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Editorial

Perspectives on Improving Value Assessment With the ISPOR SUITABILITY Checklist

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In the rapidly evolving landscape of healthcare, the introduction of new technologies—from novel therapeutics to innovative medical devices—continues to promise meaningful advances in patient care, outcomes, and overall health. However, new innovations often present high costs and may require significant changes in medical practice to adopt effectively, especially some of the most potentially transformative therapies. Additionally, for these new technologies, data on longer-term outcomes that matter to patients and how they are being integrated with other key components of a patient-centered care model, such as diagnostics, patient engagement supports, and complementary therapies, are important.

Clinical trials serve as the basis for approving such technologies and are themselves evolving into being more patient centric and community based. Use of data in the "real world," including from electronic health records (EHRs), provides a basis for further understanding the impact that these technologies have on the lives of patients and their caregivers across diverse care systems, as well as the coverage, payment, and other reforms needed to ensure patients have access to treatments that deliver value. Payment and regulatory agencies across the world are deploying new strategies for generating ongoing evidence post approval from the US Food and Drug Administration, for example, coverage with evidence development and now Transitional Coverage for Emerging Technologies in the United States, although stakeholders have significant disagreements about the impact of these tools on patient access, care affordability, and biomedical innovation. The Centers for Medicare & Medicaid Services, similar to many other global payers, is also seeking to use qualitative evidence related to value in its implementation of price negotiations under the Inflation Reduction Act. The Centers for Medicare & Medicaid Services has highlighted its desire to encourage and reward more and better real-world evidence development relevant to Medicare beneficiaries through this process, but whether and how this will happen is not yet clear and will also likely lead to further debates about how to develop and use evidence on value.

Although there are different perspectives on how to best integrate real-world data (RWD) and evidence into payment and value-based care reforms, we can agree that it is imperative that we have systems in place to understand and measure value from a multistakeholder perspective, that the EHR data used in care delivery could be an important contributor to value assessment, and that many opportunities remain to improve its use in assessing value.

The good news amidst these challenges is that the richness and scope of electronic data integrated into EHRs continues to grow exponentially. Better RWD present unprecedented opportunities to augment evidence from traditional clinical trials. Consequently, ISPOR's Good Practices report[1] is particularly timely. The report contends that health technology assessments (HTAs) have the potential to provide essential insights that inform policy decisions, clinical guidelines, and patient care strategies. Furthermore, the data from EHRs may contribute actionable information for HTA analyses. But although there is potential in the use of EHR data for better patient, provider, and payer decision making related to outcomes, costs, and other aspects of value, the report also highlights the need for appropriate attention to key aspects of RWD—in short, is the RWD underlying fit-for-purpose for providing evidence to support HTAs?

As cited in the report, Duke-Margolis has published extensively about the potential of RWD, including EHRs, for drug development and regulatory purposes[2,3] and developed a framework aimed at ensuring that RWD is a viable resource for generating real-world evidence,[4] enhancing drug evaluation processes to include broader patient populations and reflect routine clinical practices more accurately.[5,6] We believe that these data will be crucial to value assessment and the future relevance of HTA, and we have identified a range of policy steps and participate in a range of collaborative initiatives to advance the development and use of RWD for better evidence to guide practice and policy. The Duke-Margolis work cites many of the same challenges of data completeness and quality as listed by ISPOR, and we see the benefit of a checklist that helps improve the quality and completeness of these data for all of their potential uses.

The ISPOR report calls for collaborations among HTA agencies and related regulatory agencies to develop and endorse a common set of standards specific to the use of EHRs in decision making. In the United States, we agree that HTA agencies play a role in the development and generation of EHR standard setting, but such a collaboration must include representatives more broadly from the patient, payer, provider, and product development communities. Any HTA, and the payment and coverage reforms that they inform, should continue to evolve in ways to better support care delivery and access that delivers outcomes important to patients while also including the perspectives of caregivers, payers, and society.

The exploration of value is only going to become more important in an environment confronting access, affordability, and great potential for further innovation. Fortunately, the opportunities for addressing this challenge are also improving, with further progress on electronic data standards, interoperability, and methods, including embedded, real-world clinical trials and fit-for-purpose observational analyses, for turning better RWD into significantly needed evidence. The ISPOR Good Practices report provides a resource for improving one contributor to RWD and can be used to help inform the quality and use of EHR data.

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