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Health officials using new smartphone tool, traditional systems to monitor COVID-19 vaccine safety

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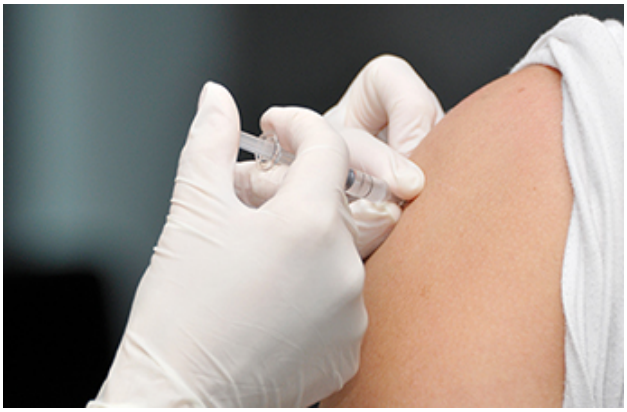

For the latest news on COVID-19, visithttps://www.aappublications.org/news/2020/01/28/coronavirus.

Federal health officials will be using a new smartphone-based tool to track whether people receiving COVID-19 vaccines are experiencing any adverse reactions.

The Vaccine Safety Assessment for Essential Workers (V-SAFE) will run alongside more traditional surveillance systems to monitor the safety of the vaccines that could begin to roll out later this month.

“Especially for these vaccines, we are going to hold ourselves to exceedingly high standards for safety monitoring after a vaccine is authorized and when it goes out more broadly,” Nancy Messonnier, M.D., director of the Centers for Disease Control and Prevention’s (CDC’s) COVID-19 Vaccine Planning Unit, told the agency’s vaccine committee this week.

Pfizer and Moderna, which have applied to the Food and Drug Administration (FDA) for emergency use authorization of their vaccines, have said they have had no serious safety concerns during their clinical trials. Some participants have reported systemic reactions like fatigue, headaches and myalgia as their immune system responds to the vaccine.

The FDA’s Vaccines and Related Biological Products Advisory Committee and the CDC’s Advisory Committee on Immunization Practices (ACIP) will be reviewing in-depth phase three clinical trial data in the coming weeks as they determine whether the vaccines are safe and effective. ACIP recommends that once a vaccine is approved, the first doses go to health care workers and residents of long-term care facilities.

Everyone who gets vaccinated will be encouraged to register for the V-SAFE tool. They will receive text messages with links to surveys on a daily basis for the first week, then weekly until six weeks. Additional

checks will be performed at three, six and 12 months.

Anyone who reports a clinically important event — missing work, being unable to do normal daily activities or receiving medical care — will get a follow-up phone call and a report may be filed in the Vaccine Adverse Event Reporting System (VAERS), according to Tom Shimabukuro, M.D., M.P.H., M.B.A., a member of the CDC's COVID-19 Vaccine Task Force.

VAERS, a long-running system managed by the CDC and FDA, is a national database covering the entire population. It will be one of the main sources monitoring the safety of COVID-19 vaccines, especially in the early months of vaccination.

Dr. Shimabukuro told ACIP this week that experts will review VAERS reports classified as serious, which include death, life-threatening illness, hospitalization, permanent disability, congenital anomaly or birth defects. Death reports will be processed in a day, serious reports in three days and non-serious reports in five days.

Multidisciplinary CDC teams will review clusters of clinically serious events reported in VAERS. The CDC's Clinical Immunization Safety Assessment Project will perform clinical case reviews, and an ACIP subgroup will review and evaluate COVID-19 safety data.

Additional safety monitoring systems also will be collecting data from electronic health records, medical claims, specific health care organizations and specific populations like the military.

"I want to reassure the ACIP, our public health and health care providers, and the public that we have the systems in place to collect safety data," Dr. Shimabukuro said. "We have validated methods to rapidly analyze the data. We have processes in place to respond to safety signals when we detect them, and we have trusted partners we will depend on when we implement the vaccination program."

He called on physicians to talk through safety concerns with patients and encourage those who get vaccinated to sign up for V-SAFE and report adverse events to VAERS.

Resources

- Information from the CDC on vaccine safety monitoring systems
- VAERS reporting
- VAERS FAQ