

Logistical pluses of Janssen vaccine & a look at vaccine for kids

Watch the AMA's daily COVID-19 update, with insights from AMA leaders and experts about the pandemic.

Featured topic and speakers

In today's COVID-19 Update, with the addition of the Johnson & Johnson (Janssen) vaccine, health experts emphasize the availability of three safe and highly effective vaccines for the COVID-19 virus. The Janssen vaccine is in addition to the Moderna and Pfizer vaccines. Experts also discuss pediatric trials on the vaccines, and how soon we can expect an authorized vaccine for kids.

Learn more at the AMA COVID-19 resource center.

Speakers

- L.J Tan, PhD, MS, chief strategy officer, Immunization Action Coalition
- James Campbell, MD, MS, infectious diseases specialist, University of Maryland Medical Center
- Sandra Fryhofer, MD, physician, AMA Trustee and AMA Liaison to ACIP

Transcript

Unger: Hello, this is the American Medical Association's COVID-19 Update. Today, we're getting a COVID-19 vaccine update, including information on the newly authorized Johnson & Johnson vaccine and where we stand on pediatric trials. 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 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 AMA's representative on the COVID-19 vaccine work group. Dr. L.J Tan, chief strategy officer of the Immunization Action Coalition in Chicago, he also

co-founded and co-chairs the National Adult and Influenza Immunization Summit. And Dr. Jim Campbell, professor of pediatrics and an infectious disease specialist with the University of Maryland Medical Center in Baltimore, Maryland. I'm Todd Unger, AMA's chief experience officer in Chicago.

Well Dr. Fryhofer, good news with the authorization of a third vaccine last week. Can you walk us through the key differences between this new vaccine and the Pfizer and Moderna options?

Dr. Fryhofer: Well Todd, this is very exciting news. On February 27th, FDA authorized emergency use of Janssen's single-dose viral vector COVID vaccine for those age 18 and older. Now, Janssen is a pharmaceutical arm of Johnson & Johnson. Janssen's vaccine is overall more than 66% effective at preventing symptomatic COVID as early as 14 days after a single dose. This vaccine also has several logistical advantages, one dose, that's all that's needed, that's a complete series. It's one dose and you're done, which means you don't have to worry about scheduling a second dose at just the right time. This makes this new vaccine a very attractive option for people who don't want to or can't return for a second dose. This might include people that are home bound as well as people who move around a lot. One dose also means only one set of vaccine side effects, injection site pain, headache, fatigue and muscle pain lasting about one to two days.

Now, like the mRNA vaccines, vaccine side effects are more severe in younger versus older individuals. Another advantage, no super freezers are needed. The Janssen vaccine can be stored in regular refrigerators at regular temperatures at 2-8 degrees C for up to three months. So this alone could help expand vaccination site opportunities to smaller physician practices. Another convenient, plus it comes in five-dose vials and no dilutions is needed before administration. Now again, since Phase 3 trial is huge and included more than 40,000 people and was conducted at the height of the pandemic and at some places where coronavirus variants of concern had already emerged, and beware, variants are here in the U.S.

Pfizer and Moderna are mRNA vaccines. This vaccine uses a completely different technology platform. It's a Viral Vector Vaccine, and with Viral Vector Vaccines, you take a weakened version of the virus which is the viral vector then genetically engineer it to make coronavirus proteins in the body which then trigger the immune response. Janssen's vaccine uses a modified adenovirus. Ad26 is a viral vector, several genes have been removed from it so it can't replicate and it can't incorporate into human DNA. The virus is basically dead, it can't give someone COVID. So bottom line, we now have three safe and highly effective COVID-19 vaccines. Since it requires only one dose, Janssen's vaccine should allow us to more quickly increase the number of people fully vaccinated.

Unger: That is great news and so many logistical advantages that we're hearing about. Do you have any sense of where this vaccine is better suited to different groups than others?

Dr. Fryhofer: Well, I think it's going to be a great option for small physician offices and it's more mobile so you could take it and give it to people perhaps that are homeless and it has a lot more

options because of these logistical advantages.

Unger: That's terrific. Well, thank you. Dr. Tan, I'm sure physicians are getting a lot of questions from patients about vaccines and efficacy. Can you begin by discussing just, what does vaccine efficacy mean and how do we help patients to understand what that is?

Dr. Tan: Yes, thank you, Todd. I really appreciate the opportunity here to be on this with such distinguished colleagues. To jump in a little bit on Dr. Fryhofer's point a little bit here, at the end of it all, is just to remind the clinicians out there and physicians out there that once the vial is opened, those five doses in those vials have to be administered within six hours because they don't store, you can't put them back into storage. Just something to keep in mind with the storage and handling there, we don't want to lose vaccine because of that too, so just to keep that in mind.

In terms of vaccine efficacy, I think it's important to think about, it's really impossible to compare vaccines, so we shouldn't be comparing vaccines, obviously, unless you do an actual head-to-head against these three different vaccines, we do not want to be comparing them. I think I want to state the most important thing here is that we have, as Dr. Fryhofer said, we have three very effective vaccines, we want to make sure everybody gets vaccinated and they should be getting the vaccine that's offered to them, they shouldn't be trying to pick and choose different vaccines.

Unger: Dr. Tan, I want to just ask you more about that because it's almost hard when you hear a 66% versus 95%, why should we not be looking at those numbers like that?

Dr. Tan: Let me drill deeper into what I just said about not comparing because these things were never compared head-to-head, right, which is the only fair way to do this, right? And so what happens obviously, as Dr. Fryhofer mentioned, is that this vaccine started its clinical trials at the height of the pandemic when a lot of these variants were actually popping up already. Remember the Pfizer and Moderna mRNA vaccines, their clinical trials were when the "original strain" was circulating and the variants had not started up yet. So, it's comparing apples and oranges, right? The Johnson & Johnson vaccine, the Janssen vaccine, obviously, here has had to deal with the variants, and in fact, in one country, South Africa, where the clinical trials were conducted, 90 plus percent of their sample were actually infected with the variant strain, so totally different situations. Therefore, the comparison is not at all appropriate or accurate. All three vaccines are effective, they protect against COVID-19 disease, we need to be getting them out.

Unger: All right, that clears that up. Dr. Campbell does this messaging change when you're talking about children? I know we don't have yet an authorized vaccine for this audience, but there are likely to be hesitant parents who are willing to risk COVID over vaccinating at all. Should we be getting the message out now?

Dr. Campbell: Yes, thanks, Todd. I think it's premature for us to try to message about safety and efficacy of the vaccines in children under the age of 16 when we don't yet have the trial data. My opinion is we are behind in starting those trials, they should have already begun but they are about to start for the younger children so I think we're going to get closer. I think once we do have those data, the message will not be that difficult, I don't think. I mean, we've have 3.1 million children have been confirmed infected in the U.S., over 10,000 have been hospitalized and currently, there've been, since January, more COVID-related deaths than influenza-related deaths in children ever recorded in any year.

We're very close to COVID being in the top 10 causes of all deaths, any cause of death for children. Even though when you compare it to adult morbidity and mortality of COVID, it doesn't seem so bad, but when you compare it to any other infection in children or other causes of death or bad disease in children, it's up there. So once we show that it's safe and effective, I think the messaging, we will be able to have a strong message.

Unger: That's a pretty important point, not to look just at the percentages but those absolute numbers are, they're very concerning and there are some additional issues that we're seeing pop-up among children and adolescents. Can you talk a little bit more about that?

Dr. Campbell: I think one, you might be talking about is this thing called MIS-C and now there's a bit of MIS-A, C being children and A being adults. Young adults and all children really, after having been infected and often the infection not being that severe, in about a month or six weeks later, have this exaggerated inflammatory response that can cause them to be very ill. The hope is that like with other vaccines, if we can prevent the infection itself, we can then also prevent its sequelae, the bad things that occur afterwards, similar to what happens with polio or what happens with encephalitis after measles and those sorts of things. That is one of the reasons why some children are dying and are so sick is this MIS-C and hopefully the vaccine will be a part of the prevention, not just for the infection, but also for the sequelae.

Dr. Tan: If I could just quickly jump in here as well, Dr. Campbell, and suggest also this, that mortality aside, I think, obviously as we've known with influenza, children and teens are going to be important vehicles for transmission as we could try to get back to life. And I think ultimately, when the data shows that it is indeed safe and effective to vaccinate children and teens, that's going to be part of stopping the transmission as well.

Dr. Campbell: Completely agree. As a pediatrician, as a parent, I've said it over and over again, the burden of this pandemic on children in the United States is not only the infection, but all of the other ways that it has affected them, and that is not being physically in school, not seeing your grandparents, not playing with their friends, not in sports and band and all the other things they could do before. If vaccine can get us out of that, then I think that's why we need to have the data on safe and effective vaccines in children.

Dr. Tan: You just sent chills up my spine, thank you.

Dr. Fryhofer: Todd, I have sort of a different take on that. Now, it's interesting hearing Dr. Campbell talk, he's a pediatrician and I'm a general internist so I'm already talking to the parents, and I do think it's important to start talking to parents now and get them up to speed on the science and the safety. I mean, as Dr. Campbell said, we don't have the results of the studies in kids back yet, but we do have the studies in adults back and I think patients need to understand that. But parents do make the decision about vaccination for their child and they want to make sure that these vaccines are safe for their children and siblings. So we don't have data yet, we can't really tell them that and have numbers to show it. But I also think it's very important to start pointing patients now to good, reliable sources of information like the CDC website so when they do have questions, they know where to look, they just won't go to the internet or to Facebook and just see what other people have to say that may not really know what they're talking about.

When I'm talking to patients about vaccination, I really think that AIMS Method is really helpful, announce, inquire, mirror, secure. To me, it's a very helpful way to organize healthy conversations about vaccination and in a way that instills the vaccine confidence. The A is for announce that your patient is due for a vaccine. Now, since we're not yet ready to vaccinate kids, you could maybe ask if they plan to get their child vaccinated and see what they say. If you get pushed back, I for inquire, you need to understand their concern, listen, don't interrupt, let them finish. Next, M for mirror, make sure they know you've listened and do you understand by respectfully repeating what they said.

And then you respond to their concerns in a non-judgemental way that S, secure is trust. You try not to trigger new concerns in the process. For example, try not to repeat a myth just to debunk it. I found this to be a very successful method and it keeps the door open for more discussion and also encourages future opportunities to vaccinate. We do need for parents to keep their hearts open to this vaccine because once we find one that is safe and effective for kids, we would really love to end this pandemic.

Unger: Absolutely. Well, Dr. Campbell, let's talk a little bit more about pediatric trials. When do you think we'll have an authorized vaccine, at least for older children, will that be by the fall?

Dr. Campbell: Todd, right now, as you probably know, one of the vaccines that's authorized for adults, adults in that instance goes down to age 16, the Pfizer study that was presented and authorized is down to age 16, now, Pfizer and Moderna, the two mRNA vaccines, have completed their 12 to 17-year-old trials. So the data are accumulating on them and our expectation is that those data will be presented in the near future to the Food and Drug Administration in order to be able to go all the way down to age 12.

What the near future is and when exactly they will provide that data, I can't say for sure, but I'm hopeful that by the summertime, they will be able to provide those data so we could have those

vaccines down to middle school age kids relatively soon. For the other vaccines in the pipeline and for the younger children, they're kind of coming behind. They're about to start now for six to 11-year-olds and then down in the two to five and then under two. Each of those studies is on the launching pad right now and is going through regulatory review and we expect that they're going to start, you're going to hear news very soon that there'll be starting.

Unger: Excellent. Well, Dr. Fryhofer, when we spoke the last time which was several months ago, we talked about the data gaps. Is there additional data you'd still like to see and how are we keeping physicians informed about any new safety data and recommendations that emerge as more people get the vaccine?

Dr. Fryhofer: Well, I'm really looking forward to seeing those studies in kids and it will be several months before we had that data for sure, but we also need more data on safety in pregnant and lactating women. The Developmental and Reproductive Toxicity studies in animals, those were often referred to as the DART studies, they have demonstrated no safety concerns. But we need studies in humans and on this front, Janssen's vaccine has a leg up. The safety profile of Janssen's Ad26 Adenovirus Vector Platform is supported by data from more than 193,000 patients including children and pregnant women, and studies of other investigational vaccines for Zika, HIV and RSV, including an ad-based Ebola virus vaccine that was recently approved by the European Medicines Agency in July of 2020.

Now in the Pfizer study, 23 women became pregnant, in the Moderna study, 13 women became pregnant, and in the Janssen study, eight women have and of course, these patients will be closely followed. V-safe, which is CDC's smartphone-based vaccine health checker, has reported check-ins for more than 30,000 pregnant women who've received COVID vaccines and nearly 2,000 of them have already enrolled in V-safe's Pregnancy Registry. So, more information is on the way. ACIP is carefully following all available safety data which to me is very reassuring.

We also need more data on coadministration of COVID vaccines with other vaccines, especially flu vaccine. Right now, CDC recommends at least a two-week window between COVID vaccines and other vaccine doses. I'm very worried about these emerging variants, we need more genomic sequencing to determine what's circulating and CDC has come up with the plan, they've engaged with other laboratories and universities around the country so we should have more data coming in. But we have to make sure that existing COVID vaccines remain protective. Vaccine companies need to stay nimble and ready. Moderna's already working on a booster targeting the South Africa variant, that's that B.1.351 variant that has everybody worried. Variants are also another reason we must continue mitigation efforts for now which includes masks, social distancing, hand hygiene. But everyone, please get a COVID vaccine when you can, when it's your turn and as soon as you can.

Unger: Great. One thing that the data does show is should not be mixing vaccines. Is that what the data's saying?

Dr. Fryhofer: Right. Right now CDC recommends that there be at least a two-week window between getting a COVID vaccine and administering any other kind of vaccine. That two-week window can sometimes be inconvenient if the patient is in need of other vaccines and it's so much easier when we have a patient and they're in our office, if we can get everything done at one time, but right now they're being very careful because in the studies, that's what the vaccine makers required in doing their research so we want to get these COVID vaccines their best way to give us the most protection. But those kinds of studies are being done as we speak.

Dr. Tan: And I think... Sorry, go ahead, Dr. Campbell.

Dr. Campbell: No, I was just going to say, Todd, you may have also been trying to get at the point of not mixing COVID vaccines, not just routine vaccines, and currently that is because those or all the data that we have is using the same vaccine, well, one dose for J&J, but then the same vaccine, if you're doing Moderna or Pfizer, is people should try to stick to that now. There are some studies that are just about to start which are what we call mix and match studies, which we'll be looking at, "Can you use a different vaccine for your second dose?" Or using a variant vaccine and the original one to start and different doses, all of those are just about to get started. But for now, everyone, when possible, you should get the same, if you're on a two dose schedule, the same vaccine as the first.

Dr. Fryhofer: Todd, if I could just make another comment, all these recommendations are changing as we get more data in. I have really found that the clinical indications page on the CDC website about COVID vaccines, if you just Google "Interim Clinical Recommendations COVID Vaccine," it'd come up, it gives at the top of the document the last date at which that document has been updated and it covers a lot of this information. As Dr. Campbell said, I mean, you want to do what's recommended, you want to give the two doses of the Pfizer vaccine three weeks apart, you want to do the Moderna vaccine four weeks apart and with the Janssen vaccine, it's just one dose so you don't have to worry about that second appointment. But sometimes life isn't always as clear. A patient may come in that doesn't know which vaccine they got, they know that it was three weeks ago.

Well, if they have no idea, then what they say is to wait another week so make it a fourth week and then give a dose of one of the second mRNA vaccines. In some of the places that give vaccines that say that you've got one that was Pfizer, you go back to get your second one and it's not available. So they're saying then that you could just wait another week and get a Moderna vaccine. But all those details, they're clarified and constantly being updated on the CDC website so if you're in that situation and that comes up with one of your patients, your best bet, just go to the website, find out the most up-to-date recommendations because we're all learning as we go along. We've never had a pandemic like this, we've never had seen this virus before, and we need to end this pandemic.

Unger: Absolutely. Dr. Tan, did you have anything you wanted to add?

Dr. Tan: Yes, I was going to just jump in quickly and help reassure all of us too as we go forward. I think the data's beginning to accumulate because we've obviously vaccinating more and more people around the world. Very, very good data coming out of Israel and the United Kingdom that indeed some of the data gaps that Dr. Fryhofer mentioned regarding transmission is actually very reassuring, now potentially up to 90% effective against transmission. And so I think, again, we still need to keep watching, but I think this is a way out. I want to reemphasize what everyone has said, Dr. Campbell and Dr. Fryhofer that we need to keep vaccinating because this is the way out. The data's reassuring us that this is the way out and that means we need to get people vaccinated. I do want to bring up this very interesting situation that right now we have a very interesting time where our supply is less than our demand.

So our demand outstrips supply right now with vaccines, but it's going to become a point in the next couple of months where that's going to flip 180 degrees and all of a sudden we're going to have supply outstripping demand. We, at that point, will really be dependent on physicians to be really helping educate the public, why they need to keep on vaccinating. Viruses will continue to mutate, we know that and we've known that for hundreds of years, well, maybe not hundreds of years, but for decades. But the point here is that if we stop them replicating, we stop them evolving variants, right?

The way to stop them replicating is to vaccinate our public, so we need to have everyone vaccinating. Dr. Fryhofer, that Interim Clinical Considerations page from CDC, excellent, but however, I want to point out that the group I work for, Immunization Action Coalition at immunize.org/COVID-19, has a resource where we've gathered everybody's clinical considerations, including ACOGs physician vaccinating pregnant women and AAPs physicians. So if you want one size for everything, come visit our site too, because I think obviously it's a great resource and I think these COVID-19 updates from AMA are fantastic.

Unger: Well, thank you very much. Dr. Tan, I cannot wait for that situation where supply exceeds demand. We are kind of in a race, so to speak as between emerging variants and just getting vaccines into more arms. Final question, Dr. Campbell, what are your thoughts on what we can do to win that race and how physicians can help?

Dr. Campbell: We're so close. What physicians can do is, we as physicians, are in every survey ever done, are the most trusted source of information about vaccinations. We do it well. I think pediatricians do it extraordinarily well because they do it every day, but internists and family doctors, and everyone does it well. So be confident in yourself, these are vaccines just like our other vaccines and know the data well enough and know some good talking points to be able to talk with your patients. They're moving out into your clinics now, they may have been in mass vaccination areas to start, but they're going to be in clinics, everyone's clinics soon. So, be confident in your messaging and realize this is our way out.

Unger: Dr. Fryhofer, besides the AIMS Method which you outlined before, any tips?

Dr. Fryhofer: Sure. This is the message I'm telling my patients and I think that everyone needs to remember, we now have three safe and highly effective COVID vaccines. Getting more people vaccinated as quickly as we can, can prevent more COVID cases, hospitalizations, and deaths. Now, for some practice, these practices, this new Janssen vaccine may be just the game changer you need to get a vaccination clinic started so I encourage you to go for it. As Dr. Campbell said, physician recommendation is one of the most important motivators for successful vaccination. Remember, vaccines don't save lives, vaccinations do so we must get vaccines out of the refrigerators and into arms. We want to end this pandemic.

Unger: Excellent. Dr. Tan, any final thought?

Dr. Tan: I was just going to say one final thought with Dr. Fryhofer and Dr. Campbell, I hope you guys agree also, absolutely, we want to be vaccinating and getting people out of this, let's just also at the same time, recognizing that 14-day window between vaccines, we still need to think about all the other routine immunizations and catch-up immunizations that are all the patients out there have missed because of this incredible public health journey we're taking right now. While we talk about COVID-19, let's not forget the other vaccines as well.

Unger: Excellent. Well, Dr. Fryhofer, Dr. Campbell, Dr. Tan. It is great to talk to you and I've learned so much. Thanks for sharing your perspective with us. That's it for today's COVID-19 Update. For resources on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us, please take care.

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