Physicians see big promise in use of real-world data, evidence

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Sara Berg, MS
Senior News Writer

Physicians have traditionally relied on evidence from randomized controlled trials to help guide their decisions on which drugs and devices to use in treatment. However, real-world data (RWD) and real-world evidence (RWE) are now increasingly used in health care to enhance evidence from randomized controlled trials to provide proper patient care.

It is important for physicians to understand RWD and RWE and how they are being are used, specifically how the U.S. Food and Drug Administration (FDA) is using this data for medical products, according to an AMA Council on Science and Public Health report whose recommendations were adopted at the 2019 AMA Interim Meeting in San Diego.

“Data is more widely collected, available and accessible than in the past. Evidence and opportunities are mounting on ways to leverage new data sources such as RWD and RWE to support regulatory efforts and value-based payment arrangements for medical products, yet accessibility and privacy concerns remain,” says the council’s report.

The AMA House of Delegates (HOD) adopted policy supporting the generation and use of real-world data and real-world evidence fit for regulatory purpose to:

- Evaluate effectiveness and safety of medical products, while assuring patient privacy and confidentiality.
- Improve regulatory decision-making.
- Decrease medical product costs.
- Increase research efficiency.
- Advance innovative and new models of drug development.
- Improve clinical care and patient outcomes.

Delegates also adopted new policy supporting the aim of the FDA to expand and clarify the use of RWD and RWE in regulatory decision-making in:

- Understanding the potential of fit-for-purpose RWE to meet the established standards for adequate and well-controlled clinical investigations.
- Pursuing the integration of RWE into medical product development and regulatory review.
- Using RWE to support new indications for approved medical products and its ability to satisfy post-approval study requirements.

The HOD also adopted policy supporting:

- Adequate funding of data infrastructure to allow for transparent data management capabilities, improved access to data by clinicians, especially physicians, as well as researchers and other stakeholders, and improved reliability and relevance of data.
- Cooperation and collaboration of stakeholders to facilitate the collection and use of RWD and RWE that is deemed fit for regulatory purpose.

Additionally, delegates called on the AMA to “evaluate and develop a response to the educational needs of physicians seeking to understand the use of fit for purpose RWD and RWE in clinical practice.”