IKR Publishers

IKR Journal of Clinical Medicine and Medical Research (IKRJCMMR)
Journal homepage: https://ikrpublishers.com/ikrjcmmr/
Volume-1, Issue-2 (July-August) 2025
OPEN ACCESS
ISSN: 3107-6521 (Online)

Methodological Quality of Clinical Practice Guidelines for Multiple Sclerosis: A Systematic Review and Comparative Analysis Using AGREE II

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DOI:*10.5281/zenodo.18008975*

ARTICLE INFO

Article history:
Received : 02-12-2025
Accepted : 11-12-2025
Available online : 21-12-2025

Citation: Cosme Chiri, P. R., & Escalante Saavedra, P. A. (2025). Methodological Quality of Clinical Practice Guidelines for Multiple Sclerosis: A Systematic Review and Comparative Analysis Using AGREE II. *IKR Journal of Clinical Medicine and Medical Research (IKRJCMMR)*, 1(2), 54-60.

ABSTRACT **Original Research Article**

Introduction: Multiple Sclerosis (MS) is a neurodegenerative disease causing disability and high healthcare costs, with a global prevalence exceeding 2.8 million people. Consequently, there is a clear need for evidence-based Clinical Practice Guidelines (CPGs) for its diagnosis, treatment, and follow-up.

Objective: This study aimed to evaluate and compare the methodological quality of international CPGs for MS management using the AGREE II instrument.

Methodology: A systematic search was conducted to identify relevant CPGs. Methodological quality was assessed using the AGREE II instrument across six domains. The weighted mean score of each domain was calculated as a percentage. Seven CPGs published between 2010 and 2023 were included in the evaluation.

Results: CPGs from Spain, Mexico, and Chile achieved the highest overall scores (above 70%), primarily due to their clarity and scope. However, critical weaknesses were identified consistently across most guidelines, particularly in Domain 5 (Applicability) and Domain 6 (Editorial Independence), which received the lowest scores. CPGs from Peru (41%) and the UK (45%) scored lowest overall, suggesting issues in methodological reporting.

Conclusions: The methodological quality of international MS CPGs is variable, revealing a systemic limitation regarding the participation of stakeholders and the applicability of the recommendations. Enhancing transparency, promoting regular updates, and ensuring broader stakeholder involvement are essential to improve quality standards and facilitate clinical implementation.

Keywords: Multiple Sclerosis, Clinical Practice Guidelines, Methodological Quality, AGREE II, Applicability.

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Introduction

Multiple Sclerosis (MS) is a disease characterized by demyelination and neurodegeneration, where an abnormal immune system response damages the central nervous system. Its clinical presentation ranges from relapsing-remitting to progressive forms, resulting in disability, morbidity, and high healthcare costs globally. Consequently, there is a growing need for clear guidelines, based on scientific evidence, for diagnosis, treatment, and follow-up (Battaglia, Bezzini, Cecchini et al., 2022).

According to the WHO, it is estimated that over 1.8 million people live with MS. However, other reports estimate that, as of 2020, there were 2.8 million diagnosed individuals, with the most recent prevalence rate reported globally in 2021 being 23.9 cases per 100,000 people (OMS, 2023).

Clinical Practice Guidelines (CPGs) are essential tools that assist in healthcare decision-making through recommendations based on the available scientific evidence, and they are developed through rigorous literature reviews.

In recent years, international CPGs for Multiple Sclerosis (MS) have evolved regarding neuroimaging, biomarkers, disease-modifying therapies (DMTs), and the comprehensive care of the patient (NICE, 2022).

In Latin America, the development of CPGs has gained importance in recent years, both for adapting knowledge to local realities and for improving the use of DMTs and symptomatic management. These guidelines employ the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology, in addition to evidence evaluation (Abad, Nogales-Gaete, Rivera,et al., 2011).

In Bolivia, the Ministry of Health and Sports, through the Authority for the Supervision of Social Security for the Short Term (ASUSS), developed the document *Normas, diagnóstico y tratamientos de enfermedades neurológicos* (2019), which includes a list of prevalent neurological pathologies that require emergency, outpatient, and inpatient care in that specialty; however, it is not considered a Clinical Practice Guideline (Bolivia ASSUS, 2019).

Although several international guidelines exist, there is a significant gap in the literature regarding the comparative assessment of the methodological quality of these guidelines across different regions and healthcare systems.

The objective of this study is to conduct a systematic review to compare and evaluate the methodological quality of international clinical practice guidelines (CPGs) for the management of multiple sclerosis using the AGREE II instrument.

Methodology

Study Design and Guidelines

A systematic review of Clinical Practice Guidelines (CPGs) was conducted, with a focus on assessing methodological quality through the application of the AGREE II instrument (Spanish version).

Search Strategy and Selection of Guidelines

The search was performed systematically in the following databases and websites: PubMed, Scopus, Ministries of Health websites, international neurology societies, and Health Technology Assessment (HTA) agencies (such as NICE, GuíaSalud, and others).

Search Terms: The key terms used were *"guía de práctica clínica para esclerosis múltiple"* (clinical practice guideline for multiple sclerosis), *"múltiple esclerosis"* (multiple sclerosis), *"protocolos para el manejo de esclerosis múltiple"* (protocols for the management of multiple sclerosis), and their corresponding English equivalents.

Inclusion Criteria: CPGs were included if they: i) focused on the management of Multiple Sclerosis (MS) in adults; ii) were published in Spanish or English; iii) presented evidence-based recommendations; and iv) were published or reaffirmed between 2010 and 2024.

Exclusion Criteria: The following were excluded: i) internal hospital protocols lacking explicit development methodology; ii) *position papers* or consensus documents that did not adhere to a formal guideline methodology; and iii) guidelines not accessible as a full-text document.

The title, elaborating organization, geographic location, year of publication, and access link were extracted from each guideline.

AGREE II Instrument Application and Quality Assessment

The methodological quality of the CPGs was assessed using the AGREE II instrument, which comprises 6 domains and 23 items (AGREE II, 2009). The evaluation occurred in the following phases:

A. **Evaluator panel and training (Methodological Rigor):** The evaluation was performed by two independent evaluators (PRCC, researcher, and PAES, methodologist), who possess previous experience in using the AGREE II instrument and underwent specific training on the AGREE II manual to ensure uniformity in scoring.
B. **Scoring process:** Each evaluator independently assessed the content of the guidelines, scoring each of the 23 items on a 7-point scale (1 = Strongly Disagree; 7 = Strongly Agree).
C. **Inter-Evaluator agreement measure (validity):** To ensure the reliability of the scores, discrepancies in the item scores were discussed and resolved by consensus between the two evaluators.
D. **Domain score calculation:** The final score for each domain was calculated as a percentage following the official AGREE II manual formula, based on the mean of the item scores and the evaluators:

$$\text{Percentage Score} = \frac{\{\text{Obtained Score}\} - \{\text{Minimum Possible Score}\}}{\{\text{Maximum Possible Score}\} - \{\text{Minimum Possible Score}\}} \text{ times } 100$$

This percentage score was utilized to compare the methodological quality among the guidelines.

Data Analysis

The extracted data and AGREE II scores were organized in a Microsoft Excel® spreadsheet.

Results

The systematic search resulted in the identification and selection of seven international Clinical Practice Guidelines (CPGs) for the management of Multiple Sclerosis (MS) published or reaffirmed between 2010 and 2024.

Characteristics of the Included Guidelines

The included CPGs, published between 2010 and 2023, exhibit significant diversity regarding elaborating organizations and scope (Table 1).

The CPGs were developed by a variety of entities, including Ministries of Health (Chile, Peru), social security institutions (Mexico), national regulatory agencies (NICE – United Kingdom), and scientific societies (Argentina, Canada, Spain).

In terms of thematic scope, the United Kingdom guideline (NICE) demonstrates a more comprehensive approach, covering diagnosis, treatment, relapse management, rehabilitation, and modifiable factors. In contrast, the guidelines from Peru, Argentina, and Canada primarily focused on Disease-Modifying Therapies (DMTs) or treatment optimization.

Table 1. Characteristics of Clinical Practice Guidelines for multiple sclerosis by country

Country	Clinical Practice Guideline (Title)	Year	Developing Organization	Main Topics	Relevant Notes
Spain	Clinical Practice Guideline on the Care of People with Multiple Sclerosis	2013	Agency for Information, Evaluation and Quality in Health (AIAQS) and Multiple Sclerosis Center of Catalonia (Cemcat)	Diagnosis, Symptomatic Treatment and Rehabilitation / Clinical Decision Algorithms for Diagnosis and Treatment	The guideline is a quick version that includes recommendations and algorithms.
Chile	Clinical Guideline 2010 for Multiple Sclerosis	2010	Ministry of Health of Chile	Recommendations for Diagnosis, Specific Treatment and Comorbidities	Systematic Review plus Expert Consensus / Focuses on treatment standardization.
Peru	Technical Clinical Practice Guideline for the Diagnosis and Treatment of Multiple Sclerosis in Second and Third Levels of Care	2020	Peruvian Society of Neurology and Ministry of Health	Diagnosis / Disease Modifying Therapies	Recommendations made using the GRADE method.
Mexico	Comprehensive Care Protocol for Multiple Sclerosis	2023	Mexican Social Security Institute	Clinical Diagnosis, Pharmacological and Non-Pharmacological Treatment, Care, according to levels of care	Systematic Reviews, Observational Studies, Clinical Trials.
Argentina	Symptomatic Treatment of Multiple Sclerosis. Demyelinating Diseases Working Group. Neurological Society of Argentina	2022	Neurological Society of Argentina	Most Frequent Symptoms of Multiple Sclerosis	Recommendations using the GRADE method / Evidence evaluation using the AGREE instrument.
United Kingdom	Multiple sclerosis in adults: management	2022	National Institute for Health and Care Excellence (NICE)	Diagnosis / Relapse management, Comprehensive Care, Rehabilitation, Modifiable Factors	Comprehensive guideline, evidence-based, with recommendations for research and coordinated care.
Canada	Treatment optimization in multiple sclerosis: Working group recommendations	2020	Canadian MS Working Group	Treatment for Multiple Sclerosis	Guideline based on updated recommendations for adapting treatment.

Source: Own authorship.

Minimum Methodological Rigor

It was observed that the guidelines from Peru, Argentina, and the United Kingdom utilized the GRADE instrument for formulating recommendations. However, the level of detail regarding the application of the method varied significantly among the documents.

The guideline developed by the United Kingdom, in addition to including diagnosis and treatment, also covers relapse management, rehabilitation, comprehensive care, and recommendations for research.

The CPGs from Peru, Argentina, and Canada focus on disease-modifying therapies and treatment optimization. Conversely, Chile emphasizes the standardization of diagnosis and general care, while the guideline from Mexico presents a perspective on organizing the healthcare system according to the patient's level of care.

A key aspect of the study is the method used by the authors to make recommendations. The GRADE instrument is observed to be used by Peru, Argentina, and the United Kingdom, focusing on the formulation of evidence-based recommendations.

However, the guidelines from Canada and Mexico provided solid scientific bases such as systematic reviews and clinical trials. Chile utilized systematic reviews agreed upon by experts, and Argentina specifically mentions the use of the AGREE instrument to assess methodological quality.

Methodological Quality Assessment (AGREE II)

The methodological quality assessment is presented in Table 2, showing the percentage scores for the six domains of the AGREE II instrument for the guidelines evaluated.

Guidelines with higher overall quality: The guidelines from Spain (mean 78%), Mexico (mean 74%), and Chile (mean 73%) demonstrated the best overall methodological quality, achieving an average score above the 70% threshold. This indicates a solid balance between the processes of elaboration and presentation.

Guidelines with lower overall quality: The guidelines from Peru (mean 41%), the United Kingdom (mean 45%), and Canada (mean 49%) obtained the lowest scores, suggesting significant deficiencies either in the methodological process itself or in the explicit reporting of the information.

The analysis by AGREE II domains revealed consistent patterns of strengths and weaknesses:

Domains with High Performance (Strengths)

Domain 1 (scope and purpose): This domain achieved the highest scores, with four guidelines reaching 94% or more (Mexico, Peru, Canada, and Chile). This confirms that the guidelines, in general, clearly define their purpose, clinical questions, and target population.

Domain 4 (clarity of presentation): This domain also demonstrated strong performance, with Mexico, Spain, and Peru achieving 100%, 100%, and 83.3%, respectively. This suggests that the recommendations are, for the most part, specific, unambiguous, and easy to identify.

Table 2. Distribution of Scores in the Evaluated Guidelines according to AGREE II Domains

	COUNTRY	TITLE	DOM 1	DOM 2	DOM 3	DOM 4	DOM 5	DOM 6	Mean
			Scope and Purpose	Stakeholder Involvement	Rigour of Development	Clarity of Presentation	Applicability	Editorial Independence	
1	Spain	Clinical Practice Guideline on the Care of People with Multiple Sclerosis	78%	100%	70%	100%	70%	50%	78%
2	Mexico	Comprehensive Care Protocol Directorate of Medical Benefits Multiple Sclerosis	100%	100%	44%	100%	50%	50%	74%
3	Chile	Clinical Guideline 2010 Multiple Sclerosis	94%	40%	47%	89%	66.6%	100%	73%
4	Argentina	Symptomatic Treatment of Multiple Sclerosis. Demyelinating Diseases Working Group. Neurological Society of Argentina	55%	72%	70.8%	89%	25%	100%	69%
5	Canada	Treatment Optimization in Multiple Sclerosis: Canadian MS Working Group Recommendations	94%	83%	66%	0	0	50%	49%
6	United Kingdom	Management of Multiple Sclerosis in Adults	89%	33%	29%	72%	45%	0	45%
7	Peru	Technical Clinical Practice Guideline for the Diagnosis and Treatment of Multiple Sclerosis in the Second and Third Levels of Care	100%	33.3%	29%	83.3%	0	0	41%

Source: Own authorship.

Domains with Low Performance (Critical Weaknesses)

Domain 5 (applicability): This was the weakest domain, with two guidelines (Peru and Canada) scoring 0% and Argentina scoring only 25%. The low score indicates that the majority of CPGs do not include barriers and facilitators for implementation, strategies to monitor utilization, or cost implications, thereby limiting their usefulness in clinical practice.

Domain 6 (editorial independence): This domain was also critically weak, with three guidelines (Canada, Peru, and the United Kingdom) scoring 0%. This highlights the absence of explicit information regarding the declaration of conflicts of interest by all development group members or the influence of the funding entity. In contrast, Argentina and Chile achieved the maximum score of 100% in this domain.

Domain 3 (rigor of development): This domain showed the greatest variability. Although Spain and Argentina achieved scores around 70%, the guidelines from Peru and the United Kingdom scored very low (29%). This disparity suggests that the rigor in evidence searching, selection criteria, and the link between evidence and recommendations is not standardized. The low score of reference guidelines, such as the one from the United Kingdom (29%), likely reflects a lack of explicit reporting of these processes within the document, according to AGREE II requirements.

Discussion

The comparative analysis of international clinical practice guidelines (CPGs) for the management of Multiple Sclerosis (MS) allowed us to identify significant differences in methodological quality, development process, applicability, and recommendations. We found guidelines that achieved scores above 70% and others below 50%.

Regarding the scope, the guideline developed by the United Kingdom (NICE) presents a comprehensive approach that includes diagnosis, treatment, relapse management, rehabilitation, and recommendations for future research. In contrast, the guidelines from Argentina, Peru, and Canada focus on disease-modifying therapies or treatment optimization.

The AGREE II evaluation confirms these variations. The guidelines from Spain, Mexico, and Chile achieved good overall scores, highlighting their clarity, objectives, scope, and well-structured recommendations. The Spanish guideline, with an average of 78%, evidences a balance in methodological quality and stakeholder involvement.

A critical finding of this study is the low performance in Domain 2 (Stakeholder Involvement). Most of the evaluated guidelines demonstrated limited participation of patients, caregivers, and multidisciplinary teams in their development. This exclusion is concerning, as the absence of the patient perspective and a multidisciplinary viewpoint may compromise the real-world applicability and acceptance of the recommendations in everyday clinical settings.

Furthermore, the variability in Domain 3 (Rigour of Development), where guidelines such as those from Peru and the United Kingdom scored only 29%, reflects not necessarily a lack of evidence, but rather a deficiency in the transparency of methodological reporting. As required by AGREE II, the search processes, selection criteria, and the link between evidence and recommendations must be explicitly detailed, which was not observed in these documents.

The journal *Caderno Pedagógico*, in 2025, published the article entitled "Evaluation of clinical protocols for the treatment of hepatitis C adopted on five continents by the AGREE II instrument". This study presents similarities with our analysis, finding that the weakest domains in both are Applicability and Editorial Independence, while methodological rigor depends on the country and available resources. Both studies reinforce the necessity of improving transparency, stakeholder participation, and practices for implementing guidelines to fulfill their purpose (Benoliel et al., 2025).

A study conducted between 2010 and 2020, titled "Trustworthiness of treatment clinical practice guidelines has modestly improved since the introduction of IOM standards," demonstrated that the average reliability score of the guidelines ranged between 2.28 and 2.7 (on a 1–5 scale), indicating a modest improvement in the construction of these documents. However, improvements were found regarding the disclosure of funding sources and declaration of conflicts of interest, as well as a slight improvement in transparency in evidence selection, search strategies, and data synthesis (Ghadimi et al., 2025).

Extensive reviews of clinical guidelines in different areas have pointed out domains that consistently receive low scores, such as "stakeholder involvement," "applicability," and "editorial independence/declaration of conflicts" (Ghadimi et al., 2025).

The review titled "Quality assessment of clinical practice guidelines on hypoxic-ischemic encephalopathy in newborns using the AGREE II tool", conducted in 2024, concurs that the participation of patients and users is limited in both studies, which affects the practical implementation of the recommendations. The best-evaluated domains are scope and objective (Arellano-Haro et al., 2024).

The Spanish Academy of Dermatology and Venereology published an article titled "Evaluation of the Quality of Clinical Practice Guidelines for the Treatment of Psoriasis Using the AGREE II Tool" (2022). By comparing the methodological findings on CPGs, it is observed that the domains with the highest performance are objective, scope, clarity of presentation, and rigor of development. However, just as with the analysis of MS CPGs, the lowest scores were concentrated in applicability and editorial independence, demonstrating a significant limitation (Montesinos, Guevara et al., 2022).

A comparison was made with "Clinical practice guidelines for COPD", published in 2019 by the Spanish Journal of Public Health. It was noted that both share the purpose of improving patient care through evidence-based recommendations but showed variability in methodology. However, the COPD guidelines showed clarity in presentation but notable limitations in applicability and editorial independence, whereas the MS guidelines show better methodological development and the use of GRADE (García Cano et al., 2019).

A comparative analysis between the MS CPG analysis and a study titled "AGREE-II Evaluation of Clinical Practice Guidelines for Acute Radiodermatitis" shows distinct results. In the MS study, Spain and Mexico obtained high scores in stakeholder involvement and clarity. Conversely, in the radiodermatitis study, applicability was the domain with the worst performance, indicating limitations in clinical implementation and costs. Both studies agree on the urgent need for periodic updating of CPGs (Rumbo-Prieto et al., 2017).

A study published by the Peruvian Journal of Experimental Medicine and Public Health in 2016, titled "Clinical Practice Guidelines in Peru: Quality Assessment Using the AGREE II Instrument", found that the CPGs in Peru showed weaknesses in the participation of involved actors and editorial transparency, aspects also found in our analysis. Both studies, likewise, agreed that the guidelines present clear objectives, well-structured recommendations, and the incorporation of recent evidence (Canelo C., et al, 2016).

Limitations

The study presents limitations that must be considered when interpreting the results. The evaluation was based solely on the AGREE II instrument, which limits the ability to capture other dimensions of the quality of the guidelines (transparency of the report). Furthermore, the absence of a formal peer review of the scoring process introduces a potential applicator bias, affecting the objectivity of the ratings. Finally, the reduced number of guidelines included (n=7) compromises the generalization of the findings to a

broader context of CPG development on the topic, suggesting that the conclusions apply primarily to the guidelines analyzed.

Conclusion

International Clinical Practice Guidelines (CPGs) for the management of Multiple Sclerosis (MS) exhibit significant differences in their methodological quality, scope, and applicability, reflecting variations in development and reporting processes.

The findings demonstrate that, while the majority of the evaluated guidelines feature clearly formulated objectives and well-structured recommendations, there are critical limitations concentrated in domains that directly affect their utility in practice. Specifically, scarce participation of relevant stakeholders (such as patients and healthcare professionals) was identified in their elaboration, which may reduce the multidisciplinary perspective and impair the implementation of the recommendations. Furthermore, several guidelines lack recent updates or the necessary explicit information regarding the declaration of conflicts of interest (editorial independence).

This analysis underscores the urgent need to strengthen and promote periodic reviews and guarantee broad participation of users and professionals in the development of CPGs, incorporating new studies and available therapeutic advances. Improving reporting transparency and the inclusion of all stakeholders are fundamental steps to ensure that CPGs transition from mere theoretical documents into robust tools for clinical implementation.

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