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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Conclusions. The characterization of the main factors driving the integration of RWE in reimbursement appraisals at INESSS serves as a basis for communicating the requirements for evaluation submissions by sponsors. It further reinforces INESSS capabilities in assessing innovations, which can imply an appraisal of value at various moments along the lifecycle and with a diversity of evidence types. Considering the rapidly evolving literature and international experience, this work is expected to evolve too, and will be updated as needed.

OP44 Does The Health Economic Modelling Structure Matter? An External Validation Of Three Approaches Commonly Used In Obesity Modelling

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Introduction. Obesity, defined as a body mass index (BMI) greater than 30kg/m^2, is a multifactorial disease with severe health and economic consequences. As obesity associated events impact long-term survival, health economic (HE) modelling is commonly used. However, the current set of modelling approaches are very diverse and lack external model validation. The aim of our research was to compare the event simulation and the HE outcomes of different structural approaches.
Methods. We performed an external validation of three main structural modelling approaches for estimating obesity-associated events: (i) continuous BMI-related risks; (ii) general risk equations; and (iii) categorical BMI-related risks. The Swedish Obese Subjects (SOS) intervention study was used for validation. Outcomes compared were mortality, cardiovascular events (CVE), and type 2 diabetes (T2D), over time using the long-term data from the SOS study, looking at both the surgery arm and the control arm. Concordance between modelling results and the external validation study was measured by visual examination of the best fitting linear regression lines, R^2 coefficients, the root mean squared errors, and F-tests. Furthermore, we compared the HE modelling results, comparing surgery versus control, expressed as cost per quality-adjusted life-year (QALY) gained based on 1,000 Monte Carlo simulation samples.
Results. Mortality was overestimated by all approaches irrespective of the study arm. For CVE an overestimation by all structural approaches was observed for the control arm. The CVE surgery arm was overestimated by the categorical BMI approach and slightly underestimated by the others. For T2D an underestimation was observed for the continuous and the categorial BMI approaches, whereas there was an overestimation by the risk equation approach. Considering different confidence interval limits, the cost per QALY gained are comparable between all structural approaches.
Conclusions. None of the structural approaches provided perfect external event validation results although the risk equation approach showed the smallest deviations compared to the external validation study. The cost per QALY gained resulting from the three approaches were fairly comparable.

OP46 Assessing The Quality Of Pharmacoeconomic Evaluations About Type 2 Diabetes Mellitus Drugs In National Reimbursement Drug List

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Introduction. With the disease spectrum changing in China, type 2 diabetes mellitus (T2DM) has become the main chronic disease which affects people's health severely, bring patients serious economic burden of disease. For T2DM patients, reliable quality of evidence in decision-making are significant, improving the efficiency of the adjustment of the National Reimbursement Drug List (NRDL). Based on the Consolidated Health Economic Evaluation Reporting Standards (CHEERS), we aimed to evaluate the quality of all published pharmacoeconomic evaluations on T2DM drugs in 2020 NRDL.
Methods. Because the 2020 NRDL came into effect on 1 March 2021, we searched all published pharmacoeconomic evaluations about T2DM drugs in 2020 NRDL before March 2021 in China National Knowledge Infrastructure (CNKI), Wan fang Data, China Science and Technology Journal Database (VIP), PubMed, and Web of Science. According to the criterion of inclusion and exclusion, all documents were screened and then relevant basic information of targeted documents was extracted. The quality was evaluated by calculating the final scores based on CHEERS. Two reviewers assessed each publication's quality using the CHEERS instrument and summarized study quality.
Results. A total of 910 papers were searched, and 24 papers were included. These involved six T2DM drugs, specifically IDegAsp, exenatide, liraglutide, lixisenatide, dapagliflozin and empagliflozin. The average score was 18.31, the standard deviation was 3.67, and the average scoring rate was 77.41 percent. Among all items, "characterizing heterogeneity" scored 0.04, least satisfied with requirements. "Setting and location", "choice of health outcomes" and "assumptions" scored one, most satisfied with requirements. Among the average scores of all parts, "results" scored lowest at 0.55, and "methods" scored highest at 0.85. The Wilcoxon sum-rank tests showed that score rate which represented reporting quality of economic evaluation (EE) was significantly related to "journal type", "EEs type", "model choice" and "study perspective".
Conclusions. The methodological quality of pharmacoeconomic evaluations about T2DM drugs in 2020 NRDL needs to be improved. Improving the quality of literature is the basic guarantee of scientific decision-making in national medical insurance negotiation.

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