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Appraisal of the "pediatric ARDS: consensus recommendations from the pediatric acute lung injury consensus conference" with the AGREE II instrument

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Background/aim: The "Pediatric Acute Lung Injury Consensus Conference" (PALICC) was convened in order to develop a taxonomy to define pediatric acute respiratory distress syndrome (ARDS). The Appraisal of Guidelines for Research and Evaluation (AGREE) assesses the quality of guidelines. The aim of this study is to evaluate the new pediatric ARDS guideline using the AGREE II instrument. To the best of our knowledge, this is the first assessment of the new pediatric ARDS clinical practice guideline in the English literature.

Materials and methods: Four appraisers assessed the new pediatric ARDS guideline with the AGREE II instrument. At the end of the evaluation each appraiser rated the overall quality of the guidelines.

Results: Results of the assessment were editorial independence 100%, clarity of presentation 94%, scope and purpose 89%, stakeholder involvement 78%, rigor of development 78%, and applicability 78%.

Conclusion: The new pediatric ARDS guideline received good scores especially with respect to editorial independence and clarity of presentation. Our overall AGREE II review of the PALICC guideline indicates that it has been created using high quality methodology and should be recommended for use and implementation as currently published.

Key words: Acute respiratory distress syndrome, AGREE II, pediatric critical care, quality

1. Introduction

Acute respiratory distress syndrome (ARDS) was first described by Ashbaugh et al. (1) in 1967. Since then clinicians and also pediatricians are using the definitions given by the American-European Consensus Conference (1994) and the Berlin Definition (2012) for ARDS (2,3). However, both definitions were created without specific consideration of children (4–6). Pediatric ARDS has different etiologies, pathophysiology, risk factors, and treatment modalities than adult ARDS. The differences between children and adults were not considered in either the Berlin Definition or the American-European Consensus Conference (4). Therefore, the Pediatric Acute Lung Injury Consensus Conference (PALICC) was organized to "develop a taxonomy to define pediatric ARDS", to "offer recommendations regarding therapeutic support of the patient with pediatric ARDS", and to "identify priorities for future research in pediatric ARDS" (4,5). The concept originated with the Pediatric Acute Lung Injury and Sepsis Investigators (PALISI) Network (4). The conference was supported by the Australian and New Zealand Intensive Care Society, Canadian Critical Care Trials Group, European Society for Pediatric and Neonatal Intensive Care, World Federation of Pediatric Intensive and Critical Care Societies, and French Group for Pediatric Intensive Care and Emergency Medicine (4).

The Institute of Medicine defined clinical practice guidelines (CPG) as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" in 1990 (7–9). Since the 1990s, CPGs have become a very important part of clinical practice (10). There was also a need for assessment tools for CPG as it was understood that the guidelines had potential benefits and harms (11). Various tools have been created in the fields of both guideline development and assessment and the AGREE instrument was developed in 2003 (11–14).

The AGREE instrument assesses the methodological rigor and transparency in which the CPG is developed. The original AGREE instrument was refined as AGREE II and translated into 33 different languages in 2009 (14–16). The Appraisal of Guidelines for Research and Evaluation

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II is composed of the appraisal tool (six domains, 23 items, 7-point response scale) and User's Manual (Table 1) (16). A recent initial scan of the literature revealed over 600 articles that have referenced the AGREE tools (16). Appraisal of Guidelines for Research and Evaluation Instrument has the most potential to serve as a basis for the development of an appraisal tool for clinical pathways in the "systematic review of appraisal tools for clinical practice guidelines" study conducted by Vlayen et al. (17). The AGREE II can be applied to clinical practice guidelines about any disease, treatment, or interventions.

To the best of our knowledge, the quality of the new pediatric ARDS clinical practice guideline has not been assessed using a guideline appraisal tool. In the present study, we aimed to assess the new pediatric ARDS clinical practice guideline (final recommendations of the Pediatric Acute Lung Injury Consensus Conference) using the AGREE II instrument.

2. Materials and methods

The new pediatric ARDS guideline was retrieved from *Pediatric Critical Care Medicine* (4). The Appraisal of Guidelines for Research and Evaluation II instrument and guideline document was retrieved from the AGREE Enterprise website (14–16). Before applying the AGREE II, users carefully read the guideline document. Users attempted to identify all information about the guideline development process prior to the appraisal. Assessors completed the online AGREE II overview tutorial and practice exercise and pilot tested the tool's use in two separate sets of CPGs before the guidelines' evaluation (14,15). The AGREE II developers recommend that each guideline is assessed by at least 2 appraisers and preferably 4 as this will increase the reliability of the assessment. The investigation team (OT, İT, RDY, and ÜÇ) applied the AGREE II instrument independently. All of the assessors responded to the 23 questions using a scale (1 for "strongly disagree" to 7 for "strongly agree") based on instructions described in the AGREE II manual (8,14,18). AGREE II uses six domains to assess guideline quality (Table 1). The domains include scope and purpose (3 items), rigor of development (7 items), stakeholder involvement (4 items), applicability (3 items), clarity of presentation (4 items), and editorial independence (2 items) (8,14,18). Two of the assessors were pediatric intensivists, two were pediatricians (division chief - PICU and clinical director - pediatric clinics and intensive care units).

2.1. Data analysis

Domain scores are calculated by summing up all the scores of the individual items in a domain and by scaling the total as a percentage of the maximum possible score for that domain (Table 2). Upon completing the 23 items, the users are also asked whether they would recommend use of the guideline and are requested to rate it (8,14). Statistical analyses were performed using SPSS Version 20. Categorical variables were provided as numbers and percentages, and numerical variables were given as mean ± standard deviation. Interrater reliability was calculated for each available domain of the AGREE instrument using the intraclass correlation coefficient (ICC) with a 95% CI.

3. Results

3.1. Domain 1: scope and purpose

This domain deals with the potential health impact of the CPG guideline on patients. The overall objective of the CPG should be described and the possible health benefits from the guideline should be specific to the disease. A detailed description of the health questions and clear description of the population covered by the CPG should be provided. General evaluation of scope and purpose was calculated as 89%.

3.2. Domain 2: stakeholder involvement

This item refers to the healthcare professionals who were involved in the development of the CPG. The target users should be defined in the CPG. The readers can determine if the CPG is relevant to them. General evaluation of stakeholder involvement was calculated as 78%.

3.3. Domain 3: rigor of development

This item refers to the details of the strategy used to search for evidence. Statements highlighting the strengths and limitations of the evidence should be in the CPG. A description of the methods used for the final decisions and recommendations should be provided. The relationship between the recommendations and the evidence on which they are based should be in the guideline. Clinical practice guidelines need to reflect current research on their topics and should be reviewed externally before they are published. General evaluation of rigor of development was calculated as 78%.

3.4. Domain 4: clarity of presentation

This item refers to the fact that "a recommendation should provide a concrete and precise description of which option is appropriate in which population group and which situation". Users of the CPG should be able to find the most relevant recommendations easily. General evaluation of clarity of presentation was calculated as 94%.

3.5. Domain 5: applicability

This item concerns the fact that the CPG should describe the facilitators and barriers to its application and should provide tools on how the recommendations can be put into practice. General evaluation of applicability was calculated as 78%.

3.6. Domain 6: editorial independence

This item refers to the fact that there should be a clear statement that the interests of the funding body have not

Table 1. The Appraisal of Guidelines for Research and Evaluation II domains and domains' purposes.

Domain 1. Scope and Purpose Contains 3 items, concerned with the overall aim of the guideline, the specific health questions, and the target population. 1. The overall objectives of the guideline are specifically described? 2. The health questions covered by the guideline are specifically described? 3. The patients to whom the guideline is meant to apply are specifically described?
Domain 2. Stakeholder Involvement: Contains 3 items, focuses on the extent to which the guideline was developed by the appropriate stakeholders and represents the views of its intended users. 1. The guideline development group includes individuals from all relevant professional groups? 2. The views and preferences of the target population have been sought? 3. The target users of the guideline are clearly defined?
Domain 3. Rigor of Development: Contains 8 items, relates to the process used to gather and synthesize the evidence, the methods to formulate the recommendations, and to update them. 1. Systematic methods were used to search for evidence? 2. The criteria for selecting the evidence are clearly described? 3. The strengths and limitations of the body of evidence are clearly described? 4. The methods for formulating the recommendations are clearly described? 5. The health benefits, side effects, and risks have been considered in formulating the recommendations? 6. There is an explicit link between the recommendations and the supporting evidence? 7. The guideline has been externally reviewed by experts prior to its publication? 8. A procedure for updating the guideline is provided?
Domain 4. Clarity of Presentation: Contains 3 items, deals with the language, structure, and format of the guideline. 1. The recommendations are specific and unambiguous? 2. The different options for management of the condition or health issue are clearly presented? 3. Key recommendations are easily identifiable?
Domain 5. Applicability: Contains 4 items, pertains to the likely barriers and facilitators to implementation, strategies to improve uptake, and resource implications of applying the guideline. 1. The guideline describes facilitators and barriers to its application? 2. The guideline provides advice and/or tools on how the recommendations can be put into practice? 3. The potential resource implications of applying the recommendations have been considered? 4. The guideline presents monitoring and/or auditing criteria?
Domain 6. Editorial Independence: Contains 2 items, concerned with the formulation of recommendations not being unduly biased with competing interests. 1. The views of the funding body have not influenced the content of the guideline? 2. Competing interests of guideline development group members have been recorded and addressed?
Domain 1. Scope and Purpose Contains 3 items, concerned with the overall aim of the guideline, the specific health questions, and the target population.
Domain 2. Stakeholder Involvement: Contains 3 items, focuses on the extent to which the guideline was developed by the appropriate stakeholders and represents the views of its intended users.
Domain 3. Rigor of Development: Contains 8 items, relates to the process used to gather and synthesize the evidence, the methods to formulate the recommendations, and to update them.
Domain 4. Clarity of Presentation: Contains 3 items, deals with the language, structure, and format of the guideline.
Domain 5. Applicability: Contains 4 items, pertains to the likely barriers and facilitators to implementation, strategies to improve uptake, and resource implications of applying the guideline.
Domain 6. Editorial Independence: Contains 2 items, concerned with the formulation of recommendations not being unduly biased with competing interests.

Table 2. Calculating the domain scores.

$$\text{The scaled domain score} = \frac{\text{Obtained score*-Minimum Possible score**}}{\text{Maximum possible score***-Minimum possible score}} \times 100$$

*Obtained score = Sum of the scores given by the appraisers
**Minimum possible score (Domain 1, includes 3 items) = 1 (strongly disagree) × 3 (items) × 4 (appraisers) = 12
***Maximum possible score (Domain 1, includes 3 items) = 7 (strongly agree) × 3 (items) × 4 (appraisers) = 84

influenced the final recommendations of the CPG. All group members should have declared whether they have any conflict of interests. General evaluation of editorial independence was calculated as 100%.

In the general evaluation of the new pediatric clinical practice ARDS guideline, assessors were asked whether they would recommend this guide for use and requested to rate the new pediatric clinical practice ARDS guideline (1 for lowest possible quality, 7 for highest possible quality). All assessors were suggested to use the present version and the assessors also agreed on the new pediatric clinical practice ARDS guideline's quality (possible highest quality).

The ICC values for the pediatric ARDS guideline appraisal using the AGREE II ranged from 0.474 to 0.936. The ICC could not be done for the domain "Applicability" because there were too few cases for the analysis (Applicability contains one item). All of the appraisers were convinced about the "Editorial independence" and thus an ICC was not necessary. The mean ICC value for "Scope and purpose", "Stakeholder involvement", "Rigor of development", and "Clarity and presentation" was 0.772 ± 0.201. The ICC values for the AGREE II instrument appraisal are listed in Table 3.

4. Discussion

The American-European Consensus Conference (1994) used for ARDS and the following Berlin Definition (2012) criteria are far from being completely applicable to pediatric patients. The lack of diagnosis and treatment CPG for the definition, treatment, and monitoring of children with ARDS has been fulfilled by the outcomes of the Pediatric Acute Lung Injury Consensus Conference (4). The AGREE scale has been used for the evaluation of CPGs since 2003 and is continuously updated (12,14). The new AGREE scale, AGREE II, is one of the best scales to evaluate the new pediatric ARDS guideline (13,17). New and old CPGs for ARDS have not been subject to evaluation. Although the results of the Pediatric Acute Lung Injury Consensus Conference seem to be newly generated, they have been composed depending on years' long experience from pediatric intensive care units. The new pediatric ARDS guideline has also satisfied the goals of each of the AGREE II domains according to a new CPG.

As it has been prepared by experts in their fields and is based on many resources, the new pediatric ARDS guideline has received a high score (100%) in editorial independence by assessors. Another field that has received high scores (94%) was clarity of presentation. When the pediatric ARDS guideline was prepared, the format, language, and structure were found quite satisfactory by the assessors. The first domain (scope and purpose) of the AGREE II scale, evaluating the general aim of the guide, the target group, and special health problems, has received 89% scores from assessors. The guide has been thought to be satisfactory in this field too. In contrast, it received lower scores (78%) in domains 2, 3, and 5. This may be related to the fact that the guide is new and does not represent users' opinions and therefore it has received lower scores in domain 2, which evaluates stakeholder involvement.

Table 3. Interrater reliability for each domain.

Domains	ICC (95% CI)
Scope and purpose	0.857 (–0.037–0.996)
Stakeholder involvement	0.936 (0.533–0.998)
Rigor of development	0.474 (–0.561–0.882)
Clarity and presentation	0.821 (–0.303–0.995)

Domain 5, which deals with applicability, has received lower scores from assessors although difficulties in the implementation have been explained in the guideline. Domain 3, which deals with rigor of development, also received lower scores, which may be due to the fact that the subject is poor in studies based on evidence, the guideline has been subject to external evaluation, and date of update has not been provided.

Most of the domains showed a high reliability. Thus, the scores between the appraisers showed a strong correlation, and values were high for most domains except for "Rigor of development". The domain "Rigor of development" has eight items and this was the most important reason for the relatively low ICC value.

In conclusion, when evaluated with AGREE II instrument, the new pediatric ARDS guideline received good scores especially with respect to editorial independence, clarity of presentation, and scope & purpose. Our overall AGREE II review of the new pediatric ARDS guideline indicates that it has been created using high quality methodology and should be recommended for use and implementation as currently published.

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