What physicians need to know about Pfizer vaccine use and allocation

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Featured topic and speakers

In today’s COVID-19 update, in the first of a two-part series, AMA discusses the recent Pfizer vaccine authorization, ACIP’s recommendations and what physicians and patients need to know about use, allocation and vaccine confidence.

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Speakers

- Sandra Fryhofer, MD, internal medicine physician, adjunct associate professor of medicine at Emory University School of Medicine, AMA Board of Trustees, AMA liaison to ACIP
- Shannon Curtis, assistant director, federal affairs, AMA
- Marcus Plescia, MD, chief medical officer, Association of State and Territorial Health Officials (ASTHO), ASTHO Liaison to ACIP

Transcript

Unger: Hello, this is the American Medical Association’s COVID-19 Update. Today we have the first episode of a special two-part series discussing the recent Pfizer vaccine authorization and what physicians and patients need to know. I’m joined today by Dr. Sandra Fryhofer, an internal medicine physician, adjunct associate professor of medicine at Emory University School of Medicine, and an

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AMA Trustee in Atlanta. Dr. Fryhofer is the AMA liaison to the CDC's Advisory Committee on Immunization Practices or ACIP, and serves as the AMS representative on the COVID-19 Vaccine Work Group. Dr. Marcus Plescia, chief medical officer, the Association of State and Territorial Health Officials, or ASTHO in Atlanta. Dr. Plescia is ASTHO's liaison to ACIP. And Shannon Curtis, the AMS assistant director, Federal Affairs in Alexandria, Virginia. I'm Todd Unger, AMA chief experience officer in Chicago.

There's been a lot of anticipation and excitement about the first authorization of a COVID-19 vaccine. Dr. Fryhofer, can you tell us what ACIP's top line recommendations were, and talk briefly about the evidence that supported that recommendation?

Dr. Fryhofer: Sure, Todd. On December 11, 2020, Pfizer-BioNTech's mRNA vaccine became the first COVID vaccine to receive FDA's Emergency Use Authorization. It also became the first ever mRNA vaccine approved by FDA. Now the following day, ACIP had an emergency meeting and voted to recommend it for those age 16 and older. And I will tell you, the study results are impressive. Pfizer's vaccine is 95% effective at preventing COVID. You need two doses 21 days apart to get that 95% protection and getting both doses is very important. It does take about one to two weeks to build up protective antibodies.

There's another company, Moderna that also has an mRNA vaccine that seems to be equally effective. Now, Phase 3 trials of both of these mRNA vaccines have been huge, nearly 44,000 participants in the Pfizer vaccine study, 30,000 in the Moderna vaccine study, and these trials included patients with diverse backgrounds, considering race, ethnicity, age, both young and old, as well as those with underlying medical conditions. Things like obesity, diabetes, lung disease.

The companies put their protocols and their diversity breakdown on their website. FDA has been very transparent in its requirements. Now, these mRNA vaccines they're new, but they're not unknown. Researchers have been working with them and studying them for years. mRNA vaccines do not contain live virus so they cannot cause an infection. They cannot give someone COVID. mRNA vaccines do not affect or interact with our own DNA in any way. The messenger RNA never enters the nucleus of the cell and it doesn't hang around. The body breaks it down with hours. And I will tell you, I've been very impressed, Todd, with the transparency of the process, as well as the science and the evidence behind these two mRNA vaccines.

Unger: Well, that's an incredible description of that process. Ms. Curtis, I'd like you to dig in a little bit deeper about the whole process that led up to this point. Can you take us through some of the initial highlights?

Curtis: Sure. As you probably know, before anything can go to ACIP and CDC for their review and their approval, it has to go through the FDA process. FDA really is the ultimate arbiter of safety and efficacy of medical products in the U.S. and really is the gold standard regulator globally for the entire
world. You probably have heard a little bit about the process so far, and that the fact that these vaccines are going through what they call the Emergency Use Authorization process. It's a little bit different than what we typically see from a medical product at FDA. It's somewhat of an expedited process, but I think it's very important that everybody knows that it's not necessarily cutting corners or short-cutting FDA's review or any look at the safety and efficacy. And it doesn't really require any less by way of showings of safety and efficacy on the part of the applicant. In this case, initially Pfizer, and down the road, I'm looking at Moderna and potentially other vaccine candidates from other manufacturers as well.

Really, we just cut out a little bit of the bureaucracy, some of the paperwork, and the time that it takes to do that instead of cutting any corners on the safety and efficacy or short cutting the process. Really important to know that FDA has made a really tremendous effort at being transparent to this process, making their standards and what they were looking for transparent as early as they could. And another really key element of that transparency through the FDA process was that we actually had another advisory committee besides ACIP at CDC, looking at this data and making recommendations as well. That's FDA's Vaccines and Related Biological Products Advisory Committee. Several members looked at this data, overwhelmingly voted that the data was good, that we should recommend this vaccine go forward, and that the benefits of this vaccine outweighed any potential risks, which as Dr. Fryhofer mentioned, there weren't actually that many. We didn't see a lot of significant, serious adverse events associated with the Pfizer vaccine in this very large trial.

So, a big process over at FDA and for the Pfizer vaccine. Moderna is up this week. They're actually going to be meeting on Thursday, the advisory committee to review the safety and efficacy data associated with Moderna and a couple more in the pipeline over the coming months as well. So big process. We also expect those vaccines to come back and apply for Biologics License Application, which will be that regular approval that we're used to seeing for vaccines. They'll probably do that in the next few months.

**Unger:** Great. Transparent seems to be the keyword in what we've heard so far. Dr. Plescia, can you tell us a little bit more about what ACIP is and the role that it plays following the FDA's EUA? There were a lot of parties involved and it might be confusing to people.

**Dr. Plescia:** Yeah. So, a couple of things about the ACIP or the Advisory Council on Immunization Practices. First of all, it's an advisory council and it's made up, although it's staffed by the Centers for Disease Control, it's made up of voting members who have nothing to do with the government. Most of them are from clinical practice or academic institutions. So, they have a significant amount of independence and their decisions and their recommendations are not influenced by the government or anybody else. And I think that's really reassuring.

The ACIP has an excellent reputation. I would say that they're even revered, particularly by those of us who practice clinically. If you're a clinician and particularly if you're involved with pediatric vaccination,
I'm pretty certain you know about the ACIP. That's where we go to sort out what the immunization schedules are. And particularly when you're seeing a child who's behind on their immunizations, that's where you tend to go to again. So it's something that clinicians are very, very familiar with. Now, Dr. Fryhofer and I both serve as liaisons on the ACIP. We're liaisons on the committee, we're also liaisons on the work group, which is meeting far more frequently than the committee and advising the committee on sort of next steps of what to do.

Oftentimes I find when you're a liaison on one of these advisory committees, it's kind of an invitation to listen, not so with the ACIP. The liaisons in the ACIP are very, very outspoken, and there's a reason for that. The ACIP serves as an advisory council to the CDC director. So they give the CDC director advice on how to move forward. But probably more importantly, the ACIP informs all of these professional groups that are around the table and we go back out and put those recommendations forward to our own groups. And I think particularly when you have a group like the American Medical Association, it's that piece of the liaison that really, really makes a huge difference. And for good reason, what's very important here is that physicians and clinicians are confident about this vaccine and I think that the long-standing reputation of the ACIP is really going to help a great deal with that.

**Unger:** Dr. Fryhofer you mentioned upfront the approval for 16 and older, there's been a lot of talk about prioritization in this. Let's first start by talking about who should be getting the vaccine. Are there any guidelines otherwise?

**Dr. Fryhofer:** Well, one thing if you've already had COVID, you should definitely get the vaccine. We know that it's safe and likely efficacious, but for timing, you do have a little wiggle room. The current evidence suggests that reinfection is uncommon in the first 90 days after that initial infection. However, if you've had COVID and received one of these new therapies like monoclonal antibodies or convalescent serum, you definitely need to wait at least 90 days, so that way the treatment won't interfere with the vaccine's immune response. Now, remember I said that the study included patients with chronic medical conditions. And so, people with chronic medical conditions like obesity, diabetes, lung disease should definitely get it because they were part of this study. Immunocompromised patients may receive it, but understand it may not work as well because your immune system doesn't work as well.

Now, pregnant and lactating women may receive it if they choose. And this is very important. They need to discuss the issues with their physician because we really don't have any safety data regarding pregnant and lactating women. I will tell you ACOG and AAP at the ACIP meeting were very supportive of lactating women getting vaccinated, but the woman needs to decide with her physician what's best for her and her baby. And this is so important because about 75% of all health care personnel are female, and health care personnel are in Phase 1a of vaccine allocation. And what that means is that at least 330,000 women could be pregnant or recently postpartum at the time of vaccine implementation, which is starting now. In the Pfizer vaccine study, 23 women have already become
pregnant. You have this study, it has women, some are going to get pregnant and I assure you, these patients will be closely followed.

There are some patients who should not get vaccinated. The vaccine is contraindicated if you have a history of an allergic reaction to one of the components of this vaccine. The vaccine was given in the United Kingdom last week, and you might recall that there were two patients that had a severe allergic reaction. This did not show up in the trial, but it's showing up now as we're vaccinating millions. And so, because of that precaution in the light of transparency and being very careful, ACIP says that having a severe reaction to any vaccine or any injectable therapy is a precaution for vaccination at this time. Now, it's not a contraindication just a precaution. You would discuss the pros and cons with your doctor, and you would need to be observed a little longer after vaccination for about 30 minutes rather than the standard 15 minutes.

One more thing. And this is really important because it's flu season and I hope everyone's gotten their flu vaccination. The COVID vaccine should not be given in combination with other vaccines right now. The study protocol for these vaccines did not allow co-administration with other vaccines, so don't do it. We want this vaccine to do its best job. And what CDC is saying is you need to allow at least a two-week window from other vaccines, Todd.

Unger: Well, thanks so much Dr. Fryhofer and Dr. Plescia and Ms. Curtis for being here today. There's so much important information about vaccines. If you want more information, please check out our vaccine resource center on the AMA site. We'll be back tomorrow for part two of this series. In the meantime, for updated resources on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us, please take care.

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