



Centre for Clinical and Translational Research, Kyushu University Hospital, Fukuoka, Japan

Correspondence to: K Todaka
ktod@med.kyushu-u.ac.jp

Cite this as: *BMJ* 2026;395:e101065

<http://doi.org/10.1136/bmj-2026-101065>

Postmarket surveillance of medical devices

Spontaneous reporting systems and clinical registries serve complementary purposes

Koji Todaka *senior vice president*

Early signals, uncertain risks

Medical devices often enter clinical practice on the basis of premarket studies that are smaller and shorter than those required for medicines, while device performance may depend on operator experience and real world use. Postmarket surveillance is used to identify emerging hazards and determine whether they represent genuine increases in risk.

Individual medical device reports are important in identifying hazards, providing public visibility and alerting regulators, clinicians, and researchers to previously unrecognised problems. Direct reports to the US Food and Drug Administration's (FDA's) Medical Device Reporting programme have provided the initial signal for many FDA medical device safety communications.¹ However, spontaneous reporting systems are limited by underreporting, incomplete information, uncertain causality, and a lack of reliable information on how many patients received each device.^{2 3} These systems can generate hypotheses but cannot reliably estimate incidence or compare device performance.

In the linked study (doi: 10.1136/bmj-2026-100812),⁴ Zhou and colleagues identify important shortcomings in adverse event summary reports submitted to the FDA manufacturer and user facility device experience (MAUDE) database between 2019 and 2025. More than 6000 reports represented about 160 000 adverse events, mostly involving high risk cardiovascular devices. Fifty-seven percent lacked meaningful information about device problems, 423 reports (7%) incorrectly listed a single event, undercounting 11 902 adverse events. More than half (55%) missed reporting deadlines. These findings raise concerns about transparency in a system intended to support public scrutiny of medical device safety.

What registries add

These limitations help explain the emergence of large clinical registries, particularly in cardiovascular medicine. A clinical registry systematically collects standardised information on a defined group of patients receiving a treatment or device, allowing outcomes to be related to the number of patients exposed. Major registries such as the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), and the National Cardiovascular Data Registry also support longitudinal follow-up.⁵⁻⁹ These registries are therefore well suited to evaluating complication rates, mortality trends, and comparative safety and performance.

Registry based surveillance has already demonstrated value: INTERMACS identified increasing rates of

pump thrombosis among recipients of the HeartMate II left ventricular assist device, while National Cardiovascular Data Registry programmes have demonstrated the feasibility of prospective surveillance of high risk cardiovascular devices.⁵⁻⁸ Linked registry analyses have also enabled long term assessment of prosthetic heart valve performance.⁹

The advantages of registries extend beyond cardiovascular medicine. In England and Wales, the National Joint Registry identified substantially higher revision rates among patients receiving metal-on-metal hip prostheses.^{10 11} In contrast, a 2018 analysis of more than 83 000 MAUDE reports related to the same class of implants found little evidence that MAUDE could identify meaningful warning signals for most manifestations of suspected cobalt toxicity, highlighting limitations in detecting and quantifying device related risks using spontaneous reports alone.¹² This difference in reporting illustrates how registries may be better suited to quantifying risk and assessing the importance of potential safety signals.

Nevertheless, spontaneous reporting systems retain important strengths. Hauser and colleagues recently analysed MAUDE reports related to a recalled pacemaker and identified hundreds of safety mode failures and associated serious adverse events before a manufacturer recall was issued.¹³ As a continuously updated public repository, MAUDE can reveal an emerging pattern without waiting for a purpose built registry or longitudinal follow-up. However, this retrospective analysis did not show that MAUDE prompted earlier regulatory action. The researchers concluded that the recall may have been delayed, but also argued that more sensitive and specific postmarket surveillance techniques are needed to detect defects earlier and implement corrective action before larger patient populations are affected.¹³

Linking transparency with evidence

The linked study assessed the completeness, accuracy, and timeliness of publicly available summary reports, not the quality of the underlying registries.⁴ The findings therefore support reform of the reporting pathway rather than abandonment of registry based surveillance. Aggregation must not come at the expense of transparency. Regulators should require accurate and timely summary reporting, standardised device identification, and transparent linkage to underlying registries where appropriate. Researchers should integrate spontaneous reports, registries, and linked healthcare data rather than treating any single source as definitive.

Transparency is important not only for signal detection but also for maintaining confidence in regulatory oversight. Public reporting enables clinicians, researchers, patients, and regulators to evaluate emerging safety concerns independently. When safety information is incomplete, delayed, or inaccessible, confidence in postmarket surveillance may be undermined. A cross national survey of the general public found that acceptance of medical technologies depends not only on perceptions of risk and benefit but also on confidence that regulators and healthcare professionals will identify and communicate emerging safety concerns appropriately.¹⁴ Transparency and scientific rigour therefore reinforce one another, supporting effective surveillance and confidence in the systems responsible for safeguarding patients.

MAUDE and clinical registries serve complementary purposes. Public adverse event reports provide openness and early signals for further investigation; registries provide denominators, clinical context, and quantitative evaluation. Experience from metal-on-metal hip implants suggests that registries may be better suited to quantifying risk, whereas experience from pacemaker recalls shows that public reporting systems can reveal important safety concerns before regulatory action occurs.^{12 13} The FDA is currently transitioning to a new adverse event monitoring system database, intended to consolidate existing reporting systems and publish adverse event reports in real time.¹⁵ Transparency builds trust, evidence improves safety, and both are essential to effective postmarket surveillance and safer medical devices.

Competing interests: The BMJ has judged that there are no disqualifying financial ties to commercial companies. The author declares the following other interests: none. Further details of The BMJ policy on financial interests are [here](#).

AI statement: An AI was used to assist with language editing and revision. The author reviewed and approved all AI assisted content and accepts full responsibility for the final manuscript.

Provenance and peer review: Commissioned; not externally peer reviewed

- 1 Tau N, Shepshelovich D. Assessment of Data Sources That Support US Food and Drug Administration Medical Devices Safety Communications. *JAMA Intern Med* 2020;180:-6. pmid: 32986074. doi: 10.1001/jamainternmed.2020.3514
- 2 US Food and Drug Administration. About Manufacturer and User Facility Device Experience (MAUDE) database. Available from: <https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/about-manufacturer-and-user-facility-device-experience-maude-database> (3 September 2026).
- 3 US Food and Drug Administration. Medical Device Reporting (MDR): how to report medical device problems. Available from: <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems> (3 September 2026).
- 4 Zhou A, Kinard M, Tingley S, Redberg RF. Evaluation of the accuracy, completeness, and compliance of current summary reporting of adverse events to the Food and Drug Administration using the manufacturer and user facility device experience (MAUDE) database: cross sectional study. *BMJ* 2026;395:e101065. doi: 10.1136/bmj-2026-100812
- 5 Resnic FS, Majithia A, Marinac-Dabic D, et al. Registry-Based Prospective, Active Surveillance of Medical-Device Safety. *N Engl J Med* 2017;376:-35. pmid: 28121489. doi: 10.1056/NEJMoa1516333
- 6 Resnic FS, Majithia A, Dhruva SS, et al. Active Surveillance of the Implantable Cardioverter-Defibrillator Registry for Defibrillator Lead Failures. *Circ Cardiovasc Qual Outcomes* 2020;13:e006105. pmid: 32283971. doi: 10.1161/CIRCOUTCOMES.119.006105
- 7 Kirklin JK, Naftel DC, Pagani FD, et al. Pump thrombosis in the Thoratec HeartMate II device: An update analysis of the INTERMACS Registry. *J Heart Lung Transplant* 2015;34:-26. pmid: 26681121. doi: 10.1016/j.healun.2015.10.024
- 8 Starling RC, Moazami N, Silvestry SC, et al. Unexpected abrupt increase in left ventricular assist device thrombosis. *N Engl J Med* 2014;370:-40. pmid: 24283197. doi: 10.1056/NEJMoa1313385
- 9 Hickey GL, Bridgewater B, Grant SW, et al. National Registry Data and Record Linkage to Inform Postmarket Surveillance of Prosthetic Aortic Valve Models Over 15 Years. *JAMA Intern Med* 2017;177:-86. pmid: 27820610. doi: 10.1001/jamainternmed.2016.6936
- 10 Smith AJ, Dieppe P, Vernon K, et al. Failure rates of stemmed metal-on-metal hip replacements: analysis of data from the National Joint Registry of England and Wales. *Lancet* 2012;379:-204. pmid: 22417410. doi: 10.1016/S0140-6736(12)60353-5
- 11 Cohen D. Out of joint: the story of the ASR. *BMJ* 2011;342. pmid: 21572134. doi: 10.1136/bmj.d2905
- 12 Kavanagh KT, Kraman SS, Kavanagh SP. An Analysis of the FDA MAUDE Database and the Search for Cobalt Toxicity in Class 3 Johnson & Johnson/DePuy Metal-on-Metal Hip Implants. *J Patient Saf* 2018;14:-96. doi: 10.1097/PTS.0000000000000534

- 13 Hauser RG, Kapphahn-Bergs M, Bahbah A, et al. A delayed pacemaker recall. *Heart Rhythm* 2025;22:-5. pmid: 40204012. doi: 10.1016/j.hrthm.2025.03.1992
- 14 Todaka K, Kishimoto J, Ikeda M, et al. Impact of Risk-Benefit Perception and Trust on Medical Technology Acceptance in Relation to Drug and Device Lag: A Tripartite Cross-Sectional Survey. *Ther Innov Regul Sci* 2018;52:-40. pmid: 29714546. doi: 10.1177/2168479017739267
- 15 US Food and Drug Administration. FDA launches new adverse event look-up tool. 2026. Available from: <https://www.fda.gov/news-events/press-announcements/fda-launches-new-adverse-event-look-tool> (3 September 2026).