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BMJ INVESTIGATION

# Is the US's Vaccine Adverse Event Reporting System broken?

**A BMJ investigation has raised concerns that the VAERS system isn't operating as intended and that signals are being missed. Jennifer Block reports**

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Three weeks after receiving a second dose of a covid vaccine, Robert Sullivan collapsed at home on his treadmill. An anaesthesiologist in Maryland, USA, he was a particularly fit 49 year old: the week before falling ill, he'd been happily skiing at altitude in Colorado.

Sullivan was given a diagnosis of sudden onset pulmonary hypertension, which is generally progressive, can be fatal, and in most cases can't be cured. The condition is rare, especially in middle aged men. Sullivan decided to file a report in the Vaccine Adverse Event Reporting System (VAERS), which collects reports of symptoms, diagnoses, hospital admissions, and deaths after vaccination for the purpose of capturing post-market safety signals.

But the submission process was a glitchy race against the clock. "The format is cumbersome and it times you out," he tells *The BMJ*. For his troubles, Sullivan received a confirmation by email and a temporary "e-report" number. He learnt from his doctor's office that a VAERS representative had requested medical records. Then he didn't hear back for a year.

VAERS is supposed to be user friendly, responsive, and transparent. However, investigations by *The BMJ* have uncovered that it's not meeting its own standards. Not only have staffing levels failed to keep pace with the unprecedented number of reports since the rollout of covid vaccines but there are signs that the system is overwhelmed, reports aren't being followed up, and signals are being missed.

*The BMJ* has spoken to more than a dozen people, including physicians and a state medical examiner, who have filed VAERS reports of a serious nature on behalf of themselves or patients and were never contacted by clinical reviewers or were contacted months later.

Our investigation has also found that, in stark contrast to the US government's handling of adverse reaction reports on drugs and devices, the publicly accessible VAERS database on vaccines includes only initial reports, while case updates and corrections are kept on a separate, back end system. Officials told *The BMJ* that this was to protect patient confidentiality—but this means that patients, doctors, and other public users of the database have access only to an incomplete and uncorrected version.

## Understaffed

Co-managed by the US Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration, the VAERS reporting system relies on a mixture of voluntary adverse event reports from doctors and patients and mandatory reporting from vaccine manufacturers, which are required by law to report all adverse events they become aware of.

Good pharmacovigilance requires prompt data collection, review by people with clinical expertise, and adequate follow-up, says Marie Lindquist, former director of the Uppsala Monitoring Centre in Sweden, an internationally recognised non-profit pharmacovigilance body. "We know that even the best clinical trials won't detect [rare adverse events]," she tells *The BMJ*.

VAERS's standard operating procedure for covid-19 states that reports must be processed quickly, within days of receipt.[1 2] "Serious reports" trigger the requisition of medical records and at minimum a "manual review," while deaths and other "adverse events of special interest" may undergo a more "in-depth" clinical review by CDC staff.

However, *The BMJ* has learnt that in the face of an unprecedented 1.7 million reports since the rollout of covid vaccines, VAERS's staffing was likely not commensurate with the demands of reviewing the serious reports submitted, including reports of death. While other countries have acknowledged deaths that were "likely" or "probably" related to mRNA vaccination, the CDC—which says that it has reviewed nearly 20 000 preliminary reports of death using VAERS (far more than other countries)—has not acknowledged a single death linked to mRNA vaccines.

Before the pandemic VAERS was receiving nearly 60 000 adverse event reports each year. A 2015 CDC article suggests that the agency had the capacity to request records for just a few thousand serious reports each year.[3] But in 2021 the total number of reports shot up to a million, and another 660 000 have been filed since. Nearly one in five meet the criteria of serious. This surge reflects the unprecedented campaign to vaccinate against covid-19—in the US alone some 675 million doses have been administered—and the vast majority of recent reports are related to covid vaccines. The CDC states that, "in the event of a significant increase" in VAERS reports warranting clinical review, the standard operating procedure requires additional CDC Immunization Safety Office staff to process cases.[1 2]

Freedom of Information Act documents seen by *The BMJ* suggest that Pfizer has around 1000 more full time employees working on vaccine surveillance than the CDC, despite the latter's responsibility for

handling adverse event reports on all products. The CDC didn't provide *The BMJ* with specific numbers, instead stating that its staffing "reflects the needs of the office" at any given time and can range from "several dozen to hundreds," including contractors and individuals reassigned "from across the agency." The latest confirmed number of staff, as of November 2022—at the Immunization Safety Office, which houses VAERS—is 70-80 full time equivalent workers.

In comparison, a February 2021 Pfizer analysis of adverse event reports showed that the company had onboarded 600 additional full time employees to handle the volume and planned to employ a total of 1800.[4] Pfizer didn't respond to *The BMJ*'s requests for information on current staffing.

## The user experience

Interviews with more than a dozen VAERS users by *The BMJ*—all of whom were trying to file reports of a serious nature—revealed a patchy and frustrating experience. Some users heard back from clinical reviewers months after making their first report, while others never heard anything. Some of those making reports were told conflicting information about updating their report or were discouraged from making a report altogether.

Those people include Patrick Whelan, a rheumatologist and researcher at the University of California Los Angeles, who in 2022 reported how one of his patients, a 7 year old boy, had a cardiac arrest after covid vaccination. The patient was intubated when Whelan filed a VAERS report, and he expected a prompt follow-up call from a CDC investigator.

"I assumed that, since it was a catastrophic event, the safety committee would want to hear about it right away," he says. But, to his knowledge, nobody called or requested medical records. In an email sent to Whelan months later the FDA said that it had followed up "soon after" receiving his report and had made "several requests" for medical records. The agency added, "Generally speaking, staff might not reach out to providers unless they have specific questions about a case or a VAERS report."

James Gill has been a medical examiner and forensic pathologist for 25 years and is currently chief medical examiner for the state of Connecticut. In June 2021 he made the first VAERS report of his career. It was for a 15 year old boy who died suddenly days after getting a second jab—what Gill concluded on autopsy was "stress cardiomyopathy following second dose of the Pfizer-BioNTech covid-19 vaccine."[5-7]

Gill, who has appointments at Yale University and the University of Connecticut, can't recall getting any calls from VAERS after he filled out the online form, and he still has only a temporary "e-report" number. After he published the case reports in the *Archives of Pathology & Laboratory Medicine* in February 2022, however, the CDC did respond—in the form of a letter to the editor contesting Gill's findings.[5-7]

In November 2022, React19, an advocacy group of some 30 000 people who have experienced prolonged illness after covid vaccination, reviewed 126 VAERS reports among its ranks. In its audit, which was conducted by volunteers inside and outside the organisation, 22% had never been given a permanent VAERS ID number and 12% had disappeared from the system entirely—in other words, one in three of the reports they looked for didn't show up in the publicly searchable database.[8]

## Searching for answers

A group of physicians and advocates have met multiple times with FDA representatives from 2021 to 2022, including Peter Marks, director of the Center for Biologics Evaluation and Research, and Narayan Nair, the FDA division director who oversees VAERS, to express their concerns that the system isn't operating as intended and that signals are being missed.

One participant in the group—Helen, an intensive care and emergency physician who asked to use a pseudonym to protect her employment—had filed reports on behalf of several patients, including six who died, among them a 40 year old man. She tells *The BMJ* that she received a request for medical records for just one of the deaths and for two of her patients admitted to hospital. "You're not meeting your defined definition of follow-up," she told Nair and Marks during an online meeting on 22 March last year. "There's a breakdown in your system."

*The BMJ* obtained audio of these meetings, totalling seven. In March 2022, in response to the physician, Nair responded that if a report meets the definition of serious, "there really should be a request for records." In the case of a reported death, "we prioritise getting the records for those extremely quickly." He added, "You know, we've received a large volume [of serious reports]. And I don't know what the back-up is."

At the following meeting in May 2022 an FDA spokesperson, Lorrie McNeill, said that "for all of the reports categorised as serious, the VAERS contractor either obtained records, or made several attempts to do so and closed out a report if they didn't get a response."

In response to several questions about these meetings and the issues they raised, the FDA responded by email that the agency "is actively engaged in safety surveillance of these vaccines to identify and address potential safety concerns" and that "physicians and epidemiologists from the FDA and CDC continuously screen and analyse data from VAERS for covid-19 vaccines to identify potential signals that would indicate the need for further study."

## Two VAERS—only one public

A week after Whelan filed the VAERS report for his young patient in Los Angeles, he had cause to update it. The boy's condition didn't improve, and the decision was made to terminate life support. But "there was no mechanism for [updating] it," he tells *The BMJ*. "The only option I had was to make a new VAERS report."

Three weeks later he met with the FDA in his capacity as a researcher to discuss a forthcoming paper, and without having planned to he mentioned the case and the lack of follow-up. Nair reached out by email the next day, and six weeks later Whelan discussed the case with Nair and a press officer for around 35 minutes.

Today, however, that VAERS report still shows the child as having been admitted to hospital. "I made the false assumption that that conversation would result in an adjustment in the publicly reported case," says Whelan. "Think of all the people who are using VAERS data as a means to assess what's happening with the vaccines—except in this case you'd be left with the false impression that the child had had a serious adverse event," rather than seeing that he'd died.

*The BMJ* has found that the FDA and CDC essentially maintain two separate VAERS databases: a public facing database, containing only initial reports; and a private, back end system containing all updates and corrections—such as a formal diagnosis, recovery, or death.

In December last year Nair explained the situation at a meeting with advocates. He said, "There's two parts to VAERS, the front end system and the back end . . . Anything derived from medical records by law" can't be posted on the public facing system. The CDC has told *The BMJ* that "protecting patient confidentiality is a priority."

Interestingly, the FDA Adverse Event Reporting System (FAERS), which collects reports on drugs, does maintain a publicly accessible database that gets updated, as does the agency's Medical Device Reporting system—raising the question of why VAERS can't do the same. Neither the CDC nor the FDA provided an explanation. An FDA spokesperson told *The BMJ* that "patients can submit formal requests under FOIA [Freedom of Information Act] to obtain the full record of their report."

For serious cases, reporters to VAERS are supposed to receive emails prompting them to provide updates. These emails include a code and upload link, but the reporters *The BMJ* spoke to didn't get confirmation emails, and if they searched for their report in the database it remained unchanged. Similarly, if a reporter successfully treated a diagnosis and the patient improved, or if they confirmed that the cause of the illness was unrelated to a vaccine, this wouldn't be reflected in the public database.

Nair acknowledged in a meeting with advocates that people get frustrated when they look for an updated report, find the original untouched, and feel "ignored." He said, "They never see it on the front end, because we don't alter that initial report."

## Detecting signals

Pharmacovigilance has been effective in alerting the public to unusual, acute reactions, even when based on few reports. For example, it took just six VAERS reports of thrombosis with thrombocytopenia syndrome after administration of the Janssen covid vaccine for regulators to issue a "pause" in April 2021.[9]

Ralph Edwards, former director of the Uppsala Monitoring Centre and until recently editor in chief of the *International Journal of Risk & Safety in Medicine*, explains that monitoring systems such as VAERS excel at detecting adverse reactions that occur very soon after vaccination or are known from other vaccines, such as anaphylaxis or Guillain-Barré syndrome. But detecting new and unusual reactions, especially those with latent effects, has been an ongoing challenge in the world of pharmacovigilance.

Edwards tells *The BMJ*, "If something hasn't been heard of before, it tends to be ignored." He explains that regulators may be relying too heavily on epidemiological evidence to acknowledge a signal. VAERS alone is unlikely to capture such long term adverse outcomes unless reports are regularly updated and reviewers are closely following such cases—"a real catch 22," he says. "You'll never get the evidence unless you have the idea to look for it in the first place."

Addressing an October 2021 meeting, Helen said that most doctors were "only willing to talk about the FDA recognised vaccine adverse events." She asked the FDA to alert doctors to potential adverse neurological reactions, as had been done with myocarditis. But more than once the FDA's Peter Marks expressed confusion about why it would matter to doctors whether or not regulators acknowledged that a condition might be related to the vaccine. "Aren't they treating what's in front of them?" he asked.

However, Svetlana Blitshteyn, a neurologist and researcher at the University at Buffalo, New York, who has been treating postural orthostatic tachycardia syndrome for around 20 years and has seen the condition present after vaccination, tells *The BMJ* that if physicians aren't educated to look for the condition they're unlikely to test for it or know how to treat it.

Helen is calling for an end to the "negative feedback loop . . . the FDA is not naming additional adverse reactions to the vaccines because the passive surveillance systems aren't displaying it. But the passive surveillance systems aren't displaying it because physicians are blinded to the adverse reactions in their patients, and thus aren't reporting them."

The European Union, for its part, has added hypoaesthesia and paraesthesia (reduced or abnormal sensation in the skin such as numbness, tingling, or burning) to the labelling on mRNA covid vaccines—based on around 21 000 cases reported by August 2021—as well as including heavy menstrual bleeding.[10 11] Japan has also added paraesthesia and hypoaesthesia.

Harlan Krumholz, a cardiologist and researcher at Yale, has been recruiting members of React19 to study their reactions.[12] "We are working hard to understand the experience, clinical course, and potential mechanisms of the ailments reported by those who have had severe symptoms arise soon after the vaccination," he tells *The BMJ*. "There are so many people whose lives have been changed dramatically—but what I don't know is how many or why."

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