The latest on FDA authorization for a second booster with Andrea Garcia, JD, MPH

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Featured topic and speakers

In today’s COVID-19 Update, AMA Chief Experience Officer Todd Unger reviews rising COVID-19 case numbers and trending topics related to the pandemic over the past week with AMA Director of Science, Medicine and Public Health Andrea Garcia, JD, MPH. Also covering the FDA's authorization of a 2nd booster shot, as well as changes in COVID treatments and therapies. Additionally, uninsured patients may have to pay high prices out-of-pocket for COVID tests and vaccinations due to lack of federal funding and stalled budget approval.

Learn more at the AMA COVID-19 resource center.

Speaker

- Andrea Garcia, JD, MPH, director of science, medicine & public health, American Medical Association

Transcript

Unger: Hello, this is the American Medical Association's COVID-19 Update video and podcast. Today we have our weekly look at the numbers, trends and latest news about COVID-19 with the AMA's Director of Science, Medicine and Public Health Andrea Garcia in Chicago.

I'm Todd Unger, AMA's chief experience officer, also in Chicago. Andrea, thanks so much for joining us. Big news today from the FDA, has anticipated a second booster shot's been authorized for people 50 and up. What do folks think about this update and what do we need to tell everybody?

Garcia: Well, thanks for having me, Todd, and as you mentioned, we're expecting and we did see that authorization from the FDA this morning, authorizing boosters of Pfizer and Moderna for those 50 and older. But the agency also authorized a second booster dose of the Pfizer vaccine for those 12 and up with certain immune deficiencies, such as people who've undergone solid organ transplants. And that second booster of Moderna is authorized for those 18 and older, who are similarly immunocompromised.

The timing for that is four months after the first booster dose. And of course, since that just happened, that action of FDA just happened as of the time of this conversation, we have not yet seen the CDC weigh in but they're expected to issue advice on who should consider getting that shot.

As soon as later today, as of last week, what we were reading in the news and hearing is that the CDC was going to put forth a permissive recommendation for older Americans or people with underlying medical conditions without making a full recommendation.

Unger: So what drove this decision?

Garcia: Last week, the Biden administration had decided that we needed to bolster weaning immunity in older Americans in case there is a new wave of COVID that hits before the fall. It's designed to protect those older populations, people who are immunocompromised until the fall. And at that point, federal health officials say they expect that everyone is going to need another shot.

I think there's also a chance. We know scientists are working on new versions of the vaccine that'll better protect us against variants. So we could see those emerge over the coming months.

Unger: Interesting. What about those folks that are under 50?

Garcia: For those that are under 50, we just, at this point, don't have the data that they need a second booster dose. So at this point, they should be waiting until fall. We'll see, like I said, additional recommendations coming then that are likely to impact that population.

Unger: Let's talk a little bit about the science about the second booster shot. What do we know so far?

Garcia: We don't have as much data as we'd like and that's mostly because the second boosters are so new. There's some data out of Israel that suggests that second booster dose could significantly lower the COVID death rate in older populations. But I would caution that this data out of Israel, it's a pre-print study. It hasn't yet been peer-reviewed. But what we're seeing in that data, which was a 40-

day study conducted by the largest health care provider there, it included over 500,000 people and that age range was 60—

Unger: Wow.

Garcia: ... to a hundred years old. That study found that older adults who received that second booster of Pfizer, the Pfizer vaccine, specifically, had a 78% lower mortality rate than those who only had one booster. So I think the question is how long is that protection going to last. Obviously, the booster campaign in Israel is fairly new. We only have data for about two months or less and we know that the studies in the U.S., we've talked about those studies that have shown the mRNA vaccines are holding steady against hospitalization and death but we know that protection from infection is weaning. So we'll obviously have to get more data before we see a recommendation for broader populations.

And we also have to decide what the overall goal here is for our COVID vaccines. Is it to protect people from severe disease or from infections? I think we'll have to keep in mind that even less serious infections can lead to long COVID. Of course, not widespread agreement on that overall goal right now but hopefully we'll be working toward that in the future.

Unger: Speaking of infectious, how does something like BA.2 factor into this?

Garcia: I think the one thing we know about COVID is it's difficult to predict and this becomes a question of timing. So for older adults with where we are with BA.2, getting that second booster sooner may make sense.

BA.2 is continuing to drive surges and infections in Europe. As of now, it's about 54.9% of cases in the U.S., so it is now that dominant variant. And the percentage is as high as about 72% in some regions, including the Northeast.

I think with that being said, according to the New York Times, reports of new cases are still declining. Though that pace has slowed down in recent days, the average of new cases is hovering around 30,000 and that's a level last seen in July. Several states in the Northeast, in the South are seeing cases start to increase and that is being driven by BA.2. So New York, Connecticut, Arkansas, cases in those states are up by 20%. But in most states, we're still seeing steady declines.

Unger: Are we also seeing the kind of declines in hospitalizations and deaths, which of course are lagging?

Garcia: Yeah, hospitalizations are falling. In the last two weeks, they've dropped by about 36% to about 18,000 per day. Intensive care unit hospitalizations have fallen too by about 43% to under 3,000. And we're now seeing about fewer than 800 COVID deaths reported each day, which is the lowest daily average since last fall.

Unger: That's really good news. In other news, with the increase in BA.2, we've also seen a change in the authorization for treatments. What do physicians need to know about these changes?

Garcia: Yeah, the FDA recently announced that sotrovimab is no longer authorized in much of the Northeast where that BA.2 subvariant is dominant. That is because it's reduced effectiveness against BA.2. We do expect that those restrictions are going to expand in the coming weeks as BA.2 increases in prevalence nationally. And we're hearing that the NIH COVID-19 treatment guidelines panel may be issuing updated treatment recommendations for non-hospitalized COVID-19 patients in the near future because of the increasing prevalence of BA.2.

Unger: What does that leave in terms of treatments that are proving effective against BA.2?

Garcia: There are other therapies, including the antivirals, so Paxlovid, remdesivir, molnupiravir, as well as Eli Lilly's monoclonal antibody treatment that we are expecting to be effective against the BA.2 subvariant. But overall, we should expect these kind of shifts in treatment guidelines to continue as new variants emerge and we're going to have to adjust our treatments as the virus continues to evolve.

Unger: Last week, we talked about the impact that a lack of funding could have on our continued pandemic response. Big article from our surgeon general this morning talking about the impact of that. What's the update on this issue?

Garcia: We know that a U.S. reimbursement fund for uninsured COVID patients has stopped taking claims due to insufficient funds that has caused some U.S. health care providers to begin informing people who are uninsured that they'll now have to pay to be tested for COVID. So on Sunday, we heard a spokes—

Unger: And it's a lot.

Garcia: Yes. We heard a spokesperson from Quest, who operates one of the largest networks of testing and laboratory sites in the U.S., say that they're going to be notifying clients that reimbursement is no longer available. This doesn't affect customers enrolled in private insurance plans or those covered by Medicare or Medicaid.

Unger: So I saw the figures on that. It can get pretty expensive for an uninsured patient.

Garcia: Yeah, so they'll have to pay $125 for molecular testing through Quest, a hundred dollars if that test is ordered by a physician that's affiliated with Quest and some other testing services may charge up to $195. We know that HRSA has stopped accepting claims for testing and treatment for patients who are uninsured, and on April 6, they will stop reimbursing providers for vaccinating people who are uninsured. And that population in the U.S., according to federal data, is around 31.2 million Americans

who are uninsured. So the current concern here is obviously that it's going to widen the disparities in care that we know already exist.

Unger: And which we've seen magnified by this pandemic. So this seems like a real problem that needs to be addressed. Do we expect the funding to come through anytime soon?

Garcia: At this point, we don't know. We know top public health officials continue to voice concerns about the impact of stalled funding. We know the president has released a new $5.8 trillion budget proposal. That proposal includes funding for pandemic preparedness, for local public health spending. But Secretary Becerra of HHS told reporters on Monday that the requests in the budget proposal are different from the funds needed more immediately to cover test, treatments and vaccines. He indicated that what we need to continue to finish the job on COVID, we need immediately. And what we're asking for in the president's budget is for long-term preparedness and that's very separate.

Unger: Yeah, so we've talked with a number of physicians about this idea of moving into an endemic phase. So much of that is built on testing and continuing to monitor the situation out there and, of course, treatments. So this will be very important and we'll be keeping our eye on that.

Thanks so much for the update today, Andrea. We'll be back soon with another COVID-19 Update. For resources on COVID-19, you can always check ama-assn.org/COVID-19. Thanks for joining us today and please take care.
