

Providers report dozens of errors giving Pfizer's COVID vaccine. Experts worry new boosters will fuel more

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At least 87 times in the last few months, a health care provider has given a young child the wrong dose of COVID-19 vaccine.

Luckily, none resulted in a serious medical problem, according to the Centers for Disease Control and Prevention.

But it shows the challenge of delivering a vaccine that comes in multiple doses from different companies, some that require diluting and others that don't. The decision last week to add new COVID-19 boosters for everyone over 12 adds another layer of complexity.

Add to the mix new monkeypox vaccines, which have a [delivery system](#) most providers haven't used before, and the onset of the annual flu shot season—administering vaccines today can be complicated

"There is definitely opportunity for error," said Dr. Kelly Moore, chief executive officer of Immunize.org, which educates [health care professionals](#) about U.S. vaccine recommendations. "These errors aren't necessarily dangerous but they are likely to occur due to people's unfamiliarity with the new products."

According to the CDC's VAERS reporting system, 87 dosage mistakes were made when giving a Pfizer-BioNTech COVID-19 vaccine to a child younger than 5, representing 18% of the reported errors with that vaccine in that age group but only a fraction of the total 890,000 shots administered.

White House COVID-19 coordinator Dr. Ashish Jha said there has been no evidence of "wide-scale mistakes" but assured the Food and Drug Administration is "very aware" of the issue.

"I am confident the systems continue to work effectively, but I know the FDA continues to monitor this very closely," he said during a White House briefing Tuesday.

Both Moderna and Pfizer-BioNTech vaccines have been available since

late June to the youngest children, but one of Pfizer-BioNTech's vaccines requires dilution.

In addition to clear labeling, manufacturers distinguish the COVID-19 vaccines by using different colors for vial caps.

Pfizer-BioNTech's COVID-19 vaccine comes in gray for those over 12, orange for children 5 to 11, and maroon caps for younger children over 6 months. The companies also have an adult dose that requires dilution in a purple cap. Moderna's vaccines come in a red cap, a blue cap with a purple label, and blue cap with a magenta label.

Labels and colored caps can help, but there are now so many different doses and bottles that it's hard to keep straight, said Dr. Grace Lee, a professor of pediatrics at Stanford University School of Medicine and associate chief medical officer of Lucile Packard Children's Hospital.

The labeling issues are "impairing our ability to deliver vaccines," said Lee, who is also a chair of a federal advisory committee that reviewed the vaccines last week. "The growing complexity of the immunization schedule and the multiple products needed for different age groups for different purposes, and with different time intervals between doses is challenging."

This is especially true now that Pfizer is using another gray cap for its new bivalent booster, said Michael Cohen, founder and president emeritus of the Institute for Safe Medication Practices, a nonprofit working to prevent medication errors.

"It is very confusing," he said. Pfizer's bivalent booster "label doesn't look all that different from the gray label that is presently out there."

Another advisory committee member, Dr. Matthew Daley said during

last week's meeting he's heard of families who were hesitant about vaccinations and then learned their children received the higher dose.

"We run the risk of losing confidence in the program more broadly the more that happens," said Daley, a senior clinician investigator at the Institute for Health Research at Kaiser Permanente Colorado.

A best practice is to triple-check patient information and the vaccine label before administering a shot, Moore said. But it's easier to spot a mistake when there are different cap colors. Some electronic health record systems also incorporate cap colors into shorthand when ordering shots.

Now that Pfizer has two shots with gray caps, Moore said some health care providers will have to change those systems.

"We refer to Pfizer's product for adults and adolescents as the 'gray cap,'" she said. "We have to modify our own website to distinguish the monovalent primary series vaccines from the bivalent booster vaccine."

Pfizer's label could also be clearer, Cohen argued. In addition to the product description, Moderna's label has a large gray banner that says in all caps "booster doses only," according to the National Institutes of Health's National Library of Medicine.

Explicit expiration dates also don't appear on any of the COVID-19 vaccine labels, Cohen said. Instead, [health care providers](#) must look up the expiration date through a lot number or QR code depending on the company.

"We have had people contact us that they gave a vaccine that was expired because they didn't see the expiration date," he said.

Cohen suggested pharmacies look up and print out their own expiration date to add to the label when preparing vaccines.

It's not uncommon for clinics to implement their own strategies to avoid further confusion and error, Lee said, as many clinics are administering certain vaccines on certain days.

It "means access can be limited by day and by site, and particularly if the volume of patients is small," she said. "In an ideal world, our job is to ensure we do not miss opportunities to vaccinate, but these complexities make it challenging to manage."

Daley, of Kaiser Permanente Colorado, said simplification is essential and encouraged vaccine manufacturers to work with the FDA. CDC director Dr. Rochelle Walensky said federal agencies are looking into strategies without reducing product volume.

"This is a concern that has been raised," Walensky said during Tuesday's White House briefing. "We are doing an extraordinary amount of education for those administering the vaccine for exactly that reason."

The FDA has not yet responded to requests for comment on the incidence of errors or efforts being done to prevent them.

In the meantime, health experts encourage providers to take extra time to ensure the right vaccine is going in the right patient's arm.

Patients can also reduce the risk of errors by being more involved in their care. Health experts say patients can ask to see the label before the pharmacist or nurse administers the [vaccine](#). They can also help free up appointment times by getting their COVID-19 booster and flu shot in one visit, Moore said.

As a whole new generation of COVID-19 vaccines are unboxed this week, she said patience will be key during times of confusion.

"There's feelings of frustration among everyone," Moore said. "Having some grace on both sides is going to be essential for everyone in the health care world."

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