

BACKGROUND

The Brazilian National Health System (SUS) provides universal health coverage for over 200 million people, with 75% of them exclusively covered by it. Despite the great demand for clinical guidelines, currently there aren't clearly established methodological standards for their development in the country.

OBJECTIVE

To describe the main recommendations of the Ministry of Health's new manual for clinical guidelines development, adaptation and implementation to be published in 2015.

METHODS

This guide is based on the following instruments: AGREE II that evaluates the process of guideline development and quality of reporting, ADAPTE to endorse a guideline produced in one cultural setting for application in a different context; AMSTAR for evaluation of the methodological quality of systematic reviews, and GRADE for grading quality of evidence and strength of recommendations. The guide of guidelines produced by other organizations such as NICE, SIGN and WHO were also reviewed, as well as the Cochrane Handbook for Systematic Reviews.

RESULTS

The main focus of the handbook refers to methodological aspects of guideline development, such as PICOS questions definition, search strategies, studies selection process, quality assessment, summary of findings and the elaboration of recommendations. Other related issues such as formation of the Guideline Development Group, management of conflicts of interest, scope definition, methods for consensus development, elaboration of texts in plain language and other materials for patients, adaptation, implementation and quality assessment of guidelines are also addressed.

DISCUSSION

The principles for guidelines' development described in the handbook are: well-defined scope, comprehensive literature review, pre-established selection criteria, evaluation of the quality of the selected studies, and use of the GRADE system to synthesize evidence and make recommendations.

Overview of the stages of clinical guidelines development and implementation

1. Theme definition
2. Scope definition
3. Definition of the PICOS questions
4. Development of search strategies
5. Study selection process
6. Quality assessment of selected studies
7. Quality assessment of the body of evidence for each outcome (GRADE)
8. Formulation of recommendations (GRADE)
9. Drafting the text of the guideline
10. External review by stakeholders
11. Assessment of new evidence
12. Final version writing and publication.
13. Difusion, dissemination and implementation
14. Monitoring and evaluation of the implementation
15. Updating of the guideline

Division of the tasks in the clinical guidelines development process



IMPLICATIONS FOR GUIDELINE DEVELOPERS/USERS

This handbook will serve as a guide for clinical guidelines development in Brazil, contributing to improve their quality, transparency and potential for implementation.

Keywords: Guideline development; GRADE system; National Health System; Brazil

Acknowledgments: to Renata Leborato Guerra for her contributions to the final review of this text. This project received funding from Ministry of Health's public research call: Chamada pública para apoio a projetos de avaliação de tecnologias no âmbito da Rede Brasileira de Avaliação de Tecnologias em Saúde – REBRATS.