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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