



CDC/IDSA COVID-19 Clinician Call September 25, 2021

Welcome & Introductions

Dana Wollins, DrPH, MGC
Vice President, Clinical Affairs & Guidelines
IDSA

- 75th in a series of weekly calls, initiated by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.

Vaccine Boosters Update and Q&A



Understanding adaptive immunity and immune memory to SARS-CoV-2 and COVID-19 vaccines

Shane Crotty, PhD

Professor, Center for Infectious Disease and Vaccine Research
La Jolla Institute for Immunology



Perspectives from the Vaccines and Related Biological Products Advisory Committee (VRBPAC)

Hana M. El Sahly, MD

Professor of Molecular Virology and Microbiology, Baylor College of Medicine
Chair, VRBPAC, U.S. Food and Drug Administration



Archana Chatterjee, MD, PhD

Dean, Chicago Medical School and Vice President for Medical Affairs, Rosalind Franklin University
Member, VRBPAC, U.S. Food and Drug Administration



FDA Update

Peter Marks, MD, PhD

Director, Center for Biologics Evaluation and Research
U.S. Food and Drug Administration



Overview of CDC's Interim Recommendation for use of a single Pfizer-BioNTech vaccine booster dose

Erin Tromble, MD

Chief Medical Officer, Vaccine Task Force, CDC COVID-19 Response
Centers for Disease Control and Prevention

Vaccine Boosters Update and Q&A (continued)



Jennifer Layden, MD, PhD
Co-Lead, Vaccine Task Force
CDC COVID-19 Response



Neela D. Goswami, MD, MPH
Lead, Clinical Guidelines Team, Vaccine
Task Force, CDC COVID-19 Response

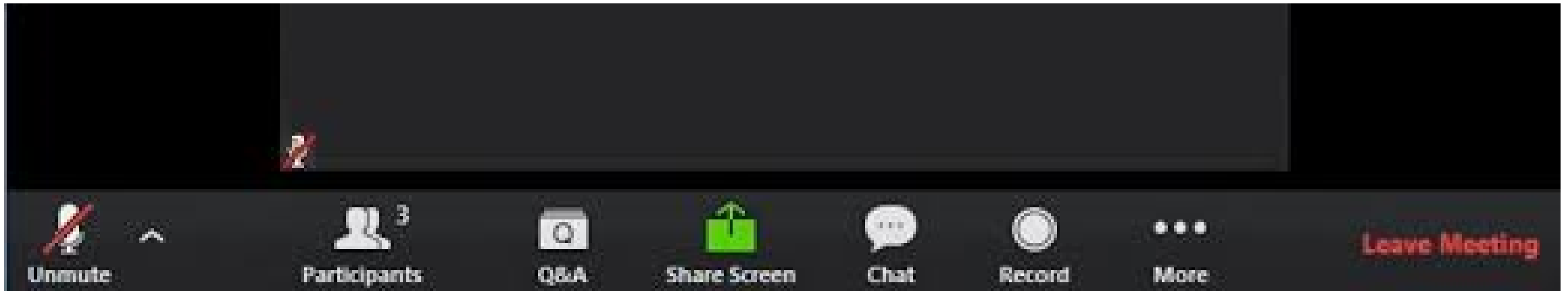
Disclosures

- **Shane Crotty, PhD:** None related to this vaccine topic. Dr. Crotty has consulted for GSK, JP Morgan, Citi, Morgan Stanley, Avalia NZ, Roche.
- **Hana M. El Sahly, MD:** Received NIH funding as co-PI of P301, the Phase 3 study evaluating the efficacy of mRNA1273 (Moderna vaccine), NIH funding as co-Investigator of the Phase 3 study evaluating the efficacy of NVX-CoV2373 (Novavax vaccine)
- **Archana Chatterjee, MD, PhD:** Nothing to disclose
- **Peter Marks, MD, PhD:** Nothing to disclose
- **Erin Tromble, MD:** Nothing to disclose
- **Jennifer Layden, MD, PhD:** Nothing to disclose
- **Neela D. Goswami, MD, MPH:** Nothing to disclose

Question?
Use the “Q&A” Button



Comment?
Use the “Chat” Button



Vaccine Boosters and Q&A

Understanding adaptive immunity and immune memory to SARS-CoV-2 and COVID-19 vaccines



Shane Crotty, PhD

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Understanding adaptive immunity and immune memory to SARS-CoV-2 and COVID-19 vaccines

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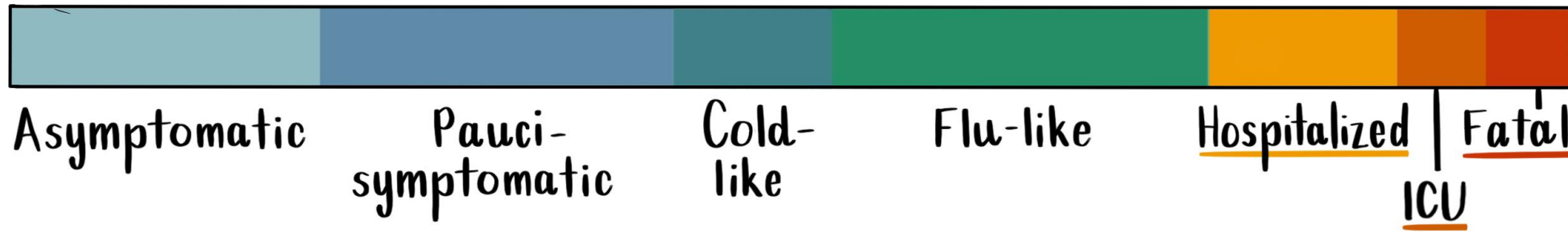
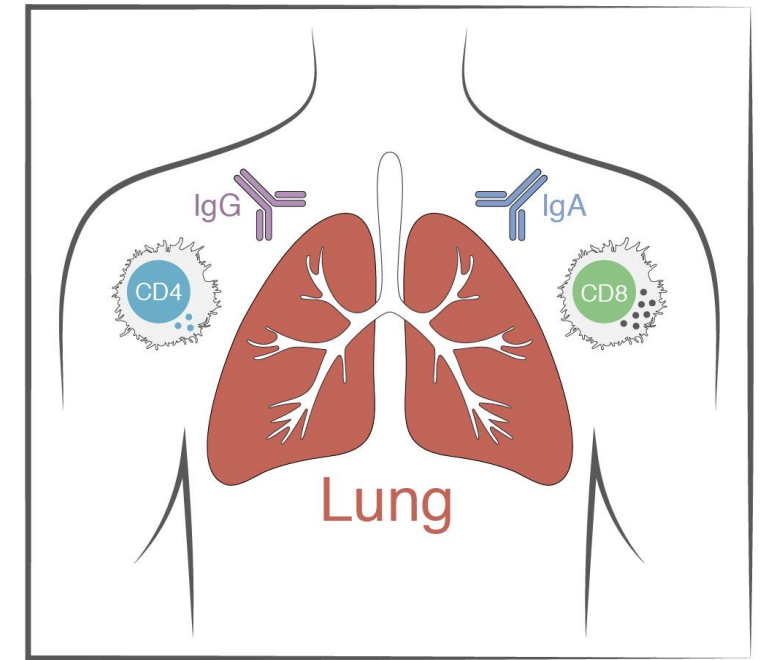
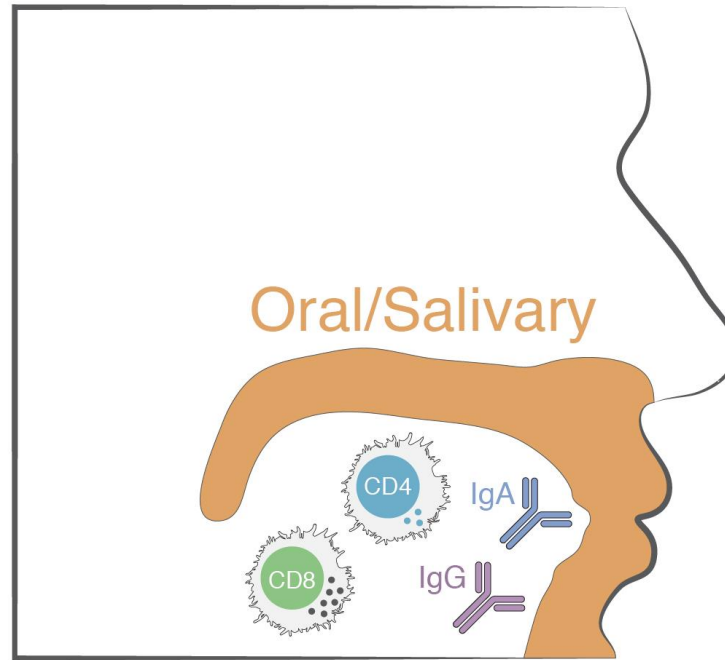
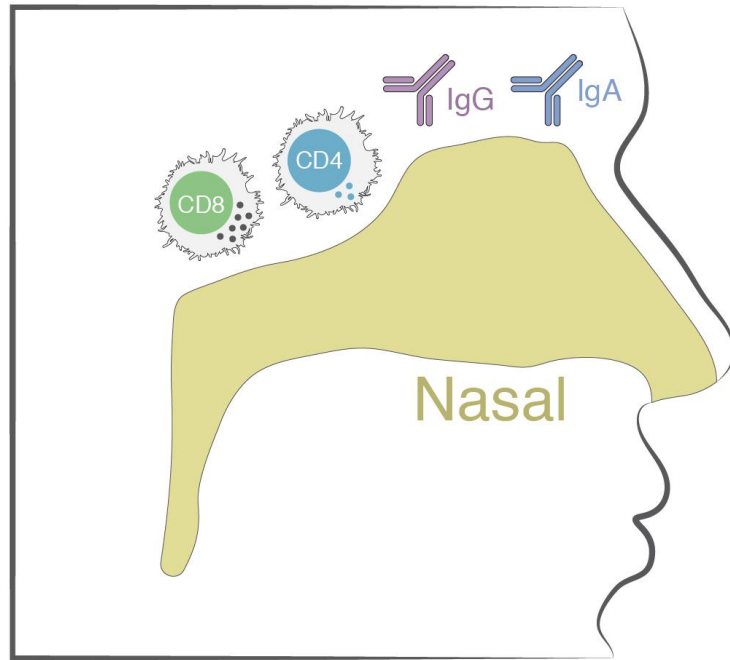
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Life
Without
Disease.®

What are mechanisms of protective immunity against COVID-19?

- ❖ The simplest option for any vaccine development is high level, long lasting, neutralizing antibodies.
- ❖ Various lines of evidence point to protective contributions of T cells against COVID-19
- ❖ It is reasonable to consider that hospitalization-level COVID-19 is prevented by any decent combination of antibody, memory B cells, CD4 T cells, and CD8 T cells.

Anatomy of adaptive immunity to SARS-CoV-2



It is all a race

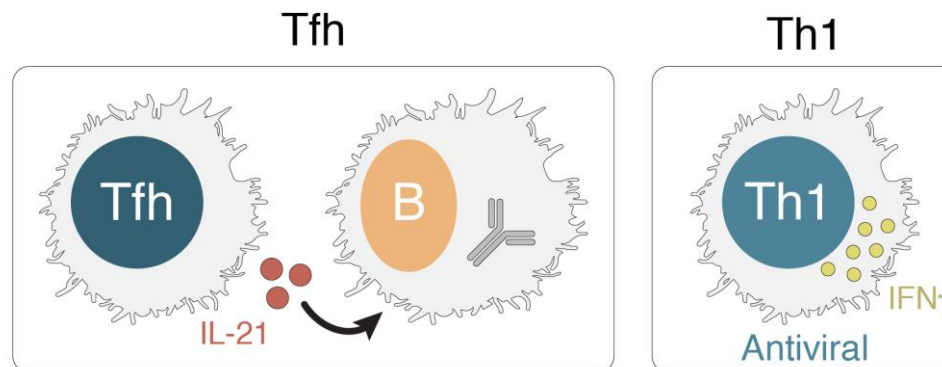
A race between the virus and your immune system.

Vaccines change the race. You then have the headstart instead of the virus.

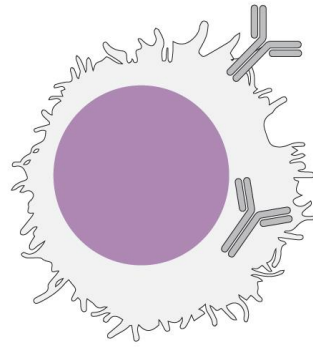
What are mechanisms of protective immunity against COVID-19?

The simplest option for any vaccine development is high level, long lasting, neutralizing antibodies.

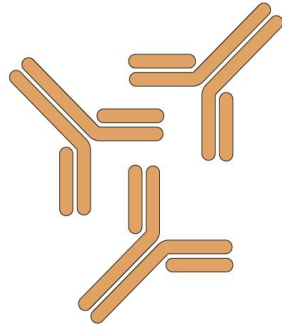
- This virus is clearly susceptible to neutralizing antibodies.
- Antibodies can clearly protect against COVID-19 in humans and animal models when present before infection. (Monoclonal antibody studies)
- Antibodies are the only mechanism that can provide truly sterilizing immunity.
- Antibodies correlate with protection from symptomatic COVID-19 in multiple human vaccine studies.
- Antibodies are a correlate of CD4 T cells: Neutralizing antibodies almost always depend on CD4 T cells. Thus, antibodies are usually a surrogate marker of vaccine-specific CD4 T cells, at least T follicular helper (T_{FH}) cells.



What are mechanisms of protective immunity against COVID-19?



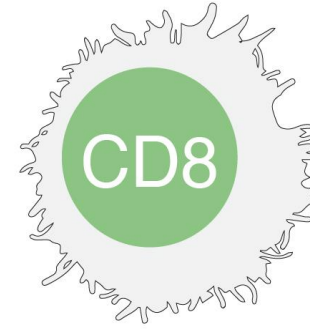
**Memory
B cell**



Antibodies

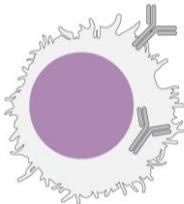


CD4+ T cells



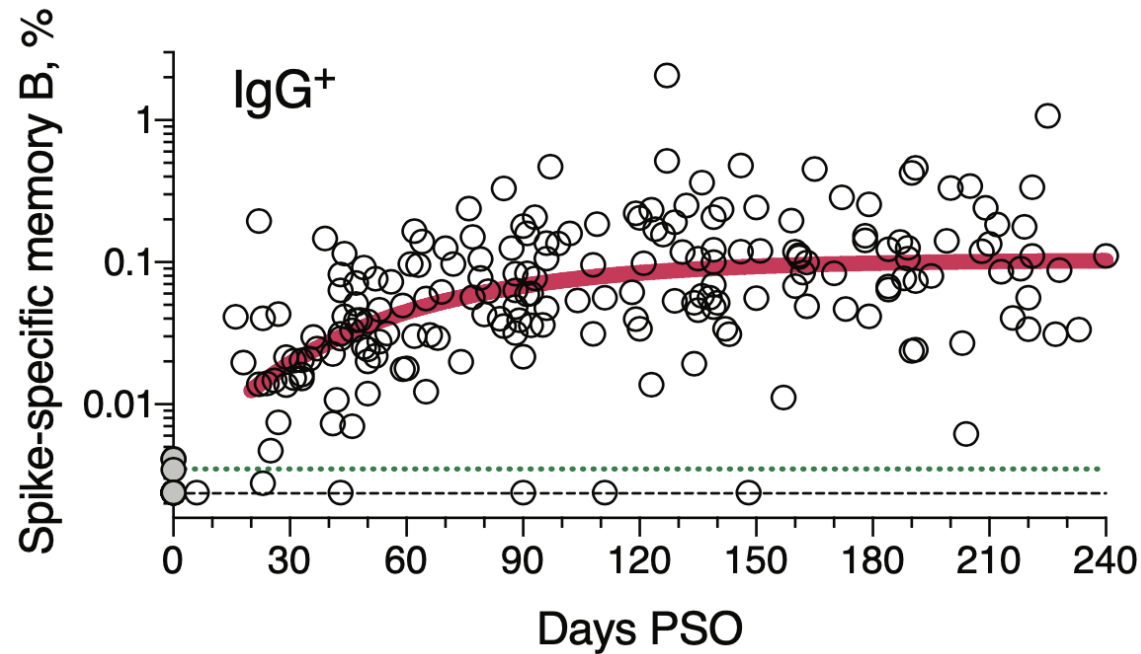
CD8+ T cells

Memory B cells to SARS-CoV-2



Memory B cell

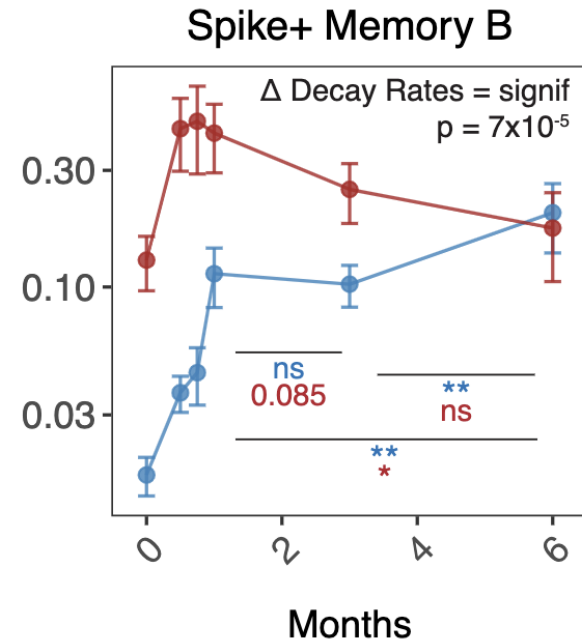
Memory B cells after SARS-CoV-2 infection



Memory B cells are present at substantial frequencies,
And actually increase between 1 and 8 months post-infection

Dan et al., Science. Jan 2021
doi: 10.1126/science.abf4063

Memory B cells after RNA vaccine

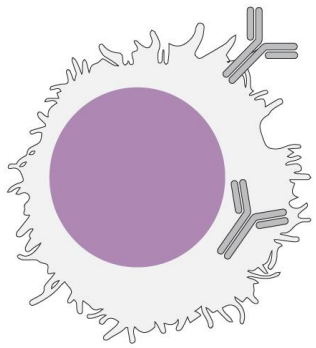


vaxxed

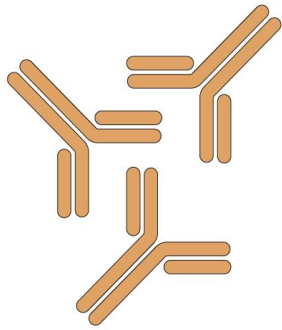
Inf + vaxxed

Goel et al., pre-print. Aug 2021
doi: 10.1101/2021.08.23.457229

What are mechanisms of protective immunity against COVID-19?



Memory
B cell

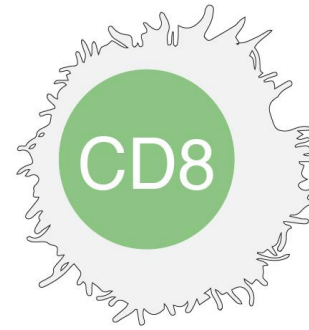


Antibodies



CD4+ T cells

Helpers



CD8+ T cells

Killers

* Important in many viral infections

* Critical for antibody responses

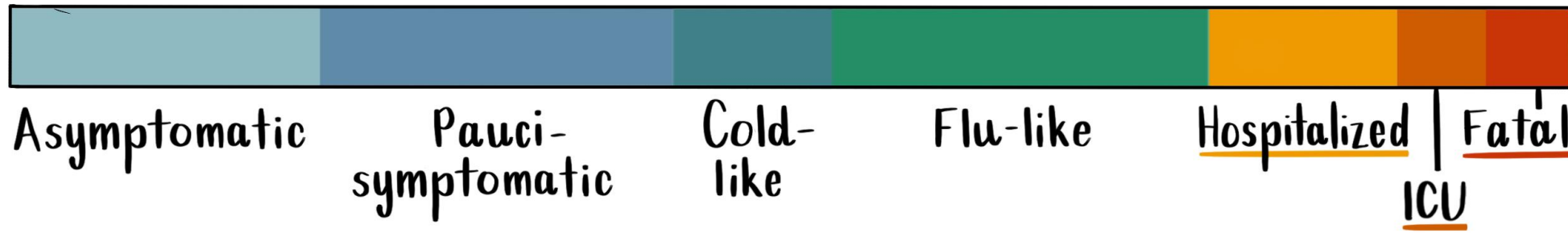
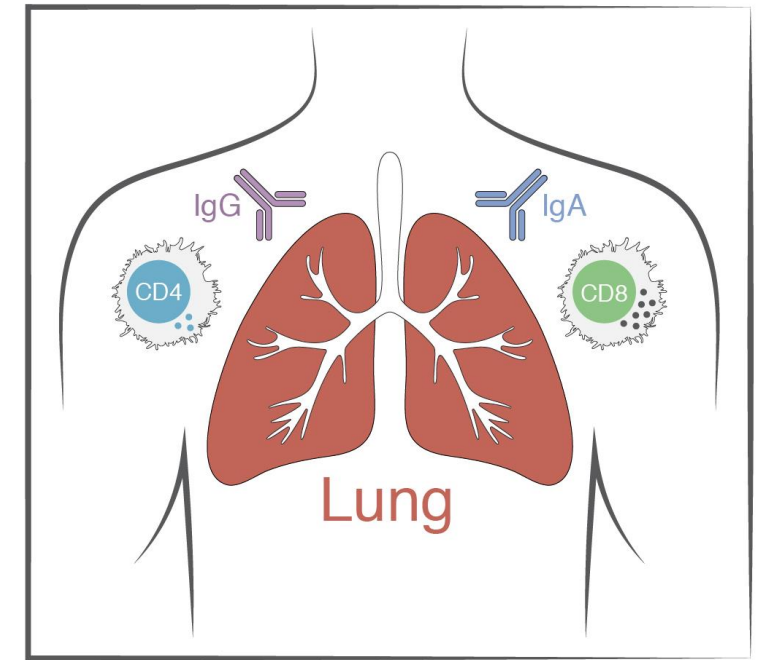
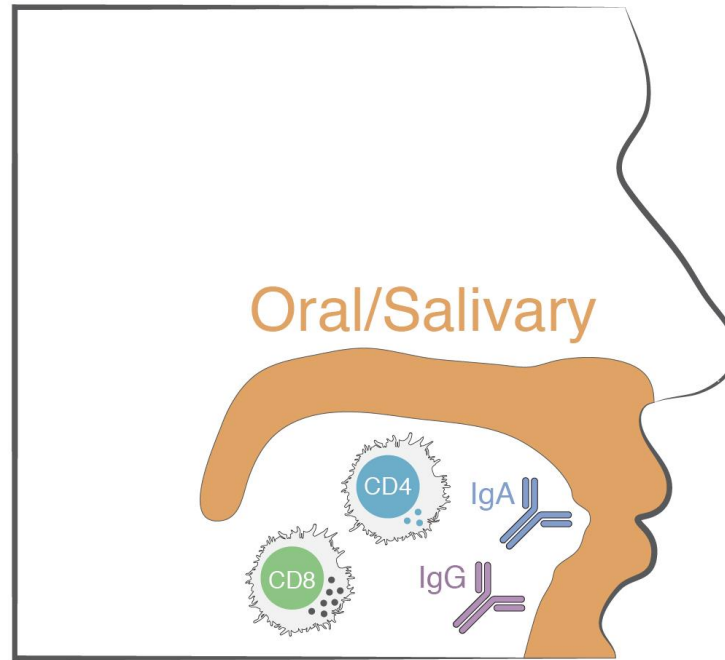
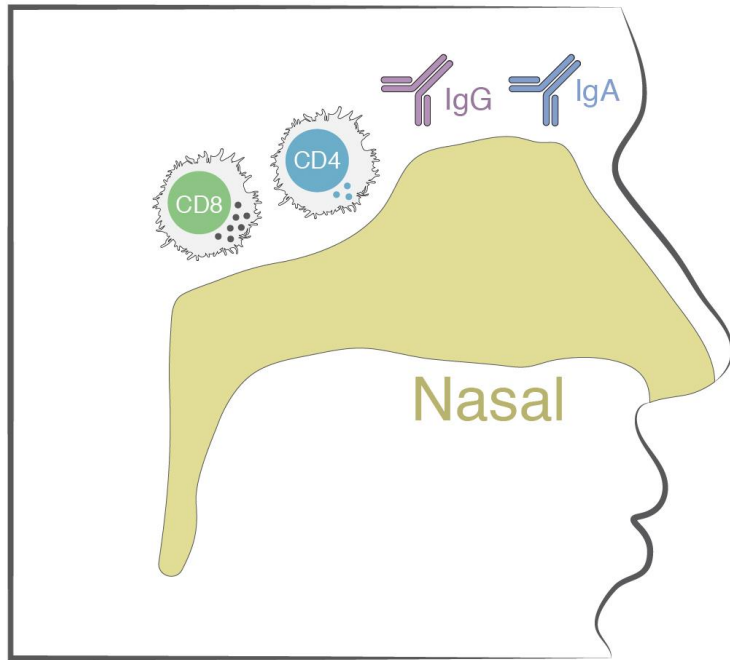
* Can have direct antiviral activities

What are mechanisms of protective immunity against COVID-19?

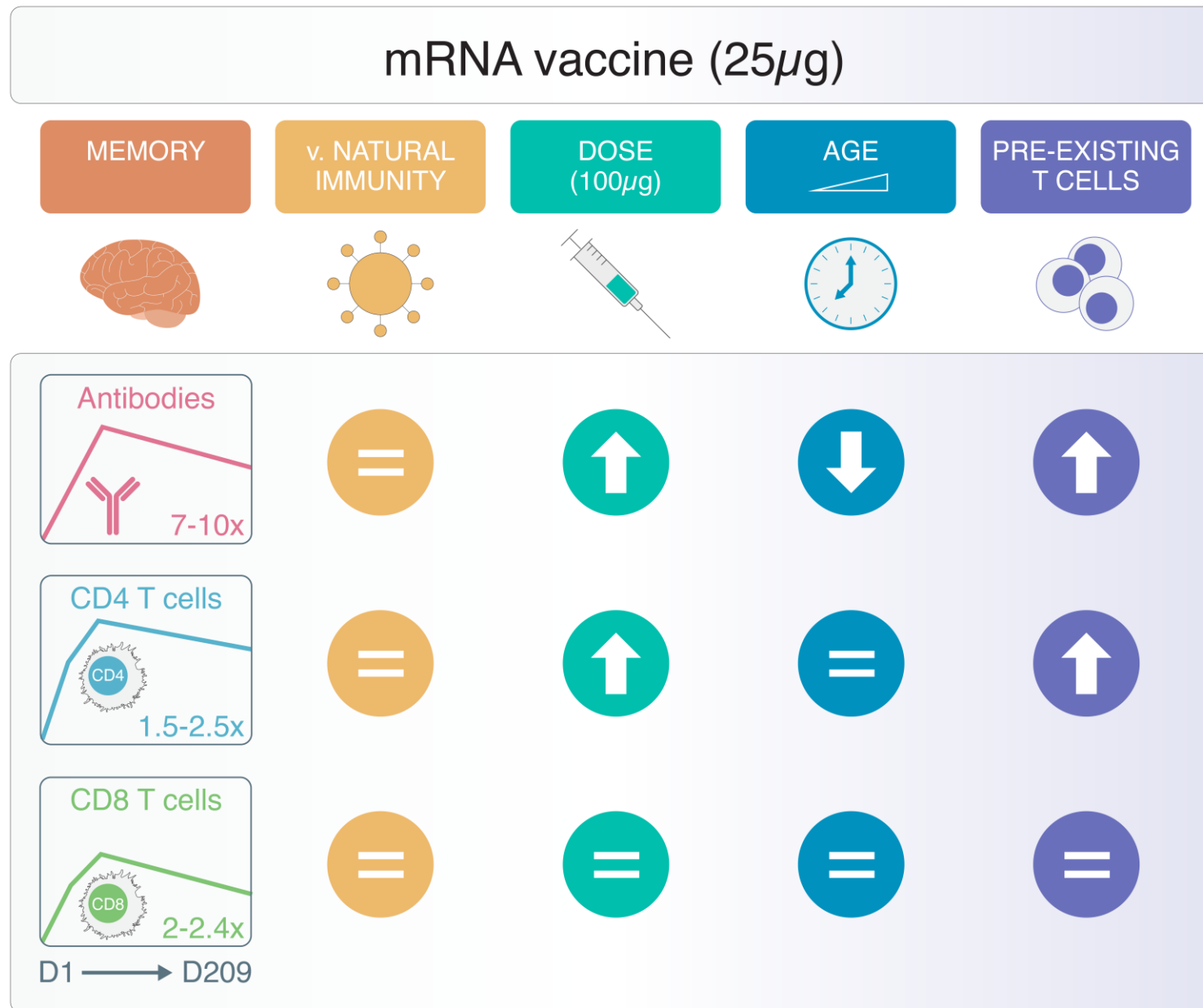
Various lines of evidence point to protective contributions of T cells

- T cell responses correlate with better outcomes and lower viral loads in SARS-CoV-2 infection
- CD8 T cells provide control in monkeys
- Regeneron and Lilly outpatient and inpatient monoclonal antibody clinical trials. Modest impact on viral loads
- Agammaglobulinemic and B cell depleted individuals
 - moderately increased risk of hospitalization with COVID-19
 - COVID-19 in ocrelizumab-treated people with MS is predominantly mild
- 1-dose of Moderna or Pfizer vaccine provided substantial protection with low or absent neutralizing antibodies in most individuals
- Crossreactive T cells in human may be associated with partial protection
- T cell responses to vaccines in NHPs correlate with better outcomes and lower viral loads

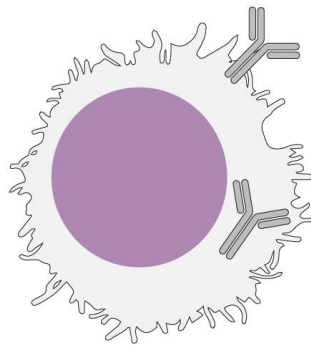
Anatomy of adaptive immunity to SARS-CoV-2



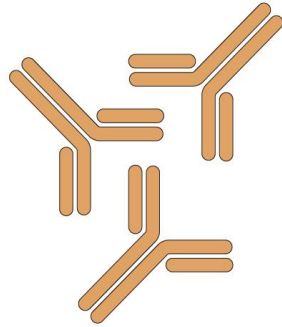
Low dose Moderna mRNA-1273 COVID-19 vaccine



What are mechanisms of protective immunity against COVID-19?



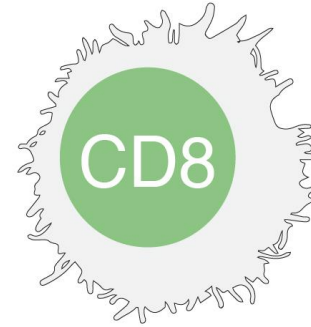
**Memory
B cell**



Antibodies



CD4+ T cells

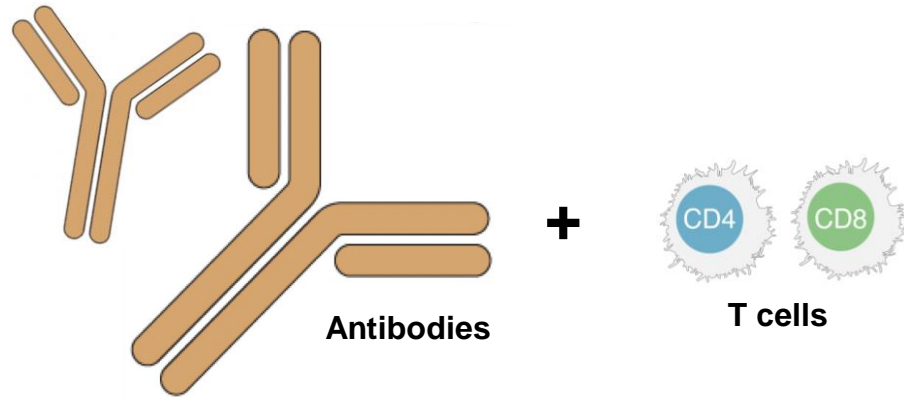


CD8+ T cells

It is reasonable to consider that hospitalization-level COVID-19 is prevented by any decent combination of antibody, memory B cells, CD4 T cells, and CD8 T cells.

Vaccine protection against SARS-CoV-2

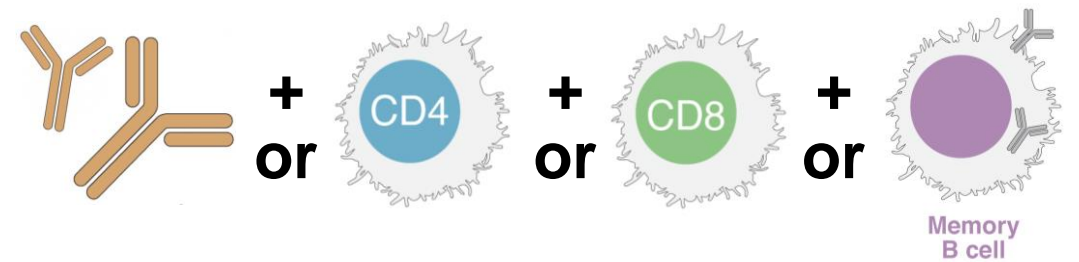
Protection against
Detectable Infection



Major

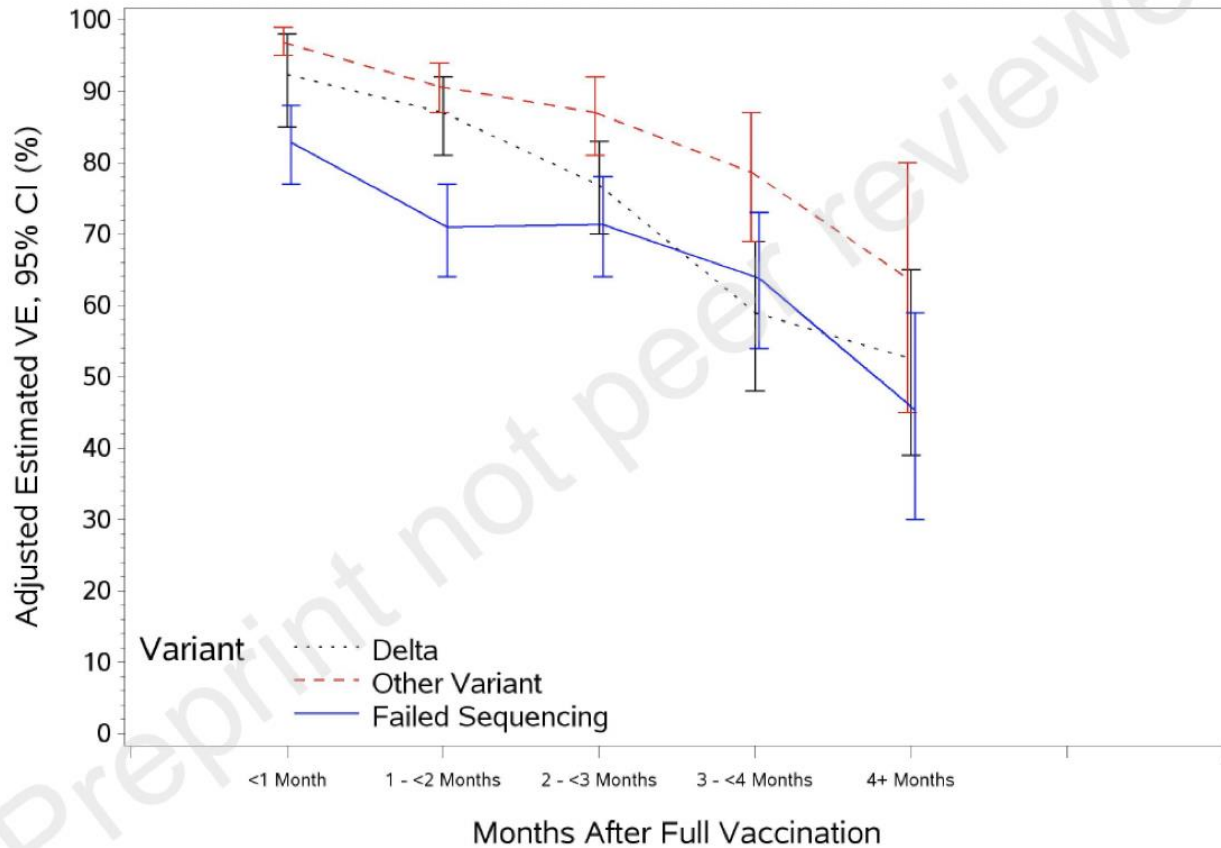
Minor

Protection against
Hospitalizations & Deaths



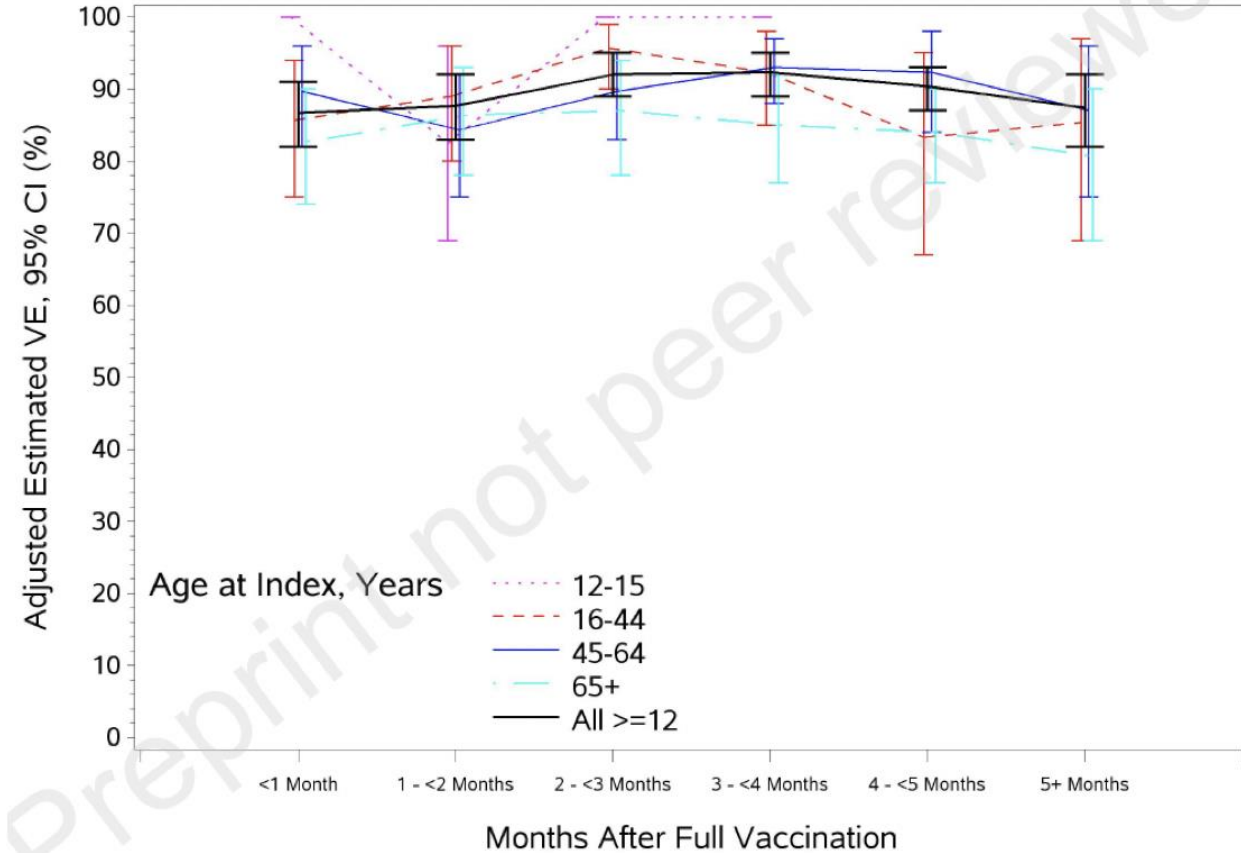
Waning protection against Detectable Infection

C4591014 VE study, Age 12+

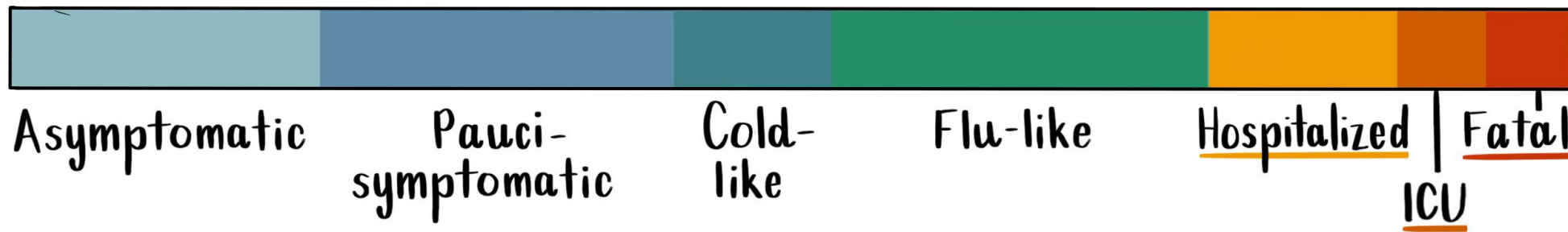
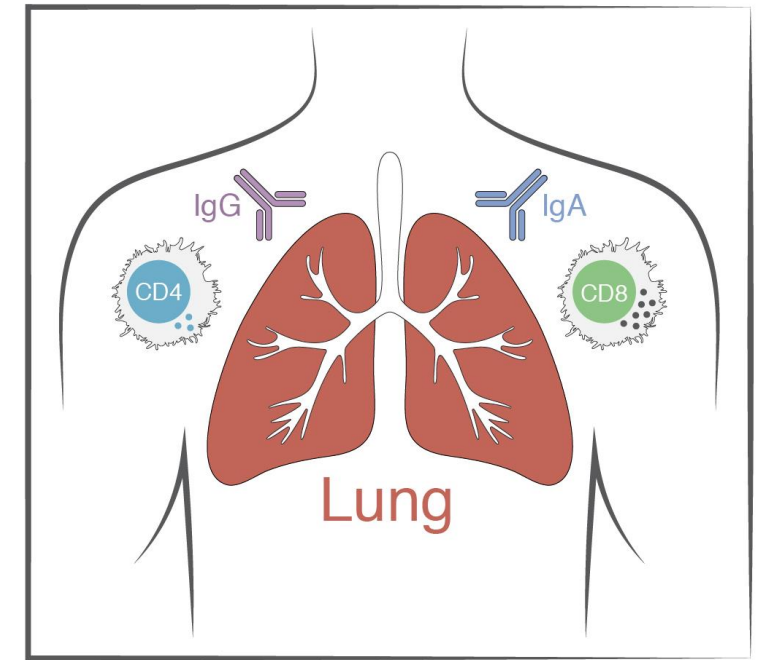
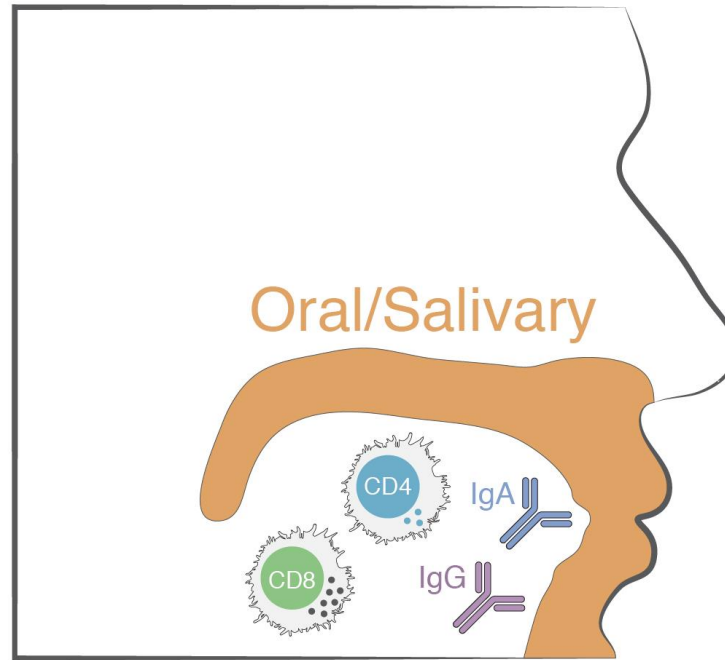
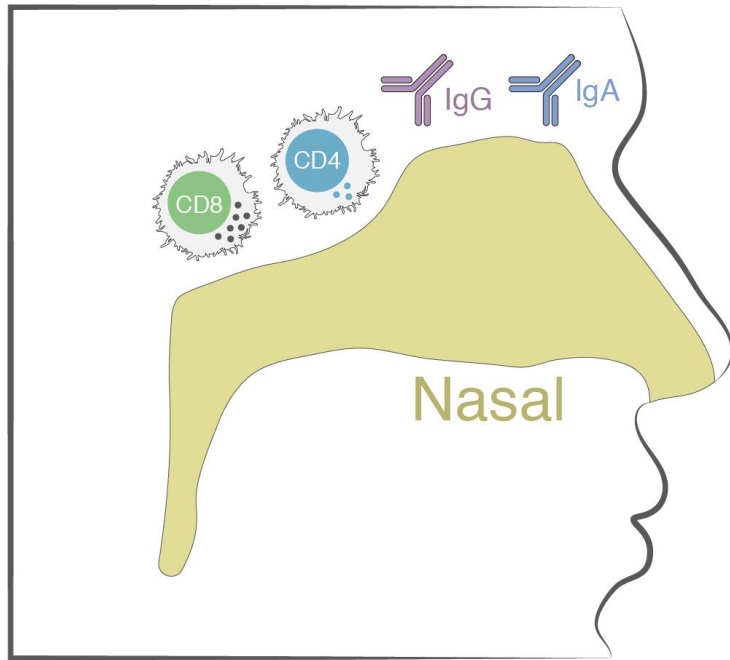


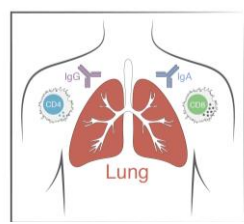
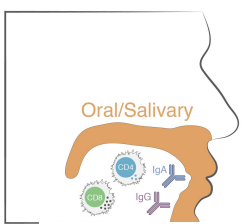
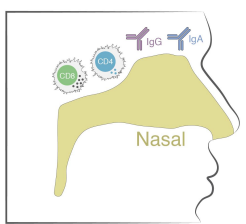
No waning protection against Hospitalizations & Deaths

C4591014 VE study, Age 12+

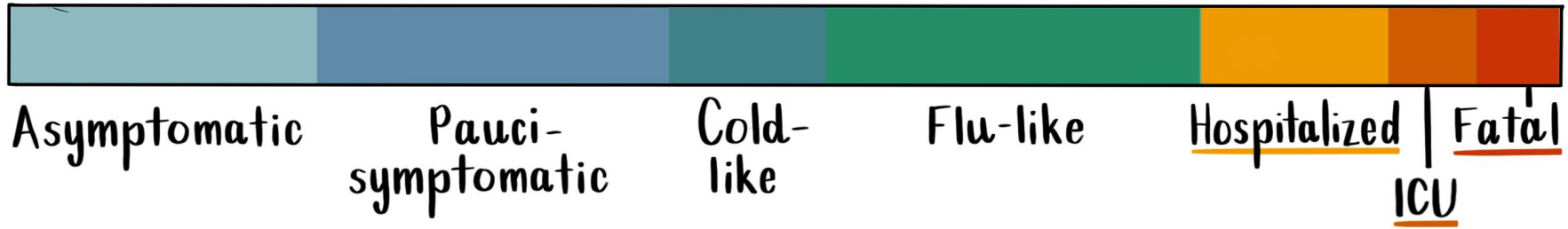


Anatomy of adaptive immunity to SARS-CoV-2



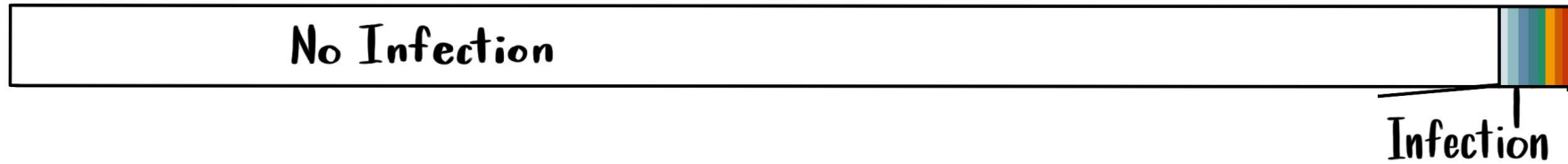


Unvaccinated



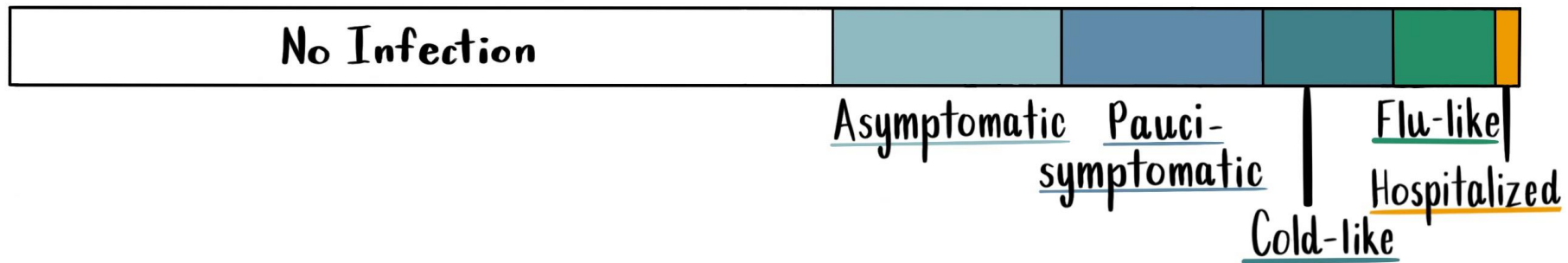
Vaccinated

Recent

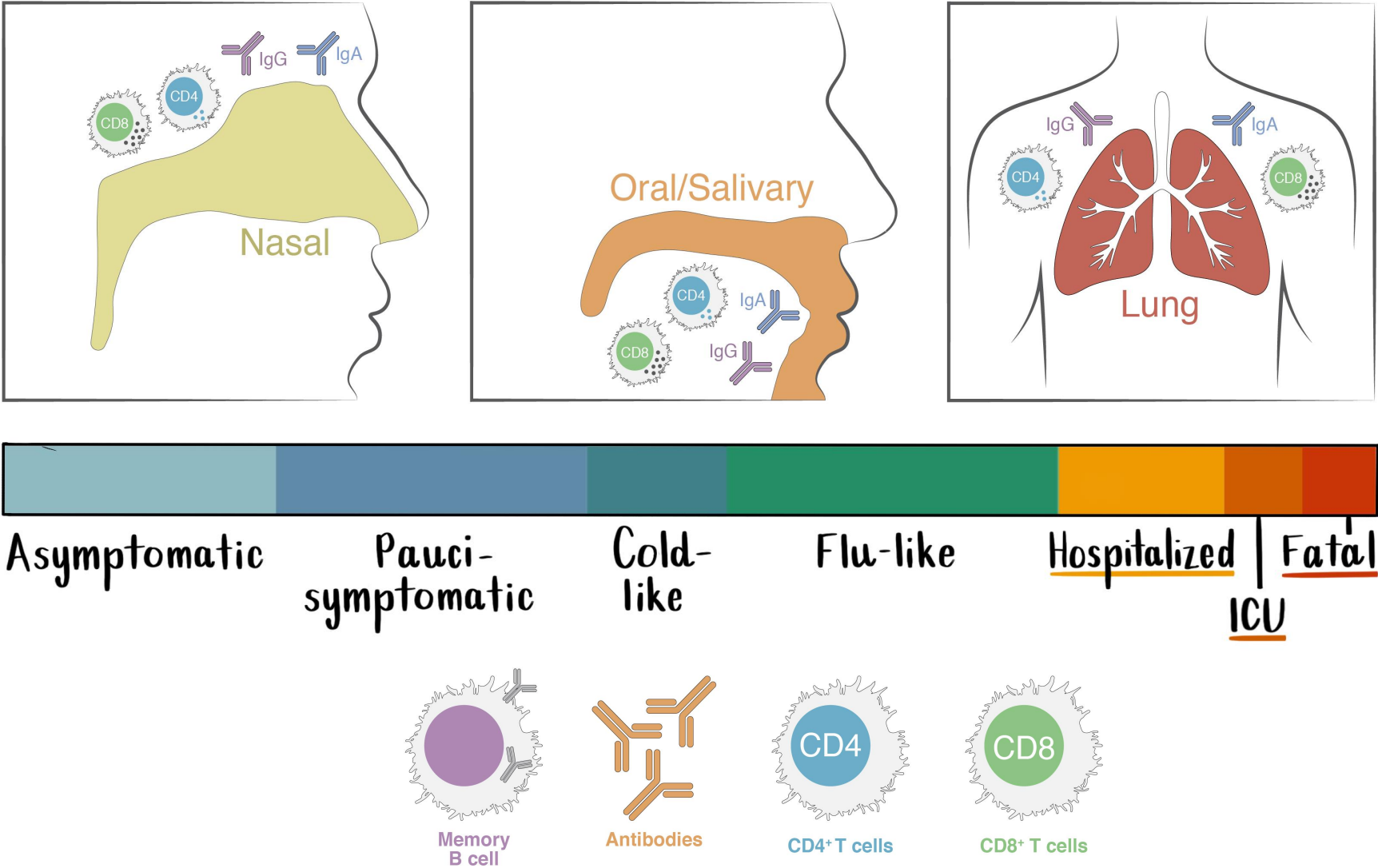


Vaccinated

6 months ago



Limitations: A working model has been presented here of immunological factors that may contribute to protective immunity in humans, based on a preponderance of data, but these are not proven.



THE TEAM

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Prof. Shane Crotty



Carolyn Rydyznski
Moderbacher, PhD



Sydney Ramirez,
MD/PhD



Prof. Jen Dan
MD/PhD



Yu 'Alex' Kato, PhD



Prof. Alex Sette



Alba Grifoni, PhD



Prof. Daniela
Weiskopf



Jose Mateus, PhD



Alison Tarke, PhD



Anonymous Philanthropic Support



Crotty Lab

Carolyn Rydyznski
Moderbacher
Sydney Ramirez
Prof. Jennifer Dan
Yu 'Alex' Kato
Simon Belanger
Katia Faliti
Christina Kim

Robert Abbott
Eleanor Crotty
Jinyong Choi
Sonya Haupt
Zeli Zhang
Nate Bloom
Ben Goodwin

Sette Lab

Alba Grifoni
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Esther Yu
Ricardo Da
Silva Antunes
Nils Methot
Jenna Memollo
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Jose Mateus
James Chang

Sapphire Lab

Kathryn Hastie
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Clinical Studies Core

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Shariza Bautista
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LJI Bioinformatics Core

Jason Greenbaum

LJI Flow Cytometry Core

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UCSD

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Mt. Sinai Med

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Viviana Simon

Vanderbilt University

Simon Mallal

JCVI

Richard Scheuermann

Vaccine Boosters and Q&A

Perspectives from the Vaccines and Related Biological Products Advisory Committee (VRBPAC)



Hana M. El Sahly, MD

Professor of Molecular Virology and Microbiology
Baylor College of Medicine
Chair, VRBPAC, U.S. Food and Drug Administration



Archana Chatterjee, MD, PhD

Dean, Chicago Medical School
Vice President for Medical Affairs
Rosalind Franklin University
Member, VRBPAC, U.S. Food and Drug Administration

VRBPAC MEETING

17SEP2021

Pfizer-BioNTech's supplemental BLA for a third dose, or "booster" dose, of Comirnaty in individuals 16 years of age and older

Hana El Sahly, MD and Archana Chatterjee, MD PhD

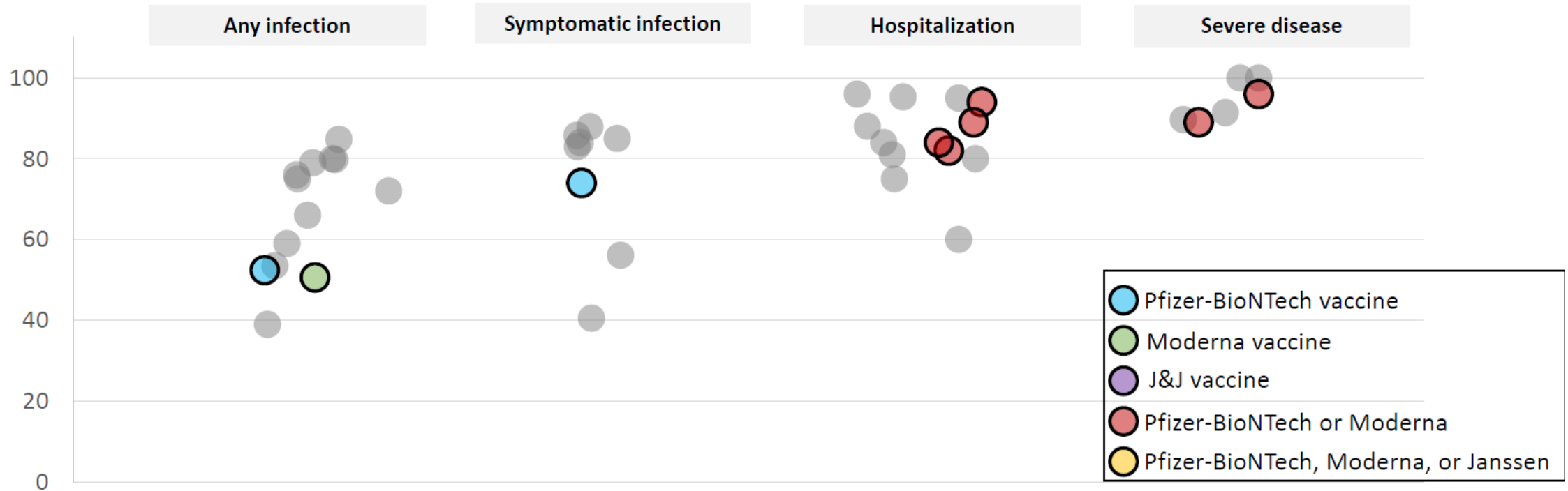
COVID-19 Epidemiology and COVID-19 Vaccines

Dr. Sara Oliver (CDC)

- Trends in number of COVID-19 cases in the US: delta wave has peaked
- After a rapid rise, there is a decline in weekly of COVID-19 associated hospitalizations.
- As of Sep 14th: 82.5% of elderly population and 63.1% of those 12 years of age and older were fully vaccinated
- After an increase in daily number of new vaccinees in July, a decline began in Sep
- COVID-19 vaccines continue to maintain high protection against severe disease, hospitalization, and death
- Protection against infection lower in recent months: time since primary series versus Delta variant?

Summary of **VE estimates** since introduction of the Delta variant

Adults ≥ 60 years of age



- Vaccine effectiveness of Pfizer-BioNTech COVID-19 vaccine against symptomatic illness with Delta is similar among those aged ≥ 60 years compared with younger age groups
- Persistence of vaccine effectiveness against hospitalization remains high

See reference list in later slides

“Real-world” effectiveness of vaccines

Dr. Jonathan Sterne

- Estimated effectiveness of vaccines that is biased, by an unknown amount
- Baseline confounding (presence of characteristics predicting both vaccination and outcome)
- Defining the comparison group: Very rapid rollout of vaccination, so unvaccinated people rapidly become vaccinated. Solution: split follow up time for each individual into unvaccinated and post-vaccination
- Time-varying confounding
- Unmeasured confounding
- Accounting for pandemic waves
- Characterising persistently unvaccinated individuals

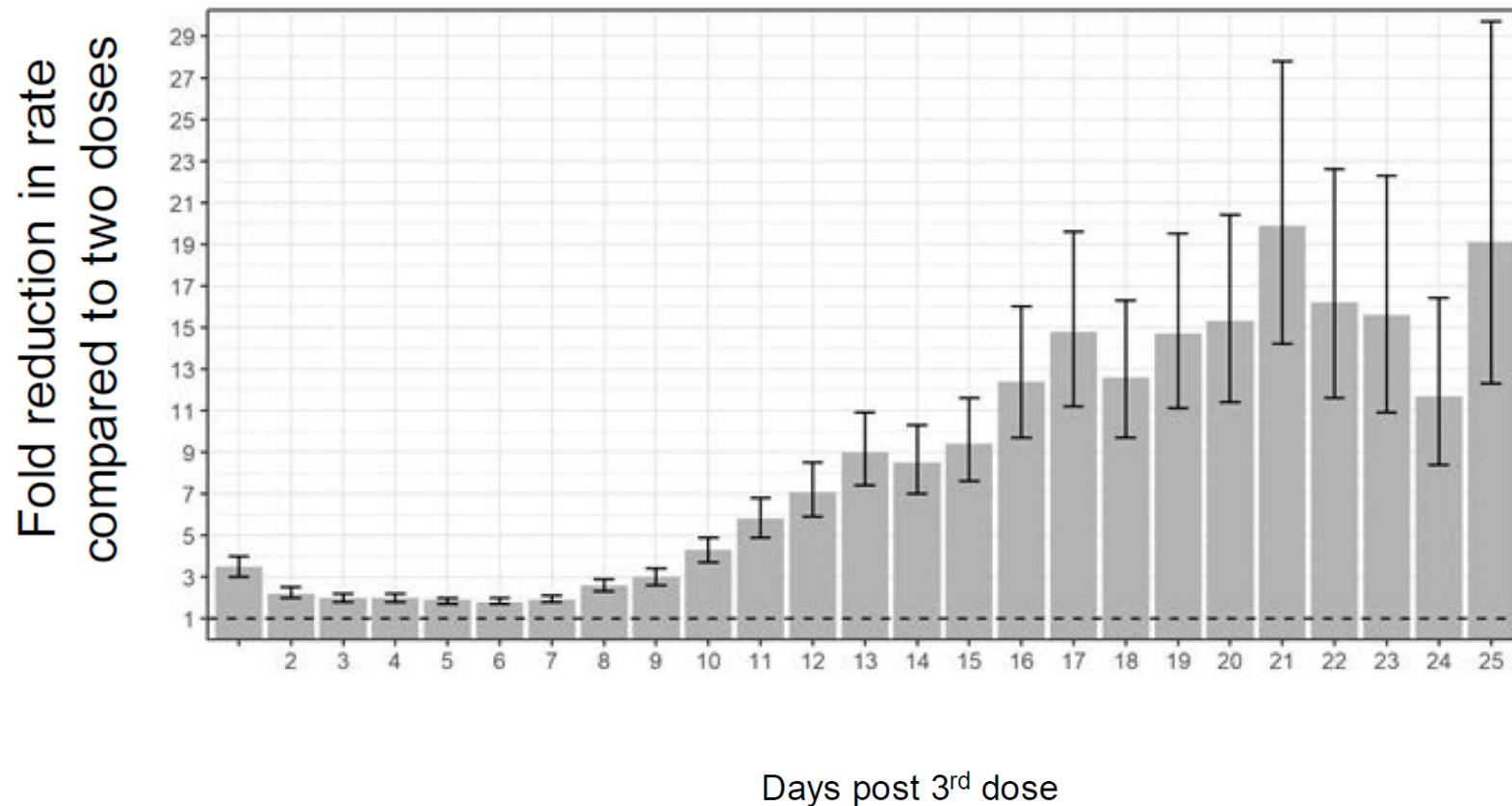
“Real-world” effectiveness of vaccines

Dr. Jonathan Sterne

Study Location (reference)	Vaccine	Effectiveness vs. severe disease or hospitalization	Lower limit of 95% CI	Upper limit of 95% CI
USA, Southern California KPSC (1)	BNT162b2 or mRNA-1273	93	84	96
USA, Minnesota (2)	BNT162b2	75	24	94
	mRNA-1273	81	33	96
USA, New York (3)	BNT162b2; mRNA-1273; Ad26.COVS.2.S	94.4	92.7	95.7
USA 13 jurisdictions (5)	BNT162b2; mRNA-1273; Ad26.COVS.2.S	90.4	87.7	92.5
USA, 7 locations VISION network (7)	BNT162b2	87	85	90
	mRNA-1273	91	83	93
USA, 9 States VISION network (8)	BNT162b2	80	73	85
	mRNA-1273	95	92	97
USA, 5 VA Medical Centers (9)	mRNA-1273	89	80	94
USA (14)	mRNA-1273	96	91	98
Israel, (4)	BNT162b2	88	94	91
Qatar (10)	BNT162b2	89.7	61	98.1
Qatar (11)	mRNA-1273	100	41.2	100
Singapore (12)	BNT162b2 or mRNA-1273	93	66	98
UK (13)	BNT162b2	96	86	99

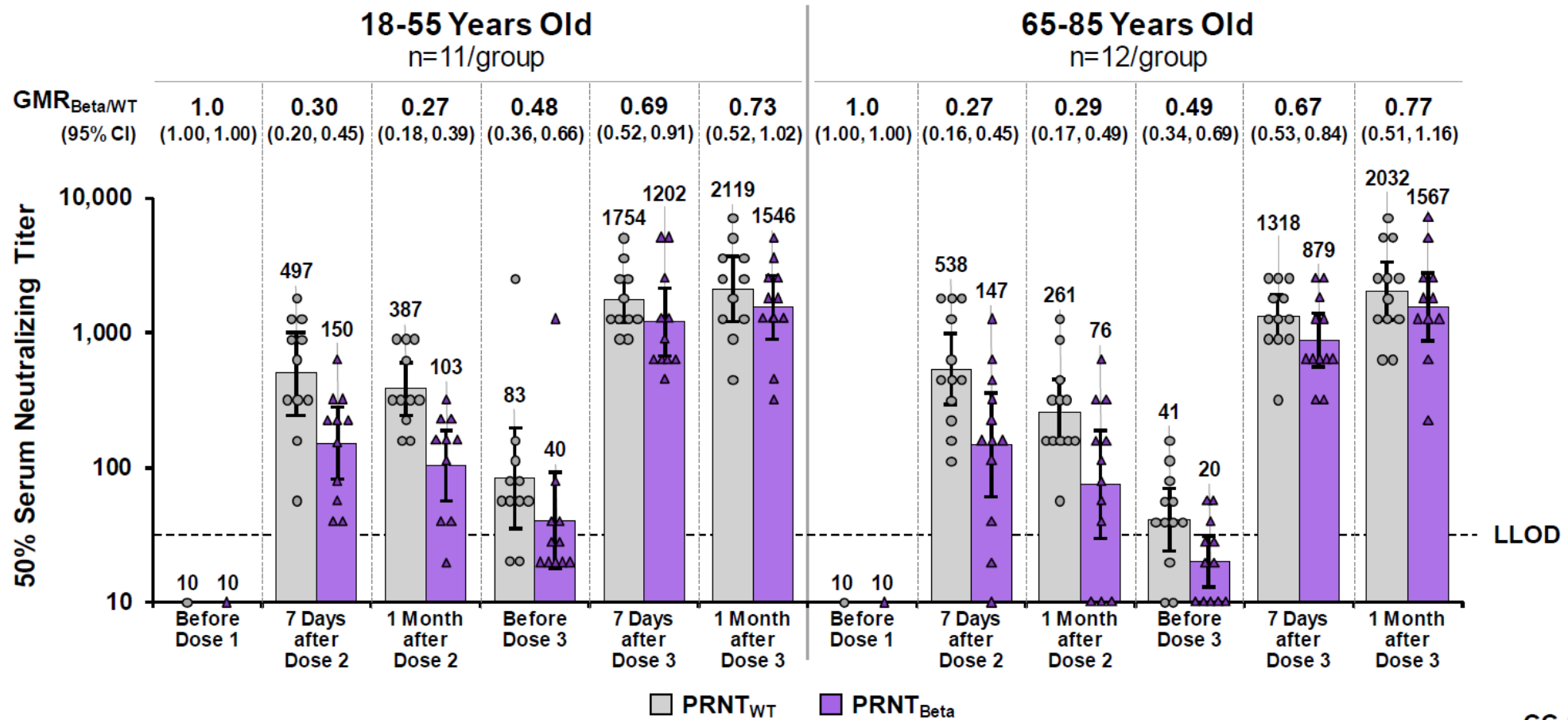
Booster Effectiveness- data from Israel

Drs. S. Alroy-Preis and Dr. R. Milo



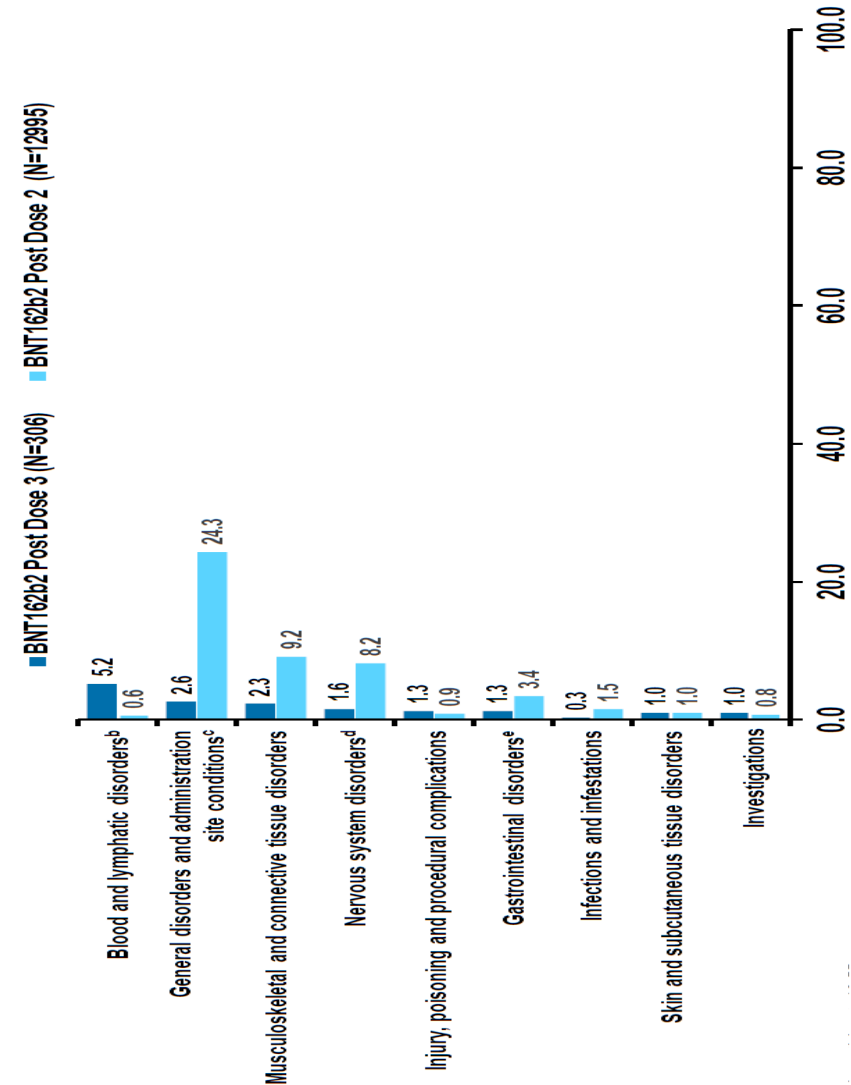
- Vaccinated vs Unvaccinated population Differences
- Brief Duration of follow up
- Severity Criteria Differences
- Epidemiologic Differences

COMIRNATY® Booster (Third) Dose Pfizer



COMIRNATY® Booster (Third) Dose Pfizer

- In another study: 306 participants received a 3rd dose 7 mo post dose 2
- Systemic Events by Maximum Severity within 7 Days of 3rd Dose Similar to Post-dose 2
- Local Reactions by Maximum Severity within 7 Days of 3rd Dose Similar to Post-dose 2



Question to the Committee

1. Do the safety and effectiveness data from clinical trial C4591001 support approval of a COMIRNATY booster dose administered at least 6 months after completion of the primary series for use in individuals 16 years of age and older?

VRBPAC Deliberations and Concerns

- Is there an unmet need? VE against outcomes of interest (Severe COVID) remains very high in the US.
- Unmet need remains expanding vaccine coverage: adults, adolescents and children
- Unclear incremental public health advantage of vaccinating the vaccinated
- Age groups in the Q to the committee not represented in the clinical trial
- Data presented from clinical trials on a very limited # of participants
- The BLA expansion to a booster rests heavily on immunogenicity data in the absence of an antibody threshold for protection
- What is the role of cellular immunity?

Voting Question to the Committee

- Do the safety and effectiveness data from clinical trial C₄₅₉₁₀₀₁ support approval of a COMIRNATY booster dose administered at least 6 months after completion of the primary series for use in individuals 16 years of age and older?

Please vote Yes or No

16 NO votes vs 2 Yes votes



EUA CRITERIA

- Serious or Life-Threatening Disease or Condition
- Medical products that may be considered for an EUA are those that "may be effective" to prevent serious or life-threatening diseases or conditions
- Known and potential benefits of the product... outweigh the known and potential risks of the product
- No Alternatives

Amended Voting Question to the Committee

- Based on the totality of scientific evidence available, including the safety and effectiveness data from clinical trial C4591001, do the known and potential benefits outweigh the known and potential risks of a Pfizer-BioNTech COVID-19 vaccine booster dose administered at least six months after completion of the primary series for:
 - individuals 65 years of age and older; and
 - individuals at high risk of severe COVID-19.

Please vote Yes or No



18 Yes votes

Polling Question to the Committee

- Should healthcare workers or others at high risk for occupational exposure be included in the EUA?

Please vote Yes or No  **18 Yes votes**

Vaccine Boosters and Q&A

FDA Update



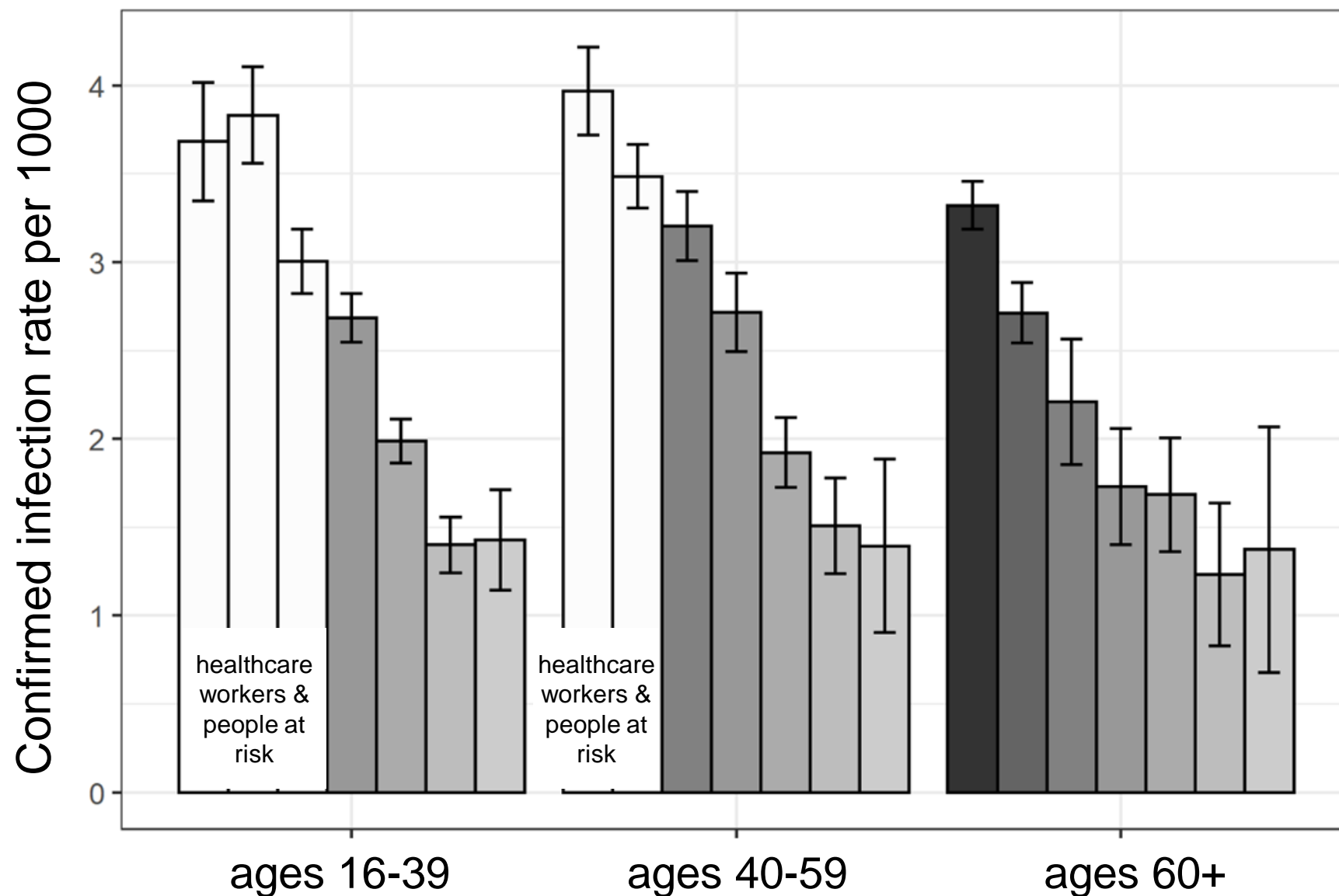
Peter Marks, MD, PhD

Director, Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

Waning immunity in Israel was observed across age groups

Rate of confirmed **SARS-CoV-2 infections** stratified by vaccination period and age group

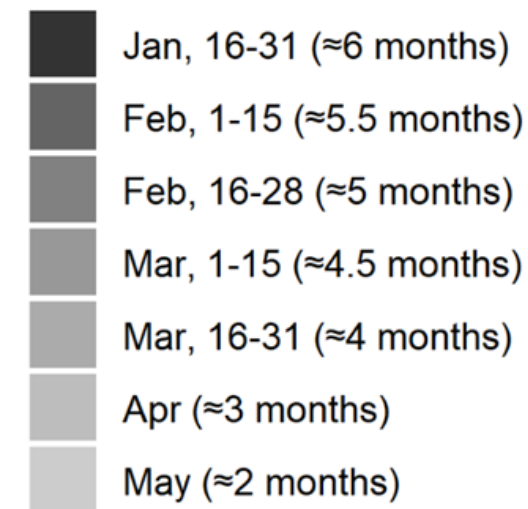
Per 1000 persons, during July 11, 2021 and July 31, 2021



Goldberg et al.,

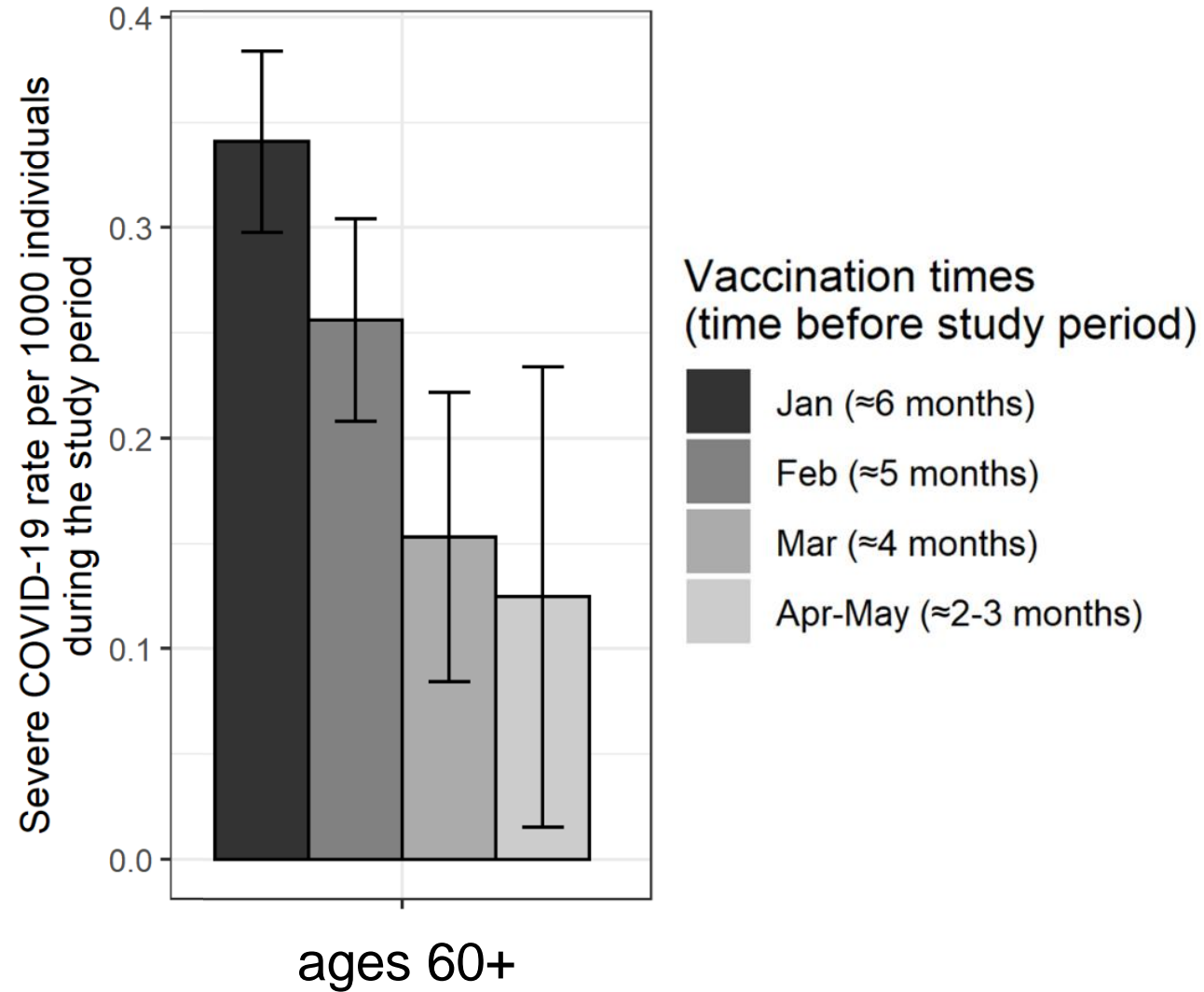
<https://www.medrxiv.org/content/10.1101/2021.08.24.21262423v1>

Vaccination times
(time before study period)



Waning immunity also observed for severe disease in 60+ group

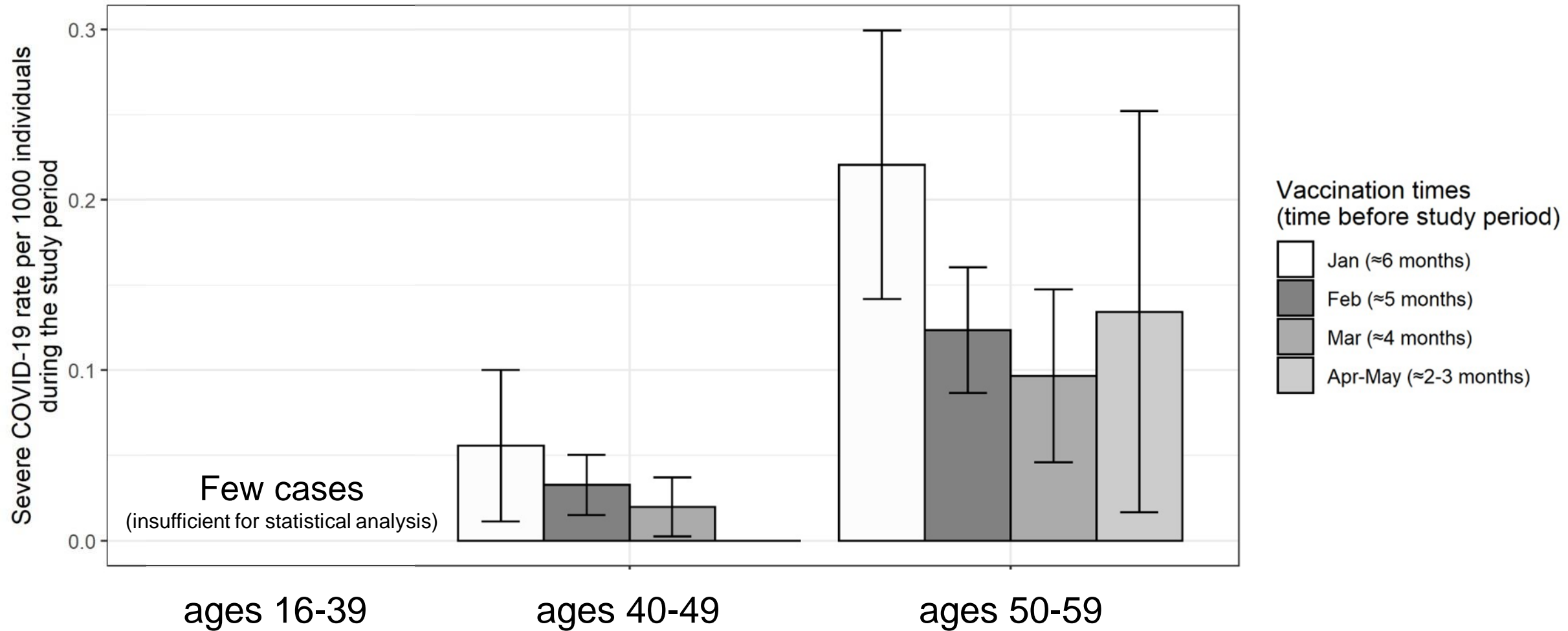
Per 1000 persons, during July 11, 2021 and July 31, 2021



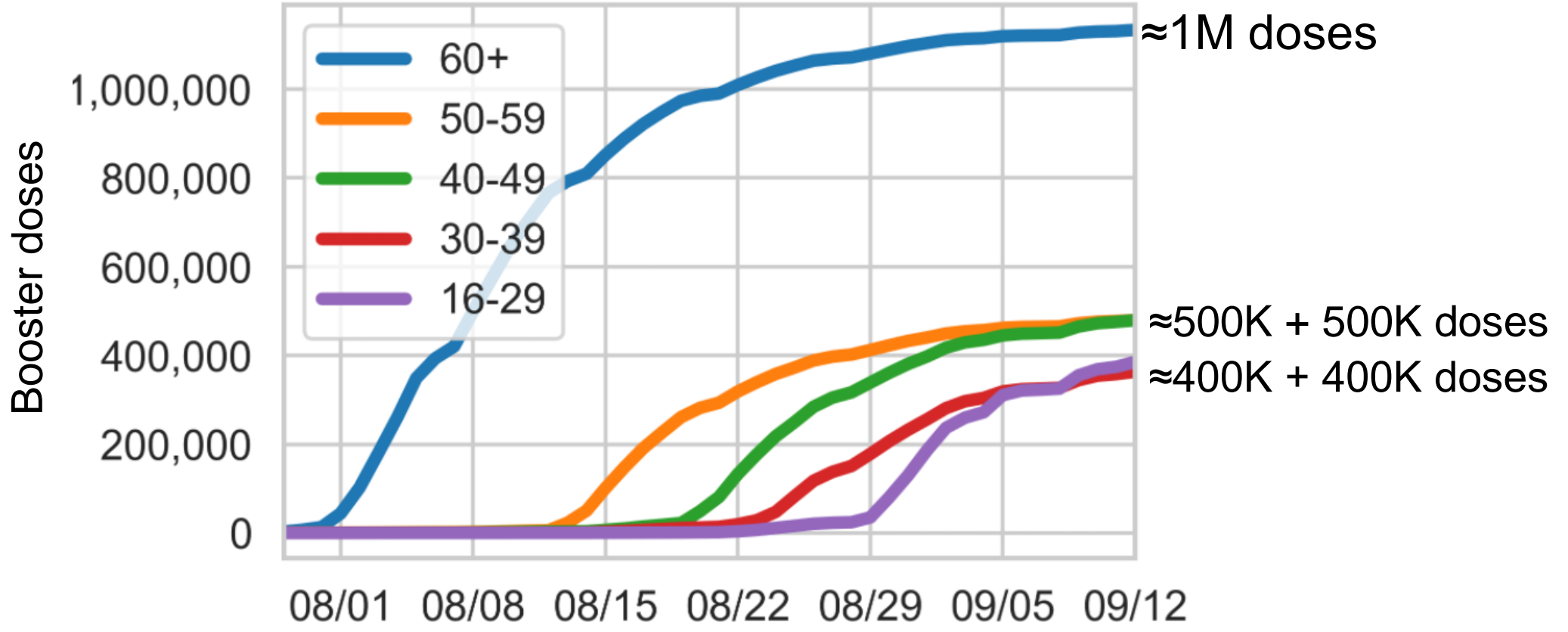
Goldberg et al.,
<https://www.medrxiv.org/content/10.1101/2021.08.24.21262423v1>

Waning immunity against severe disease may occur also in younger age groups

Rates of severe COVID-19 stratified by vaccination period and age group per 1000 persons, July 11 – Aug 15, 2021

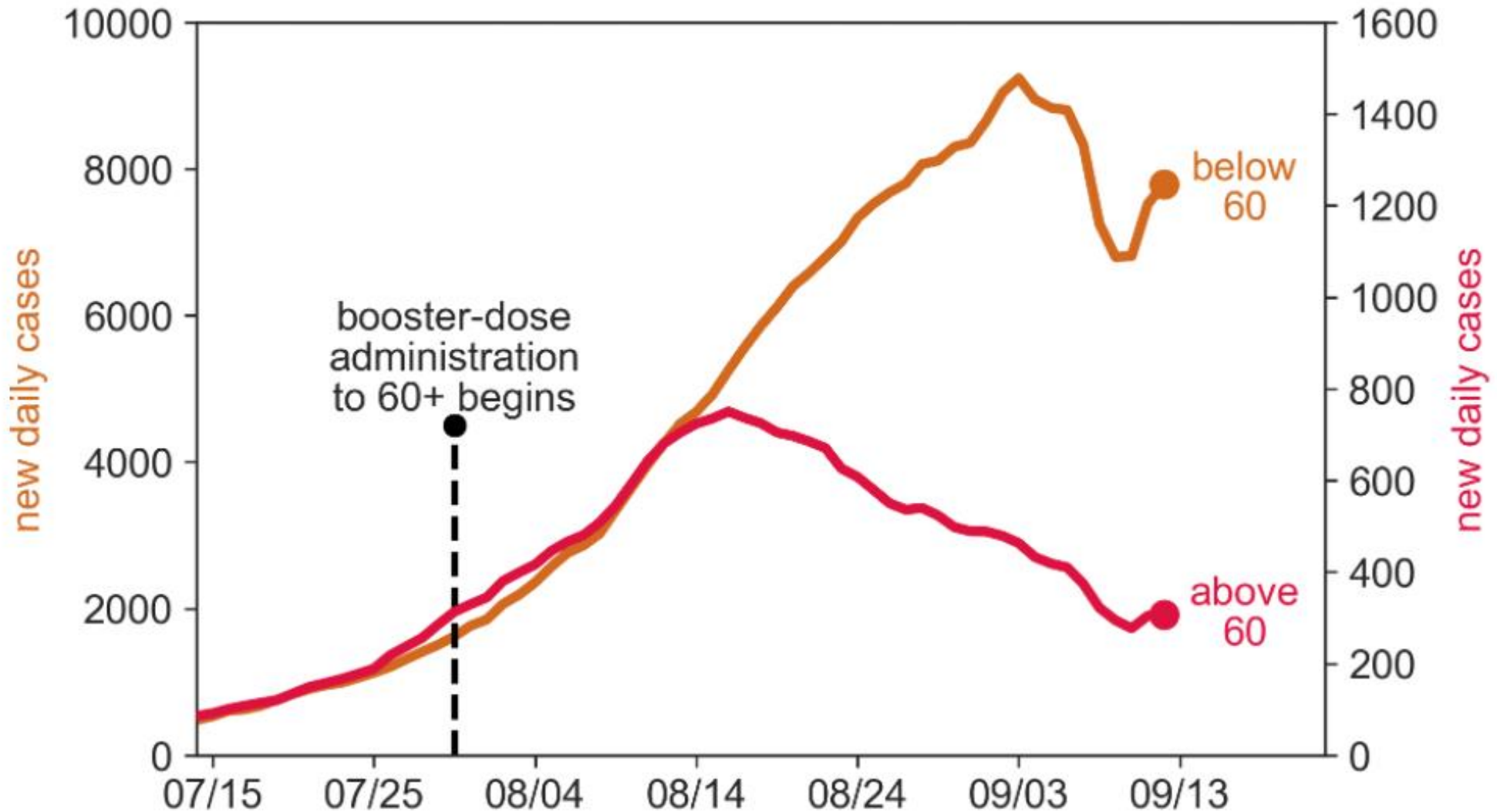


Booster campaign began in Israel on July 30th

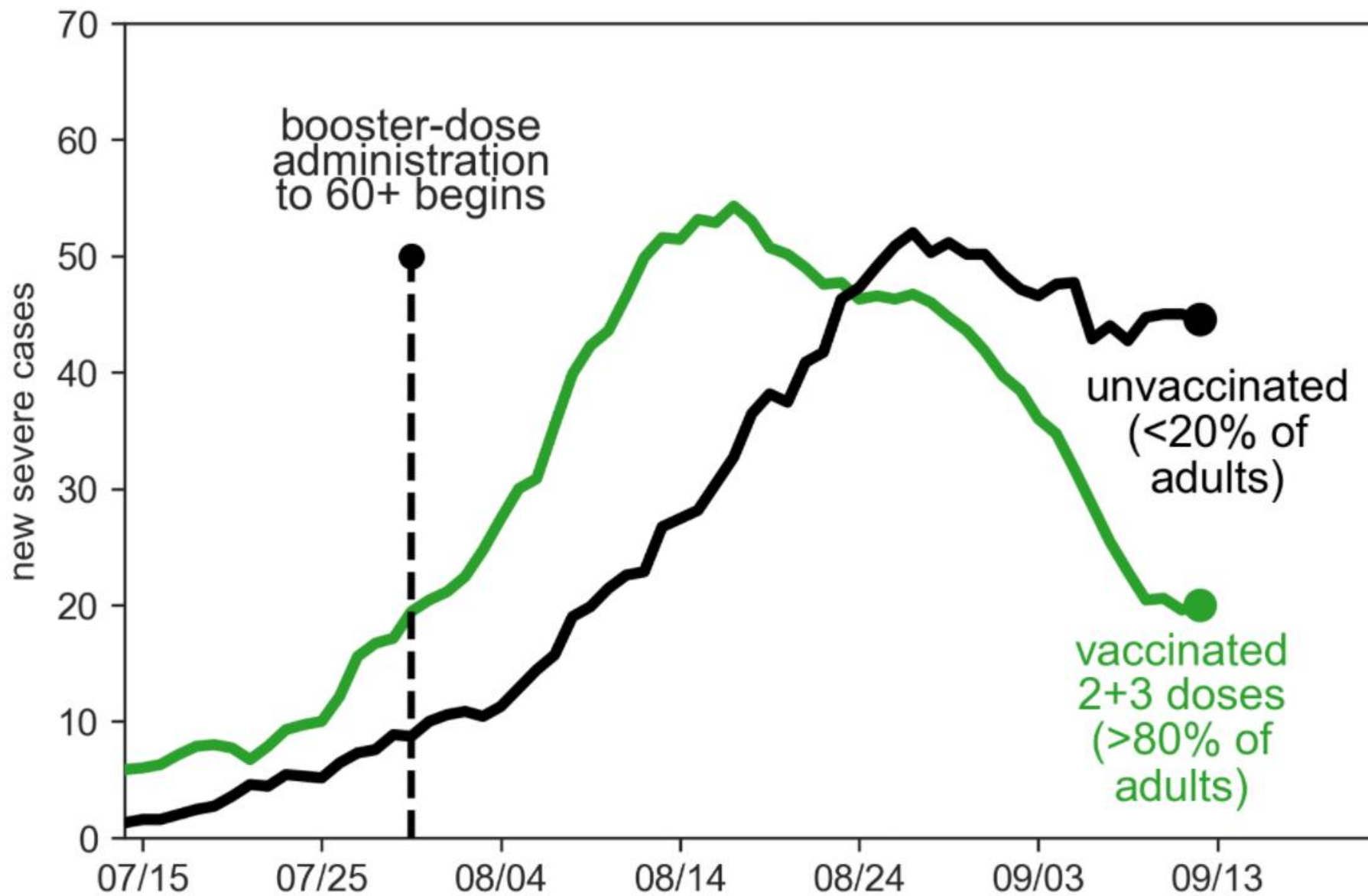


>2.8 million booster doses to date

Large fraction of the older population received a third dose, leading to a substantial decrease in confirmed infections among people over 60y



Following the third dose, severe cases sharply decreased



FDA Emergency Use Authorization



A Pfizer-BioNTech COVID-19 vaccine booster dose administered at least 6 months after completion of the primary series is authorized for use in:

- individuals 65 years of age and older,
- individuals 18 through 64 years of age at high risk of severe COVID-19, and
- individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

Vaccine Boosters and Q&A

Overview of CDC's Interim Recommendation for use of a single Pfizer-BioNTech vaccine booster dose



Erin Tromble, MD

Chief Medical Officer, Vaccine Task Force,
CDC COVID-19 Response
Centers for Disease Control and Prevention

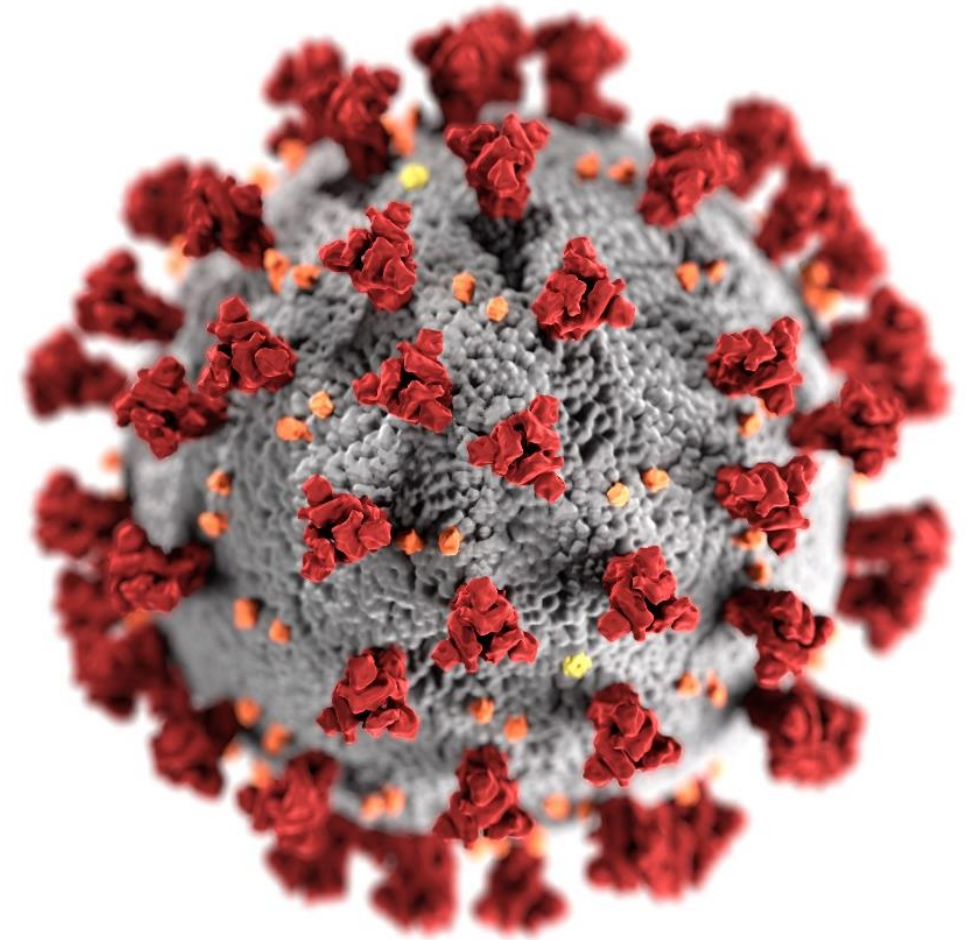
Overview of CDC's Interim Recommendation for use of a single Pfizer-BioNTech vaccine booster dose

Erin Tromble, MD

Chief Medical Officer

Vaccine Task Force, CDC COVID-19 Response

September 25th, 2021



cdc.gov/coronavirus

ACIP Meeting September 22nd-23rd

■ Review of latest data:

- Data from a small clinical trial show that a booster dose of Pfizer-BioNTech COVID-19 vaccine increased immune response in those who completed a primary series six months prior
- Among adults 65 years and older, data show vaccines remain effective in preventing hospitalization and severe disease, but recent evidence suggests they are less effective in preventing infection or milder symptomatic illness due to waning over time and the Delta variant
- Emerging evidence show that among healthcare and other frontline essential workers, vaccine effectiveness is waning against COVID-19 infections.



Groups at risk for severe COVID-19 or SARS-CoV-2 infection after primary series vaccination



Age-Based Group: people aged ≥ 65 years

- Increased risk of severe COVID-19 (including hospitalization and death) among this age group of fully vaccinated people compared to younger fully vaccinated people
- Waning of COVID-19 vaccine effectiveness against severe disease has been observed in people aged ≥ 65 yrs

Risk-Based Group: Long Term Care Facility (LTCF) residents

- Residents of LTCFs, aged ≥ 18 years
- Likely increased risk of severe COVID-19 (including hospitalization and death) among fully vaccinated residents compared to fully vaccinated people living independently
- Some waning of COVID-19 vaccine protection against infection has been observed in LTCF residents
- Congregate living setting associated with increased risk of COVID-19

Risk-Based Group: underlying medical conditions

- Aged ≥ 18 years
- Fully vaccinated persons with underlying medical conditions may be at risk of severe COVID-19 if they become infected with SARS-CoV-2

Examples:

- Cancer
- Cerebrovascular disease
- Chronic kidney disease
- Chronic obstructive pulmonary disease
- Diabetes mellitus, type 1 and type 2
- Heart conditions
- Obesity (BMI ≥ 30 kg/m²)
- Pregnancy and recent pregnancy
- Smoking, current and former

Risk-Based Group: occupation or setting

- Aged ≥ 18 years
- Fully vaccinated persons may be at increased risk of SARS-CoV-2 infection due to occupation or setting
- Absence from occupation due to SARS-CoV-2 infection may hinder societal functions

Interim Recommendations



CDC Interim Recommendations for COVID-19 Pfizer-BioNTech Vaccine Booster Dose:

People 65 years and older and residents in long-term care settings **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series



CDC Interim Recommendations for COVID-19 Pfizer-BioNTech Vaccine Booster Dose:

People aged 50 to 64 with certain underlying medical conditions **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series



CDC Interim Recommendations for COVID-19 Pfizer-BioNTech Vaccine Booster Dose:

People 18 to 49 who are at high risk for severe COVID-19 due to certain underlying medical conditions **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks



CDC Interim Recommendations for COVID-19 Pfizer-BioNTech Vaccine Booster Dose:

People aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.



Additional Considerations



Booster dose - Administration

- Pfizer-BioNTech COVID-Vaccine (BTN162b2), 0.3ml, intramuscular administration
- Timing: ≥ 6 months after completion of the primary series
 - Immunity wanes gradually over time, therefore a booster may be given at an interval greater than 6 months
- Co-administration: a Pfizer-BioNTech COVID-Vaccine booster dose may be given with other vaccines, without regard to timing. This includes simultaneous administration of COVID-19 and other vaccines on the same day.



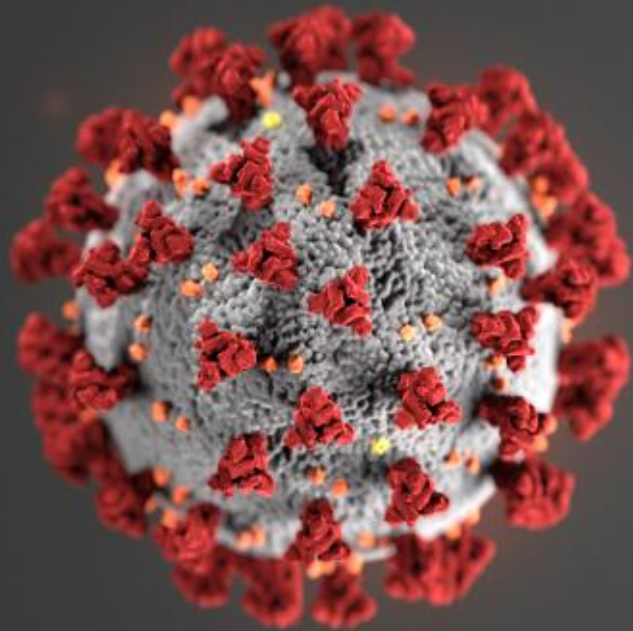
Definition of ‘fully vaccinated’ unchanged

- For public health purposes, people who have completed a primary vaccine series (i.e. 2-dose mRNA vaccine series or a single dose of the Janssen vaccine) are considered fully vaccinated ≥ 2 weeks after completion of the primary series
- The above definition applies to all people including those who receive an additional dose as recommended for moderate to severely immunocompromised people and those who receive a booster dose



Thank you!





For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

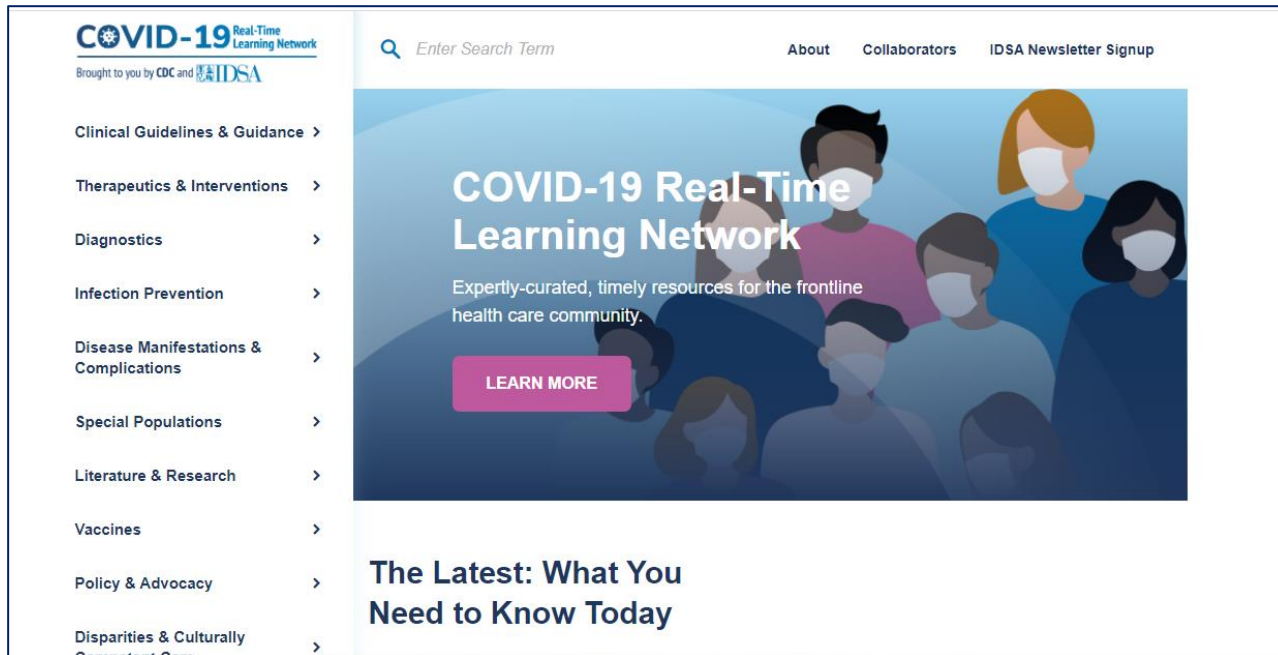


Q&A/Discussion

COVID-19 Real-Time Learning Network

Brought to you by CDC and IDSA

An online community bringing together information and opportunities for discussion on latest research, guidelines, tools and resources from a variety of medical subspecialties around the world.



Specialty Society Collaborators

American Academy of Family Physicians
American Academy of Pediatrics
American College of Emergency Physicians
American College of Physicians
American Geriatrics Society
American Thoracic Society
Pediatric Infectious Diseases Society
Society for Critical Care Medicine
Society for Healthcare Epidemiology of America
Society of Hospital Medicine
Society of Infectious Diseases Pharmacists

www.COVID19LearningNetwork.org

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1th Anniversary IDWeek

Sept. 29 – Oct. 3, 2021
Virtual Conference



Register by Aug. 27 to Save!
[idweek.org](https://www.idweek.org)



Chasing the Sun: COVID-19
Beyond the Horizon

Attend, Learn & Collaborate.

Advancing Science, Improving Care

*Join the event and access
COVID-19 content at no charge!*

CDC-IDSA Partnership: Clinical Management Call Support

FOR WHOM?

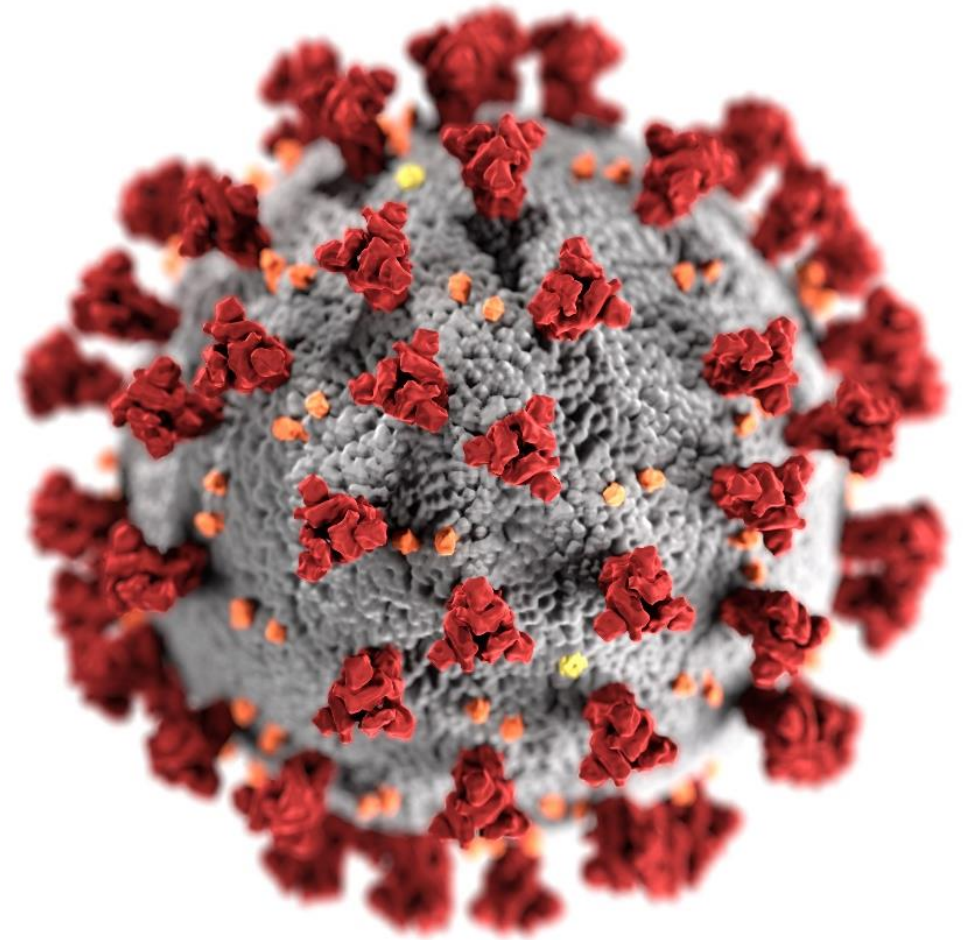
- Clinicians who have questions about the clinical management of COVID-19

WHAT?

- Calls from clinicians will be triaged by CDC to a group of IDSA volunteer clinicians for peer-to-peer support

HOW?

- Clinicians may call the main CDC information line at 800-CDC-INFO (800-232-4636)
- To submit your question in writing, go to www.cdc.gov/cdc-info and click on Contact Form



IDSA
Infectious Diseases Society of America

cdc.gov/coronavirus

Continue the
conversation on Twitter

@RealTimeCOVID19
#RealTimeCOVID19



We want to hear from you!
Please complete the post-call survey.

Next Call:

Saturday, Oct. 9th

A recording of this call will be posted at
www.idsociety.org/cliniciancalls
-- library of all past calls now available --

Contact Us:

Dana Wollins (dwollins@idsociety.org)

Deirdre Lewis (dlewis@idsociety.org)