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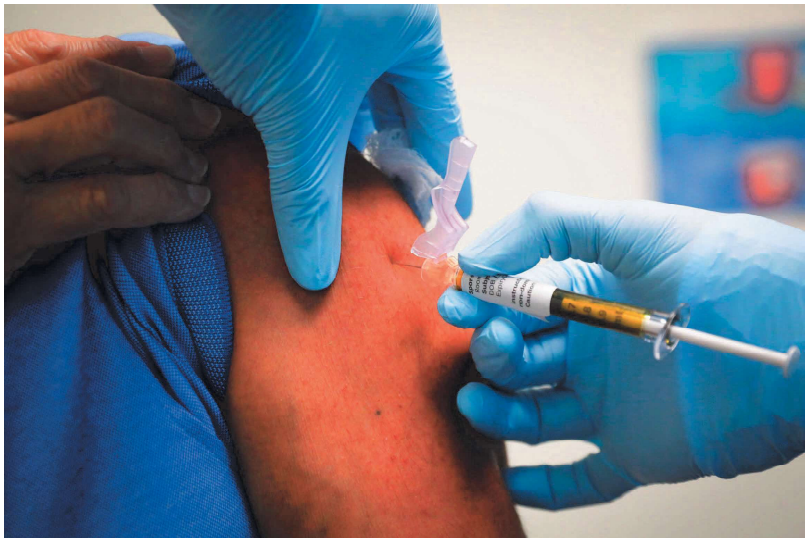
HEALTH

Covid-19 Vaccine Safety Efforts to Feature App Tracking

Health officials and drugmakers plan to roll out extra tools to detect whether coronavirus vaccines cause any serious side effects once the shots are cleared for widespread use.



By Peter Loftus

Government health officials and drugmakers plan to roll out extra tools to detect whether Covid-19 vaccines cause any serious side effects once the shots are cleared for widespread use, aiming to fill gaps in existing safeguards given the expected speed and scope of the rollout.

The measures include surveys tracked through a smartphone app developed by the Centers for Disease Control and Prevention and special monitoring for groups including pregnant women and the elderly, according to health officials and company executives involved in the plans.

“We want to have early eyes on safety as soon as possible,” said Grace M. Lee, who leads a Covid-19 vaccine safety group on the CDC’s Advisory Committee on Immunization Practices.

The CDC plans to send daily texts to people who get vaccinated, steering them to web surveys to self-report chills and other potential symptoms following vaccination. The smartphone-based system, V-SAFE, will send the surveys to anyone vaccinated who provides contact information, officials said. The surveys will be sent out daily for the first week post-vaccination, then weekly for six weeks.

There is no approved Covid-19 vaccine in the U.S., but several, including those developed by Pfizer Inc. and Moderna Inc., are being tested in tens of thousands of people in studies aimed at determining whether the shots safely protect from the disease. Initial results could come this month, with potential for government authorization of one or more vaccines by the end of this year.

Safety concerns led to temporary pauses in vaccine trials run by Johnson & Johnson and AstraZeneca PLC, but they have been cleared to resume. Vaccine specialists said it isn’t unusual to see adverse events in large vaccine trials. Covid-19 vaccine developers plan to do their own safety monitoring once wider vaccination begins, and will continue tracking safety in the people who received vaccines in clinical trials.

The new tools go beyond the typical patchwork of safety-surveillance systems that have been in place for many years to detect risks with vaccines approved for widespread use. The Food and Drug Administration approves vaccines based on safety and efficacy results from clinical trials, and a CDC advisory committee recommends which population groups should receive them, and at what age. Both the FDA and CDC monitor safety as approved vaccines are distributed.

Health officials want more safety monitoring of Covid-19 vaccines because they expect a large segment of the population to get vaccinated. There will also be limited safety data from ongoing clinical trials if a vaccine does get authorized by regulators for emergency use in the coming weeks or months. Some safety issues may not emerge until many more people get vaccinated, requiring careful surveillance of recipients. If serious safety issues do emerge, health authorities could withdraw the vaccine or modify how it is used.Typically, by the time a new vaccine is cleared for use, researchers have already followed people vaccinated in clinical studies for at least six months and often longer, to make sure no serious safety issues occurred. Given the urgency of the coronavirus pandemic, the FDA said it would require only two months of safety follow-up for at least half of the people in clinical trials before it authorizes emergency use of a vaccine.

Another reason for the enhanced measures is gaps in the current systems. One CDC system, for instance, relies heavily on information gathered from health-care networks on the West Coast, but less from elsewhere. Data gleaned from the federal Medicare program can yield clues about safety in the elderly, but little about younger people.

The CDC will ask hospitals to report how their workers fare after getting a Covid-19 vaccine. Front-line health workers, certain older adults and employees in food supply, transportation and other essential industries are expected to be among the first to receive limited supplies of any authorized vaccine in the U.S.

The CDC will also work with Genesis Healthcare Inc., a company that manages skilled nursing centers and senior-living communities, to monitor the safety of people vaccinated at 350 long-term care facilities in 25 states. A Genesis spokeswoman said the company couldn't disclose details at this time.

The Race for a VaccineCovid-19 Vaccines: What's Coming and When? (Oct. 22, 2020)

Covid-19 Vaccines Should First Go to Health Workers, First Responders, Group Recommends (Oct. 2, 2020)

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As Covid-19 Vaccine Development Pushes Ahead, Researchers Probe Safety (July 12, 2020)

Vaccine manufacturers also are taking steps to monitor safety. Moderna plans to tap into health-insurance claims databases covering about 130 million people for any early safety signals. It will also set up a study specifically to monitor what happens in pregnant women who get its vaccine, since that population group wasn't included in the company's large clinical study. Johnson & Johnson may set up a registry of people who receive its vaccine, a company executive said.

Moderna's measures will try to fill gaps in government surveillance systems, said David Martin, vice president of pharmacovigilance. "When you have a mass-vaccination campaign, you have to react more quickly," he said.

Moderna plans to monitor pregnant women because it isn't clear what effect a vaccine will have on their health or the health of their fetus or newborn. Pregnant women aren't supposed to enroll in clinical testing of most Covid-19 vaccines, and it's possible that an emergency authorization of a vaccine will state that pregnant women shouldn't receive it,

Mr. Martin said. But some pregnant women may mistakenly receive the vaccine, or a woman may become pregnant soon after vaccination.

Existing vaccine-safety surveillance systems, run by various government agencies, will also monitor Covid-19 vaccine safety. The Vaccine Adverse Event Reporting System collects reports of suspected side effects from doctors, patients and companies. Federal scientists analyze the reports to determine whether a vaccine caused the problems.

Other systems will monitor side effects reported by hospitals, outpatient clinics and Veterans Affairs facilities.

Coordinating findings from the data across the various agencies will be a challenge. Edward Belongia, an epidemiologist advising the CDC's Covid-19 safety group, said the group is drawing up a list of potential side effects, and a common definition of each side effect and its symptoms, to guide safety-tracking efforts. He says the group is also trying to define a "risk window" to determine how long patients should be monitored for each side effect.

The FDA will attempt near-real-time surveillance of side effects in about 55 million older adults covered by the federal Medicare agency.

Federal authorities will be looking for neurological conditions, seizures, stroke and anaphylactic reactions, as well as a rare type of complication in which a vaccine actually worsens the severity of the disease it is meant to guard against.

Susan Pulliam and Anna Wilde Mathews contributed to this article.

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Side Effects

Approximate rates of serious adverse reactions to vaccines

VACCINE	REACTION	RATE
Diphtheria, tetanus, pertussis*	Serious allergic reaction	**1 per 1,000,000 doses**
Measles, mumps, rubella	Drop in blood platelets†	**1 per 20,000**
Measles, mumps, rubella and varicella	Seizures caused by fever	**8.5 per 10,000**
Rotavirus	Intestinal damage**	**1 per 20,000 – 100,000**

*DTaP; †Immune thrombocytopenic purpura; **Intussusception

Source: American Family Physician journal, 2017