

PP09 Use Of Real-World Evidence For Managing Health Technologies Throughout The Life Cycle Of Transcatheter Aortic Valve Interventions

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Introduction. A Cardiology Evaluation Unit was established in 2004 within Québec's Institut national d'excellence en santé et en services sociaux (INESSS) with a novel mandate to collect real-world evidence (RWE) to complement literature-based health technology assessment. In 2010 following publication of the seminal PARTNER trial, INESSS was mandated by the health ministry to review the evidence on transcatheter aortic valve intervention (TAVI) for patients with aortic stenosis. Herein we show how RWE was used to evaluate health system performance throughout the technology's life cycle and inform organizational and clinical decisions.

Methods. Various products were diffused by INESSS over the years: a guidance (2012), an updated literature review (2017) and provincial standards (2017), in parallel with RWE reports covering TAVI use from 2013-2015, from 2013-2018, and a 2021 RWE report combined with administrative data covering transcatheter and surgical treatment of aortic stenosis from 2013-2019.

Results. Based on the guidance's review of evidence, TAVI was initially recommended for patients considered at too high risk for the surgical approach, under the condition of continued evidence generation to address uncertainty. The subsequent literature review update highlighted that the indication for TAVI had been extended to patients at moderate surgical risk. INESSS produced standards in collaboration with clinical experts to optimize and harmonize the use of TAVI in designated centers. Evaluation of structures, processes and outcomes by INESSS continued until 2019, showing a continuous increase in the use of TAVI, improved short-term survival, and careful patient selection via a multidisciplinary process. RWE also highlighted the impact of TAVI on the overall organization of care for patients with aortic stenosis, as selection criteria further expanded to patients at lower surgical risk, raising important issues regarding patient selection processes, wait times, and longer-term outcomes.

Conclusions. TAVI clinical practice is constantly evolving and leads to changes in the management of aortic stenosis. RWE provided essential organizational and clinical input to inform clinical guidance and decision-making by Québec policy-makers, clinicians and patients.

PP10 Impact Of COVID-19 On The Management Of Breast Cancer In Italy: The Perspectives Of Patients And Coordinators

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Introduction. Breast Units (BU) represent an opportunity to adequately manage and improve quality of care for patients with breast cancer. The presence of specific national guidelines should promote safe and good quality, integrated care. In fact, the presence of a multidisciplinary team of specialists whose workflows follow specific guidelines, set to the highest European standards, should ensure that patients in Breast Units receive appropriate care at diagnosis and throughout the course of the disease.

Methods. Two surveys were developed and administered to Breast Unit coordinators and patients throughout Italy. The surveys investigated the provision of healthcare services and the implementation of a new organizational model over two time periods: the first wave of the coronavirus disease 2019 (COVID-19) pandemic from March 2020 to August 2020 and the second wave from September 2020 to December 2020. The surveys aimed to assess the continuity of care during the pandemic from the clinician and patient perspective.

Results. Patients observed a reduction in the postponement of care between the first wave of COVID-19 and the second wave. Some services were delayed, particularly in the second wave where a large number of services were not rescheduled. Management of the COVID-19 pandemic resulted in many healthcare professionals being reallocated to other duties and hospital departments. The effect of this was particularly relevant for both patients and clinicians, with few healthcare professionals having the capacity to focus on conditions other than COVID-19. In the first wave of the pandemic 42 percent of professionals were redeployed, compared with 27 percent in the second wave.

Conclusions. This study demonstrates how COVID-19 affected the care of patients with breast cancer in Italy. Patients and coordinators from Breast Units across the country highlighted many important aspects that should be considered when assessing the effects of the COVID-19 pandemic on the entire healthcare system in order to be better prepared for future pandemics.

PP11 Impact Of Qualitative Research In The Spanish Network Of Health Technology Assessment

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Introduction. Qualitative research is being increasingly integrated in health technology assessments (HTA) within the Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS). Qualitative research methodological guidelines are given in RedETS HTA guidelines and the Patient Involvement Strategy. A specific methodological guideline to systematically review qualitative studies was published in 2007 and is pending its update. The impact of their implementation is unknown. The aim of this work is to analyze the techniques, impact and reporting of qualitative research (primary and secondary) in HTAs.

Methods. A manual search of the HTAs published in the last 5 years in RedETS was conducted to locate assessments that include qualitative research. To ensure a complete identification, RedETS agencies and units were consulted to provide information about the assessments that have used qualitative techniques in their development over the past 5 years. A content analysis of the selected assessments was conducted to analyze the techniques, impact and reporting of qualitative research in HTA.

Results. In the past five years, focus groups, semi-structured interviews, evidence synthesis of observational studies including qualitative studies have been used and integrated in HTA in RedETS. Most of them have been linked to patient involvement facilitation or the inclusion of patient perspectives in HTA. Qualitative research has been used to analyze patient's experiences and values, to elicit and select important outcome measures for patients, to research for barriers-facilitators for technology implementation and to inform evidence to decision frameworks.

Conclusions. Qualitative primary and secondary research is being used in HTA in Spain. It is mainly linked to patient involvement strategies both to elicit patient perspectives directly or to collect patient-based evidence. The impact of qualitative research in HTA is broad and diverse, extending from the scope of the assessments to the drafting of the recommendations.

PP12 Challenges In Assessing The Efficacy Of Non-Pharmacological Measures In The Context Of The COVID-19 Pandemic

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Introduction. The outbreak of the COVID-19 global pandemic in 2020 has been a major challenge for the world's population and governments. The lack of vaccines, the saturation of health systems, and its rapid spread forced governments to take non-pharmacological interventions (NPI) that had a high impact on the population. Assessing the efficacy of these measures is a challenge for health technology assessment bodies.

Methods. The main NPIs for which assessment was required were: mobility restrictions, social distancing, cancellation of events or reduction of seating capacity, closure or reduction of seating capacity in non-essential businesses, closure or limitation of seating capacity in educational establishments, and promotion of teleworking in

potential jobs. The implementation of these measures at a global level provides a large population for the study of the impact of these measures. However, the challenges for their evaluation are numerous:

- The joint implementation of these measures makes it difficult to evaluate them in an isolated manner.
- The heterogeneity between countries and regions of the pandemic situation at the time when these measures are initiated and terminated.
- The different accuracy in the application of the measures.
- Heterogeneity in the quality and accessibility of public health services for citizens.

Results. Outcome variables to assess the effectiveness of these measures should include parameters related to:

- Incidence variables: the number of new or accumulated cases in a given time range, the variation in the number of cases in a given time range and the proportion of positive tests.
- Transmission variables: the basic reproductive number (R_0) and the effective reproductive number (R_t).
- Severity and mortality variables: the number or variation of hospitalizations, the number or variation of intensive care unit (ICU) hospitalizations and the number or variation of deaths.

Conclusions. The large number of available data, the heterogeneity of the measures, the differences between populations, the numerous outcome variables and the possible inclusion of mathematical modelling studies, are a methodological challenge for the HTA bodies.

PP13 Development Of Recommendations And Proposal For A Value-Based Managed Entry Agreement For Italian Setting

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Introduction. The continuous and pressing challenge that the drug regulatory authorities in Italy and in Europe are facing is that of guaranteeing patients' quick access to new drugs, ensuring the economic sustainability of the system at the same time. In recent years, flexible and diversified approaches have been developed known as Managed Entry Agreements (MEA).

Methods. We performed an analysis of the Italian legislative and regulatory aspects in reference to a new Value-based Managed Entry Agreement (VBMEA) pathway. Thus, we tried to investigate the rationale for a new pathway analyzing three main dimensions related to the new medical product (MP): value; time to entry access; and, data quality and registry design. Moreover, we shared the discussion of the proposal with an international experts' panel.

Results. The proposal for a new pathway of VBMEA from a procedural point of view shows the novelty related to the possibility to organize joint CTS (Technical Scientific Committee) and CPR (Price