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Active postmarketing device surveillance as a legislative priority

Active surveillance using routine health data can improve patient safety

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The US Food and Drug Administration (FDA) requires manufacturers of medical devices, such as ventilators and defibrillators, to report certain adverse safety events, which are then compiled in a centralized database known as the Manufacturer and User Facility Device Experience (MAUDE).[1] Manufacturers must disclose safety event details within 30 days, and the FDA relies on these disclosures to decide whether to communicate safety concerns or pursue other regulatory actions. Everhart and colleagues show, in a far-reaching and rigorous analysis of over four million MAUDE database submissions from 2019 to 2022, that manufacturers do not strictly adhere to deadlines when reporting these critical events.[2] Approximately 15% of adverse events were submitted after 30 days, and another 15% contained missing or invalid information that precluded a determination of submission timing. Such delays and information gaps can hinder regulatory action, undermine trust in the MAUDE system, and harm patients if problems with sensitive diagnostic equipment (eg, glucose monitors) or life-saving treatments (eg, insulin pumps) are not swiftly addressed.

This study of delayed MAUDE database submissions adds to a growing body of literature on the important limits of passive surveillance, not only for medical devices but also for pharmaceuticals and other products regulated by the FDA. Passive surveillance relies on spontaneous reporting by patients, physicians, and manufacturers, and has been associated with poor capture of relevant outcomes due to under-reporting (missing safety events), biased reporting (capturing only some types of safety events), and duplication (counting safety events more than once).[3-5] Missing data for the number of patients who received a given intervention also prevent assessments of incidence and prevalence, and attempts to draw causal connections between exposures and adverse outcomes can be limited by confounding. The reporting delays identified by Everhart and colleagues draw attention to a particular problem of passive surveillance systems that rely on information disclosed by manufacturers with financial incentives to withhold such data.

Recognising such limitations, the FDA has taken steps in recent years to enhance active surveillance of medical products using data collected in routine clinical care, including electronic medical records and insurance claims. Rigorous surveillance studies with active comparators designed to assess validated outcome measures using state-of-the-art methods for confounding control can enable robust causal inference. Advanced hypothesis-free signal detection approaches, such as tree-base scan statistics methods, allow for the simultaneous evaluation of thousands of unsuspected safety signals in comparative studies while trying to account for type 1 error.[6,7] The FDA's Sentinel Initiative, launched in 2008, has advanced these methods in the field of pharmacoepidemiology and has helped to initiate other surveillance efforts across the agency. We are working with the FDA's Office of Generic Drugs, for example, to develop a framework for scalable, routine assessments of generic drug-device combinations compared with brand name reference products in the setting of routine clinical use.[8] The National Evaluation System for health Technology (NEST), which focuses on medical devices, has accumulated data assets from collaborating hospitals and insurers over the past decade and funded several pilot studies to evaluate medical devices.[9] NEST has thus far only launched active surveillance programs on two products—a duodenoscope and a robotic cholecystectomy device—but similar initiatives are planned to launch for at least 18 products by 2028.[5]

Perhaps the most fundamental hurdle for expanded device surveillance in the US is that unique device identifiers (UDIs) are not routinely recorded in electronic medical records or insurance claims.[10-12] Unlike pharmaceutical claims, which contain standardized national drug codes for each prescription filled and thereby link the product dispensed to a given manufacturer, device claims with missing UDIs do not have such linkages. Lawmakers from both parties, including Senators Elizabeth Warren (Democratic party, Massachusetts) and Charles Grassley (Republican party, Iowa), have long pushed for inclusion of UDIs as fields in Medicare claims.[13] Unfortunately, amid industry pushback, a federal advisory group recently voted against recommending such measures.[14] In the absence of action by the Centers for Medicare and Medicaid Services, the US Congress could instead take up the cause and mandate inclusion of UDIs in medical claims, both for public and commercial payers. Better tracking of medical devices would not only improve patient safety, but could also save payers and patients money. A report from the Office of Inspector General found that problems with just seven cardiac devices, including defibrillators and pacemakers, led to US$1.5 billion (£1.16 billion; €1.38 billion) in additional health care costs from 2005 to 2014.[13,15]

Although requiring UDIs in medical claims is a necessary and commonsense next step for improving device safety, this change alone is not sufficient. Active device surveillance requires ongoing financial commitment by the FDA. According to FDA officials, such a program would cost only $8 million per year, but user fees from device manufacturers cannot currently be redirected to surveillance efforts; instead, the FDA must request specific appropriations

to fund these activities—requests that were denied in 2024.[5] Manufacturer resistance to safety surveillance is one of many reasons why the current user fee system needs reform. But if lawmakers would expand the budget for device monitoring activities, substantial savings from reductions in wasteful spending on harmful products and more timely recalls would likely accrue.

The MAUDE database can be a useful adjunct to active surveillance efforts, particularly if some of the problems identified by Everhart and colleagues are rectified. But ultimately, support for active surveillance using data from routine health encounters is essential to improving the safety of medical devices for patients.

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1 Food and Drug Administration. Mandatory reporting requirements: manufacturers, importers and device user facilities. https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities. Accessed 4 March 2025.

2 Everhart AO, Karaca-Mandic P, Redberg RF, Ross JS, Dhruva SS. Late adverse event reporting from medical device manufacturers to the US Food and Drug Administration: cross sectional study. *BMJ* 2025;388:e081518. doi: 10.1136/bmj-2024-081518

3 Nevo ON. FDA post-marketing drug safety surveillance. 17 March 2017. https://www.fda.gov/media/103424/download. Accessed 4 March 2025.

4 Shuren J, Califf RM. Need for a national evaluation system for health technology. *JAMA* 2016;316:-4. doi: 10.1001/jama.2016.8708 pmid: 27398696

5 US Government Accountability Office. Medical devices: FDA has begun building an active postmarket surveillance system. GAO-24-106699. 24 July 2024. https://www.gao.gov/products/gao-24-106699. Accessed 4 March 2025.

6 Hallas J, Wang SV, Gagne JJ, Schneeweiss S, Pratt N, Pottegård A. Hypothesis-free screening of large administrative databases for unsuspected drug-outcome associations. *Eur J Epidemiol* 2018;33:-55. doi: 10.1007/s10654-018-0386-8 pmid: 29605890

7 Wang SV, Maro JC, Baro E, etal. Data mining for adverse drug events with a propensity score-matched tree-based scan statistic. *Epidemiology* 2018;29:-903. doi: 10.1097/EDE.0000000000000907 pmid: 30074538

8 US Food and Drug Administration. Draft FY24 GDUFA science and research priorities. https://www.fda.gov/media/185257/download. Accessed 4 March 2025.

9 US Food and Drug Administration. National Evaluation System for health Technology (NEST). https://www.fda.gov/about-fda/cdrh-reports/national-evaluation-system-health-technology-nest. Accessed 4 March 2025.

10 Kadakia KT, Rathi VK, Dhruva SS, Ross JS, Krumholz HM. Modernizing medical device regulation: challenges and opportunities for the 510(k) clearance process. *Ann Intern Med* 2024;177:-65. doi: 10.7326/ANNALS-24-00728 pmid: 39374526

11 Kadakia KT, Dhruva SS, Ross JS, Krumholz HM. Adding device identifiers to claims forms-a key step to advance medical device safety. *BMJ* 2023;380:. doi: 10.1136/bmj.p82 pmid: 36631149

12 Timbie JW, Kim AY, Baker L, Li R, W Concannon T. Lessons on the use of real-world data in medical device research: findings from the National Evaluation System for Health Technology Test-Cases. *J Comp Eff Res* 2024;13:e240078. doi: 10.57264/cer-2024-0078 pmid: 39150225

13 Grassley senate. Grassley & Warren push FDA to move expeditiously as decade-long effort to add device identifiers on Medicare claims forms nears conclusion. https://www.grassley.senate.gov/news/news-releases/grassley-and-warren-push-fda-to-move-expeditiously-as-decade-long-effort-to-add-device-identifiers-on-medicare-claims-forms-nears-conclusion. Accessed 4 March 2025.

14 Lawrence L. Federal advisory group rejects proposal to make medical device tracking easier. STAT. 14 June 2023. https://www.statnews.com/2023/06/14/medical-device-identifier-code-recall-medicare/. Accessed 4 March 2025.

15 US Department of Health and Human Services. Office of the Inspector General. Shortcommings of device claims data complicate and potentially increase Medicare costs for recalled and prematurely failed devices. September 2017. https://oig.hhs.gov/oas/reports/region1/11500504.pdf. Accessed 4 March 2025.