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The use of guidelines development standards in recommendations and guidelines for retinopathy of prematurity

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Abstract

Objective: Our publication aimed to identify and present standards and tools implemented in the development of guidelines for retinopathy of prematurity (ROP).

Methods: The results were based on complementary data extraction from records identified in the systematic review of the guidelines for retinopathy of prematurity performed in 2022. We examined the type of evidence used to develop the guidelines, the standards followed by authors in developing guidelines, and the system for classifying scientific evidence quality. The identified standards for guideline development were checked for validity and the methodology for assessing scientific evidence and presenting recommendations was described.

Results: Our analysis of twenty-three retinopathy of prematurity guidelines uncovered two standards: World Health Organization Handbook and Setting Standards for the Development of Clinical Guidelines in Paediatrics and Child Health by Royal College of Paediatrics and Child Health (RCPCH). Only two guidelines from India and Latin America followed the WHO handbook and applied the GRADE system for assessing the quality of evidence and recommendations, while the United Kingdom guidelines adhered to the RCPCH standard and SIGN Grading Hierarchy.

Conclusion: Our analysis revealed the need for improvement in the process of creating guidelines for retinopathy of prematurity in most countries. We believe that by raising awareness about the tools available to support authors we are able to spread their use as a standard practice.

Introduction

The clinical practice guidelines are documents that aim to help practitioners make decisions in the therapeutic process. It is essential to present evidence-based data transparently and in a systematised way. Guideline development is a sustained and challenging process therefore obtaining valuable data requires a precise approach to the issue.

Many tools and qualification systems, such as GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) include a methodology on how to formulate guidelines to ensure that presented data are of high quality.[1] GRADE is the widely adopted tool for grading the quality of evidence and provides a clear and structured methodology for developing and presenting evidence summaries. Due to its comprehensiveness and transparency, it was adopted in numerous countries. Many organisations and societies such as World Health Organisation (WHO)[2], and National Institute for Health and Clinical Excellence[3] base their guidelines on the GRADE methodology. Unfortunately, not all guidelines include the GRADE approach. This was demonstrated by research, which revealed that among 240 Australian practice guidelines only fifteen embraced GRADE for assessing evidence.[4]

The aim of our publication was to define what tools were implemented in the development of guidelines for retinopathy of prematurity (ROP) and with what frequency they were used globally.

Methods

The results are based on complementary data extraction from records identified in the systematic review of the guidelines for retinopathy of prematurity that was performed in 2022.[5] Search strategy, inclusion, and exclusion criteria have been described in the systematic review. Data extraction included: 1. the type of evidence on which guidelines were developed, 2. standards followed by authors during the process of guideline development, and 3. a system for classifying scientific evidence quality. The identified standards for guideline development were checked for validity on the publishers' websites. The methodology of assessing the quality of scientific evidence and presenting the strength of recommendations in these standards was described. Previous versions of standards were excluded.

Results

Our analysis of twenty-three retinopathy of prematurity guidelines revealed that two standards were used during the guideline development process: 1. WHO Handbook for Guideline Development [2] and 2. Standards for Development of Clinical Guidelines in Paediatrics and Child

Health by Royal College of Paediatrics and Child Health (RCPCH).[6] When verifying the validity of these two standards, an updated version of the RCPCH standards for the development of guidelines was found, included in the review, and discussed later.[7]

Only guidelines from India and Latin America adhered to the WHO handbook, while the United Kingdom followed the standards set by the RCPCH. These findings are presented in Table 1 and demonstrate significant variations in guideline adoption strategies among countries. Two guidelines implementing WHO handbook applied the GRADE system for data classification, and the guidelines from the United Kingdom applied the Scottish Intercollegiate Guidelines Network (SIGN) grading hierarchy,[8] indicating a standardised approach to evidence evaluation. In contrast, other countries employed diverse methodologies such as literature reviews, expert consensus, or the use of national data without a standardised classification system.

Discussion

The use of an appropriate methodology that takes into account the GRADE tool, provides high-reliability recommendations and increases the chance of positive assessment using guideline evaluation tools.[32] For this reason, organisations such as WHO and RCPCH in their new standards[7] both recommend the GRADE methodology for guideline development. Unfortunately, many authors do not conduct a systematic approach to the process of creating guidelines and the quality of including data remains often unsatisfactory.[4, 5] Using non-systematic methods compromises the validity and reliability of recommendations, leading to potentially untrustworthy results.

WHO actively incorporates the GRADE methodology into its guideline development process. The GRADE methodology serves as a systematic and transparent approach used in the WHO handbook to assess the quality of evidence. When creating guidelines, WHO applies the GRADE methodology to varying extents, depending on factors such as the nature of the guideline and the available evidence.[33, 34]

During the development of guidelines, the WHO handbook recommends a comprehensive assessment of each relevant research. This assessment includes evaluating the study design, examining the potential risks of bias, ensuring consistency of findings across multiple studies, assessing the precision of the reported results, and considering the possibility of publication bias. In this process, WHO conducts systematic reviews of available studies that investigate various treatment approaches. The design of each study is critically evaluated to determine its reliability and potential sources of bias. This evaluation process allows WHO to ensure the use of high-quality evidence and minimizes the risk of drawing incorrect conclusions. Based on the accumulated evidence, WHO recommends assigning a GRADE rating to each body of evidence. This rating indicates the level of confidence in the estimated effect derived from the analysed evidence. The GRADE rating system classifies the evidence as high, moderate, low, or very low, providing transparency about the strength of the recommendations. The incorporation of the GRADE methodology helps to thoughtfully examine both the benefits and potential limitations of interventions. By considering all of these factors of guideline development, WHO aims to publish guidelines that are of high quality, evidence-based, and clinically useful.[2]
Setting Standards for the Development of Clinical Guidelines in Paediatrics and Child Health provides the newest summary of the RCPCH standards for guideline development within the United Kingdom. RCPCH aims to improve and diminish inequalities in clinical practice in paediatrics by ensuring that guidelines are based on the proper evidence.[7]

RCPCH incorporates National Institute for Health and Care Excellence (NICE) methodology[3] into its standards. When creating guidelines, the NICE key principles are followed: 1. ensuring that guidance is based on the best evidence of effectiveness and cost, 2. involving independent committees of experts, 3. including at least two lay members, 4. conducting consultations to allow stakeholders to comment on the recommendations, 5. reviewing and updating published guidelines if necessary, 6. ensuring the processes, methods and policies necessary for guideline development remain up-to-date.

RCPCH Guideline Development Group (GDG) collaborate with stakeholders to ensure the usefulness of guidelines in daily clinical practice. RCPCH conducts an assessment of collected data and each relevant publication is evaluated with respect to its methodology and reliability. Since 2013 the GRADE approach has been recommended to assess the quality of evidence, replacing the earlier system used in the SIGN methodology.[7] The previous was based on grades of recommendations (A-D, Good Practice Point), the assignment of which depended on the strength of the evidence and the possibility of extrapolating the results to the target population. Good Practice Points grades were based on the clinical experience and consensus of the GDG.[8]

Incorporation of GRADE methodology enables the comparison of collected data on many levels, including internal validity, inconsistency, indirectness, imprecision, or publication bias. RCPCH emphasises the significance of GRADE methodology due to its comprehensiveness

Table 1. Characteristics of the retrieved guidelines and recommendations.

Country	Author, reference	Year	Title	Standard followed	Classification system
Canada	Jefferies et al.[9]	2016	Retinopathy of prematurity: An update on screening and management	-	-
Czech Republic	Zobanová et al.[10]	2018	Screening, treatment and long-term observation of retinopathy of prematurely born children in the Czech Republic	-	-
Egypt	United States Agency for International Development et al.[11]	2010	Neonatal Care Protocol for Hospital Physicians	-	-
India	Chandra et al.[12]	2020	Screening and Management of Retinopathy of Prematurity	WHO	GRADE
India	Ministry of Health & Family Welfare India[13]	2017	Guidelines for Universal Eye Screening in Newborns Including Retinopathy of Prematurity	-	-
India	Public Health Foundation of India et al.[14]	2018	Project Operational Guidelines. Prevention of Blindness from Retinopathy of Prematurity in Neonatal Care Units	-	-
Indonesia	Siswanto et al.[15]	2020	How to prevent ROP in preterm infants in Indonesia?	-	-
Kenya	Ministry of Health Kenya[16]	2018	National guidelines for the Screening and Management of Retinopathy of Prematurity in Kenya	-	-
Latin America	International Agency for the Prevention of Blindness - Latin America[17]	2010	Guidelines for ROP Screening and Treatment in Latin American Countries	-	-
Latin America	Pan American Health Organization [18]	2019	Clinical Practice Guidelines for the Management of Retinopathy of Prematurity. Summarised Version 2017	WHO	GRADE
Malaysia	Ministry of Health Malaysia et al.[19]	2005	Clinical Practice Guidelines. Retinopathy of Prematurity	-	-
New Zealand	Newborn Clinical Network et al.[20]	2017	Consensus statement for Screening for Retinopathy of Prematurity	-	-
Philippines	Philippine Academy of Ophthalmology et al.[21]	2013	Recommended Philippine Guidelines for Screening and Referral of Retinopathy of Prematurity	-	-
Philippines	Philippine Pediatric Society et al.[22]	2020	Retinopathy of Prematurity Philippine Preventive Care Plan Strategy	-	-
Poland	Gotz-Więckowska et al.[23]	2020	Polish Ophthalmological Society revised guidelines for the management of retinopathy of prematurity	-	-
Saudi Arabia	Al Amro et al.[24]	2018	Practical guidelines for screening and treatment of retinopathy of prematurity in Saudi Arabia	-	-
Slovakia	Prepiaková et al.[25]	2014	Screening of Retinopathy of Prematurity (ROP)	-	-
South Africa	Visser et al. [26]	2013	Guideline for the prevention, screening and treatment of retinopathy of prematurity (ROP)	-	-
Spain	Ferrer Novella et al. [27]	2013	Screening program for retinopathy of prematurity in Spain	-	-
Sri Lanka	College of Ophthalmologists of Sri Lanka et al. [28]	2019	National Guidelines for Screening for Retinopathy of Prematurity	-	-
Turkey	Koç et al. [29]	2018	Turkish Neonatal and Turkish Ophthalmology Societies consensus guideline on the retinopathy of prematurity	-	-
United Kingdom	Royal College of Paediatrics and Child Health et al. [30]	2008	Guideline for the Screening and Treatment of Retinopathy of Prematurity	RCPCH [6]	SIGN
United States of America	Fierson et al. [31]	2018	Screening Examination of Premature Infants for Retinopathy of Prematurity		

GRADE = Grading of Recommendations, Assessment, Development, and Evaluation, RCPCH = Royal College of Paediatrics and Child Health, SIGN = Scottish Intercollegiate Guidelines Network, WHO = World Health Organization.

and transparency. However, this approach may be more demanding and pose difficulties for small organisations, which collaborate with RCPCH. For this reason, RCPCH also considers utilising a non-GRADE approach.[7]

Although GRADE tool is an excellent standard for guideline development, only three[12, 18, 30] from twenty-three guidelines in this review used GRADE. This review indicates significant variations in the strategies used to collect and present data on ROP across different countries. While some authors rely on rigorous literature reviews, others base their guidelines on national or international data without any standardised methodology. Understanding the reasons behind these differences and identifying country-specific limitations is crucial for harmonising global guideline development processes.

Conclusions

Determining the quality of the evidence and the strength of the recommendations is essential to present evidence-based data transparently, enabling their easy use in clinical practice. Our analysis revealed the need for significant improvement in the process of creating guidelines for retinopathy of prematurity in most countries. We hope that raising awareness about the tools available to support authors will help spread their use as a standard practice.

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