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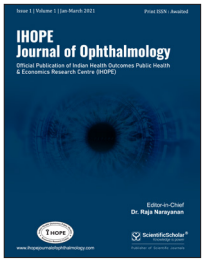

Updates

Using real-world data alongside evidence in guideline development

Knowledge exchange seminar series
A collaboration between NICE International and IHOPE

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This knowledge exchange seminar series was organized as a part of the collaborative project between the National Institute for Health and Care Excellence (NICE) International and IHOPE to develop and implement evidence-based clinical guidelines in India. This paper is the fifth in the series and further information on the other papers can be found at https://ihopejournalofophthalmology.com/current-issue.

An important aspect in developing guidelines is the usage of available data. This article summarizes the NICE process for using real world evidence in clinical guidelines which can be adapted to the IHOPE context.

REAL WORLD DATA- AN INTRODUCTION

Real world data have been critical for guidelines since their conception, yet its meaning and subsequent usage have evolved considerably. Initially "real world" data were used as data from a research study. The emphasis was on the type of data, when it was collected and how it was collected. However, now the emphasis is on the data itself, and how that data can be used for guideline development.

Depending on the guideline review question, good quality randomized controlled trials (RCT) will always be the optimal source of data, for example, where relative treatment effects estimates are needed. However, good quality RCTs may not always be available or be sufficient for decision-making. For example, the available RCTs may have a small sample size, or have generalizability issues. In these scenarios, it would be important to consider the benefits of using other types of data including real world data to support decision-making. It will be important for the guideline committee to balance the methodological limitations of non-RCTs alongside the higher level of generalizability these data can provide. Hence, it is crucial to assess how reflective the real world data are to the general practice of the local context of relevance.

To ensure methodological robustness of the real world data used in guideline development, NICE has developed quality criteria for the use of real-world data in guidelines.

In most cases, real world data is used in NICE guidelines for the following purposes:

- To characterize the health condition, interventions available, care pathways, patient outcomes, and experiences
- To design, populate, and validate health economic models. This might include sourcing real world data to obtain estimates such as baseline rates of events or disease progression, outcomes including quality of life, or long-term extrapolation of outcomes. Other estimates that can be sourced from real world data include data on diagnostic accuracy and downstream effects on care pathways.

CASE STUDIES

1. Disease progression: NICE used registry data (The Health Improvement Network database) to establish the demographics of the population or the sub-populations attending primary care clinics for diabetes care
2. Risk prediction: Real world evidence was used to examine a risk prediction model for cardiovascular disease. It found that for the average patient, the QRisk3 was good at predicting risk. When the data was reanalyzed using the number of co-morbidities it was found that the QRisk3 did not perform as well depending on the number of com-morbidities
3. Treatment Pathways for age related macular Degeneration: NICE used RCTs to understand the short-term efficacy of interventions and real world data to understand the longer-term outcomes

CONCLUSION

To date, the real world data that have been generated have had limited use for guideline development. The reasons for this include methodological flaws in how these data have been collected and analyzed. Ongoing development of methodologies around real world data has improved our understanding of what constitutes real world evidence and in what circumstances it is expected to be most reliable and useful. NICE is developing and is about to publish an evidence standards framework for real world evidence to provide clear guidance on the expectations for the planning, conduct, reporting, and appraisal of real world evidence studies.

Declaration of patient consent

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

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Nil.

Conflicts of interest

There are no conflicts of interest.

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