Conclusions. FOSP population-based cancer registries are a powerful tool to obtain information for planning, and improving the management of healthcare services especially for São Paulo.

PD23 Assessing The Suitability Of Real-World Data For Answering Decision Problems – NICE's Data Suitability Assessment Tool

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Introduction. The National Institute for Health and Care Excellence (NICE) intends to increasingly use real-world evidence in developing guidance. To increase trust in such evidence, NICE has developed a framework for developing and assessing real-world evidence studies, including understanding the value of the selected data source for the decision problem.
Methods. Starting with published high-quality studies about data quality, we developed a conceptual model of the elements needed to understand the quality of a data source. Results from a literature search were then mapped to the model. We used this to design a structured reporting tool, the data Suitability Assessment Tool (dataSAT), and tested it in several cases studies. Additionally, we engaged with internal and external stakeholders to obtain feedback on the tool and revised it accordingly.
Results. DataSAT covers provenance of the data, assessment of data quality, and the data's relevance to the research question. For data provenance, information is requested about the data source independent of the study's interests, including the purpose, setting, dates of operation, funding, data specification, and management and quality assurance plans for the data sources. Data quality is covered by quantitively assessing the completeness and accuracy of the following key study elements to inform critical appraisal of the study: population inclusion and exclusion criteria; intervention; comparator; and outcomes and key covariates. The findings on data sources and data quality are then interpreted in terms of relevance to the decision problem. This includes relevance to the population in the United Kingdom, the treatment pathway and care setting, the availability of key study elements, time-related factors such as length of follow up, and the effects of sample size and missing data on the validity of findings.
Conclusions. DataSAT allows summary information on source data, including quality and relevance, to be reported in a structured manner, enabling decision makers to better understand how the data influence the robustness of analyses used in health technology assessment. This helps increase trust in the use of real-world evidence.

PD24 Robust Real-World Evidence Generation In Comparative Effects Studies – NICE's Methods Guidance

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Introduction. Recent reviews have shown that many real-world evidence (RWE) studies suffer from avoidable methodological flaws. Meanwhile, the National Institute for Health and Care Excellence (NICE) is seeing an increase in RWE submissions in Health Technology Appraisals and is keen to support the use of this evidence. However, limited guidance exists for the development and assessment of RWE, risking both missed opportunities for unbiased evidence generation and inconsistent decision making based on that evidence. As part of its RWE framework, NICE has developed methods guidance to provide clear expectations for the conduct and reporting of non-randomized comparative effects studies using real world data.
Methods. A conceptual model and draft framework were developed based on established international best practices in RWE and observational research. This was refined with focused literature searches, for example, on the use of external control arm studies. We then engaged with external stakeholders to incorporate their feedback and develop case studies. A reporting template was developed and tested on multiple use cases.
Results & Conclusions. The guidance stresses the central importance of a target trial approach to study design, e.g., adopting an active comparator, new user design, where possible. Target trial emulation is a useful tool to improve the quality and transparency of RWE studies, helping to overcome selection and confounding biases. Various other study design and analytical approaches are outlined for addressing confounding bias and biases due to missing data, measurement error, or misclassification, which are common challenges in RWE. Alongside traditional approaches to sensitivity analysis, the framework promotes quantitative bias analyses which includes a range of methods to assess and communicate the potential impact of remaining bias to study findings by quantifying the direction, magnitude, and uncertainty of bias. A reporting template, based on common methodological pitfalls, is provided to help evidence developers consider key areas of bias in their work and to inform reviewers of any approaches used to investigate or resolve these.

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