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Critical Appraisal of the Clinical Practice Guidelines for the Management of Dyslipidaemias: Lipid Modification to Reduce Cardiovascular Risk: European Society of Cardiology (ESC) and European Atherosclerosis Society (ESC/EAS) 2019 Guidelines

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Abstract

Objective The aim of the study was to assess the quality of the recently published European clinical practice guidelines for the management of dyslipidaemias, utilizing the refined Appraisal of Guidelines for Research & Evaluation tool.

Method The 2019 European Society of Cardiology and European Atherosclerosis Society Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk was appraised and scored for methodological rigour and transparency by 5 independent appraisers using a validated tool.

Key findings The guideline scored highest in the domains that evaluated editorial independence (100%) and clarity of presentation (98.6%) and lowest in the domains that addressed stakeholder involvement (55.56%) and rigour of development (63%). Overall the quality of the guideline was high, and all reviewers recommended its use in practice.

Conclusion The guideline's overall quality was judged to be high, and all appraisers recommended its use in practice without modifications.

Keywords clinical practice guidelines; dyslipidaemias; management; cardiovascular risk; EAS; ESC

Introduction

Atherosclerotic cardiovascular disease (ASCVD) is a leading cause of morbidity and mortality.^[1,2]

It is the leading cause of death in the United States among most racial/ethnic groups, with an estimated annual cost that exceeds \$200 billion, most of which is related to sub-optimal prevention practices and inadequate control of ASCVD risk factors in many adults.^[1,2]

The figures are striking in Europe as well, with estimations of more than 4 million deaths annually due to cardiovascular disease, of which ASCVD is the major component.^[3]

Thus, comes the demand for an updated guideline that incorporates latest evidence with expertise to guide actions in clinical practice for the prevention of ASCVD.

Recently, the Task Force for the management of dyslipidaemias of the European Society of Cardiology (ESC) and European Atherosclerosis Society (EAS) updated their lipid guidelines to be aligned with latest evidence about ASCVD prevention through lipid management.^[4]

The aim of this research is to evaluate the quality of the latest ESC/EAS lipid guidelines through utilizing a validated tool.

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Table 1 Summary of domains appraisal results

Domain 1. Scope & Purpose						
	Item 1 The overall objective(s) of the guideline is (are) specifically described	Item 2 The health question(s) covered by the guideline is (are) specifically described	Item 3 The population to whom the guideline is meant to apply is specifically described	Total		
Appraiser 1	5	6	5	16		
Appraiser 2	7	7	7	21		
Appraiser 3	7	6	7	20		
Appraiser 4	7	6	4	17		
Total	26	25	23	74		
Scaled domain score: $(74-12)/(84-12) = (62/72) \times 100 = 86\%$						
Domain 2. Stakeholder Involvement						
	Item 4 The guideline development group includes individuals from all relevant professional groups	Item 5 The views and preferences of the target population have been sought	Item 6 The target users of the guideline are clearly defined	Total		
Appraiser 1	2	1	4	7		
Appraiser 2	5	3	7	15		
Appraiser 3	5	6	6	17		
Appraiser 4	7	1	5	13		
Total	19	11	22	52		
Scaled domain score: $(52-12)/(84-12) = (40/72) \times 100 = 55.56\%$						
Domain 3. Rigour of Development						
	Item 7 Systematic methods were used to search for evidence	Item 8 The criteria for selecting evidence are clearly described	Item 9 The strengths and limitations of the body of evidence are clearly described	Item 10 The methods for formulating the recommendations are clearly described	Item 11 The health benefits, side effects and risks have been considered in formulating the recommendations	Item 12 There is an explicit link between the recommendations and the supporting evidence
	Item 13 The guideline has been externally reviewed by experts prior to its publication	Item 14 A procedure for updating the guideline is provided				
Total						
Appraiser 1	4	3	2	4	5	7
Appraiser 2	2	4	3	2	7	7
Appraiser 3	2	2	2	1	6	6
Appraiser 4	5	5	5	1	7	7
Total	13	14	12	8	25	27
Scaled domain score: $(153-32)/(224-32) = (121/192) \times 100 = 63\%$						

Table 1 (Continued).

Domain 4. Clarity of presentation					
	Item 15 The recommendations are specific and unambiguous	Item 16 The different options for management of the condition or health issue are clearly presented	Item 17 Key recommendations are easily identifiable	Total	
Appraiser 1	7	7	7	21	
Appraiser 2	6	7	7	20	
Appraiser 3	7	7	7	21	
Appraiser 4	7	7	7	21	
Total	27	28	28	83	
Scaled domain score: $(83-12)/(84-12) = (71/72) \times 100 = 98.6\%$					
Domain 5. Applicability					
	Item 18 The guideline describes facilitators and barriers to its application. 20. The potential resource implications of applying the recommendations have been considered	Item 19 The guideline provides advice and/or tools on how the recommendations can be put into practice	Item 20 The potential resource implications of applying the recommendations have been considered.	Item 21 The guideline presents monitoring and/or auditing criteria.	Total
Appraiser 1	3	7	6	7	23
Appraiser 2	1	7	3	3	14
Appraiser 3	4	7	6	3	20
Appraiser 4	6	7	7	5	25
Total	14	28	22	18	82
Scaled domain score: $(82-12)/(112-12) = (70/100) \times 100 = 70\%$					
Domain 6. Editorial independence					
	Item 22 The views of the funding body have not influenced the content of the guideline.	Item 23 Competing interests of guideline development group members have been recorded and addressed	Total		
Appraiser 1	7	7	14		
Appraiser 2	7	7	14		
Appraiser 3	7	7	14		
Appraiser 4	7	7	14		
Total	28	28	56		
Scaled domain score: $(56-12)/(56-12) = (44/44) \times 100 = 100\%$					

Methods

The Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument is a tool that assesses the methodological rigour and transparency of guideline development.^[5] It was originally designed to address the issue of variability in guideline quality and later modified into the currently available AGREE II.^[6]

The later consists of 6 domains (entailing 23 key items), each of which ‘captures a unique dimension of guideline quality’.^[6] The domains are followed by 2 global rating items that reflect overall assessment and recommendation for use in practice.

Four evaluators, who are clinical pharmacists with background experience in general medicine and cardiology, read the guideline and supplementary data thoroughly and performed the guideline review and appraisal independently. The evaluators were trained to use the AGREE II instrument through the online tutorials on the AGREE website in addition to studying the AGREE II user’s manual.^[7]

The scores were then submitted independently to a fifth investigator, who calculated the overall domain scores. Descriptive statistical analysis was used to calculate the score per domain by summing item scores within each domain, then standardizing them as a percentage of the maximum possible score, based on AGREEII guidance. The agreement between different reviewers was measured by intraclass correlation (ICC) with a 95% CI and was calculated via IBM SPSS 16.0. using two-way mixed effects model where people effects are random and measures effects are fixed considering a consistency definition. The ICC score ranges from 0 to 1. The closer the score is to 1, the smaller the variation between different appraisers, and an ICC ≥ 0.70 is considered acceptable.

Results

The guideline scored highest in the dimensions that evaluated editorial independence (100%) and clarity of presentation (98.6%) and lowest in the domains that addressed stakeholder involvement (55.56%) and rigour of development (63%). As all domains scored more than 50%, authors recommended this guideline to be used in practice.

Table 1 provides a summary of details on 6 domains and 23 items of the appraisal tool and corresponding appraisers ratings.

Intraclass correlation coefficient (ICC) with 95% confidence interval for average measures was 0.864 (0.746–0.935), which is considered acceptable (Table 2).

Discussion

Quality of clinical practice guidelines need to be criticized for methodological rigour and transparency before

incorporating them in patient care and decision-making. Thus, guideline appraisal tools were developed and applied for this purpose. Currently, AGREEII tool is the most extensively validated and utilized tool.^[8]

The current appraisal of the guideline indicates its high quality and supports its application in practice. The domains related to editorial independence and clarity of presentation scored highest. However, domains addressing stakeholder involvement and rigour of development scored lowest. The guideline did not provide a clear description about seeking views and preferences of target population. Patient engagement has become a key element of high-quality evidence-based clinical practice guidelines (CPGs).^[9] In addition to AGREE II recommendations, World Health Organization (WHO) recommends involvement of relevant stakeholders ‘if feasible and efficient’ to ensure integration of appropriate values in guideline recommendations.^[9]

Moreover, UK’s National Institute for Health and Care Excellence (NICE) mandates inclusion of at least two patient/caregiver/advocate members in all guidelines developed.^[10]

Patient engagement in CPGs is meant to ensure the development of more patient-centred guidelines that lead to patients’ empowerment and improvement of guideline execution and related quality of care.

With regard to methodological quality and rigour of the guideline development, reviewers questioned comprehensiveness and reproducibility of the literature search as the guideline only included a general statement of conducting a structured literature search without providing further details. Overall quality assessment of the guideline was high. All appraisers agreed that guideline would be recommended for use in practice without any modification.

One limitation for this research might be that it was conducted by pharmacists only, without involvement of other healthcare disciplines. Although all guideline appraisers had underwent AGREE II online training, subjectivity in differentiating between scale scores and variability in how scoring was done might be another limitation.

Conclusion

Critical appraisal of the quality of the recently published 2019 ESC/EAS Guidelines for the management of dyslipidaemias indicates overall high quality and agreement to recommend its use in practice without modifications.

Declarations

Conflict of interest

All authors of this research declare that they have no conflicts of interest to disclose.

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Table 2 Intraclass Correlation Coefficient ICC

	ICC	95% Confidence interval
Single measures	0.613	(0.423– 0.782)
Average measures	0.864	(0.746– 0.935)

Authors' contributions

All Authors state that they had complete access to the study data that support the publication.

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