monitoring safety; and informing HTA assessments and payer coverage decisions. Some stakeholders see great value in RWE and want to make greater use of these data sources, including for: drug effectiveness evaluations (including supplementing network meta-analyses); innovative study designs (including pragmatic trials); real time patient monitoring; and adaptive pathways or coverage with evidence development. However, others see numerous challenges, many of which are related to the quality and reliability of RWE sources. Acceptance of an expanded future role for RWE is not universal, and payers and developers must work together to find mutually beneficial strategies for progressing the development and use of RWE.

CONCLUSIONS:

Specific and actionable recommendations will be presented which highlight the role that each stakeholder group can play in overcoming the challenges and realizing the potential for RWE.

OP04 Cardiac Implant Registries: Systematic Review Of Global Practices

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INTRODUCTION:

The importance of Cardiac Implant Registry (CIR) for ensuring a long-term follow-up in post-marked surveillance has been recognized and approved, but there is a lack of consensus standards on how to establish a CIR. The aim of this study is to investigate the structure and key elements of CIRs in the past decade (2006–2016) and to provide recommendations on "best practice" approaches.

METHODS:

A systematic search on CIR was employed in line with the PRISMA guidelines. The following databases were searched: the PubMed (Medline), ScienceDirect, EMBASE and the Scopus database. After identifying the existing CIR, an inductive approach was used to explore key elements emerging in the identified registries.

RESULTS:

The following eighty-two registries were identified: eighteen ICD registries, seven CRT registries, five pacemaker registries, and six Cardiovascular Implantable Electronic Device (CIED) registries which combined ICD, pacemaker and CRT implantation data; as well as twenty-two coronary stent registries and twenty-four TAVI registries. While seventy-one national or local registries are from a single country, forty-four are from European countries, and nine are located in USA. The following criteria have been summarized from the identified registries, including: registry working group, ethic issues, transparency, research objective, inclusion criteria, compulsory participation, endpoint, sample size, data collection basement, data collection methods, data entry, data validation and statistical analysis.

CONCLUSIONS:

For HTA as well as regulatory decision making, medical device registries provide a "real-world" picture for patients, physicians, manufacturers, payers, decision-makers and other stakeholders. CIRs are important for regulatory decisions concerning the safety and approval issues of medical devices; for payers CIRs provide evidence on the medical device benefits and drive the decision as to whether the product should be reimbursed or not; for hospitals data from CIRs are important for sound procurement decisions, and CIRs also help patients and their physicians to reach a joint decision on which of the products is the most appropriate. However, many current CIRs are still lacking standards to inform on patient safety and ensure transparency.

OP07 Real World Evidence: How Can It Improve Health Technology Assessment?

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INTRODUCTION:

Health Technology Assessment (HTA) considers the question of whether evaluated technologies are cost-effective in real world settings. As observed in HTA conducted by the Australian Medical Services Advisory Committee (MSAC), questions regarding the validity of

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data inputs to economic analyses that reflect real-world practice is a common reason for uncertainty on the cost effectiveness of new technologies. In addition to resource use and costs, there may be other uncertainties regarding the eligible patient population, patient management pathways and comparator selection. Our objective in this study was to present case studies from Australia where real world linked datasets could be better utilized to inform HTA conducted by the MSAC.

METHODS:

For selected therapy areas, assessment reports and public summary documents of HTA conducted by the MSAC published between January 2015 and November 2017 were reviewed. Our analysis identified HTAs where uncertainties around the inputs for health economic evaluations, as well as uncertainties in defining eligible patient numbers or current patient pathways of care were shown to exist. We then explored whether these uncertainties could have been addressed through real world linked datasets.

RESULTS:

Our preliminary investigations identified two assessments: MSAC assessment of capsule endoscopy and transcatheter aortic valve implantation - where availability of real world linked data could have addressed uncertainties around the inputs required for the health economic evaluations.

CONCLUSIONS:

Australia has a range of real world datasets with the potential to be used to inform HTA conducted by the MSAC. This can only be achieved if the datasets could be better linked and accessible for use by key stakeholders in the MSAC HTA process (e.g. industry, clinician, patient societies). Use of these data sets in HTA will enable timelier patient access to cost-effective technologies and more effective implementation and review of technologies after adoption into clinical practice.

OP08 Using Real World Data To Support National Postmarketing Surveillance

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INTRODUCTION:

While medicines and medical tests are developed in a controlled clinical trial environment, postmarketing surveillance in the real world can be challenging. MedicineInsight—a database of longitudinal patient-level clinical information from primary care practices in Australia—is a novel program that collects primary care data to improve postmarketing surveillance at a national level.

METHODS:

MedicineInsight collects de-identified clinical information from primary care practice information systems using data extraction tools. MedicineInsight currently includes 3.6 million regular patients of 3,300 family physicians (general practitioners) from 650 primary care practices across Australia. MedicineInsight data include longitudinal clinical information on diagnosis and medicines (dose, strength, route of administration, medication switches over time, adverse events, and allergies), and pathology testing data. A series of observational studies was developed for postmarketing surveillance of management of a range of health priorities including type 2 diabetes mellitus (T2DM), chronic obstructive pulmonary disease (COPD), depression, and antibiotics use.

RESULTS:

Forty-four percent of patients with T2DM in the MedicineInsight database did not have a recorded hemoglobin A1c result and thirty-one percent did not have a recorded blood pressure reading in the previous 6 months. While guidelines recommend a stepwise approach to the initiation of COPD therapy, forty-nine percent of patients with COPD (with or without asthma) were prescribed dual therapy at initiation and a small number (4.5 percent) were prescribed triple therapy. Between 2011 and 2015, the annual rate of antidepressant prescribing per 1,000 family physician encounters increased by eight percent. High volumes of antibiotics were prescribed for respiratory tract infections in Australian primary care, notwithstanding guideline recommendations that antibiotics are not recommended in most cases.

CONCLUSIONS:

Large scale, real-world clinical data from primary care practices can play an important role in postmarketing surveillance at a national level.

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