



# Clinical practice guidelines: a qualitative study of their implementation in the Chilean health system\*

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## ABSTRACT

**Objective.** Characterize the implementation process, barriers, and facilitators of evidence-based recommendations in the context of developing clinical practice guidelines (CPGs) generated by the Ministry of Health of Chile, in order to make proposals to optimize the process.

**Methods.** Qualitative “action-oriented research” study. Nineteen semi-structured interviews were conducted and nine discussion groups were organized at various levels of the Chilean public health system. The analysis was conducted using Atlas.ti<sup>®</sup> software and manually, in a content analysis framework, by categorizing and coding information according to pre-specified dimensions and with the inclusion of emerging categories where relevant.

**Results.** The main challenge mentioned with regard to implementing recommendations is the lack of an explicit and structured process. Actors in the health system recognized difficulties specific to the context in which the recommendations are followed. In this unprecedented institutional review, participants suggested a series of strategies that could be implemented to address these challenges, presented in a management flowchart optimized for CPG development and implementation. This process has raised awareness of the importance of implementing CPGs in Chile.

**Conclusion.** After characterizing the implementation process, barriers, and facilitators, a plan to implement recommendations was developed in order to orient and monitor the process. Including key informants inside and outside of the Ministry of Health in the review process would facilitate the implementation of strategies and the introduction of improvements to the CPG development process. Studies of this kind should be conducted with physicians and patients in order to complement the collected information.

## Keywords

Practice guidelines as topic, health systems, Chile.

Clinical practice guidelines (CPGs) are a set of recommendations based on a systematic review of the evidence and on a

risk-benefit evaluation of the different alternatives, aimed at optimizing health-care provided to patients (1). Multiple

studies have shown that CPGs have the potential to transfer knowledge, reduce clinical variability, and improve health-care quality. However, in order to achieve these objectives, implementing the CPG recommendations must be feasible (2).

As part of its health system reform, in 2005 Chile passed the Explicit Health Guarantees (known by the Spanish acronym GES) Act, which guarantees access, timeliness of care with defined waiting periods, financing, and quality for

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a series of health problems, prioritized according to burden of disease, effectiveness, cost-effectiveness, and social preferences. However, these prioritization criteria are not compulsory (3). Under the Health Authority Act, one of the functions of the Ministry of Health (MINSAL) is to establish healthcare protocols, which are intended to serve as a reference (4). Consequently, MINSAL has taken on the development of CPGs for each health problem falling under the GES Act; its Disease Prevention and Control Division is responsible for developing these CPGs, with support from the Department of Explicit Health Guarantees and of Evidence-based and Methodological Coordination.

A study carried out in 2016 aimed to evaluate the methodological quality of the CPGs formulated by the Disease Prevention and Control Division, using the Appraisal of Guidelines for Research and Evaluation (AGREE II) instrument. After the AGREE II evaluation, it was concluded that the guidelines were, in general, of moderate to poor quality, with low scores on rigor of development (41.4%), applicability (33.6%) and stakeholder involvement (51.3%) (5).

Due to these results, MINSAL decided to draw up a plan to improve CPG quality, reviewing aspects of their development and implementation. As a first step, Chilean and international experts were invited to prepare a methodological manual for CPG development, using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) method (6, 7). At present, this “guidelines guide”—mainly focused on describing a development methodology adhering to international quality standards, addressing general implementation strategies—is being disseminated and implemented.

The second action planned by the ministerial expert team was to analyze and optimize the implementation of the recommendations contained in the 82 CPGs, formulated at MINSAL, provided for in the GES Act. The present study analyzing the current implementation process aimed to generate proposals to optimize the process of implementing the recommendations contained in evidence-based CPGs. The specific objectives were to: 1) define a methodology for diagnosing the challenges of implementing MINSAL’s guideline recommendations; 2) apply this methodology in order to obtain a

diagnosis of the current implementation challenges; and 3) propose strategies for addressing these challenges at different levels of the health system.

## MATERIALS AND METHODS

A qualitative methodology was used—one in line with the action-oriented research model—aimed at solving the problems defined, in a parallel process that considers the complexity of the observed phenomenon. In the context of the present study, the implementation of recommendations was understood to be a strategic process including educational, social, organizational, technological, and financial elements (8). In practical terms, the purpose of the implementation process was to translate the CPG recommendations into everyday clinical practice.

Since the team considered it essential to examine the situation in depth, 19 semi-structured interviews were conducted, along with nine discussion groups. Representatives from different levels of the Chilean public health system were included (figure 1), encompassing officials, decision-makers, public policy designers, and civil servants from administrative health agencies having different degrees of complexity. The selection of participants sought to achieve a balanced representation of different institutions and regions.

This study was approved by the Ethics Committees of the Central Metropolitan Health Services, MINSAL, and the Pan American Health Organization (PAHO). A standard informed consent process was designed, according to which each subject of the study was informed, consulted, and agreed to participate.

The instruments designed were organized around four pre-specified dimensions: ideas and opinions about CPGs in general, and in Chile; CPG design and preparation; CPG management and dissemination; and CPG implementation. Details on the content of the interviews, discussion groups, and dimensions addressed are described in figure 2. Field work using the instruments was carried out by collaborators (anthropologists and sociologists), who received training on the subject of the study and on the instruments.

Different ethical safeguards were incorporated into the study design: in the discussion groups, senior officials did not meet together with technical

specialists, taking care to consider the balance of power between individuals and their positions; moreover, the field researchers were from outside the institutions with ties to the study.

Analysis of the interview and discussion group transcripts was conducted manually and using Atlas.ti® software, in a content analysis framework, categorizing and coding the information according to pre-specified dimensions, and including emerging categories when relevant.

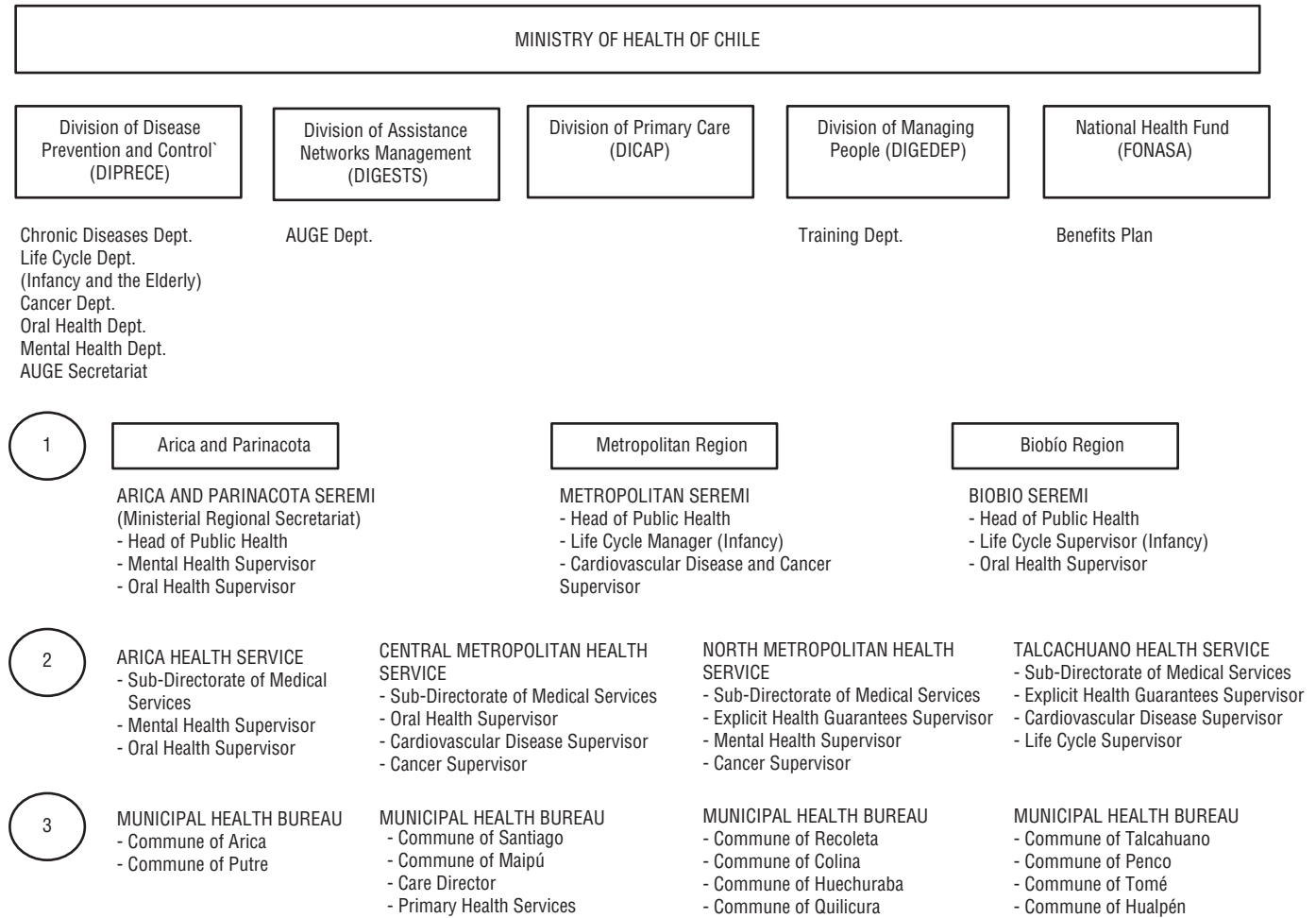
Researchers from the University of Chile and MINSAL met in two workshops where they analyzed the findings in order to draft both general conclusions and conclusions for different levels. Furthermore, qualitative indicators were generated which served as inputs for a workshop to share the results with key individuals in the process of developing and implementing CPGs at the public and academic levels. This workshop generated specific action proposals for the CPGs’ effective implementation. The teams’ joint efforts enabled a discussion which led to the implementation of the study results by these same key actors. This experience made it possible to carry out an exhaustive process of institutional self-analysis at the ministerial level.

The workshops’ results were analyzed by the Department of Explicit Health Guarantees and of Evidence-based and Methodological Coordination, to pinpoint the challenges identified, express them in clear language, and suggest strategies that would make it possible to address them over time, as well as to define a plan to optimize the process of implementing the recommendations contained in the CPGs drawn up by MINSAL.

## RESULTS

The selection of the study subjects was made taking into account their roles and functions within the institutions to which they belonged. Data collection techniques were applied at the national level, with samples from the regions of Arica and Parinacota (north), Biobío (south), and the Metropolitan Region (the capital), with the intention of obtaining information on the implementation challenges faced in different areas within the health system. Subsequently, general conclusions were formulated on

**FIGURE 1. Levels of the Chilean health system included in this study, by geographical area and institutional division**



**FIGURE 2. Thematic guidelines followed in the interviews and discussion groups**

Thematic guidelines for the discussion groups
<ul style="list-style-type: none"> <li>• What are the difficulties and advantages of the design and preparation of the CPGs in your departments (programs)?</li> <li>• How far along is the process of disseminating the CPGs among end users?</li> <li>• How far along is the process of implementing the CPGs among end users in your respective programs?</li> <li>• What proposals could you make for these processes?</li> <li>• What is the impact of geographical distance? (When appropriate)</li> </ul>
Thematic guidelines of the in-depth interviews (dimensions)
<ul style="list-style-type: none"> <li>• Ideas and appraisals regarding the CPGs in general and in Chile</li> <li>• Design and preparation of the CPGs in Chile</li> <li>• Dissemination and distribution of the CPGs</li> <li>• Implementation of the CPGs (difficulties and advantages) Proposals for each of these dimensions</li> </ul>

the challenges of implementing CPG recommendations, including findings from all of the levels studied.

Among the challenges described for the dimension *ideas and opinions about CPGs in general, and in Chile*, the participants highlighted the multiple meanings of guidelines used at the different levels of the system, which led to different expectations and uses.

As to the dimension of *CPG design and preparation*, participants reported difficulties in incorporating Chile’s geographical and healthcare variability when making recommendations, an issue also perceived by the end users. Another challenge they indicated was the need to make CPGs more accessible to patients and caregivers as a way of facilitating their implementation at the clinical level. A third element reported by interviewees was that the implementation of recommendations is insufficiently addressed in the current CPGs.

In relation to *CPG management and dissemination*, participants said that there are currently difficulties in accessing CPGs and their recommendations. Furthermore, although the need for training professionals in the content and use of the guidelines was suggested, it was also recognized that the high rate of health staff turnover posed an additional challenge, so that ongoing training strategies should be developed, and CPGs should be continually reviewed by the work teams.

Regarding *CPG implementation*, there was a recognition of the need to reposition this aspect as a crucial element, since the option of implementing CPGs remains a solely local decision. Moreover, there is not yet a standardized process guiding implementation, nor permanent methods in place for future monitoring.

Among the means of facilitating CPG implementation, participants stressed recognizing them as support tools for

decision-making at different levels of care. Furthermore, they acknowledged the efforts made to improve the guidelines' methodological quality, based on the standardization of their development process.

Using these challenges as a starting point, a flowchart was drawn up using an integrated approach to optimize the CPG implementation process throughout the entire course of their development, including specific actions aimed at overcoming the barriers identified (figure 3).

The flowchart begins with the process of drafting a guideline, proposing a series of actions for each area in the process of design, dissemination, and implementation.

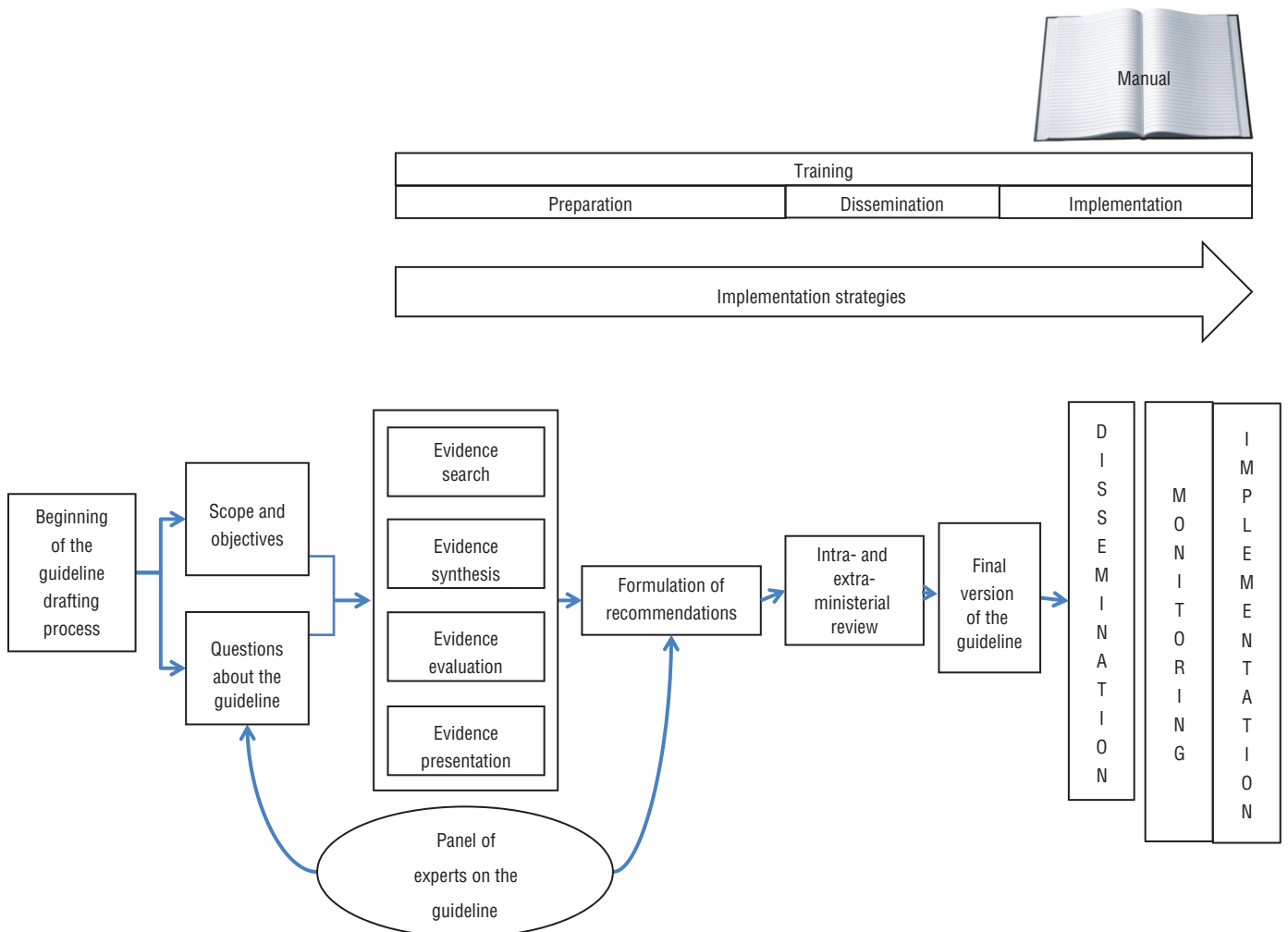
With respect to a *guideline's breadth and objectives*, participants highlighted the importance of indicating its definition and scope, according to the context. They

also stressed the need to incorporate aspects reflecting a given region's situation (epidemiology, network management, and available resources) in the CPG questions, in order to include management alternatives according to their feasibility of implementation, carrying out an open public consultation process on the questions proposed by the panel developing them.

On the *CPG development panel*, the importance of having an open call for experts to participate in the panel was indicated, as well as of inviting experts from different geographic areas representing the different end users (clinicians and non-clinicians). Another recommendation addressed the importance of educating the development panel on CPGs' definition, scope, and development methodology.

In the area of evidence, it was stressed that there is a need for MINSAL experts

**FIGURE 3. Management flow chart optimized for developing and implementing clinical practice guidelines**



who are familiar with the network to collect information on epidemiology, network management, and available resources (human, physical, financial, technological) at the regional level for each CPG. This information should be presented to the CPG development panel in order to be considered within the process of drawing up recommendations to evaluate the feasibility of their implementation. Furthermore, it was proposed that during this phase strategies be established for overcoming the barriers to implementation identified for each of the recommendations.

Regarding the stage of each CPG's intraministerial and external review, participants pointed out that it is necessary to link CPGs to the guidelines established for the country's outpatient care network and to consider, in that harmonization process, the importance of concordance between documents related to the CPG and the network.

Looking at CPG dissemination, participants highlighted the need for a user-friendly webpage to provide information about each guideline's phase in the process, with links to related documents, ordering them with a life-course perspective. Furthermore, it is necessary to promote a more standardized structure, format, terminology, and methodology in CPG development, and to draw up complementary documents for patients, caregivers, and family members, considering cultural differences and possible disabilities, as well as differences in access to technology, formats, and general preferences.

For implementation strategies, there were proposals to consider these aspects from the beginning of the CPG development process, and to give special consideration to regional situations (epidemiology, network management, and available resources) in order to decide the recommendations to be implemented and the strategies to be used at the local level. Moreover, it is necessary to consider additional healthcare planning for those recommendations which cannot be immediately implemented due to lack of resources.

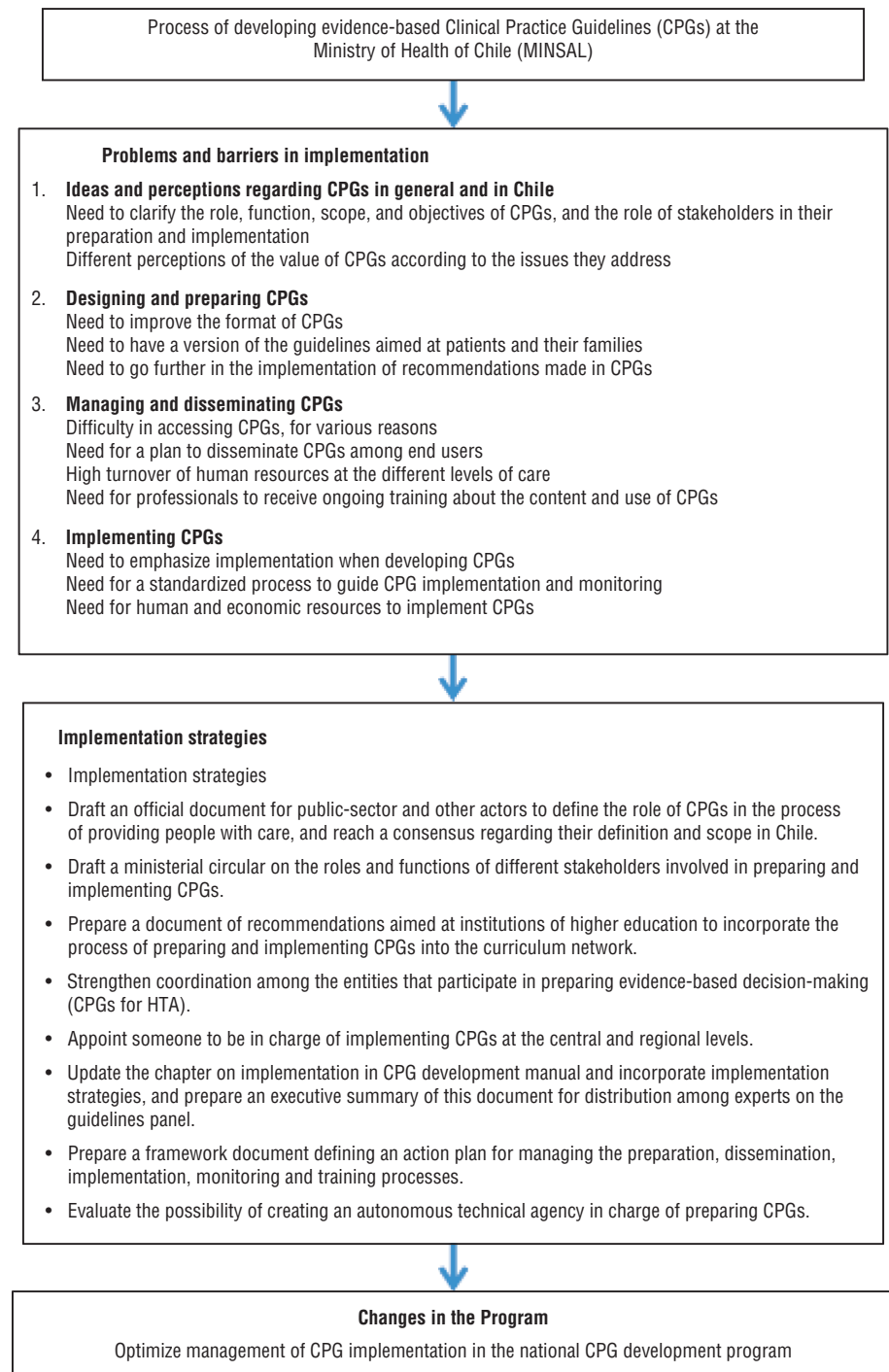
The need for periodic training in CPGs—both for those developing them and for end users—was also highlighted. Moreover, it is necessary to define and integrate CPG training strategies for patients, leveraging the potential of civil society. Participants also pointed out the

importance of defining the profile of the target audience, including training objectives, methodology, frequency, format, and contents of the training according to their roles, functions, and local needs, and of specifying the qualifications criteria for those who would be carrying out this training, above all

when it could not be provided by the developing agency.

Other strategies were identified to be implemented within MINSAL to address the challenges identified and to carry out the proposed flowchart with the actions previously presented (figure 4). Work is currently underway to update the CPG

**FIGURE 4. Suggested strategies for addressing the challenges identified in the process of preparing the Ministry of Health's Clinical Practice Guidelines**



development manual, considering the previously presented aspects, as well as to craft an organizational framework document for the department in charge of the national program to develop MINSAL's CPGs.

## DISCUSSION

The purpose of the CPGs and their recommendations is to assist clinicians and decision-makers in carrying out risk-benefit evaluations to consider different alternatives in order to optimize patient care. Although guidelines are seen as a way to reduce clinical variability—which makes it possible for patients to obtain the best available healthcare option—the possibility for the different options or interventions presented in the recommendations to be used effectively depends a great deal on context. Until now, no study had carried out an in-depth examination of aspects related to the implementation of recommendations.

MINSAL, as part of its mission to assist clinical decision-making by providing evidence-based recommendations, defined a series of interventions to optimize and review the CPG development process. Since the implementation of recommendations can only be understood within the context of high-quality methodological guidelines, MINSAL made efforts to ensure this first requirement through training its staff members and drafting technical recommendations for developing CPGs, such as the Methodological Manual issued in 2014, with the collaboration of external institutions including PAHO, McMaster University (Canada), and Pontifical Catholic University (Chile) (6, 7). As part of the review and optimization of these processes, the present study corresponds to the component related to aspects of implementing recommendations.

Highlights among the study's findings include the positive assessment of the CPGs and MINSAL's commitment to prioritizing their development, as well as the improvements in methodological quality observed to date, due to the standardization of the development process.

Furthermore, challenges were identified, such as the lack of clarity regarding the role and clinical and legal scope that a CPG would have within the Chilean health system, as well as the lack of widespread and strategic dissemination of MINSAL's CPGs. Although, in

practical terms, CPGs' dissemination is differentiated from their implementation, both processes are interconnected. The literature suggests that in order to ensure compliance and implementation, it is not enough for guidelines to be widely disseminated and for clinicians to be informed about their contents (9).

Another salient point is the need to recognize certain inherent challenges in the health system, considering the country's particularities. For example, the huge variability in geography, culture, and availability of resources identified by the participants makes it foreseeable that the implementability of a recommendation can also vary from one setting to another. However, it is important to understand that this variability should be reflected in the strength of the recommendation and, therefore, those who formulate recommendations should consider this implementability. For example, a recommendation can be weak or conditional over a given time period, until human and material resources, access, or complementarity with the medicine of native peoples are elucidated and organized in an active implementation process (10). Therefore, it was suggested that ministerial manuals should make an effort to recruit and inform clinicians and other stakeholders regarding these kinds of challenges, and to provide management alternatives when implementability conditions are still unmet.

A third crucial point which emerged was that the identification of implementing and monitoring recommendations is another process in CPG development, and as such, requires an explicit methodology and an organized work plan, with clearly defined functions and roles within the various health institutions. In this regard, MINSAL itself would be the one to propose these roles and functions, incorporating them into the corresponding institutional and policy frameworks. Together with defining the strategies set out in figure 4, it was also determined which MINSAL actors should be in charge of these actions over the course of the implementation process in order to strengthen and optimize it.

A fourth point stresses the need for continuous training in methodological areas such as evidence gathering, quality assessment, and synthesizing evidence from the different stakeholders in the CPG development process, in light of which it is important to highlight the

work that MINSAL has done in this regard, with intraministerial training activities for guideline developers.

A final implementation objective aimed at improving the CPG development process is to incorporate the proposed actions and a summary of Chile's specific implementation challenges into the next updated version of MINSAL's methodological manual for clinical guidelines development, and into the Ministry's annual training program.

Although the results of this study are particularly relevant to the Chilean health system's local conditions, many of the findings presented here have already been described in the limited scientific literature devoted to guideline implementation (11-15). A systematic review, aimed at synthesizing the studies and reporting on the effectiveness of different implementation interventions, concluded that there is no single clear strategy to be implemented, and that the actual impact of each one is small.<sup>16</sup> These findings support the idea that all the strategies proposed by the work team should be implemented together in order to achieve the desired effect.

Among the strengths of this study, we can mention the use of action-oriented research methodology, with the same institution as both stakeholder and subject. This made it possible to position the study topic as a problem to be addressed, by highlighting the issue of CPGs within a discussion involving influential health decision-makers. Such an experience of reviewing internal ministerial processes linked to CPG implementation through an action-oriented research methodology is unprecedented in Latin America. However, this study also has certain limitations. For example, there was no participation of the guidelines' end users, whether clinicians or the target patients. The data collected concerning these actors came from other key informants, who stated their own views on how patients and clinicians perceived the implementation challenges facing MINSAL. Furthermore, the methodology was developed without knowing whether the guidelines were being applied at the local level, which means that in many cases it could be unnecessary to implement the strategies recommended in this study, since they would not change outcomes for patients. In one discussion group the interview methodology was adjusted due to the nonattendance of

some key actors who had been invited, so that in the end a group interview was conducted.

The potential integration and sustainability of the proposed strategies in the CPG implementation process are necessary to generate an impact on the healthcare network; therefore, it is important to highlight that they can only be carried out with support from ministry officials, providing sufficient time and resources.

Future research at the local level should address more specific problems concerning the implementation of CPG recommendations; for example, through the use of case studies or measuring

compliance with the recommendations already formulated, as a way to identify successful and unsuccessful implementation experiences.

### Conclusion

With the current scenario as a starting point, plus MINSAL's initial efforts to ensure the methodological quality of its clinical guidelines, the need now arises to develop a plan to implement recommendations to guide and monitor this process. Ministry officials contributed strategies to address the challenges of obtaining CPGs with a high degree of

implementability, considering geographic and cultural characteristics and the complexity of the Chilean health system. This action-oriented research methodology can also be used by other ministries in the Region interested in applying it to their CPG programs.

**Conflict of interest.** None declared by the authors.

**Declaration.** The opinions expressed in this manuscript are the responsibility of the authors and do not necessarily reflect the criteria or policies of the *RPSP/PAJPH* and/or of PAHO.

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## Guías de práctica clínica: estudio cualitativo sobre su implementación en el sistema de salud de Chile

### RESUMEN

**Objetivo.** Caracterizar el proceso de implementación, barreras y facilitadores de recomendaciones basadas en evidencia en el contexto del desarrollo de guías prácticas clínicas (CPG) generadas por el Ministerio de Salud de Chile, a fin de brindar propuestas para la optimización del proceso.

**Métodos.** Estudio cualitativo del tipo “investigación-acción”. Se realizaron 19 entrevistas semiestructuradas y se armaron nueve grupos de discusión a distintos niveles del sistema público de salud chileno. El análisis se realizó mediante el software Atlas.ti® y en forma manual, desde un marco de análisis de contenido, mediante la categorización y codificación de la información según dimensiones preespecificadas y con la inclusión de categorías emergentes cuando fue pertinente.

**Resultados.** El principal desafío de implementación de recomendaciones mencionado es la falta de un proceso explícito y estructurado. Los actores del sistema de salud reconocen dificultades dependientes del contexto al momento de usar las recomendaciones. En esta experiencia inédita de revisión institucional, los participantes sugirieron una serie de estrategias a poner en práctica para superar dichos desafíos, representadas en un flujograma de gestión optimizada para el desarrollo e implementación de CPG. El mismo proceso ha permitido tomar conciencia de la importancia de la implementación de CPG en Chile.

**Conclusión.** Tras caracterizar el proceso de implementación, barreras y facilitadores se articuló un plan de implementación de recomendaciones que permitiría orientar y monitorizar dicho proceso. Hacer partícipes del proceso de revisión a informantes claves dentro y fuera del Ministerio de Salud facilitaría la implementación de estrategias y la introducción de mejoras al proceso de desarrollo de CPG. Estudios de este tipo deberían ser realizados en médicos y pacientes para complementar la información recogida.

### Palabras clave

Guías de práctica clínica como asunto, sistemas de salud, Chile.

## Guias de prática clínica: estudo qualitativo sobre sua implementação no sistema de saúde do Chile

### RESUMO

**Objetivo.** Caracterizar o processo de implementação, as barreiras e os fatores facilitadores de recomendações baseadas em evidências no contexto do desenvolvimento de guias de prática clínica (CPGs) criados pelo Ministério da Saúde do Chile, a fim de fazer propostas para a otimização do processo.

**Métodos.** Estudo qualitativo do tipo “investigação-ação”. Foram realizadas 19 entrevistas semiestructuradas e organizados nove grupos de discussão em diferentes níveis do sistema público de saúde chileno. A análise foi realizada com o software Atlas.ti® e de forma manual utilizando um quadro de análise de conteúdo, mediante a categorização e codificação das informações segundo dimensões pré-especificadas e com a inclusão de categorias emergentes, quando pertinente.

**Resultados.** O principal desafio identificado para a implementação das recomendações foi a falta de um processo explícito e estruturado. Os atores do sistema de saúde reconhecem dificuldades dependentes do contexto no momento de usar as recomendações. Nesta experiência inédita de revisão institucional, os participantes sugeriram uma série de estratégias que podem ser postas em prática para superar tais desafios, representadas em um fluxograma de gestão otimizada para o desenvolvimento e a implementação dos CPGs. O mesmo processo tem gerado conscientização sobre a importância da implementação de CPGs no Chile.

**Conclusão.** Uma vez caracterizado o processo de implementação, as barreiras e os fatores facilitadores, articulou-se um plano de implementação de recomendações que permitirá orientar e monitorar esse processo. O envolvimento de informantes-chave dentro e fora do Ministério da Saúde no processo de revisão poderá facilitar a implementação de estratégias e a introdução de melhorias no processo de desenvolvimento de CPGs. É preciso realizar estudos deste tipo com médicos e pacientes para complementar as informações coletadas.

### Palavras-chave

Guias de prática clínica como assunto; sistemas de saúde; Chile.