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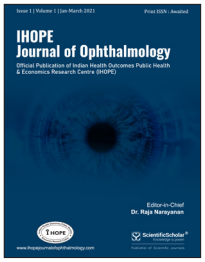

NICE Knowledge Exchange Seminars

Quality assurance in guidelines development

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ABSTRACT

Background: This study explores the pivotal role of quality assurance (QA) in shaping evidence-based clinical guidelines, examining its significance within individual guidelines and broader guideline portfolios.

Considerations for Guideline Development: (1) Importance of Guidelines: Clinical guidelines act as foundational pillars in defining quality care, establishing best practices, and standardizing patient care, significantly influencing healthcare delivery and resource allocation. Consequently, stringent QA measures are crucial to maintain their integrity. (2) Essential QA Team Expertise: A robust QA team requires proficiency in guideline methodologies, systematic reviews, meta-analysis, health economics, and clinical insights, ensuring a comprehensive perspective and adherence to established methods. (3) QA Processes for Guidelines: QA processes aim to ensure the methodological robustness, relevance, and alignment of each guideline with national policies and developer mandates. Simultaneously, QA across multiple guidelines ensures consistency, mitigating conflicts and overlaps in specialized areas. (4) Key QA Challenges: Challenges such as methodological appropriateness, adherence to guideline remits, and consistency in terminology demand careful QA oversight to uphold guideline credibility.

Conclusion: The indispensable role of QA in guideline development cannot be overstated. Adhering to prescribed methods and processes is vital to prevent flawed or unimplementable recommendations, thereby safeguarding the credibility of guideline developers and fostering trust in the guideline development process.

Keywords: Guidelines development, Quality assurance, Evidence-based guideline

A second knowledge exchange seminar series was organized as a part of the collaborative project between NICE International and IHOPE to develop and implement evidence-based clinical guidelines in India. This paper is number 2 in the second series of this collaboration, and further information on the other papers can be found at: https://ihopejournalofophthalmology.com/issue/2022-1-2/

INTRODUCTION

The objective of this paper is to consider the role of quality assurance when developing guidelines from both an individual guideline perspective and a guideline portfolio perspective.

Evidence-based clinical guidelines are a benchmark of quality care. They identify best practices to be carried out and outline the standard of care that patients should be offered. Clinical guidelines, thus, have a huge impact on the delivery of care and healthcare resource use. The guidelines that are produced should be of the highest quality to help improve the care provided.

An error in even one guideline can compromise the entire guideline program as well as negatively impact the reputation of the guideline developer.

WHO IS NEEDED FOR A QA TEAM?

A quality assurance team generally should include people with skills and experience to ensure that guidelines meet the established standard. These skills and experience include guideline development methodology, systematic reviewing, meta-analysis, and health economics as appropriate, knowledge of the processes to be followed, experience of quality assurance, and clinical knowledge. These are important to provide a clinical perspective on the draft recommendations as well as to ensure that the agreed methods and processes have been followed.

QUALITY ASSURANCE TASKS ON SINGLE GUIDELINE

The quality assurance function should ensure that each guideline is methodologically robust, up-to-date, credible, implementable, and relevant to the healthcare system. The quality assurance function will also ensure that there is no conflict with national or state policy or if it is outside the remit of the guideline developer. For example, in the UK, decisions on screening sit with the National Screening Committee[1], so a guideline on diabetic retinopathy (DR) should not include annual retinal screening for people with diabetes.[1]

All guideline outputs are subject to the quality assurance process. For example, suppose monitoring of a condition is listed as a topic to be covered in the guideline. In that case, a draft review question, review protocol, evidence review, and a discussion of the evidence should be produced, and quality should be assured to support any draft recommendations.

The quality assurance team should ensure that the evidence reviews follow the methods outlined in the review protocol and are consistent with methods outlined in the guideline methods manual. It is considered best practice to document any deviations from a protocol that has been agreed upon with the quality assurance team or to use methods that are not included in the methods manual. With this in mind, those responsible for quality assurance should liaise closely with the technical team throughout the guideline development process. This process should be outlined in the guideline development process and followed for each guideline. This close liaison will ensure that any issues that may arise, such as the committee wanting to draft recommendations that are outside the remit of the guideline, are resolved as soon as possible.

The IHOPE team will receive QA support from the NCG, as agreed by both bodies. This will be because IHOPE currently does not have a QA process in place for the current screening guidelines for DR. For the glaucoma guidelines, which are under development, we have referred to the NCG guidelines Sections 7.1/7.2/7.3, respectively. A summary of the same is provided in the Table 1.

Table 1: Summary of NCG guidelines for quality assurance (QA) Support in IHOPE.

Quality assurance guidelines	Post-drafting, the guideline development group (GDG) coordinators undertake their screening to ensure all processes and principles of the NCG are met. It also helps identify areas that might require further clarity. It is important to note that no recommendations can be changed at this stage.
Consulting with the grid network and stakeholders	Stakeholder consultation improves the guideline's quality, legitimacy, and acceptability to users and improves its chances of adoption. They also have the potential to: • Manage controversies earlier • Feedback from a wider audience identifies any gaps in evidence • Improve the wording of the guidelines • Obtain feedback on the effective dissemination of guideline implementation. The full guideline draft is published on the website for two months for open consultation to wider audiences. Next, the guideline development process, the parameters for comments, and the template for the comment submission are explained to the consulting stakeholders. Finally, the comments are compiled and presented thematically in a guideline consultation table, and the coordinators prepare a report on areas of major concern. The GDG discusses these comments in a meeting, and the final decision to accept or reject the changes is mentioned clearly with requisite reasoning.
Responding to stakeholder comments	The GDG might undertake an external review before publication under exceptional circumstances, such as technical or clinical expertise and lack of evidence. The final patient leaflet can be shared with laypeople to get feedback from the patients' perspective. The final decision has to be taken based on the recommendations and not only on these reviews.

With each evidence review, the quality assurance function should also look for a clear explanation of how and why the committee made the recommendations, and the committee discussion should clearly state the link between the evidence and the draft recommendations.

During the guideline consultation phase, external stakeholders will have an opportunity to comment on the draft recommendations and the supporting evidence and committee discussions. Once the consultation has been completed and the comments addressed by the topic expert committee, it is the role of the quality assurance function to ensure the stakeholders' comments have been addressed appropriately and that the guideline have been updated accordingly.

QUALITY ASSURANCE TASKS ACROSS MULTIPLE GUIDELINES

When multiple guidelines are being developed at the same time, the quality assurance function should check for and ensure consistency in terminology and content across all topics to avoid confusion and misunderstandings. This is to minimize the risk of conflicting advice in different guidelines. For example, a DR guideline should not cover the management of type 1 diabetes if this is already covered in another guideline relating to type 1 diabetes. It is expected that topics within specialized areas, such as ophthalmology, will have the potential for overlap. Hence, the quality assurance function should also include an assessment of possible overlaps and help mitigate this risk starting at the planning stage and throughout the development phase.

QUALITY ASSURANCE – LIKELY KEY ISSUES FOR THE SECRETARIAT

1. The methods and processes used are not appropriate or inconsistent. Each guideline recommendation should be developed in accordance with the methods manual[2]. So, the quality assurance function should check that all evidence reviews have been conducted appropriately and also for inconsistency in methods and presentation of findings across reviews.
2. Guideline remit creep – A guideline committee may want to stray outside the agreed remit and evidence base when drafting recommendations. For example, if the guideline remit excludes children and young people, but the evidence base includes studies with children as well as adults. A committee may be tempted to draft recommendations covering the whole population.
3. Inconsistent use of terminology and inadequate justification of the recommendations or explanation of how the topic expert committee reached their conclusions.

CONCLUSION

The importance of the quality assurance function in guidelines should not be underestimated. Guidelines must be developed according to the agreed methods and processes to minimize the risk of poor practice through lack of clarity in the guidance, incorrect recommendations, or unimplementable recommendations that will follow a poorly developed guideline. A poorly developed guideline will also negatively affect the reputation of the developing organization and lead to a lack of trust and engagement with the process.

Ethical approval

The Institutional Review Board approval is not required.

Declaration of patient consent

Patient's consent was not required as there are no patients in this study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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