

Fall Boosters ACIP Meeting: Cliff notes



Katelyn Jetelina

2 hr ago

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Today [ACIP](#)— the external advisory committee to the CDC— met to discuss the bivalent fall boosters in the United States. This committee’s main purpose is to evaluate the safety and effectiveness of vaccines as well as policy recommendations for dissemination (who should get one and when).

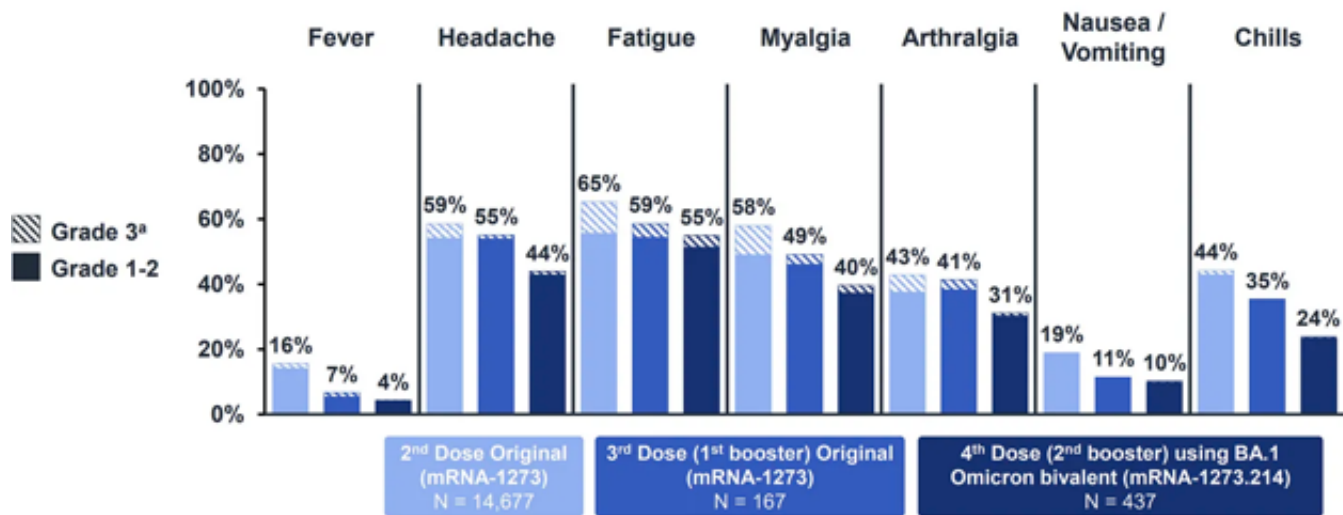
This was a much anticipated meeting, as we have seen barely any data on the BA.4/5 bivalent booster. We also had some [other burning questions](#). [Here](#) was the agenda for the meeting. [Here](#) were the presentations. And here are your cliff notes.

(If you haven’t already, be sure to read my [previous post](#) first. I’m picking up from there.)

Safety

Moderna and Pfizer presented data on the safety of the BA.1 bivalent vaccine among humans. We have data on more than 1,400 adults. While this is *not* the vaccine being rolled out in the U.S. (we are rolling out the BA.5 bivalent vaccine instead), the differences between BA.1 and BA.5 boosters are minimal. Literally the difference of a few amino acids—like a few letter edits on a Word document. We aren’t changing the number of words in the paper (like dosage of RNA), or the content of the paper, or the platform (like Word to Excel). Because of the minimal change, we are confident that BA.1 bivalent safety data will accurately reflect BA.5 safety.

In general, the rate of side effects from the BA.1 bivalent booster were the same or lower than from the original booster formula or the original series. For example, Moderna found 4% of participants had a fever after the bivalent vaccine (dose 4) compared to 16% who got a fever after the original series (after dose 2). There were two severe adverse events after the bivalent vaccine (prostate cancer and bone fracture), but they were not linked to the vaccine.

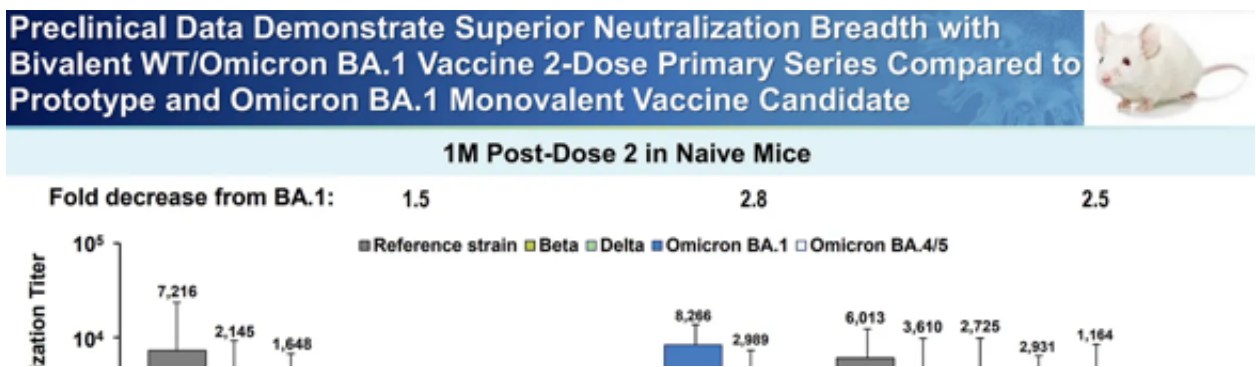


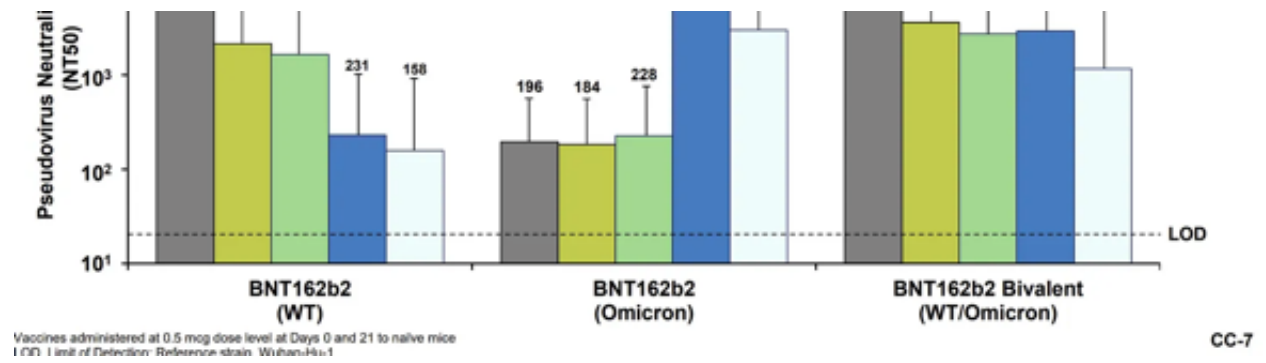
Moderna Side Effects of Bivalent BA.1 vaccine; Source: Slide [here](#) from ACIP meeting

Effectiveness

We don't know the effectiveness of the BA.5 fall booster among humans. Given the rapidly evolving virus, we need to triangulate four other data sources:

1. **Bivalent BA.1 among humans.** Compared to the original formula, the number of neutralizing antibodies (i.e. our first line of defense) induced by the bivalent BA.1 vaccine was better—about 1.22 times better. This isn't amazing, but it isn't terrible. This means that we will likely see a slight increase in vaccine effectiveness against infection, but not a huge jump.
2. **Bivalent vs. monovalent.** Many wonder why we need a bivalent vaccine instead of monovalent (with only the Omicron formula). Pfizer showed us why. If Omicron continues to mutate, we would be okay with monovalent. However, if we get another random variant, say Delta again, the monovalent wouldn't be as protective as the bivalent. Bivalent is key in providing broader protection taking into account the unpredictability of the future.





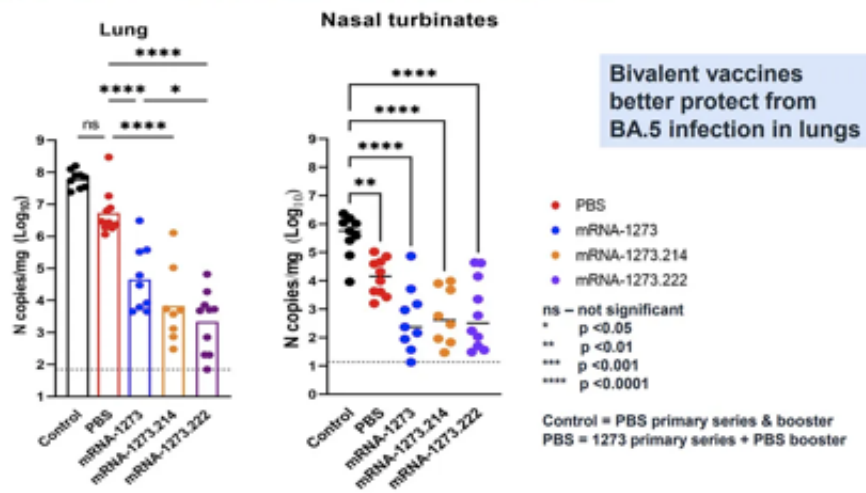
(Pfizer)

- Bivalent Beta vaccine.** We hope that an updated bivalent vaccine will last longer compared to the original vaccine. But we don't have much data. We have the duration that the bivalent *Beta* boosters lasted. Moderna showed that bivalent Beta remained durable at 6 months. If this translates to our BA.5 vaccines, this would be great news.
- BA.4/5 mice data.** The only data we have on the bivalent BA.5 fall boosters is from mice. Honestly, there wasn't much data presented today, but what we did see was promising. Moderna highlighted that the bivalent BA.5 vaccine is particularly better at reducing replicating virus in the lungs than other vaccine variants. This means that the BA.5 bivalent may be similar or even slightly better than the BA.1 bivalent vaccine.

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Increased Protection from BA.5 Challenge after Booster Dose of BA.4/BA.5 & BA.1 Omicron Vaccines (mRNA-1273.214 & mRNA-1273.222) in Mice

• Mice challenged with 10^4 PFU of BA.5 virus 4 weeks after booster dose



Scheaffer et al, manuscript under preparation

(Moderna slide)

Benefits and Risks

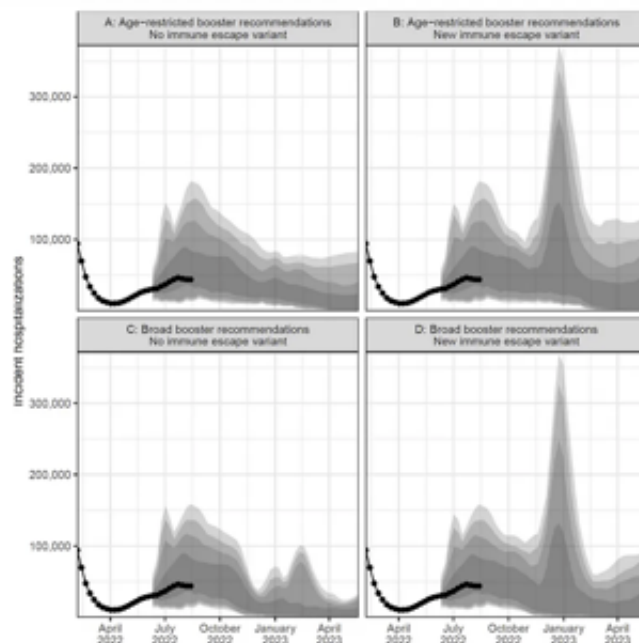
CDC followed the vaccine manufacturers' presentation with their fantastic benefit/harm analysis, as per usual.

Benefits

- **Reduce disease.** Models show hospitalizations and deaths will increase this winter. How *big* this wave will be is dependent on viral mutations, booster uptake, behaviors, and a lot of other things. But if we have a booster campaign that matches the influenza vaccination rate, we have the potential to avert 101,000 deaths, 1,028,000 hospitalizations, and 24.9 million infections. That's a lot. And equates to diverting \$62 billion in medical costs.

Round 14: National ensemble projection intervals - Hospitalizations

Round 14
Regardless of presence of a new variant, flu-like vaccine uptake in individuals ages ≥ 18 years would lead to a **>20% reduction in hospitalizations** and **>15% reduction in deaths** versus a recommendation for individuals ages ≥ 50 years only



<https://covid19scenariomodelinzhub.org/>

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- **High interest.** I was shocked to see that 72% of Americans in a survey said they will definitely or probably get the updated Omicron vaccine. If this is truly the case, this fall booster will help... a lot.
- **Limited imprinting.** I need to update my last [original antigenic sin post](#), but we've gotten some great news suggesting an *improved* response after the bivalent vaccine. This suggests bivalent vaccines expand immune response, which is great news.

Risks.

- **Myocarditis.** We are still seeing a rare, but real, safety signal of myocarditis after a booster among male adolescents and young males. But keep in mind the risk is

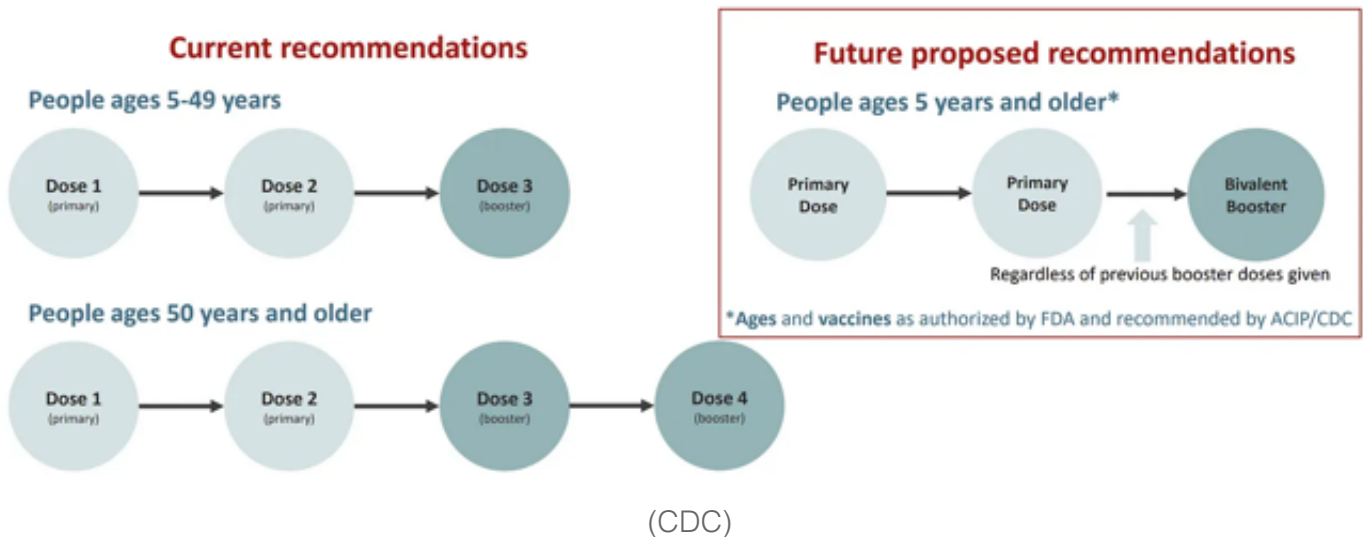
smaller than after dose 2 (thanks to the longer time period), and the risk of myocarditis after COVID19 *infection* (compared to vaccination) is 1.8 - 5.6 times higher among young males.

Discussion and vote

Some voting members voiced uneasiness around the lack of human data for BA.5 boosters, but we rely on similar data and background with flu every year. Ultimately, ACIP voted 13-1 for boosters this fall:

- Pfizer: Everyone over the age of 12.
- Moderna: Everyone over the age of 18.

Going forward, CDC will shift away from naming boosters dose 3, 4, 5, etc. From now on, everyone needs the primary series (with the original formula) and bivalent booster. This will equate to being fully vaccinated.



The puck now goes to Dr. Walensky at the CDC to sign off. I expect she will do this ASAP. This vaccine should be available to you very soon, depending on the timeliness of delivery to pharmacies and doctors offices.

Bottom line

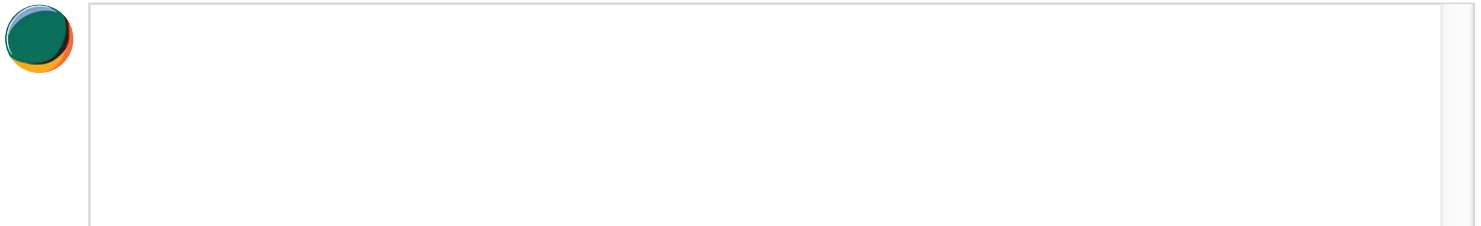
Everyone aged 12+ years old should get a booster this fall. It is safe. And we are more confident than not that it will be better than the previous vaccine. It will not be the silver bullet, but will no doubt help greatly on an individual and population level through the winter months. Protect yourself and those around you.

Love, YLE

P.S. Everyone should get a booster. But, we *can* be data driven on *when* to get this vaccine based on vaccination status, age, previous infections, etc. I will write a post for tomorrow to explain my thinking. Too much for one day. Stay tuned.

“Your Local Epidemiologist (YLE)” is written by Dr. Katelyn Jetelina, MPH PhD—an epidemiologist, biostatistician, wife, and mom of two little girls. During the day she works at a nonpartisan health policy think tank, and at night she writes this newsletter. Her main goal is to “translate” the ever-evolving public health science so that people will be well equipped to make evidence-based decisions. This newsletter is free thanks to the generous support of fellow YLE community members.

26 Comments



John Vann 10 min ago

Did they discuss timing of the bivalent booster? 5 months after the last primary series vaccine? Any thoughts on timing of the bivalent booster after a documented infection? Thanks as always for the information!

♡ Reply Collapse ...



Jessica Margolin 26 min ago

Dr. Jetelina, a suggested edit:

"If Omicron continues to mutate, we would be okay with monovalent. However, if we get another random variant, say Delta again, the monovalent wouldn't be as protective as the bivalent."

I think this is slightly difficult to parse for us normies. If I got it right -- big "if" -- I'd suggest something like:

"If **CIRCULATING STRAINS CONTINUE TO BE DOMINATED BY OMICRON VARIANTS**, we would be okay with monovalent. However, if we get another random variant **BECOMING DOMINANT**, say Delta again, the monovalent wouldn't be as protective as the bivalent."
(**BOLD** for identifying changes)

♡ Reply Collapse ...

24 more comments...
