Sandra Fryhofer, MD, discusses boosters and the latest vaccine safety data

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In today’s COVID-19 Update, a discussion with Sandra Fryhofer, MD, AMA’s liaison to the Advisory Committee on Immunization Practices (ACIP), a member of the ACIP COVID-19 Vaccine Workgroup and chair-elect of the AMA Board of Trustees, shares details from the latest ACIP meeting, including more details on the Pfizer approval, the latest vaccine safety data and the timeline for booster shots.

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Speaker

Sandra Fryhofer, MD, chair-elect, AMA Board of Trustees; AMA’s liaison to the Advisory Committee on Immunization Practices

Transcript

Unger: Hello, this is the American Medical Association’s COVID-19 Update. Today we’re discussing the latest news from ACIP, the Advisory Committee on Immunization Practices, with Dr. Sandra Fryhofer, AMA’s liaison to ACIP and a member of ACIP’s COVID-19 Vaccine Workgroup. Dr. Fryhofer is also the chair-elect of the AMA Board of Trustees. I’m Todd Unger, AMA’s chief experience officer in Chicago. Dr. Fryhofer, thanks for joining us again to give us the latest update from ACIP meetings, August 30. Can you tell us what the focus of that meeting and key topics were?

Dr. Fryhofer: Well, this emergency meeting was dedicated to Pfizer’s FDA approval. There was also an update on where we are with boosters. On Monday, August 23, Pfizer-BioNTech’s mRNA vaccine aka BNT162b2, became the first COVID vaccine ever to receive full FDA approval. A two-dose series
is now fully approved for those 16 and older. EUA, Emergency Use Authorization, still applies to those 12 through 15 and for an additional dose for immunocompromised patients who received a two-dose mRNA vaccine series. Data submitted to FDA had a cutoff date of March 13, so much of this data was pre-Delta. Pfizer vaccine with overall 91% effective in preventing COVID. ACIP’s comprehensive evidence-based review looked at both published and pre-print studies through August 20 and many of the observational studies took place in July and August when Delta began to dominate.

This has truly been a remarkable achievement. It took only nine months to bring Pfizer’s vaccine to market. It took FDA only 97 days to review Pfizer’s BLA once all the required data was submitted. ACIP called an emergency meeting just one week after FDA approval and voted unanimously to recommend Pfizer vaccine for those 16 and older under FDA’s BLA, Biologics License Application approval. Full FDA approval and now ACIP’s thumbs up should instill additional confidence to the vaccine hesitant. This vaccine is safe and effective so go ahead and get vaccinated.

**Unger:** Well, in the discussion and the data that was presented is part of this, was there any news about side effects or adverse events that you would want to share?

**Dr. Fryhofer:** Well, fortunately, there were no new surprises. We all know the expected side effects, pain at the injection site, fatigue, headache, muscle and joint pain, fevers and chills. FDA also took a rigorous look at the risk of myocarditis and pericarditis after Pfizer’s vaccine. There is an increased risk of myocarditis, particularly within seven days after the second dose. Prescribing information includes a specific warning about these risks. The risk is higher in males under 40 and highest in young males age 12 to 17. Some of these patients required hospitalization. Some required ICU admission. Follow-up so far seems to show resolution of symptoms. ACIP presented CDC’s safety update from theirs, CDC’s vaccine event reporting system, and from VSD, CDC’s Vaccine Safety Data link. VSD is a collaborative project between CDC and nine integrated health care organizations scattered throughout the country.

The two systems look at safety data in different ways. Both confirmed the increased risk of myocarditis after mRNA COVID vaccines but understand, myocarditis can also occur with SARS-CoV-2 infection and it occurs at higher rates after COVID infection than after mRNA vaccination. Patients with COVID had 16 to 18 times higher risk for myocarditis compared to those without COVID. Risk did vary by age and sex. Risk of myocarditis due to COVID infection was six times higher for 16- to 17-year-olds compared to those receiving the vaccine. Another study looked at data from more than 800 hospitals. Review of EHR data from 42 health care systems showed anywhere from six to 34 times higher risk for myocarditis after COVID infection as compared to risk after COVID vaccination.

And if you look at hospitalization outcomes, main length of stay for young adults hospitalized with COVID is five days. 5% to 6% required mechanical ventilation and young people have died from COVID infection. For young adults hospitalized with post-vaccination myocarditis, the main length of stay is only one to two days and none have died. Bottom line, risk of myocarditis is higher with COVID
infection than after COVID vaccination.

**Unger:** That's a pretty important piece of data. In terms of other safety concerns, anything else discussed of note?

**Dr. Fryhofer:** Anaphylaxis and we've talked about that early on. A VSD safety update showed risk of anaphylaxis after mRNA vaccine is about five per million doses. And to put this in perspective, risk of anaphylaxis after flu vaccination is one to two per million doses administered. Anaphylaxis is a clinically serious adverse event. That's why everyone has to be observed for at least 15 to 30 minutes after COVID vaccination.

**Unger:** We spoke in our last segment about boosters. I'm sure you and many of your fellow physicians are being bombarded with questions about that. Do you have any new information about boosters and any perspective on the announcement that made headlines that everyone would need a booster after September 20?

**Dr. Fryhofer:** Well, there has been a little bit of confusion and on August 18, HHS along with public health and medical experts released a joint statement about COVID boosters. The announcement said HHS, CDC and FDA continue to study data to understand how long vaccine protection lasts. Three studies published in MMWR that same day, August 18, suggests we're beginning to see a decrease in vaccine effectiveness against infection. The statement also announced a plan to begin offering booster shots in the fall. But read the fine print. The decision on when to boost is subject to FDA conducting an independent review of the safety and effectiveness of a third dose and on ACIP issuing booster dose recommendations based on a thorough review of the evidence. ACIP's evidence review is still in progress but their framework for boosters was discussed at ACIP along with some study trends.

**Unger:** You mentioned before about the data reflecting pre-Delta. Did ACIP review any study specifically looking at vaccine effectiveness now that Delta is so widespread?

**Dr. Fryhofer:** Well VE, which is vaccine effectiveness, has seemed to decrease over the last one to two months. Vaccine effectiveness pre-Delta was high, about 87%. Studies done as Delta became dominant show VE against infection has ranged from 39% to 84%. There is some reassuring news. Even with Delta, all vaccines remain effective in preventing hospitalization and severe disease but they might be less effective in preventing infection or milder symptomatic illness. Hospitalization rates in unvaccinated adults are 16 times higher than in those who’ve been vaccinated. Studies in long-term care facilities show VE against infection has fallen from 75% pre-Delta to just over 50% once Delta hit the scene. Vaccine efficacy against infection among frontline workers has also declined somewhat over time and also since the pre-Delta period.

All three vaccine manufacturers, Pfizer-BioNTech, Moderna and Janssen, are conducting studies to evaluate safety and immunogenicity of COVID-19 vaccine booster doses, and at this time, ACIP is
considering a risk-based approach for booster dose recommendation. Time since vaccination with the primary series is also important. The priority for a booster dose policy is prevention of severe disease and at-risk populations but the top priority is still to vaccinate those not yet vaccinated.

Unger: So given that information, where do we stand with this September 20 date for boosters?

Dr. Fryhofer: Well, stay tuned. The announcement said the administration is prepared to offer booster shots for all Americans beginning the week of September 20 and starting eight months after an individual's second dose. Prepared is the keyword. And remember, the federal government owns all the vaccine doses available in the United States. At the ACIP meeting, a CDC representative reminded that COVID vaccines are distributed by the federal government through provider agreements under CICP, the Countermeasures Injury Protection Program. They should not be administered off-label. Doing so would be a violation of the CDC provider agreement. In summary, boosters are not yet authorized. Additional doses for immunocompromised patients who received a two-dose mRNA vaccine series are authorized under EUA. So are doses for kids aged 12 to 16. COVID vaccine doses for children under 12 are not yet authorized.

Unger: And we'll talk a little bit more about that. Is there any additional information about vaccine doses for those that received the Janssen viral vector vaccine?

Dr. Fryhofer: Well, to review, for immunocompromised patients, an additional dose is now recommended at least one month after a primary two-dose mRNA vaccine series. This does not apply to those who receive Janssen's "one dose and you're done" viral vector vaccine, which leaves those receiving Janssen vaccine in the dark as to what to do. New data about Janssen's durability just published in the New England Journal of Medicine demonstrates strong immune response eight months after vaccination. Pre-print release of the company's study of an additional Janssen dose boosting immune response is also encouraging but not yet peer-reviewed. Janssen vaccine has been linked to TTS, thrombosis with thrombocytosis syndrome, a rare but potentially deadly adverse effect. So safety of a second Janssen dose must also be verified. Now, how these new studies will affect recommendations for immunocompromised adults who received Janssen's vaccine is still not clear. That said, since Janssen vaccine was authorized much later, the number of immunocompromised patients who may have received it is probably small. I look forward to an ACIP review of these studies and their possible impact on future recommendations.

Unger: Dr. Fryhofer, I want to go back to something you mentioned because I think it's worth talking more about which is about that five to 11 age group. We're, of course, heading back to school. It's on a lot of people's minds right now. Now that the Pfizer vaccine is fully licensed, can doctors go off-label and give it to younger children in the five to 11 age group? And if not, why? What's the data?

Dr. Fryhofer: Well, I know it's tempting but no, you should not. Remember, the federal government doesn't want you to do that and AAP, the American Academy of Pediatrics says, "Please, don't." AAP says, "Don't go off-label and give it to younger children, those under 12." The dose for 12- to 16-year-old
olds is the same as the dose for adults. Younger children, those under 12, will likely need a kiddie dose. So hold off on vaccinating children under 12 for now. Those safety studies are still in progress. The company has not yet submitted their data for FDA review. Those study results should be available soon. News reports say Pfizer expects to apply for EUA for five to 11-year-olds by the end of September and data for children two to five should be available shortly after. The bottom line, don't give vaccine off-label to younger kids, those under 12. The dose may be different for younger children but all age eligible adolescents should be vaccinated now. As of August 19, there were 180,000 new COVID cases in children and adolescents.

Unger: So that is strong advice and does not change but given the full FDA approval, what are the things that will change now that the Pfizer vaccine has that?

Dr. Fryhofer: Well, since all doses distributed in the U.S. are still owned by the federal government, you can't buy them from a company like would do other vaccines. They're still free, or rather they've already been paid for with our tax dollars. Vaccine hesitant patients concerned about safety because the vaccine wasn't fully approved, don't have that excuse anymore, so it's time for them to roll up their sleeves and get vaccinated. Some are. Hopefully more will and will continue to do so. A new CDC report looking at data out of L.A. County strengthens why they should get vaccinated now. The study says vaccinated people are 29 times less likely to be hospitalized and five times less likely to be infected.

We can also expect to see more companies making vaccination mandatory and we are. United Airlines now requires vaccinations for all its employees. Delta Airlines stopped short of a vaccine mandate but the airline is now making unvaccinated employees pay a $200 per month health insurance surcharge. And now that the vaccines fully licensed, the company can start to advertise it. But don't look for the name BNT162b2. Pfizer's vaccine now has two new names. The generic name is Tozinameran. The brand name is Comirnaty.

Unger: I'm not sure which of those is the catchiest. But on that topic, how do they come up with those names?

Dr. Fryhofer: Well, the generic name is crafted according to strict nomenclature as per USAN, the United States Adopted Names Council. The drug company gets to decide on the first part, Tozina-. The last part, -meran, applies to all mRNA vaccines. The Co- and the brand name, Comirnaty, is for COVID. Mirna is for mRNA. The brand name Comirnaty sounds like a cross between community and immunity, and that's no coincidence. FDA doesn't allow brand names until drugs are fully approved. Moderna's mRNA vaccine and Janssen's viral vector vaccines are still under EUA for those 18 and older. Their European Commission, however, does when it issues a conditional marketing authorization. Moderna's proposed brand name is Spykevax, which to me sounds hip and edgy.
Unger: It does. It seems like this FDA approval came just in time for the surge that we’re seeing in COVID cases. Any final thoughts on that?

Dr. Fryhofer: Well, if you look at the daily trends, the COVID case counts are up. They’ve been increasing since July. Hospitalizations are increasing. So are COVID deaths. The COVID surge is putting strain on health care resources. Many states are facing ICU bed shortages. ICU beds are filling up. At least 16 states are over 80% of ICU capacity. The Delta variant’s dominant, it’s taking over and it’s more than twice as contagious as the Alpha variant. A June Kaiser Family Foundation survey found that 31% of the unvaccinated said they would be more likely to get vaccinated after full FDA approval. For Pfizer vaccine for those 16 and older, that’s happened. This should instill additional confidence to the vaccine hesitant. This vaccine is safe and effective so go ahead and get vaccinated. Over 173 million people already have. But as of August 28, 2021, 38% of people 16 and older have not been fully vaccinated. We have much work to do.

Unger: Well, thank you so much, Dr. Fryhofer, and thank you to all the physicians and health care teams out there, that are those important folks helping with this surge right now. That wraps up our COVID-19 Update for today. Thanks again for being with us. For more information on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us. Please take care.

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