Medical Xpress

Nation should implement a medical device evaluation system for safer, innovative medical devices

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Evidence on the safety and effectiveness of medical devices is difficult to coordinate and assess, despite the critical role medical devices play in diagnosing and treating patients.

A new report from the planning board for a national medical device evaluation system (NMDES) describes how the nation can implement a coordinated network of partners to improve evidence on the safety and effectiveness of medical devices. The system will work to improve patient outcomes by being smarter and more efficient when generating and evaluating real-world electronic health data on medical devices.

The planning board consists of a diverse set of experts representing patients, clinicians, academic researchers, the medical device industry, and others, and is supported in its work by the Duke-Margolis Center for Health Policy.

In its previous work, the planning board described how major gaps in the nation's ability to reliably track medical device safety and effectiveness significantly affect public health. This shortcoming makes it more difficult for patients and clinicians to make informed decisions, adds to long delays and gaps in managing defective device recalls, and harms biomedical innovation by hindering the timely development of new treatment options. Altogether, the inability to collect robust and timely evidence on devices increases the costs and inefficiency of our

healthcare system.

The new report, "Enabling Better Evidence on Medical Devices: A Coordinating Center for a 21st Century National Medical Device Evaluation System," describes how the nation can establish a national system by coordinating and building on the work of a nationwide network of partners, including the U.S. Food and Drug Administration (FDA) and other public agencies, patient communities, provider systems, medical device manufacturers, academic institutions, health payers and others. The report emphasizes more efficient approaches, such as using routine reporting of standard electronic data as well as patient-reported data, to develop this evidence at significantly lower cost than is possible in existing systems.

The planning board's report outlines recommendations on the objectives, tasks and capabilities that a coordinating center would be charged to undertake. The panel hopes to encourage a public discussion on this pressing need for better information about medical devices.

"As the vision of the NMDES becomes a reality, more complete and accurate information regarding the safety and performance on medical devices will be readily available to clinicians and patients," said Dr. Michael Mack, a planning board member and chair of the Cardiovascular Service Line at Baylor Scott & White Health. "This allows them to make better, more informed decisions."

The NMDES should give device manufacturers a faster, more predictable path to approval and health care coverage decisions, the report notes. Then, once products are on the market, the NMDES will provide more cost-effective approaches to developing real-world evidence, which would give clinicians and insurers greater confidence in the products they use. And health insurance payers would benefit from better evidence to improve their coverage decisions and to understand

the state of care.

The planning board envisions NMDES as a coordinated network of voluntary partners, including device manufacturers, institutional data partners, methods partners and patient communities. All would be working toward generating higher-quality data at lower costs. The system would develop resources that improve medical device safety updates, recall management and effectiveness data.

A recommended public-private coordinated partnership would ensure that all stakeholders can participate in the formation and use of the NMDES, the report says. This coordinating center would continually assess the needs of stakeholders and ensure that the NMDES's tools and methods stay up-to-date, flexible and adaptable. And the coordinating center would be responsible for demonstration projects to show the value of NMDES in its early stages.

The first demonstration projects might include improving and expanding an existing medical device registry by linking with other data sources and data types or by creating a new virtual registry using electronic health records and claims data on a higher-risk device with potentially serious but rare adverse events.

The concept of a national evaluation system for medical devices grew out of a 2012 action plan by the FDA's Center for Devices and Radiologic Health (CDRH). Under the guidance of the Brookings Institution, the planning board released its first report "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System," in February 2015. FDA then asked the Duke-Margolis Center for Health Policy to reconvene the planning board in late 2015 to help lead the next phase of planning for the system's coordinating center and governing body.

In January 2016, CDRH released its 2016-2017 Strategic Priorities, which included the establishment of a national system for evaluating medical devices with real-world evidence to support regulatory decision-making and technological innovation.

"The planning board believes that to improve high-quality, safe, effective, and timely care for patients, better information about medical devices must be a priority for the nation," said Mark McClellan, director of the Duke-Margolis Center for Health Policy.

More information: A copy of the report is at healthpolicy.duke.edu/files/20 … evice-report-web.pdf

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