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**Editor’s Note**

**Strengthening Medical Device Postmarket Safety Surveillance**

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**The system** by which the US Food and Drug Administration engages in medical device postmarket safety surveillance needs strengthening.1-4 Efforts are limited by reliance on passively aggregated adverse events through the Manufacturer and User Facility Device Experience (MAUDE) database, investigated adverse events at select clinical sites within the Medical Product Safety Network (MedSun), and select active surveillance efforts using Post-Approval Studies and Postmarket Surveillance Studies (also known as the 522 Postmarket Surveillance Studies Program). While these efforts have successfully detected potential safety issues and contributed to reassessments of the benefits and risks of medical devices, these systems are likely to identify only a small proportion of the totality of adverse events that occur. Passive surveillance is undermined by the frequent reporting of incomplete, inaccurate, untimely, unverified, or biased data, whereas active surveillance is expensive, often narrow in scope, and impaired by the frequent delays in completion of requested studies. Efforts will be enhanced by the planned addition of a Unique Device Identification System integrated within electronic health care data, such as administrative claims data collected by health insurance payers for billing purposes, which would allow large-scale, proactive assessments of medical device safety.4

Without a better functioning system, postmarket surveillance of medical devices has largely been driven by experiences at select institutions, where individuals identify and publicize potential safety issues that the Food and Drug Administration subsequently investigates, such as the recent class I recall of implantable cardioverter defibrillator leads.3
This issue of *JAMA Internal Medicine* describes another such experience. The Postmortem Systematic Investigation of Sudden Cardiac Death study, led by investigators at the University of California, San Francisco, and funded by the National Institutes of Health, has provided a unique opportunity to investigate the cause of death among all adults experiencing sudden cardiac death in the San Francisco area, including those with pacemakers and implantable cardioverter defibrillators. The results of device interrogation and autopsies suggested that substantial proportions of adults with these high-risk medical devices experienced cardiac causes of death, including the ventricular arrhythmic events that these devices are intended to prevent. These findings of previously unsuspected device malfunction and ineffectiveness are critical to the accurate understanding of the benefits and risks of these implanted devices. We anticipate that this study will motivate other cities and health care systems to investigate the cause of death in patients with implanted cardiac medical devices. Our medical device postmarket safety surveillance system needs strengthening, which requires more data and better reporting, so that questions like this one can be identified and resolved quickly and the safety of the medical devices on which patients and physicians depend can be assured.

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