This study reviewed the influence of RWE submitted as part of the evidence base for NICE oncology appraisals.
Methods. A search for NICE HTEs was conducted for interventions supported by SATs from January 2017-November 2021. Evidence was stratified by submission packages with SAT evidence alone or in combination with randomized controlled trial (RCT) evidence, with or without RWE.
Results. Thirty-two decisions for interventions supported by SATs were made by NICE between 2017-2021, all in oncology indications. Fifty percent were supported by SAT evidence and fifty percent by RCT plus SAT evidence, both with or without RWE. A lower proportion of RCT/ SAT HTEs submitted RWE compared to SAT HTEs (fifty vs ninety four percent). Seventy five percent and nineteen percent of SAT HTEs received a positive recommendation, with and without restrictions, irrespective of submitting RWE. One negative decision was observed for SATs supported by RWE. Sixty three percent and thirty eight percent of RCT/ SAT HTEs received a positive recommendation, with and without restrictions. Overall, the proportion of positive recommendations were lower for HTEs submitting RWE (ninety six percent) compared to HTEs not submitting RWE (one hundred percent), which is in contrast to recent findings specific to orphan oncology HTEs (one hundred versus seventy eight percent).
Conclusions. RWE was more commonly submitted to support SAT HTEs, than RCT HTEs. The use of RWE seems to be established as a necessity to supplement a SAT evidence base, whereas RWE is more generally a nice to have in RCT HTEs. However, RWE appears to positively influence decision-making for orphan oncology indications with a more neutral influence for non-orphan indications.

PD21 Data Sources And Real-World Data On Medical Devices In The Brazilian Scenario

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Introduction. The Brazilian government has made efforts in systems to generate data from medical devices (MD). This work explores the main systems and data sources in the perspective of contributing as a source to generate real world data (RDW).
Methods. Document review of relevant national data sources for MD. In addition, a structured search was carried out in EMBASE using key descriptors for RWD applied to the regulatory context and to the management of health technologies, without date or language restrictions.
Results. Eighteen primary federal government data sources for MD were identified. Not all sources are publicly accessible. Of the articles, the search returned 1,185 results, of which 29 titles were selected and 8 met the protocol's objective. Included articles were from Europe, the United States and Canada. As in other countries, Brazil initially systematized DM administrative data to meet commercial and financial demands. With the evolution of health technology assessment methods, the use of RDW has become imperative to assess the value of MD to society. Common examples from these countries are implantable MD databases. Current challenges focus on data linkage and quality, in addition to standardized naming. The adoption of the Unique Device Identification (UDI) is one of the promising initiatives to facilitate traceability throughout the lifecycle proposed in the International Medical Device Regulators Forum (IMDRF) of which Brazil is a member. Among the systems, the following stand out: i) ConectSUS, which intends to provide access to health information centered on the patient, anywhere and at any time; ii) National implant registry that generates data on implanted prostheses and stents, surgical techniques used, the profile of patients and the health services involved.
Conclusions. This work showed the similarities between Brazil and other countries in the management of MD data throughout its life cycle, as well as mapped the national primary data sources for MD.

PD22 Exploratory Analysis of a Brazilian Real-World Open Database Applied to Prostate Cancer

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Introduction. Prostate cancer was the second most frequent cancer and the fifth leading cause of cancer death among men in 2020. The incidence rates vary substantially in countries with different Human Development Indexes (HDI), while the mortality rates decrease with improved access to the health system, availability of therapies and earlier detection. Worldwide, population-based cancer registries are important tools for planning and managing health systems. The Fundação Oncocentro de São Paulo (FOSP) is responsible to collect, clean and publicize data from cancer treatment institutions. This study aimed to describe retrospectively the demographic and clinical profile of prostate cancer (PC) in Brazil using this database. It is not an incidence study as data is representative only from specific institutions.
Methods. This was a retrospective observational study of the years 2000 to 2020 from analysis of the publicly available FOSP database (http://www.fosp.saude.sp.gov.br).
The records were extracted, merged, and cleaned using a fully documented and validated data process. Only patients included on the register with a primary PC diagnosis were considered.
Results. From January 2010 to June 2020, there were 943,660 patients diagnosed with C61 in FOSP database for the considered time period. The majority of the FOSP database records are from patients who live and/or were born in SP (91.8 and 58.4%, respectively) or MG (2.8 and 10.5%, respectively). The mean age of PC at baseline was 69 years. Considering the stage of the disease, the mean ages are 55, 70, 67, 66 and 61, for stages 0, 1, 2, 3 and 4, respectively. This cohort was also analyzed in relation to treatments received, and status at the end of treatment (51.3% are disease-free, 18.4% are alive with cancer, and 30.3% are dead).

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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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