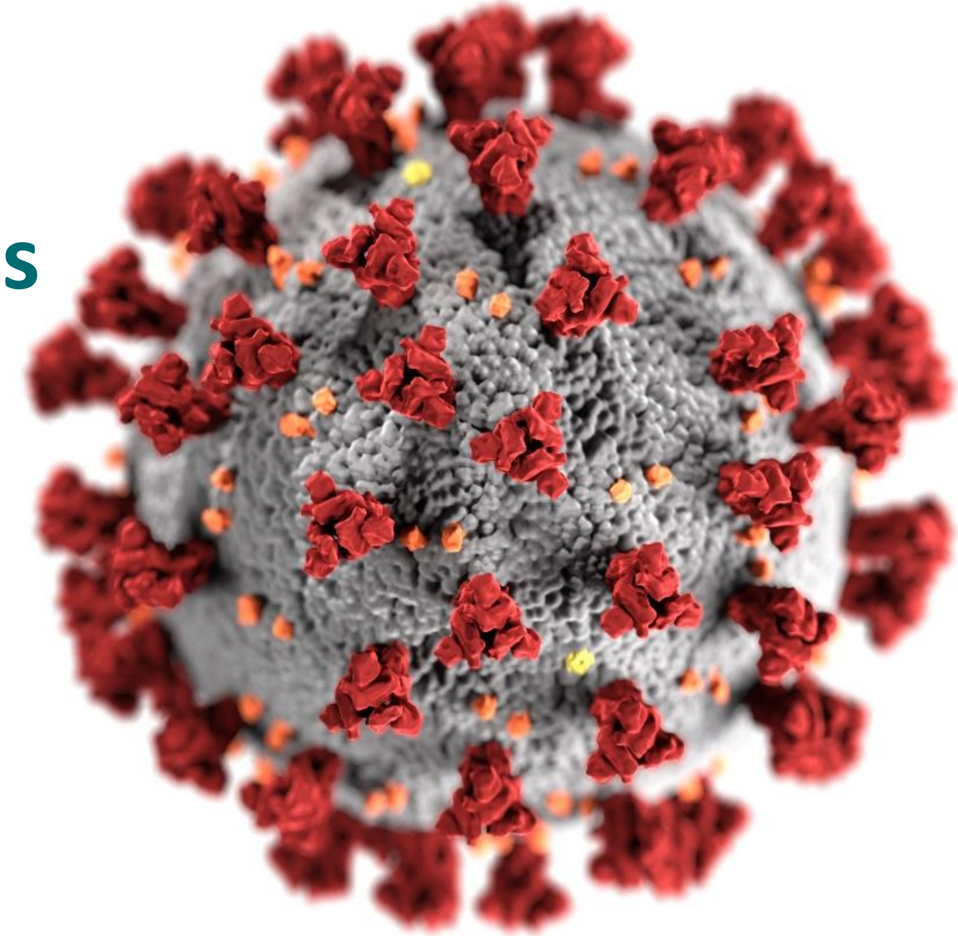
Overview of data to inform recommendations for booster doses of COVID-19 vaccines



Sara Oliver MD, MSPH
ACIP Meeting
June 23, 2021

cdc.gov/coronavirus

Policy questions:
Recommendations for booster doses of COVID-19 vaccines

- **Main policy question: Are booster doses of COVID-19 vaccines needed for those previously vaccinated with a primary series?**

- Other questions:
  - Are booster doses needed for all persons or only in specific populations?
  - What is the optimal timing of booster doses after primary series?
  - Can these be given as a ‘mixed dose’ or do they need to be matched to a primary series?

Note: Decisions around strains for vaccine production likely to be made separately

Policy questions:
Recommendations for booster doses of COVID-19 vaccines

- Policy on booster doses coordinated with FDA for possible amendments to EUA, and ACIP for recommendations around use in specific populations
  - Both will require data on **safety, immunogenicity** and **public health need**

- "**Booster dose**": Vaccine doses after primary (1 or 2-dose) series that are needed to increase immunity after waning of initial immune response

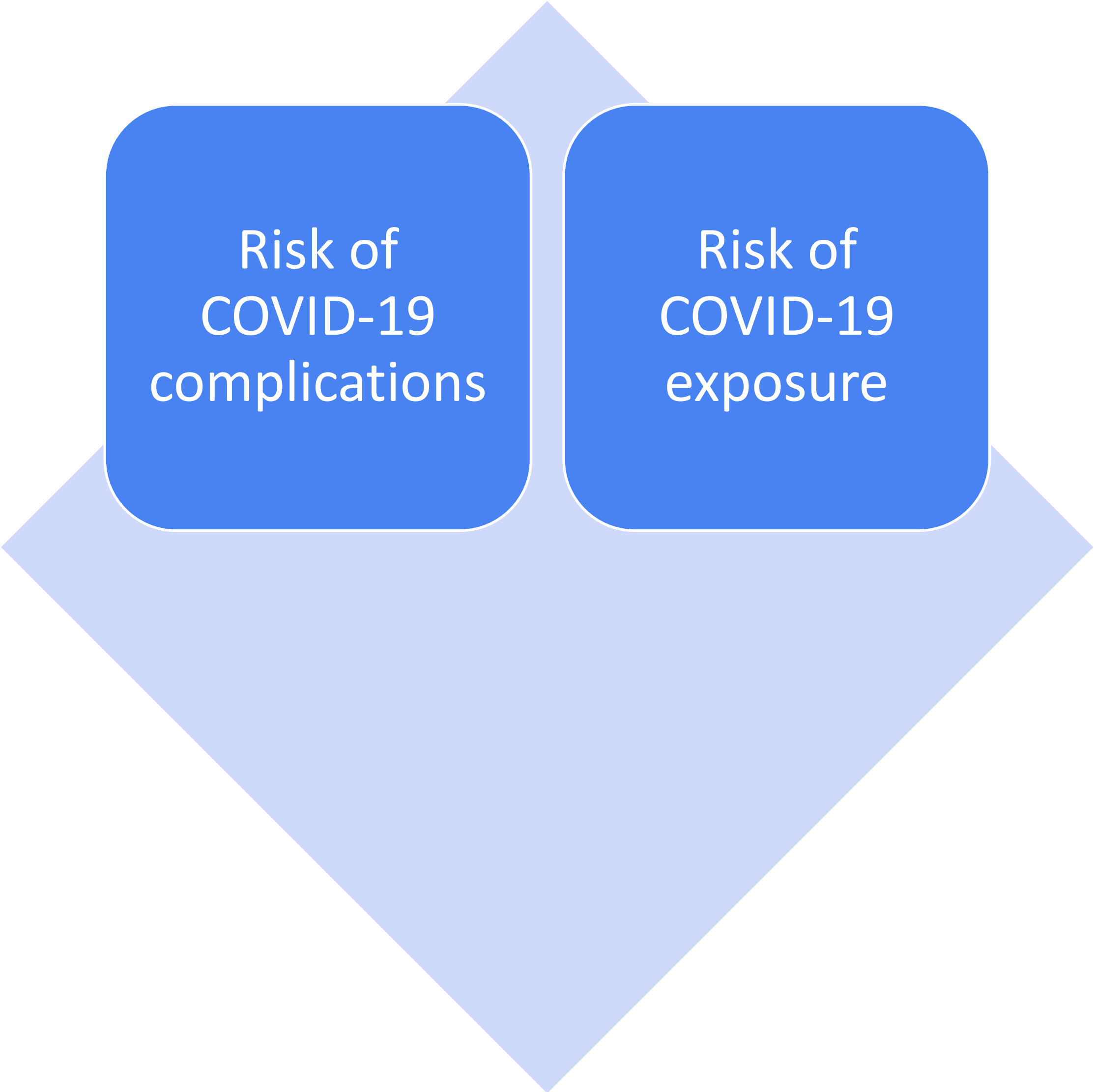
  Some individuals may not have mounted sufficient immune response after primary series and could need an additional dose to reach protective immunity

Initial doses of COVID-19 vaccines:
Data to inform recommendations

LTCF residents

Persons ≥65 years

Persons 16–64 with high-risk medical conditions



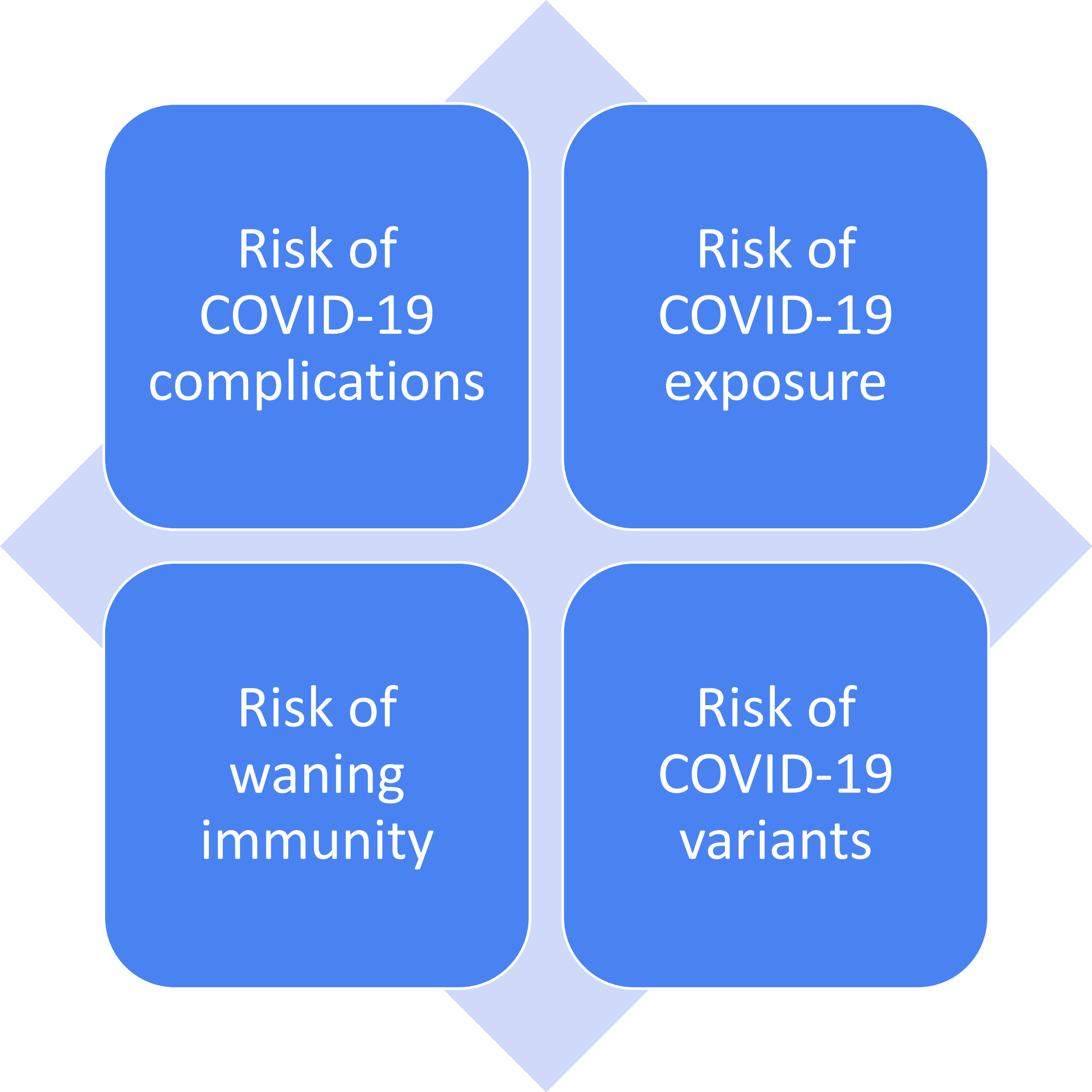
Health care personnel

Frontline Essential Workers

Other Essential Workers

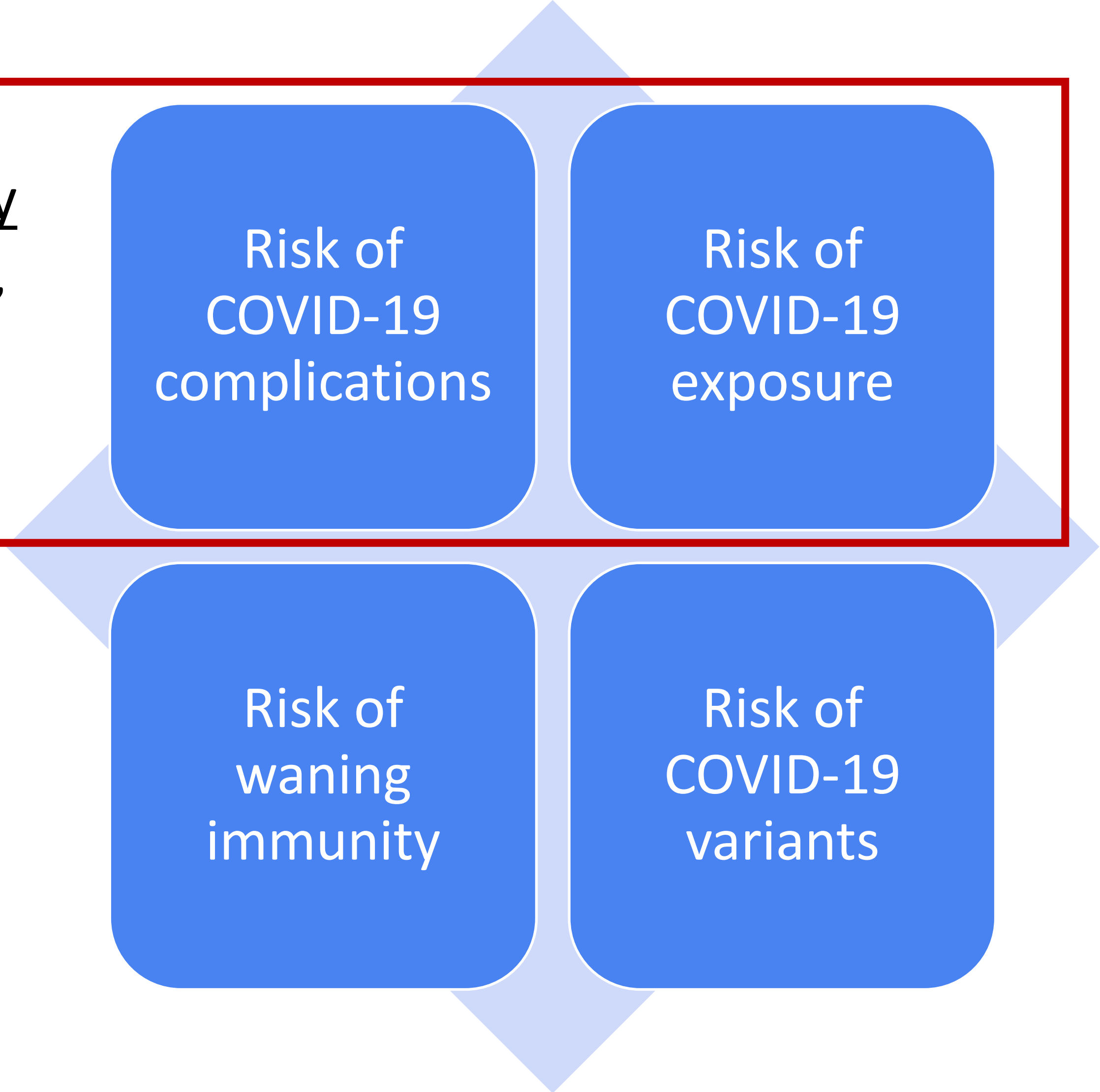
LTCF= Long Term Care Facility

<u>Booster</u> doses of COVID-19 vaccines:
Data to inform recommendations

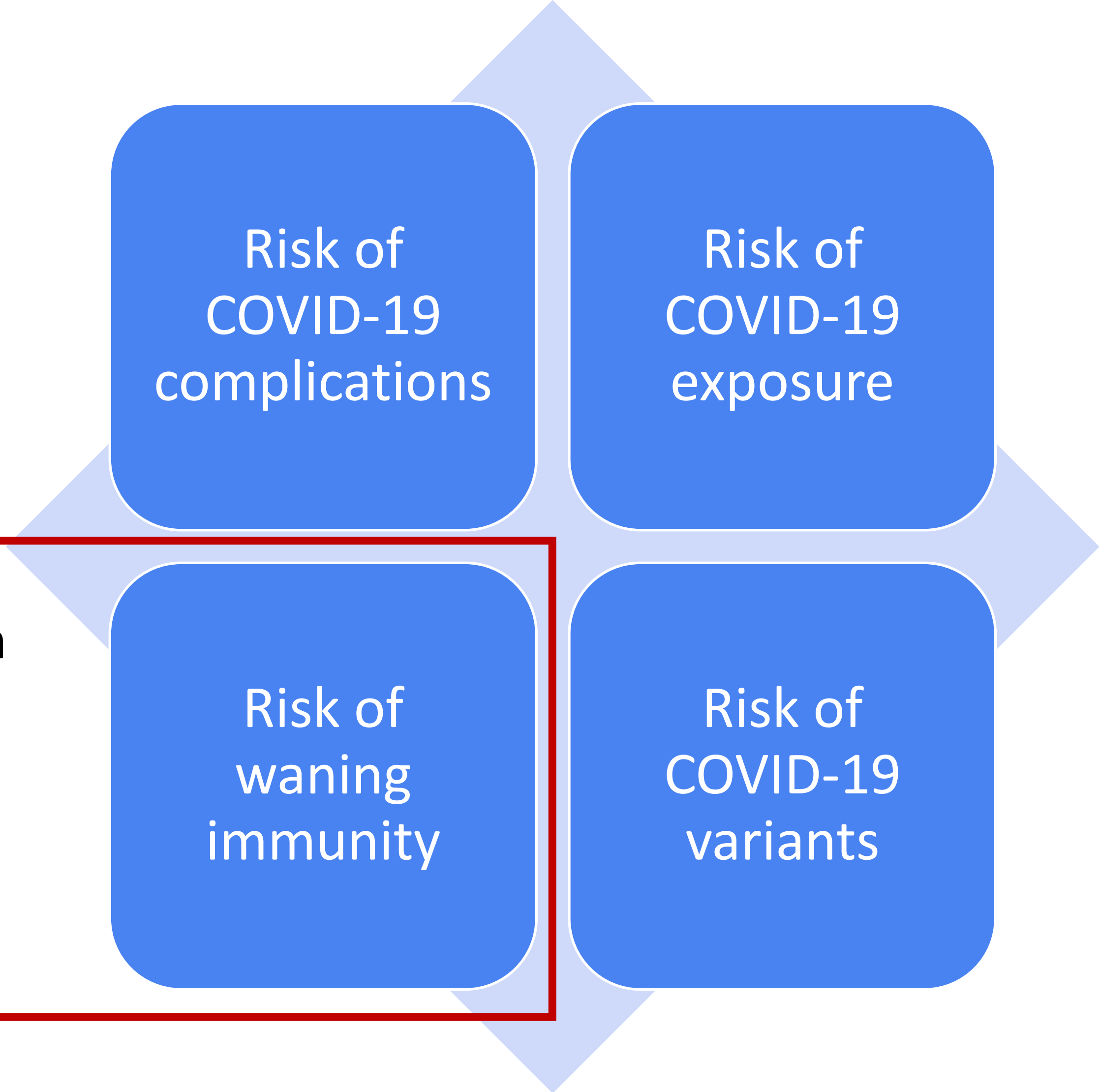


<u>Booster</u> doses of COVID-19 vaccines:
Data to inform recommendations

<u>COVID-19 epidemiology</u>
Cases, hospitalizations, deaths by age, setting, and medical condition



Booster doses of COVID-19 vaccines:
Data to inform recommendations



Duration of protection (antibodies, VE) after primary series

Ability to 'boost' with additional doses

VE= Vaccine efficacy/effectiveness

Booster doses of COVID-19 vaccines:
Data to inform recommendations

Risk of COVID-19 complications

Risk of COVID-19 exposure

Vaccine effectiveness studies & assessment of vaccine breakthrough cases

Time since vaccination, age, setting, medical condition

Risk of waning immunity

Risk of COVID-19 variants

Booster doses of COVID-19 vaccines:
Data to inform recommendations

Risk of COVID-19 complications

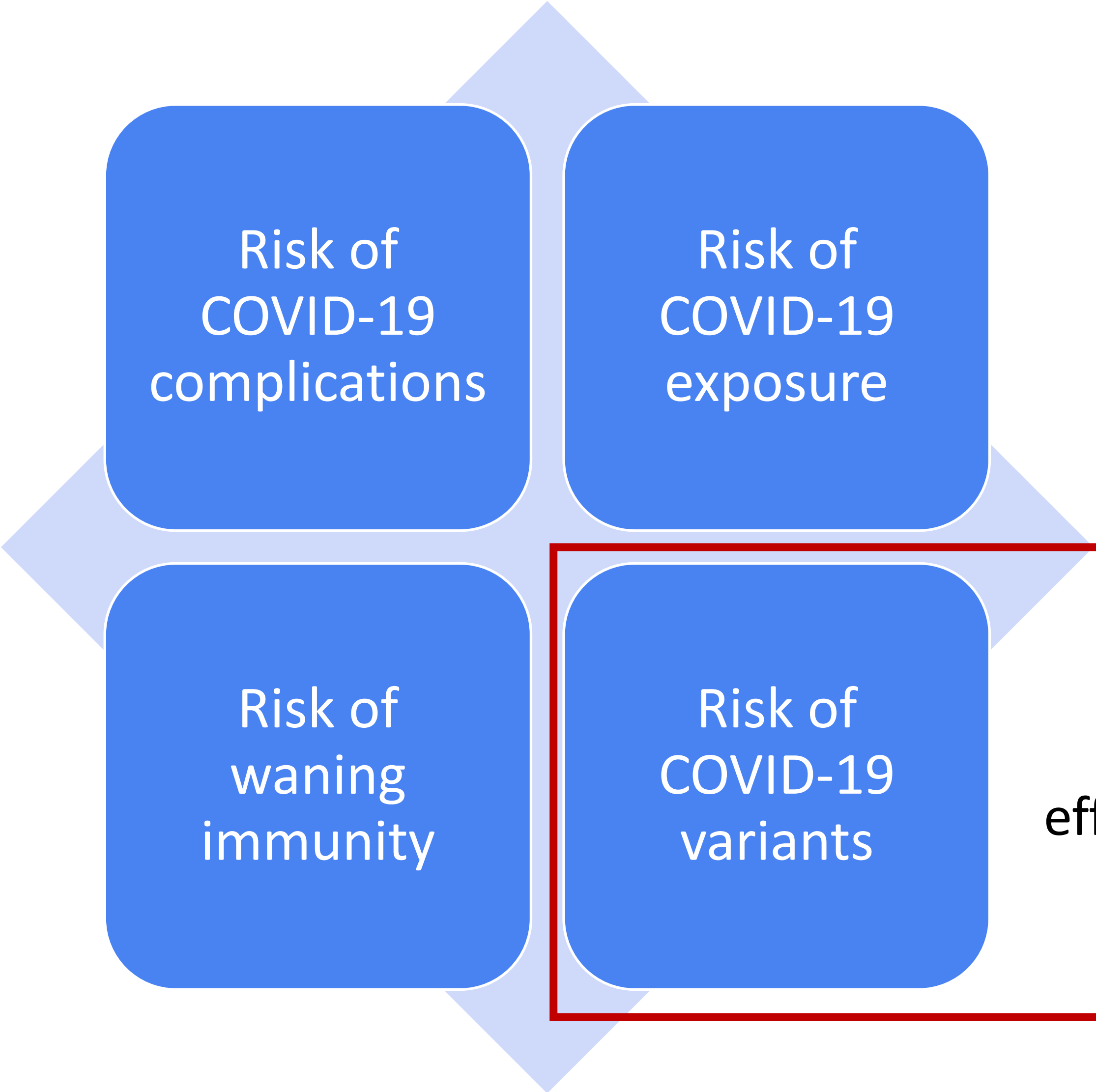
Risk of COVID-19 exposure

Risk of waning immunity

Risk of COVID-19 variants

Correlates of Protection

Booster doses of COVID-19 vaccines:
Data to inform recommendations



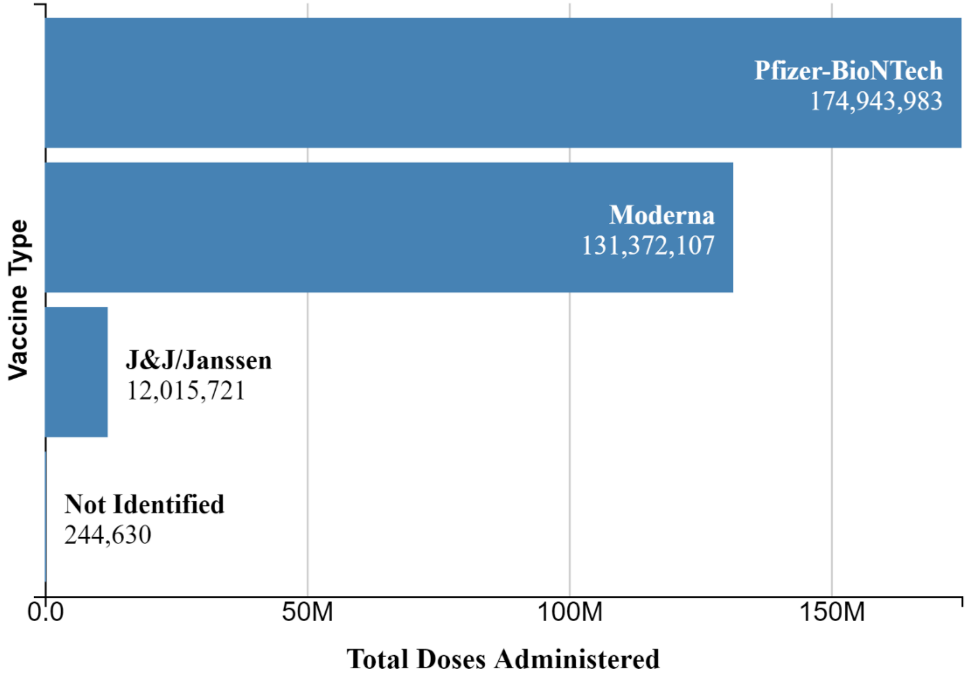
Variant proportions, antibody response, and effectiveness for each variant and vaccine

Booster doses of COVID-19 vaccines: What do we know now?

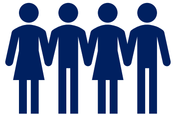
COVID-19 vaccines administered

As of June 21, 2021

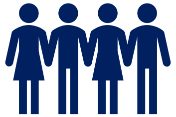
Total Vaccine Doses Administered: 318,576,441



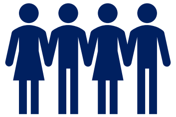
% of Population With At Least 1 Dose:



≥12 years of age: **62.5%**



≥18 years of age: **65.4%**



≥65 years of age: **87.3%**

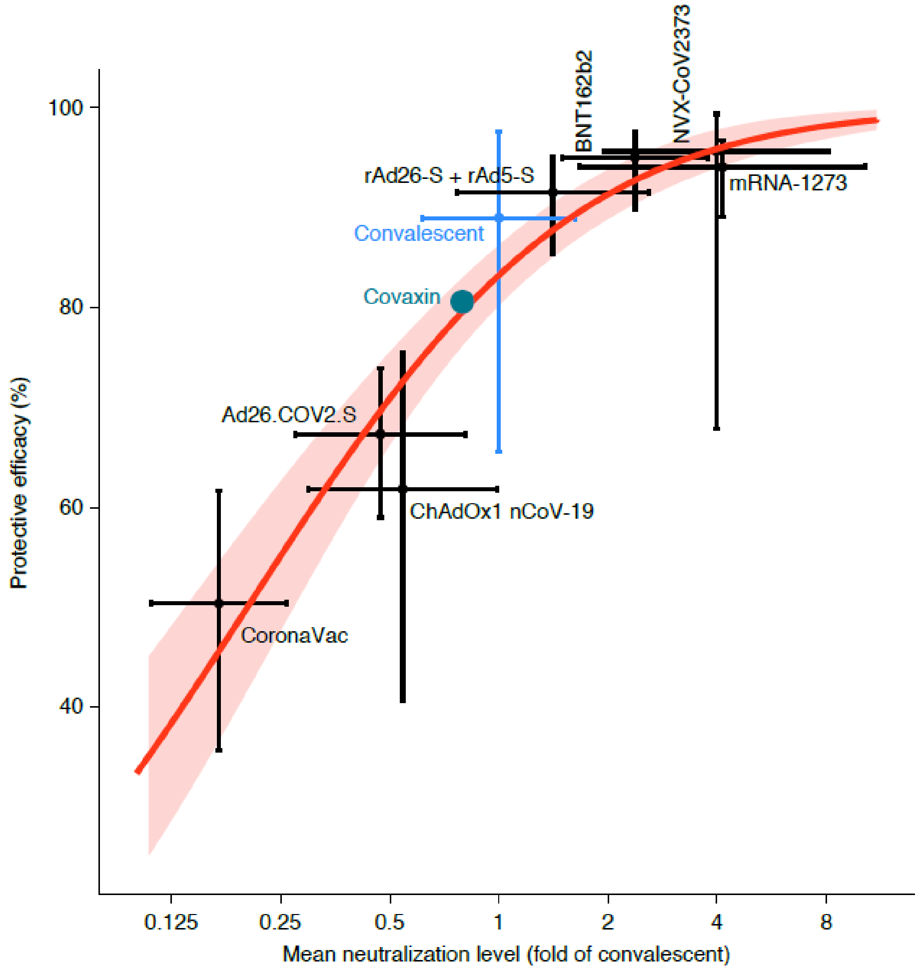
CDC. https://covid.cdc.gov/covid-data-tracker

Booster doses of COVID-19 vaccines:

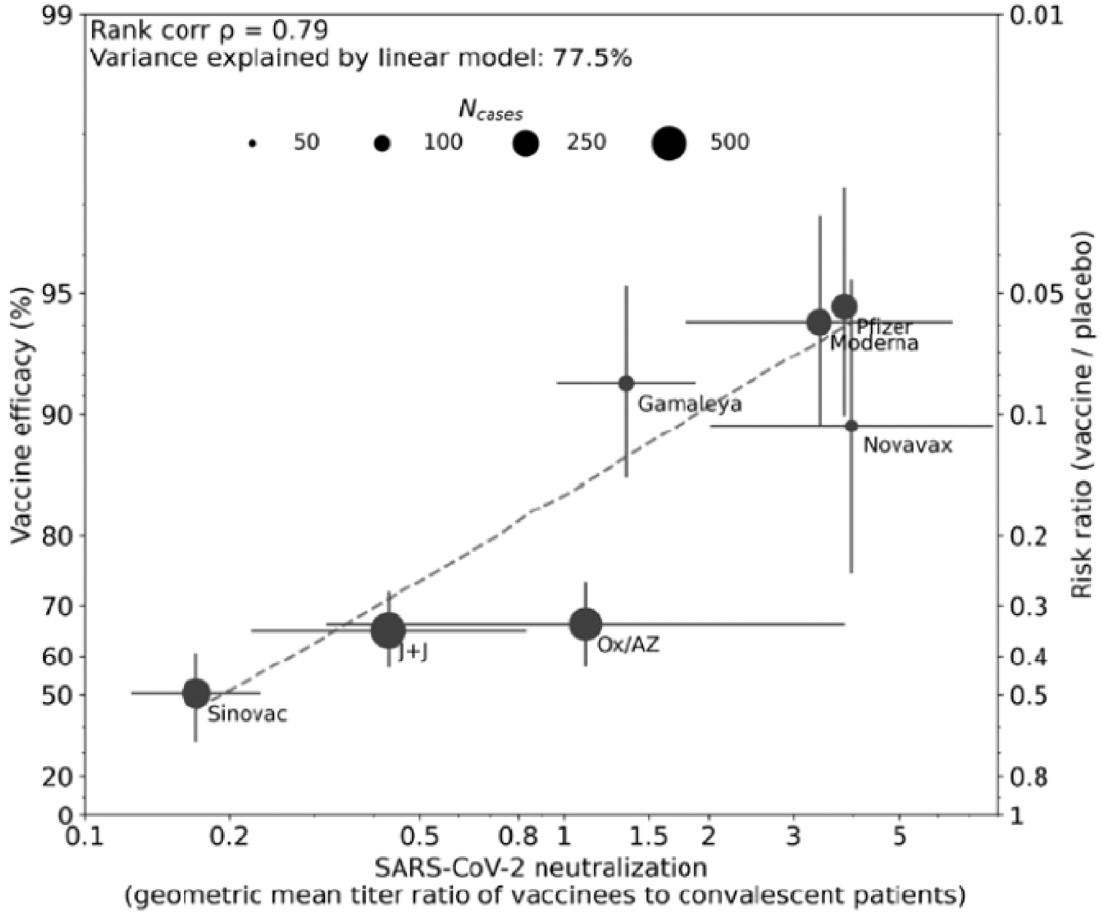
Immunogenicity and antibody response

- Correlates of protection:
  - Immune response that allows prediction of the degree of protection against infection or disease
  - Work ongoing, no correlate established yet
- Duration of protection:
  - Monitor kinetics of antibody response, efficacy from early phase clinical trials
- Antibody response to variant-specific boosters

Robust correlation between vaccine efficacy against symptomatic disease and mean neutralizing antibody titer: Two studies

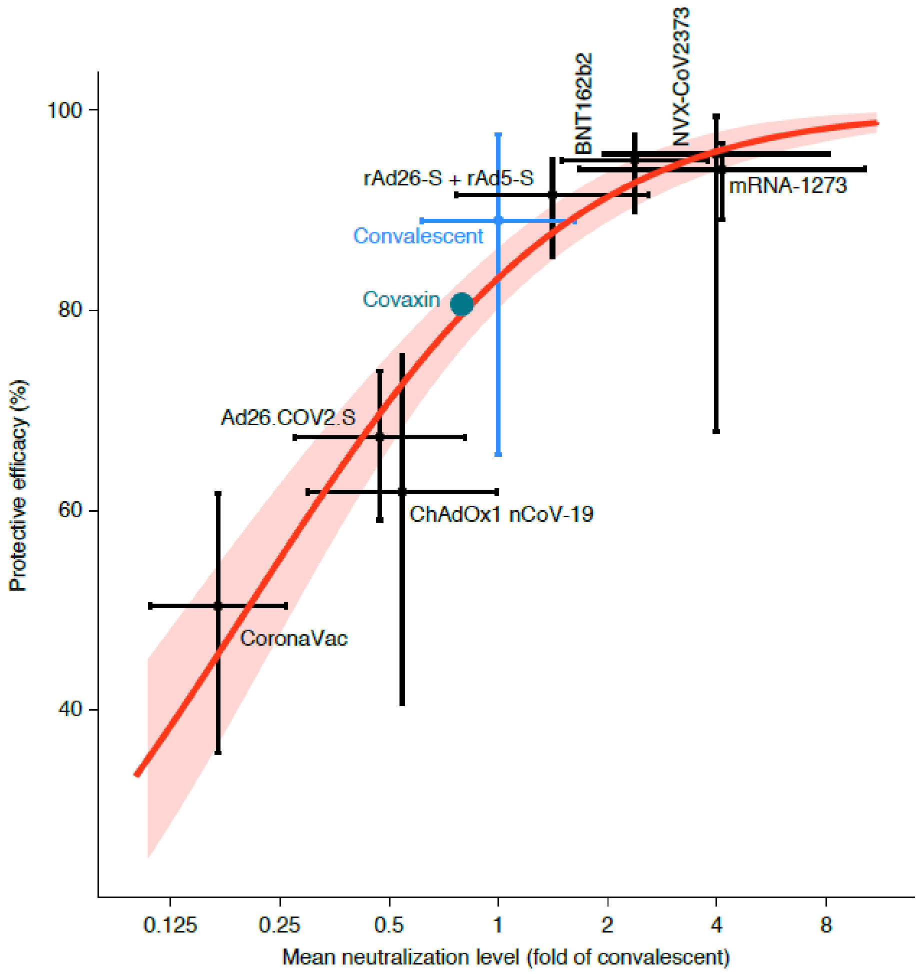


Khoury et al. Nature Medicine (2021)



Earle et al. medRxiv preprint (Mar 20 2021)

Robust correlation between vaccine efficacy against symptomatic disease and mean neutralizing antibody titer: Two studies

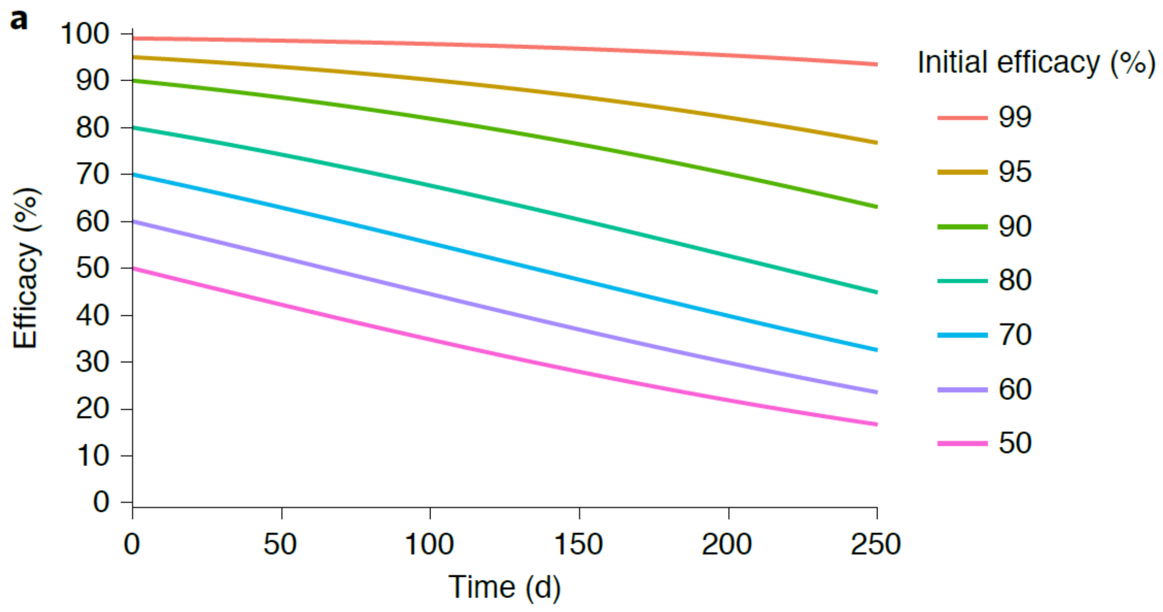


[Khoury et al. Nature Medicine (2021)]

- Suggests **54** IU/ml as correlate of protection (20% of mean convalescent titer)
- Threshold of protection against **severe disease** is lower (3% of mean convalescent titer), less affected by vaccine differences
- For variants, 5-fold lower neutralizing titer predicted to reduce efficacy from 95% to 77% in high efficacy vaccine, or from 70% to 32% for lower efficacy vaccine

Predicted duration of immunity varies with initial vaccine efficacy

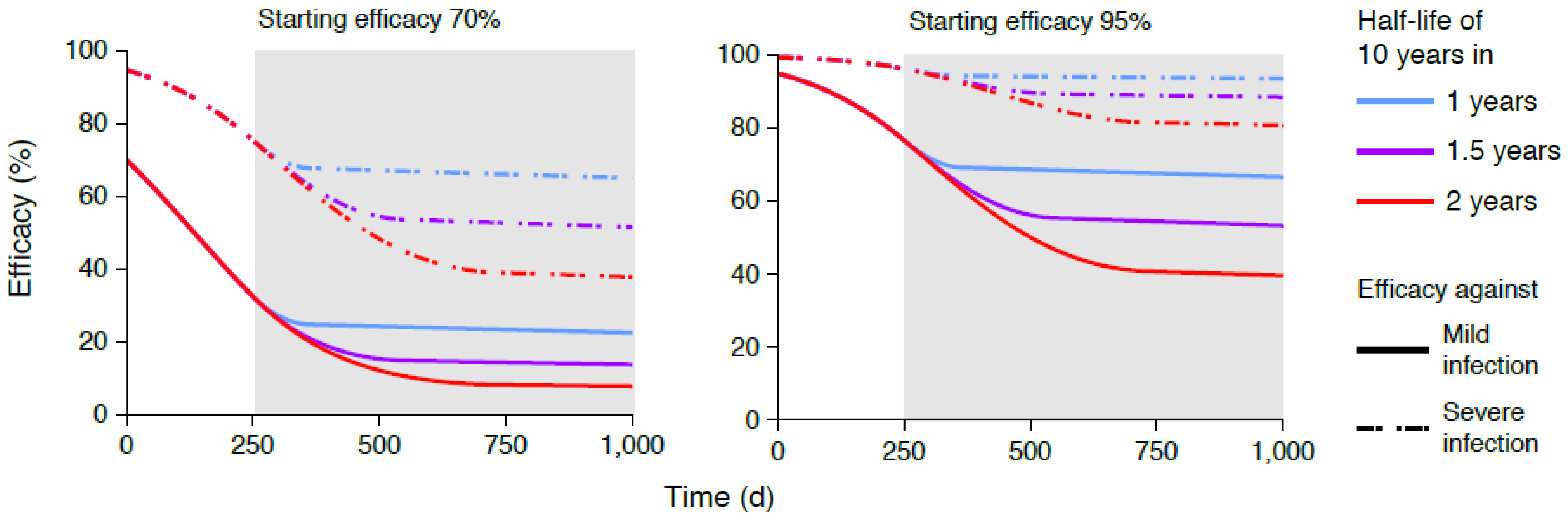
- Initial efficacy may be useful in predicting time until boosting may be needed



Khoury et al. Nature Medicine (2021)

- Vaccine starting with initial efficacy of 95% expected to maintain high efficacy (77%) after 250 days
- Vaccine starting with initial efficacy of 70% may result in drop to lower efficacy (33%) after 250 days
- Model assumes **neutralization** is major mechanism of protection

Protection from severe infection predicted to persist longer than protection against mild infection



- After initial exponential decay, antibody half-lives generally stabilize to ≥10 years (linear decline)
- Depending on when transition occurs, proportion of individuals predicted to be protected against severe disease long-term, even without boosters, but may be susceptible to mild infection

Khoury *et al.* *Nat Med* (2021). https://doi.org/10.1038/s41591-021-01377-8

Duration of immunity

- To date, antibody persistence demonstrated for up to **8 months** after COVID-19 infection and up to **6 months** after the 2^{nd} mRNA vaccine dose
- Two studies, 6 months after receiving Moderna vaccine: Lower neutralizing titers & higher proportions (~50%) with undetectable titers against B.1.351 and P.1, compared with ancestral strain
  - Third modeling study makes similar conclusions
- Many studies have shown larger reductions in variant neutralization for convalescent sera than post-vaccine sera

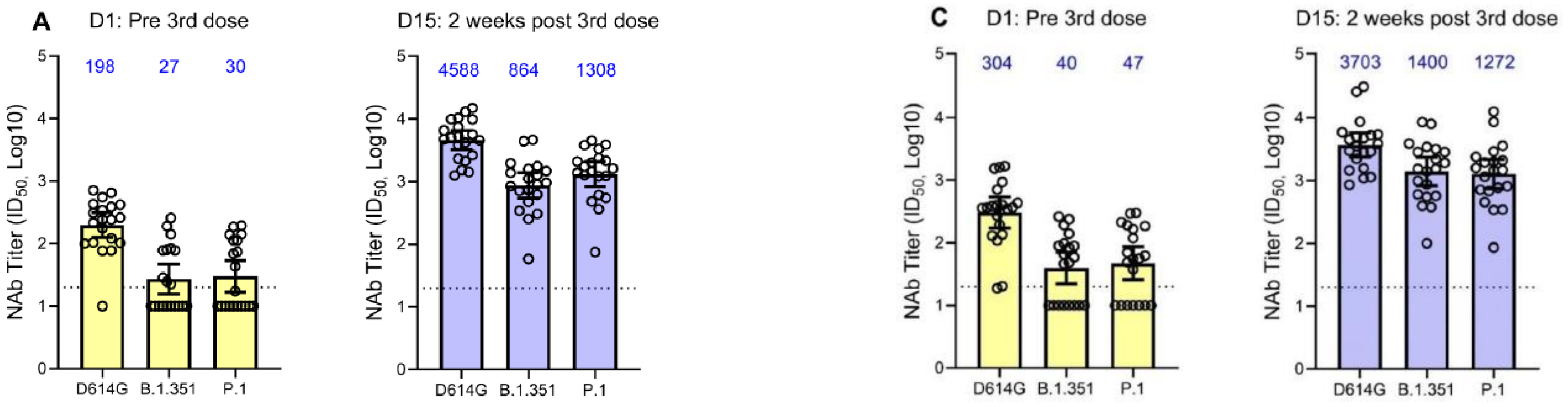
Gaebler, C. et al. Evolution of antibody immunity to SARS-CoV-2. Nature 591, 639–644 (2021).
Dan, J. M. et al. Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. Science 371, eabf4063 (2021)
Choe et al. Antibody Responses 8 Months after Asymptomatic or Mild SARS-CoV-2 Infection. Emerg Infect Dis. 2021;27(3):928-931.
Doria-Rose et al. Antibody Persistence through 6 Months after the Second Dose of mRNA-1273 Vaccine for Covid-19. N Engl J Med 2021; 384:2259-226
https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious
Khoury *et al. Nat Med* (2021). https://doi.org/10.1038/s41591-021-01377-8 ; Pegu et al. bioRxiv preprint (May 16 2021): https://doi.org/10.1101/2021.05.13.444010
Wu et al. medRxiv preprint (2021): https://doi.org/10.1101/2021.05.05.21256716 Luo, Hu, Letterio, medRxiv preprint (4 2021): medRxiv preprint doi: https://doi.org/10.1101/2021.05.04.21256537

Variant-specific booster

Preliminary analysis of safety and immunogenicity of a SARS-CoV-2 variant vaccine booster

50 µg booster dose of **mRNA-1273**

50 µg booster dose of **mRNA-1273.351**



- Two weeks after booster vaccination, titers against wild-type original strain, B.1.351 and P.1 variants increased to levels similar to or higher than peak titers after the primary series vaccinations

https://www.medrxiv.org/content/10.1101/2021.05.05.21256716v1

Variant-specific booster

Preliminary analysis of safety and immunogenicity of a SARS-CoV-2 variant vaccine booster

50 µg booster dose of **mRNA-1273**

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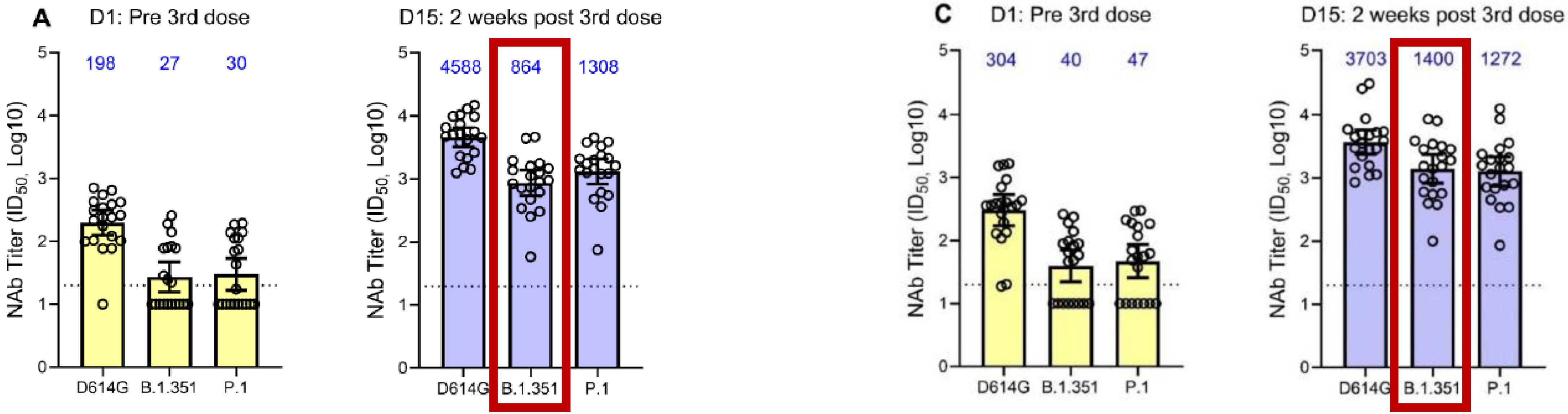


- Both vaccines demonstrated broad antibody boosting

https://www.medrxiv.org/content/10.1101/2021.05.05.21256716v1

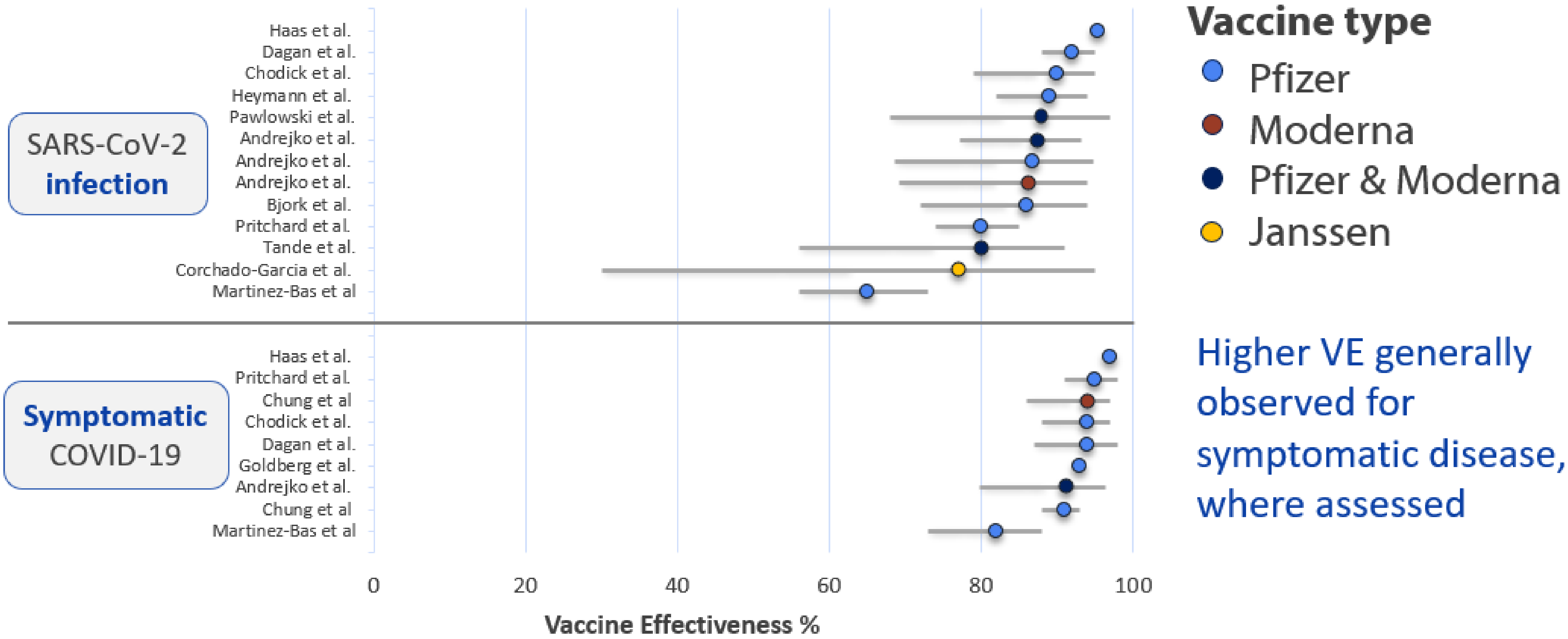
Booster doses of COVID-19 vaccines:

Vaccine effectiveness

- Overall "real world" vaccine effectiveness
- Efficacy/effectiveness against variants
- Effectiveness in specific populations

"Real world" vaccine effectiveness:

VE in fully vaccinated adult population

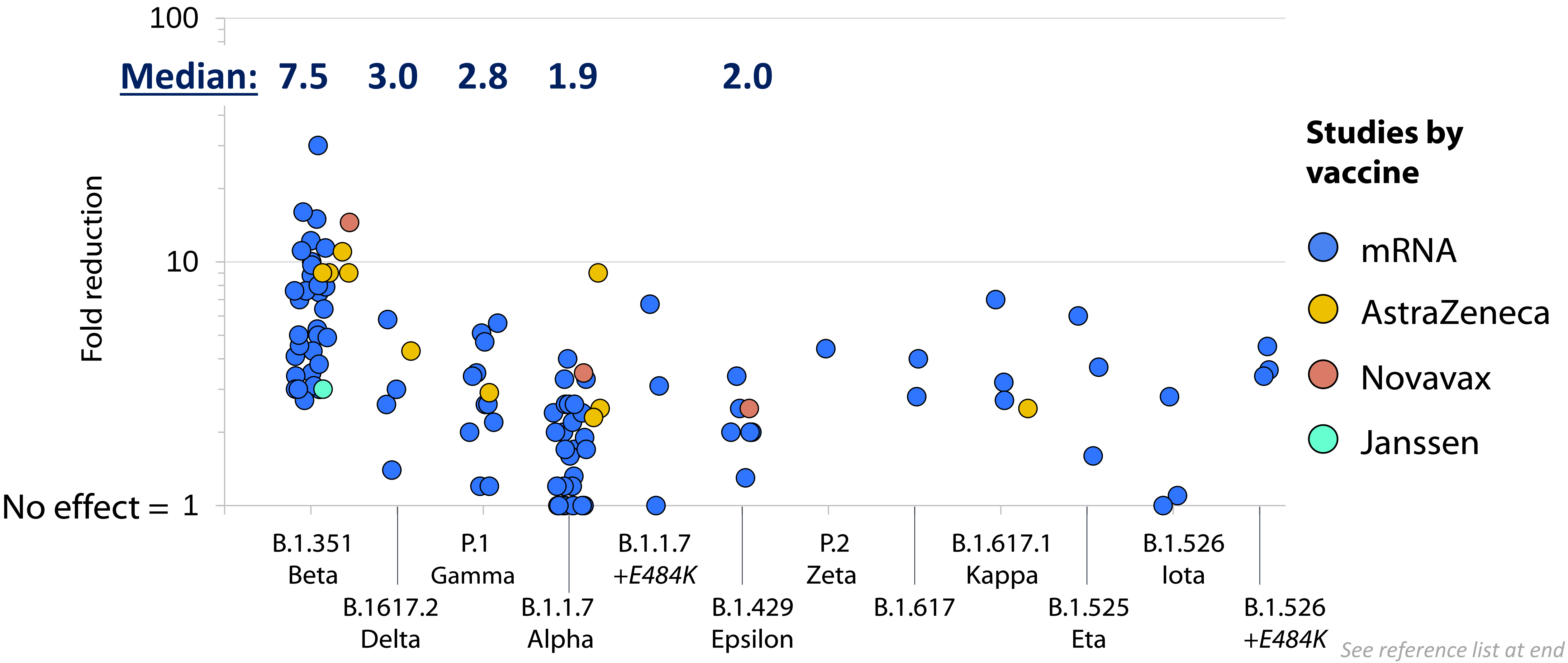


Higher VE generally observed for symptomatic disease, where assessed

<u>Fully vaccinated against COVID-19</u>: ≥2 weeks after receipt of 2nd dose in a 2-dose series (Pfizer and Moderna) or ≥2 weeks after receipt of the single dose of the Janssen vaccine

See reference list at end

Reduced antibody neutralization activity of vaccine sera relative to wildtype/dominant strain by study (n=48)



See reference list at end

"Real world" vaccine effectiveness:

Studies to inform VE against variants of concern

Country	Vaccine	Dominant strain(s)	Fully vaccinated VE
Israel, Europe & U.K	Pfizer	B.1.1.7 (Alpha)	>85%
Canada	mRNA	B.1.1.7, P.1 (Alpha, Gamma)	79% (65%–88%)
Canada	mRNA	P.1/B.1.351 (Gamma/Beta)	88% (61%–96%)*
Qatar	Pfizer	B.1.1.7 (Alpha)	90% (86%–92%)*
		B.1.351 (Beta)	75% (71%–79%)*
South Africa	Janssen	B.1.351 (Beta)	52% (30%–67%)

* Variant-specific VE

For B.1.351 (Beta), VE shown to be higher for prevention of severe disease

CDC Science Brief : https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html
Abu-Radad and Butt. NEJM (2021); Sandoff et al. NEJM (2021); Chung et al. medRxiv preprint (May 28 2021); Yassi et al. medRxiv preprint (May 25 2021))

Vaccines & new variant of concern: Delta B.1.617.2

B.1.617.2-specific VE

- **PCR-confirmed infection:** Scotland, 2 doses Pfizer vaccine: **79%** (vs. 92% for B.1.1.7)
- **Symptomatic infection:** England, 2 doses Pfizer vaccine: **88%** (vs. 93% for B.1.1.7)
- **Hospitalization:** England, 2 doses Pfizer vaccine: **96%** (similar to B.1.1.7)

B.1.617.2 antibody neutralization studies

- 4 studies, 2 doses Pfizer vaccine: 1.4, 2.5, 3, and 5.8-fold reduction (vs. wild-type)

Recent study in UK showing resurgence driven by replacement of B.1.1.7 with B.1.617.2, which has higher transmission rate, and infections in unvaccinated children and young adults

Sheikh et al. Lancet (2021): https://doi.org/10.1016/S0140-6736(21)01358-1; Lopez Bernal et al. medRxiv preprint (May 26 2001); https://doi.org/10.1101/2021.05.22.21257658
Stowe et al. PHE preprint: https://khub.net/web/phe-national/public-library/-/document_library/v2WsRK3ZlEig/view/479607266 ; Planas et al. bioRxiv preprint (May 27 2021); https://doi.org/10.1101/2021.05.26.445838 ; Wall et al. Lancet (2021). https://doi.org/10.1016/ S0140-6736(21)01290-3: Liu et al. Cell (2021). https://doi.org/10.1016/j.cell.2021.06.020
Riley et al. medRxiv (June 21 2021): https://doi.org/10.1101/2021.06.17.21259103 ; Liu et al. Nature (2021); https://doi.org/10.1038/s41586-021-03693-y

Booster doses of COVID-19 vaccines:
Specific populations

- Need for booster doses of COVID-19 vaccines may only be demonstrated in some populations
- Populations to closely monitor:

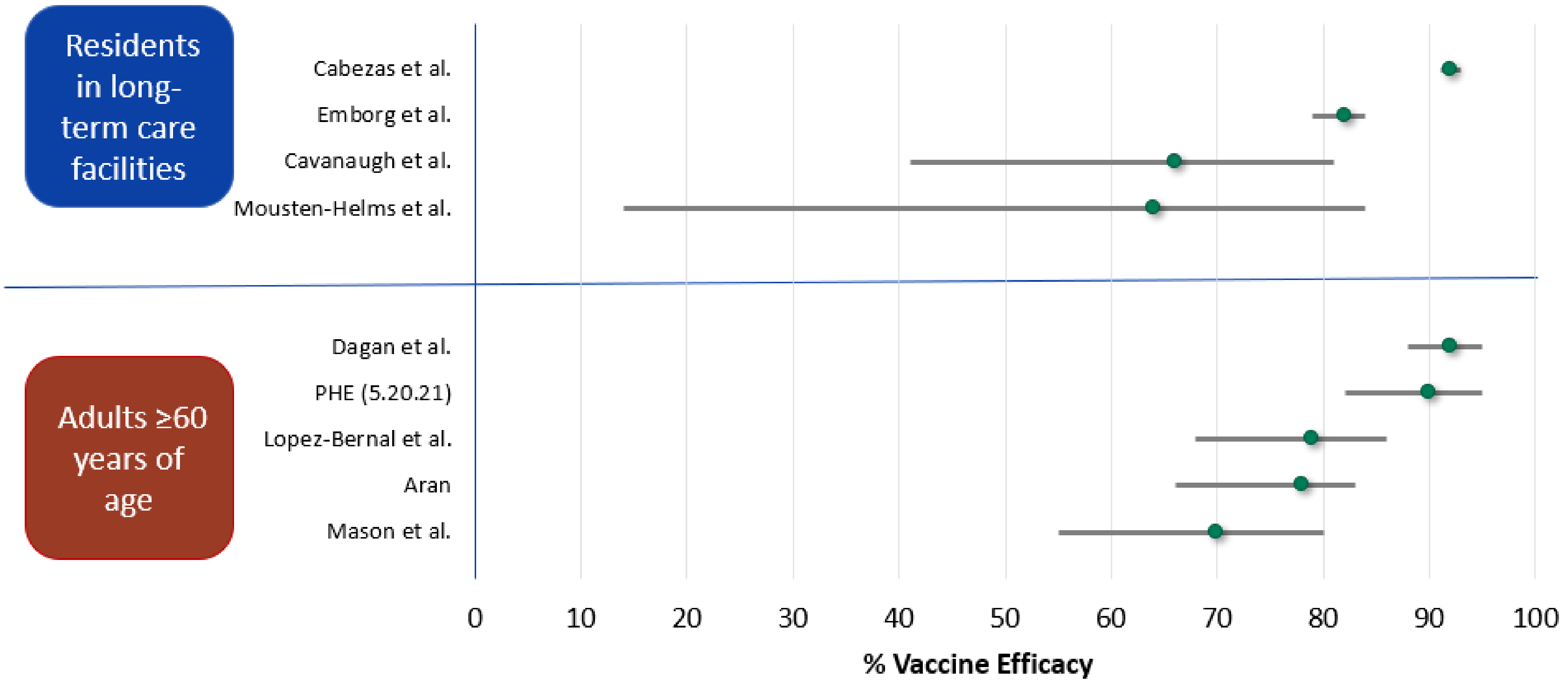
Residents of long-term care facilities

Adults ≥65 years of age

Healthcare personnel

Immunocompromised persons

Two-dose mRNA vaccine effectiveness against SARS-CoV-2 infection in older adults (60+ years) & residents in long-term care facilities



<u>Fully vaccinated against COVID-19</u>: ≥2 weeks after receipt of 2nd dose in a 2-dose series (Pfizer and Moderna)

See reference list at end

“Real world” vaccine effectiveness

Healthcare personnel

VE against SARS-CoV-2 infection

Country	Vaccine	Fully vaccinated VE
United States	Pfizer	97%
	Moderna	99%
United States	Pfizer or Moderna	90%
United States	Pfizer	96%
United Kingdom	Pfizer or AstraZeneca	90%
United Kingdom	Pfizer	86%
United Kingdom (Scotland)	Pfizer or AstraZeneca	92%
Italy	Pfizer	95%
Denmark	Pfizer	90%

VE against symptomatic COVID-19

Country	Vaccine	Fully vaccinated VE
United States	Pfizer or Moderna	94%
United States	Pfizer	87%
Israel	Pfizer	97%
Israel	Pfizer	90%

https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html

People with clinically or therapeutically suppressed immunity

- Represent ≥2.7% of U.S. adults[1], including people living with rheumatologic conditions, organ transplants, HIV, leukemia, on cancer treatment, etc.
- More likely to get severely ill from COVID-19[2]
- Might be at higher risk for:
  - Prolonged SARS-CoV-2 infection[3-7]
  - Viral evolution during infection and treatment[3,6,8-10]
  - Susceptibility to infection with SARS-CoV-2 variants[12]
- Might more frequently transmit SARS-CoV-2 to household contacts[11]

References: (1) Harpaz *et al*. Prevalence of Immunosuppression Among US Adults, 2013. *JAMA* 2016. (2) Williamson *et al*. Factors associated with COVID-19-related death using OpenSAFELY. *Nature* 2020. (3) Truong *et al*. Persistent SARS-CoV-2 infection and increasing viral variants in children and young adults with impaired humoral immunity. *medRxiv* 2021. (4) Hensley *et al*. Intractable Coronavirus Disease 2019 (COVID-19) and Prolonged Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Replication in a Chimeric Antigen Receptor-Modified T-Cell Therapy Recipient: A Case Study. *CID* 2021. (5) Baang *et al*. Prolonged Severe Acute Respiratory Syndrome Coronavirus 2 Replication in an Immunocompromised Patient. *JID* 2021. (6) Choi *et al*. Persistence and Evolution of SARS-CoV-2 in an Immunocompromised Host. *NEJM* 2020. (7) Helleberg *et al*. Persistent COVID-19 in an immunocompromised patient temporarily responsive to two courses of remdesivir therapy. *JID* 2020. (8) Clark *et al*. SARS-CoV-2 evolution in an immunocompromised host reveals shared neutralization escape mechanisms. *Cell* 2021. (9) Kemp *et al*. SARS-CoV-2 evolution during treatment of chronic infection. *Nature* 2021. (10) Khatamzas *et al*. Emergence of multiple SARS-CoV-2 mutations in an immunocompromised host. *medRxiv* 2021. (11) Lewis et al. Household Transmission of Severe Acute Respiratory Syndrome Coronavirus-2 in the United States. *CID* 2020.(12) Stengert et al. Cellular and humoral immunogenicity of a SARS-CoV-2 mRNA vaccine inpatients on hemodialysis. medRxiv preprint 2021.

Factors that may decrease vaccine response among immunocompromised populations

- Older age
- Primary immunodeficiency
- Lower lymphocyte count*
- Decreased kidney function
- Immunosuppressive drugs**
- High-dose corticosteroids
- Current or recent (<6 mos) cancer treatment***

* Including lower CD4 count for people living with HIV

** Immunosuppressive drugs include methotrexate, mycophenolate, rituximab, infliximab, calcineurin-inhibitors

*** BTK inhibitors, anti-CD20 and anti-CD38 therapies, chemotherapy

mRNA vaccine effectiveness studies of COVID-19 infection among immunocompromised populations

- **71%** effective against **SARS-CoV-2 infection** from 7-27 days after 2nd Pfizer dose among immunocompromised* people vs. **90%** overall
  - **75%** protection against **symptomatic COVID-19** among immunosuppressed vs. 94% overall
  - Lower protection with increasing age group

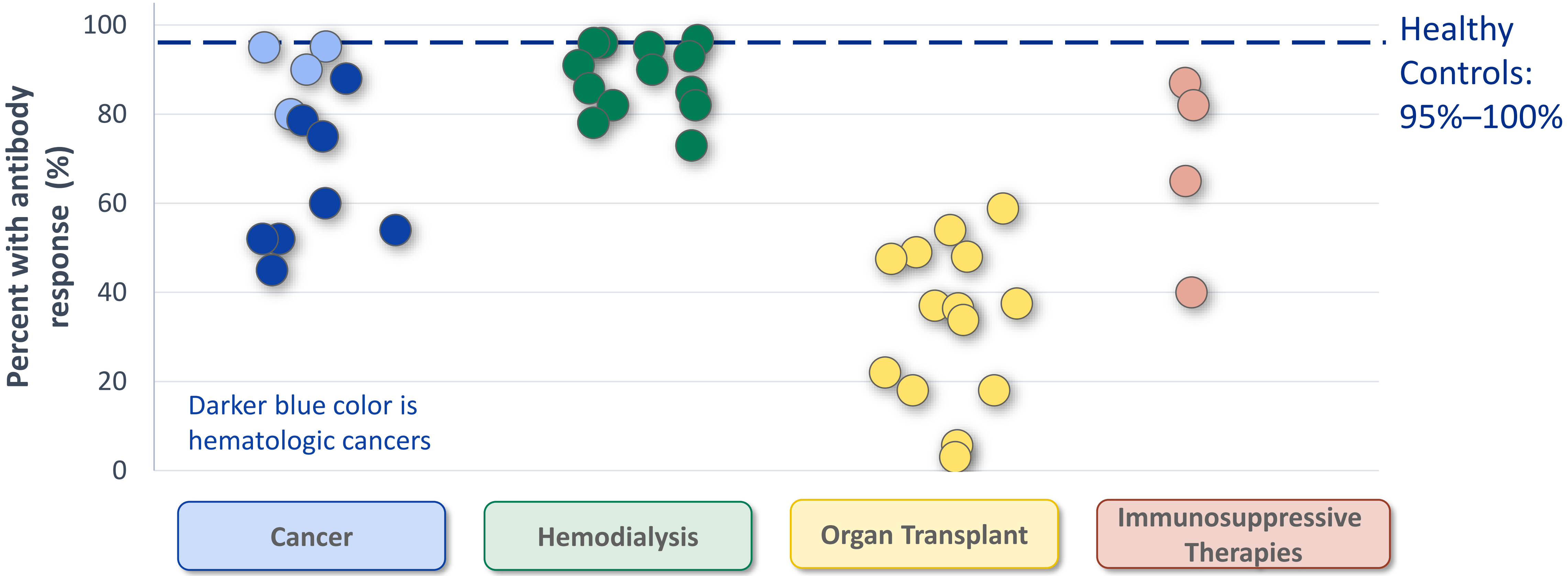
- **80%** effective against **SARS-CoV-2 infection** from 7 days after 2nd mRNA dose among people with inflammatory bowel disease on various immunosuppressive medications
  - One mRNA dose: 25% effective
  - No difference in effectiveness noted between Pfizer and Moderna

*Immunocompromised conditions (e.g. recipients of hematopoietic cell or solid organs transplant, patients under immunosuppressive therapy, asplenia, and chronic renal failure: advanced kidney disease, dialysis, or nephrotic syndrome)

Chodick et al. *Clinical Infectious Diseases*, ciab438, https://doi.org/10.1093/cid/ciab438

Khan et al. Gastroenterology (2021). https://www.gastrojournal.org/article/S0016-5085(21)03066-3/pdf

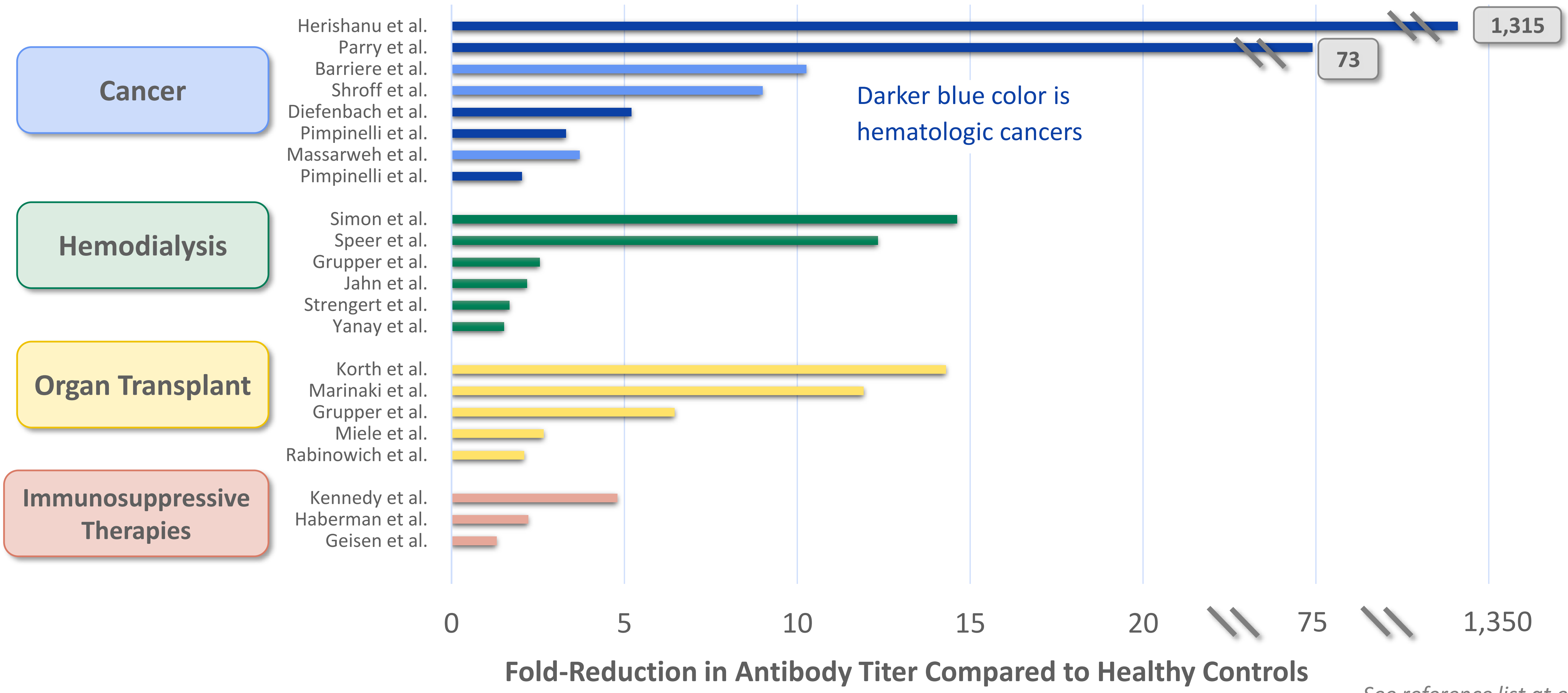
Percent antibody response after two mRNA vaccine doses by immunocompromised condition and study (n=40)



- Studies that compared response after 1st and 2nd dose demonstrated poor response to dose 1
- Antibody measurement and threshold levels vary by study protocol

See reference list at end

Fold-reduction in antibody titers after two mRNA vaccine doses among immunocompromised populations vs. healthy controls



See reference list at end

Evidence on providing 3rd COVID-19 vaccine dose to immunosuppressed people with suboptimal response

- Solid organ transplant recipients (n=30) who had suboptimal response to standard vaccination and subsequently received 3rd dose of vaccine
  - 57% received Pfizer series; 43% received Moderna series
  - 24 (80%) had negative antibody titers; 6 (20%) 'low-positive' after primary series
  - Received 3rd dose median of 67 days after 2nd dose: Janssen (n=15), Moderna (n=9), Pfizer (n=6)
  - After 3rd dose: **14 (47%)** responded, including all low-positives; **16 (53%) remained negative**

- People on hemodialysis (n=77, no COVID-19 history) vaccinated with up to 3 Pfizer doses
  - 64 (83%) seroconverted after 2nd dose
  - Of those negative after 2nd dose:
    - **5 (41%)** of 12 people given 3rd dose seroconverted; **7 (59%) remained negative**
- At least one clinical trial pending of 3rd dose of Moderna vaccine in transplant recipients

Werbel et al. Annals of Internal Medicine. https://www.acpjournals.org/doi/pdf/10.7326/L21-0282
Longlune et al.. *Nephrology Dialysis Transplantation*, gfab193, https://doi.org/10.1093/ndt/gfab193
https://clinicaltrials.gov/ct2/show/NCT04885907

Considerations for specific populations

LTCF residents, adults ≥65 years of age

- Initial VE encouraging
- Vaccinated in early phase of COVID-19 vaccine roll-out
- Needed special considerations for other vaccines (boosters, higher-dose vaccines)

Healthcare personnel

- Vaccinated in early phase of COVID-19 vaccine roll-out
- Continued exposure to SARS-CoV-2, even as rates of community transmission improve

Immunocompromised persons

- Emerging literature suggesting a reduced antibody response after primary series
- By definition, population with an impaired immune response
- Concern for ability to mount an immune response after additional vaccine doses: consider if other prevention measures needed (monoclonal antibodies, etc.)

Mix-and-match:

Heterologous primary series and booster vaccine

- Recent studies from Europe have assessed heterologous primary series with Pfizer and Astra Zeneca with reassuring results
- Evidence is needed regarding the ability to use a different vaccine as a booster than what was used in the primary series
  - Studies specific to U.S. authorized vaccines

Borobia et. Al Reactogenicity and Immunogenicity of BNT162b2 in Subjects Having Received a First Dose of ChAdOx1s: Initial Results of a Randomized, Adaptive, Phase 2 Trial (CombiVacS). Available at SSRN: https://ssrn.com/abstract=3854768

Shaw et. al Heterologous prime-boost COVID-19 vaccination: initial reactogenicity data, ISSN 0140-6736, https://doi.org/10.1016/S0140-6736(21)01115-6.

Hillus D, Schwarz T, Tober-Lau P, et al. Safety, reactogenicity, and immunogenicity of homologous and heterologous prime-boost immunization with ChAdOx1-nCoV19 and BNT162b2: a prospective cohort study. medRxiv; 2021. DOI: 10.1101/2021.05.19.21257334.

Schmidt et al. medRxiv preprint (June 15 2021): https://doi.org/10.1101/2021.06.13.21258859

Booster doses of COVID-19 vaccines: Timing of additional data

Upcoming studies:

NIH or manufacturer studies

Data from Phase I/II/III trials

- Monitor kinetics of antibody response, efficacy from early phase clinical trials
- BLA submission: Include efficacy for ~6 months

Heterologous boost

- Primary series followed by different boost vaccine
- NIH-sponsored study: 150 individuals, 12-20 weeks following initial series (any series)
  Results expected late summer 2021

Booster studies

- Moderna: Preliminary results for mRNA-1273 (50µg) published May 2021;
  Additional data on mRNA-1273 and other variants as boosters expected July-Sept 2021
- Pfizer: Data on BNT162b2 (30µg) and variant booster studies expected July-Sept 2021

https://www.nih.gov/news-events/news-releases/nih-clinical-trial-evaluating-mixed-covid-19-vaccine-schedules-begins

Upcoming studies:
CDC studies

Vaccine breakthrough cases

- Track breakthrough infections
- Monitor severity of disease and genomic sequence (specifically for variants of concern)

Vaccine effectiveness studies

- Continue to monitor VE studies over time:
  Stratify by **age, time since vaccination**, **setting** and **medical condition**
- Ability to track any waning VE could be impacted by declining incidence, changes in variant prevalence
- Over time, individuals who are vaccinated may become increasingly less comparable to the unvaccinated population

Vaccine effectiveness: Select upcoming studies

HEROES-RECOVER Cohort

- Following ~5,000 essential workers with weekly SARS-CoV-2 testing and quarterly serology
- To date, fully vaccinated populations followed for ~130 days (~4 months) post-vaccination
- Assess neutralizing antibodies 6-months post-vaccination

VISION VE Network

- Multi-state network of 8 integrated care systems and research centers; assess COVID-19 confirmed by molecular assays and vaccination documented by EHR and registries
- Network assesses waning effectiveness using test-negative VE design

IVY VE Network

- Collaborative of hospital-based investigators, through 18 tertiary academic medical centers in 16 states
- Plans to assess duration of protection by adapting prior methods used for influenza

EHR=Electronic Health Registries

Timeline for additional data

Summer:
July-September

Manufacturer data
Safety and Immunogenicity of booster doses

Manufacturer data
Phase I/II/III follow-up

Mix-and-match studies
Heterologous prime-boost

Early Fall:
September-October

COVID-19 epi
Incidence of cases, hospitalizations, deaths

COVID-19 variants
Variant proportions, VE by variant

VE studies
VE by age, setting, time since vaccination

Breakthrough cases
Comparison of variants and clinical outcomes

Timeline for additional data

Summer:
July-September

Manufacturer data
Safety and Immunogenicity of booster doses

Manufacturer data
Phase I/II/III follow-up

Mix-and-match studies
Heterologous prime-boost

Early Fall:
September-October

COVID-19 epi
Incidence of cases, hospitalizations, deaths

COVID-19 variants
Variant proportions, VE by variant

VE studies
VE by age, setting, time since vaccination

Breakthrough cases
Comparison of variants and clinical outcomes

ACIP meetings
Continue to provide updates. Vote could occur whenever data support updating policy

Booster doses of COVID-19 vaccines:
Work Group interpretation

- Work Group felt that recommendation for booster doses would only occur after:
    1. Evidence of declining protection against illness, such as **declines in vaccine effectiveness**, not only waning antibody response
    2. An escape **variant** (variant of concern substantially impacting vaccine protection)

- No data to support recommendations for booster doses currently, but will continue to monitor

- Global vaccine availability should be considered in discussions as well

Questions for ACIP

1. What does ACIP feel would be needed to move forward with booster recommendations?

2. Is the risk of disease enough to warrant a recommendation for boosters, before additional data may be available?

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- Vaccine Task Force
- Epi Task Force
- Respiratory Viruses Branch

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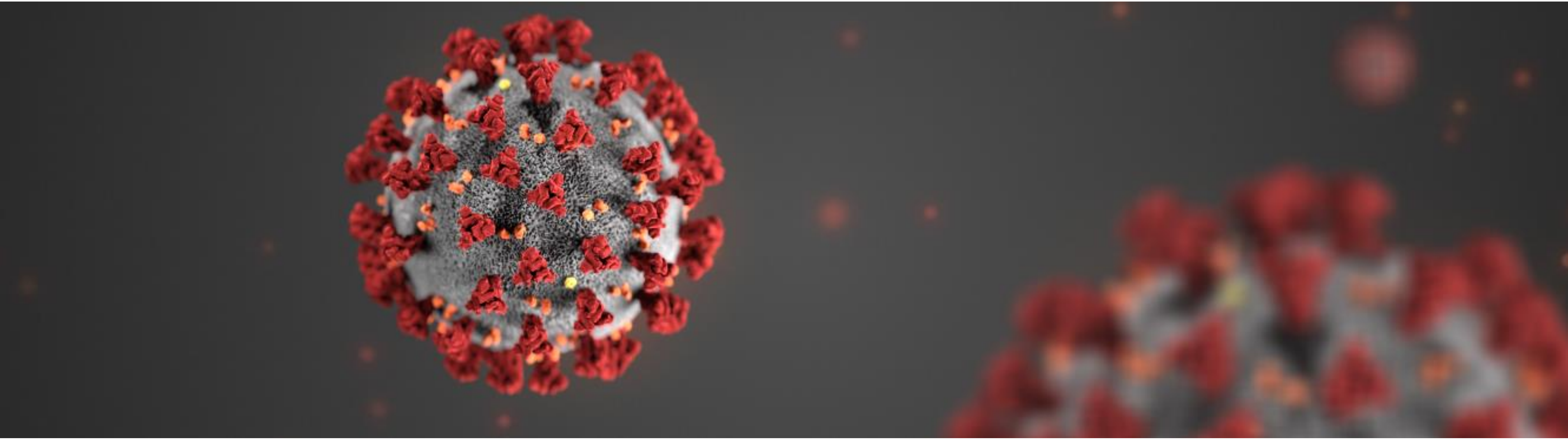

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