MEDICAL DEVICES

FDA Has Begun Building an Active Postmarket Surveillance System

Report to Congressional Requesters

July 2024
GAO-24-106699
United States Government Accountability Office

Accessible Version

GAO Highlights

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Highlights of GAO-24-106699, a report to congressional requesters
July 2024

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FDA Has Begun Building an Active Postmarket Surveillance System

Why GAO Did This Study

FDA is responsible for ensuring the safety and effectiveness of medical devices marketed in the U.S. GAO has previously reported on challenges FDA has faced in its oversight of the safety of medical products, including medical devices, and designated this as a high-risk issue area since 2009. Federal law mandated in 2012 that FDA establish an active postmarket surveillance system for medical devices.

GAO was asked to review FDA's efforts related to postmarket surveillance of medical devices. This report identifies and discusses the steps FDA has taken to establish an active postmarket surveillance system, and the key challenges FDA has faced in establishing this system and actions it has taken to address them.

GAO reviewed documentation and interviewed officials from FDA and the coordinating center working with FDA to establish its active surveillance system. In addition, GAO interviewed representatives from three health systems and one research organization. These were selected in part based on the types of data they contributed to the network organized by the coordinating center. GAO also interviewed associations representing device manufacturers, health care providers, and patients for their views on FDA's efforts to establish its system. These were selected in part based on their work related to medical devices or active surveillance.

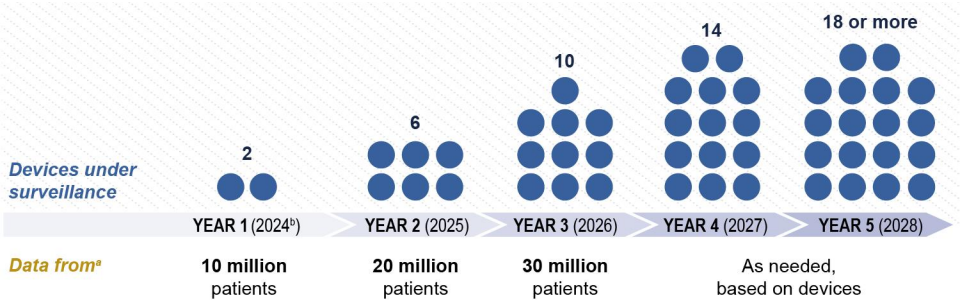
The Department of Health and Human Services (of which FDA is a part) and the coordinating center working with FDA provided technical comments on a draft of this report, which GAO incorporated as appropriate.

What GAO Found

More than 1.7 million injuries and 83,000 deaths in the United States over a 10-year period were potentially linked to medical devices, according to a 2018 study of Food and Drug Administration (FDA) data. Medical devices include a wide range of products from surgical masks to implantable pacemakers. Active postmarket surveillance involves the ongoing review of evidence—derived from the analysis of data sources such as electronic health records, billing claims, pharmacy and other data—to detect medical device safety issues that may otherwise go unreported. FDA has taken steps to establish an active postmarket surveillance system for medical devices. These include:

- establishing a coordinating center in 2016 to partner with FDA to organize a network of data sources (health systems and other collaborators);
- completing in 2021 the cloud-based data infrastructure necessary to collect evidence of medical device performance while protecting patient privacy; and
- planning to begin active postmarket surveillance of two medical devices by December 2024, with plans to expand over 5 years (see figure).

Planned Expansion of FDA's Active Postmarket Surveillance System



Source: GAO analysis of Food and Drug Administration information; GAO (illustrations). | GAO-24-106699

Accessible Data for Planned Expansion of FDA's Active Postmarket Surveillance System

Year	Total number of devices under surveillance	Data (Total number of patients, in millions)
Year 1: (Anticipated completion December 2024)	2	10
Year 2	6	20
Year 3	10	30
Year 4	14	As needed, based on devices
Year 5	18 or more	As needed, based on devices

Source: GAO analysis of Food and Drug Administration information; GAO (illustrations). I GAO-24-106699

[a]Represents anticipated patient data totals. Not all patients will have necessarily used the devices under surveillance.

[b]FDA anticipates completion of year 1 expansion by December 2024, contingent on funding availability.

FDA has faced two key challenges establishing its system, according to agency officials: (1) limited use of unique device identifiers in electronic health records and billing claims, which makes identifying devices used by patients more difficult; and (2) funding considerations to support active surveillance. FDA has taken actions to encourage use of unique device identifiers, such as coordinating with federal entities and publishing a document advertising the benefits of use to health systems. In addition, FDA has estimated current and future active surveillance costs and is considering options for how to fund the work by advocating for alternative funding sources.

GAO will continue to monitor FDA's progress in establishing an active postmarket surveillance system.

Contents

Abbreviations

CDRH	Center for Devices and Radiological Health
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
NESTcc	National Evaluation System for health Technology Coordinating Center

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

July 24, 2024

The Honorable Anna G. Eshoo
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The Honorable Debbie Dingell
House of Representatives

According to an analysis of 10 years of data from the Food and Drug Administration (FDA), more than 1.7 million injuries and 83,000 deaths in the United States were potentially linked to medical devices.[1] Medical devices include a wide range of products—from surgical masks to implantable pacemakers—intended to prevent, diagnose, cure, treat, or mitigate disease or other conditions.[2] Within FDA, the Center for Devices and Radiological Health (CDRH) is responsible for oversight of most medical devices marketed in the United States.[3] This oversight includes monitoring the safety and effectiveness of devices after they enter the market—known as postmarket surveillance.

We have previously reported on challenges FDA has faced in its oversight of the safety of medical products, including medical devices. We have designated this as a high-risk issue area since 2009.[4] For example, in 2012, we found that FDA's process for identifying adverse events associated with medical devices (such as serious injuries or deaths) may not fully capture cybersecurity vulnerabilities for certain devices.[5] We recommended that FDA develop a more comprehensive plan to better identify and investigate these vulnerabilities. FDA agreed with and has implemented this recommendation.

One postmarket surveillance mechanism FDA uses to identify adverse events is the agency's Medical Device Reporting process. This passive postmarket surveillance depends on mandatory and voluntary reporting whereby device manufacturers, hospitals, patients, and others notify FDA about adverse events after they occur. FDA has recognized that this passive mechanism is inadequate due to incomplete and untimely reporting, as well as underreporting of adverse events. As a result, according to FDA, the Medical Device Reporting process should be used in tandem with other postmarket surveillance activities, including active surveillance.

[1]This analysis reviewed FDA data from 2008 through 2017. See International Consortium of Investigative Journalists, *Medical Devices Harm Patients Worldwide As Governments Fail on Safety* (Nov. 25, 2018). https://www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety/.

[2]See 21 U.S.C. § 321(h).

[3]Within FDA, the Center for Biologics Evaluation and Research regulates devices related to licensed blood and cellular products.

[4]For GAO's full list of high-risk issue areas, see *High-Risk Series: Efforts Made to Achieve Progress Need to Be Maintained and Expanded to Fully Address All Areas*, GAO-23-106203 (Washington, D.C.: Apr. 20, 2023).

[5]GAO, *Medical Devices: FDA Should Expand Its Consideration of Information Security for Certain Types of Devices*, GAO-12-816 (Washington, D.C.: Aug. 31, 2012).

In contrast to passive postmarket surveillance, active postmarket surveillance involves the ongoing review of what FDA refers to as "real-world evidence." Real-world evidence is produced by analyzing health care data, such as electronic health records and billing claims. Real-world evidence can be used to help understand a potential association between a device and an adverse event and to determine if any action should be taken as a result, such as initiating a device recall.[6]

For example, active surveillance analyses may identify safety issues such as reintervention, rehospitalizations, or other events, which may need to be investigated further to determine a potential association with a device. According to FDA's website, active postmarket surveillance compliments existing passive postmarket surveillance by detecting potential safety risks that might not otherwise have been identified as quickly, or at all. The Food and Drug Administration Amendments Act of 2007 mandated that the agency establish an active postmarket risk identification and analysis system for drugs approved for the U.S. market; in 2012, the Food and Drug Administration Safety and Innovation Act specified that this system should also include medical devices.[7]

You asked us to review FDA's efforts to establish an active postmarket surveillance system for medical devices. In this report, we identify and discuss:

(1) the steps FDA has taken to establish an active postmarket surveillance system; and

(2) key challenges FDA has faced in establishing the system and actions the agency has taken to address these challenges.

To identify the steps FDA has taken to establish an active postmarket surveillance system, we reviewed documentation from FDA and the National Evaluation System for health Technology Coordinating Center (NESTcc), the organization working with FDA to establish an active postmarket surveillance system for medical devices. We reviewed documentation from 2012, when Congress mandated FDA establish the system, through March 2024. The information we reviewed included a draft document published by NESTcc describing progress it has made to establish an active postmarket surveillance system. NESTcc's real-world evidence network consists of health systems and other organizations contributing data to generate real-world evidence. We also reviewed statements of work and other documents developed by NESTcc governing the activities of contractors hired to help design and build the active surveillance system. In addition, we interviewed and received written responses from CDRH and NESTcc officials about their efforts to build an active postmarket surveillance system. We learned during the course of our review that NESTcc had conducted outreach with federal programs, such as within the Department of Defense and the Department of Veterans Affairs, to partner in FDA's efforts to establish an active surveillance system. However, as of June 2024, NESTcc has not yet secured participation from a federal entity. Therefore, we focused our review on FDA.

[6]For a recent GAO review of efforts at the Veterans Health Administration to monitor safety issues with implantable medical devices and efforts to track devices to patients, see *Veterans Health Care: Improvements Needed in Patient Tracking for Non-Biological Implantable Medical Devices*, GAO-24-106621 (Washington, D.C.: Mar. 27, 2024).

[7]Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 905, 121 Stat. 823, 944; Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 615, 126 Stat. 993, 1061 (2012).

To identify key challenges FDA has faced with establishing an active postmarket surveillance system and actions the agency has taken to address these challenges, we reviewed a RAND Corporation report commissioned by NESTcc evaluating the sufficiency of electronic health record and other data that could be used to support an active postmarket surveillance system.[8] We also interviewed CDRH and NESTcc officials to learn about challenges they have identified and actions taken to address challenges. In addition, we obtained perspectives on challenges from active surveillance stakeholders. This included interviews with a nongeneralizable selection of the following:

- Representatives from three health systems and one research organization, chosen from among the 19 entities that contributed data to NESTcc's real-world evidence network at the time of our review. NESTcc refers to these entities as network collaborators. We selected these four network collaborators to achieve diversity in the types of data contributed, including data such as from electronic health records, billing claims, pharmacies, and registries.[9] These network collaborators were Mercy Health; Lahey Hospital and Medical Center; Duke University Health System; and the Stakeholders, Technology and Research Clinical Research Network. Two of these network collaborators (Mercy and Lahey) also participated in NESTcc pilot projects to test the use of real-world evidence to study medical devices.
- Representatives from two medical device manufacturer associations—AdvaMed and the Medical Device Manufacturers Association. We selected these associations to achieve diversity in the size of the companies represented. Specifically, AdvaMed represented 400 companies of all sizes at the time of our review and the Medical Device Manufacturers Association represented 280 companies of all sizes, according to online information from these associations. We also selected these associations based on their work related to active postmarket surveillance, such as issuing public comments on active surveillance or publishing statements on real-world evidence.
- Representatives from three medical associations whose providers treat patients that may use medical devices—the American College of Obstetricians and Gynecologists, the American College of Cardiology, and the American Academy of Orthopaedic Surgeons. For example, the American Academy of Orthopaedic Surgeons is the professional association representing surgeons performing joint replacements using artificial hips, knees, and other implantable medical devices. We also selected these associations based on their work related to medical devices, such as publishing information for providers on FDA's oversight of medical devices.
- Representatives from two patient associations that cover a broad range of patient health conditions and that have focused on medical device issues—the National Health Council and the American Heart Association. For example, the National Health Council published information on patient perspectives regarding real-world evidence.[10]

We conducted this performance audit from March 2023 to July 2024 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit

[8]RAND Corporation, *Final Report on Lessons from the National Evaluation System for health Technology Coordinating Center (NESTcc) Test-Cases* (Santa Monica, Ca.: 2022).

[9]Registries contain data from patients receiving care in clinical settings. For example, device registries capture information about patient experiences using medical devices, such as outcomes over time, and can be used to inform clinical decision-making.

[10]National Health Council, *Patient Perspectives on Real-World Evidence: A Roundtable to Gather Views, Needs, And Recommendations.* (Washington, D.C.: n.d.).

to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

FDA's Medical Device Reporting Process

FDA conducts passive postmarket surveillance on medical devices, including through the agency's Medical Device Reporting process. Through this process, device manufacturers, importers, and device user facilities (e.g., hospitals and nursing homes) are required to submit reports informing FDA about adverse events that have occurred, such as device-related deaths, serious injuries, and certain device malfunctions.[11] FDA also encourages health care professionals, patients, and consumers to voluntarily submit reports. FDA reviews these reports and examines the adverse event history of specific devices as well as the histories of similar devices. According to FDA's website, the Medical Device Reporting process may provide incomplete information related to adverse events or contain inaccurate, untimely, and unverified data. As a result, Medical Device Reporting comprises only one component of a postmarket surveillance system and must be supplemented by other efforts such as active surveillance to identify adverse events, according to FDA's website.

Active Postmarket Surveillance and Other Applications of Real-World Evidence for Medical Devices

Active surveillance involves the use of real-world evidence to detect medical device safety issues that may otherwise go unreported. Real-world evidence relies on the analyses of data from sources such as electronic health records, billing claims, pharmacy data, as well as medical device and disease registries. Real-world evidence can also come from patient-generated data, such as from mobile health applications, or wearable devices.

[11]User facilities submit reports of deaths to FDA and the manufacturer, and reports of serious injuries to the manufacturer or, if the manufacturer is unknown, to FDA. User facilities are not required to submit device malfunction reports. Importers submit reports of death and serious injuries to FDA and the manufacturer, and reports of device malfunctions to the manufacturer. Importers are not required to submit device malfunction reports to FDA. Manufacturers submit reports of deaths, serious injuries, and device malfunctions to FDA. See 21 C.F.R. § 803.20(b).

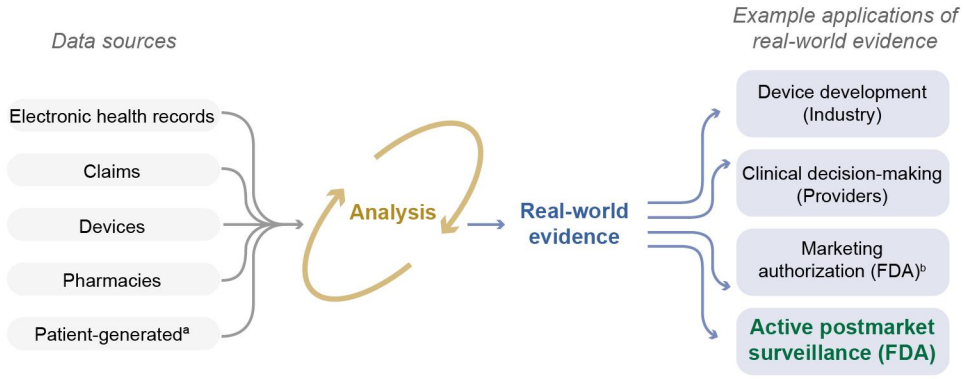
Example Use of Real-World Evidence to Inform Clinical Care

Kaiser Permanente has used real-world evidence from device registries and electronic health records to identify which medical devices have higher-than-expected rates of revision. Revision may result from complications or device-associated problems. This information may inform clinical decisions about patient care.

Source: Joint Commission Journal on Quality and Patient Safety. | GAO-24-106699

Real-world evidence can be used for other purposes beyond active postmarket surveillance. This includes the use of real-world evidence to support the marketing authorization process for certain devices, for which FDA must determine if sufficient evidence exists to ensure the safety and effectiveness of a given device before authorizing the device for the U.S. market. In addition, the device industry can use real-world evidence to support the development of new devices and providers can use real-world evidence to assist with clinical decision-making regarding a device (see figure 1 and sidebar).

Figure 1: Example Applications of Real-World Evidence for Medical Devices



Source: GAO analysis of information from the Food and Drug Administration (FDA) and the National Evaluation System for health Technology Coordinating Center. | GAO-24-106699

Accessible Text for Figure 1: Example Applications of Real-World Evidence for Medical Devices

1. **Data sources:** Electronic health records, claims, devices, pharmacies, and patient-generated.
2. **Data are analyzed and synthesized into real-world evidence.**
3. **Example applications of real-world evidence:** Device development (industry), clinical decision-making (providers), Marketing authorization (FDA), and active postmarket surveillance (FDA).

Source: GAO analysis of information from the Food and Drug Administration (FDA) and the National Evaluation System for health Technology Coordinating Center. I GAO-24-106699

[a]Patient-generated data includes information from mobile health applications and wearable devices.

[b]Marketing authorization for certain devices requires FDA to determine if sufficient evidence exists to ensure the safety and effectiveness of a given device before authorizing the device for the U.S. market.

FDA Has Conducted Foundational Activities for Its Active Postmarket Surveillance System and Plans to Begin Surveillance of Two Medical Devices

FDA has partnered with NESTcc to conduct foundational activities, such as obtaining data from network collaborators to generate and evaluate real-world evidence to support its active postmarket surveillance system. In 2023, FDA partnered with NESTcc to begin active surveillance of two devices by December 2024, with plans to further expand the system.

FDA Has Conducted Three Foundational Activities Necessary for Its Active Postmarket Surveillance System

In 2013, FDA published a report outlining its vision for a national system for medical device postmarket surveillance, which included the ability to identify potential safety issues in near real-time from a variety of privacy-protected data sources. The report discussed the need to identify a governing structure, practices, and methods necessary to facilitate the creation of a sustainable national postmarket surveillance system that would complement existing medical device postmarket surveillance efforts.[12]

Since then, to support its active postmarket surveillance system, FDA has partnered with NESTcc to conduct three foundational activities: (1) organized collaborators to contribute data to its real-world evidence network; (2) built the data infrastructure for a real-world evidence network; and (3) leveraged stakeholder expertise to plan an active surveillance system.

Organized Collaborators to Contribute to a Real-World Evidence Network

In September 2016, FDA awarded a grant to the Medical Device Innovation Consortium—a public-private partnership of government and medical device industry stakeholders—to build a data network. The purpose of this network was to generate real-world evidence for a variety of uses including premarket uses, such as FDA's marketing authorization process, as well as postmarket uses, such as active surveillance. Using this FDA funding, the Medical Device Innovation Consortium established NESTcc in 2016 to build this real-world evidence network. As of March 2024, NESTcc had organized 19 network collaborators. These collaborators are mostly health systems, but also include research organizations and others to contribute electronic health records, billing claims, and other data (see table 1).[13]

[12]FDA, *Strengthening Our National System For Medical Device Postmarket Surveillance: Update and Next Steps.* (Silver Spring, Md.: April 2013).

[13]A health system comprises at least one hospital and one group of physicians that provide health care services including primary and specialty care and are connected under common ownership or joint management.

Table 1: National Evaluation System for health Technology Coordinating Center (NESTcc) Research Network

Network collaborator (Month/year joined)	Organization type	Data sources
CVS Health (November 2020)	Health care company	Claims, patient-generated[a], pharmacy, and billing
Duke Health (July 2017)	Health system[b]	Electronic health records, public claims, private claims, unique device identifier, pharmacy, and registry
Carelon Research (Formerly Health Core) (July 2017)	Health care research organization	Private claims, unique device identifier, and registry
INSIGHT Clinical Research Network (August 2017)	Health care research organization	Electronic health records, public claims, private claims, pharmacy, registry, and patient-generated
Lahey Hospital & Medical Center (January 2018)	Health system	Electronic health records
Mayo Clinic (July 2017)	Health system	Electronic health records, public claims, private claims, pharmacy, registry, and patient-generated
MDEpiNet (August 2017)	Health care research organization	Electronic health records, public claims, private claims, pharmacy, and registry
MedStar Health (December 2020)	Health system	Electronic health records, pharmacy, billing, supply chain, and claims
Mercy (July 2017)	Health system	Electronic health records, public claims, private claims, unique device identifiers, pharmacy, and registry
NorthWest EHealth/Discover-Now (July 2020)	Health care research organization	Electronic health records, claims, and pharmacy
OneFlorida+ Clinical Research Network (January 2017)	Health care research organization	Electronic health records, public claims, private claims, and registry
PEDSnet (July 2017)	Health system	Electronic health records, public claims, private claims, pharmacy, and registry
Regenstrief Institute (October 2020)	Health care research organization	Electronic health records, claims, and pharmacy
Stanford Health Care (December 2021)	Health system	Electronic health records, pharmacy
Stakeholders, Technology, and Research Clinical Research Network (June 2018)	Health care research organization	Electronic health records, public claims, private claims, pharmacy, registry, and patient-generated
University of California San Francisco Health (July 2021)	Health system	Electronic health records, claims, pharmacy, and registry
Vanderbilt University Medical Center (August 2017)	Health system	Electronic health records, public claims, private claims, pharmacy, registry, and patient-generated

Network collaborator (Month/year joined)	Organization type	Data sources
Weill Cornell Medicine (August 2017)	Medical school with physician practices and affiliated hospitals	Electronic health records, public claims, private claims, pharmacy, registry, and patient-generated
Yale New Haven Health (July 2017)	Health system	Electronic health records, public claims, private claims, and registry

Source: GAO analysis of NESTcc information. | GAO-24-106699

[a]Patient-generated data includes information from mobile health applications and wearable devices.

[b]A health system comprises at least one hospital and one group of physicians that provide health care services including primary and specialty care and are connected under common ownership or joint management.

Built the Data Infrastructure for a Real-World Evidence Network

In June 2019, FDA awarded funds to NESTcc to begin work on an active postmarket surveillance system. Since then, NESTcc has built the infrastructure to analyze data from network collaborators to generate real-world evidence for a variety of purposes, including to support active surveillance. According to NESTcc documentation, this included developing data governance principles and analytic methods, as well as building a data cloud to protect patient data privacy. NESTcc also sponsored pilot projects to evaluate the use of data sources needed to generate real-world evidence.

Data governance. Data governance is a framework or structure for ensuring the accessibility, quality, and transparency of data. In February 2020, NESTcc published a Data Quality Framework that included data governance principles for network collaborators and other organizations wishing to work with NESTcc. These standards included protocols for data access and use, such as guidance on data quality assurance for accurate, traceable, and timely data. Representatives from the two device industry stakeholder groups we interviewed underscored the importance of data governance when using real-world evidence.

Analytic methods. In February 2020, NESTcc published a Methods Framework to identify principles for medical device study designs using real-world evidence. This included guidance on a range of study areas such as objectives, target population, sample size, and how to appropriately characterize a medical device in a study. For example, when characterizing a device, NESTcc requires researchers to include the device brand and model number, any accessories, sizing, mode of action, and intended use.

Example Pilot Project for Real-World Evidence Generation

NESTcc sponsored 21 pilot projects to evaluate the use of real-world evidence for active surveillance, among other purposes. One project examined the feasibility of using electronic health records and claims data to study failures in implantable leads (electrodes) for pacemakers and defibrillators.

Source: GAO review of National Evaluation System for health Technology Coordinating Center (NESTcc) information. | GAO-24-106699

Data cloud. In November 2020, NESTcc began work on a federated data cloud to safeguard data access and patient privacy. According to NESTcc documentation, this federated data cloud protects patient privacy because patient-level data remains under the control of the entities where the data

originated. Specifically, analyses occur within the data systems of the health system or other source, and only aggregated results are shared to the data cloud. Two NESTcc network collaborators we interviewed stressed the importance of protecting patient privacy. NESTcc built this cloud using data from two health systems within NESTcc's real-world evidence network. By July 2021, NESTcc had an operational data cloud that was made available for research projects.

Pilot projects. Beginning in 2018, NESTcc funded 21 pilot projects to evaluate the use of real-world evidence for a variety of purposes, including active surveillance (see sidebar). NESTcc also contracted with the RAND Corporation to summarize lessons learned from these pilot projects and to identify opportunities for improving the use of real-world evidence to study medical devices.[14] For example, RAND highlighted the importance of identifying network collaborators with large enough data sets to address pilot project research questions. RAND published its final report in 2022.

Leveraged Stakeholder Expertise to Plan an Active Postmarket Surveillance System

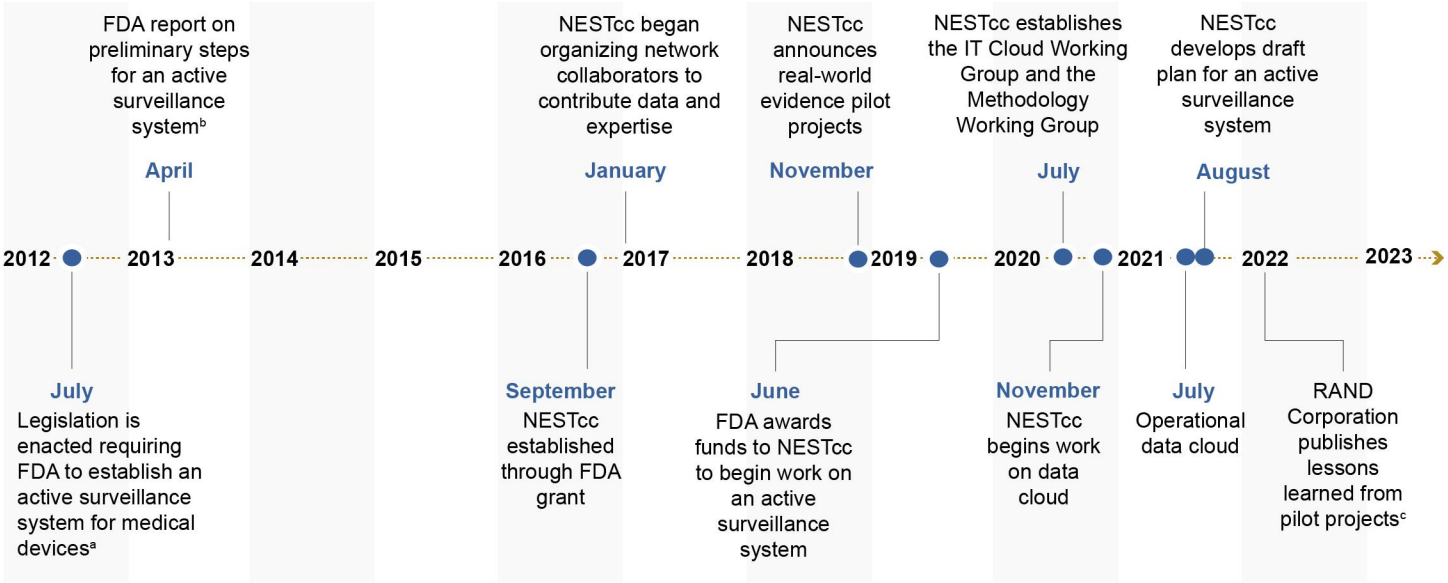
NESTcc convened working groups to guide plans to build its active postmarket surveillance system. These working groups included stakeholders from the device industry, providers, and health systems. Beginning in July 2020, NESTcc formed or planned working groups to assist with planning the active surveillance system:

- IT Cloud working group, tasked with designing the data infrastructure needed to perform active surveillance.
- Active Surveillance Methodology working group, tasked with developing methods to analyze real-world evidence to support active surveillance.
- Data Curation working group, tasked with ensuring data standardization across network collaborators for the purposes of active surveillance.

In August 2021, NESTcc published a draft plan outlining detailed project management and technical steps for the active surveillance system, which included goals for the overall system architecture and established project milestones.

[14]RAND Corporation, 2022.

Figure 2: Timeline of Foundational Activities to Support an Active Surveillance System for Medical Devices



Source: GAO analysis of National Evaluation System for health Technology Coordinating Center (NESTcc) information. | GAO-24-106699

Accessible Data for Figure 2: Timeline of Foundational Activities to Support an Active Surveillance System for Medical Devices

- July 2012 - Legislation is enacted requiring FDA to establish an active surveillance system for medical devices. [a]
- April 2013 - FDA report on preliminary steps for an active surveillance system.[b]
- September 2016 - NESTcc established through FDA grant.
- January 2017 - NESTcc began organizing network collaborators to contribute data and expertise.
- November 2018 - NESTcc announces real-world evidence pilot projects.
- June 2019 - FDA awards funds to NESTcc to begin work on an active surveillance system.
- July 2020 - NESTcc establishes the IT Cloud Working Group and the Methodology Working Group.
- November 2020 – NESTcc begins work on data cloud.
- July 2021 – Operational data cloud.
- August 2021 - NESTcc develops draft plan for an active surveillance system.
- 2022 - RAND Corporation published lessons learned from pilot projects.[c]

Source: GAO analysis of National Evaluation System for health Technology Coordinating Center (NESTcc) information. I GA0-24-106699

[a]Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 615, 126 Stat. 993, 1061 (2012).

[b]Food and Drug Administration (FDA), Strengthening Our National System For Medical Device Postmarket Surveillance: Update and Next Steps. (Silver Spring, Md: April 2013).

[c]Through NESTcc, FDA contracted with the RAND Corporation to conduct an evaluation of lessons learned from pilot projects that assessed the use of real-world evidence for medical device safety and effectiveness. See RAND Corporation, Final Report on Lessons from the National Evaluation System for health Technology Coordinating Center (NESTcc) Test-Cases (Santa Monica, Ca.: 2022).

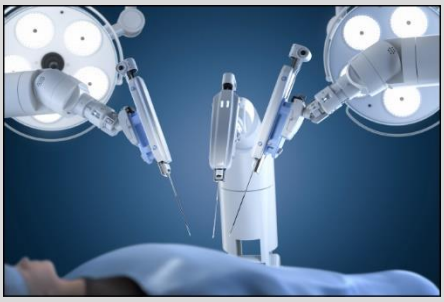
FDA Plans to Begin Active Postmarket Surveillance of Two Medical Devices

Initial Devices Monitored Under the Food and Drug Administration's (FDA) Active Surveillance System

Duodenoscope

Duodenoscopes are flexible tubes inserted through the mouth, throat, and stomach to view the small intestine to diagnose and treat problems in the pancreas. According to FDA, in the United States, duodenoscopes are used in more than 500,000 procedures per year. FDA has conducted ongoing surveillance activities to monitor infections associated with procedures using duodenoscopes.

Robotically Assisted Surgical Devices Used in Gallbladder Removal (Cholecystectomy)



These devices enable surgeons to use computer software and technology to perform pre-operative activities and surgical procedures. These devices can be leveraged for a range of procedures including gallbladder removal.

Source: GAO summary of FDA information; phonlamaiphoto, olgasparrow/stock.adobe.com (photos). | GAO-24-106699

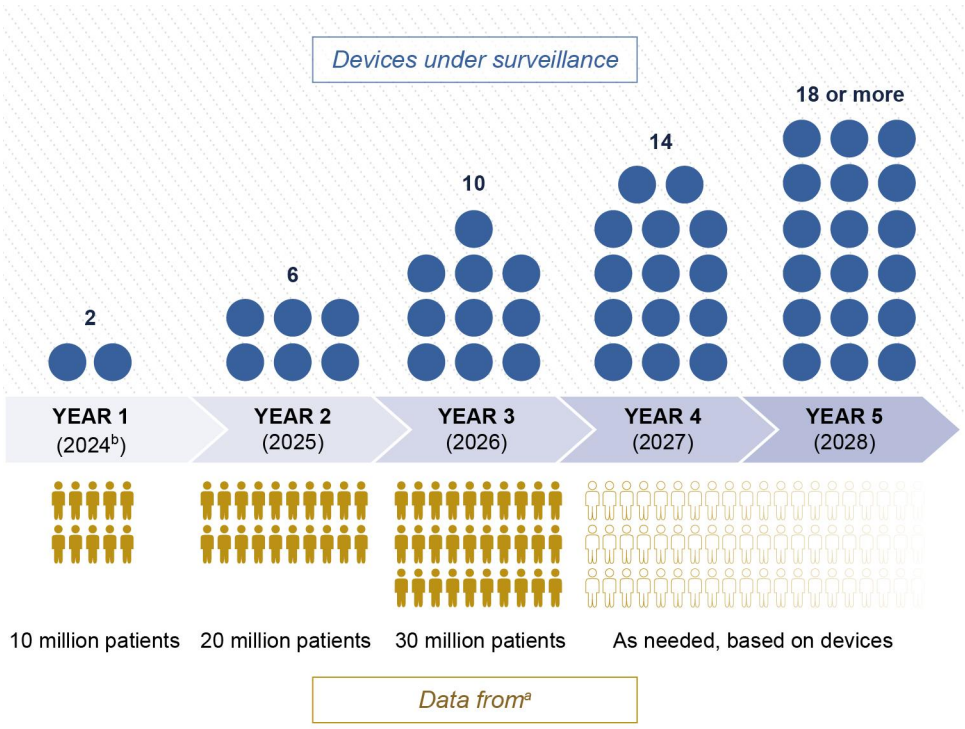
In October 2023, NESTcc contracted with a vendor to develop the capability for FDA to begin active surveillance of two medical devices. These two devices are the duodenoscope, which is a lighted tube used for viewing the small intestine, and devices used in gallbladder removal, such as robotically assisted surgical devices (see sidebar). The duodenoscope was selected due to known safety issues (infections) related to use of the device, according to FDA officials. The robotically assisted surgical devices for gallbladder removal were selected because use of these devices is more likely to be captured in electronic health records and claims data, according to these officials.

The vendor was tasked with developing the capability for FDA to monitor data on these devices from at least two and up to six entities, which FDA refers to as data partners. Data partners may be existing NESTcc network collaborators, or they may be new entities; the goal is to have access to data for at least 10 million patients, according to FDA documentation. Representatives from two NESTcc network collaborators we spoke with commented that building a data network with enough data sources is critical to ensuring that an active postmarket surveillance system can detect adverse events.

NESTcc and its vendor began outreach to 14 potential data partners beginning in February 2024. As of April 2024, they have secured the participation of one data partner.[15] FDA officials estimate this work will be completed by December 2024, contingent on funding availability.

According to FDA officials, after the completion of this work, the agency plans to carry out a stepwise expansion of its active surveillance capabilities over 5 years. In 2025 and 2026, FDA plans to add four devices per year and to onboard data partners yielding 10 million new patients in each of years 2 and 3, with further additions as needed annually (see figure 3).

Figure 3: Planned Expansion of FDA's Active Postmarket Surveillance System



Source: GAO analysis of Food and Drug Administration information; GAO (illustrations). | GAO-24-106699

[15]NESTcc is also conducting outreach with programs across various federal entities, including the Department of Defense and the Department of Veterans Affairs but, as of June 2024, has not yet secured participation, according to NESTcc officials.

Accessible Data for Figure 3: Planned Expansion of FDA's Active Postmarket Surveillance System

Year	Total number of devices under surveillance	Data (Total number of patients, in millions)
Year 1: (Anticipated completion December 2024)	2	10
Year 2	6	20
Year 3	10	30
Year 4	14	As needed, based on devices
Year 5	18 or more	As needed, based on devices

Source: GAO analysis of Food and Drug Administration information; GAO (illustrations). I GAO-24-106699

[a]Represents anticipated patient data totals. Not all patients will have necessarily used the devices under surveillance.

[b]FDA anticipates completion of Year 1 expansion by December 2024, contingent on funding availability.

FDA Has Taken Actions to Address Challenges with Device Identification and Funding

FDA has faced two key challenges in establishing its active postmarket surveillance system for medical devices, according to FDA officials. First, there is limited use of unique device identifiers among health care providers and payers, which makes identifying devices that patients use more difficult. Second, there are funding considerations regarding the establishment of FDA's active postmarket surveillance system. FDA has taken actions to address these challenges.

Limited Use of Unique Device Identifiers Among Providers and Payers

Unique Device Identifiers

A unique device identifier is a unique identification code associated with a given device. This code identifies the device manufacturer and provides device-specific information (such as model) and production-specific information (such as a lot number). The Unique Device Identification System final rule, published by the Food and Drug Administration in 2013 in response to federal law, requires the label and package of a medical device to include a unique device identifier, with some exceptions, to provide for adequate identification of devices in the United States through distribution and use. FDA has phased in compliance over the past decade, as required by the rule.

Source: GAO review of 78 Fed. Reg. 58786. | GAO-24-106699

Unique device identifiers are important for linking patients to the medical devices they use (see sidebar); yet health care providers and payers generally do not capture these identifiers in electronic health and claims records, according to FDA officials and NESTcc. This can make identification of devices used by patients, and therefore active surveillance related to those devices, challenging.

The RAND Corporation, in its assessment of NESTcc's pilot projects testing the use of real-world evidence to study medical devices, also identified this as a challenge. RAND found that pilot projects using electronic health records that did not contain unique device identifiers took significantly more time to identify patients using specific devices of interest when compared to projects where unique device identifier information was available. Moreover, in some cases, pilot projects had difficulty identifying a sufficient number of patients using a given device to allow the project to move forward due to a lack of device identifier information.[16]

Representatives from one health system and two provider groups we interviewed said there are challenges with collecting unique device identifier information at the point of care, including administrative burden on providers and lack of a consistent mechanism to capture this information.

While FDA has the authority to require that medical devices include a unique device identifier, the agency does not have the authority to mandate that providers capture such identifiers in electronic health records at the point of care or use identifiers for billing purposes, according to FDA officials. FDA has taken actions to encourage this adoption, including:

Promoted the benefits of unique device identifiers to health systems. Supported in part by funding from FDA, in April 2023, NESTcc published *A Playbook for Health System Unique Device Identifier Implementation at the Point of Care* that described benefits to health systems of using

[16]RAND Corporation, 2022.

unique device identifiers.[17] Those benefits include better information through unique device identifiers for clinical decision-making, supply chain management, and device recall management. For example, the document describes traditional recall management for health systems without the aid of unique device identifiers as a labor-intensive and inefficient process that requires manual review of potentially hundreds of patient health records. The document also describes testimonial evidence from a provider indicating that use of unique device identifiers to support recalls resulted in quicker and more definitive identification of devices and patients and required significantly less effort from staff.

Advocated for capture of unique device identifiers in health care claims transactions. FDA has advocated for the capture of unique device identifiers in the Department of Health and Human Services' (HHS) national standard for electronic health care billing claims transactions.[18] For example, FDA has supported capture of certain parts of unique device identifiers in this national standard—specifically, for high-risk implantable devices and only where both the provider and payer agree to the exchange of this information, according to FDA officials. This proposal was one of several changes, the others not specific to medical devices, included in an updated version of the standard considered by HHS.

However, in June 2023, HHS's National Committee on Vital and Health Statistics, which is one federal committee that advises the Secretary of Health and Human Services on national health information policy, did not recommend an updated version of the standard. The addition of a field for unique device identifier was not one of the reasons the committee cited for its decision against adoption of the updated standard, according to documentation from the committee. The committee noted that the capability to capture unique device identifiers in health care claims transactions was an important concern pertaining to HHS implementation guidance rather than the standard update under consideration. Accordingly, the committee encouraged FDA to review the stakeholder concerns the committee received regarding the capture of these identifiers. In July 2023, FDA published a letter to the committee acknowledging this as a setback in the agency's efforts to promote adoption of unique device identifiers and encouraged the committee to work to resolve open issues with adopting the updated standard.[19]

Coordinated with HHS's Office of the National Coordinator for Health Information Technology. FDA has been in conversations with this office to discuss expanded capture of unique device identifiers in health information technology, according to FDA officials. For example, FDA met with this office in December 2023 to discuss expanded capture of unique device identifiers in electronic health record software and other technology certified by this office under the federal Health Information Technology Certification Program. This office helps coordinate nationwide efforts to implement and use health information technology and the electronic exchange of health information in the United States. The Health Information Technology Certification Program is a voluntary program that certifies that health information technology products available in the United States meet criteria related to the capture, access, and exchange of a patient's health data,

[17]National Evaluation System for health Technology Coordinating Center. *A Playbook for Health System Unique Device Identifier Implementation at the Point of Care* (Arlington, Va.: April 2023).

[18]Federal law requires HHS to maintain a national standard for electronic claims transactions that applies to all health plans and health care providers who conduct such transactions. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, §§ 261-64, 110 Stat. 1936, 2021 (codified at 42 U.S.C. § 1320d et seq).

[19]FDA, *FDA Letter Regarding the National Committee of Vital Health Statistics Recommendation on the Updated Version of the X12 Standard for Claims and Electronic Remittance Advice Transactions* (July 28, 2023).

according to officials from this office. Currently, to meet requirements under this program, certified health information technology must make a data field available for unique device identifiers for patient data related to implantable devices only.[20] FDA has pushed to expand the capture of unique device identifiers under this program for all devices for which unique device identifier rule requirements apply. As of March 2024, this change has not been adopted. However, even if adopted under the program, officials from the Office of the National Coordinator noted that this would enable health information technology to capture and exchange unique device identifiers for non-implantable devices but would not require that identifiers be used by providers or others.

Funding Considerations to Support an Active Postmarket Surveillance System

FDA officials told us that the agency is considering how to fund its active surveillance work, including funding necessary to onboard data partners. The estimated cost to establish and maintain an active postmarket surveillance system is $8 million per year, and FDA plans to allocate $5 million of its current annual appropriations for this purpose, according to FDA officials. To address this challenge, FDA has taken the following actions:

Estimated current and future active postmarket surveillance costs. FDA has estimated current and future active postmarket surveillance costs by conducting an Independent Government Cost Estimate, completed in January 2023, to inform the agency's understanding of the contracting costs to build and maintain its active surveillance system, according to agency officials.[21] Also, in February 2023, FDA issued a Sources Sought Notice, which solicited information from potential contractors on technical capabilities and costs to build and maintain the system. As part of these efforts, FDA has estimated costs to onboard data partners to contribute data to the system to be between $600,000 and $1 million (annual cost per partner).

Requested additional appropriations. To fund active postmarket surveillance for fiscal year 2024, FDA requested an additional $3 million in annual appropriations, as documented in the agency's fiscal year 2024 budget justification.[22] In April 2024, FDA officials told us that the agency did not receive the requested increase in its fiscal year 2024 appropriations.[23] FDA officials stated that they intend to continue building the active surveillance system using current appropriations. However, doing so without an addition to FDA's appropriations would mean taking away from other postmarket priorities at FDA, according to officials, such as investigating adverse events reported to the agency.

Advocated for additional funding through device user fees. FDA has advocated that funding generated from device user fees be applied to the agency's postmarket surveillance activities, including establishing an active surveillance system. Federal law allows FDA to use device user fees primarily to fund its device premarket activities, such as FDA's review of applications to market

[20]See 45 C.F.R. § 170.315(a)(14).

[21]An Independent Government Cost Estimate is an estimate of the expected cost of a contract. These estimates are developed by government personnel before soliciting contractor proposals or making contract awards.

[22]Department of Health and Human Services, *Food and Drug Administration Fiscal Year 2024 Justification of Estimates for Appropriations Committees*.

[23]FDA did not make a similar request in the agency's fiscal year 2025 budget justification.

devices.[24] Using device fees solely for the establishment of a postmarket active surveillance system is not likely to be allowed under current law, according to FDA.[25] To change activities device user fees can be used for, FDA would need to work with industry and Congress. Specifically, as part of the user fee reauthorization process, FDA is required to negotiate user fees amounts with industry stakeholders and submit recommendations to Congress based on these negotiations to inform reauthorization.

During the most recent round of negotiations for the 2022 reauthorization, FDA proposed using some user fee funds to enhance postmarket surveillance activities, including establishing an active surveillance system, according to FDA officials. According to these officials, industry did not agree to this change for the 2022 reauthorization. In contrast to medical device user fees, beginning in 2002, federal law allowed FDA to use funding from drug user fees to support the agency's drug-related postmarket surveillance activities, such as developing and using improved analytical tools to assess potential safety problems.[26]

FDA has taken the important step of engaging its stakeholders, including potential data contributors and Congress, to develop and communicate the costs of an active surveillance system. Engaging these stakeholders is a critical ongoing effort to ensuring an adequately funded, robust active postmarket surveillance system that can help FDA better fulfill its mission of ensuring the safety and effectiveness of medical devices marketed in the United States. We will continue to monitor FDA's progress in establishing this system.

Agency Comments and Third-Party Views

We provided a draft of this report to HHS, of which FDA is a part, and NESTcc for review and comment. HHS and NESTcc provided technical comments, which we incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, the Commissioner of the Food and Drug Administration, and other interested parties. In addition, the report is available at no charge on the GAO website at https://www.gao.gov.

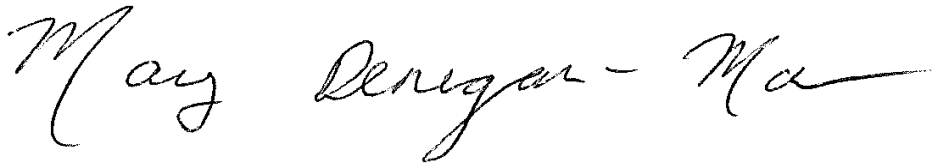
If you or your staff have any questions about this report, please contact me at (202) 512-7114 or DeniganMacauleyM@gao.gov. Contact points for our Offices of Congressional Relations and Public

[24]Federal law authorizes FDA to collect user fees to supplement the annual funding that Congress provides the agency for the purposes of conducting specified activities. Fees are collected and available for obligation only to the extent and in the amount provided in advance in appropriations acts. The Medical Device User Fee and Modernization Act of 2002 authorized user fees for medical devices. Pub. L. No. 107-250, § 102(a), 116 Stat. 1588, 1589 (codified as amended at 21 U.S.C. §§ 379i and 379j). It must be reauthorized every 5 years; the user fees were most recently reauthorized in 2022 and will be in place until 2027. Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023, Pub. L. No. 117-180, 136 Stat. 2114 (2022).

[25]See also 21 U.S.C. §§ 379j(h)(1); 379i(9).

[26]Prescription Drug User Fee Amendments of 2002, Pub. L. 107-188, tit. V, subtit. A, § 503, 116 Stat. 687 (codified at 21 U.S.C. § 379g(6)(F)).

Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix II.



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Appendix I: GAO Contact and Staff Acknowledgments

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In addition to the contact listed above, Jennel Lockley (Assistant Director); Ramsey Asaly (Analyst-in-Charge); Sam Amrhein; Sonia Chakrabarty; Shannell Ciruso; Bethany Gracer; Ethiene Salgado-Rodriguez; Haley Samuel-Jakubos; and Ravi Sharma made key contributions to this report.

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