

Health officials track safety as COVID-19 vaccines roll out

December 16 2020, by Lauran Neergaard



Catalina Gonzalez-Marques, an emergency medical physician, receives the Pfizer-BioNTech coronavirus vaccine at Brigham and Women's Hospital, Wednesday, Dec. 16, 2020, in Boston. (Brian Snyder/Pool via AP)

As COVID-19 vaccinations roll out to more and more people, health

authorities are keeping close watch for any unexpected side effects.

On Tuesday, a health worker in Alaska suffered a severe allergic reaction after receiving the Pfizer COVID-19 vaccine. She is in the hospital for another night under observation while another worker, vaccinated Wednesday, has recovered. Doctors already knew to be on the lookout after Britain reported two similar cases last week.

In the U.S., vaccine recipients are supposed to hang around after the injection in case signs of an allergy appear and they need immediate treatment—exactly what happened when the health worker in Juneau became flushed and short of breath 10 minutes after the shot. The second worker experienced eye puffiness, light headedness and scratchy throat.

Allergies are always a question with a new medical product, but monitoring COVID-19 vaccines for any other, unexpected side effects is a bigger challenge than usual. It's not just because so many people need to be vaccinated over the next year. Never before have so many vaccines made in different ways converged at the same time—and it's possible that one shot option will come with different side effects than another.

The first vaccine beginning widespread use in the U.S. and many Western countries, made by Pfizer Inc. and Germany's BioNTech, and a second option expected soon from competitor Moderna Inc. both are made the same way. The Food and Drug Administration says huge studies of each have uncovered no major safety risks.

But the allergy concern "points out again the importance of real-time safety monitoring," said Dr. Jesse Goodman of Georgetown University, a former FDA vaccine chief.

And authorities have multiple ways of tracking how people fare as these

COVID-19 vaccines, and hopefully additional ones in coming months, get into more arms.

HOW WILL I FEEL AFTER VACCINATION?

Getting either the Pfizer-BioNTech shot or the Moderna version can cause some temporary discomfort, just like many vaccines do.



A droplet falls from a syringe after a health care worker was injected with the Pfizer-BioNTech COVID-19 vaccine at Women & Infants Hospital in Providence, R.I., Tuesday, Dec. 15, 2020. (AP Photo/David Goldman)

In addition to a sore arm, people can experience a fever and some flu-like symptoms—fatigue, aches, chills, headache. They last about a day, sometimes bad enough that recipients miss work, and are more common after the second dose and in younger people.

These reactions are a sign that the immune system is revving up. COVID-19 vaccines tend to cause more of those reactions than a flu shot, about what people experience with shingles vaccinations. But some are similar to early coronavirus symptoms, one reason hospitals are staggering when their employees get vaccinated.

WHAT ABOUT SERIOUS RISKS?

The FDA found no serious side effects in the tens of thousands enrolled in studies of the two vaccines.

Still, problems so rare they don't occur in even very large studies sometimes crop up when a vaccine is used more widely and without the stringent rules of a clinical trial.

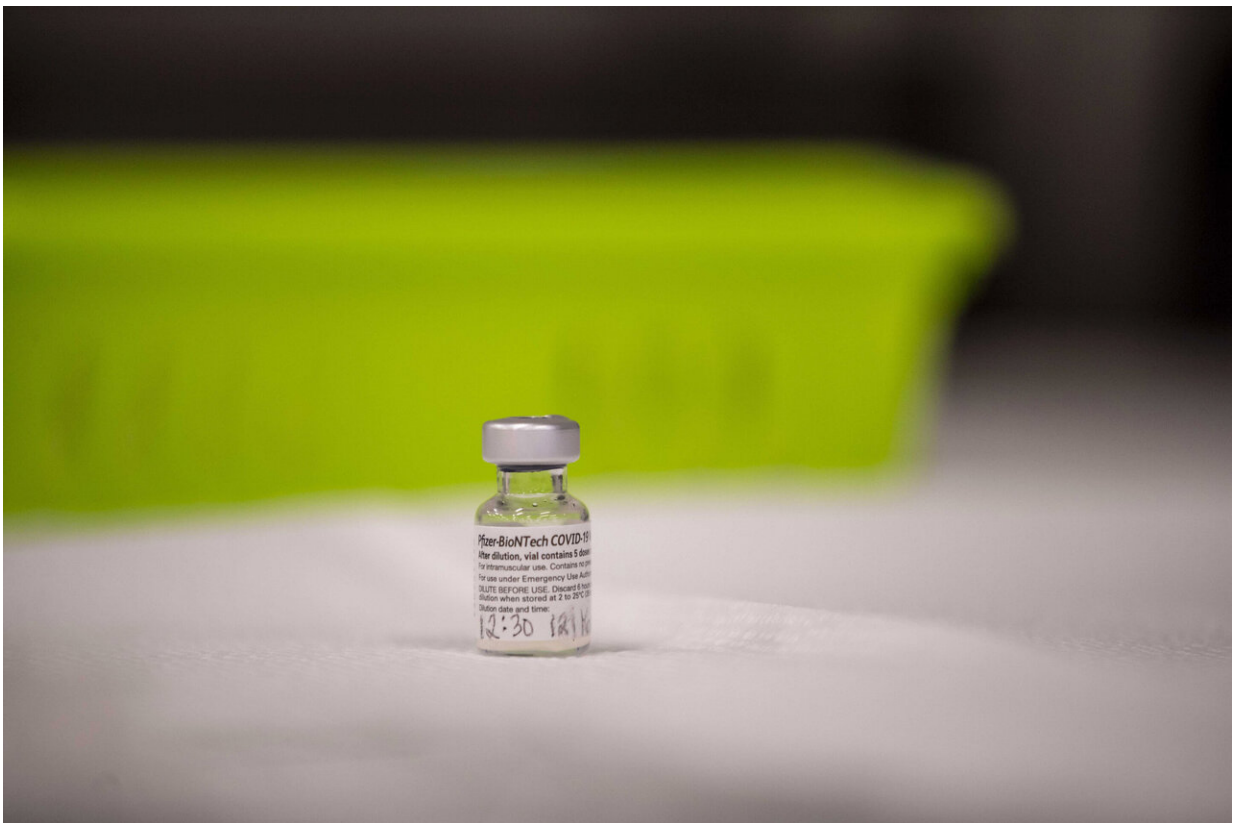
The first allergy reports from England were in people with a history of serious allergies, and British authorities warned those with severe prior experiences to hold off vaccination as they determine what ingredient might be a problem.

U.S. health authorities are giving more nuanced advice. People always are asked about allergies before vaccinations, and instructions for the Pfizer-BioNTech shot say avoid it if you're severely allergic to one of its ingredients or had a severe reaction to a prior dose. Health workers can go over the ingredient list.

The Centers for Disease Control and Prevention advises people to stick around for 15 minutes after vaccination, and those with a history of

other allergies for 30 minutes, so they can be treated immediately if they have a reaction.

The Alaska health worker, who doctors said had no history of allergies, was following that advice and got prompt care for a particularly severe reaction called anaphylaxis. She has recovered after a night of observation in the hospital—but won't be allowed a second vaccine dose.



The COVID-19 Pfizer BioNTech vaccination waits to be administered at the Gwinnett, Rockdale and Newton County Health Department's district office in Lawrenceville, Ga., Wednesday, Dec. 16, 2020. The Gwinnett district received 2,000 Pfizer vaccines for distribution. (Alyssa Pointer/Atlanta Journal-Constitution via AP)

Alaska doctors alerted U.S. authorities, who will continue the monitoring required to tell just how common this kind of reaction really is. That will be especially important as enough vaccine arrives for injections to be given outside of health care settings that have lots of experience handling this type of reaction.

"Balancing any potential risks with the benefits the vaccine provides in the pandemic is an ongoing process," CDC's Dr. Jay Butler cautioned Wednesday.

WHAT IF OTHER RISKS CROP UP?

The challenge is telling whether the vaccine caused a health problem or if it's coincidence. Don't jump to conclusions that there's a connection, health authorities stress.

The way to tell: Comparing any reports of possible side effects with data showing how often that same condition occurs routinely in the population.

The government has multiple ways to do that. Doctors are required to report any patient problems. But the FDA is scrutinizing massive databases of insurance claims for early red flags that any health problems are occurring more often in the newly vaccinated than everyone else.

On its list to check is Bell's palsy, a temporary facial paralysis that occurred in a handful of people in both vaccine studies. The FDA said it's probably coincidence, but will track to be sure.

Vaccine recipients can help with the extra safety tracking. Called "[v-safe](#)," the program run by CDC automatically sends a daily text the first week after each vaccine dose asking how people feel, and then a weekly

text for the next five weeks. Any responses that suggest concern prompt a phone call for further information.

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Citation: Health officials track safety as COVID-19 vaccines roll out (2020, December 16)
retrieved 3 May 2024 from

<https://medicalxpress.com/news/2020-12-health-track-safety-covid-vaccines.html>

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