AMA Update covers a range of health care topics affecting the lives of physicians, residents, medical students and patients. From private practice and health system leaders to scientists and public health officials, hear from the experts in medicine on COVID-19, medical education, advocacy issues, burnout, vaccines and more.

Featured topic and speakers

In today’s AMA Update, AMA Vice President of Science, Medicine and Public Health Andrea Garcia, JD, MPH, shares the latest research findings, efficacy and safety concerns for the new RSV vaccine. Also covering recommended vaccines for pregnant peoples and protecting yourself against monkeypox. AMA Chief Experience Officer Todd Unger hosts.

Speaker

- Andrea Garcia, JD, MPH, vice president, science, medicine & public health, American Medical Association

Transcript

Unger: Hello and welcome to the AMA Update video and podcast series. Today we have our weekly look at the headlines with the AMA’s Vice President of Science, Medicine and Public Health, Andrea Garcia in Chicago. I'm Todd Unger, AMA’s chief experience officer also in Chicago. Welcome back, Andrea.

Garcia: Thanks, it’s good to be here as always.

Unger: Well, let’s start off with some big news about an RSV vaccine to protect infants. Andrea, what do we need to know about that?
Garcia: Yeah. Last time we talked about the RSV vaccines we did mention that we were expecting this to be coming and last week VRBPAC, which is FDA's Vaccine Advisory Committee voted in favor of approving an RSV vaccine by Pfizer that is designed to protect infants. It's called Abrysvo. It would be the first vaccine to protect babies from RSV.

It is a maternal vaccine. It's a single dose. It'd be given to pregnant people between 24 and 36 weeks of pregnancy, which would then trigger the development of antibodies, which would be passed on to the fetus. These antibodies would provide protection for about the first six months of the baby's life when we know they're extremely vulnerable to a disease like RSV.

Unger: Andrea, what kind of impact do we expect something like this to have?

Garcia: Well, according to the CDC we up to about 80,000 children younger than five are hospitalized in the U.S. each year because of RSV and up to 300 children die from RSV. So this could potentially have an enormous impact for babies younger than six months of age. That rate of hospitalization is one to two out of every 100 kids infected with RSV. And that risk for severe illness is highest among premature infants and those with underlying medical conditions such as weakened immune systems. So both of those groups could benefit from this vaccine.

Unger: And what is the data show in regard to effectiveness?

Garcia: Yeah. So the vaccine was tested at about 7,300 women after the twenty-fourth week of pregnancy. Half received a placebo, half were given the vaccine. And the data showed the vaccine was about 82% effective at protecting newborns from severe lower respiratory tract infections in the first three months after birth. And that's according to the FDA analysis of the data. It was also about 57% effective at keeping babies from having to see their doctor after an RSV infection. And then by about six months after birth that vaccine was still about 69% effective at preventing severe disease and 51% effective at keeping them out of the doctor's office for breathing problems.

Unger: And Andrea, are there any safety concerns?

Garcia: So there were some concerns raised in the VRBPAC meeting about elevated risk of preterm births among mothers who got that vaccine compared to those who received the placebo. And those rates were about 5.7% to 4.7% respectively. That difference is not statistically significant. So that could just be due to chance. Most members of the committee concluded that the benefits of reducing that risk of severe RSV infection in children in those first six months of life carried more weight. If this vaccine is approved, we do expect that Pfizer will plan to do a large post-market safety study that will help evaluate those endpoints, including preterm birth, in everyone who gets the vaccine.

Unger: And what's the next step?
Garcia: So FDA is expected to follow the recommendations of its advisory panel and approve the vaccine. We know this follows behind FDA's recent approval of that first RSV vaccine for adults age 60 and older, that GSK vaccine called Arexvy was approved by the FDA earlier this month. But both of those vaccines will still need to be recommended by the CDC. We know ACIP is meeting in June. So we could see that recommendation come as early as then. And that means both of those vaccines would be available by the fall and winter when we know that cases of RSV are likely to surge. We also know that more RSV vaccines are on the way, including an mRNA vaccine from Moderna for older adults. That vaccine is currently finishing its phase III trial.

Unger: Well, that all sounds very promising. Let's turn our attention now to a different vaccine, one for COVID. And there are some new data about the safety of COVID vaccines and boosters during pregnancy. Andrea, what's the news there?

Garcia: Yeah, so there were a couple of new studies published in JAMA Network Open and the American Journal of Epidemiology where researchers were looking at data from over 100,000 pregnancies. And what they found is that those monovalent COVID-19 vaccines given during early pregnancy was not associated with an increased risk for miscarriage, also known as spontaneous abortion or loss of pregnancy before 20 weeks of gestation. And together these studies make a strong case for why getting vaccinated for COVID during pregnancy is both safe and important.

These were observational case-control surveillance studies. Data was from the CDC's vaccine safety data link and it came from eight different health systems. I think it is important to note that data for these studies came before the availability of the bivalent COVID vaccines, so they were from the monovalent vaccine.

Unger: It's probably obvious, but why are studies like this so important?

Garcia: Well, I think one of the barriers to these COVID booster vaccines is uncertainty about the safety among pregnant people. And I think these findings help reinforce the safety of the COVID booster vaccines, including in pregnant populations. And it's important because pregnant people we know are more likely to get very sick from COVID compared to others.

Unger: And what about the effect on the baby?

Garcia: Well, we know that people who get COVID during pregnancy are at increased risk for complications that can affect their pregnancy and the developing fetus. Data has shown us that vaccination during pregnancy also helps protect babies younger than six-months-old when we know they're too young to be vaccinated themselves. This passive immunity is similar to what we just talked about with the RSV vaccine, protecting the mother also protects the baby. And vaccination continues to be the most effective way to prevent severe illness from COVID. And people who are pregnant should definitely be staying up to date on their COVID vaccines.
Unger: Well, thank you for that. Andrea, let's move on to virus number three and vaccine number three. Talk about another one that is making headlines. Let's talk about Mpox. We talked about it last week, particularly about a cluster of cases here in Chicago. And this week we have news about the vaccine for Mpox. What do we need to know?

Garcia: Yeah, so the New York Times reported on a couple of observational studies published both by the CDC and MMWR and the New England Journal of Medicine. The Jynneos vaccine, which is the vaccine for Mpox, does provide real-world protection against the disease. Two doses does appear to be more effective than one. That effectiveness for two doses of the vaccine range from 66 to about 88% depending on the study. And the effectiveness of that single dose was about 36% to 75%.

Researchers also looked at intradermal dosing, which involves giving that vaccine between the layers of the skin rather than underneath it. And that requires just one-fifth of the dose. And that provided protection roughly equivalent to the conventional subcutaneous injection. The vaccines had not been widely used before last summer's Mpox outbreak and certainly more research is needed to determine how well that vaccine works in immunocompromised people, how long that protection lasts and, again, that variability on how the vaccine or the vaccines are administered.

Unger: Andrea, is this the first time that we have real-world data for this vaccine?

Garcia: So if you recall, Jynneos was initially intended at as a two-dose subcutaneous vaccine to be administered 28 days apart. But if you recall back to the early days of the Mpox outbreak, those vaccine supplies were very limited. We saw officials sort of deviate from that intended regimen. Some had been administering a single dose of the vaccine. And some studies had suggested that could provide considerable protection. And then last August we saw federal officials provide an EUA for that intradermal dosing. And that was intended to stretch that availability of the supply. There had been little evidence until now regarding the effectiveness of these strategies, which were based largely previously on human immunologic and animal studies and not on the real-world experience of patients.

Unger: Well, it sounds like this is good news and it's coming just in time.

Garcia: Yeah, I think the findings are good news. They're coming at a time when people are going to be gathering for festivals or other events. And we know that will mean more opportunities for transmission. Dr. Christopher Braden, who's the impacts incident response manager at the CDC, said in a recent news briefing that the outbreak is not over. We need to remain alert and we need to continue our prevention efforts. We know public health experts and officials are urging people who are at risk to get vaccinated before Pride events begin next month. And although we know vaccine-induced immunity is not complete, we do know these vaccines continue to be one of the most important prevention measures and they can certainly help reduce the severity of symptoms.
Unger: Absolutely. And that, again, it's good news and something we will keep an eye on on Mpox, of course, throughout the summer. Andrea, Thanks so much for being here. That wraps up today's episode. We'll be back with another AMA Update soon enough. You can find all our videos and podcasts at ama-assn.org/podcasts. Thanks for joining us today. Please take care.

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