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The COVID-19 pandemic is in its second year and the Omicron BA.5 subvariant continues to drive cases in the United States, including among vaccinated people. But that doesn’t mean COVID-19 vaccines and boosters are ineffective. That seeming juxtaposition causes confusion among many patients. One physician vaccine researcher sets out to clear the air about how well COVID-19 vaccines work.

SARS-CoV-2 vaccines manufactured by Pfizer-BioNTech and Moderna became the first two COVID-19 vaccines approved in the United States. Both vaccines have been shown to be safe and effective against SARS-CoV-2 infection or severe COVID-19 outcomes such as hospitalization and death.

The AMA’s What Doctors Wish Patients Knew™ series provides physicians with a platform to share what they want patients to understand about today’s health care headlines, especially throughout the COVID-19 pandemic.

In this installment, AMA member Purvi Parikh, MD, an allergist and immunologist as well as a vaccine researcher in New York City, took the time to discuss what patients need to know about COVID-19 vaccine and booster effectiveness.

Efficacy is defined by clinical trials, real world use

“When it comes to vaccines, there are a few things that we look for. The most important thing for efficacy in vaccines is, of course, preventing the most serious complications,” said Dr. Parikh. “That includes death, hospitalizations and then—even if you’re not hospitalized—a lot of long-term complications that you can get from any given infection.

“So, that could be long COVID, for example, or blood clots, breathing issues and lung damage that can persist after the fact. There’s a whole list of them,” she added, noting “those are some of the most important efficacy endpoints.”
For example, if a vaccine has an efficacy of 80%, that doesn’t mean you have a 20% chance of getting the disease, Dr. Parikh explained. “It depends on what the clinical endpoints are (i.e., symptomatic infection versus death versus hospitalization), but it’s usually looking at getting symptomatic infection, so that means 80% of the people didn’t get it and likely more prevented severe outcomes.”

In addition, “effectiveness percentages always change from a very controlled setting where you’ll only have 30,000 or 40,000 people,” she said. “And then now there’s billions that have received it, so the numbers are very different from when the trials started.”

On top of that, “many of the vaccines were studied and granted emergency use authorization before all of these new variants like Delta variant and BA.2 Omicron subvariant and now BA.5, so you should take that into consideration too,” she said.

Effectiveness occurs in the “real world”

Vaccine effectiveness is the measure of how well vaccination protects people against infection, symptomatic illness, hospitalization and death. It is typically measured through observational studies that are specifically designed to estimate individual protection from vaccination under “real world” conditions, according to the Centers for Disease Control and Prevention.

“While a vaccine starts protecting you within weeks of immunization, maximum effectiveness is once a population has been vaccinated for many years and it is that herd immunity everyone talks about where the actual infections themselves become few and far between,” said Dr. Parikh. “There’s a lot of talk about herd immunity and things like that. We have seen real world examples of this with polio and measles.

“But there’s not a single infectious disease, actually, that has reached that status without a vaccine through the history of time,” she added.

It's about the immune system

“With most of the initial studies, they’re looking at not just antibody levels, but also other parts of your immune system like your T cells to make sure they are still recognizing and protecting you against the virus itself,” said Dr. Parikh. “One would argue that that’s even more important, because it’s those T cells—even though nobody talks about them—that keep people from getting very ill and staying out of the hospital and intensive care unit.”
“The other side of it is actual symptoms. So, the other way that we look at it is how symptomatic infection is avoided,” she said. “That means positive tests too. That is a little bit trickier to track, especially if you don’t have any symptoms, so someone may not even realize they’re positive.”

**Boosters are very effective**

“With the initial series and then with COVID-19 vaccine boosters, predominantly people have been looking mostly at the antibody titers,” said Dr. Parikh, noting that “is the wrong way to look at it because there’s been a lot of misconception in the media—even in the medical community—that they are not effective because the antibody titers are either waning with the new variants or are not neutralizing.”

“But there is data and studies that show that the T cells are still very resilient even with boosters protecting against the most severe outcomes,” she said. “So, when people tell me that they don’t work or they’re worthless, I actually disagree.”

“It’s all about risk mitigation. If you are someone who’s high risk, they’re still very effective, especially against the most severe forms of illness,” Dr. Parikh said.

**Symptoms tend to be minimal**

When individuals have tested positive for COVID-19 even after being vaccinated and boosted, many jumped to the conclusion that vaccines and boosters are ineffective, but they’re missing the point that they likely had a much milder case of it, said Dr. Parikh. Before the vaccines were available, anyone who got COVID-19 and had to be admitted to the hospital may have needed remdesivir and oxygen.

It was a whole different story because, unfortunately, they got it before they could get vaccinated, she added, noting “I’m seeing a lot of cases where—for the last 90 days—I’ve prescribed Paxlovid every single day, if not multiple times a day.”

That shows that these patients had some protection due to vaccination or receiving a booster dose and were able to be treated as outpatients instead of being admitted to the hospital.

“It’s not that mild. Even for people recovering at home, people are still struggling with extreme fatigue weeks later and people who are healthier and younger are also having a lot of issues still,” Dr. Parikh said. “So, you don’t want to know what it would be like had you not been vaccinated or boosted.”
New variants play a role too

“Because there is different effectiveness against BA.5 compared to whatever else comes down the road, it is important that there are more variant-specific vaccines being studied,” said Dr. Parikh. “Those vaccines also have to evolve as the variants evolve.”

That is why the Food and Drug Administration authorized and the Centers for Disease Control and Prevention recommended the use of the bivalent COVID-19 vaccine, which is half original strain, half Omicron BA.4 and BA5.

“This is going to be the future of COVID-19 vaccines, where we’re going to be using different ones as the variants evolve.”

Studies on effectiveness are ongoing

“Understanding and studying the effectiveness of COVID-19 vaccines and boosters will be ongoing for however long it takes,” said Dr. Parikh. “We never stop tracking infectious diseases as we’re seeing it now with polio and measles coming back.”

“When we have certain outbreaks, it’s not something that’s done and forgotten about. It’s constantly being studied,” she said. “Even though the media doesn’t share it, it’s always there in the background.”

It’s about preventing severe long-term issues

Even with highly effective vaccines, there is still a chance for breakthrough infections to occur. The idea is to prevent “severe disease and keeping people out of the hospital as well as the long-term complications that may occur,” Dr. Parikh said.

“Yale is studying it currently and studies have already been published that vaccines may provide protection against long COVID, which so many people are struggling with,” she said. “That’s going to be the next big public health emergency because so many more people are now living with the consequences than who have passed away.”

Don’t try to compare the vaccines
“You shouldn’t compare effectiveness of COVID-19 vaccines like Pfizer and Moderna until there’s a large blinded controlled study that actually compares them head-to-head in the same study,” said Dr. Parikh. “It’s not like apples and apples. These are all independent studies, so it doesn’t correlate in the same way to say this is better than that.”

“The important thing is if they’re all showing they prevent those worse outcomes and prevent infection, then you should get whichever one you can get first unless we get to a point where you find one is not doing that,” she said.