Methods. Literature reviews covering earlier reviews of RWE use, academic papers, and HTA agency websites were combined with case studies involving interviews with decision-makers in four countries (England, France, Italy, Sweden) to identify the circumstances of breakdown of RWE use and to build a categorization of the uses of RWE and associated difficulties. This evidence supported the creation of a taxonomy of pairings of data sources and the questions they were used to address. The face validity of the approach was tested at an advisory board of senior HTA practitioners.
Results. In total, 27 questions were identified and 10 types of data source, giving 270 pairings. These pairings were linked to relevant methods guidance and to examples of their use, itemizing HTA issues and decisions made. Reports are being prepared for publication, covering the detail of the methods of the literature searches; methods of the country case studies; a description of the taxonomy; and guidance on governance.
Conclusions. When using RWE in HTA decision-making, the detail of the particular data sources and question addressed matter. Recently, both the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and the Real-World Transparency Initiative have argued for a registry of the uses of RWE. The work described here offers a starting classification of the material that should be held in such a registry, and which in itself could be developed by the stakeholders, both agencies and companies, that use it, furthering trust and confidence.

OP42 Increasing Access To Real-World Data To Move From Health Technology Assessment To Health Technology Management

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Introduction. When assessing existing or emerging technologies using a one-off health technology assessment (HTA) we do not take into consideration the effects on people who will receive the technology once approved. Developments in real-world data (RWD) can help to address this by moving to ongoing health technology management (HTM).
Methods. To move to HTM, we first need to develop HTM data requirements. We undertook user interviews with National Institute for Health and Care Excellence (NICE) HTA developers to develop a list of requirements. We surveyed the types of data that NICE currently has access to and performed a gap analysis to understand where further data is needed. We then worked with external systems partners to identify and review available data sources that could support HTM.
Results. From our user interviews we established eight HTM data requirements. Data needed to be linked, cover full care pathways, contain data from new collections, be shareable, have direct access, be of high quality, have comprehensive coverage, and be responsive to technological developments (such as artificial intelligence). The review of data sources revealed a fragmented landscape of health data in the United Kingdom (UK). We identified National Health Service Digital's (NHSD) Trusted Research Environment as the main data source that could address HTM requirements. This addresses challenges with fragmented data by providing approved researchers with timely and secure access to a range of linked health and care data. We also identified that a large national data collection would not capture all technologies, such as orphan technologies for rare conditions. We therefore established a process for accessing data from smaller data collections such as disease specific registries. To address how we can use this data, we developed the NICE Real-World Evidence (RWE) Framework that provides clear guidance on the expectations for the planning, conduct, reporting, and appraisal of RWE studies.
Conclusions. We have established requirements for the type of data that will help to deliver HTM as well as developed a process for accessing several suitable data sources that meet these requirements.

OP43 Conceptual And Methodological Factors Driving The Integration Of Real-World Evidence In Drugs And Technologies Reimbursement Appraisals

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Introduction. Real-world evidence (RWE) can be of value to support comparative effectiveness of drugs and technologies by providing additional information about their use for a variety of patients in real contexts of care. However, the integration of RWE in appraisals can be challenging, and INESSS felt the need to reinforce and explicit the underlying methodological and theoretical foundations.
Methods. A comprehensive literature review was carried out, followed by collaborative development work by members of the methodological and assessment teams.
Results. The literature review led to a common understanding of RWE underlying principles and fed the subsequent phases of the project. Three factors were identified as driving the integration of RWE in reimbursement appraisals at INESSS. Specifically, (i) the design and conduct of the real-world studies are done in accordance with best practices, (ii) the results are presented transparently and include all relevant information to assess the quality of the study and the data, and (iii) the RWE submitted is appropriate and relevant for decision-making. This third component is further ascertained by considering the decisional context (what are the circumstances motivating the submission of RWE and how does it correlate or not with existing evidence?), the data (is the dataset fit for decision needs?) and the study methods (are study design and analytical methods robust enough?). Globally, INESSS considers the integration of RWE in appraisals and its weighting, in relation with the (more traditional) available evidence, to be a case-by-case exercise.

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