Jornal de Assistência Farmacêutica e Farmacoeconomia
v.9, n.1, 2024.
Original Article

Evaluation of clinical guidelines for otitis and impacted earwax: an analysis of quality and treatment proposals

Avaliação de diretrizes clínicas de otite e cerume impactado: uma análise da qualidade e das propostas de tratamento

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How to cite this article:
Alvares MG, Vaz FLC, Santana RS, Lima RF, Barbosa APO, Gomes RM. Evaluation of clinical guidelines for otitis and impacted cerumen: an analysis of quality and treatment proposals. JAFF [Internet]; 9(1). 2024.

doi: 10.22563/25257323.2024.v9.n.1.p.26-35e

Received on: 09/29/2023.

Accepted for publication on: 01/29/2024..

ABSTRACT

Objective: To evaluate the methodological quality and treatment profile of clinical guidelines for the management of otitis and impacted earwax. **Methods**: To identify clinical guidelines, a search was carried out in different databases. The selection of evidence went through the peer review process and consensus was used to resolve disagreements. The evaluation was carried out by AGREE II. The criteria adopted to recommend the guideline were the scores found in this domain, with 50% being the minimum expected value. Therefore, guidelines that scored between 30% and 50% in "development rigor" and achieved averages above 50% in two other domains were considered recommended, with modifications. The Kappa test was used to evaluate agreement. **Results**: Six clinical guidelines were selected and evaluated. Among them, five were considered. Items such as applicability, development rigor, editorial independence and stakeholder involvement obtained lower scores. Non-pharmacological therapy is focused on in all guidelines as first-line treatment. Symptomatic management mediated by pharmacological therapy is recommended in combination in the second line of treatment. **Conclusion**: The guidelines evaluated were assessed with good quality. The need to qualify recommendations in terms of the evidence that supports them is highlighted, as well as to make recommendations available in an informed manner, reduce conflicting interests and increase the involvement of interested parties, so that the best care for patients is offered.

Keywords: Clinical Practice Guide; Evidence-Based Pharmacy Practice; Otitis; Cerumen; Pain management.

RESUMO

Objetivo: Avaliar a qualidade metodológica das diretrizes de prática clínica para o manejo das otites e cerume impactado e suas principais recomendações. **Métodos:** Para identificação das diretrizes clínicas realizou-se busca em diferentes bases de dados. A seleção das evidências passou pelo processo de revisão por pares e o consenso foi usado para resolver divergências A avaliação foi realizada pelo AGREE II. Os critérios adotados para recomendação da diretriz foram as pontuações encontradas neste domínio, sendo 50% o valor mínimo esperado. Assim, as diretrizes que pontuaram entre 30% e 50% no "rigor de desenvolvimento" e alcançaram médias superiores a 50% em dois outros domínios foram consideradas recomendadas com modificações. O teste Kappa foi utilizado para avaliar a concordância. **Resultados:** Foram selecionadas e avaliadas seis diretrizes clínicas. Dentre elas, cinco foram consideradas recomendadas. Itens como aplicabilidade, rigor do desenvolvimento, independência editorial e envolvimento das partes interessadas, obtiveram menores pontuação. A terapia não farmacológica é enfatizada em todas as diretrizes como tratamento de primeira linha. O manejo sintomático mediado por terapia farmacológica é recomendado em associação na segunda linha de tratamento. **Conclusão:** As diretrizes avaliadas apresentaram boa qualidade. Destaca-se a necessidade de qualificar as recomendações quanto às evidências que as fundamentam, assim como dispor as recomendações de forma compreensível, diminuir os interesses conflitantes e aumentar o envolvimento de partes interessadas, para que o melhor cuidado aos pacientes possa ser ofertado.

Palavras-chave: Guia de Prática Clínica; Cuidado farmacêutico baseado em evidência; Otite; Cerume; Manejo da dor.

Introduction

Ear health is a complex area, with significant gaps in prevalence data and disease outcome burdens. Currently, over 1.5 billion people (almost 20% of the global population) experience some level of hearing loss, resulting in an annual cost of $980 billion due to untreated hearing loss. These global figures have been progressively increasing, with 90% occurring in low- and middle-income countries[1]. In Brazil, according to data from the National Health Survey, 2.2 million people (about 1.1% of the population) have hearing disabilities.[1]

Hearing loss has detrimental effects when not diagnosed and treated appropriately, impacting language, communication, and the academic life of affected individuals. According to the World Health Organization (WHO), it is estimated that 50% of hearing loss can be prevented through public health measures.[1,2] In Brazil, earache is one of the most common complaints in spontaneous demand attendances in primary care[1]. The most common diagnoses in patients with ear pain are of primary origin, particularly otitis, usually uncomplicated.[2,3]

Otitis accounts for a large number of consultations in primary care and represents 33% of antibiotic prescriptions at this level of health care[4]. According to the WHO, bacterial resistance to antibiotics is one of the main health problems in the world.[5] It is worth noting that the indiscriminate use of antibiotics for upper respiratory infections is one of the main causes of the emergence of resistant bacterial strains.[6]

Clinical guidelines are informative documents that include recommendations aimed at optimizing the health care provided to patients.[7] Thus, they constitute an important tool for making patient care practices more homogeneous and of better scientific quality.[8] Due to the large volume of information generated in health care and the variability in the quality of scientific production, there is a need to develop a synthesis that facilitates access to this knowledge and allows for recommendations based on results from multiple sources, providing scientific support for decision-making.[7]

In this scenario, the AGREE instrument (Appraisal of Guidelines for Research & Evaluation) was created through an international collaboration between guideline developers and researchers. The AGREE aimed to assess the methodological rigor and transparency with which clinical guidelines are developed.[9,10] Subsequently, given the ongoing development to ensure measurement properties, applicability, and feasibility, the instrument was updated, resulting in AGREE II.[9,10] The instrument aids not only in the evaluation of existing guidelines but also informs the criteria and domains necessary for constructing a guideline, emphasizing the relevance of methodological rigor and transparency in the development of applicability and the presentation of information in these documents.[10]

In this perspective, this study aims to evaluate the methodological quality of clinical guidelines for the management of otitis and impacted cerumen using the AGREE II instrument.

Methods

Literature searches were conducted using MeSH terms and boolean operators “Ear Infection” OR “Otite” OR “Otitis” OR “Ear Inflammation” OR “Infection, Ear” OR “Inflammation, Ear” OR “Cerumen” OR “Cerume” in June 2022. Clinical guidelines for the management of otitis and other ear problems were sought in various scientific databases such as Medscape, Best Medicine Journal (BMJ), UptoDate, Dynamed, PubMed, Cochrane, and the Virtual Health Library (BVS). Health category websites included NICE - National Institute for Health and Clinical Excellence, which provide clinical practice guidelines, Guidelines International Network (GIN), and the Ministry of Health. Availability in the form of open access to the searched clinical guidelines was verified. In situations where more than one guideline existed for the same clinical condition, the selection of the most recent guideline related to the pharmacological treatment of the disease was prioritized.

Clinical guidelines published between June 2012 and June 2022 with free access to the full text, in English and Portuguese, were included. Publications whose scope did not encompass the treatment of otitis and impacted cerumen; those aimed at spe-

cific populations; those directed to the context of urgency, emergency, and/or patient hospitalization; and those focused on a single type of treatment were excluded. The selection of studies was carried out by two researchers, and consensus was used to resolve any discrepancies.

Since the study only addressed publicly and universally accessible data and did not involve research involving human beings, it was not submitted to the Research Ethics Committee in accordance with Resolution CNS No. 466/2012.

AGREE II (Appraisal of Guidelines for Research & Evaluation)

The Appraisal of Guidelines for Research & Evaluation (AGREE II) instrument was developed to address variability in guideline quality. With the growth in the number of clinical guidelines published over the years, combined with contradictions among such documents, concerns regarding the quality of these guidelines arose. In this scenario, the AGREE instrument (Appraisal of Guidelines for Research & Evaluation) was created through an international collaboration between guideline developers and researchers.[10]

This instrument provides a foundation for how guidelines should be developed and their information reported to ensure high reliability of research. It informs the criteria and domains necessary for constructing a guideline, emphasizing the relevance of methodological rigor and transparency in the development of applicability and the presentation of information in these documents.[10]

The practices for AGREE II to exhibit quality are those in which the guidelines have been appropriately addressed, the recommendations present internal and external validity, and are evidence-based.[10,11] AGREE II evaluates the quality of a guideline based on twenty-three items organized into six domains: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence.[9,10] The structure of AGREE II has different provisions; the first domain, "scope and purpose," reflects the general objective of the guideline, the specific health issues, and the target population.[9,10] The second domain, "stakeholder involvement," presents the extent to which the guideline was developed by stakeholders and represents the perspective of the users.[9,10] Domain three, "rigor of development," is considered the main domain and relates to the process used to collect and synthesize evidence, the methods for formulating recommendations, and their respective updates.[9,10] Domain four, "clarity of presentation," discusses the language, structure, and format of the guideline.[10] Domain five, "applicability," establishes likely facilitating factors and barriers to implementation, strategies to improve application, as well as the involvement of resources related to the utilization of the guideline.[10] To close the domains, domain six, "editorial independence," pertains to the formulation of recommendations in a way that does not present biases resulting from conflicting interests.[10] Each item is given a score from 1 to 7, where 1 means "strongly disagree" and 7 means "strongly agree".[9,10] The scores for the domains should be calculated by summing all the scores of the individual items to establish the total result as a percentage of the maximum possible score in each domain.[9,10]

The calculation for determining the scores of the domains is performed according to the following formula:

$$\frac{\text{Score Obtained} - \text{Minimum}}{\text{Score} \div \text{Maximum Score} - \text{Minimum Score}} \text{ X } 100$$

According to the recommendations of the AGREE II instrument, the guidelines included in this study were evaluated by four independent assessors (MGA, FLCV, APOB, and RMG), who had prior knowledge of the method.[10] Each item was scored by the assessors on a seven-point Likert scale based on how poorly or well each characteristic of the clinical practice guideline (CPG) met the criteria established by the AGREE II users. Subsequently, a percentage of adequacy between 0% and 100% for each domain was obtained from the sum of the scores assigned by all assessors and the maximum possible score,[10] in accordance with previous studies.[12–14]

The agreement among the assessors was evaluated using the Kappa test.[15] The Kappa test has a value of 1 if there is perfect agreement among the assessors and a value of 0 if the observed percentage of agreement is equal to the agreement expected by chance.[15] Conducting the test is a requirement of the AGREE II instrument, but for practicality and conjunction of the two evaluation methods, the values 1, 2, and 3 for Kappa were used in order to relate to the AGREE II test (Table 1). For the analysis of agreement, the assessors defined that scores of 1 and 2 would be considered "low," scores between 3 and 5 would be "intermediate," and scores of 6 and 7 would be "high".[15]

Table 1. Scoring scheme for Kappa and AGREE II tests

Evaluation Level	Kappa Evaluation Score	AGREE II Evaluation Score
Low	1	1 to 2
Intermediate	2	3 to 5
High	3	6 to 7

The following comparison parameters were considered:

- Poor agreement: (<0.00)
- Slight: (0.00 – 0.20)
- Fair: (0.21 – 0.40)
- Moderate: (0.41 – 0.60)
- Substantial: (0.61 – 0.80)
- Almost perfect: (0.81 – 1)

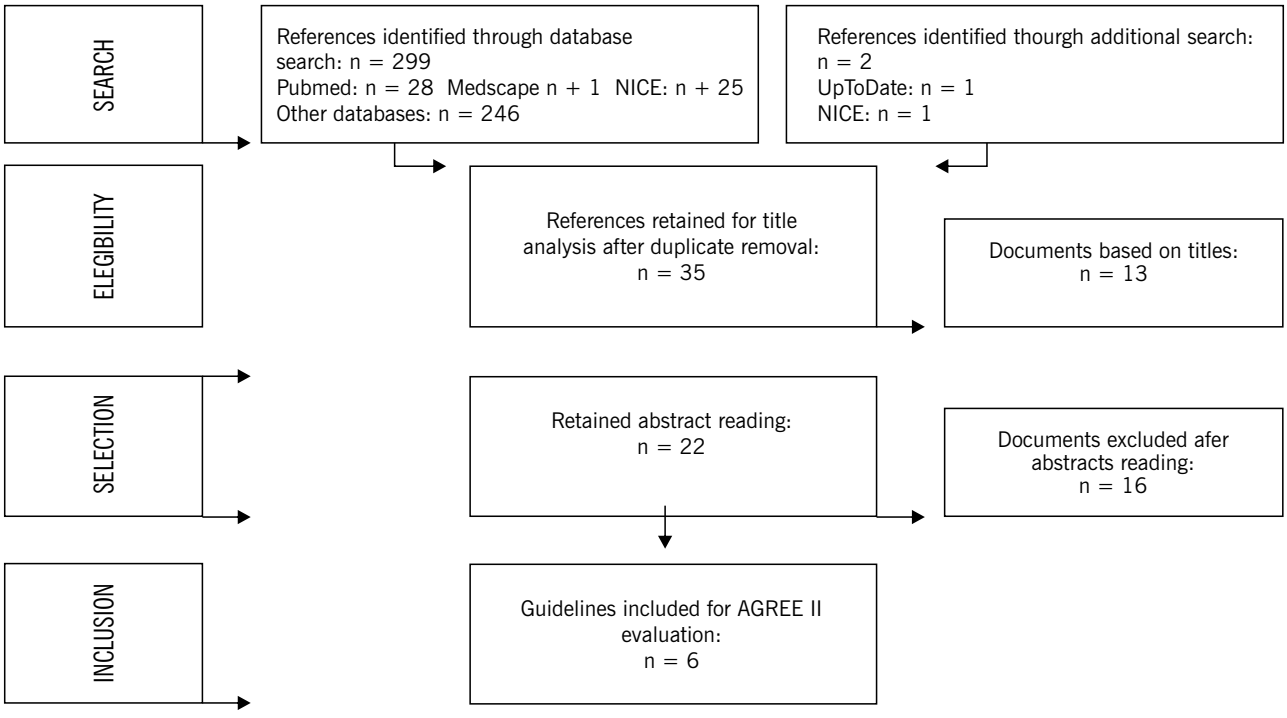
Considering that AGREE II does not provide a specific parameter for the recommendation or non-recommendation of clinical guidelines, classifying them as high or low quality, domain three (rigor of development) was used as the main evaluation criterion, since this domain addresses the process used to collect and synthesize evidence, the methods for formulating recommendations, and their respective updates.[10]

Thus, the guideline that achieved 50% in "rigor of development" and in two other domains was considered "recommended"; the guideline that scored between 30% and 50% in "rigor of development" and above 50% in two other domains was considered "recommended with modifications"; and finally, the guideline that scored below 30% in "rigor of development" was considered "not recommended".[10,15]

Results

Six clinical guidelines were included for evaluation (Flowchart 1).

Flowchart 1. Selection process of clinical guidelines



The guidelines included for evaluation are presented in Table 2. The clinical practice guidelines (CPGs) originate from different locations. One Brazilian guideline was found, but as it was published more than 10 years ago, it did not meet the criteria for inclusion in this study.

General Recommendations of the Guidelines

The clinical guidelines follow a consensus that an initial treatment method is necessary as a preventive line; these measures are guided by non-pharmacological practices that can mediate the diseases, provided they are not severe.[16–18] The preventive measures result in reduced discomfort and irritation.[18]

Among the evaluated guidelines, 50% recommend vaccination as a preventive care measure for otitis.[17–19]

CPG 6 (Clinical Practice Guideline (Update): Earwax (Cerumen Impaction)) that addresses impacted cerumen presents proper hygiene of the auditory canal, followed by irrigation with water or saline solution, as the main recommendations aimed at hydrating the wax and facilitating the exit of cerumen, in addition to recommending the manual removal of excess impacted cerumen from the ear.[19]

The non-pharmacological recommendations from the evaluated guidelines include vaccination, watchful waiting, reduction of risk factors, and preventive information as preventive care measures for otitis (Table 3).[16–18,20]

Table 2. Characteristics of clinical guidelines for the management of otitis and impacted cerúmen

	Clinical Guideline	Country of Origin	Year	Responsible Group/Organization
CPG 1	Korean clinical practice guidelines: otitis media in children	South Korea	2012	Korean Otologic Society
CPG 2	The Diagnosis and Management of Acute Otitis Media	United States	2013	American Academy of Pediatrics
CPG 3	Clinical Practice Guideline: Otitis Media with Effusion Executive Summary (Update)	United States	2016	American Academy of Otolaryngology – Head and Neck Surgery Foundation
CPG 4	Clinical Practice Guideline (Update): Earwax (Cerumen Impaction)	United States	2017	American Academy of Otolaryngology – Head and Neck Surgery Foundation
CPG 5	Management of otitis media with effusion in children. Société française d'ORL et de chirurgie cervico-faciale clinical practice guidelines.	France	2018	French Society of ENT and Head and Neck Surgery
CPG 6	Updated Guidelines for the Management of Acute Otitis Media in Children by the Italian Society of Pediatrics: Treatment.	Italy	2019	Italian Society of Pediatrics

Table 3. Recommendations for non-pharmacological treatment

NON-PHARMACOLOGICAL TREATMENT FOR OTITIS AND EAR CONDITIONS					
Recommendation	**CPG 1**	**CPG 2**	**CPG 3**	**CPG 4**	**CPG 5**
Watchful waiting	Yes	Yes	Yes	Yes	Yes
Preventive information	Yes	Yes	Yes	Yes	No
Risk factor reduction	Yes	Yes	Yes	Yes	Yes
Vaccination	Yes	Yes	No	Yes	No

Following the proposal for non-pharmacological treatment, pharmacological treatment continues (Table 4). The guidelines recommend pharmacological management for acute otitis media (AOM).[18] The discomfort caused by pain is addressed as the primary criterion among the evaluated guidelines. Analgesics are strongly recommended for otalgia in the context of initial intervention.[16–18,21]

Antibiotics are indicated in more severe cases as a second-line intervention.[16–18]

The guideline for impacted cerumen recommends pharmaceutical solutions, referred to as ceruminolytic agents (carbamide peroxide, hydroxyquinoline + trolamine, 0.9% sodium chloride), capable of emulsifying and hydrolyzing cerumen, facilitating its removal and improving discomfort.[19,22–26]

Evaluation of the Quality of Guidelines by AGREE II

After assessing the criteria using AGREE II, the average for each of the six domains of each selected clinical guideline was calculated.[10] The averages can be observed in Table 5. After applying the criteria, it was found that among the six guidelines, five received scores greater than 50% in domain three, rigor of development, and in two other domains, characterizing them as recommended for use in healthcare practice.[16–20] CPG 5 received a score of 42% in domain three (rigor of development) and above 50% in two other domains, characterizing it as recommended with modifications[21].

Table 4. Chart with recommendations for pharmacological treatment [16,17,19–21,23,25,27–31]

PHARMACOLOGICAL TREATMENT FOR OTITIS AND EAR CONDITIONS							
Medication Class	**CPG 1**	**CPG 2**	**CPG 3**	**CPG 4**	**CPG 5**	**CPG 6**	**Examples**
Systemic and topical analgesics	Yes	Yes	No	Yes	No	No	Acetaminophen, Lidocaine (topical), Procaine (topical), Benzocaine (topical)
Antibiotics	Yes	Yes	No	Yes	No	No	Amoxicillin + Clavulanate, Azithromycin, Cefuroxime, Cefditoren, Clindamycin, Chloramphenicol, Cefaclor, Cefprozil, Cefdinir
Nonsteroidal anti-inflammatory drugs (NSAIDs)	Yes	No	No	Yes	No	No	Ibuprofen, Phenazone

Table 5. Scores for each domain of the AGREE II instrument

Guideline	Scope and Purpose	Stakeholder Involvement	Rigor of Development	Clarity of Presentation	Applicability	Editorial Independence	Recommendation
CPG 1	100%	100%	97%	100%	83%	48%	Recommended
CPG 2	100%	100%	100%	100%	81%	100%	Recommended
CPG 3	100%	94%	91%	100%	68%	85%	Recommended
CPG 4	100%	91%	100%	100%	81%	100%	Recommended
CPG 5	68%	44%	42%	84%	28%	58%	Recommended with Modifications
CPG 6	100%	89%	100%	100%	81%	100%	Recommended

The guidelines achieved an overall average of 94.66% within the first domain "scope and purpose," clearly demonstrating the general objectives of identification, classification, treatment, and prevention in a specific manner[1].[16–21] CPG 5, "Management of otitis media with effusion in children. Société française d'ORL et de chirurgie cervico-faciale clinical practice guidelines," did not provide good descriptions and received a score (68%) lower than the other evaluated guidelines[21].

The second domain, "stakeholder involvement," received an overall average of 86.33%, establishing good involvement of healthcare teams concerning disease management. The guideline from France (CPG 5) did not show relevant involvement from professionals[21].

Regarding domain three, "rigor of development," the guidelines from the United States (CPGs 2, 3, 4), South Korea (CPG 1), and Italy (CPG 6) had an average above 90%, demonstrating methodological rigor and clarity in description.[16–20] In contrast, CPG 5 received a score below 50%, corresponding to a lack of methodological rigor[21]. The overall average in this domain was 88.33%, indicating that, in general, the guidelines are being developed with methodological rigor.

In relation to domain four, "clarity of presentation," the CPGs scored above 80%, achieving an overall average of 97.33%. The overall average was 70.33%. CPG 5 received the lowest score (28%), suggesting a need for improvement in this domain for better applicability.[21]

Finally, domain six, "editorial independence," presented values lower than the other domains, with CPG 1 and CPG 5 scoring 48% and 58%, respectively.[17,21]

The Kappa test achieved a score of 0.85, corresponding to the almost perfect classification proposed by the test, indicating an excellent agreement in the evaluations and highlighting a higher quality due to the certainties proposed by the assessors.[17,21]

Discussion

Clinical guidelines, in line with healthcare provision, have undergone significant changes in recent decades.[8] The evaluated guidelines in this study, the guidelines were considered to have good methodological quality. This result was expected considering the complexity and high cost of developing a quality CPG, as the process requires qualified professionals, external review, tools, and resources for dissemination.[7]

Out of the six guidelines studied, five (83%) (one from South Korea, one from Italy, and three from the United States) were classified as recommended, and one guideline (from France) was evaluated as "recommended with modifications." Although the AGREE II instrument[10] also has the potential to be used as a checklist during the development of guidelines to enhance quality, and not just to evaluate it after publication, the studied guidelines did not report having utilized the instrument at this stage.

The domains "clarity of presentation" and "scope and purpose" received the highest scores across all guidelines, as previously noted by other studies evaluating guidelines[32,33]. High scores in these domains suggest that the methodological requirements in areas that assist professionals in their decisions regarding the usefulness of the guidelines in their work contexts are being met.

The lowest percentages in AGREE II were obtained in the domains "applicability" and "editorial independence." Deficiencies in the area of editorial independence may compromise the reliability of the guidelines, leading to distrust among users due to the perception of possible influences resulting from conflicts of interest of the team and funding bodies.[34] This suggests the need for studies to clarify whether guideline developers are neglecting to include statements about funding and conflicts of interest or omitting them intentionally due to existing conflicts of interest that may have negative effects on the content of the guidelines.[35] Regarding the domain "applicability," a discussion is warranted on the tools that can stimulate the practical application of guideline recommendations, such as the use of educational instruments, summary documents, guides, and/or digital tools.[7,35]

The domain "rigor of development" presented an average score of 88%. Only one CPG (5) received a low score (42%) in this domain, while the other guidelines scored above 90%. It is noteworthy that the low score in this domain is particularly concern-

ing, as this domain may be a stronger indicator of quality than any other, given its more direct effect on the quality of the recommendations. This was demonstrated in a study on guideline evaluations using AGREE II, which showed that items 7 to 12 of the domain "Rigor of Development" had a strong influence on the recommendation for the use of the guidelines.[36] It is important to highlight that the low scores in the items of this domain, especially in CPG 5, were related to the lack of description of the procedures that led to the selection of evidence and the formulation of recommendations. The absence of an explicit relationship between the recommendations contained in the guidelines and the evidence that supported them can undermine the reliability of these recommendations. Improvements in this regard could be achieved by including a more detailed description of the process adopted for evidence selection and reporting the recommendation process.[7,37]

Finally, the domain "stakeholder involvement" is considered fundamental to ensure that the priority topics of the guidelines are identified and that comprehensive evaluations of evidence and other considerations are made. Development groups should ideally consist of individuals with expertise in research methodology, a combination of general practitioners and specialists, healthcare professionals, as well as public managers and patients or end-users of the document.[38] In this study, the average found in this domain was 86%, suggesting that, in general, the evaluated CPGs had good stakeholder involvement.

Within the pharmacological interventions, the guidelines demonstrated uniformity in treatments with analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) for initial intervention. This management aims to alleviate pain symptoms and is considered the first-line treatment. This care process seeks to avoid unnecessary use of antibiotics.[16–18,21]

The use of medication was not recommended for the treatment of otitis media with effusion in any of the guidelines.[20,21,30]

Regarding non-pharmacological practices for otitis, the interventions followed the same pattern aimed at preventing and reducing the risks of disease exacerbation. The prevention risks are modifiable; that is, the recommendations are to avoid exposure to passive smoking and to conduct proper health monitoring.[16–18]

Concerning the guideline for impacted cerumen, preventive care is also addressed to minimize discomfort symptoms through the use of ceruminolytics for the removal of wax in the auditory canal.[19]

This article has some limitations. The inclusion of access criteria to the language of the text and the choice of its database for searching clinical practice guidelines, as guidelines written in languages other than English and Portuguese, which had restricted access and were not indexed in the selected databases, were beyond the scope of this article. Secondly, the AGREE II user manual indicates that some of the information necessary for evaluating the quality of CPGs may not be included in the guidelines themselves but may be recorded in a separate document.[10] To standardize the search, a methodological decision was made to include in the quality assessment of AGREE II only information from the corresponding guideline and supporting documents that could be retrieved from the systematic online search conducted. Therefore, it is possible that the information on the development of the CPGs, while existing, was not accessible to the evaluators, which directly impacts the scores assigned to each domain of each CPG.

Conclusion

The results, in accordance with AGREE II, indicate that the evaluated guidelines demonstrate good quality and offer opportunities for improvements, both individual and collective. These improvements pertain to the evidence underpinning them, as well as presenting the recommendations in a more comprehensible manner, reducing conflicting interests, enhancing applicability and editorial independence, and increasing stakeholder involvement. Enhancing these aspects could contribute to improving the reliability and adherence of healthcare professionals and health managers. Furthermore, there is an established pattern of recommendation for non-pharmacological treatment and medications among all the evaluated guidelines.

Acknowledgments

The authors thank the institutional support.

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