informed guidelines** and are developed through a rigorous methodology based on systematic reviews of the literature (GuíaSalud, 2014). Clinical protocols are defined as action guidelines that contain the sequence of activities that should be carried out on groups of patients with given pathologies in a limited or defined segment of a treatment area (MSN, 2007).

Table 1. Main differences between guidelines and protocols

Guidelines	Protocols
More general scope	More specific/local scope
Public health or clinical practice flexibility	Normative
Based on a systematic knowledge	Not necessarily based on a systematic knowledge synthesis
Systematic synthesis methodology	Generally developed by groups of experts but may be based on guidelines or systematic reviews
Multidisciplinary approach to their development	There may or may not be a multidisciplinary team

Source: adapted from MSN, 2007.

From the point of view of the Right to Health, norms are a tool of obligatory fulfillment that allows regulation in health. It is not required that norms have their foundation in guidelines (MSN, 2006 the warranty systems) (MSN, 2007).

Guidelines are intended to help health systems: 1.) Improve clinicians' knowledge through the use of evidence-informed recommendations; 2.) Inform decision-makers about the most appropriate interventions for addressing the population's health; 3.) Modify clinical practice standards by seeking to improve the quality of care for the population, and 4.) Increase the impact on health outcomes (Lohr, 1998; Concepcion, 2014).

According to WHO, quality of care is "The extent to which health care services provided to individuals and patient populations improve desired health outcomes. In order to achieve this, health care needs to be safe, effective, timely, efficient, equitable and people-centred," (WHO, 2006).

Quality of care is associated with patient safety, where guidelines (clinical practice or public health) are relevant for making recommendations on safe, efficacious, and effective interventions to achieve the best health outcome possible. In addition, given the demand for scientific information on different health conditions, it may be necessary to consider other types of studies such as health technology assessments (HTA) to determine the efficacy, safety, and cost-effectiveness of specific technologies that could be considered during the guideline development process (WHO, 2000, 2006).

The quality assurance system, which is one of the tools in each country's national health system, is intended to position the use of evidence-informed guidelines and protocols as a line of action for promoting best health practices. Each country may plan to develop and evaluate policies and programs for the national health system, seeking to integrate the guidelines or protocols into such processes (Sosa-García et al., 2016).

1.3. National guideline programs

The guidelines themselves do not have an impact on health systems, but should be consistent with quality assurance systems, insurance systems, and national guideline programs (NGPs). Accordingly, national guidelines should be developed, adapted, and implemented within the framework of an NGP to develop standards, allocate resources, and potentially institutionalize them (Deflorian, 2016).

It is recommended that the countries have an NGP that will be used to establish a national reference to encourage clinical evidence-informed decision-making, to reduce the use of unnecessary and ineffective interventions and facilitate the maximum benefits and safe treatments at acceptable costs (NICE, 2011-2014; Sosa-García et al., 2016; Vander Schaaf, Seashore and Randolph, 2015).

In several countries, national guideline development programs and centers were created based on the report of the US. IOM on healthcare quality and patient safety (Durieux et al., 2000; IOM, 2009). Partnerships were initially formed between governmental agencies, scientific societies, academia, and opinion-makers for the purpose of creating the guideline programs. These were linked with programs for accrediting the institutions that provide health service and served as support for national and regional subnational authorities (Durieux, et al., 2000; NICE, 2014).

Regardless of the country, four health policy areas have been identified that should be addressed by decision-makers, insurers, payers and patients, where guideline programs play an important role (WHO, 2006; Monegain, 2011):

1. The cost of access to care, and decisions concerning coverage or charges for services or pharmaceuticals.
2. The quality of care (clinical variability), satisfaction with treatment, and responsibility for health care.
3. Professional and public education regarding health care, health care policy-making, and research.
4. Determination of health priorities.

1.3.1. Characteristics of national guideline programs

Once the need for a national guideline program in public policy is determined, the following items should be considered to ensure proper functioning:

- A. Establishment of the objectives of the national guideline program.
- B. Identification of the entity responsible for the national guideline program and its activities.
- C. Participation of key stakeholders involved in the development and implementation of guidelines at the national level.
- D. Levels of national guideline program management and sustainability.
- E. Incorporate community participation.
- F. Implementation of guidelines at the national level.
- G. Evaluation of the national guideline program.
- H. Institutionalization of the national guideline program.
- I. Prioritization of guidelines.

1.3.1.1. Establishment of national guideline program objectives

The objective of the national guideline program (NGP) is to create a regulatory and operational space to allow the development, adaptation, and implementation of guidelines for national priority conditions, seeking to achieve quality standards and improve health outcomes while promoting patient safety and cost containment. Each country should establish general strategic objectives with their respective lines of action in the NGP.

The guidelines developed in connection with the national guideline program should follow the methodological standards of the GRADE approach, which has been identified as the international standard methodology because it allows the inclusion of other factors (risk-benefit balance, patient preferences, and costs) besides quality of evidence, in order to make more implementable recommendations (WHO, 2014).

The scope of the program will include everything from the planning, development, and implementation of the guidelines and monitoring of guideline compliance, to the coordination of updating the clinical practice guideline.

1.3.1.2. Identification of the entity responsible for the national guideline program and respective activities

There are different governance models in the Americas for structuring a NGP. Regardless of the model, it is recommended that each country designate an entity responsible for NGP activities so that all of the program's activities can be properly coordinated and implemented.

The countries with the longest track record in the development of national guidelines (England, France, Mexico, the Netherlands, and the United States) have created a National Guidelines Committee within their respective ministries of health, comprised of a multidisciplinary group that includes executives of key stakeholders in the health system. This Committee has the following advantages: it facilitates guideline prioritization processes, develops guidelines in coordination with all government agencies and stakeholders, promotes implementation, and maximizes available resources (Monegan, 2011; NICE, 2014; Sosa-García, 2016).

Other countries develop national guidelines through specific sections of their ministries of health that have the technical and structural capacity to develop or adapt quality guidelines (MSC, 2014). Other mixed working arrangements have been identified, such as assigning NGP activities to government agencies other than the ministries of health (national institutes of health, social security administrations, etc.). It is recommended that countries with this type of model follow the methodological recommendations established in the NGP and work in a coordinated manner to avoid duplication of efforts, and that they work together in the best interest of the population's health and the system's resources.

In another model, the ministries of health—through their offices or units in charge of guidelines or through the committees, commission the development of prioritized guidelines to reference centers or guideline development groups under certain quality criteria established in the program.

Activities of the entities responsible for the national guidelines program

The activities involved in developing a national evidence-informed guideline program are listed below (Schaaf, Seashore and Randolph, 2015; Frutos Pérez-Surio, Sala-Piñol and Sanmartí-Martínez, 2016; IOM, 2009):

1. Document the national evidence-informed guideline program.
2. Facilitate the creation and operation of guideline development reference centers or groups (either within government agencies or as support for external development groups).
3. Define methodologies for the adaptation, implementation, and monitoring of guidelines and provide support with approved methodological manuals.
4. Create opportunities for the participation and transparency of all health system stakeholders.
5. Connect government stakeholders, regulatory actions, quality assurance processes, and processes to the accreditation of the institutions that provide health services, with the development and implementation of the guidelines.
6. Establish priority conditions for the development of national guidelines.
7. Promote the education of decision-makers, guideline developers, and health care providers.
8. Provide information for patients.
9. Support the integration of the guidelines within information and quality management systems.
10. Suggest and promote the inclusion of guidelines in the curricula of schools of medicine and health sciences in order to foment use of the guidelines.

11. Incorporate the implementation of national guidelines as hospital accreditation activities.
12. Create a network of guideline developers and implementers that includes government stakeholders, scientific societies, health providers, academia, patient associations, etc.
13. Create strategies and tools for implementing guidelines.
14. Evaluate the impact and implementation of the guidelines.
15. Support the institutionalization and sustainability of the guidelines through the management of resources and regulatory systems.
16. Articulate the development of the guidelines with the assessment of locally developed technologies.

1.3.1.3. Participation of key stakeholders in the development and implementation of guidelines at the national level

A determining factor in the satisfactory operation of the program is the identification of key stakeholders, along with their respective roles. In general, these stakeholders are the competent government agencies and other relevant institutions in the health system, such as scientific societies, academia, and research centers, depending on each country's governance model.

The key stakeholders and their roles are as follows:

Government agencies:

- Coordinate and carry out the activities of the NGP and support its operation through regulations.
- Coordinate intersectoral work and collaboration.
- Identify resources and ensure that guidelines are not affected by conflicts of interest.
- Identify official sources of information that may be useful for prioritizing the guidelines and monitoring their implementation.
- Generate the necessary regulations to encourage the uptake of guideline recommendations. Facilitate their implementation by health service providers and ensure that health professionals comply with the recommendations.
- Create a guideline repository that facilitates the compilation of CPGs and the participation of system users during development and implementation of the guidelines.
- Include the guideline management process in the Institutional Quality Management System.

Scientific societies:

- Support the activities included in the NGP.
- Assist with guideline planning, implementation, and monitoring processes, based on their specific area of technical expertise.
- Incorporate knowledge and best clinical practices into their institutional management, through use of the guidelines.
- Promote self-regulation and quality assurance among their members.

Academia and research centers:

- Support the activities of the NGP.

- Help define the methodologies used in the development and implementation of the guidelines.
- Support technical capacity-building for the human resources involved in the development and implementation of the guidelines.

Civil society (professionals/patients):

- Support the activities of the NGP based on their specific areas of competence and areas of influence.

1.3.1.4. Levels of management and sustainability of the national guideline program

Some countries have a legal framework that establishes the basis for the operation of NGP and implementation of the respective activities. Management of the NGP will be carried out at different levels in the country. Cooperation with other countries, specialized networks, and nongovernmental organizations should be defined in order to facilitate adaptation and collaborative work processes.

Table 2 shows the national guideline program activities by management level at the national, regional, health care provider, and professional/patient level.

Table 2. Activities of the National Guidelines Program by Management Level

NGP management level				
	National	Regional	Health care provider	Professional/patient
Objective	Establish a national reference to promote clinical or management decision-making based on evidence-informed recommendations, seeking to reduce the use of unnecessary and ineffective interventions and facilitating the maximum benefit and safety of treatment at acceptable costs.			
Stakeholders	Government and nongovernmental agencies.	Regional government and nongovernmental agencies.	Health care providers.	Patient associations, health professionals and professionals that support health management.
Activities	Designate the entity responsible for implementation of activities (guidelines committee or specialized area).	Designate the entity responsible for implementation of activities (guidelines committee or specialized area).	Designate the entity responsible for implementation of activities (guidelines committee or specialized area).	Participate with the responsible entity in the formulation and implementation of institutional CPG programs.
	Document the national evidence-informed guidelines program. Quality Management System .	Document the national evidence-informed guidelines program. Quality Management System.	Document the national evidence-informed guidelines program. Quality Management System.	
	Create a network of guideline developers and implementers.	Create a network of facilitators for the adaptation and implementation of guidelines.	Create a facilitator team for the adaptation and implementation of guidelines.	

NGP management level				
	National	Regional	Health care provider	Professional/patient
Activities	Carry out strategic planning for the adaptation and implementation of guidelines. National needs. Financial Resources Management	Carry out strategic planning for the adaptation and implementation of guidelines. Regional needs	Carry out strategic planning for the adaptation and implementation of guidelines. Institutional needs	Assist with the identification of institutional needs
	Guide stakeholders in the system by identifying methodologies to be used for the adaptation and implementation of guidelines	Recognize and implement methodologies at the national level	Recognize and implement methodologies at the national level	Train professionals in guideline adaptation and implementation methodologies
	Coordinate the development of new guidelines or the adaptation of existing ones at the national level	Coordinate the adoption or adaptation of guidelines at the national level	Coordinate the adoption or adaptation of CPGs at the national level	Participate in guideline adaptation and implementation processes
	Incorporate guideline recommendations in the formulation of policies, programs, or projects	Incorporate guideline recommendations in the formulation of regional policies, programs, or projects	Incorporate CPG recommendations in the deployment of health care policies and programs	Incorporate the recommendations in daily clinical practice
	Manage obstacles to implementation	Manage obstacles to implementation	Manage obstacles to implementation	Manage obstacles to implementation
	Define sources of information for guidelines	Define sources of information for guidelines (prioritization and monitoring of compliance)	Define sources of information for guidelines (evaluation of compliance)	Participate in the formulation of compliance evaluation indicators
	Intersectoral coordination	Intersectoral coordination	Inter-agency coordination	Recognition of inter-agency links
	Develop incentive plans	Develop incentive plans	Develop incentive plans	Motivation
	Take steps for the institutionalization and sustainability of the guidelines	Be part of the organizational structure	Be part of the organizational structure	Accept the CPGs as a necessary reference in clinical practice.
	Incorporate ICTs in dissemination and implementation (Repository of national guidelines)	Incorporate ICTs in dissemination and implementation (Link to national guidelines)	Incorporate ICTs in dissemination and implementation (Link to national guidelines)	Recognition of national guidelines and tools for implementation
	Align guideline needs with the assessments of locally developed technologies	Align guideline needs with the assessments of locally developed technologies	Align guideline needs with the assessments of locally developed technologies	Knowledgeable about technology assessments

1.3.1.4.1. Sustainability of the program

The availability of resources is essential for any health program. The NGP should take into consideration building technical capacity in the following areas: access to bibliographic resources; acquisition and development of technological resources; developing strategies for the design and dissemination of guidelines; and training of professionals in the development of GRADE guidelines with a change management approach (Peirson, 2012). The aforementioned factors require ongoing efforts and investment, which will provide the country with human capital that has the ability to support different guideline projects or the formulation of evidence-informed public policy.

To determine the required investment, potential resources must be identified which do not create conflicts of interest when the recommendations are made, do not interfere with other programs, and ensure satisfactory operation of the national guideline program (Garner, Hill and Schünemann, 2015; Wiltsey et al., 2012).

It is important to formulate strategies that will ensure the sustainability of the national guideline program so that it becomes part of organizations and communities. Even when implementation efforts are successful, the programs do not necessarily continue the same way they were originally proposed. The adaptations or partial continuation of programs, including the integration of new practices may occur in response to new evidence, changing priorities, availability of resources, or other contextual factors (Stirman et al., 2012).

As a result, support for sustainability should be entrenched in the NGP strengthening process. Some of the factors that were identified to improve sustainability are (NARBHA, 2017; Peirson, et al., 2012):

- Identification of factors related to context: formulation of policies, regulations, technical capacity building, and creation of a guidelines culture.
- Development of guidelines with high quality standards that demonstrate the benefits of the evidence, which can be adapted to specific national and regional implementation circumstances.
- Support for the development of adaptation and implementation processes, provided by the ministries of health: adoption or development of a manual on guideline preparation and implementation, management of training resources.
- Ability to sustain the program: allocation of resources and available technical capacity.
- Support of health system stakeholders in the adaptation and implementation of guidelines.

1.3.1.5. Define population participation

During the formulation of public policies, programs and the execution of specific projects, the active participation of stakeholders is strongly recommended to ensure the transparency, the legitimacy of the policy, the formulation of national guideline recommendations. To this end, specific forms of participation should be defined and adapted so that stakeholders are able to express their points of view and provide feedback, and to ensure transparency regarding the decision-making process during the development of the guideline.

According to the methodologies defined for guideline development, stakeholders may participate in person or through physical and electronic means in different stages of the process. It is important to have both virtual and physical spaces that facilitate stakeholder participation during the development or adaptation of guidelines, and that support implementation processes. These spaces can be on the websites of government agencies, institutions, or development groups. Each country's legislation should be considered when implementing participation mechanisms (MSPS, 2013).

Harmonizing guidelines management with ICTs facilitates not only access to documentation, but also the deployment of effective strategies with national coverage. In this context, it is useful to identify who will benefit from the guidelines as well as their competencies. Users can be profiled and invited to specific participation events, thereby fulfilling the criteria for ensuring guideline quality. Identification of stakeholders will also serve as input for structuring implementation plans and strengthening technical capacity.

Stakeholders may be from the health sector or from other sectors that directly or indirectly support their decisions regarding health directives. Some of the key stakeholders are listed below:

Government stakeholders

- Health system stakeholders: identify the national and regional institutions responsible for management and administration of the health system
- Institutions responsible for delivering health services
- Representatives of the judicial sector
- Representatives of the education sector responsible for training human resources in the area of health
- Organizations responsible for protecting the rights of users of the health system
- Entities that provide financing in each country

Nongovernmental stakeholders

- Scientific societies
- Research centers that work in the health sector
- Health professional associations
- Pharmaceutical industry
- Institutions responsible for providing health services
- Organized patient associations

Others

- Media
- General population that uses the health system

1.3.1.6. Guideline implementation

At the national level, the implementation of guidelines poses multiple challenges to the health system and its various stakeholders, including challenges inherent to the health system structure, services networks, differences in the level of complexity of the institutions, the needs of the population, and the delivery of services in different cultural and social contexts.

To ensure that guidelines will contribute to improving the health conditions of the population and the quality of the services provided, the implementation policy should be considered from the standpoint of the NGP. It should encourage adoption by the health institutions and provide efficient support for the implementation processes. Accordingly, the formulation of the national implementation policy should consider the following aspects (MSPS, 2013):

- Include the activities proposed in the guideline recommendations as part of the activities offered by the health system or if applicable, by benefit plans.

- Allocate the resources necessary to put the guidelines into practice at the regional or institutional level, creating national implementation tools (guideline repositories, mobile applications, etc.), developing or adopting an implementation manual, etc.
- Have information systems that make it possible to evaluate the implementation process and its impact.
- Identify and include the pertinent stakeholders.
- Promote dissemination, adoption, publicity, and monitoring strategies, including the allocation of resources.
- Identify the incentive plan.
- Include the adoption of guidelines in the Health Services Quality Assurance System, for example, in qualification and accreditation processes.
- Promote the inclusion of the national guideline implementation policy in the formulation of policies, strategies, and activities carried out by institutional health service providers.
- Promote the monitoring, evaluation, and control system for use of the guidelines at the national level.
- Support the regional and institutional implementation policy in each country.
- Determine how the information on implementation is presented in the guidelines.

Chapter 3 describes the principal considerations to be taken into account for guideline implementation at the national, regional, and institutional level.

1.3.1.7. Institutionalization of the national guideline program

Institutionalization refers to making a new practice part of the routine or establishing it as a standard within an organizational structure, and it depends on the legitimization of self-reinforcing feedback dynamics and an increase in activities in which the new practice is accepted as an “obvious” way of doing things (Novotná, Dobbins and Henderson, 2012).

The institutionalization of the NGP is a determining factor for ensuring continuity regardless of the political environment. In addition, institutionalization seeks to promote structures and processes that can be adapted to guideline development for the purpose of pointing policy and clinical practice toward better health outcomes. This includes the consideration of activities for improving the quality of care or the integration of other activities for improvement of patient safety and quality of care.

The institutionalization policy should make the role of the guidelines very clear with respect to the delivery of health services and should estimate sufficient resources and create mechanisms for guideline development based on the needs of each country. With respect to the decision-making process, guidelines must be developed within the stipulated timeframes and must have the required scope. For this reason, it is critical that the NGP consider issues involving institutionalization in order to provide the necessary guidelines to the health system on an ongoing basis.

To establish formal directives between the health policy and guidelines considering resources, the guidelines should be integrated into regulatory processes. The identified steps for doing so are as follows:

1. **At the policy level:** establish a legal basis for the adaptation, implementation, and use of guidelines, including independence and financing.
2. **At the management level:** the guidelines should be part of technical capacity building through training and the establishment of centers of excellence, as well as quality management systems (WHO, 2006).

1.3.1.7.1. Quality Management System (QMS)

National guideline programs and quality assurance programs may be complementary to support the implementation and institutionalization of the guidelines, standardize quality care, and help break down barriers to the guidelines at the level of health workers, government agencies, and health providers (WHO, 2000). The intent is for the quality assurance system—as one of the tools of the national health system—to establish the use of guidelines as a course of action to promote best practices in health (Sosa-García et al., 2016).

The QMS facilitates achievement of the objectives of national health plans, forces the strategic planning units of the ministries of health to support the activities of the NGP, reduces the use of interventions that negatively affect patient safety and quality of care, and supports the institutionalization of the guidelines (Collins and Patel, 2009).

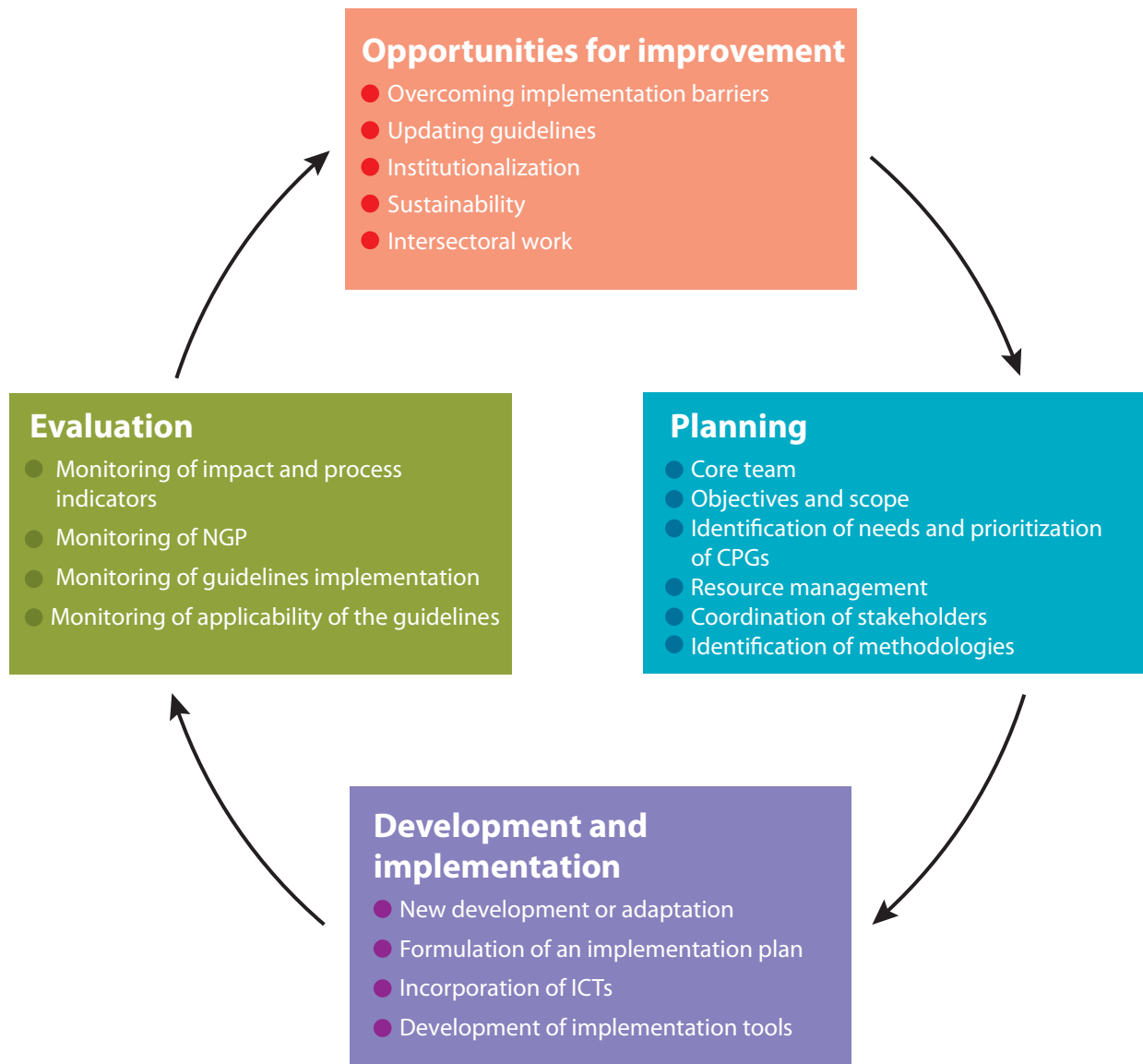
In some countries, the national guideline programs fall within the framework of continuous quality improvement and PDCA cycles (plan, do, check, and act). Figure 1 shows the structure of the guidelines program within the framework of the QMS, which has four main areas: 1.) Opportunities for improvement, including guidelines program strengthening issues; 2.) Planning, where the general management of the program and programming of its activities are considered, with multisectoral support; 3.) Development and implementation, which illustrates how the national guideline development, adaptation, and implementation processes work, and 4.) Evaluation, which monitors the guidelines program.

1.3.1.8. Program evaluation

As part of quality management, the guideline program requires continuous improvement, which is why it is essential to devise a system for monitoring the execution of the NGP, in general, as well as monitoring of compliance with the guideline recommendations.

Continuous improvement encourages the NGP to establish effective measures that satisfy the patient and the national health system. This evaluation should be conducted based on impact, process, and outcome indicators, considering existing sources of information in each country to ensure measurement feasibility without requiring the creation of new records (see Chapter 3 for more information).

Figure 1. Structure of the guidelines program as part of the quality management system



1.3.1.9. Guideline prioritization

Although all health problems that afflict a population in particular would ideally be addressed based on an evidence-informed decision-making process using guidelines, in reality this does not occur. The development of guidelines requires intense work and the availability of human, technological and financial resources. This is why countries or institutions entrusted with developing guidelines need to prioritize the health problems where having guidelines would help achieve the best health outcomes (ACSQHC, 2017).

The first step to ensure that countries and health institutions in the Region participate in the process of quickly adapting up-to-date guidelines, is to prioritize the health problems where having guidelines would be of benefit to the health system.

Prioritization is an efficient approach in which decision-makers determine where to focus health efforts with the intention to decrease inequity and disease burden, as well as to improve the planning of the

required guidelines (Atkins et al., 2012). Prioritization is then a response to the economic limitations that threaten the sustainability of the systems and partially provides a solution to the growing demand for more and better health resources (MSPS, 2013). For this reason, a true prioritization exercise requires an explicit, systematic, and participatory method, taking into consideration the scope of the decision that is made, its potential impact on public health, common welfare, and the use of resources (GETS 2010).

Selecting the topic that will lead to the development of a national practice guideline is usually the responsibility of the regulatory agency (or agency responsible for the NGP) that sets standards and issues directives in the area of health and public policy. This agency, based on a list of potential issues (originating, for example, from consultations with interested parties or conditions with the greatest disease burden or impact on costs to the system), takes the first step in the development of a guideline (Frutos Pérez-Surio, Sala-Piñol and Sanmartí-Martínez, 2016).

Chapter 2 describes some of the tools used to prioritize guidelines as part of the national adaptation process and adaptation of the guidelines that were prioritized.

1.4. Challenges of the national guideline program

The first obstacle to creating the program is the lack of trust in guidelines. Therefore, the program must base the adaptation and development of guidelines on rigorous, unbiased methods using the GRADE system, with a mechanism to ensure the participation of system stakeholders (Rossof, 2012).

It is challenging to provide guidelines covering all priority issues and to have up-to-date national guidelines that are easy to access and accepted by users. Therefore, having the technical ability to maintain the program and stay up-to-date on guideline methodologies is essential (Ellen et al., 2013). To address this challenge, there should be continuing education for the pertinent national personnel, taking the following into consideration: the limited number of academics and experts with experience in the Region, the large number of guidelines that need to be developed, the constant development of new technologies, staff turnover, and limitations in obtaining local and global evidence. Among the strategies used to maintain technical capacity is the creation of national and international alliances with experts, organizations, and centers of excellence, and the allocation of resources to the national guideline program. Chapter 1 describes the operational characteristics of the program that facilitate the development of guidelines.

The success of the NGP is based on having the support of the government structures related to guidelines. For this reason, it is very important to find support when the program is being strengthened and create participatory dynamics with all relevant stakeholders in the health system.

Chaper 2: Adaptation of guidelines

2.1. Introduction

The proposed guideline adaptation methodologies described in this chapter are designed to support NGP activities for the establishment of guideline adaptation methodologies, formation of guideline development groups, and completion of the guideline reporting template.

2.2. Guideline adaptation as a model

Developing high-quality methodological and transparent guidelines is a significant challenge facing health institutions throughout the world. One of the principal limitations to the actual use of the recommendations contained in the guidelines is the fact that although evidence on the benefits and risks associated with a health intervention can be extrapolated to the majority of people around the world, this is often not the case in other decision-making areas, such as patient values and preferences, feasibility of implementation, and availability of resources. This leads to the conclusion that two guideline panels working in different settings but looking at the same evidence on effectiveness, could make diametrically opposed recommendations, which are both valid in their particular contexts.

Guideline adaptation is defined as a systematic methodology for using and adapting a preexisting guideline developed in one context for use in another new context, culture, or organizational structure. This guideline adaptation process and associated recommendations should ensure that the newly adapted guideline effectively incorporates recommendations relevant to the context in which it will be used, and that the local needs of the health system, health priorities, legislation, policies, and resources in the new context of use have been taken into consideration (ADAPTE, 2009; Schünemann et al., 2016).

Adapting guidelines has a number of benefits: 1) it helps reduce the time it takes to develop guidelines; 2) it reduces the amount and degree of methodological experience required of the adaptation team; and 3) it facilitates bringing the health evidence collected and synthesized by professionals who are highly trained in these areas into contexts where obtaining the same results would take a long time and a great deal of effort.

However, the adaptation process is not problem-free: 1) it relies on the methodological work performed by other guideline development teams; 2) available evidence has to be re-contextualized; 3) it does not keep the institution responsible for adaptation from having to form a panel of experts for the guideline; 4) a guideline may be extremely relevant, but could require that existing evidence be updated; and 5) local barriers to and facilitators of the implementation of recommendations must be analyzed.

Considering the benefits described above, we recommend using the guideline adaptation methodology. The recommended model described below is primarily based on the content of the guideline adaptation methodology that uses the GRADE-ADOLOPMENT approach (Schünemann et al., 2017), the methodological manual for guideline development used by the World Health Organization (WHO, 2014), the GRADE manual in English and Spanish available at gradeworkinggroup.com, and the experience of the development group.

This document offers two possible scenarios for GRADE guideline adaptation in the countries of the Region.

2.2.1. Rapid adaptation of updated GRADE guidelines

This model is based on the early identification of recently published GRADE guidelines, so they can be adapted in a short enough period of time for the adapted version to still be considered current when it is published. Haby et al. designed a rapid response methodology for decision-making that is in line with rapid guideline adaptation methods (Haby et al., 2016b). This model puts an emphasis on maximizing the adapta-

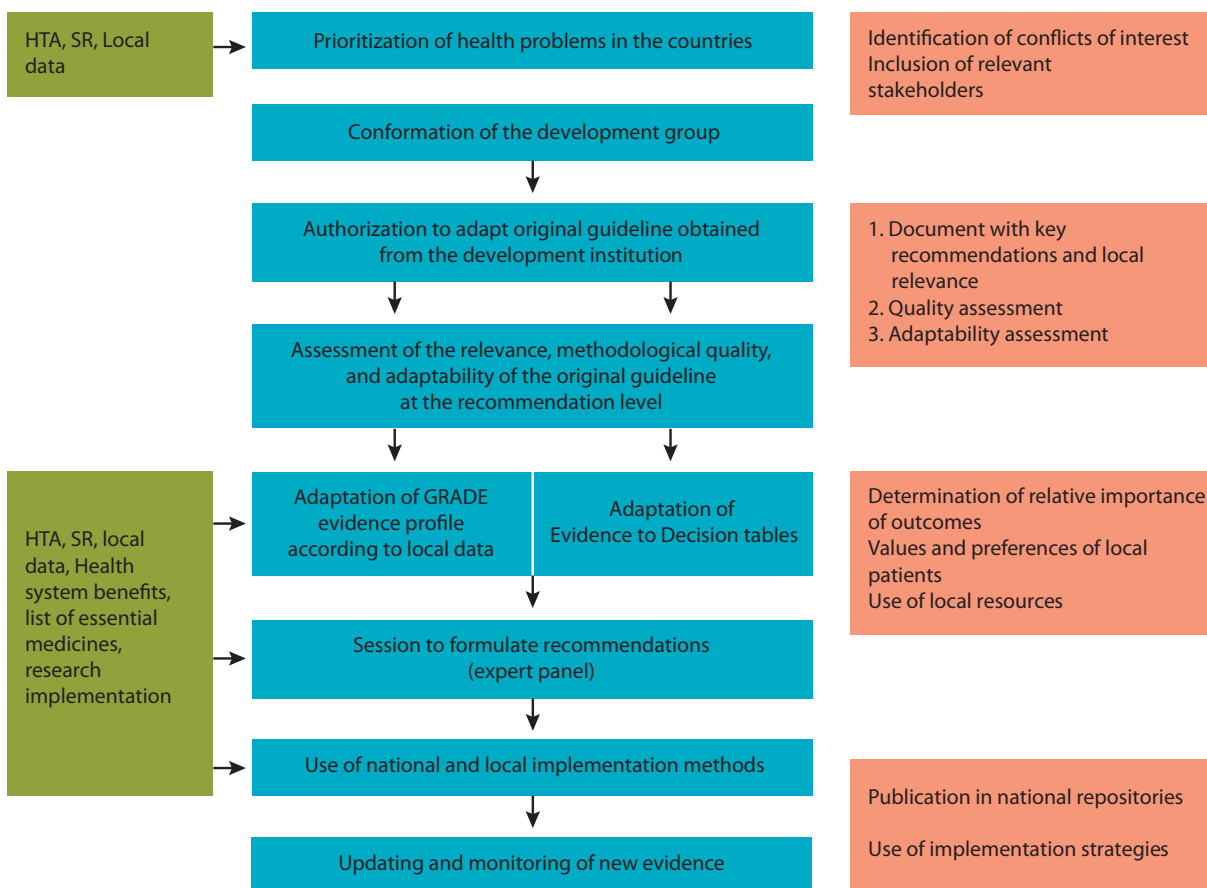
tion process, thereby eliminating the workload associated with the collection, evaluation, and synthesis of evidence, while optimizing time and resources. In general, a recently published high-quality guideline undergoes a process of contextualizing its recommendations in order to facilitate their implementation. The adaptation of the guideline depends on the scope and questions raised by the guideline development group (GDG).

Local data, evaluation of local health technologies, policy reports, implementation research, benefit plans, essential list of medications and national programs should be considered when the guidelines are prepared.

This model is practicable, given that the most recognized organizations in the development of quality guidelines (such as WHO and NICE) publish between 10 and 20 guidelines each year (see Figure 2).

Additionally, health technology assessment (HTA), systematic reviews (SR) and national data among others should be considered (see Figure 2).

Figure 2. Broad outline for rapid adaptation of updated GRADE guidelines



HTA: health technology assessments; SR: systematic reviews.

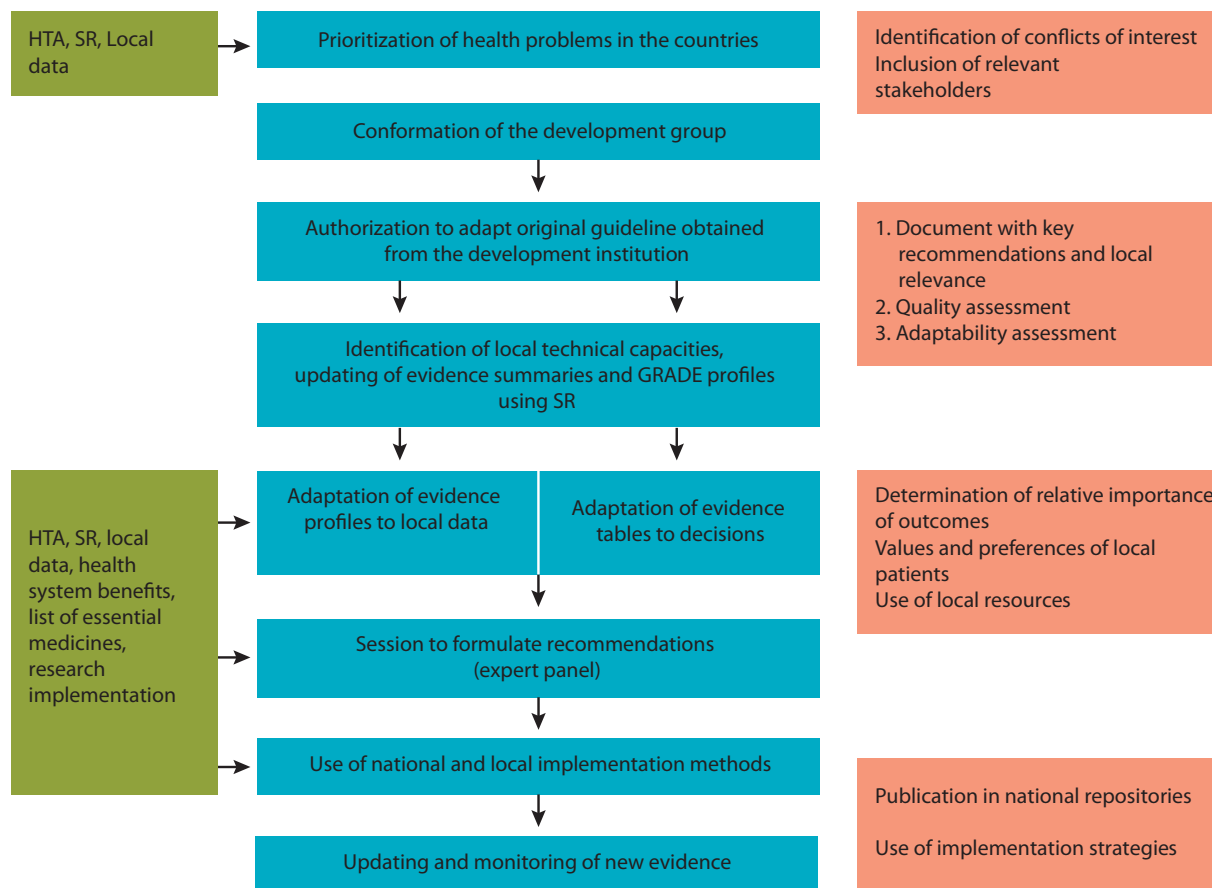
2.2.2. Adaptation of GRADE guidelines that require updated evidence

This model is based on the identification of a GRADE guideline relevant to the institution's health problem, when the guideline needs to be adapted, but has not been updated. The methodological group needs to update the respective evidence, making use of the search strategies suggested in the original guideline or else systematic reviews that can be effectively updated by answering the guideline's questions. This process requires the methodological group to have specific skills and abilities related to evidence searches,

evaluation, and synthesis. The duration of this process varies, depending on the number of recommendations that need updating, the technical capacity of the development group, the available resources, and the number of new primary studies that must be included.

Figure 3 shows the steps for adapting updated GRADE guidelines.

Figure 3. Broad outline for rapid adaptation of GRADE guideline that need updating



HTA: health technology assessments; SR: systematic reviews.

Based on these two adaptation models, the following are basic steps for adapting guidelines.

2.3. Prioritization

During the prioritization exercise, it is important to ensure the participation of all stakeholders. Plurality and representation are key components when it comes to identifying the true needs of a nation, while safeguarding the legitimacy process (GETS 2010). It is therefore important that the entity responsible for the NGP in each country carry out a multisectoral prioritization exercise and prepare a list of the most important guidelines to be developed or adapted at the national level.

Some of the guideline prioritization tools are described below.

2.3.1. Prioritization tools

We recommend using tools in the national guideline prioritization process that make the process more objective through the use of specific criteria (MSPS, 2013). There are currently several prioritization approaches that can be used. The most common are described below:

World Health Organization criteria

The criteria recommended by WHO for prioritizing health issues and developing guidelines include the following (Oxman, Schünemann and Fretheim, 2006):

- Major interventions than could have an impact on the health system beyond the scope of the health professional patient relationship.
- The underutilization of a health intervention that keeps health indicators below the expected estimates.
- The existence of interventions with questionable effectiveness that are nonetheless widely used in the health system.
- The existence of a new health intervention for which there is currently no clear information on how health professionals should act.
- There is variability in practice clinical, which could mean that some patients are not receiving interventions with proven effectiveness.

PriGPC Tool

GuíaSalud, a Spanish development group, recommends the use of the PriGPC instrument, which is an automatic application developed to systematize the topic covered by the guideline. This instrument consists of 28 items grouped into three areas: health problem, social and health care, and potential impact (GuíaSalud, 2016).

PRIO Tool

Another tool that is a prioritization scale is the PRIO Tool (Reveiz et al., 2010). This instrument uses the following prioritization criteria: disease burden; health sector's need for information; feasibility of making recommendations that promote better health conditions based on available resources and public policy priorities; availability of interventions with proven effectiveness; potential impact on consumption of resources; unjustified variation in clinical practice; impact of the issue on vulnerable or the disadvantaged populations; acceptability of the issue among system users and health professionals; frequency of adverse events; and probability of positive impact on existing risk factors (Reveiz et al., 2010). This tool gives a score in each area, so that issues with the highest scores can be prioritized. More information on the tool can be found at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2846928/>. and the Methodological Guide to Guideline Development in Colombia describes an adaptation of the tool (MSPS, 2013).

Prioritization considerations

Once the prioritization process is complete, guidelines should be developed without long delays since priorities may change. For this reason, there should be a current list of guidelines to be prioritized, as well as a streamlined selection process (GETS, 2010). The selection of the prioritization tool will depend on the expertise of the entities responsible for prioritization and the availability of national prioritization tools.

2.4. Formation of the guideline development group

Once the subject of the guideline has been selected, the guideline development group (GDG) is formed, which consists of the professionals directly responsible for adapting the guideline, including patients or their representatives. The work team should be multidisciplinary to ensure that the views of all potential users of the guideline are included in the process, all relevant evidence is retrieved, key issues related to patient care and treatment are included, practical problems stemming from the use of future recommendations are detected and analyzed, and the implementation processes are supported (PAHO, 2006).

The functions of the guideline development group in rapid adaptation and adaptation with updating processes have some things in common but also differences, as illustrated in Table 3.

There is no recommended number of participants that will ensure the success of the project. Nevertheless, development groups traditionally suggest that the team be formed based on the complexity of the issue, the number of questions formulated, and the volume of available evidence (MSPS, 2013). Another aspect to consider is that the number of professionals who will be part of the GDG should be appropriate to avoid creating an excessive workload, being careful that the size does not become unmanageable. The recommended number of members is 6 to 12, including patient representatives (GETS, 2010).

Table 3. Functions of the GDG by adaptation type

GDG functions	Rapid adaptation	Adaptation with updating
Define scope and objectives		
Formulate clinical questions		
Select guidelines to be adapted		
Systematic searches		
Extract evidence and build GRADE profiles		
Include local evidence		
Adapt GRADE profiles to the context where the guideline will be used		
Review recommendations		
Draft guideline		

If the cell is blank, then no process is required

In this way, the members of the development group can be placed in five categories. Their position, professional profile, and duties appear schematically in Table 4.

Table 4. Members and functions of the guideline development group

Position	Professional's profile	Functions
GDG leader	<ul style="list-style-type: none"> • Expert recognized in the guideline subject area • Leadership and teamwork • Experience in guideline development and knowledge of basic issues related to EBM • Must provide conflict of interest statement 	<ul style="list-style-type: none"> • Ensures harmonious functioning of the group • Leads, coordinates, and manages the group's internal processes • Ensures that the group has the resources required to perform their work • Promotes the participation of all team members and ensures transparency of the process • Facilitates interaction among participants • Encourages discussion and does not pressure members to reach an agreement • Helps make the decision to adapt or develop the guideline • Participates in guideline implementation and dissemination processes • Ensures compliance with the project timeline • Supports drafting of the document
Methodological coordinator	<ul style="list-style-type: none"> • Professional with education and experience in guideline development and/or adaptation • Ideally has formal training in clinical epidemiology, biostatistics, public health, research methodology, or health technology assessment • Must provide conflict of interest statement 	<ul style="list-style-type: none"> • With the leaders' support, the coordinator determines the activities to carry out throughout the process • Trains team members in the development or adaptation process • Supports the formulation of clinical questions and ranking of outcomes • Quality control of the products developed • Coordinates the formulation of recommendations • Ensures adherence to the method • Supports drafting of the document • Participates in the guideline implementation and dissemination processes
Methods experts	<ul style="list-style-type: none"> • Professionals with education and experience in the field of medical research • Ideally has formal training in clinical epidemiology, biostatistics, public health, research methodology, or health technology assessment • Must provide conflict of interest statement 	<ul style="list-style-type: none"> • Train team members in the development or adaptation process • Helps make the adaptation decision • Supports the formulation of clinical questions and the ranking of outcomes • Searches and compiles the required scientific evidence • Evaluates the strengths and weaknesses of the evidence • Supports drafting of the document • Participates in guideline implementation and dissemination processes

Table 4 (continued)

Position	Professional's profile	Functions
Clinical experts	<ul style="list-style-type: none"> • Professionals with experience in the area of interest for the guideline • This group is comprised of clinical professionals involved with the patient care covered by the guideline (will be users of the guideline) • Must provide conflict of interest statement 	<ul style="list-style-type: none"> • Participates in the meetings convened throughout the process • Helps with the decision to adapt or develop the guideline • Contributes to the formulation of clinical questions and the ranking of outcomes • Supports the methodological group during evidence search and selection processes • Provides relevant contributions regarding retrieved evidence • Actively participates in the consensus that leads to the recommendations • Participates in guideline implementation and dissemination processes • Supports the drafting of the document
Patient or caregiver representative	<ul style="list-style-type: none"> • Has first-hand knowledge of the condition covered by the guideline (represents or is in charge of a patient with the condition covered by the guideline) • Belongs to a patient support group on the guideline's subject • Must provide conflict of interest statement 	<ul style="list-style-type: none"> • Participates in meetings convened throughout the process • Contributes to the formulation of clinical questions and the ranking of outcomes • Provides relevant contributions regarding the retrieved evidence • Actively participates in the consensus that leads to the recommendations
Other professionals	<ul style="list-style-type: none"> • Based on the project's needs. May be part of this group of experts in health economics, implementation specialists, document management experts, administrative staff, external reviewers, or consultants • Must provide conflict of interest statement 	<ul style="list-style-type: none"> • Will have specific functions as determined by the leader of the guideline development group, depending on when the professional participates in the process

Source: Adapted from GETS, 2010.

2.5. Managing conflicts of interest

Once GDC members have been identified, it must be confirmed that there are no obstacles that would disqualify any potential candidates who might become part of the GDG from performing their duties. This process, known as a conflict of interest declaration, is critical to making impartial and unbiased evidence-based recommendations (no special interests), and is an indispensable step to fill a position (Norris et al., 2011).

The United States Institute of Medicine (IOM) defines a “conflict of interest” as a set of circumstances that create a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest (for example, patient safety or validity of an investigation) (IOM, 2009). Conflicts of interest represent a serious threat to the validity of the recommendations, and in the worst-case scenario could jeopardize the health of an entire population if they lead to biased recommendations based on value judgments (Norris et al., 2011).

In the case of WHO, a general framework for collaboration with non-state actors (FENSA) was estab-

lished, which contains specific policies related to collaboration with each of the groups of non state agents, namely, non-governmental organizations (NGOs), private sector entities, philanthropic foundations and academic institutions. The Member States of PAHO adopted FENSA through resolution CD55.R3, approved at the 55th Directing Council in September 2016. For WHO “the existence of a conflict of interest in any of its forms does not imply that an unlawful action was committed, but rather that there is a risk that this unlawful action will be committed. Conflicts of interest are not only financial but can also take other forms” (WHO, 2014). The incorporation of the declaration and analysis of conflicts of interest in the practice guides should be given in the legal framework of the country.

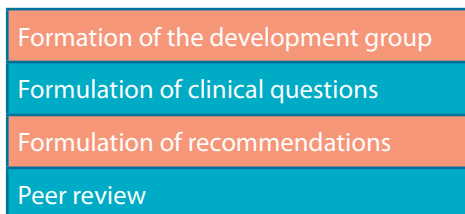
2.5.1. Types of conflicts of interest

Conflicts of interest are classified as specific or nonspecific, which are in turn classified as personal (financial or non financial) and non personal (financial or non financial) (WHO, 2015). Some of the characteristics of different types of conflict of interest (MSPS, 2013; WHO, 2014) are:

1. A specific conflict of interest is one that is closely related to the technology or intervention to be evaluated in the guideline.
2. A nonspecific conflict of interest is one that is indirectly linked to a product or technology, through interactions with the manufacturer, seller, or user.
3. A financial conflict of interest (specific or nonspecific) occurs when the professional’s relationship to the industry involves receiving compensation in cash or in kind for activities performed (such as consulting), which are related to the subject of the guideline.
4. Non financial or intellectual conflicts of interest refer to a prior public statement made by the professional concerning the subject of discussion, or those that may jeopardize reputation or prestige.
5. Financial and non financial conflicts of interest may be personal or familial in nature, depending on whether the professional directly benefits from certain privileges or if the benefit is received by someone that the person making the declaration says has some legal or moral responsibility (for example, a family member, department, or organization). There are no financial limits to be declared.

All potential members of the GDG should complete the respective form, as should any other person who is either part of the guideline development process or could influence the guideline’s content. It is recommended to periodically update the declarations, when necessary (GETS, 2010; WHO, 2016).

It is recommended that conflicts of interests be identified in the following stages of the guideline adaptation process:

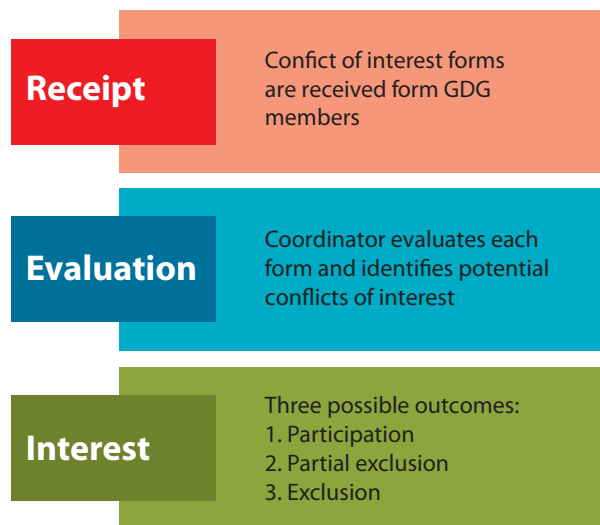


There are several formats for the declaration of conflicts of interest that can be found in both WHO and PAHO methodological manuals and official formats of the developer groups.

2.5.2. Assessment of conflict of interest declarations

In terms of assessing the conflict of interest declarations of each member of the GDG, each declaration is first assessed by the leader and coordinator of the methodological team, who make preliminary decisions on each member’s participation. Next, this preliminary decision is presented to other members of the team, who individually read and assess the original form, then express their agreement or disagreement with the decision made. Decisions are final when a consensus is reached. If this does not occur, there will be an opportunity to discuss the case to reach a consensus. If the dispute cannot be resolved or is considered “difficult,” it may be beneficial to ask an independent committee to review it (MSPS, 2010). Figure 4 summarizes the conflict of interest assessment process. In addition, the institutions that develop the guide have legal and ethical evaluation mechanisms within which the processes of declaration and analysis of conflicts of interest must be articulated.

Figure 4. Sequence for assessing conflict of interest declarations



2.6. Definition of the guideline’s scope and objectives

Considering that guidelines are intended to help making informed decisions based on the specific context of a condition, it is essential that the development group define the guideline’s scope and objectives, as well as the audience it is intended for and the type of patients that will be targeted. All these aspects must be delineated within the scope and objectives (Frutos Frutos Pérez-Surio, Sala-Piñol and Sanmartí-Martínez, 2016).

An objective refers to the aim or purpose of the guideline to be developed. Traditionally, an objective is expressed in the form of a simple sentence in which the health goal (prevention, diagnosis, or treatment), the expected benefit, and the target population are clearly stated (GETS, 2010).

An example of a clearly formulated objective is the following:

“...to reduce unjustified variability in the treatment of patients with deep venous thrombosis during pregnancy ...”		
Objective sought	Expected benefit	Target population
Treatment	Reduce unjustified variability	Pregnant women with deep venous thrombosis

Depending on the complexity of the issue, a guideline may include one or more objectives. However, it is crucial that they are clearly defined beforehand, are feasible, and are measurable. With regard to scope, the GDG profiles the clinical aspects that will be covered by the guideline and those that will not, as well as the target population, the level of attention, and the target users (MSPS, 2013).

Below indicates an example of a clearly formulated scope which is taken from the 2016 guideline on treating a venous thromboembolic during pregnancy and delivery (ASBOG, 2017):

Clinical aspect covered: what aspects of treatment are covered by the guideline
"This CPG serves as input for health professionals who treat pregnant women that require interventions for the treatment of a venous thromboembolic event."
Clinical aspect not covered: what aspects are excluded from the guideline
"This CPG is not intended for women who require treatment of a thromboembolic event of arterial origin, is associated with oncological or cardiac pathology, or warrants the beginning of thromboprophylaxis."
Target population: identification of patients to whom the guideline recommendations apply
Pregnant women who require the use of interventions for treatment of a venous thromboembolic event, either on an inpatient or outpatient basis.
Target users: profiles of those who will use the guideline for patient management
The guideline is specifically intended for nursing and general medicine professionals, as well as specialists in obstetrics and gynecology, emergency medicine, maternal fetal medicine, anesthesiology, and internal medicine.

The definition of the scope and objectives of national guidelines may be determined with the participation of interest groups, in order to hear the opinion of target users and involve them with the process in its early stages, which creates an environment of trust and teamwork, while laying the groundwork for dissemination and implementation (MSPS, 2013).

2.7. Formulation of PICO questions and ranking of outcomes

Once an agreement has been reached by the members on the subject of the guideline to be developed, the development group should formulate clinical questions that will help achieve the proposed objective, without exceeding the defined scope. To this end, the group of clinical experts, together with the methods consultants, should prepare a list of questions that are closely related to the disease or condition, which should in turn be relevant to clinical practice (GETS, 2010). The appropriate selection of questions ensures that the main questions facing clinicians will be answered, while facilitating the formulation of recommendations that will have an impact on the most sensitive patient issues (GETS, 2010).

To this end, these questions should be important, focused, and feasible to answer, in order to avoid the unnecessary use of resources and to facilitate the development of the search strategy (Aslam, 2010). When formulating clinical questions, the scope of the guideline, the need to respond to specific clinical questions, and the patient's journey through the health system must be considered.

Accordingly, the first step in formulating questions is to prepare a list of first-tier (or generic) questions, which then will be turned into answerable clinical (or second-tier) questions based on the PICO structure: population, intervention, comparison, and outcomes (MCI, 2009b). At the end of this process, the clinical questions will not only have the correct clinical orientation, but also will have the proper structure for identifying the relevant scientific evidence.

Following the example that appears in Table 5 below and keeping in mind the scope and objective at hand, we can see the first-tier question proposed by the clinician and how it was subsequently turned into a second-tier question by the methodologist.

Table 5. PICO questions format

First-tier question asked What pharmacological interventions exist for treating a pregnant patient who presents deep venous thrombosis?		
Second-tier question asked in PEAK format What pharmacological interventions are the safest and most effective for treating deep venous thrombosis during pregnancy?		
Population	Intervention/Comparator	Outcomes
Pregnant women	Low molecular weight heparin Unfractionated heparin Vitamin K antagonists Thrombin inhibitors	Mortality Disability Progression to pulmonary thromboembolism Lower limb edema Heparin-induced thrombocytopenia Change in prothrombin time

It is important to stress the importance of outcomes. The members of the development group should keep in mind that outcomes are the result of health providers’ efforts to provide optimal care. They should be selected based on a prioritization exercise, keeping the ones that are truly important for evaluating the effectiveness of the interventions (Guyatt et al., 2011).

The outcomes should include not only those that are favorable but also unfavorable, and if relevant, may include health care costs. Their importance may be determined using an ordinal scale of nine units as proposed by the GRADE group. Using this approach, outcomes are classified based on their rating as either not important, or important, critical, as illustrated below (Guyatt et al., 2011):

NOT IMPORTANT			IMPORTANT			CRITICAL		
1	2	3	4	5	6	7	8	9

For each question, those scoring at least 7 should be kept, preferably retaining those deemed critical for patients.

When the list of questions is prepared for the guideline, the available time and resources should be kept in mind. Being over-enthusiastic and including too many questions will only wear out the team. The development group should discuss the list based on available resources and the project’s timeline and the number of questions to be asked, without overlooking prioritization criteria such as the amount of available evidence, the feasibility of answering the question, and the impact on the guideline (GETS, 2010).

2.8. Search for existing guidelines

Once the clinical questions have been formulated following the PICO format, the next step is to conduct a systematic search for clinical practice guidelines in order to identify those national or international documents that could serve as a source for the inclusion of evidence. This step is of utmost importance and is the responsibility of the methods expert who will be assisted by a group of clinicians (Martínez et al., 2012).

The first step in conducting this systematic search is to identify databases, the websites of development groups, and electronic repositories where it is easiest to find the desired information. The search will be conducted in these places using a combination of a free and controlled vocabulary connected by means of

the efficient and appropriate use of Boolean operators (Higgins, 2011). The terms will reflect the guideline's target population and the objective that is sought (diagnosis, treatment, prognosis) (Higgins, 2011). Depending on where the search is conducted, it may be necessary to use specialized filters, which may be consulted in the respective references (GETS, 2010; MSPS, 2013). However, this will not be essential when the search is conducted in electronic repositories that only store practice guidelines or when the search is conducted on the websites of guideline development groups.

Some suggested repositories and development group websites and databases are listed below, which should be reviewed when searching for the most relevant and current guidelines on a particular subject. This list is not exclusive, and the development group must explore other additional sources of information depending on the subject matter of the guideline, such as the websites of scientific societies, as well as the Reference Centers and Development Groups in the Ministries of Health of Argentina, Brazil, Chile, Mexico, Peru, etc.

Guideline development group websites

Development Group	Country	Websites
NICE (National Institute for Clinical Excellence)	England	http://www.nice.org.uk
SIGN (Scottish Intercollegiate Network)	Scotland	http://www.sign.ac.uk/
Ministry of Health and Social Welfare of Colombia	Colombia	http://gpc.minsalud.gov.co/SitePages/default.aspx
World Health Organization	Global	http://www.who.int/publications/guidelines/es/ http://www.who.int/publications/guidelines/en/
GuíaSalud	Spain	http://www.guiasalud.es
National Health Authority of Denmark	Denmark	https://www.sst.dk/en/national-clinical-guidelines

Repositories

Compiler	Country	Websites
National Guideline Clearinghouse	United States	http://www.guideline.gov/
GIN (Guideline International Network)	Europe	http://www.g-i-n.net/
GuíaSalud	Spain	http://www.guiasalud.es/home.asp
Magic app. MAGICapp - Making GRADE the Irresistible Choice - Medical Guidelines	Canada	https://www.magicapp.org/app#/guidelines
Epistemonikos	Chile	https://www.epistemonikos.org/es/
Canadian Medical Association	Canada	https://www.cma.ca/En/Pages/clinical-practice-guidelines.aspx

Databases

Databases	Websites
PubMed	http://www.ncbi.nih.gov/entrez/query.fcgi
Embase	http://www.embase.com/
Trip database	http://www.tripdatabase.com/index.html

Search logs should be saved so that results can be confirmed if necessary or the search can be updated as required. The suggested search log format appears below:

Search Report No. 1	
Type of search	New/update
Source	Name of repository or database
Search date	Day/month/year
Language restrictions	If applicable
Search strategy	The strategy used during the search should be indicated, showing the list of key controlled or free vocabulary words used
Number of retrieved references	
Number of selected references	

Source: Adapted from Cochrane STI, 2012

2.9. Selection of eligible guidelines for quality evaluation

To identify guidelines that may be suitable for adaptation, Table 6 below provides suggested inclusion and exclusion criteria.

Table 6. Selection criteria for guidelines for adaptation

Type of adaptation	Guideline selection criteria
Rapid adaptation	<ul style="list-style-type: none"> Guidelines that have the scope of the proposed guideline Guidelines that use the GRADE methodology Guidelines published in the last 2 years Relevant languages in which the GDG is able to work
Adaptation with updating	<ul style="list-style-type: none"> Guidelines that have the scope of the proposed guideline Guidelines that are evidence informed There is no date restriction Relevant languages in which the GDG is able to work

After these steps, references that continue to be used in the process should still be screened a second time, to only keep those that are truly worth evaluating in terms of content and rigor, with the assistance of the AGREE II instrument. As a prerequisite for using this tool, bear in mind that the entire AGREE II manual should be read. It is essential to have all required information on hand (such as appendices or annexes), and the guideline should be independently evaluated by at least two members of the development group (preferably four), who should have received prior training on the use of this instrument. Once the evaluation of the retrieved guidelines is complete, any existing discrepancies must be recognized and sources evaluated. Any disagreements must be resolved so that the guideline can be generally appraised as recommended or not recommended (AGREE Next Steps Consortium, 2009).

The AGREE II instrument does not provide a specific cut-off point in terms of the overall score regarding if the CPG can be considered as having the appropriate quality. Nevertheless, it is highly desirable that if a retrieved guideline is intended to be used as source of evidence, it should have a methodological rigor score

of over 70%, with an overall appraisal of “recommended.” Nevertheless, this suggestion should not be viewed as an absolute score, since the development group, based on the project needs, will have the authority to determine the desired score for the domain(s) on which a decision will be made. Naturally, the higher the score, the greater the confidence that potential biases in the development of the guideline have been minimized (AGREE Next Steps Consortium, 2009).

2.10. Deciding which guideline can be adapted

Finally, the guideline to be adapted will be selected by informal consensus with the full participation of the development group. To reach this consensus, it is desirable to use a decision matrix that will serve as a basis and help guide and focus the discussion. The most relevant aspects for each guideline evaluated should be included in this matrix, and the group should identify and define the most appropriate guideline, based on local needs and context (MSPS, 2013).

Table 7 shows the elements of the matrix. It must be determined whether or not each selected guideline meets the following criteria: consistency with the proposed guideline’s scope and objectives; the degree to which it answers the guideline’s questions, recommendation based on the AGREE II quality rating; availability of search strategies; and availability of GRADE evidence profiles. Using this information, the GDG members will reach an agreement on which guideline or guidelines could be adapted. It is recommended that a maximum of two complementary guidelines be used.

Table 7. Example of decision matrix used to select the guideline on sexually transmitted infections

Preselected guideline	Consistent with scope and objectives of the proposed CPG?	Answers questions of the proposed guideline	AGREE II rating	Availability of search strategy	Language	Availability of GRADE evidence tables	Final GDG Decision
NICE 2017	No	Partially	Recommended	Yes	English	Yes	No
MSPS 2013	No	Yes	Recommended	Yes	Spanish	Yes	Yes

Source: Adapted from MSPS (2013).

The annex to the guideline to be developed should contain a summary of the process that led to selection of the guideline to be adapted. The guideline template in Annex 1 includes a model showing how the information should be presented.

2.11. The institution that developed the guideline authorizes its adaptation

The ministry of health of the respective country or interested institution should contact the institution that developed the original guideline to be adapted or the entity that owns the copyright (for example, publishers or development groups) to request authorization to begin the adaptation process. Partial or full permission may be requested. Some development groups charge a specific amount for the permit, in which case it is advisable to weigh whether or not it is appropriate to pay the fee, given the need for the guideline, the resources that could be saved compared to producing the evidence from scratch, the total cost, and the availability of other guidelines on the subject.

2.12. Inclusion of local evidence

To ensure the inclusion of studies that are relevant to the context where the guideline will be used, it is desirable to map regional and local evidence in order to enhance and support the academic discussion that will take place during the formulation of recommendations (Woolf, 1999). It is important to identify epidemiological data, patient preferences, patterns of use, and the costs of drugs and health and technology services related to the guideline's subject matter. This information can be found in local publications and national information systems and should be added to the body of evidence. In specific cases, it should be included in the GRADE evidence profiles. It is also important to include assessments of the technologies developed in each country on the guideline's subject.

2.13. Rapid adaptation of the selected guideline's recommendations in order to fit the implementation context

The principal advantage of the rapid adaptation process is that it maximizes resources and substantially shortens the time involved in the development of a guideline (Guyatt and Vandvik, 2014). Therefore, once a guideline that can be quickly adapted has been identified (published in the last 3 years with high-quality GRADE methodology and availability of evidence tables), and subject to approval of use, the members of the development group should proceed to validate the GRADE evidence profiles of the source guideline, in order to verify the evidence rating, the importance of outcomes, and ultimately establish the need either to update the profiles with local evidence, or use them as they are if no such need is determined.

Nevertheless, it is important to point out that a true adaptation process cannot and should not be interpreted as simply taking a set of recommendations verbatim, and then using them in a different context (Steffensen, Sørensen and Olesen, 1997). The guideline development group must bear in mind that adaptation requires a cross-cultural adjustment of the recommendations, which involves recognizing and critically assessing the evidence and local needs, in order to determine if it is necessary to assess the evidence differently or prioritize certain comparisons or outcomes that may be critical to the context where they will be adapted (Clancy and Cronin, 2005).

If the development group feels that the context specific to the development of the source guideline shares certain similarities to the specific environment where the proposed guideline is to be adapted and that the search strategies remain valid and appropriate, and included all the key terms, then it will not be necessary to perform a new search for international or local evidence as part of the adaptation process. Otherwise, a search will have to be performed and updated to identify relevant international or local studies that may change the direction or strength of the recommendations (Clancy and Cronin, 2005).

2.14. Adaptation with updated evidence

This section describes an overview of the process. The activities mentioned should be carried out by trained professionals with experience in systematic reviews and the GRADE methodology. For more information on the process, please refer to manuals on the subject such as the Cochrane Manual (Higgins, 2016); GRADE Manual (GRADE, 2017); the WHO Manual (WHO, 2014); the Colombian Methodological Guide to the Development of Guidelines (MSPS, 2014); the Brazilian GRADE handbook (MSB, 2011) or GuíaSalud (GuíaSalud, 2016) methodological guides to guideline development, etc. In addition, Annex 2 presents a map of tools that support the adaptation process, with the respective links.

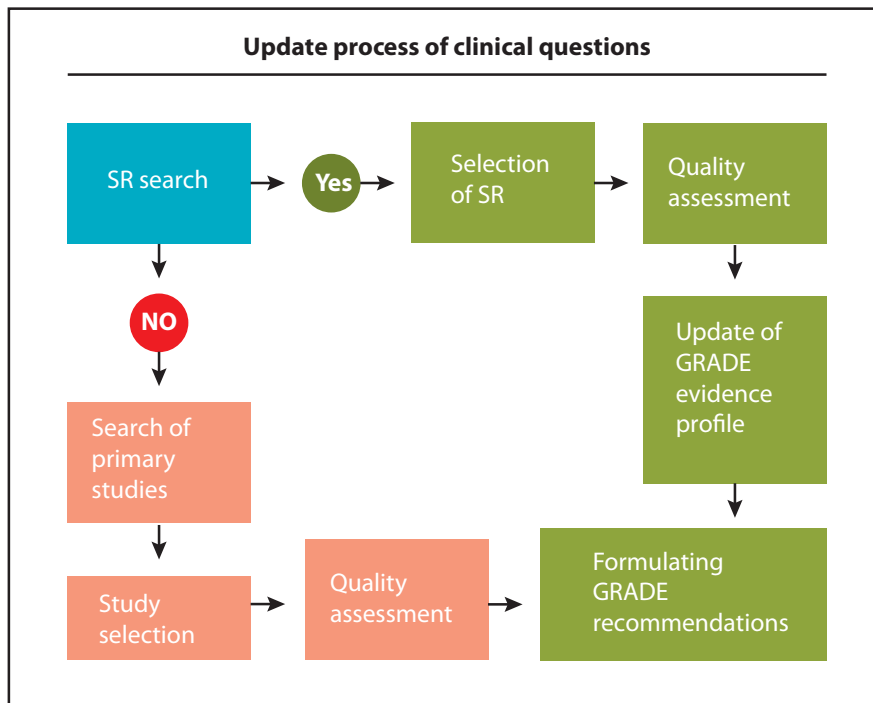
If an adaptable guideline is identified but is not up-to-date or does not use the GRADE system, the first step is to update the systematic search of selected questions based on their relevance, or of all of the guideline's questions, or conduct searches for any new questions that have been identified. The selected evidence

is subsequently evaluated, and GRADE evidence profiles are updated or developed.

To update clinical or public health questions, the development group should have sufficient human and technical resources as required for this process, as well as the necessary permits. With this in mind, the first step in updating the evidence involves replicating the search conducted for the primary guideline. However, on rare occasions it may be necessary to expand the search and include other sources of information, such as the Cochrane Database of Systematic Reviews (CDRS), MEDLINE, Center for Reviews and Dissemination (CRD), which includes the HTA database, Database of Abstracts of Reviews of Effects (DARE), and the NHS Economic Evaluation Database (NHS EED), LILACS, Econlit, EMBASE, or Google Scholar, following the guidelines found in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins, 2016). In this stage, the inclusion of any context-appropriate database or sources of information that may be relevant as a source of local evidence should be considered.

The results of the search should be documented, and the respective logs created and saved. The relevance of the retrieved references should be assessed, bearing in mind the inclusion and exclusion criteria, by two or more members of the development group (Higgins, 2016) who should retain the references with high-quality systematic reviews, with or without meta-analysis. If there are no studies of this nature, the development group may choose (depending on time and available resources) to include controlled clinical trials or observational studies. Figure 5 shows the process flow chart. The first step is to identify systematic reviews published since the selected guideline search date. If no systematic reviews are found or they are not up-to-date or of good quality, the next step is to conduct a search for primary studies.

Figure 5. Process for updating questions or searching new questions included in the guideline



2.14.1 Considerations for assessing the quality of the selected evidence

The quality of systematic reviews can be determined using the AMSTAR 2 tool (Shea, 2009) or the ROBIS tool (Whiting, 2016). To rank the risk of bias in the included studies, the Cochrane risk of bias tool can be used for clinical trials (Higgins, 2011). For observational studies, we recommend using the Newcastle-Ottawa scale due to its simplicity and versatility (Wells et al., 2009).

Finally, the synthesis of the selected studies should be carried out through the construction of the respective evidence profiles and the levels of evidence will be established according to the GRADE approach (Kavanagh, 2009).

To achieve transparency and simplicity, the GRADE system rates the quality of each outcome in one of four levels, as illustrated in Table 8 (Guyatt et al., 2011):

Table 8. Evidence quality based on GRADE methodology

Grade	Quality of Evidence	Meaning
A	High ⊕⊕⊕⊕	Further research is very unlikely to change our confidence in the estimate of effect.
B	Moderate ⊕⊕⊕○	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
C	Low ⊕⊕○○	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
D	Very low ⊕○○○	Any estimate of effect is very uncertain.

With the GRADE methodology, the evidence based on controlled clinical trials begins with high quality evidence, but confidence in the evidence may decrease for many reasons, including (Guyatt et al., 2011):

- Study limitations (risk of bias).
- Inconsistency of results.
- Applicability of evidence.
- Accuracy of results.
- Publication bias.

Despite the fact that observational studies (for example, cohort studies or case and control studies) are initially rated as “poor quality” evidence, their quality can be increased if the magnitude of the intervention’s effect is substantial, if there is a clear dose-response relationship, or if all plausible biases could have diminished the magnitude of the intervention’s effect (Guyatt et al., 2011). The site <https://gradepro.org/> has tutorials and a support manual on preparing evidence profiles.

The annex to the guideline should include the GRADE evidence profiles for each clinical question, following standardized guidelines. An example of a GRADE evidence profile with two outcomes (one on effectiveness and the other on safety) taken from the Guideline for the Management of *Helicobacter pylori* (Otero et al., 2015) is shown in Table 9.

Table 9. Example of a GRADE evidence profiles for a treatment question.

No. of studies	Design	Quality assessment					No. of patients		Effect		Quality	Importance
		Risk of Bias	Inconsistency	Direct evidence	Inaccuracy	Other considerations	Standard triple therapy	Other triple therapies	Relative (CI95%)	Absolute		
Outcome: Eradication of <i>Helicobacter pylori</i> (follow-up 4 weeks and thereafter; evaluated with: eradication of <i>H.pylori</i>)												
18	Randomized clinical trials	Very serious ¹	Not serious	Not serious	Serious ²	Publication bias ³	796/996 (79.9%)	906/1111 (81.5%)	RR 1.079 (0.748 to 1.557)	64 per 1000 (from -206 to 454)	Very low ⊕○○○	Critical
Safety of treatment (follow-up 4 weeks and thereafter; evaluated with: frequency of adverse events)												
16	Randomized clinical trials	Serious ¹	Not serious	Not serious	Serious ⁴	Publication bias ³	160/932 (17.2%)	183/1091 (16.8%)	RR 1.081 (0.848 to 1.378)	14 per 1000 (from -25 to 63)	Very low ⊕○○○	Critical

Authors: Hillock, L and Vallejo, MT

Date: 2015-06-22

Question: What is the effectiveness of standard triple therapy compared to other triple therapies for *Helicobacter pylori* infection

Population: Patients with *H.pylori* infection with no previous treatment

Bibliography: Wang B, Lv Z-F, Wang Y-H, et al. Standard triple therapy for *Helicobacter pylori* infection in China: a meta-analysis. World J Gastroenterol. 2014 Oct 28; 20(40): 14973–14985.

¹ All the studies have a Jadad score less than or equal to 3 (18/20 scores 1 and 2).

² Summary estimate confidence interval crosses 0.75 and 1.25.

³ Asymmetrical funnel plot.

⁴ Summary estimate confidence interval 1.25.

The tool in English to develop the profiles can be loaded from the page: <https://gradepro.org/>, and the GRADE manual is obtained in the Help> manual window.

2.15. Formulating recommendations

To formulate recommendations, the first step is to prepare a set of preliminary recommendations based on the risk-benefit balance, patient preferences, and the implementation context in each country, considering applicability. Next, these preliminary recommendations should be presented to and discussed by a panel of experts that also includes the representatives who helped to refine the recommendations and define the strength of the recommendations. Local data, evaluation of local health technologies, policy reports, implementation research, benefit plans, essential medication list and national programs should be considered when the recommendations of the guidelines are prepared.

It should be emphasized that the representatives of each and every one of the potential professional users of the guideline, such as scientific societies or decision-makers as well as patient representatives, should be invited to join the panel (Woolf, 1999). This process will ensure a sense of ownership of the guideline and its recommendations on the part of users, will contribute to the implementation of the guideline, and will reinforce the validity of the process (Clancy and Cronin, 2005; MSPS, 2013).

The panel receives information on the methodological process that led to the formulation of the recommendations, as well as the draft guideline with the GRADE evidence profiles. Using this information, the expert panel will decide on the final recommendation based on the context of implementation and strength of the recommendation according to the GRADE methodology.

The ranking of the strength and direction of each recommendation is determined based on the level of evidence and other additional factors. The panel considers the following factors to rank the strength and the direction of the recommendations:

- 1. Risk-benefit balance:** The effectiveness and safety of the interventions' outcomes are assessed.

2. **Quality of the scientific evidence:** Before formulating a recommendation, there is an analysis of confidence regarding the estimate of observed effect, based on the quality of the evidence on outcomes.
3. **Values and preferences:** Patient preferences are considered, given their importance when evaluating adherence to the recommendations.
4. **Costs:** This aspect is specific to each context where the guideline will be implemented since costs may differ. This is a relevant concern during the decision-making process and formulation of recommendations.

Once the aforementioned factors are evaluated, the strength of each recommendation is determined according to Table 10:

Table 10. Definition of strength and direction of the recommendation

Grade	Strong (for)	Weak/conditional (for)	Weak/conditional (against)	Strong (against)
Recommendation	The intervention should definitively be used	The intervention should probably be used	The intervention should probably NOT be used	The intervention should definitely NOT be used
Risk-benefit balance	The benefits clearly outweigh the risks	The benefits probably outweigh the risks	The risks probably outweigh the benefits	The risks definitively outweigh the benefits

Source: GRADE manual.

Annex 2 presents the links to the materials developed by GRADE, which will allow identifying the particularities of the process for formulating the recommendations in greater detail.

2.16. Incorporation of costs and patient preferences

During the adaptation process, the recommendations' impact on the use of resources should be considered. To this end, it is desirable that when compiling local evidence, data should also be collected on costs incurred from the interventions (Ramsey, 2002). The guideline should also include a patient representative. In addition, patient values and preferences should be identified, based on the regional context or specific disease (Van de Bovenkamp, 2009).

2.17. Guideline reporting format

It has been found that proper reporting in clear and simple language is one of the factors that facilitates the use of guidelines. To support guideline reporting and ensure compliance with the methodological guidelines, [Annex 1](#) includes the recommended guideline reporting template, which is based on WHO guidelines. This template can be accompanied by the evaluation of AGREE II so that the quality items of the report are fulfilled.

2.18. Inclusion of comments by external peer reviewers

Prior to publication, the guideline should be independently reviewed by peers who are ex-

perts in methodology and thematic content and can review and comment on the accuracy of interpretation of the evidence supporting the recommendations. The GDG should assess the relevance of each comment made by these peers and justify any disagreement (Mayden, 2012).

2.19. Resources for guideline developers

With the assistance of Epistemonikos, McMaster, and PAHO, the digital tool to support the guideline adaptation process is shown below. This tool can be found at <http://guidelines-map.epistemonikos.org/>.

Chapter 3: Implementation of guidelines

3.1. Introduction

Several terms have been used to describe the process of transferring scientific knowledge to decision-making by health service providers and patients under specific conditions. In Europe and North America, the terms “implementation science,” “knowledge transfer,” “knowledge exchange,” and “use of evidence” are commonly and interchangeably used. The term “knowledge translation” was made official in Canada based on the recommendation of the Canadian Institutes of Health Research (CIHR) and is defined as “a dynamic and iterative process that includes synthesis, dissemination, exchange [...] of application of knowledge to improve the health of Canadians, provide more effective health services and products and strengthen the health system” (CIHR, 2004).

Evidence translation should occur at different levels and should reflect the dynamics of how the health systems perform and how to make them more equitable, effective, and efficient. One of the key points is recognizing the need for all levels to use evidence as a fundamental element of the analysis and improvement of health systems (Bosch-Capblanch et al., 2012).

The formulation of specific recommendations in a guideline based on the best available evidence, which were developed by appropriate, recognized clinical teams using valid methodologies, does not guarantee their use by potential users and will therefore not impact the quality of care or health of the target population. Various studies have shown a low frequency of use of the recommendations for guidelines produced by recognized professional or government agencies (Grimshaw, et al., 2006; Francke, et al., 2008; Pinzón, 2013).

Guideline implementation, which is understood as the process of putting the proposed recommendations into use in clinical practice, involves making individual behavioral changes, as well as changes in institutional and social processes. It requires active, systematically planned and developed processes aimed at modifying the knowledge, competencies, and practices of health service providers and patients, while making the pertinent modifications in the service delivery system. These are clearly complex processes that should involve contextual factors, analyze barriers and facilitators, design pedagogical strategies, and very frequently create or modify administrative, regulatory, and legal processes, allocate professional and technical resources, and modify audit, control, monitoring, and evaluation processes (James, 1993).

When proposing changes in the practices, implementation becomes an exercise in political and social consensus-building that is dynamic, flexible, adaptable to change, and must be rigorous and able to produce measurable results. It challenges the operations and performance of institutions while entailing modifications in the evaluation of the outcomes obtained by health organizations and makes it possible to create new spaces for work, collaboration, management, and evaluation (Kristiansen et al., 2006).

This chapter describes various issues to be considered in the implementation of CPGs. For the most part, they should be considered by the guideline development group and included in guideline’s text. Similarly, they should be adjusted and adapted to local circumstances by the health care services or institutional providers in which the guideline is implemented.

3.2. Definition of terms

The terminology used in this document is based on the most frequently referenced definitions in the specialized literature (Davis, 2008).

- **Adoption:** Refers to the institutional decision and commitment to include the recommendations contained in the guidelines in clinical practice. This process tends to be undervalued by regulatory entities as well as health service providers. However, failure to define a sectoral or institutional policy in favor of implementing the guidelines negatively impacts the likelihood of success in implementation.

- **Publicity:** Refers to the information distribution processes that make the existence of CPGs and their recommendations known. The activities most frequently used include their presentation in the media or at meetings or events at the national, regional, local, or institutional level, posting them on websites, or sending hard copies. This activity is overvalued in some countries, sectors, or institutions, to the point of believing that just by informing service providers and patients of the existence of a guideline, the recommendations it contains will be utilized.
- **Dissemination:** This is an active process. It includes activities aimed at increasing the knowledge or skills of the end users of the guidelines. Besides distributing the information, it involves things like organizing workshops, discussing clinical cases, and presenting simulation scenarios. It is frequently undervalued by health system policy-making and regulatory agencies as well as by service providers and patients. To ensure the greatest likelihood of success, multiple resources should be allocated, and pertinent strategies formulated for each context.
- **Implementation:** Refers to actually putting the CPG into practice in order to implement the proposed recommendations, i.e. transferring the theoretical recommendations contained in the CPG to the work being performed in clinical practice. It involves combining effective communication strategies with strategies and activities aimed at identifying and overcoming barriers in a specific setting.

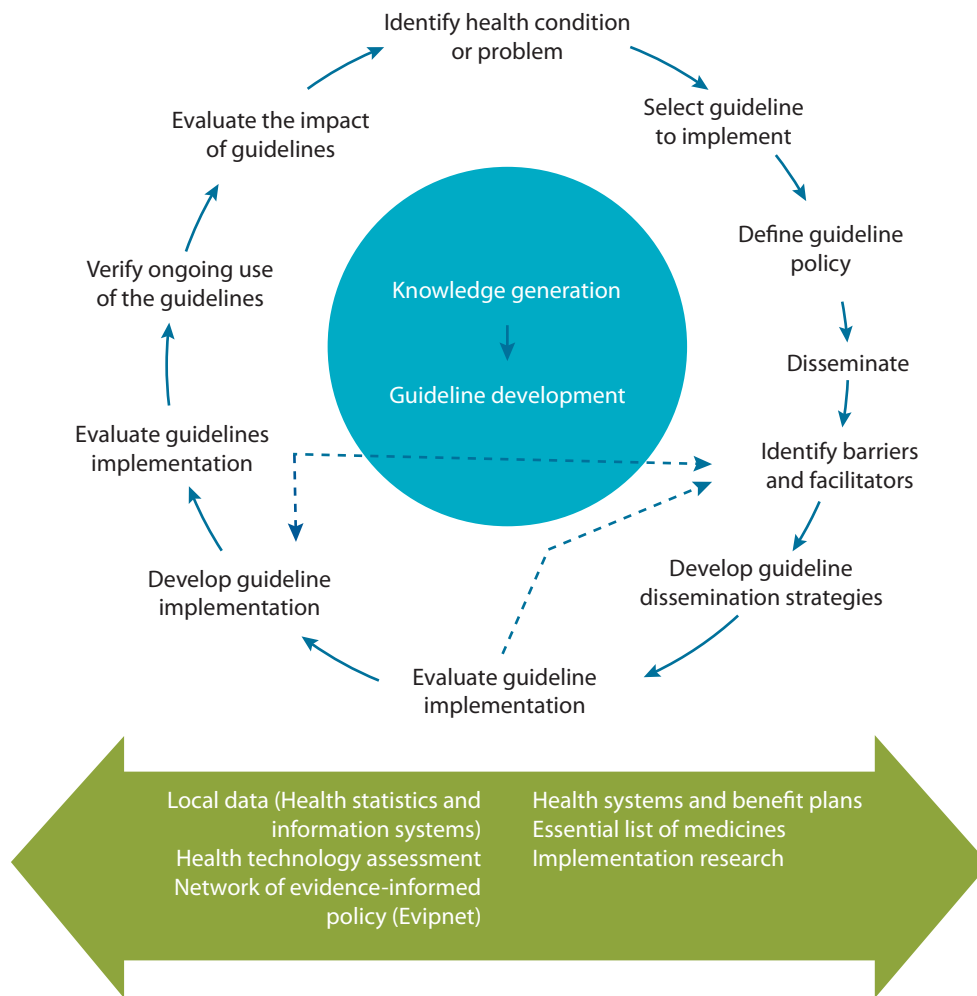
3.3. The implementation cycle

The process of implementing a CPG is an adaptation and expansion of the knowledge translation cycle (Graham, et al., 2006). It includes different steps or links, which are usually sequential (Figure 6). The process should begin with the identification of the health condition or problem to be addressed, the selection of the guideline to be implemented, the definition and dissemination of the adoption policy, dissemination of the guideline, identification of barriers and facilitators, development of dissemination strategies and activities, development of implementation-specific strategies, verification of ongoing use of the guideline, and assessment of implementation impact.

Once the impact has been assessed, new health conditions or problems that require intervention will be identified, with the option of starting the cycle over again. Dissemination and implementation strategies and activities per se may be the most sensitive links for ensuring the overall success of the implementation process, so it is also advisable to include the evaluation of these strategies or activities, which will provide an opportunity to reformulate or adjust them, if appropriate.

Local data, evaluation of local health technologies, policy reports, implementation research, benefit plans, essential list of medicines and national programs should be considered when the guidelines are implemented.

Figure 6. Implementation cycle for a clinical practice guideline



Note: Adapted from Graham (2016).

3.3.1. Guideline implementation policy

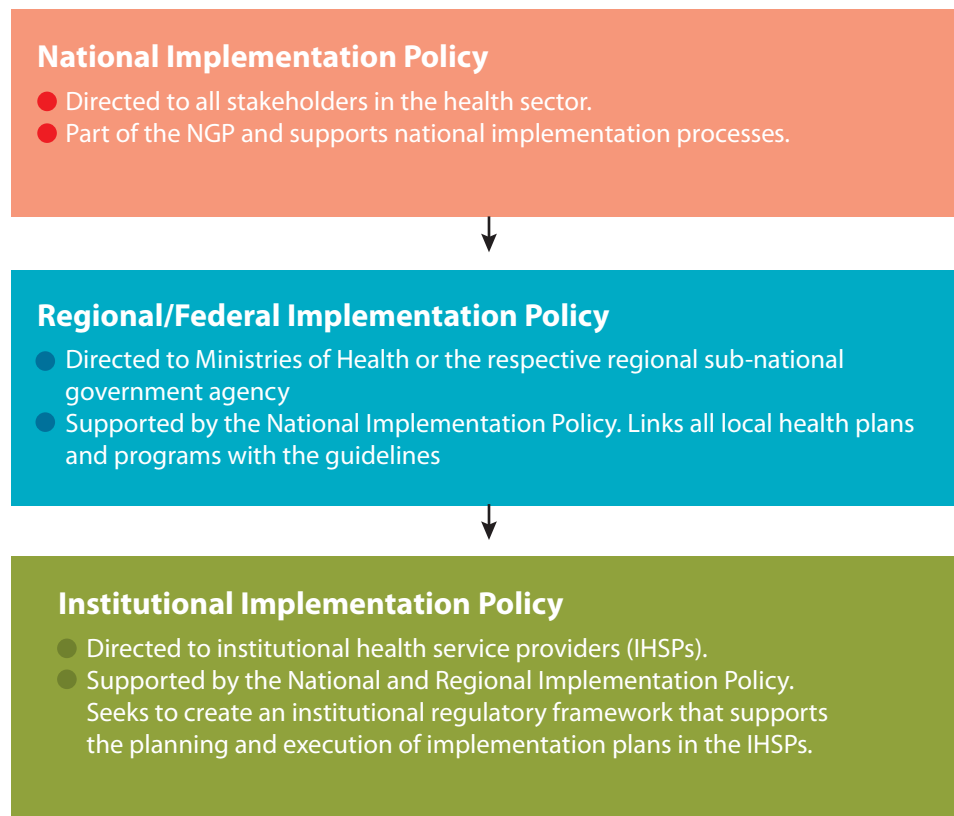
To support the implementation of the guidelines, a support policy should be formulated at three levels:

1. **National level:** As part of the activities of the NGP, it is necessary to provide a regulatory space for guideline implementation, in order to manage resources and create national guideline publicity, dissemination, and evaluation opportunities. The specific activities of this policy are described in Chapter 1.
2. **Sub-national, provincial, or federal regional level:** To develop a regulatory framework for decentralized health systems or regional governance, it is recommended to formulate a regional or federal implementation policy that links all health plans or programs for managing conditions/diseases with the guidelines, considering the network of providers and the lines of action. It should link the national implementation policy with the regional or federal context.
3. **Institutional level:** To support the implementation of the guidelines among institutional health service providers (IHSPs), there should be a clearly established implementation policy that provides

guidelines on the process within the IHSP, identifies the responsible parties, allocates resources, and demonstrates management's commitment to the guidelines. Moreover, it should ensure that the implementation of the guidelines occurs as a priority area in the IHSP and defines the composition of members of the Institutional Implementation Committee.

Figure 7 illustrates the relationships between the levels.

Figure 7. Levels of the implementation policy



3.3.1.1. Identification of stakeholders

Different stakeholders may affect or may be potentially or actually affected by the implementation of a clinical guideline. All of these stakeholders should be identified and involved in the strategic planning of the implementation process to make the success of the process more likely (Deaton, 2012).

A standard list of stakeholders may not be available for the implementation of a guideline, which will largely depend on the sector, care level, or institution where the guidelines is implemented. In general, representatives of policy-making or regulatory agencies, the development group, insurance companies or payers, local, regional, or national health services, directors of institutional health service providers, and particularly health service providers and patients or patient associations should be considered. In addition, an official should be identified to lead and be directly responsible for the implementation process in each institution, and there should be strategies that authorize this person to take on this role.

3.3.1.2. Development of an incentive plan

Incentives are different types of enticements that are offered at the individual, institutional, or sectoral level to encourage, motivate, inspire, or promote behavioral or performance changes, in this case the use of the recommendations contained in the guidelines. They are generally viewed as positive when they represent compensation, benefits, rewards, or prizes to those who demonstrate the desired behavior, or negative when they impose a cost or penalty on those who deviate from such behavior.

They are generally classified based on whether or not they provide a financial or monetary incentive. However, in a broader sense, several categories can be identified, which are generally grouped as follows:

- **Financial or monetary incentives:** These incentives link changes in behavior or performance to financial income. We recommend offering them in the positive sense, i.e., when the recommendations are used, in the right conditions, income increases. There are different experiences with both positive and negative health incentives, with different impacts tied to the base level of wealth in the country, the base income level of employees or institutions, or cultural and social conditions.
- **Reputational incentives:** These incentives link changes in behavior or performance to image or reputation. Like financial incentives, they may be positive or negative, and may contribute to improving or reducing recognition and social acceptance.
- **Legal incentives:** These incentives link changes in behavior or performance to legal issues. Through certain legal prerogatives, they may help motivate a behavior or discourage or punish a behavior through sanctions.
- **Ethical-professional incentives:** These incentives link changes in behavior or performance to ethical and professional issues. They are very common in the delivery of health services. In the case of CPGs, a powerful incentive is using the recommendations to fulfill a responsibility in clinical practice while seeking to improve patient health.

The design, planning, and implementation of an incentive plan, as well as the selection of the type or types of incentives to offer will depend on the social, political, and financial context in which a CPG is to be implemented. It may be identified for a specific level or include activities at different levels. For example, a specific incentive plan may be set up for an institutional health service provider, or at the local, regional, or even national health level.

3.3.2. CPG dissemination

As mentioned earlier, this refers to information distribution processes that facilitate communicating the existence of the CPGs and their recommendations. We currently have several information distribution channels and emphasize those that use electronic resources or media. To encourage their availability and use, the distributed materials should be accessible to end users of the CPG, i.e. health service providers and patients.

3.3.3. Identification of barriers and facilitators

In the context of CPG implementation, barriers are those factors that may impede, limit, or obstruct the proposed recommendations from being implemented in the practice, or prevent health professionals and patients from adhering to them. These barriers may be intrinsic, which means that they have to do with the methodology used to develop and present the CPG, or extrinsic, meaning barriers that refer to the context in which the guideline will be implemented. On the other hand, facilitators are considered to be factors that encourage or are conducive to the changes.

There are different proposed classifications and theoretical frameworks for the study of barriers and facilitators (Cabana et al., 1999; MCI, 2009a). Similarly, CPG implementation manuals around the world propose different strategies and activities for dealing with them (New Zealand Guidelines Group, 2001; Scottish Intercollegiate Guidelines Network, 2011). In general, we can assume that barriers and facilitators are related to the specific characteristics of the guidelines per se, as well as the beliefs, attitudes, and practices of health professionals and patients, or the local and sectoral circumstances in which the CPGs are implemented and maintained.

The identification and assessment of barriers and facilitators helps execute local implementation plans focused on the context-specific factors that have the most likelihood of success, without having to consider all potential factors or all factors that have been described (Van Bokhoven, Kok and van der Weijden, 2003).

The techniques most frequently used to identify barriers and facilitators include brainstorming (Flottorp and Oxman, 2003), techniques based on the Delphi methodology (Anselm et al., 2005; Ortiz et al., 2003), nominal group techniques (Davis et al., 2008), surveys (Newton et al., 2007), interviews (Kedward y Dakin, 2003; Hobbs y Erhard, 2002), focus groups (Robertson, Baker and Hearnshaw, 1996; Flores et al., 2000; Flortorp and Oxman, 2003), direct observations (Freeman and Loewe, 2004), case studies (Wiener-Ogilvie et al., 2008; DeGross et al., 2008), and key informant interviews (Wan et al., 2008). Several of these techniques frequently need to be used together to help ensure the reliability, accuracy, acceptability, and mainstreaming of the information obtained.

The success of guideline implementation largely depends on the identification of barriers, the formulation of efficient strategies to overcome them, and the identification and use of facilitating factors. Barriers as well as facilitators are context-dependent. This imposes significant differences in the implementation processes, for example, between high- and low-income countries, as well as between cultural groups within each country or region. There is a clear need to use implementation strategies with known effectiveness that consider context and available resources (Gagliardi and Alhabib, 2015).

In low- and middle-income countries, the most effective strategies for the implementation of informed interventions can be grouped as follows (Pantoja et al., 2017):

- **Strategies for health workers:** Training sessions, continuing education, clinical practice facilitators, opinion-makers on the subject, audits and interventions adapted to the implementation context, educational materials.
- **Strategies for health workers dealing with specific problems:** Training for health care professionals aimed at improving practices such as antibiotic management.
- **Strategies for patients:** interventions in national and local settings, disease management programs to increase knowledge on health topics, interventions based on technology (tablets, cell phones, e-mail) to create behavioral changes in the population, reminders, one-time incentives, community education, information provided by insurance companies.
- **Strategies for health care service providers:** Strategies aimed at improving the organizational environment.

Various systematic reviews have explored barriers and the strategies for overcoming them (Bero et al., 1998; Fisher, 2014; Jun, Kovner, Stimpfel, 2016; Tricco, 2017). A conceptual framework of different types of barriers was recently developed, which divides them into three categories: barriers related to clinicians' knowledge, barriers related to attitudes, and external barriers. The reviews conclude that there is no single intervention for overcoming them. Multiple activities are required to facilitate change and achieve the expected results. Their effectiveness depends on the implementation context. It was generally found that multiple strategies (several components) are the most effective (Grol and Grimshaw, 2003; Fisher et al., 2016). Table 10 summarizes the barriers, interventions, and strategies for overcoming them, as identified in the literature.

Table 11. Strategies to eliminate barriers

Barrier level		Barriers	Interventions	Strategies
Personal factors related to clinician knowledge and attitudes	Clinician knowledge	No awareness of guidelines	Increase dissemination of guidelines at the national level. Use mass media campaigns to increase knowledge of guidelines. Virtual or in-person continuing education.	Dissemination strategies: <ul style="list-style-type: none"> • Standard dissemination (sending the guideline by e-mail, putting it in national repositories). • Dissemination of training materials.
		No familiarity with guidelines	Make the guideline available with practical tools such as summarized versions and mobile applications. Printed algorithms. Virtual or in-person continuing education focused on specific guideline recommendations.	Continuing education. Learning activities for experts and opinion makers. Educational meetings. Individualized feedback and performance evaluation of the guideline. Combining guideline with quality assurance.
	Clinician attitudes	Lack of agreement	Support opinion makers. Involve clinicians in the development of the guideline. Sponsorship of the guideline by scientific societies and patient organizations. Small group learning.	Educational meetings. Educational visits. Promotional visits. Identification of opinion makers. Reminders. Opportunities for financing.
		Lack of self-efficacy	Continuing medical education on improving tools. Group training, interactive learning. Individual and group evaluation of performance, positive feedback during training and in practice, assistance with problems and questions.	Dissemination of materials. Educational visits in the workplace. Feedback. Audits.
		Lack of tools	Continuing medical education on improving tools. Audit and feedback on individual performance.	
		Lack of learning culture	Promotion of learning within organizations.	
		Lack of confidence in the result	Audit and feedback from all staff. Presentation of successful experiences with the implementation of guidelines.	
		Lack of motivation	Motivational strategies that use financial or non-financial incentives. Support opinion makers.	

Barrier Level	Barriers	Interventions	Strategies
Guideline-related factors	Lack of evidence.	Use of EBM methods in the development of guidelines. Evaluation of the evidence that informs the recommendations. Regular updates.	Use of EBM methods. Communication strategies for developers and users of the guideline. Social marketing visits. Use of computerized decision-making systems. Reminders. Pilot testing of guideline implementation.
	Feasibility of recommendations in the implementation context.	Short version for guideline use. Checklists.	
	Complex Hard to read.	Simplify the guideline, short presentation, and algorithms. Use of user-friendly reporting forms.	
	Access to the guideline.	Provide easy access to the guideline. Use systems to support decision-making.	
	Lack of applicability.	Use tablets, cell phones to obtain the guideline recommendations.	
	Focused on patients with simple diseases. Exclusion of patients with complex diseases.	Co-morbidity considerations in the guidelines.	
	Lack of clear objectives.	Present the objectives, scope, and specific goals of guideline implementation.	
External factors	Organizational restrictions.	Process and procedure standardization. Guideline development should consider the implementation context. Combine with quality assurance procedures.	Improvements in health service delivery organizations.
	Lack of resources (time, staff, administrative support, financial resources).	Financial and non-financial incentives. Presentation of activities and responsible parties. External facilitation (consultancies).	Administrative support. Institutional implementation policies.
	Lack of collaboration.	Improvement of work team communication and collaboration.	Adaptation of guideline to local, national and/or institutional context.
	Social and clinical context.	Local consensus group.	Local agreement between groups. Incorporation of the guideline into established structures.

Source: Adapted from Fisher 2016, PAHO IPIER Report, National Experiences.

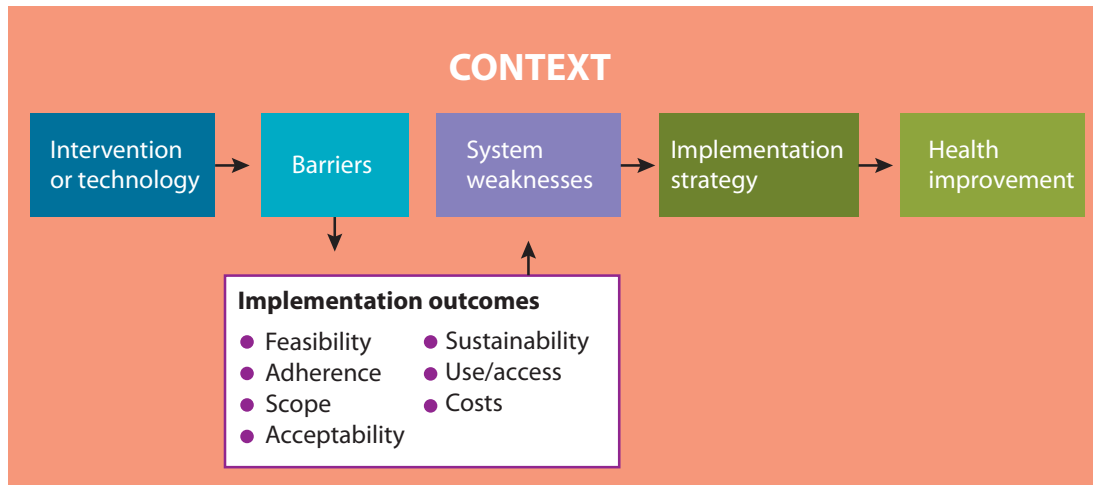
3.3.4. Identifying and addressing health systems weaknesses

A health program or model of care is responsible for implementing different guidelines and multiple recommendations. Some health system weaknesses are a crosscutting concern that affects the implementation of all guidelines and other program activities (for example, operation of surveillance systems, technical capacity, regulations, etc.). For this reason, it is essential to broadly assess health system weaknesses in the context of the health program. Figure 8 illustrates the role of identifying weaknesses in the system as part of the implementation process.

To ensure that this process is effective, implementation research provides tools to support the strengthening of programs: identifying barriers, facilitators, and program implementation strategies associated with

the system's weaknesses; helping stakeholders produce evidence with high methodological rigor; strengthening technical capacity; and evaluating the impact of implementation. An important factor in being able to perform a good analysis is the multisectoral work done by implementers, investigators, and decision-makers (Tran et al., 2017).

Figure 8. Implementation process considering weaknesses in the health system



There are several initiatives of the Pan American Health Organization, the World Health Organization, and the Alliance for Health Policy and Systems Research such as the one for health policy and system research. This initiative, as its name indicates, facilitates improvements in the implementation of health programs, policies and systems in Latin America and the Caribbean through the work based on implementers, and the development of an iterative process for generating evidence on implementation considering all components and integrating the findings into the programs for the purpose of strengthening the health system and achieving the expected health outcomes (Tran et al., 2017; Langlois et al., 2017).

3.3.5. Dissemination

This is one of the most relevant processes for ensuring successful implementation. It is developed with end-users of the CPG (health service providers and patients) and should lead to capacity building on the use of the recommendations contained in the guidelines. There is complexity inherent to capacity building, which is understood as the set of knowledge, skills, and attitudes used in the decision-making process in practice, along with the specific characteristics of the context in which the health services are provided.

Frequently, it is assumed that capacity building by optimizing the skills of individuals and providers is ongoing as part of the professional development process. However, often, capacity building strategies and activities to modify the previous clinical and public health activities are required to allow for the guideline to be updated and put into practice (Yost et al., 2014).

As in the case of professional development, there is no single dissemination strategy, and in most of cases, multiple activities must be combined. Some of these are individual activities (e.g., reading the guidelines) and many others are done in groups (e.g., simulation workshops and trainings).

3.3.6. Assessing dissemination

Dissemination should be assessed. This is where the complexity involved in assessing competencies and capacities appears, since knowledge, attitudes, skills, and the decisions that will be made in the practice must be assessed. As with capacity-building, dissemination will involve combining multiple activities. The decision to move forward in the cycle or go back to redefine barriers and facilitators and subsequently redefine the dissemination strategies will depend on this assessment (Shayo et al., 2014).

3.3.7. Implementation

Although all the elements described thus far are part of the implementation process, there is a time when the recommendations will begin to be used for decision-making in daily practice, with real patients, and in actual treatment settings. This is the actual implementation phase, i.e., putting the guideline into practice.

This step, in addition to involving end-users of the guideline, entails having made the pertinent adjustments to institutional or sectoral processes at both the operational and administrative level, in addition to having an information system for capturing the data required to evaluate the impact of the CPG.

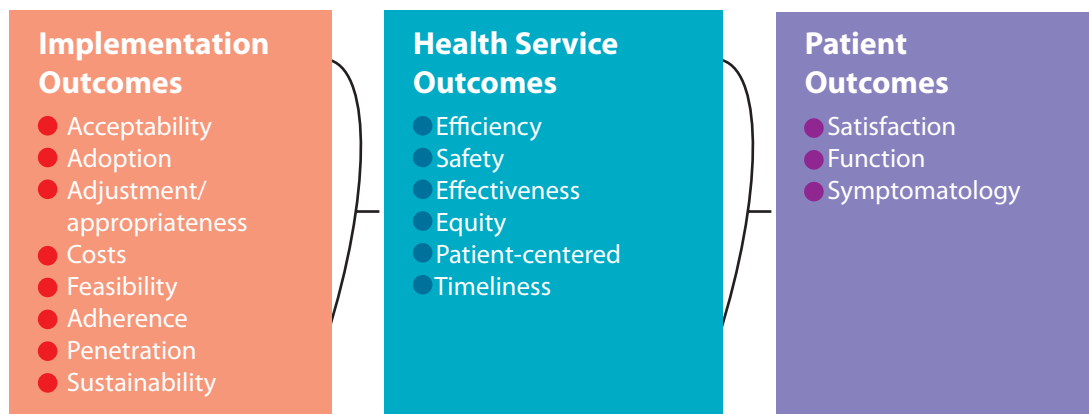
The first step in implementing the guideline in institutional health service providers is forming an implementation committee that will be in charge of planning and carrying out the activities included in the implementation plan and managing resources.

Certain tools, available in physical or electronic formats, related to the preparation of the clinical history facilitate the implementation process. Some examples of frequently used tools are reminders available at the clinician's office, alerts linked to the clinical history software, and flow charts.

3.3.8. Evaluation of implementation

The conceptualization and evaluation of successful implementation remains an unresolved issue in the field of implementation science (Proctor et al., 2011), especially since implementation outcomes are not differentiated from those that have to do with the impact on services or the client. A conceptual framework for evaluating implementation has recently been proposed, which emphasizes outcomes specific to implementation. Figure 9 illustrates these outcomes by type, followed by definitions.

Figure 9. Types of outcomes in implementation research



Source: Adapted from Proctor, 2011.

- **Acceptability:** This refers to the perception of the people involved in the implementation process, that a treatment, service, or practice is pleasant or satisfactory.
- **Adoption:** This refers to the intention, initial decision, or action taken in an attempt to use an evidence-based innovation or practice.
- **Adjustment/appropriateness:** This refers to the perception regarding how appropriate the change or innovation is for an institution, provider or consumer, when addressing a particular issue or problem.
- **Costs:** This refers to the impact of implementation costs (incremental costs).
- **Feasibility:** This refers to how a new treatment or innovation can be successfully used.
- **Adherence:** This refers to the degree to which an implemented intervention is prescribed as originally proposed.
- **Penetration:** This refers to the integration of a practice into a service and its subsystems.
- **Sustainability:** This refers to the degree to which a newly implemented treatment is retained or institutionalized.

The evaluation of implementation should contribute elements that make it possible to move forward in the cycle or go back to identifying barriers and facilitators or to the development of new implementation strategies.

3.3.9. Confirm the ongoing use of the CPG

Once the implementation process is complete and has been evaluated, the next step is to verify the ongoing use of the CPG, prior to assessing the impact of the CPG's implementation. The results obtained will contribute information for the interpretation of this evaluation.

3.3.10. Evaluate the impact of CPG implementation

The evaluation of the impact of implementing the CPG is based on an assessment of the categories included in the quality of health care, i.e., structure, process, and outcomes (Donabedian, 2005).

Accordingly, structure indicators will make it possible to assess the characteristics of the health system that affect its ability to implement the recommendations or that are affected after the CPG has been implemented. Process indicators will help assess the fulfillment of the recommendations proposed in the CPGs, and outcome indicators will facilitate assessing the impact on patient health. Outcome indicators may refer to intermediate outcomes, when they assess changes in biological variables such as how often blood pressure goals are achieved in hypertensive patients or glycosylated hemoglobin goals are achieved in diabetic patients, or final outcomes when they assess clinical outcomes such as the frequency of patients with rheumatoid arthritis who are in remission.

In order to streamline efforts and the investment of resources in the health systems, the number of indicators to be used should be limited and should be linked to information systems on quality or quality assurance. We recommend a maximum four per guideline (one for each type of indicator).

Operationally, there should be an indicator table that includes the type of indicator, the name of the indicator, the operational description for calculation purposes, the frequency of calculation, the primary sources, and the targets.

Table 12. Indicator table example

Type of Indicator	Indicator Name	Operationalization	Frequency	Primary source	Target
Structure	Number of users per rheumatologist	Number of users (members and beneficiaries) of the HPA/ Number of full-time rheumatologists hired to treat users of the HPA	Annual	HPA	Less than 50,000 users per rheumatologist
Process	Percentage of patients with Rheumatoid Arthritis (Codes ICD-10: M058, M059, M060, M068, M069) that start treatment within four (4) months from the onset of symptoms	(Number of patients with a clinical diagnosis of Rheumatoid Arthritis (Codes ICD-10: M058, M059, M060, M068, M069) that begin a DMARD recommended by the guideline within four (4) months from the onset of symptoms/ Total number of patients with a clinical diagnosis of Rheumatoid Arthritis (Codes CIE-10 M058, M059, M060, M068, M069))*100	Annual	IHSP	First year: 50% Third year: 70%
Outcome	Percentage of patients with Rheumatoid Arthritis (Codes ICD-10: M058, M059, M060, M068, M069) in remission	(Number of patients with a clinical diagnosis of Rheumatoid Arthritis (Codes ICD-10: M058, M059, M060, M068, M069) with EULAR remission criteria / Total number of patients with a clinical diagnosis of Rheumatoid Arthritis (Codes CIE-10 M058, M059, M060, M068, M069) *100	Annual	IHSP	First year: 20% Third year: 50%

Source: Adapted from the clinical practice guide to the early detection, diagnosis, and treatment of rheumatoid arthritis (MSPS, 2016).

HPA: Health promotion agency.

IHSP: Institutional health service provider.

The implementation of the CPG is expected to lead to a change in the state of the condition or health problem that led to selection of the CPG, which means there will be a new health situation that will provide the basis for restarting the cycle.

3.3.10.1 Assessment of compliance with the guidelines under the Quality Assurance System Framework

As mentioned earlier, the guidelines should fall within the framework of Quality Assurance Systems (QAS) to support their implementation and institutionalization. To assess compliance with the guidelines, the creation of a module as part of the QAS evaluation is proposed. This will make the measurement of these guideline indicators official, as part of the quality processes of institutional health service providers (IHSPs) and will support the assessment of guideline implementation at the national level.

The chapter on implementation of the guidelines report (Annex 1) should indicate which indicators are related to adherence to facilitate measurement by the responsible persons in the IHSPs and Ministries of Health.

In order to not overload the QAS, given the large number of guidelines, we recommend prioritizing the indicators that measure compliance with the guideline recommendations in the health system, which will serve as a guideline implementation proxy and will make it possible to monitor this process. Each country should have a manual on measuring indicators of compliance with the guideline recommendations, and identifying who is responsible at the national, regional subnational, and institutional level, as well as the indicators to be measured and the measurement methodology.

3.4 Institutional implementation plan

When the guidelines are to be IHSPs, there must be an implementation plan to create step-by-step instructions on how to introduce the guidelines, considering any implementation barriers, strategies, and facilitators, and taking into account the IHSPs' resources and context.

The implementation plan is the set of instructions that should be followed to put into practice and properly disseminate the guideline within each institutional health service provider. Moreover, the implementation plan should identify actions and who is responsible for them in each stage of the process (MSPS, 2014).

Following the recommendations of the *Manual para la implementación de guías en el marco del aseguramiento colombiano* [Manual for the implementation of guidelines as part of Colombian quality assurance (MSPS, 2014)], the following is an overview of the implementation process in an institutional health service provider:

- Select the guideline to be implemented based on the need to improve patient care as a priority or as criteria for accreditation.
- Form an institutional implementation committee in charge of planning and executing the implementation plan, which should be comprised of the professional responsible for implementation in the IHSP (for example, the head of the quality office) as well as users of the guidelines, which will depend on the guideline topic. The committee should also include a representative of management.
- Identify the recommendations to be implemented: may be found in the guideline or identified based on those that demonstrate variability in the usual practice compared to the recommendations in the guideline.
- Identify implementation barriers to and facilitators of the selected recommendations.
- Identify resources and the incentive plan.
- Monitor the adoption of the recommendations using the indicators proposed in the guideline, or specific indicators may be developed.

To formulate this plan, we recommend using the implementation plan form found in the *Manual para la implementación de guías en el marco del aseguramiento colombiano* (MSPS, 2014) or *GuíaSalud* (GuíaSalud, 2017).

To support the implementation of guidelines in the institutional health service providers, an institutional implementation policy should be formulated, which should:

- Ensure that the implementation of the guidelines occurs as a priority administrative order.
- Appoint a representative who will set up and support the Implementation Committee.
- Create institutional policies to support the implementation process.
- Introduce the guidelines as part of the quality assurance process.
- Include the progress made in the work agendas.

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Annexes

ANNEX 1

Guideline Reporting Template.

Title

EXECUTIVE SUMMARY

Rationale

Objectives

Methodology

How to use this guideline

Each clinical question includes a group of recommendations and good practices with indications for the management of [fill as appropriate]. Each recommendation shows the quality of the evidence based on the GRADE system:

Grade	Definition
High ⊕⊕⊕⊕	We are very confident that the true effect lies close to that of the estimate of the effect. Further research is very unlikely to change our confidence in the estimate of effect.
Moderate ⊕⊕⊕○	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low ⊕⊕○○	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect. Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very Low ⊕○○○	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

The recommendations also include the strength of the recommendation based on the GRADE system:

Strength of recommendation	Meaning
Strong for an intervention	The desirable effects clearly outweigh the undesirable effects. RECOMMENDED
Weak for an intervention	The desirable effects probably outweigh the undesirable effects. SUGGESTED
Weak against an intervention	The undesirable effects probably outweigh the desirable effects. NOT SUGGESTED
Strong against an intervention	The undesirable effects clearly outweigh the desirable effects. NOT RECOMMENDED

Recommendations

This guideline provides recommendations for [disease or condition]. The following recommendations apply to [fill as appropriate].

Recommendations with * have been selected as key recommendations for the implementation process.

QUESTION 1

Degree of recommendation	No.	Summary
	1	Quality of the evidence:

Introduction

[1 page]

Scope and users

This clinical practice guideline provides evidence-informed recommendations for [fill as appropriate].

The recommendations are directed to [fill as appropriate]. The guideline is intended for use by decision-makers and members of government agencies for the purpose of facilitating the implementation process.

This guideline will not include [fill as appropriate].

Theoretical framework and rationale

[2 pages]

Objectives and target population

This clinical practice guideline was developed with the following objectives:

The target population is comprised of:

Methodology

Composition of the development group

Thematic experts in [fill as appropriate] participated in the group. In Annexes of the worksheet [A. Development group](#) lists the complete development group (CDG).

Declaration of conflicts of interest

All members of the development group, the panel of experts, as well as the individuals that participated in the external review, signed a conflict of interest form. The assessment of conflicts appears in Annexes of the worksheet [B. Summary assessment of conflicts of interest](#).

Declaration of editorial independence

The Ministry of [fill as appropriate] and [fill as appropriate] did not influence the development of this guideline.

Decision on new development or adaptation

The GDG conducted a systematic literature search in order to identify all national and international CPGs that addressed XX and have a scope and objectives similar to those proposed for this guideline. The quality of the retrieved CPGs was evaluated using the AGREE II Instrument (Brouwers et al., 2010) and each document was independently rated by two evaluators to determine the overall quality of the guideline. The next step was to decide, using a decision matrix (Ministry of Health and Social Protection, 2016), if there was an existing guideline that could be adapted. The decision matrix considers the following issues: The identified guidelines should bear a relationship (align) with the scope and objectives of the CPG to be developed; they should be recommended based on the AGREE II tool; they should have evidence; be published within the last 4 years; and should use the GRADE approach.

Based on the results of the decision matrix, the guideline will be adapted. The required authorization was obtained to use the evidence profiles of the selected guidelines to be adapted.

The report on the process of selecting the guidelines to be adapted can be found in Annexes of the worksheet [C. Adaptation decision](#).

Formulation of clinical questions on the clinical practice guideline

The GDG, comprised of thematic experts and epidemiologists, reviewed the relevant clinical issues to be addressed and formulated preliminary generic questions which were subsequently compared with the selected CPGs and converted to specific questions by structuring them in the PICO (population, intervention, comparison, and outcomes) format. The PICO questions can be found in Annexes of the worksheet [D. PICO questions](#).

The GDG conducted an outcome prioritization exercise in order to identify the most important outcomes that should be included. Clinical outcomes on safety, effectiveness, quality of life, and anything important to patients were identified and prioritized. Each outcome was classified as critical, important but not critical, or not important to patients based on a scale of nine units proposed by the GRADE group (Guyatt et al., 2011; World Health Organization, 2014).

Rapid CPG adaptation process

Following the international methodologies proposed by this PAHO/WHO, a rapid adaptation process was developed, which is aimed at maximizing CPG resources and development times. Once the questions to be answered were identified in the guideline, the next step was to find local evidence and fill out this template. The GRADE evidence profiles were reviewed in order to identify the need to either update them or use them as they appear in the original guideline.

Formulation of recommendations

The recommendations were formulated in two steps. First, the GDG prepared the preliminary recommendations considering the risk-benefit balance, patient preferences, and the implementation context in each country, taking local evidence into account. Second, the recommendations were discussed and adjusted by an expert panel with representatives of users and patients who helped to refine the recommendations and define their strength.

Good practices

Good practices are operational suggestions based on the experience of the GDG and the GRADE work groups in which different interest groups participated. Although not evidence-based, they are part of the good practices for the diagnosis, treatment, and follow-up of patients. The purpose of good practices is to support the formulated recommendations.

Incorporation of costs and patient preferences

This guideline included local data on costs and conducted a search of patient values and preferences in Latin America.

Inclusion of comments from external peer reviewers

This CPG was independently reviewed by peers who are experts in methodology and thematic content.

Acknowledgments

Financing

Recommendations

Example

Question 1. What are the effects of lactoferrin in preventing the occurrence of retinopathy of prematurity (ROP)?

Summary of the evidence

The search identified a Cochrane systematic review (AMSTAR 11/11) that evaluated the effectiveness and safety of oral lactoferrin with or without probiotics compared to a placebo in the prevention of sepsis and necrotizing enterocolitis in premature newborns. The authors of the review included four clinical trials on the use of oral lactoferrin in any dose or duration, while the comparison was either the use of a placebo or not conducting the intervention (Pammi & Abrams, 2015). Based on the study results, the review found significant differences in favor of using oral lactoferrin in the incidence of ROP compared to the placebo (1 study, RR 0.35, CI95% 0.14 to 0.85), although no differences were found when comparing lactoferrin plus probiotics against the placebo (1 study, RR 0.76 CI95% 0.39 to 1.49). No adverse events were identified in premature newborns (Pammi & Abrams, 2015).

Factors that may strengthen a recommendation	Observation
Quality of the evidence	The quality of the evidence is poor due to limitations in the direct evidence and accuracy (Annex [fill as appropriate]. Table [fill as appropriate]).
Balance between desirable and undesirable effects	The group considers that the use of lactoferrin orally or in breast milk provides benefits to premature children given its protective factor in the occurrence of ROP. No adverse events were reported.
Values and preferences	The patient representative (evidence on patient preference) reports that any intervention that leads to the prevention of ROP and thus prevention of blindness in infants should be used.
Costs (allocation of resources)	Colombia reports that lactoferrin has a low cost and is included in the Compulsory Health Plan, which means that there is no additional expenditure to neonatal units.
Acceptability and feasibility	The group considered that neonatal unit staff have the supplies and the expertise to follow the recommendations.

Recommendations

Grade of recommendation	No.	Summary
Weak in favor	1	<p>The administration of oral lactoferrin is suggested due to its effect on reducing the incidence of ROP in the countries in which it is available.</p> <p>Quality of the evidence: Very low ⊕○○○</p>

Updating the guideline

The recommendations in this guideline should be updated in the next four years or sooner in the event there is new evidence that would modify the recommendations made herein.

In the update, we recommend searching and synthesizing evidence on [fill as appropriate]:

The following clinical trials were identified in the WHO International Clinical Trials Registry Platform (ICTRP):

Title	Code

Implementation plan

Stakeholders responsible for implementation of the CPG recommendations

The first step in implementation is to identify and create a list of the stakeholders responsible for the process.

- 1.
- 2.
- 3.
- 4.

This section includes an example of barriers and strategies for the implementation of the ROP Guideline. This information was obtained based on the information in Table 10 of this manual.

Implementation barriers

Human resources	There is a small number of pediatric ophthalmologists and retina specialists in Latin America, which affects adherence to the screening recommendations.
Awareness of the CPG	The health professionals are not aware of the CPG or where to find it.
Lack of supplies	Not all countries have medicines in the recommended dosages, which may affect the health of newborns.
Access	In remote areas, there is little access to specialists and to timely treatment and follow-up.

Implementation strategies

Training:	It is recommended that training sessions be offered at the institutional, association, and government level. Trainings may be either on-site or virtual in order to facilitate the training of neonatal care professionals.
Development of materials:	There are different ways to disseminate the guideline recommendations, such as informational brochures, posters, etc.
Digital reminders in clinical histories:	The key recommendations to be implemented in each institution appear when opening each premature child's clinical history.
Support policies:	Most of the countries in the region have technical standards, national programs, and laws intended to support the implementation of clinical practice guidelines for the prevention of retinopathy of prematurity.
Electronic systems to support decision-making:	The guideline may be included in mobile applications, institutional electronic newsletters, or on specialized web pages supporting the quick reference process.
Audit and feedback:	The purpose of this strategy is for each unit to have an ROP contact in charge of verifying adherence to the guideline recommendations.
Classical dissemination:	The guideline may be presented to interest groups and potential users.
Administrative support:	The management of each institution should support CPG implementation activities so that they can be satisfactorily carried out.

Indicators

The process and outcome indicators on implementation of the CPG appear below.

Item	Description
Indicator 1	
Type of indicator	
Description of indicator	
Calculation method	
Frequency of measurement	
Responsible party (monitoring)	

Item	Description
Indicator 2	
Type of indicator	
Description of indicator	
Calculation method	
Frequency of measurement	
Responsible party (monitoring)	

Item	Description
Indicator 3	
Type of indicator	
Description of indicator	
Calculation method	
Frequency of measurement	
Responsible party (monitoring)	

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Annexes to the template

A. Development group

To develop the adaptation of the evidence-based clinical practice guideline (CPG) for retinopathy of prematurity, a multidisciplinary team was formed in order to support the formulation of recommendations following the highest methodological standards.

1. Leaders
2. Thematic team
3. Epidemiological team
4. Patient representative
4. Peer reviewers
6. Panel of experts formed during the 2nd Latin American Summit on Prematurity, Bogotá 2016.

Name	Specialty	Position	Affiliation

B. Summary assessment of conflicts of interest

The following shows the assessment of the conflict of interest forms completed by each member of the development group, as well as the decision reached by leaders.

Name	Role in the guideline	A. Specific and/or nonspecific personal financial interest	B. Specific and/or nonspecific non-personal financial interest	C. Personal non-financial interest	D. Specific and/or nonspecific personal financial interest of a family member	Any other circumstances that could affect your objectivity or independence in the process?

C. Adaptation decision

Methodology

Based on internationally recommended guidelines, the methodology used in this phase appears below.

1. Systematic search of clinical practice guidelines (CPGs)

A systematic highly sensitive search was conducted in order to identify clinical practice guidelines (CPGs) on the topic, including institutional, national, and international CPGs, which are directed to health professionals and patients.

1.1 Sources of information

In accordance with the thematic specificity of the search, the following electronic resources were selected as a source of information:

Databases of CPG development organizations and compilers

- Guidelines International Network (GIN)
- National Institute for Health and Clinical Excellence (NICE)

- National Guideline Clearinghouse (NGC)
- New Zealand Guidelines Group (NZGG)
- Scottish Intercollegiate Guidelines Network (SIGN)
- American College of Physicians (ACP)
- National Health and Medical Research Council (NHMRC)
- Institute for Clinical Systems Improvement (ICSI)
- Canadian Medical Association (CMA)
- GuíaSalud

Biomedical databases:

- MEDLINE
- EMBASE

Generic search engines:

- Google
- Google Scholar

2. Evaluation of CPG quality and implementability of the recommendations

2.1 Evaluation of the quality of eligible CPGs

Once the eligible guidelines were identified, their quality was evaluated using the AGREE II instrument.

3. Decision on adaptation or new development

Once the aforementioned steps were taken, informal consensus meetings were held with the team for the purpose of determining whether the adaptation process was feasible, or if not, whether new development was necessary.

Results

Systematic search of existing CPGs

As a result of the search process, [fill as appropriate] references were found; after titles and summaries were reviewed and full texts were obtained and reviewed, [fill as appropriate] eligible guidelines were found which could be adapted:

[fill as appropriate]

Evaluation of CPG quality and Implementability of the recommendations

Once the eligible guidelines were identified, their quality was evaluated using the AGREE II instrument.

This table shows the consolidation of the quality evaluation process for each guideline, based on the items and domains included in the AGREE II instrument.

Summary of the quality evaluation of eligible clinical practice guidelines

Name of guideline	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Domain 6	Overall evaluation	AGREE II recommendation
	Scope and objective	Participation of stakeholders	Rigor of development	Clarity of presentation	Applicability	Editorial independence		

Final decision matrix - Possibility of implementing the CPG

Once the aforementioned steps were taken, informal consensus meetings were held with the guideline development team to determine whether the adaptation process was feasible, or if not, whether new development was necessary. To this end, the GDG consolidated the completed activities and created a decision matrix, which included the items described in the methodology section.

Table. Summary of Decisions

Guideline	Consistent with the scope and objectives of the CPG	Answers relevant questions of the CPG	AGREE II rating	Availability of search strategies	Availability of evidence tables	Implement	Decision of the GDG

D. PICO questions

Question on risk factor

Q:		
Population	Risk factors	Outcomes

Question on diagnosis

Q:		
Population	Diagnostic technique/Index test	Outcomes

Question on therapeutic intervention

Q:		
Population	Intervention/Comparator	Outcomes

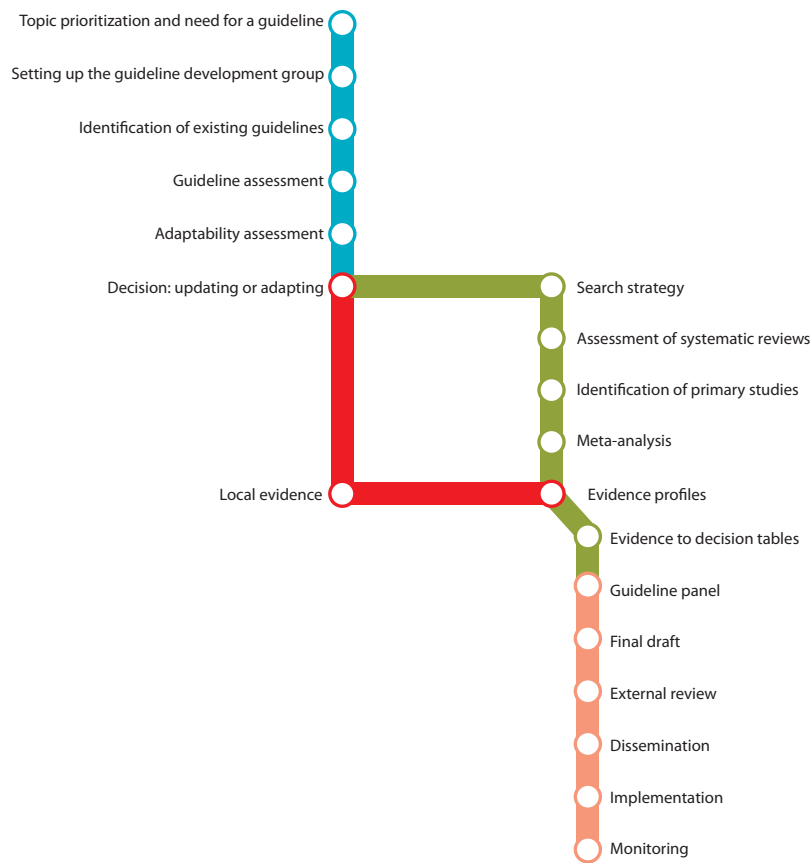
Tools for adaptation and implementation of guidelines

In order to summarize Chapter 3 and support the adaptation processes of guides with resources developed worldwide, a tool map is presented.

With the support of Epistemonikos, McMaster and OPS, the tools of the guide adaptation process are presented below. This chapter contains links to the original sources and chapters of this document. The complete tool can be found at: <http://guidelines-map.epistemonikos.org/>

ANNEX 2

Map for guideline adaptation



General information

General information about GRADE guidelines

- GRADE manual
- GIN-McMaster checklist for the development of guidelines

Guideline authoring tools

There are two main software packages developed to support the guideline process:

1. GRADEpro GDT (the official GRADE software)
2. MAGICapp

Guideline tools developed by Epistemonikos (also listed below in the pertinent steps):

- **GRADE guidelines repository:** Hundreds of GRADE guidelines, thousands of Summary of Findings tables, and all the evidence supporting them in one place (step: Identification of existing guidelines and Adaptability assessment).
- **Epistemonikos database:** The largest database of health evidence (step: Search strategy).
- **PDQ-Evidence:** A version of Epistemonikos for health systems questions (step: Search strategy).
- **L.OVE:** A new platform with all the evidence needed for guideline development, continuously updated (step: Search strategy).
- **Values and Preferences database:** This database provides a one-stop shop for guideline developers, researchers and clinicians searching for evidence about how patients value health outcomes (step: Local evidence).
- **iSoF - Interactive Summary of Findings:** The key information you need to understand the benefits and harms of treatments (step: Evidence profiles and Evidence to decision tables).
- **iEtD - Interactive Evidence to Decision Frameworks:** The iEtD tool facilitates use of EtD frameworks by guideline developers, health technology assessment agencies, policymakers and managers (step: Evidence to decision tables and Guideline panel).
 - iEtD is integrated in MAGICapp and GRADEpro GDT.

Topic prioritization and need for a guideline

Topic prioritization and need for a guideline

Setting up the guideline development group

Identification of existing guidelines

Guideline assessment

Adaptability assessment

Decision: updating or adapting

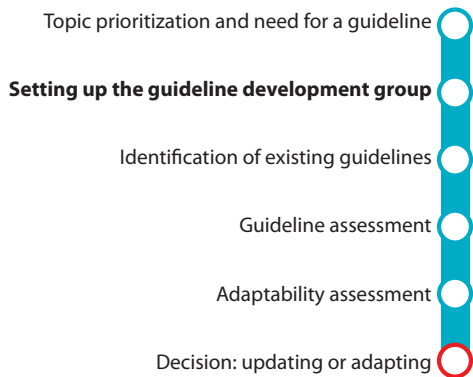
The need for a guideline can arise from different sources. However, in scenarios with resource limitations the first step is usually to prioritize between topics. This prioritization between health problems or conditions should incorporate all relevant stakeholders. They must address the need for guidance on their region/country and decide if a guideline is necessary. To correctly prioritize a health problem, it is essential to determine the importance of the particular topic and to estimate the potential impact of the document when implemented.

The World Health Organization has published the following criteria to assist in the prioritization of topics:

- Important interventions that could make a substantial impact on health systems.
- The underutilization of an intervention that maintains health indicators below expectations.
- Interventions that are not based on the best clinical evidence but are still widely used in the region.
- The presence of a new health intervention for which health professionals do not have updated information.
- Significant clinical variability across the region.

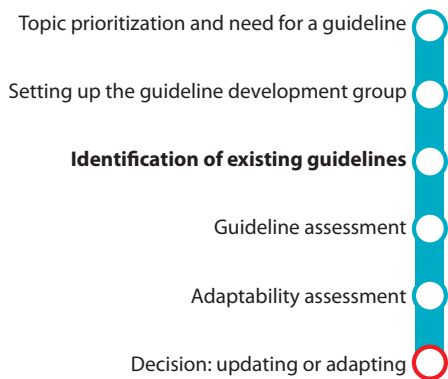
The intention of the guideline should be to improve poor practice or try to change clinical practice or health policies. The target audience and scope of the document should be defined as early as possible.

Setting up the guideline development group



When a guideline is found, its methodological quality must be determined in order to decide if can be adopted, adapted, updated, or discarded. The development group should present the panel the key recommendations of the guideline and introduce the quality assessment of the guideline. The AGREE II instrument is recommended as a tool to achieve these objectives.

Identification of existing guidelines

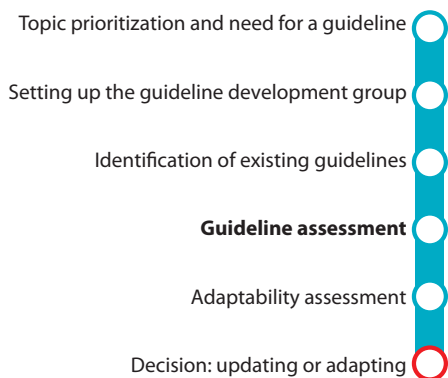


At least two authors should screen all potentially relevant guidelines. The development group should assess the relevance, timeliness, and quality of these reports.

Many guidelines cover a limited number of questions, and not all the guidelines cover the same questions. So, all high-quality guidelines must be retained for the next steps.

Relevant tools: GRADE [Guidelines repository](#) [Back to top](#).

Guideline assessment

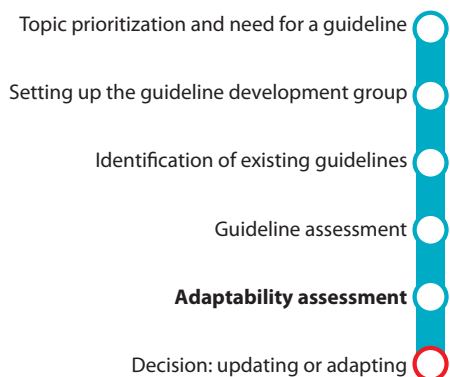


When a guideline is identified, the development group should present the local panel of experts two documents:

- 1. Key recommendations:** This document contains all the recommendations included in the original guideline, including the overall quality assessment and strength of each recommendation. The recommendations will be ranked with a number between 0 and 10 by the local panel; lower scores mean that the intervention is entirely irrelevant to the local context and higher values mean that the recommendation is critical.
- 2. Methodological quality of the guideline:** Using the [AGREE II instrument](#), the development group should present the overall methodological quality of the document to the panel.

Relevant tools: [AGREE II instrument](#), [GIN-McMaster Guideline Development Checklist](#).

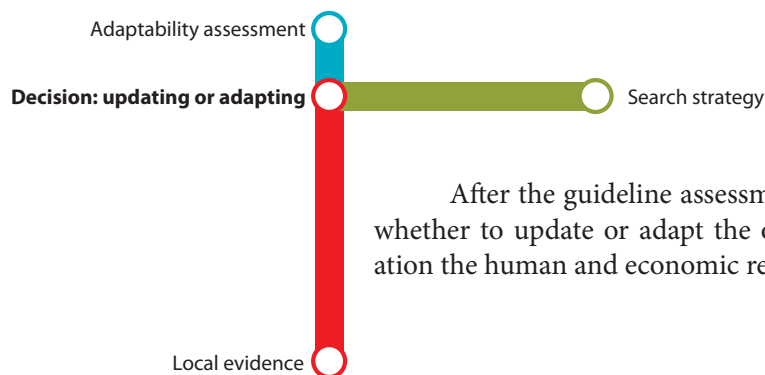
Adaptability assessment



The development group, with the local panel, should now decide if the original document should be adapted, updated, or discarded. As part of the adaptability assessment, the panel should focus on the provision of evidence profiles, the evidence to decision tables, the inclusion of the primary outcomes defined by the local group, the language of the original document, and the necessity of including local evidence to the evidence to decision table.

If the local panel feels that a key recommendation is missing, the development group should assess the possibility of developing it.

Decision: updating or adapting



After the guideline assessment, the development group must decide whether to update or adapt the original document, taking into consideration the human and economic resources needed for both processes.

Search strategy

If the decision is to update a current guideline, the recommendations need to be based on the best available evidence.

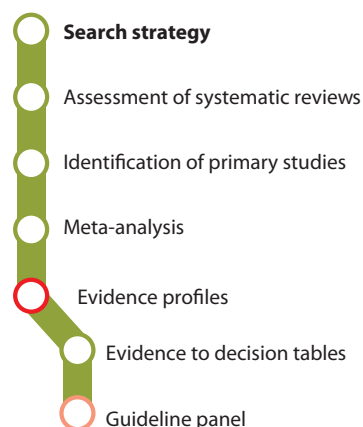
The purpose of the search strategy is to identify all published and unpublished studies pertinent to the health topic. Gray literature should also be included in the search strategy. The protocol of the systematic search should describe the databases used and the search strategy applied to each one of them.

The preferred approach is to identify existing systematic reviews, instead of conducting a new systematic review.

One alternative is to perform a systematic review of the literature for some specific questions to be updated.

Relevant tools:

- [Epistemonikos database](#)
- [PDQ-Evidence](#)
- [L.OVE](#)



Assessment of systematic reviews

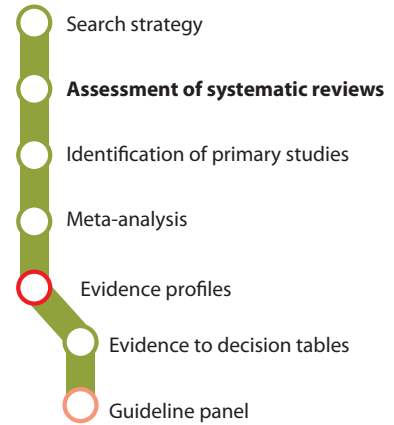
At least two authors should screen all potentially relevant systematic reviews to evaluate if they meet the inclusion criteria. Once the screening has finished, and all systematic reviews are retrieved, the development group should assess the relevance, timeliness, and quality of these reports. To determine relevance, the PICO question is useful. To evaluate the quality of a systematic review, authors can use several checklists, like [the Risk of bias in systematic reviews \(ROBIS\)](#) or [the Assessment of multiple systematic reviews \(AMSTAR\)](#).

If several reviews address the same clinical question, the development group should use the most recent, the most complete, or the highest-quality review.

The process of identification, screening, and identification must be documented. The inclusion of a PRISMA workflow provides a visual summary of the process.

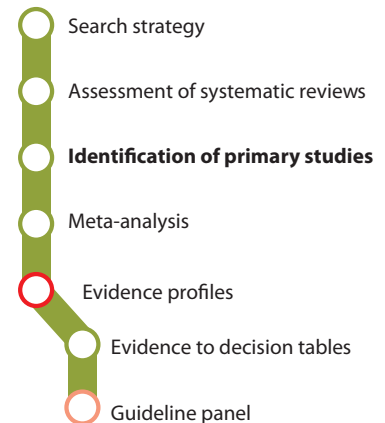
Relevant tools:

- [Epistemonikos database](#)
- [AMSTAR](#)
- [PRISMA](#)
- [ROBIS](#)



Identification of primary studies

Primary studies not included in existing systematic reviews should be identified to update the evidence profiles, the evidence to decision tables, and the recommendations. If the most recent systematic review identified in the literature systematic search is older than two years, an update of the search of primary studies is encouraged, including gray literature.

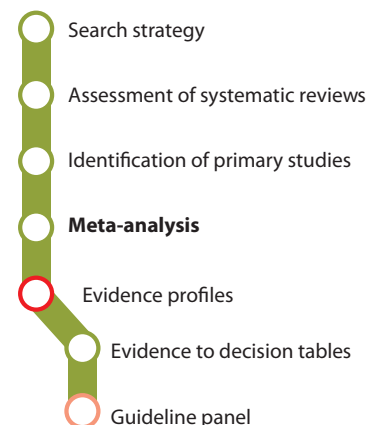


Meta-analysis

The development group should update the previous meta-analysis reported in the original guideline with the addition of the new evidence identified.

The authors have to extract the data from the systematic reviews or primary studies for each clinical question. This data should be added to the results showed in the original guideline to update the evidence profile.

With the new body of evidence (the data presented in the original guideline plus the data from the new systematic reviews or primary studies), the development group should assess the possibility of conducting a meta-analysis.



Meta-analysis is a statistical procedure that integrates the results of several studies. By combining information from all relevant studies, meta-analyses can provide a more precise estimate of the effects of health interventions than those derived from individual studies. The results are usually displayed in a figure called a forest plot.

Evidence profiles



The GRADE approach is used to create the evidence profiles. This process involves two main steps: (1) the evaluation of the quality of the evidence and (2) the summary of findings tables.

The quality of evidence is defined as the “extent to which one can be confident that an estimate of effect or association is correct.” When assessing this item, it is important to evaluate the study design, the consistency of the results across the studies, the precision of the results, the directness of the evidence, the likelihood of publication bias, the magnitude of the effect, the presence of a dose-response gradient and the direction of plausible biases. The quality of evidence is categorized as high, moderate, low, or very low.

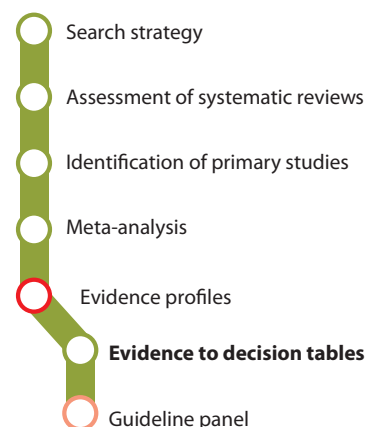
The second step consists of the [summary of findings table](#). This chart shows the results of the studies, using both relative and absolute measures, indicating the total number of patients in each group, the total number of events, an estimate of the control group risk, the effect size and the quality of evidence for each outcome.

Relevant tools:

- [GRADEpro](#)
- [iSoF](#)

Evidence to decision tables

The development group presents the evidence to decision (EtD) tables to the panel. The purpose of these tables is to help the group to make recommendations to move from evidence to decision. The EtD tables must inform the committee members’ judgment about pros and cons of each intervention and ensure that important factors that condition a decision are considered. These tables also provide a summary of the best available evidence to inform judgments about each criterion, help structure discussion, and identify reasons for disagreements and make the basis for decision transparent to guideline users.



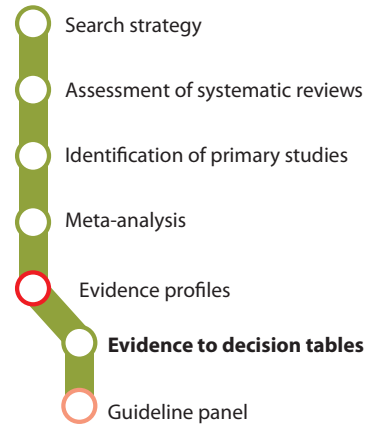
The EtD tables include key background information, criteria for making a decision, and conclusions.

Relevant tools:

- Key DECIDE Tools.

Guideline panel

The leader of the development group presents the evidence profiles and the EtD tables to the local panel to elaborate the final recommendations. The panel should determine the direction and strength of the final recommendations using the GRADE methodology, based on four key factors presented in the evidence profiles and EtD tables: the balance between benefits and harms, quality of evidence, patients' preferences and values, and resources considerations (including equity and feasibility). The panel should decide the final redaction of the recommendations.



Final draft

The development group should write the final draft of the clinical guideline. This draft must contain the evidence profiles and the evidence to decision tables. The local panel should comment on this draft, and if any change is needed, the development group should do it. It is essential that both the local experts and the development group agree on the final manuscript of the document before sending it for external review.



External review

The guideline should undergo peer review before final publication.

Experts that are neither in the development group nor on the local panel should perform the external review. The development team needs to be clear about what changes can be made in the draft.

The recommendations should not be modified during this process. It is suggested that changes in the manuscript should be limited to significant errors of facts.

The development group should be transparent regarding the handling of comments and changes during this process. After the external revision, a second draft may be necessary.



Dissemination

Once the development group has a cleared, edited, and corrected document, the manuscript can be sent for layout. Different types of designs and formats can be used to publish the guideline, but the WHO recommends that all guidelines should have an executive summary, the main body, and appendices, following the

1-3-25 rule (executive summary of 1 page, the main guideline of 3 pages, and appendices of 25 pages).

The executive summary is often read as stand-alone document, so the key recommendations, with the quality of evidence for each recommendation, should be specified in this part as well as in the main body of the guideline.

Implementation

The implementation of the guideline should be taken into consideration from the beginning of the development process. The implementation will be the responsibility of local or regional groups, following the implementation plan decided by the division or department that commissioned the project. The necessary steps for implementing a guideline are:

1. Analyze local needs and priorities.
2. Identify all potential barriers and facilitating factors.
3. Determine available resources.
4. Design a strategy to support the adoption of the recommendations and to make the overall context favorable to the proposed changes.

Monitoring

Guidelines are usually issued with an update plan. Regarding this issue, there is no rule about the length of validity. The WHO recommends a minimum of two years and a maximum of five, but it is essential to take into consideration the pace of change of research on the topic. Also, areas in which no evidence has been found and the potential need of new advice are essential to make a final decision on the length validity of the guideline.

It is clear that whenever new key evidence regarding an intervention involved in the guideline is published, the recommendation should be reviewed.

The Epistemonikos database allows to link the clinical questions of the guideline to existing systematic reviews, and to detect reviews published after the publication of the document, allowing an automatic identification of new evidence.

Relevant tools:

[Epistemonikos database](#)

Local evidence

Adapting/updating the original guideline requires the addition of local evidence (local epidemiology, patient's values and preferences, resources utilization).

The local panel of experts usually provides the local evidence to supplement the evidence to decision tables.

Evidence regarding local epidemiology, patient's values and preferences, utilization of resources involving the interventions, and feasibility is gathered and analyzed to elaborate the recommendations.

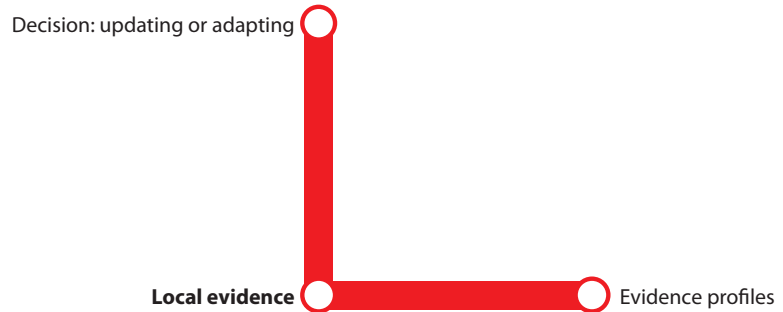


This step is crucial to successfully adapt an international document to the local context.

The amount of international research covering these topics is increasing, so it is becoming common to find research on the local context, or in a similar context. Some databases grouping these type of research are emerging.

Relevant tools:

- [Values and Preferences database.](#)



About us

Who are we?

The following people have contributed to the development of the map for guideline adaptation in the annex material:

- Ludovic Reveiz (Pan American Health Organization), Alonso Carrasco-Labra (McMaster University), Romina Brignardello (McMaster University), Gabriel Rada (Epistemonikos Foundation, and Centro Evidencia UC at Pontificia Universidad Católica de Chile), Juan Vásquez (Epistemonikos Foundation), Tomás Sáez (Epistemonikos Foundation), Marcelo Pérez (Epistemonikos Foundation), Ignacio Pineda (Centro Evidencia UC at Pontificia Universidad Católica de Chile), focusing on a model for adaptation suited for low-income countries and/or settings with limited technical resources and methodological expertise.
- We also thank the following people that have provided invaluable feedback: Iván Flores, Ignacio Neumann, Ariel Izcovich.
- Some of the methodological strategies included in this project were described in the ADOLOPMENT framework.

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