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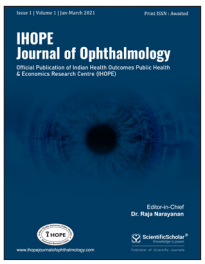

Updates

Developing and quality assuring clinical guidelines

Kriti Shukla[1], Hugh McGuire[2], Pilar Pinilla Dominguez[2]

[1]Indian Health Outcomes, Public Health and Economics Research Centre (IHOPE), Indian Institute of Public Health, Hyderabad, Telangana, India, [2]NICE International and Scientific Advice, National Institute for Health and Care Excellence, London, United Kingdom.

***Corresponding author:**
Kriti Shukla,
Indian Health Outcomes,
Public Health and Economics
Research Centre (IHOPE),
Indian Institute of Public
Health, Hyderabad, Telangana,
India.

kriti.shukla@iiphh.org

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ABSTRACT

Medicine is a dynamic and evolving discipline that calls for rational, scientific, and evidence-based decision-making to enhance patients' quality of care. The use of guidelines to support decision-making has increasingly become an important part of clinical practice. This paper highlights the rationale and importance of developing and quality assuring guidelines that underpin the NICE process for developing guidelines.

Keywords: Guideline development, Quality assurance, Guideline development process

Medicine is a dynamic and evolving discipline that calls for rational, scientific, and evidence-based decision-making to enhance patients' quality of care. The use of guidelines to support decision-making has increasingly become an important part of clinical practice. Guidelines are systematically developed evidence-based recommendations relating to the care of people with a specific condition. They are designed to assist clinicians, patients, and public health policy-makers in making informed decisions regarding – interventions, diagnostic tests, or public health measures to achieve the best possible health outcome for individuals and the population.

The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care. NICE is an executive non-departmental public body, sponsored by the Department of Health and Social Care, UK.[1] It offers services that share best practices and expertise from NICE to help drive improvements in health-care decision-making through collaboration and partnerships with health organizations, ministries, or government agencies internationally.[2]

The Indian Health Outcomes, Public Health, and Economics Research Center (IHOPE) is a collaborative and interdisciplinary research center set up in 2020, focusing on three key areas in eye health, that is, big data analysis, public health research, and health economics. A series of knowledge exchange seminars were organized as a part of the collaborative project between NICE International and IHOPE to develop and implement evidence-based clinical guidelines in India.

The objective of this paper is to summarize the areas covered on the first of this session which included:

- An insight into the rationale that underpins the NICE process for developing and quality assuring guidelines, which can be adapted to the context in which IHOPE operates
- The importance of understanding the difference between organizing a guideline development process or system and developing guidelines

- An overview of the guideline ecosystem within which NICE operates.

GUIDELINE ECOSYSTEM

Understanding the guideline, "ecosystem" in which NICE operates is fundamental to understanding the processes NICE uses to produce guidelines and make a decision about which topics to prioritize. NICE is a core part of a continuous cycle of quality improvement. From the moment, in which a guideline is published, adoption and implementation activity generate new evidence or data around uptake. This, in turn, feeds into new research in terms of data analysis and interrogation, leading to revised evidence syntheses which may lead to a guideline being updated with the new evidence. Alongside this, there is a constant supply of new research evidence, new interventions, and changes in the context in terms of national policies which may also lead to a new guideline being developed or an existing guideline being updated.

TOPIC SELECTION

NICE considers certain factors when deciding which topics to include in its guideline portfolio including whether there is variation or debate in (best) practice, any potential for cost savings or reducing ineffective care, the impact of the condition on the population, the likelihood of evidence changing practice, whether a guideline will add any value to existing advice, whether there are health inequalities which can be addressed, and if there is scope for partnering with other organizations for the development of the guideline.

Having a process in place when deciding which topics to develop a guideline on and being transparent in the decision-making process helps NICE to make its process inclusive of the wider community and increases the chance of stakeholders being involved and hence, adopting and implementing the guidelines recommendations.

GUIDELINE DEVELOPMENT PROCESS

The NICE commissioning team manages the entire guideline development process and coordinates the different teams involved in guideline development. These include a guideline development team, a quality assurance team, an editorial team, a patient and public involvement team, and implementation support team, a communications team, and a resource impact team. Having clarity on the roles and responsibilities for each team and the timings when they will be involved in each step in the process allows the NICE commissioning team to plan which guidelines will be developed years in advance. This coordination is essential to the smooth running of a guideline development program. The commissioning team aims to balance time (when a guideline is needed), quality (in terms of methodological rigor), and funding (cost of developing the guideline) when managing a guideline program.

NICE has a number of guideline development teams who work within a number of "guideline slots" to manage capacity and workload. For each individual guideline, the guideline development teams are responsible for recruiting the guideline committee, drafting the scope of the guideline, systematic reviewing, and health economic modeling, engaging with the committee to interpret the evidence, and drafting recommendations and responding to stakeholder comments.

Key stages of guideline development are illustrated in [Figure 1] and, in total, the overall period of time for developing a *de novo* guideline can take between 2 and 2.5 years to complete. The stages include scoping, reviewing the evidence, and drafting the recommendations and supporting documents. Throughout this process, equality issues related to age, gender, ethnicity, disabilities, socioeconomic status, and access to services are considered.

The scoping phase is used to develop, refine, and finalize the scope for the guideline, with inclusion and exclusion criteria in place. Scoping meetings are held to refine the scope. These are attended by the developer team, guideline committee chair, commissioning team, and quality assurance team. A stakeholder workshop is also conducted to get feedback from registered stakeholders on the contextual issues of note including sub-populations, key issues they consider should be covered in the guideline as well as what professionals should be recruited to the committee to sit alongside lay members. These stakeholders include representatives of patient or professional organizations as well as other groups such as commissioners of services or voluntary support groups who have an interest in the topic. There is an online public scope consultation on the draft scope after the workshop. All comments are collated, responded to, and discussed at the final scoping meeting when the scope is finalized. To ensure transparency, NICE then publishes the scope online alongside the stakeholder comments and the development teams response to those comments.

The development team is responsible for committee recruitment and is required to recruitment policies and procedures including the declaration of interest. The committee constituency is between 12 and 15 members with sufficient representation from relevant professional groups to ensure the committee expertise covers the whole of the scope. Usually, two patients, carers, or members of patient organizations are also recruited to ensure that the views of those affected with or related to the condition are included in the process of guideline development. Committee members are recruited through an open advertisement on the NICE website and all shortlisted applicants are interviewed by the developer lead and the committee chair.

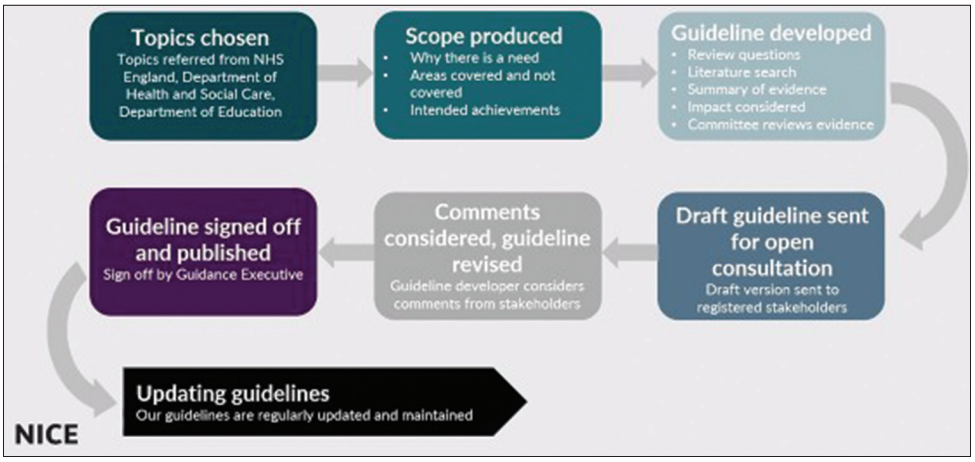

Figure 1: NICE guideline development process (taken from NICE International and IHOPE session 1 – Developing and quality assuring guidelines 9th November 2021).

Once recruitment is complete, the developer reviews the evidence, and the evidence review document is sent to the committee. The evidence review is comprised of GRADE tables, evidence tables, and draft evidence statements. The committee is expected to interpret the evidence in light of their professional and lay expertise and to consider a number of variables in their decision-making [Figure 2]. At the committee meeting, the committee agrees on recommendations. An explanation of how the committee interpreted the evidence is recorded in the "Committee discussion" section. This is important for transparency so that readers understand the detailed discussion of the evidence and the other factors the committee took into account when drafting the recommendations. There is also an accompanying "Rationale and Impact section" that provides a brief plain language overview of why the committee made the recommendation and the potential impact of the recommendations on the service.

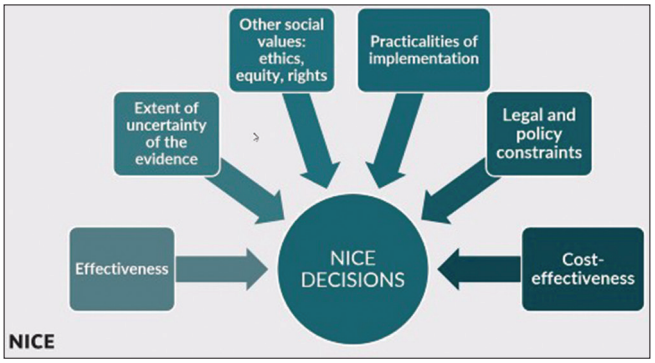

Figure 2: Considerations during evidence review and guideline development (taken from NICE International and IHOPE session 1 - Developing and quality assuring guidelines 9th November 2021).

QUALITY ASSURANCE

Independent quality assurance of the guideline development process is crucial to maintain the methodological rigor of the guidelines produced. NICE guidelines must be developed in line with the methods outlined in the Guideline Manual[3] which provides a clear framework to ensure consistency in how guidelines are developed. The quality assurance team performs this independent quality assurance role in NICE.

As well as ensuring consistency across all guidelines, this is a recognition of the fact that the impact of national guidelines is huge and so errors in developing even one of these guidelines carry a risk to all involved not least to the patients and the service in general. Given that the NICE guidelines program is supported by public funding, there is a need to demonstrate that decisions made are justifiable and that due process has been followed. The independent quality assurance is a key step in the process of demonstrating to stakeholders that NICE guidelines are produced to the highest methodological standards.

CONCLUSION

The importance of understanding the context (or ecosystem) in which guidelines are being produced cannot be underestimated. This understanding allows for guideline topics to be selected based on national priorities. Having a centralized process for managing the guideline development process facilitates the development of high-quality guidelines. Being transparent around methods and processes and having regular input from stakeholders throughout are also key components of this process to ensure the guideline are as appropriate as possible.

Declaration of the patient consent

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

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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