

FDA Proposal for the Future of COVID-19 Boosters

February 2, 2023

with Katelyn Jetelina, PhD, MPH
(Your Local Epidemiologist)

Illinois Chapter

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CME Accreditation Statement

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Nurses and Nurse Practitioners can submit Certificates of Attendance to their accrediting board to claim credit for participation in the live webinars.

This session is being recorded.

CME Disclosure Grid



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Katelyn Jetelina, MPH PhD	Faculty/Presenter	Yes	Consulting - Gilead Sciences
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None of the Planning Committee members, faculty/presenters, content reviewers, CME application reviewers or anyone in control of the training content disclosed a relevant financial relationship with a commercial interest/ineligible company.

Our Speaker



@your_local_epidemiologist



@dr_kkjetelina

Dr. Katelyn Jetelina

She has a Masters in Public Health and PhD in Epidemiology and Biostatistics.

[Your Local Epidemiologist](#)



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Objectives

Upon completion of this webinar, participants will be able to:

Describe the national plan for COVID-19 boosters going forward, as outlined by the Vaccines and Related Biological Products Advisory Committee in Jan 2023.

Discuss the current and future challenges with implementing a vaccine plan for SARS-CoV-2.

Outline who is most at risk for SARS-CoV-2.

Summarize how bivalent vaccines are working against severe SARS-CoV-2 disease.

What happened?

- ▶ Last week, VRBPAC met to discuss the future of COVID-19 vaccines in the U.S.
 - ▶ *Do we simplify the COVID-19 vaccine approach in the U.S.*
 - ▶ *If so, how?*

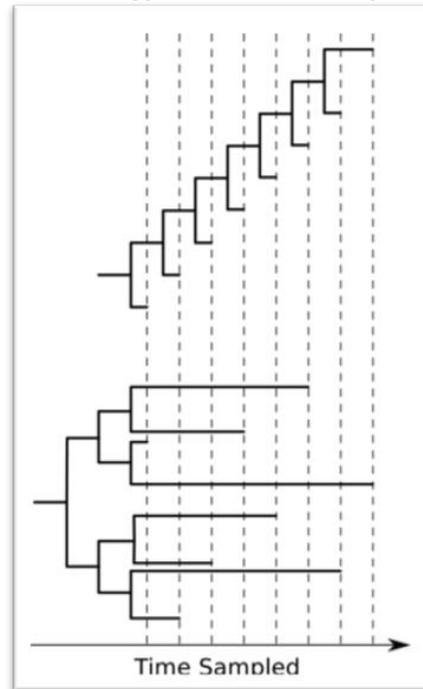
The challenge



Working for us...

- ▶ COVID-19 may be finding a more predictable path
 - ▶ Omicron is lasting for more than a year

Different types of evolution patterns

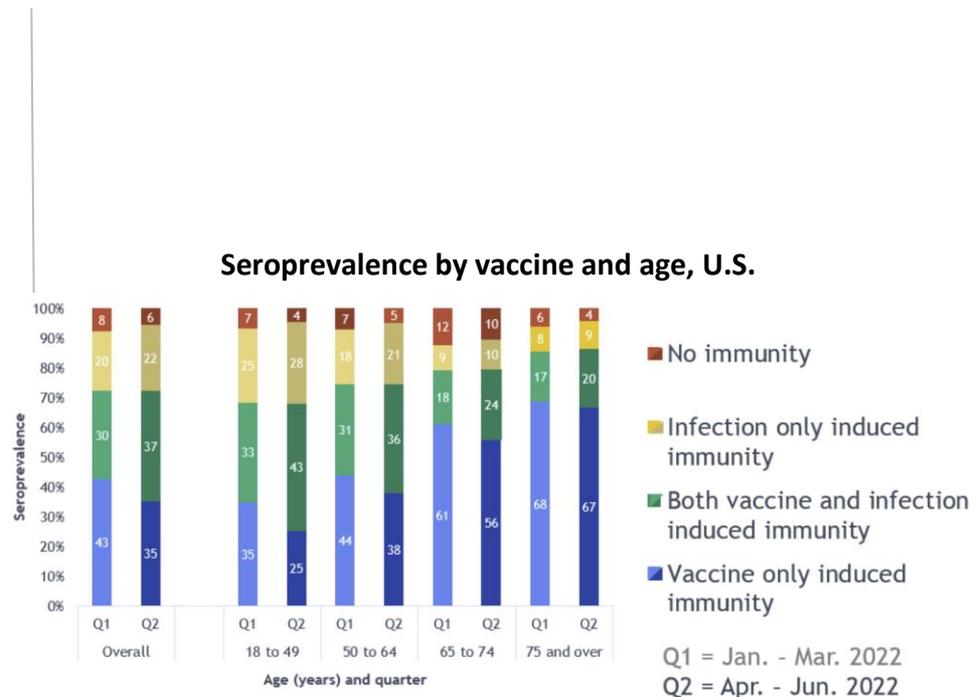


The challenge



Working for us...

- ▶ COVID-19 may be finding a more predictable path
 - ▶ Had Omicron for more than a year
- ▶ Majority of people have been exposed to the virus.
 - ▶ Hybrid immunity is robust.



The challenge



Working against us

- ▶ mRNA vaccines are not perfect
- ▶ People aren't getting vaccinated
- ▶ 4 million babies per year will be immune naïve
- ▶ Different populations have different risks
- ▶ COVID-19 is mutating 4 times faster than the flu
- ▶ US is moving out of an emergency

How are the vaccines working?

Goals of updated bivalent booster:

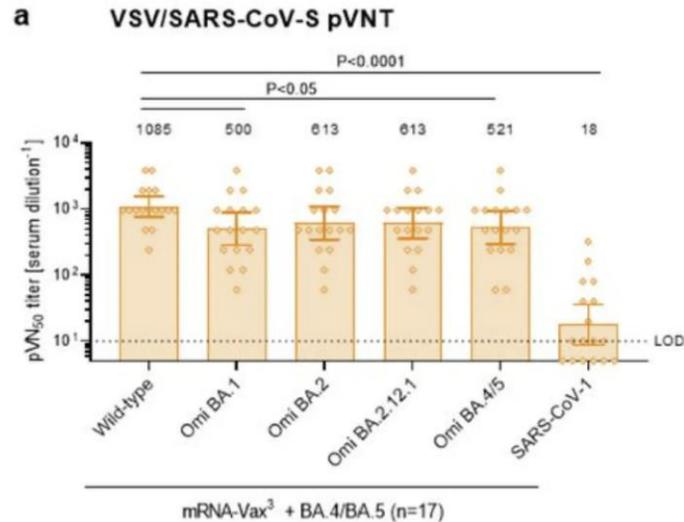
- ▶ Greater, temporary protection
- ▶ Broader protection
- ▶ Longer protection

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Lab data



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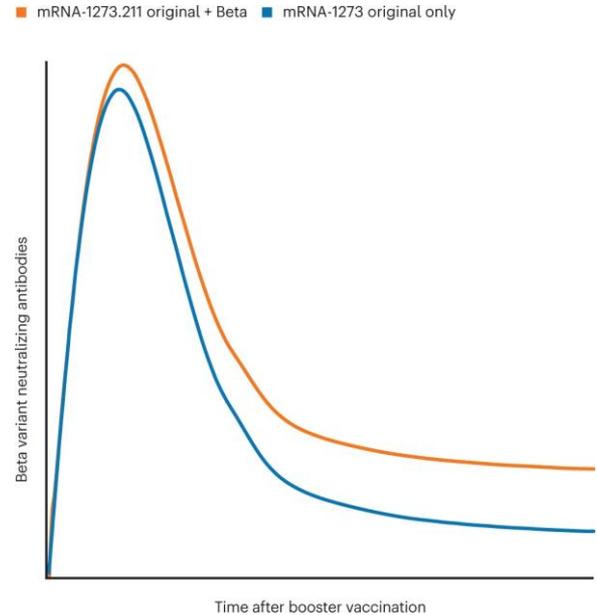


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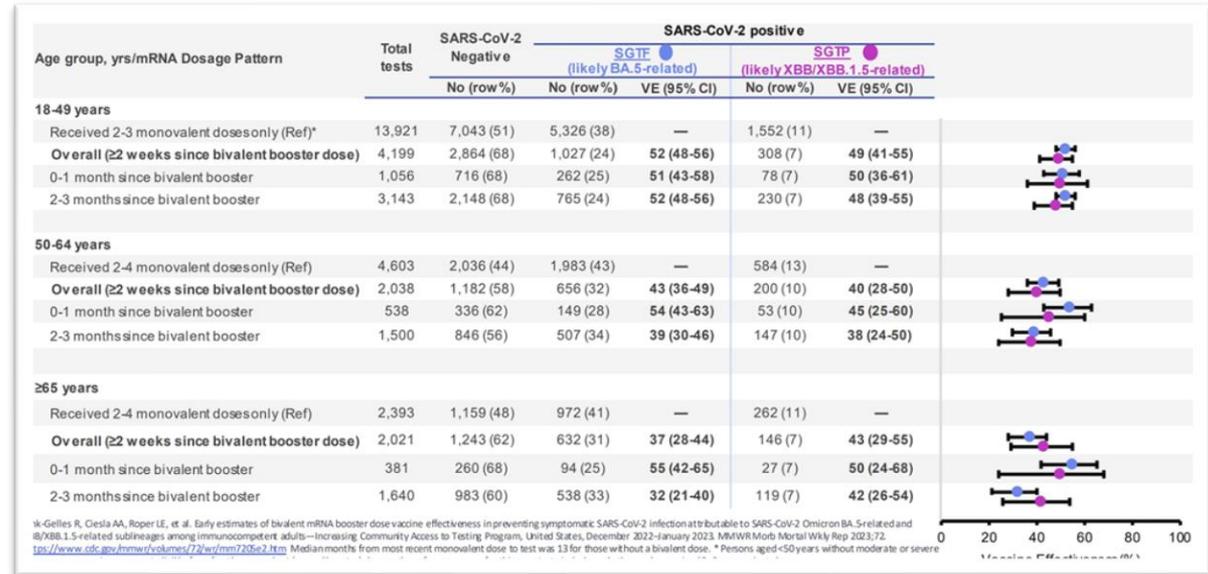


How are the vaccines working?

Goals of updated bivalent booster:

- ▶ Temporary protection
- ▶ More broad
- ▶ More durable

Epidemiological data (infection):

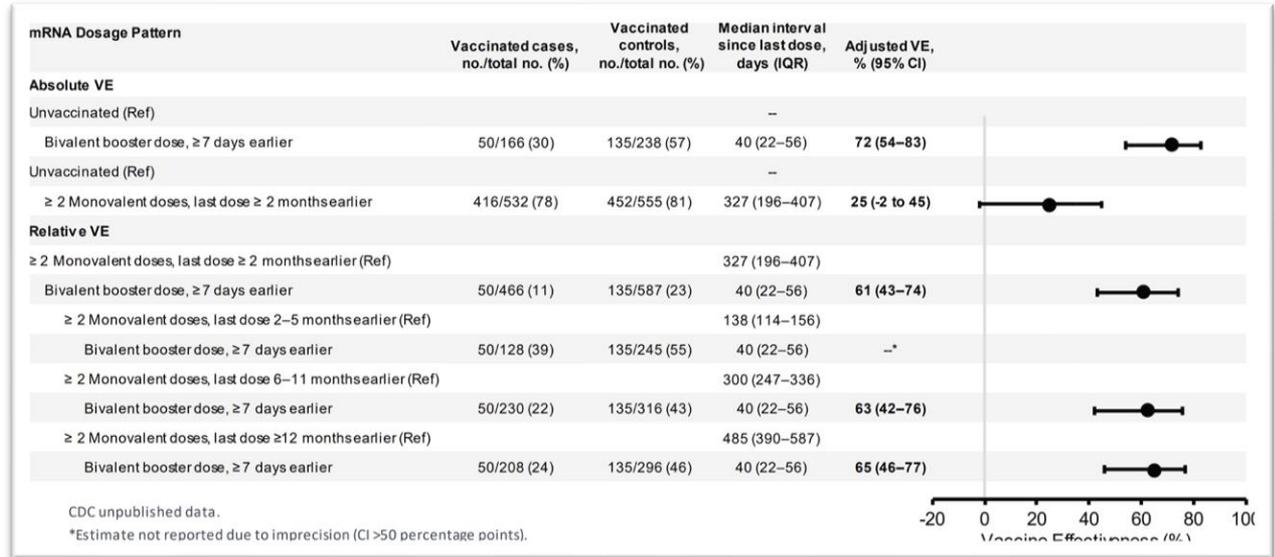


How are the vaccines working?

Goals of updated bivalent booster:

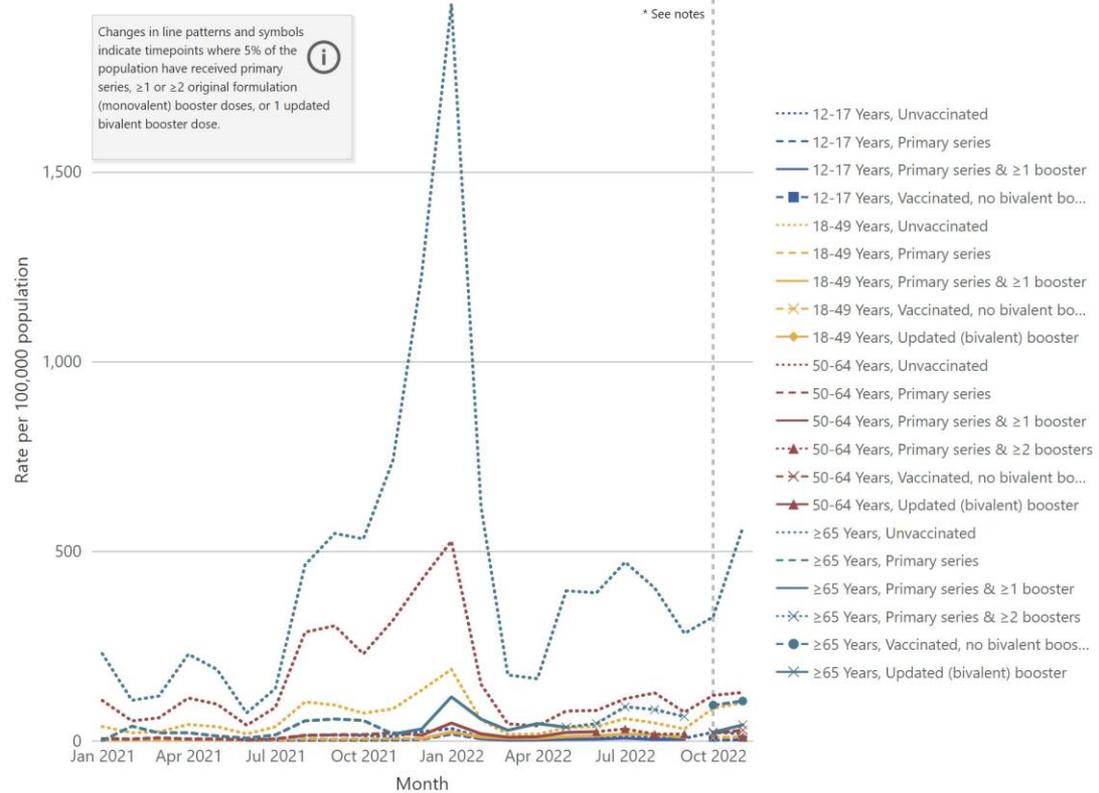
- ▶ Temporary protection
- ▶ More broad
- ▶ More durable

Epidemiological data (hospitalization over 65 years):



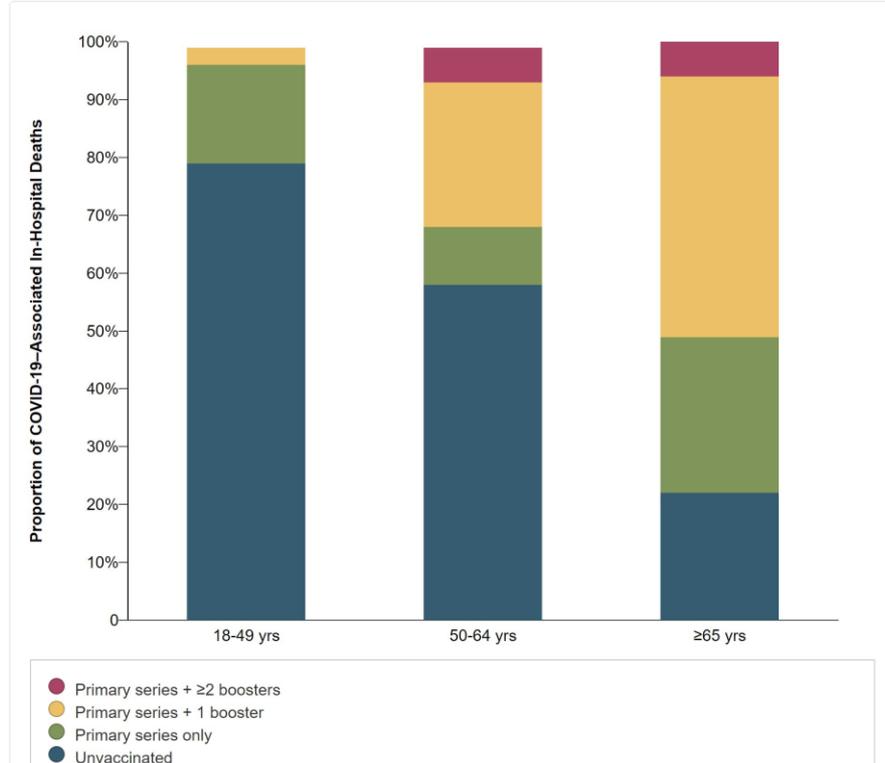
Still suffering

Monthly Rates of COVID-19-Associated Hospitalization by Vaccination Status
and Age Group, January 2021 - November 2022



Still suffering

In-Hospital Deaths by Age Group and Vaccination Status—May–August 2022



Source: CDC COVID-19 Technical Report, 2022

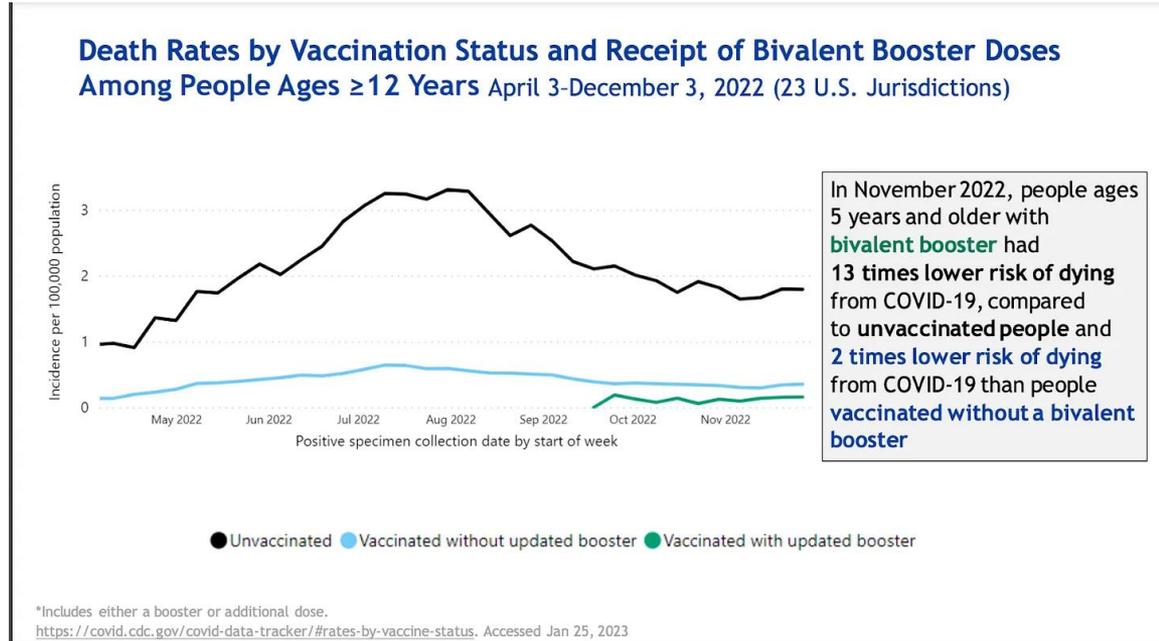
Dying "from" vs. "with"

Proportion of Deaths with COVID-19 as the Underlying Cause of Death by Year and Age Group, United States, 2020–September 2022.

Year	Persons aged <65 years	Persons aged ≥65 years
2020	92%	91%
2021	93%	89%
2022*	80%	77%

*Includes data for January–September 2022

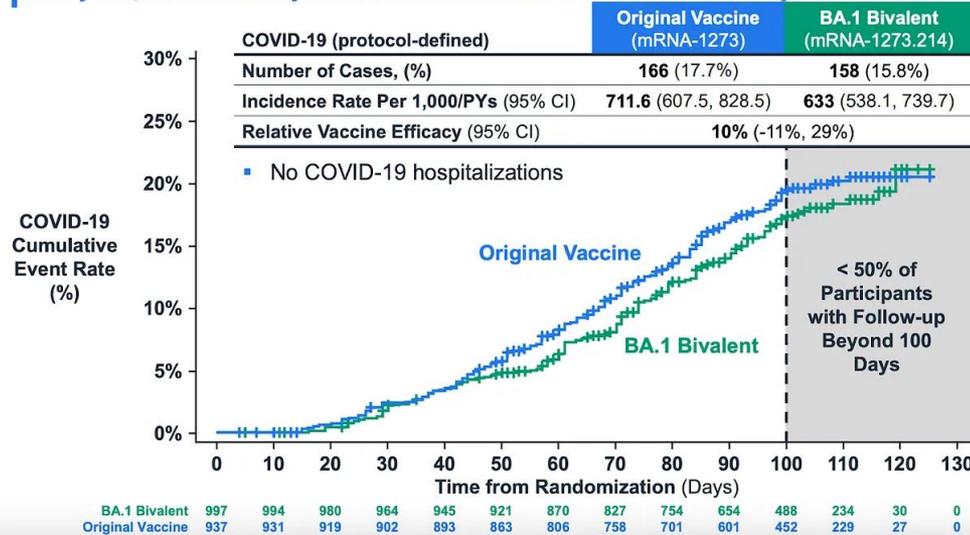
How are the vaccines working?



How are the current vaccines working?

Cumulative Incidence Curve of COVID-19 ≥ 14 Days Following Receipt of Omicron BA.1 Bivalent or Original Vaccine Booster

Study 305, Part 2: Primary Case Definition – Per Protocol Set for Efficacy



CO-21

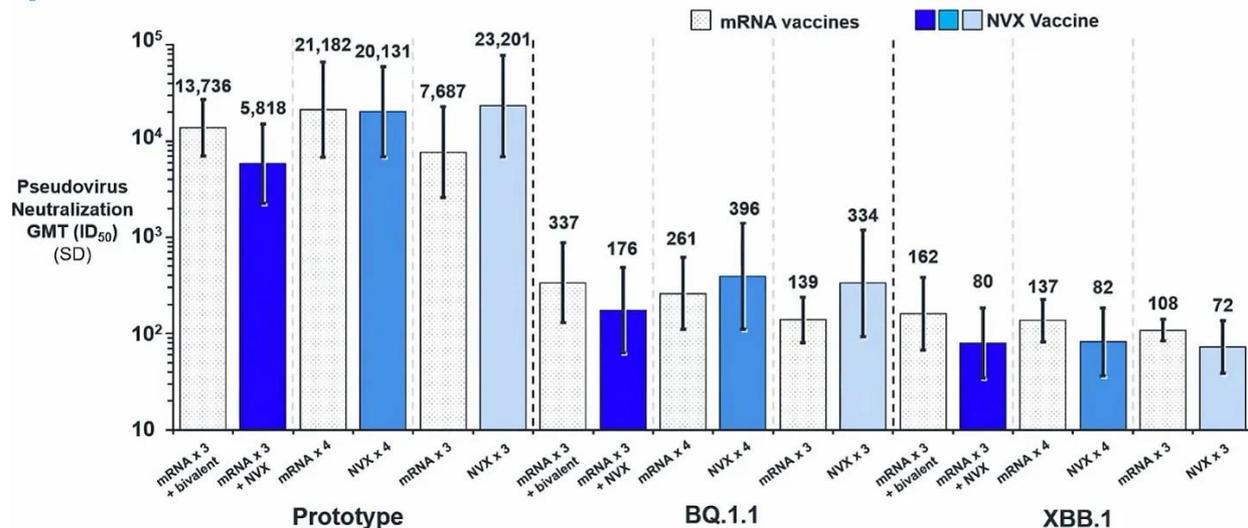
Stoke safety signal?

- ▶ Only one safety monitoring system found a signal. The other U.S. safety monitoring systems did not.
- ▶ Risk of signal was slightly elevated in the 1-21 days post vaccine
 - ▶ Risk of signal was LESS than expected in the 22-42 days post vaccine
- ▶ The safety signal attenuated last week.
- ▶ Concurrent flu vaccination did not explain this safety signal.
- ▶ Various countries in Europe, and Israel, have not seen increased risk in their surveillance systems. (This is incredibly reassuring).

Bottom line message: everyone who is eligible still needs to get vaccinated.

Pseudovirus Neutralization Responses Observed for BQ.1.1 and XBB.1 (Seronegative Participants*)

GMT levels similar across all boosting regimens



Data from Wang et al., 2022 and unpublished

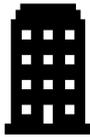
*Seronegative defined as anti-N negative as per testing in Dr. Ho's lab

FDA proposal

FLU:



Feb: Strain selection
by WHO



March: FDA decision



Fall: Vaccine roll-out

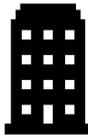


FDA proposal

FLU:



Feb: Strain selection
by WHO



March: FDA decision



Fall: Vaccine roll-out



COVID-19:



June: FDA decision



Sept: Vaccine roll-out



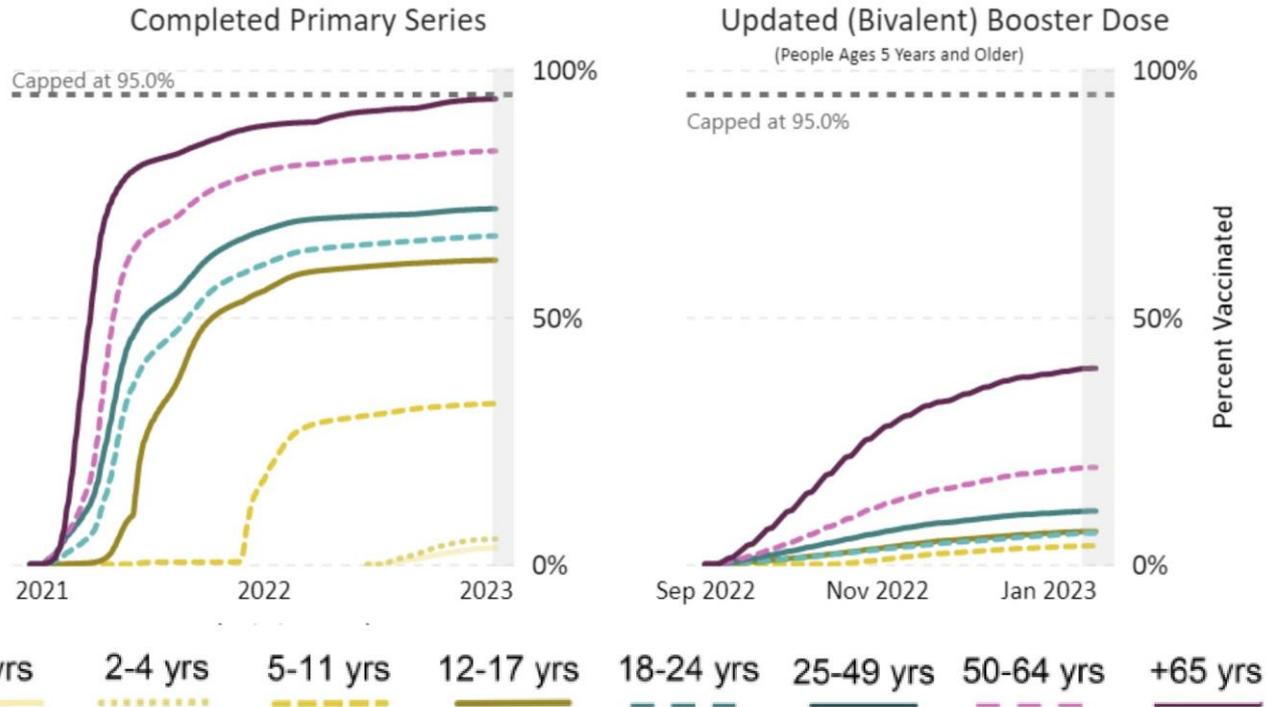
FDA proposal

The FDA defended a fall only campaign in three ways:

1. Winter is when the stress on hospital systems will be greatest
2. Already seeing seasonal patterns?
3. Eases implementation and decreases confusion for the public, which may help increase vaccine uptake.

Challenges with vaccinations

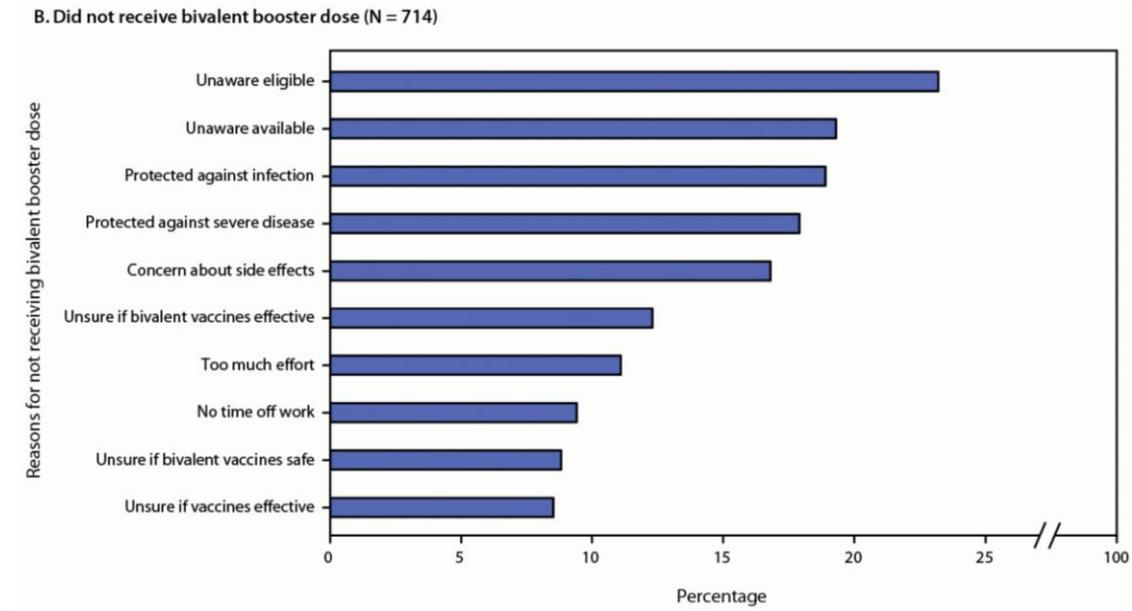
Vaccines ≠ Vaccination



Source: CDC website

Challenges with vaccinations

Vaccines \neq Vaccination



Unanswered questions

1. What about the WHO? Rest of the world?
2. Strain selection? Monovalent, bivalent?
3. What's the game plan if a random variant pops up?
4. Implication: Who gets it and when?

Time for Q & A

29

Participant Questions	Answer	Answered Time
If you have already received your Bivalent booster a year ago, should you get another one? Should those over 65 get the bivalent vaccine yearly or more frequently?	https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html?s_cid=11737:covid%20booster%20time%20frame.sem.ga:p:RG:GM:gen:PTN:FY22 you can find out when to get a booster tool here since it varies by age/immune status OR here are the schedules https://www.cdc.gov/vaccines/covid-19/downloads/covid-19-immunization-schedule-ages-6months-older.pdf	2/2/2023 12:17
Speaking on how the vaccines are doing, can you speak on what the mortality rates are per race/ethnicity of Covid patients currently? Are they going up or down?	Risk for COVID-19 Infection, Hospitalization, and Death By Race/Ethnicity https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html	2/2/2023 12:25
Are there any plans to combine with the flu vaccine?	live answered	2/2/2023 12:27
Will vaccines continue to be free?	live answered	2/2/2023 12:30
How will the vax component selection impact world travel? If I get be annual booster in the US, but it is not addressing other global variants.....I would assume I am not covered overseas. Is this true?	live answered	2/2/2023 12:33
Was there any information about people who haven't had original doses, will they need those before getting the yearly COVID vaccine?	live answered	2/2/2023 12:35
Can we address current excess death rates to highlight possible long term damage from infection, and how do we push back against claims that excess death is driven by vaccine toxicity?	live answered	2/2/2023 12:36
Since there are identified populations with the greatest morbidity and mortality risks, i.e.. >65yoa, immunocompromised, < 6mos of age, why are there no evolving recommendations focusing on these populations.	live answered	2/2/2023 12:39
For younger children (6 months) who need the vaccine now - can we start with bivalent series	No, you cannot start with bivalent vaccines right now, as a change has not been made to the clinical guidelines at this time. You can find the recommended dosing schedules for children here https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html#children As well as here https://www.illinoisvaccinates.com/vaccine-resources/#handouts	2/2/2023 12:40
In an effort to encourage folks to get vaccinated - Is it reasonable to explain to people that the bivalent vaccine provides approximately 40% protection against infection but more like 80% protection against severe disease? Correct the numbers please as needed!	live answered	2/2/2023 12:47
What surprised you most from the meeting?	live answered	2/2/2023 12:51
Just to clarify, regardless of vaccine status people ages 65 + are showing increase in death 1 year later from cardiovascular health complications?	live answered	2/2/2023 12:53
Can you comment on young children having such a robust response to the vaccine that they are more at risk of recurrence of COVID infection.	live answered	2/2/2023 12:54
Why do you believe the disparities are so great in those who are vaccinated but die 65 and older or otherwise of COVID-19?	live answered	

Please fill out this evaluation for CME/CE – **for live attendance only.**

Recording will be available on ICAAP's website.



Evaluation



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Thank You!

▶ Upcoming events:

Updates on Vaccine Hesitancy and Misinformation Wednesday, 2/22/23 at 12PM

With Dr. Peter Hotez

Register [here](#).



FREE CME available.

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Illinois Vaccinates Against COVID-19 (I-VAC) COVID-19

Vaccines Bootcamp

Friday, 3/4/23 from 8AM-12:15PM

Register [here](#).



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Bright Smiles from Birth (BSFB II) Webinar Friday, 2/24/23 at 8AM

Upon completion of this webinar, participants will be able to:

- Describe the pathogenesis of Early Childhood Caries (ECC) and its associated risks
- Conduct oral health screenings and apply fluoride varnish
- Provide anticipatory guidance to families and make referrals to a dental home when necessary.

Register [here](#).



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I-VAC Learning Collaboratives

Tuesday, 2/7/23 from 5:30-6:30PM (Pediatric)

Wednesday, 2/15/23 from 5:30-6:30PM (Adult)

Register [here](#). FREE CME available.

Register at illinoisap.org/events