CDC Ignores COVID-19 Vaccine Safety Signals, Maintains Secret Database

The nation's primary early warning system used to detect possible safety problems with vaccines is "overwhelmed," raising concerns that the system may be broken and isn't being adequately managed by the Centers for Disease Control and Prevention (CDC), according to a new investigation.

The report published on Nov. 10 by The BMJ found the Vaccine Adverse Event Reporting System (VAERS) has received an unprecedented number of reports attributed to COVID-19 vaccines, and there aren't enough staff members to meet the requirements for reviewing and following up serious reports, including deaths. Additionally, the investigation revealed that VAERS is neither transparent nor user-friendly nor responsive and suggests that the government essentially maintains two VAERS systems—only one of which the public can access.

Co-managed by the U.S. Food and Drug Administration (FDA) and

the CDC, VAERS collects reports of symptoms, diagnoses, hospital admissions, and deaths after vaccination to capture post-marketing safety signals and determine if there are any unusual or unexpected reporting patterns for adverse events.

According to the CDC, healthcare providers are "strongly encouraged" to report any adverse event following vaccination to VAERS, even if they're unclear whether the vaccine caused the adverse event. In contrast, vaccine manufacturers are required by law to report all adverse events that "come to their attention."

Although VAERS accepts reports from anyone, knowingly filing a false VAERS report violates federal law and is punishable by a fine and imprisonment. This allows VAERS to serve as an "early warning system to detect rare adverse events" and deter false reporting. Even so, VAERS has been shown to reflect only 1 percent of actual vaccine adverse events, according to a Harvard Pilgrim study.

CDC Isn't Investigating Serious COVID Vaccine Adverse Events

In 2019—prior to the pandemic—VAERS received more than 48,000 reports of vaccine adverse events, 85 percent to 90 percent of which were mild, according to the CDC. After the COVID-19 vaccine rollout, The BMJ found an "unprecedented" 1.7 million adverse events were reported to VAERS, with 1 million reported in 2021 and an additional 660,000 received thereafter. Nearly 1 in 5 cases met the criteria for a "serious" adverse event, and most reports were attributed to COVID-19 vaccines.

According to the VAERS Standard Operating Procedures for COVID-19, serious adverse events include reports of death, hospitalization, life-threatening illness, permanent disability and/or prolonged hospitalization, and congenital anomalies. Medical records are routinely requested for all

serious reports, including deaths, and adverse events of special interest may undergo a more in-depth clinical review by the CDC.

If there's a significant increase in VAERS reports warranting clinical review, the standard operating procedures require additional CDC Immunization Safety Office staff to process cases. For events classified as "serious," people who report to VAERS are supposed to receive email correspondence prompting them to provide updates, but The BMJ's investigation shows that these standards aren't being followed.

The BMJ interviewed more than a dozen people, including physicians and a state medical examiner, who filed VAERS reports for serious adverse events on behalf of themselves or patients and were either never contacted by the CDC or were contacted months later. Many never received confirmation emails when their reports were filed. Likewise, if a condition was successfully treated or was found to be unrelated to a vaccine, this wasn't reflected in the database.

Dr. Patrick Whelan, rheumatologist and researcher at the University of California—Los Angeles, filed a report in 2022 on behalf of his 7-year-old patient after he experienced cardiac arrest and was intubated following COVID-19 vaccination. To Dr. Whelan's knowledge, "nobody called or requested medical records." The FDA said it followed up "soon after" receiving the report and made several requests for medical records. It also added that staff "might not reach out to medical providers unless they have specific questions about a case or VAERS report."

Dr. James Gill, chief medical examiner for the state of Connecticut and a forensic pathologist, filed a VAERS report after a 15-year-old boy died suddenly in 2021 from stress cardiomyopathy following his second dose of Pfizer's COVID-19 vaccine. Although he completed a report online and received a temporary e-report number, Dr. Gill said that the CDC never

followed up. It wasn't until he published the boy's case report in the Archives of Pathology & Laboratory Medicine in February 2022 that the CDC responded—with a letter to the editor challenging Dr. Gill's findings.

React19, a science-based nonprofit made up of 30,000 people injured by COVID-19 vaccines, reviewed 126 VAERS reports and found that 22 percent of them were never given a permanent VAERS ID, and 1 of 3 reports filed disappeared from the system entirely, according to The BMJ.

An intensive care and emergency physician filed several reports on behalf of patients, including those involving six deaths. According to The BMJ, she received a request for medical records regarding only one death and for only two patients admitted to the hospital.

When it comes to reports of death following COVID-19 vaccination, other countries have acknowledged that deaths were "likely" or "probably" related to mRNA vaccination, but the CDC has reviewed more than 20,000 preliminary death reports, which is significantly more than other countries, yet hasn't attributed a single death to mRNA vaccines, The BMJ stated.

"A BMJ investigation has raised concerns that the VAERS system isn't operating as intended and that signals are being missed. As someone who has been studying and scrutinizing VAERS data for three years, I can confirm this observation," said researcher Jessica Rose, a VAERS expert with a doctorate in computational biology.

CDC Maintains 2 VAERS Databases—Only One Is Public

In contrast to how the U.S. government handles adverse reaction reports related to drugs and devices, the FDA and CDC

are essentially maintaining two separate VAERS databases: one that the public can access, containing initial reports, and a private system on the backend, with updates, outcomes, and corrections, Jennifer Block, the author of The BMJ report, discovered.

Dr. Narayan Nair is the FDA division director who oversees VAERS. According to The BMJ, during a December 2022 meeting, he stated that there are two parts to VAERS: "the front-end system and the back end." In a meeting with advocates, Dr. Nair admitted that initial reports are never updated, so the public never sees an updated report on the front end.

Yet the FDA's Adverse Event Reporting System for drugs does maintain a publicly accessible database that gets updated, as does the Medical Device Reporting System. It's only the VAERS system that doesn't publicly display updates. If someone wants a full copy of their record or report, they must submit a formal request under the Freedom of Information Act, an FDA spokesperson told The BMJ.

Although regulatory officials told The BMJ that this was to protect patient confidentiality, it means that patients, doctors, and other public users of the database don't have access to updated or complete records.

In an email to The Epoch Times, VAERS expert and data analyst Albert Benavides said he knew there were two VAERS databases, but of even greater concern is what the CDC isn't publishing at all.

"What supersedes even two VAERS databases (internal and external) is the fact that VAERS does not publish all legitimate reports received," Benavides said.

"The BMJ and the public are just now becoming aware that only initial reports are published, even though VAERS continues to collect follow-up data, hence the two databases. [The fact that] only initial reports are made public begs the question,

how many people are now since dead in VAERS?”

Benevides noted that the CDC stopped including follow-up data in 2011 after the Harvard Pilgrim Health Care study was published.

Regulators Are Ignoring VAERS Safety Signals

Because clinical trials involve studying products in a small number of selected individuals for a short period, some side effects may occur only when a larger and more diverse population has used the products over a longer duration. Pharmacovigilance is the practice of monitoring the effects of medical drugs and vaccines after they’ve been licensed to identify, prevent, and evaluate previously unreported adverse reactions.

“Good pharmacovigilance requires prompt data collection, review by people with clinical expertise, and adequate follow-up,” Marie Lindquist, former director of the Uppsala Monitoring Centre in Sweden, told The BMJ. “We know that even the best clinical trials won’t detect [rare adverse events].”

For example, the risk of a rare blood clotting disorder associated with the Johnson & Johnson COVID-19 vaccine, manufactured by Janssen, didn’t manifest until it was authorized. With only six cases reported, regulators in 2021 paused its use to investigate the reports and ultimately linked the rare blood-clotting disorder to the vaccine.

Ralph Edwards, former editor-in-chief of the International Journal of Risk & Safety in Medicine and author or co-author of more than 400 scientific papers, told The BMJ that VAERS is great for detecting adverse events that occur “very soon after vaccination” and those associated with other vaccines. However, it isn’t good at detecting new or latent effects

because regulators may rely too heavily on epidemiological evidence to acknowledge a VAERS signal.

In other words, if an adverse event hasn't been recognized before, it's ignored by regulators. If regulators don't acknowledge a signal, it's not acknowledged by doctors. Doctors also have to be educated to look for a condition so they know how to test for it and treat it. If physicians don't acknowledge that a medical condition could be potentially connected to a vaccine, they won't report it—so a passive surveillance system such as VAERS won't display the signal.

"It is easy to understand why VAERS is underreported and also why it needs to be *used* as the pharmacovigilance tool that it is," Rose said.

"How can doctors file a VAERS report if they do not even know what to look for it as per an adverse event occurrence? Furthermore, if a safe and effective doctrine continues to be pushed, the doctors and nurse practitioners will not feel compelled to report suspected adverse events in the first place."

In Rose's opinion, VAERS is a functioning pharmacovigilance tool. "The problem is, the owners of the data are not using it as such, and this is why the safety signals are being not so much 'missed,' as they are *hidden*," she said.

The BMJ's investigation suggests that the VAERS program is understaffed, so there aren't enough people to ensure that the CDC's standards are met. Documents obtained through the Freedom of Information Act and reviewed by The BMJ show that Pfizer had about 1,000 more full-time employees devoted to vaccine surveillance than the CDC.

The company brought in an additional 600 people to process adverse event reports attributed to its COVID-19 vaccine with the intent to employ a total of 1,800 people. The CDC has only 70 to 80 full-time equivalent workers, despite the agency's

“responsibility for handling adverse event reports on all products.”