Patients' participation in government-sponsored guidelines in Latin America: a cross-sectional study

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Abstract

Background It is recommended that patients actively participate in clinical practice guideline (CPG) development, which allows consideration of their values and preferences and improves adherence to recommendations. The development of CPGs throughout Latin America is variable and diverse, and the inclusion of patients' participation is unknown.

Objectives To evaluate the methods of patients' participation in government-sponsored CPGs in Latin America, the type of CPG development and the use of Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methods.

Design Cross-sectional study. We included CPGs developed over the last 10 years through a comprehensive hand search in official national government websites and biomedical databases.

Main outcome measure The type of patients' participation was coded according to five predefined categories. We also report the proportion of application of GRADE methods.

Results We included 408 CPGs from 10 countries: 74% (n=303) were de novo development, 13%(n=55) used an adaptation method and 10%(n=41) used both adaptation and de novo methods. Only 45% (n=185) applied the GRADE approach, ranging from 14% (n=12) of CPGs in Brazil to 89% (n=56) of CPGs in Colombia. Only 23% (n=95) of CPGs included at least one method of patients' participation. Mexico was one of the largest CPG producers (100 CPGs), but none included methods of patients' participation; in turn, in countries with lower production of government-sponsored CPGs, patients' participation was found in almost 88%. Guidelines using the GRADE approach were more likely to use methods of patients' participation. These methods were highly variable: 46% (n=44) incorporated patients in the panel, 81% (n=77) searched for evidence about patients' values and preferences, 43% (n=39) used an external review of the draft recommendations by patients, 38% (n=36) used public comments, and 2% included other methods for stakeholders' participation.

Conclusion Only one quarter of government-sponsored CPGs in the Latin American region incorporated a method for patients' participation, which varied considerably across the selected countries. These findings highlight the need to improve CPG development methods to systematically incorporate patients' values and preferences when drafting recommendations.

Summary box

What is already known about this subject?

- Clinical practice guidelines (CPGs) have become one of the most important tools to promote evidence-informed decision-making. Guidelines for the elaboration and assessment of evidence-based CPGs recommend active participation of patients in the development process, in order to incorporate their values and preferences and thus make CPGs more patient centred. Although the ideal methodological approach for patients' participation has not yet been established, it might be necessary to use different and complementary methods in each guideline.

What are the new findings?

- Nearly a fourth of CPGs developed in Latin America included methods of patients participation, with heterogeneous frequency and participation methods across countries.

How might it impact clinical practice in the foreseeable future?

- Our findings have framed a diagnosis of the general situation of patients' participation and methods applied in CPGs, which may hopefully set a starting point for future guideline development and evaluation. These findings also highlight the need to improve CPG development methods to systematically incorporate patients' values and preferences when drafting recommendations.

Introduction

Clinical practice guidelines (CPGs) have become important tools in the promotion of

evidence-informed decision-making, as they prevent unnecessary risks, allow reasonable use of limited resources, reduce inadequate clinical variability and improve the quality of healthcare systems and services.[1] The US Institute of Medicine defines CPGs as 'statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options'.[2]

Guidelines for the development and assessment of evidence-based CPGs recommend active patients' participation[3 4] in order to incorporate patients' values and preferences, which may help make CPGs more patient centred[5] and improve adherence to recommendations.[1 6] It is also argued that patients' participation in guidelines makes decision-making more democratic, leading to better quality decisions and tailor-made services and hence broadening the perspective of decision-makers, healthcare professionals and researchers.[5 7] Thus, the WHO handbook for guidelines development suggests that end-users, specifically patients, should be represented on guideline panels. However, a review of selected WHO CPGs failed to yield information about the inclusion of end-users or patients in CPG panels or the use of other methods to ensure appropriate integration of their values and preferences.[8] In this sense, it is claimed that participation in guidelines may generate an excessive responsibility burden on patients and that the intended results in terms of decision quality are questionable.[7]

The second domain of the Appraisal of Guideline Research and Evaluation instrument stipulates that a high-quality CPG should take patients' preferences into account.[9] Some of the methods for patient involvement in CPGs[10–13] include (a) the incorporation of patients or professional patient advocates in panels, (b) the search for evidence on patients' values and preferences, (c) the external review of the preliminary draft of the guidelines or recommendations and (d) public comments of the final version of the guidelines.[7 14] Studies on this topic have described further methods, such as performing surveys, granting voting rights in all voting processes during guideline development and organising interviews, focus groups or workshops with patients.[14] The ideal methodological approach for patients' participation has not yet been established and there is a paucity of information on which methods work best.[15] Nevertheless, it has been suggested that this lack of evidence should not deter patients' participation. For instance, a recent study analysed public involvement strategies and patients' participation in guidelines in the USA and concluded that few of the experienced CPG development groups included patients' participation in their methods.[16] The study also found that only 8% of CPG developers required patient and community involvement on CPG panels, while 15% of the groups requested it occasionally or described it as optional. Methods used in the appraised CPGs included posting protocols for public comment, requesting external review of draft guidelines and posting draft guidelines for public comment.[16]

However, the development of high-quality CPGs in the Latin American region is variable and diverse in topics, methods and report types. It has slowly and progressively adapted to the standards of developed countries, migrating from adaptation of high-quality foreign CPGs to full guideline development[17–20] and including recommendations addressing the specific challenges of each region.[21] Latin America reaches up to 800 million inhabitants—13% of the world population—with different healthcare systems fragmented into public sector, private sector and social security; the public sector being responsible for the health coverage of 60%–100% of the population.[22] However, healthcare institutions develop and produce their own CPGs with infrequent interaction with other sectors,[23] which may introduce unintended resource waste, overlap and duplication of efforts.[24 25]

Considering that previous studies indicated that CPGs in the region had pitfalls in the participation of stakeholders,[23 26 27] we hypothesised that patients' participation might be scarce and limited. The relative uptake of CPGs from different developers in each country is unknown. However, government-sponsored CPGs—both financed and produced by government offices—usually have important regulatory and budgetary implications, especially in the context of limited resources and inequity in access to healthcare in our region. They are also widely disseminated, implemented by healthcare practitioners and often supported by local scientific societies in the region.[23] This study aims to evaluate the methods of patients' participation in government-sponsored CPGs in Latin America, the types of CPG development and the use of Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methods.

Methods

This cross-sectional study aimed at assessing patients participation in government-sponsored CPGs developed in Latin America. We also aimed to assess the type of development and the use of GRADE guideline methods. Latin America is a variable geographic concept that usually includes South America, Central America, Mexico and a large part of Caribbean islands. We included countries commonly culturally and geographically seen as part of Latin America, although there is no consensus on the exact definition of Latin American member countries (see online supplemental appendix 1 for the list of countries included in our study). The study methods were compliant with the STrengthening the Reporting of OBservational studies in Epidemiology checklist[28] and the guidelines for reporting meta-epidemiological methodology research.[29]

Inclusion criteria

We included government-sponsored CPGs developed over the last 10 years (2009–2019), with recommendations for the management or prevention of health conditions or recommendations for a healthy lifestyle. We included documents identified as CPGs describing a method for CPG development regardless of how well those methods were described. Whenever several versions of the same CPG were available, we included the latest version of the updated guideline.

Search methods

We searched the following sources from the inception of each database.

Electronic search

We conducted a health science database search considering country terms Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Puerto Rico, Peru, Dominican Republic, Uruguay and Venezuela and terms related to CPGs as type of document. The databases searched were

- Medline (PubMed; from 1946 to October 2019).
- Embase (Elsevier.com; from 1974 to October 2019).
- LILACS (Bireme; up to October 2019).

For detailed search strategies, see online supplemental appendix 2. No restrictions were applied on the language of publication in electronic databases, ministry websites or other health organisations of the reference countries analysed.

Hand search

We hand searched the websites of the health ministries in eligible countries or the sections related to healthcare in general government websites (see online supplemental appendix 2). Subsequently, within the websites, we identified the platforms or repositories containing publications by these ministries such as 'Guidelines from South America' (https://guiasclinicassuramericanas.com/) and the 'International Database for GRADE Guidelines' (http://sites.bvsalud.org/bigg/biblio/). We searched for publications labelled as CPGs, recommendations, protocols, manuals or any other type of document aimed at framing recommendations for the management or prevention of health conditions or for a healthy lifestyle.

Data extraction and analysis

For consistency of criteria in data extraction, a pilot test of independent data extraction from the first 50 CPGs included was conducted by two reviewers who were highly trained in research methods and evidence-based medicine. Data extraction from the remaining guidelines was later conducted by a single author on topics covered by CPG, publication year, country of origin, type of development (adaptation, de novo, update or both adaptation and de novo developments within the same CPG) and use of GRADE methods. We identified the types of patients' participation by inspecting the CPG documents in their introduction and methods. On the basis of our background literature review, we defined five categories, although we maintained a sixth open category for emerging ways of patients participation, considering that there is no standard appraisal tool for assessing patient participation in guidelines:

1. Patients or professional patient advocates in panels: when a patient proxy or advocate was incorporated in the decision panel or CPG development group.
2. Search for evidence on patients' values and preferences: when the development group conducted a bibliographical search for quantitative or qualitative evidence of patients' values and preferences (eg, relative importance of outcomes).
3. External review of the preliminary draft of guidelines or recommendations: when the guidelines were submitted to external review by patient groups or the community.
4. Public comments of the final version of the guidelines: when the final version was open to public comments by patient groups or the community.
5. Other types of patients' involvement: any other method of patients' participation not identified in any previous category.
6. Open code used to identify emerging types of patients' participation.

Depending on the way the CPGs were structured, we browsed different sections to extract the methods of patients' participation. We summarised the overall proportion of CPGs with a certain type of patients' participation and we also calculated the proportion by country. We registered the proportion according to the use of GRADE methods as well. We reported continuous variables as means and SD or medians and IQRs according to the distribution, using visual analysis of histograms and standardised normal probability plots. We reported categorical variables as proportions.

On the basis of additional feedback received during interim analysis at a local Cochrane meeting (June 2019, Argentina), we decided to add the analysis of the association between the use of GRADE and patients' participation, estimating its OR and the 95% CI. The rationale behind this decision was the wide use of GRADE methods in guideline development and the fact that this approach recommends the incorporation of patients' values and preferences in the evidence to decision framework. Data were statistically analysed using STATA V.16.0 software (StataCorp, Texas, USA).[30]

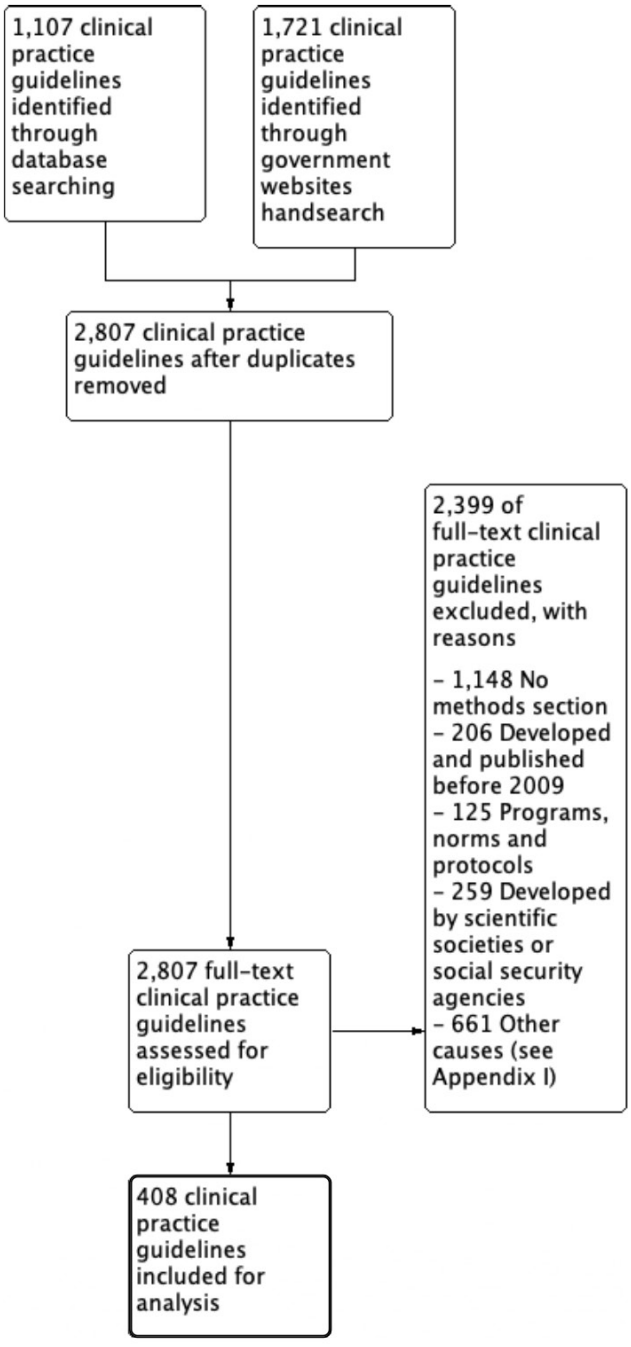

Figure 1 Study flow diagram

Results

We identified 2828 records through a hand search of websites and biomedical databases and finally included 408 CPGs from Argentina, Brazil, Chile, Colombia, Cuba, Ecuador, Honduras, México, Perú and Uruguay. The main reason for the exclusion of documents was the lack of methods describing guideline development. The flowchart with detailed information about search results is shown in figure 1.

Table 1 Total CPGs by country and their patients' participation method

Country	Total CPGs	Number of CPGs with patients in the panel	Number of CPGs with search for values and preferences	Number of CPGs with external review by patients	Number of CPGs with public comments
Argentina	22	4	3	2	0
Brazil	88	0	1	2	3
Chile	82	3	25	1	1
Colombia	63	35	45	34	32
Cuba	2	0	0	0	0
Ecuador	44	1	0	0	0
Honduras	1	0	1	1	0
México	100	0	0	0	0
Perú	2	1	2	1	0
Uruguay	4	0	0	0	0
Totals	**408**	**44**	**77**	**39**	**36**

We did not list countries for which we foundno eligible guidelines.

*Represents theproportion of each type of method from the total of CPGs that used atleast one method; the total percentage may exceed 100% because someguidelines used more than one method.

CPG, Clinical practice guideline.

Topics covered by CPGs were highly variable, ranging from breast cancer screening, arrhythmias, Chagas disease and critical care to endocrinology, genetics, neurology, obstetrics and rare diseases. Publication dates covered the entire 10-year period considered from 2009 to 2019, with 1% of CPGs published in 2009, 4% in 2010, 1% in 2011, <1% in 2012, 12% in 2013, 12% in 2014, 10% in 2015, 11% in 2016, 21% in 2017, 22% in 2018 and 5% in 2019.

We found that 74% (n=303) CPGs were fully de novo developed, followed by 13% (n=55) CPGs that used an adaptation method and 10% (n=41) that used both adaptation and de novo methods. Additionally, only 45% (n=185) CPGs used the GRADE approach, ranging from 14% (n=12) (in Brazil) to 89% (n=56) (in Colombia). Almost all non-GRADE-based CPGs failed to specify other methods for guideline development.

We also found that 23% of CPGs (n=95) reported at least one method of patients' participation, while 77% of them (n=313) did not. This proportion varied across countries (for detailed information per country, see table 1). For example, Mexico was the largest CPG producer in our study with a total of 100 CPGs, but none of them included patients' participation. Meanwhile, in countries like Colombia or Chile—with lower production of government-sponsored CPGs—patients' participation was found in almost 88% CPGs. Guidelines using the GRADE approach were more likely to include methods for patients' participation (43% vs 6%, OR 12, 95% CI 6 to 21, p<0.0001) (see table 1).

The methods used for patients' participation were also highly variable: 46% CPGs incorporated patients in the panel, 81% searched for evidence of patients' values and preferences, 43% used an external review of the draft recommendations by patients and 38% used public comments. While some CPGs included more than one method for patients' participation, only 2% included other methods for stakeholders' participation, such as external review by experts and the general public, presentation of guidelines in an open event with comments and observations and debates among interested parties including those with potential conflicts of interest, as participation in these debates was open to policymakers, patients, carers and the medical industry.

Discussion

Our findings show that patients' participation in government-sponsored CPGs in Latin America remains scarce and highly variable across countries. The search for evidence of patients' values and preferences was the most widely used method, although methods were altogether highly heterogeneous. These results differ from those reported by van de Bovenkamp and Zuiderent-Jerak,[7] who analysed 62 Dutch CPGs for the 'top 25 conditions' developed by the Dutch Council for Quality of Healthcare. The authors found that, among multiple reported methods, patients' participation in guideline panels was the most commonly used. Nevertheless, issues reported in the use of this method included patients' perception of barriers to be heard, lack of articulation between patients' experience-based expertise and the evidence-based development group and patients' input not being reflected in the final product.[7] In addition, Legaré *et al*[11] appraised 71 CPGs elaborated in the USA, the UK, Australia and Germany and found that direct participation was the most common type of patients' and public involvement, on the basis of a typology proposed by Rowe and Frewer.[31] This typology includes direct participation (patient representatives as members of the CPG development group), consultation (information collected from patients and the community through surveys) and communication (information communicated to patients/consumers and the community through plain language versions of CPGs).[11]

In turn, the variable number of guidelines found in our study may be associated with the variable production of government-supported guidelines across countries. Furthermore, considering that some methods of patient's participation are resource intensive, these differences may respond to country income inequalities.

As regards the use of the GRADE approach, our findings are in line with those reported by Dixon *et al*,[32] who assessed whether CPGs published by US-based organisations complied with GRADE recommendations. The authors found that only a third of organisations developing evidence-based guidelines reported the use of GRADE and that CPGs showed low adherence to the GRADE framework. These results may be explained mostly by the inclusion of evidence about patients' values and preferences in the evidence to decision framework in CPGs using the GRADE approach from Colombia and Chile. This issue has been addressed by GRADE developers by calling guideline panels for detailed descriptions of how evidence is evaluated.[33] Worth highlighting, GRADE is the most widely adopted tool for grading evidence quality and making recommendations, officially endorsed by over 100 organisations worldwide.[34 35]

Regarding the limitations of our research, we highly depended on hand search, as few government-sponsored CPGs followed a formal editorial process in indexed scientific journals. While hand search is the mainstay of CPG searches,[36 37] it posed several disadvantages in our study. First, guidelines' storage in government websites was highly variable across countries, with several links to full versions or even agency websites unavailable. Second, there was great variability on the very definition of CPG. As we meant to inspect the methods for CPG development, we narrowed in the Inclusion criteria down to those with the Methods section, which may have excluded guidelines with patients' participation not accounted for in the guideline document or supplementary materials. Third, we lacked information about the dissemination or implementation process, not covered in guideline documents, although we acknowledge that these are key steps in guideline development. Finally, focus on government-led initiatives may have rendered a relatively narrow perspective of the guideline

spectrum in the region, as guideline production by social security, private sector and scientific societies was not considered. Nevertheless, the choice of government-sponsored CPGs responds to increasing public sector regulation and coordination in Latin America due to persistent inequality in access to healthcare as well as insufficient and inadequate distribution of public spending on health.[22]

We used a comprehensive approach to patients' participation in CPGs throughout Latin America, a region with a wide heterogeneity in healthcare systems and economic resources for research or CPG development. We also included a large number of guidelines in both Spanish and Portuguese and conducted a thorough literature search in order to identify all available CPGs. Our focus on government-led initiatives and public sector CPGs allowed us to frame a general diagnosis of patients' participation and methods applied in CPGs which may hopefully set a starting point for future guideline development and evaluation.

Further research should target the implementation of CPG quality assessment and the inclusion of low and middle-income countries beyond the Latin American region, to determine the potential association between available resources for CPG development and patients' participation. In addition, it may be of interest to further investigate whether our findings on government-sponsored CPGs resemble those of the social security, the private sector or scientific societies, as all of them influence clinicians' professional practice and healthcare services. Qualitative research could identify barriers and enablers for the effective implementation of patients' participation in guideline development. We also believe that further research could explore the regional aspects for the low levels of patients' participation found in our study.

Conclusion

Only one fourth of government-sponsored CPGs in the Latin American region incorporated a method for patients' participation, and this varied considerably across the selected countries. These findings highlight the need to improve CPG development methods to systematically incorporate patients' values and preferences when drafting recommendations.

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Contributors LIG and JVAF planned the research, extracted data from CPGs and wrote the first draft of the manuscript. NM and EM extracted data from CPGs, revised the first draft of the manuscript and wrote part of the results and conclusion sections. PR-R extracted data form CPGs. CME-L planned and conducted the search strategies. MA extracted data from CPGs and revised the manuscript. All authors reviewed and approved the manuscript.

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