Invited Commentary

Identification and Market Removal of Risky Medical Devices

Madris Tomes, MBA

Reporting of adverse events to the US Food and Drug Administration (FDA) has long been the primary mechanism of identifying safety issues with medical devices—ranging from nasal swabs to cardiac defibrillators to in vitro diagnostic test kits. Each day, approximately 3500 adverse event reports are collected in the agency's Manufacturer and User Facility Device Experience (MAUDE) database. As anyone who has tried to use it will attest, the database provides a difficult-to-use interface to search these reports.

Related article

In this issue, Tau and Shepshelovich[1] report a cross-sectional study of Medical Device Safety Communications issued by the FDA. This study accurately describes the agency's use of these communications to identify safety signals, especially identification of deaths, that lead to subsequent FDA enforcement actions.

These enforcement actions are not always recalls of unsafe medical devices. For example, if there is no competing product available, the agency may not recommend a recall after identifying a safety signal. A recall may be announced in conjunction with the approval or clearance of a newer version of the same product, whether planned or coincidentally. Delaying until the clearance of the new version may reduce the likelihood of a shortage but means leaving risky or faulty, often implanted, devices on the market longer, sometimes exposing patients who are unaware of the associated risk of serious harms, particularly when the faulty device cannot be easily removed.

The FDA's Center for Devices and Radiological Health has long sought a better way to collect postmarket surveillance data that lead to effective signal identification. The agency's Sentinel System has successfully identified issues with drugs using a combination of claims and electronic health record data, but unlike MAUDE, the Sentinel System data are not publicly available, and the wait time for data requests can be several months. Drug-related adverse events are easier to link to Sentinel System data because of the National Drug Code, which uniquely identifies a drug so it can be linked directly to the report. In 2019, less than 2% of the 1.3 million adverse event reports for devices contained a Unique Device Identifier (UDI), and the UDI is often redacted by the FDA in whole or in part because the agency's Freedom of Information Act team is unsure of which portions of the UDI are protected health information, even though only the serial number should be redacted. This redaction is important because all other methods of postmarket surveillance for medical devices in development by government agencies, hospitals, device registries, and insurance companies rely on the UDI. In addition, until all devices contain a UDI, the use of the Sentinel System for medical device surveillance is not feasible.

The still nascent National Evaluation System for Health Technology relies on the adoption of the UDI in device registries and electronic health records, which would be an ambitious and proactive way to identify safety signals. This approach, however, might not be as timely or comprehensive as other reporting mechanisms. For example, delays occur because the manufacturer has a maximum of 30 days (5 days for serious injuries that could reoccur) to send an adverse event report to the FDA. Furthermore, if a stent has a faulty guidewire, the physician may identify this at the time of implant and place another stent. The faulty stent would not be recorded in the patient's electronic health record or in a device registry because it was discarded and not used. Without the medical device report, this problem may become known to the manufacturer when the physician requests a replacement device but may not appear in MAUDE database. In the case of premature battery depletion of a cardiac device, a hospital may consider a single event to be an anomaly and not report it. The FDA, however, may identify a pattern from multiple reports from different institutions.

The study by Tau and Shepshelovich[1] found that although the FDA has an elongated time frame to identify a signal using medical device reports, the MAUDE database remains the primary mechanism for identifying safety signals for devices that require enforcement action. The FDA should require immediately (and enforce) the listing of the UDI on every adverse event report and discontinue all redactions of the identifier to decrease chances that patients are not unknowingly receiving harmful devices.

The FDA could also improve medical device reporting by requiring that physicians submit reports directly to the FDA instead of the current system in which almost all these reports are first submitted to the manufacturer (often to get a replacement device or report an event). Under current law, only hospitals and manufacturers, not physicians, are mandated to report to the FDA. The Medical Device Guardians Act,[2] a bipartisan bill introduced in the US House of Representatives in 2019, would provide the FDA with a mechanism to require that physicians report adverse events directly to the agency. Direct reporting with the UDI would greatly speed the time to identify signals and improve the chances that all the relevant details of the event are submitted. A copy of the report could be sent to the manufacturer simultaneously.

Data from the MAUDE database can be improved on, and even more can be done without waiting for the components of National Evaluation System for Health Technology to be implemented. For example, the FDA should reinstate the acceptance of adverse events via the Medwatcher, a third-party iPhone and Android application that allows submission of adverse events directly via smartphone and facilitates reporting by patients and physicians.

The FDA can also improve the time to identify signals through the use of algorithms to identify misreported events (ie, deaths reported as device malfunctions)[3] and by increasing

the number of analysts who review the reports. Safety signal identification and prompt removal of risky devices from the market should be prioritized. As the FDA moves to speed medical devices to market in the name of innovation in response to congressional directives, the overall goal should remain safety first. Patients must be protected from dangerous devices.

ARTICLE INFORMATION

Author Affiliation: Device Events, York, Pennsylvania.

Corresponding Author: Madris Tomes, MBA, Device Events, 1539 Heritage Lane, York, PA 17403 (madris@deviceevents.com).

Published Online: September 28, 2020. doi:10.1001/jamainternmed.2020.3512

Conflict of Interest Disclosures: Ms Tomes is the owner of Device Events, a commercial software tool that identifies patterns of problems with medical devices using publicly available US Food and Drug Administration (FDA) data sources. Ms Tomes previously worked as a public health analyst for the FDA.

REFERENCES

1. Tau N, Shepshelovich D. Assessment of data sources that support US Food and Drug Administration medical devices safety communications. *JAMA Intern Med*. Published online September 28, 2020. doi:10.1001/jamainternmed.2020.3514

2. Medical Device Guardian Act, HR 2915, 116th Cong (2020). Accessed August 6, 2020. https://www.congress.gov/bill/116th-congress/house-bill/2915/text?r=39&s=1

3. Meier L, Wang EY, Tomes M, Redberg RF. Miscategorization of deaths in the US Food and Drug Administration adverse events database. *JAMA Intern Med*. 2019;180(1):147-148. doi:10.1001/jamainternmed.2019.4030