8-19-2021

Covid-19 Clinical Update 8/19/2021

George Washington University

U.S. chimp sanctuary is poised to give its primates a COVID-19 vaccine—will others follow its lead?

By Alex Viveros | Aug. 13, 2021 , 6:15 PM

As the COVID-19 vaccine rollout has continued in the United States, a parallel vaccination effort has taken place in some U.S. zoos to protect their animals, particularly great apes. Now, a chimpanzee sanctuary in Georgia is ready to do the same, saying it intends to soon give an experimental COVID-19 vaccine to its primates, who are likely also vulnerable to the coronavirus.

COVID-19 UPDATE

HANA AKSELROD, MD, MPH

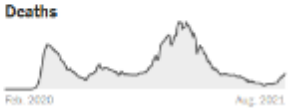
GW DIVISION OF INFECTIOUS DISEASES

MFA COVID-19 LEAD

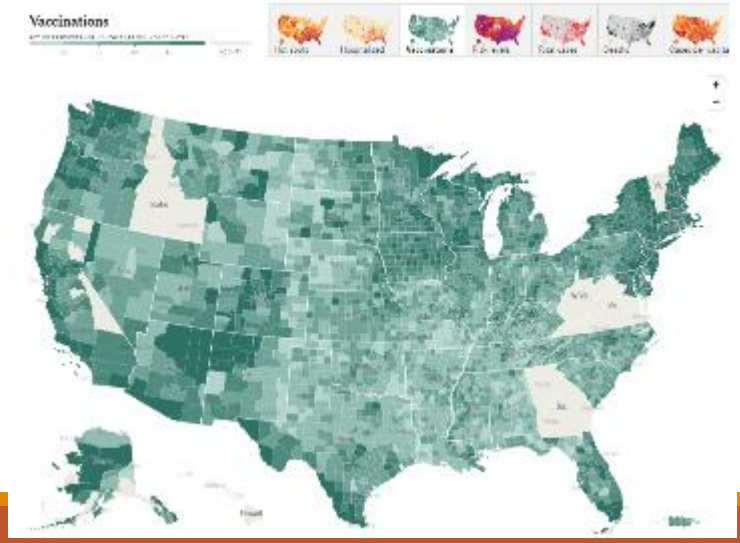
8/19/2021

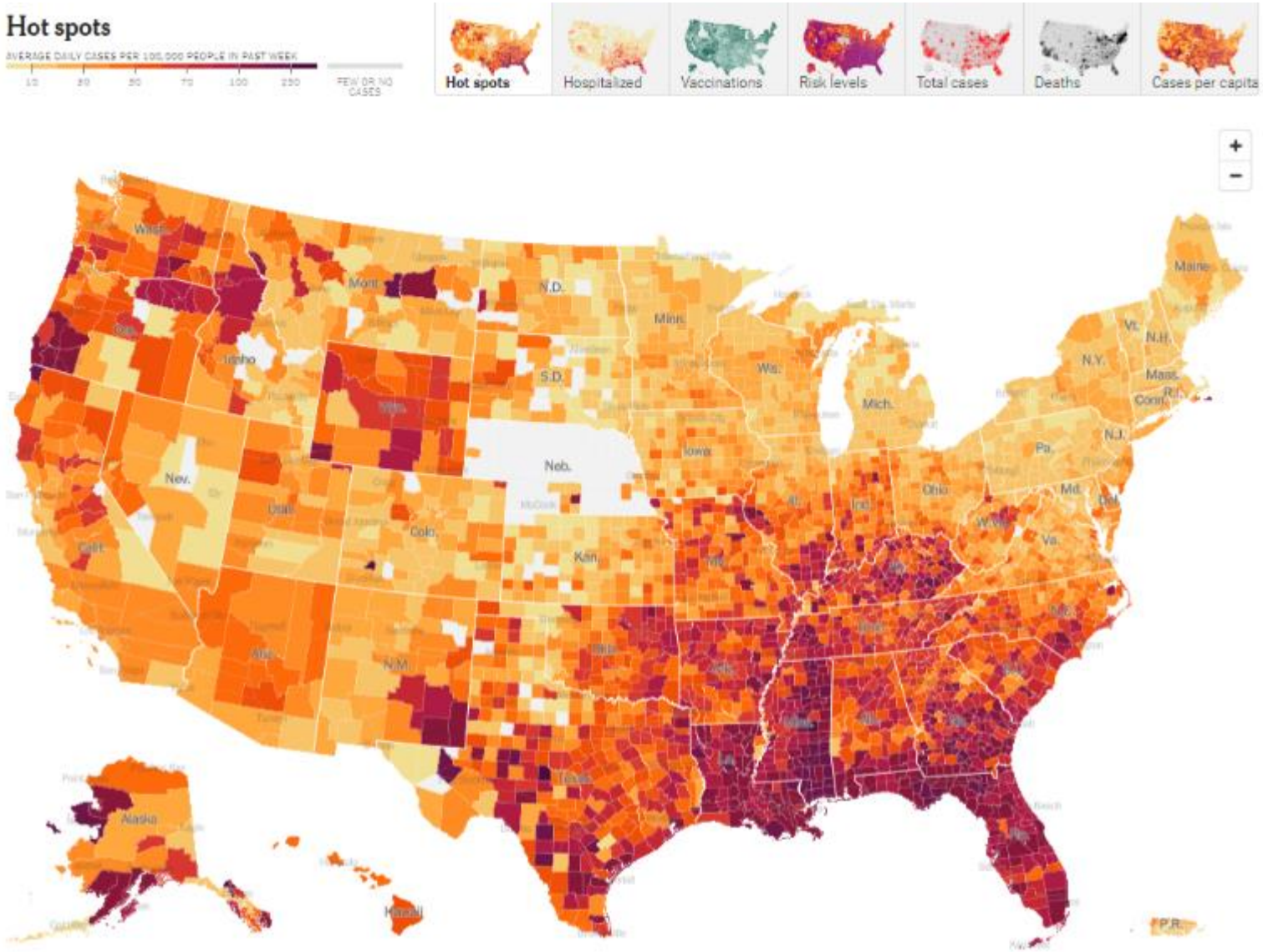
1. EPIDEMIOLOGY
2. TREATMENT
3. PREVENTION
4. GW UPDATES

No Financial COI. Investigator on ongoing clinical trials as part of GW ID Division and Clinical Trials Unit. Preprints are marked as such.

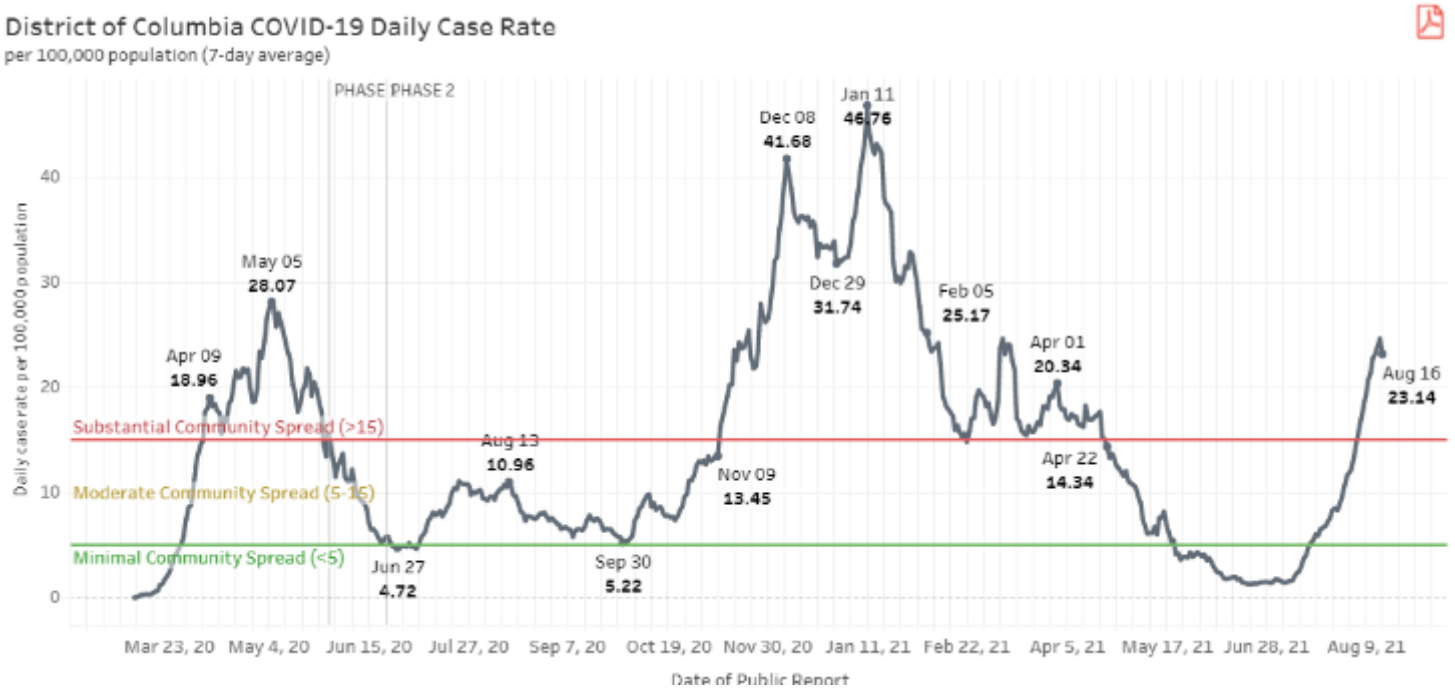


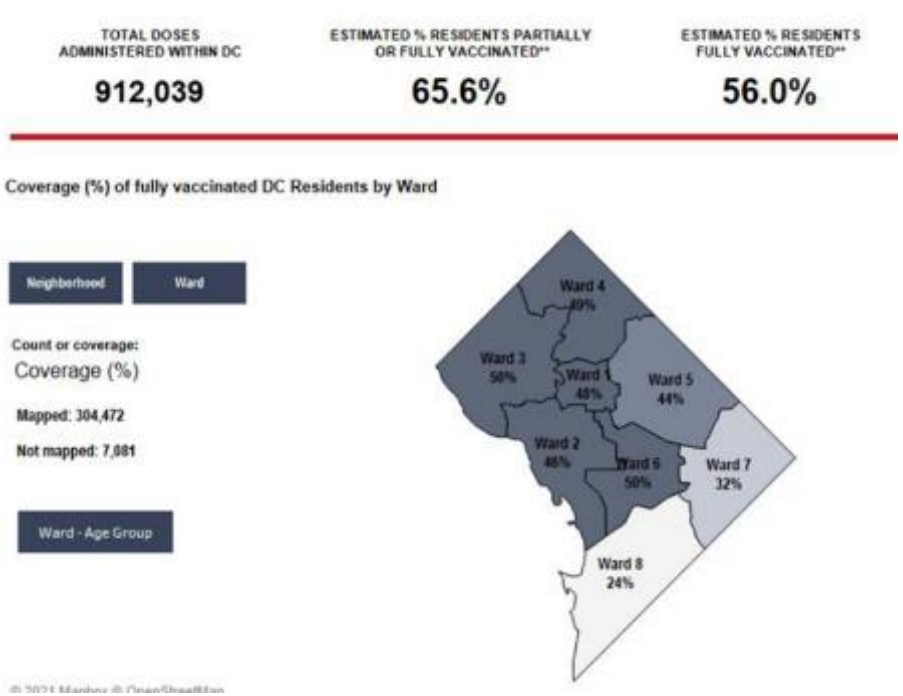
	DAILY AVG. ON AUG. 18	14-DAY CHANGE	TOTAL REPORTED
Cases	140,893	+47%	37,296,398
Tests	1,046,915	+36%	—
Hospitalized	85,118	+56%	—
Deaths	809	+97%	624,365

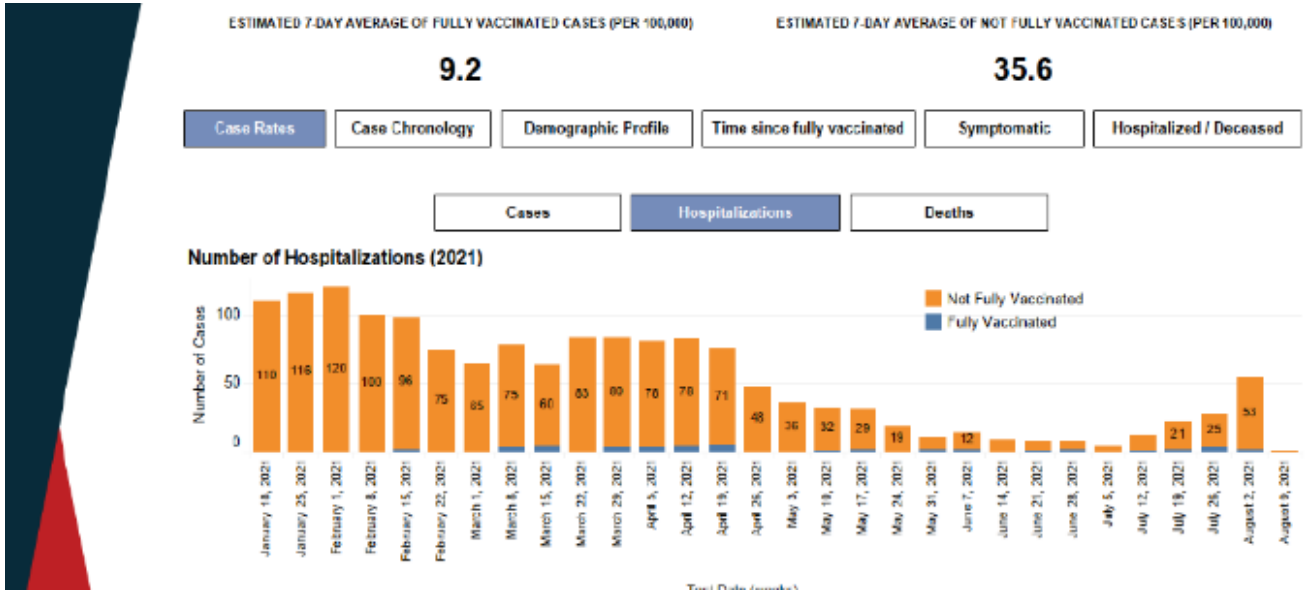




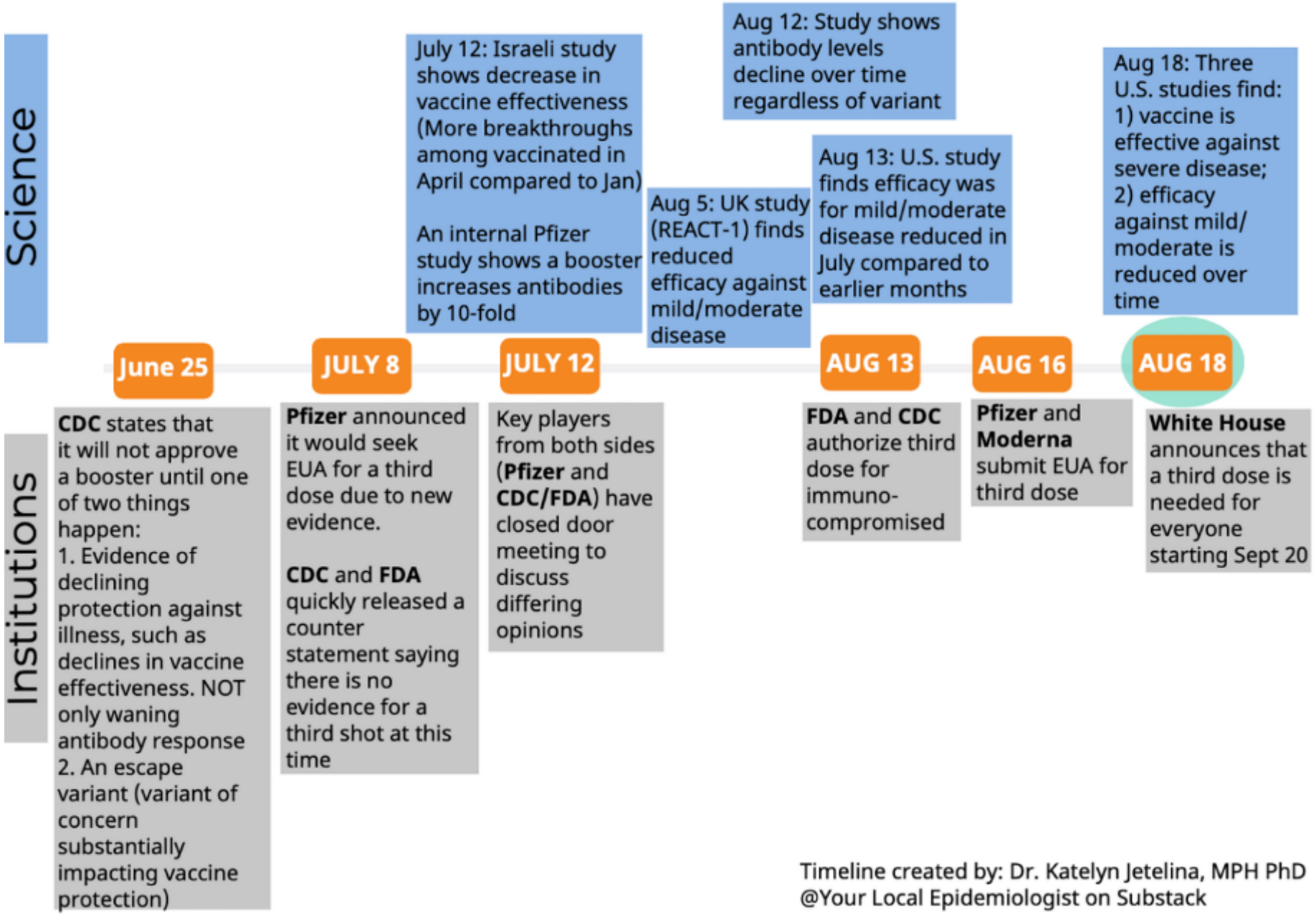
https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html







https://coronavirus.dc.gov/page/reopening-metrics



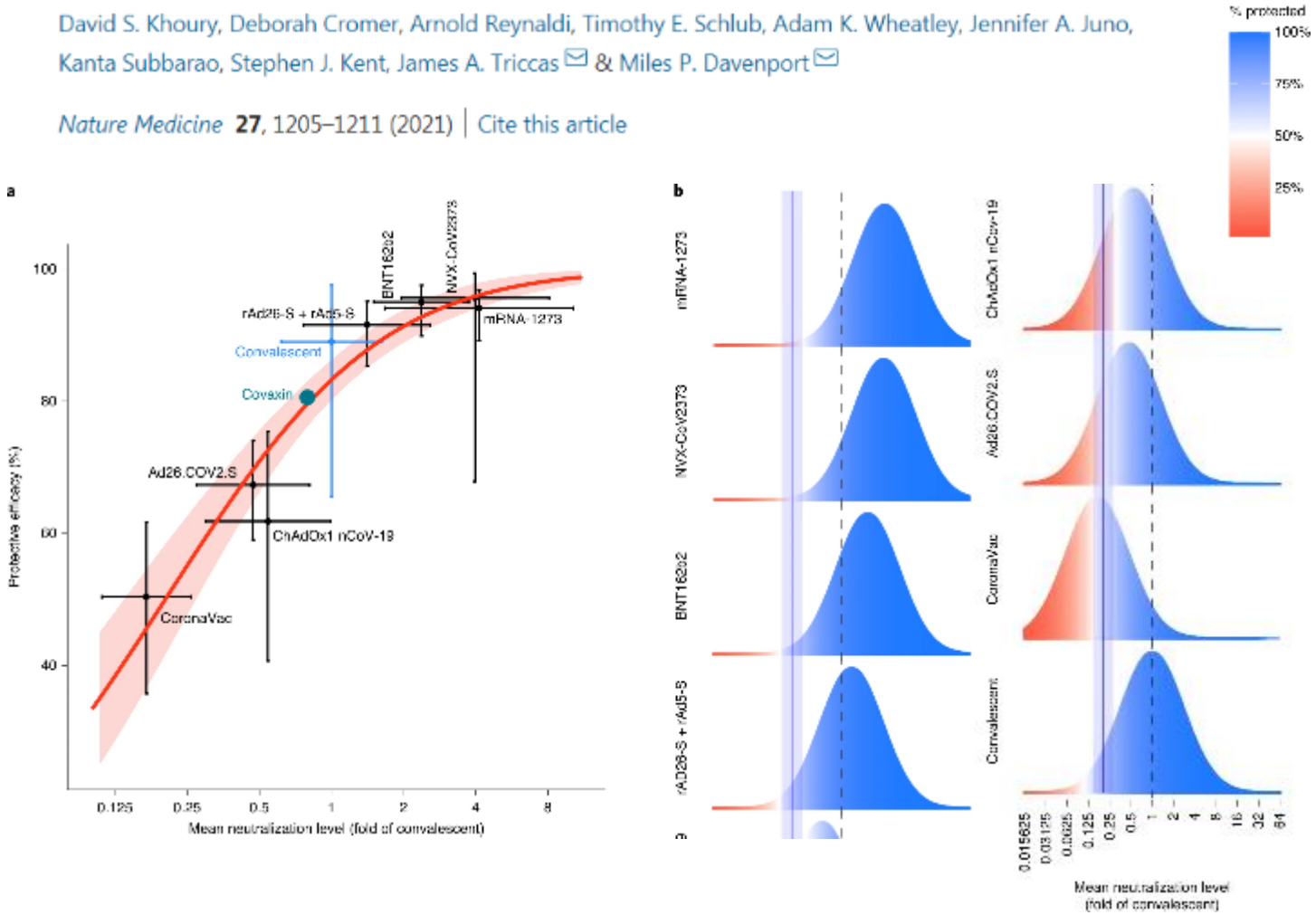
https://yourlocalepidemiologist.substack.com/p/confused-about-the-3rd-dose-me-too

Article | Published: 17 May 2021

Neutralizing antibody levels are highly predictive of immune protection from symptomatic SARS-CoV-2 infection

David S. Khoury, Deborah Cromer, Arnold Reynaldi, Timothy E. Schlub, Adam K. Wheatley, Jennifer A. Juno, Kanta Subbarao, Stephen J. Kent, James A. Triccas & Miles P. Davenport

Nature Medicine **27**, 1205–1211 (2021) | Cite this article



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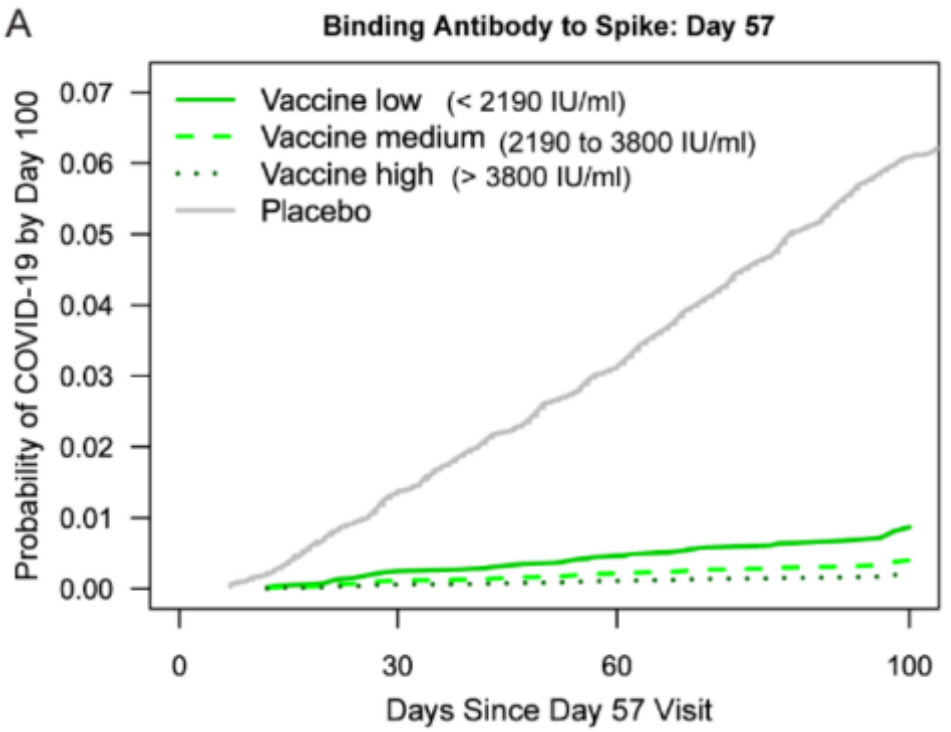
Immune Correlates Analysis of the mRNA-1273 COVID-19 Vaccine Efficacy Trial

Peter B. Gilbert, David C. Montefiori, Adrian McDermott, Youyi Fong, David Benkeser, Weiping Deng,



https://www.nature.com/articles/s41591-021-01377-8/figures/1

VE at 5+ Months

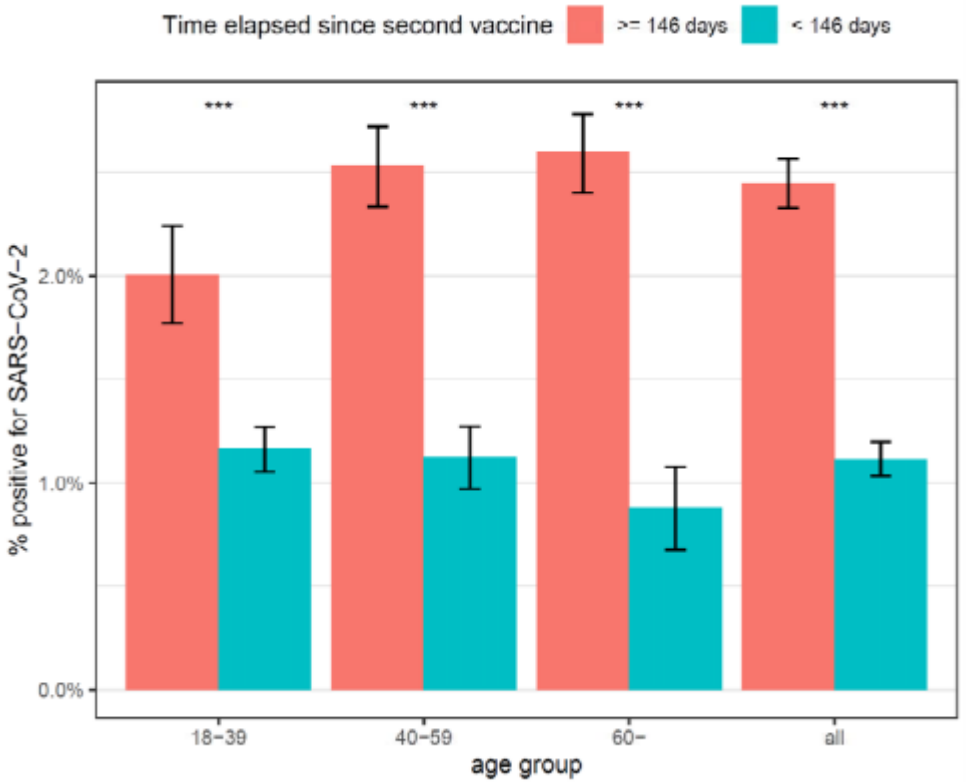
- Study in Israel, early mass rollout of Pfizer mRNA
- Nationwide healthcare system, EHR data
- 33,993 fully vaccinated adults tested 05-07/2021
- Significantly higher rate of positive results among patients who received second vaccine dose ≥146 days before the RT-PCR test compared to patients who have vaccinated <146 days before. Severity not included.
- OR for infection: Overall 2.23 (95% CI: 1.87-2.66)
  - 3.00 for patients aged ≥60 (95% CI: 1.86-5.11)
  - 2.29 for patients aged 40-59 (95% CI: 1.67-3.17)
  - 1.74 for patients aged 18-39 (95% CI: 1.27-2.37)
- "Interpretation of study findings is limited by the observational design; but may warrant the consideration of an additional vaccine dose in individuals at risk for severe disease."

medRxiv
THE PREPRINT SERVER FOR HEALTH SCIENCES

Elapsed time since BNT162b2 vaccine and risk of SARS-CoV-2 infection in a large cohort

Ariel Israel, Eugene Merzon, Alejandro A Schäffer, Yotam Shenhar, Ilan Green, Avivit Golan-Cohen, Eytan Ruppin, Eli Magen, Shlomo Vinker

doi: https://doi.org/10.1101/2021.08.03.21261496



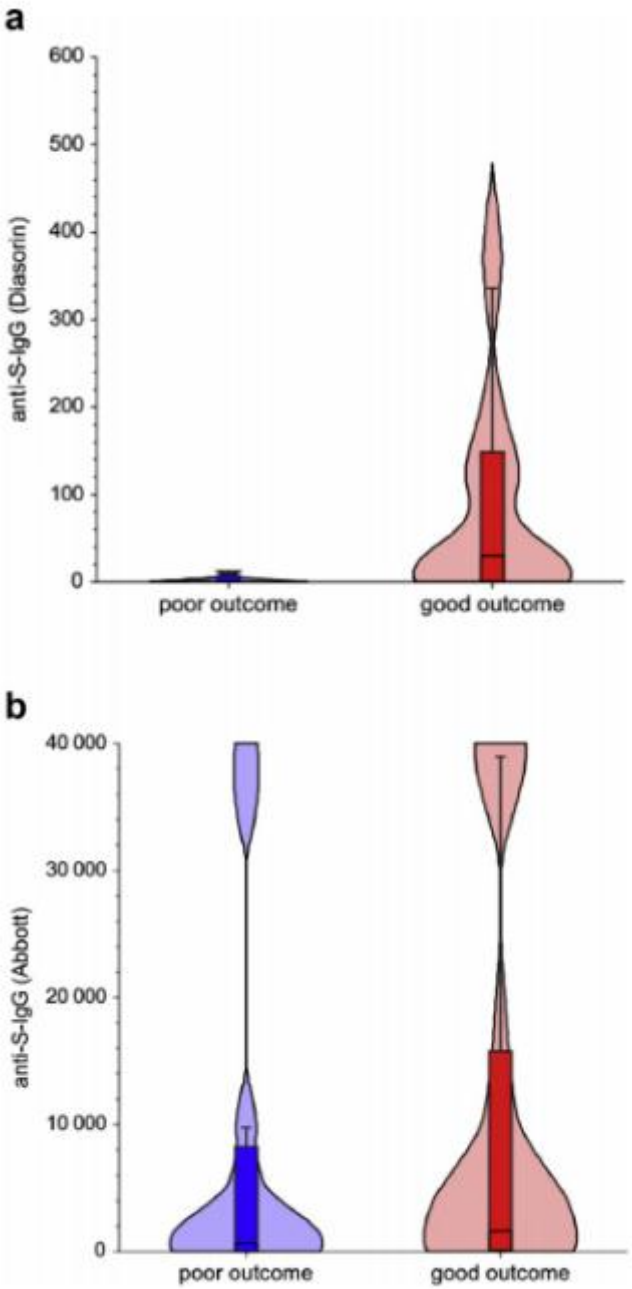
https://www.medrxiv.org/content/10.1101/2021.08.03.21261496v1

BNT162b2 vaccine breakthrough: clinical characteristics of 152 fully vaccinated hospitalized COVID-19 patients in Israel

Tal Brosh-Nissimov • Efrat Orenbuch-Harroch • Michal Chowers • ... Hiba Zayyad • Galia Rahav • Yonit Wiener-Well • Show all authors

Published: July 06, 2021 • DOI: https://doi.org/10.1016/j.cmi.2021.06.036

- Retrospective cohort of 17 hospitals, patients who developed COVID-19 >7 days after dose #2 of Pfizer BNT162b2 and required hospitalization.
- 152 patients = half of hospitalized breakthrough patients in Israel in spring 2021.
- 45 SARS-CoV2 sequences; 40/45 (89%) were **B.1.1.7 (alpha)**.
- Mean age 71.1 ± 14.3 yrs overall, 74.7 ± 10.5 for those w/ poor outcome.
- Poor outcome (MV or death) in 38/152, **mortality rate 22% (34/152).**
- High rate of comorbidities predisposing to severe COVID-19: HTN (71%), DM (48%), CHF (27%), CKD (24%), chronic lung disease (24%), cancer (24%), dementia (19%). Only 6/152 (4%) had no comorbidities.
- Sixty (40%) of the patients were immunocompromised: chemotherapy (18%), corticosteroids (19%), SOT (11%), anti-CD20 (7%).
- Higher SARS-CoV2 viral load was associated with poor outcome.
- Poor outcomes more common in patients receiving anti-CD20 treatment (5/10) and in patients with low titers of anti-Spike IgG, though the latter varied by assay (figure) and did not reach statistical significance.



https://www.clinicalmicrobiologyandinfection.com/article/S1198-743X(21)00367-0/fulltext

Comments (7)

Full vaccination is imperative to suppress SARS-CoV-2 delta variant mutation frequency

Ting-Yu Yeh, Gregory P. Contreras

doi: https://doi.org/10.1101/2021.08.08.21261768

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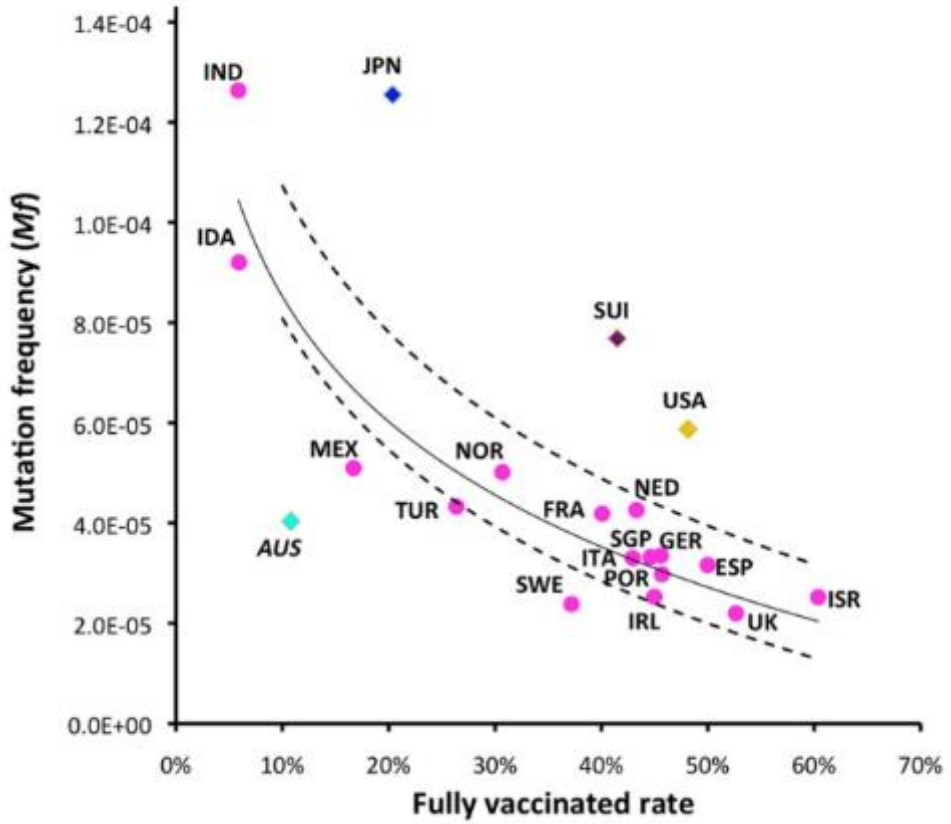
CSH Cold Spring Harbor Laboratory BMJ Yale



- "Vaccination coverage rate is inversely correlated to the mutation frequency of the SARS-CoV-2 delta variant in 16 countries (R^2=0.878)"
- "Full vaccination against COVID-19 is critical to suppress emergent mutations."

https://www.medrxiv.org/content/10.1101/2021.08.08.21261768v2

CDC Centers for Disease Control and Prevention

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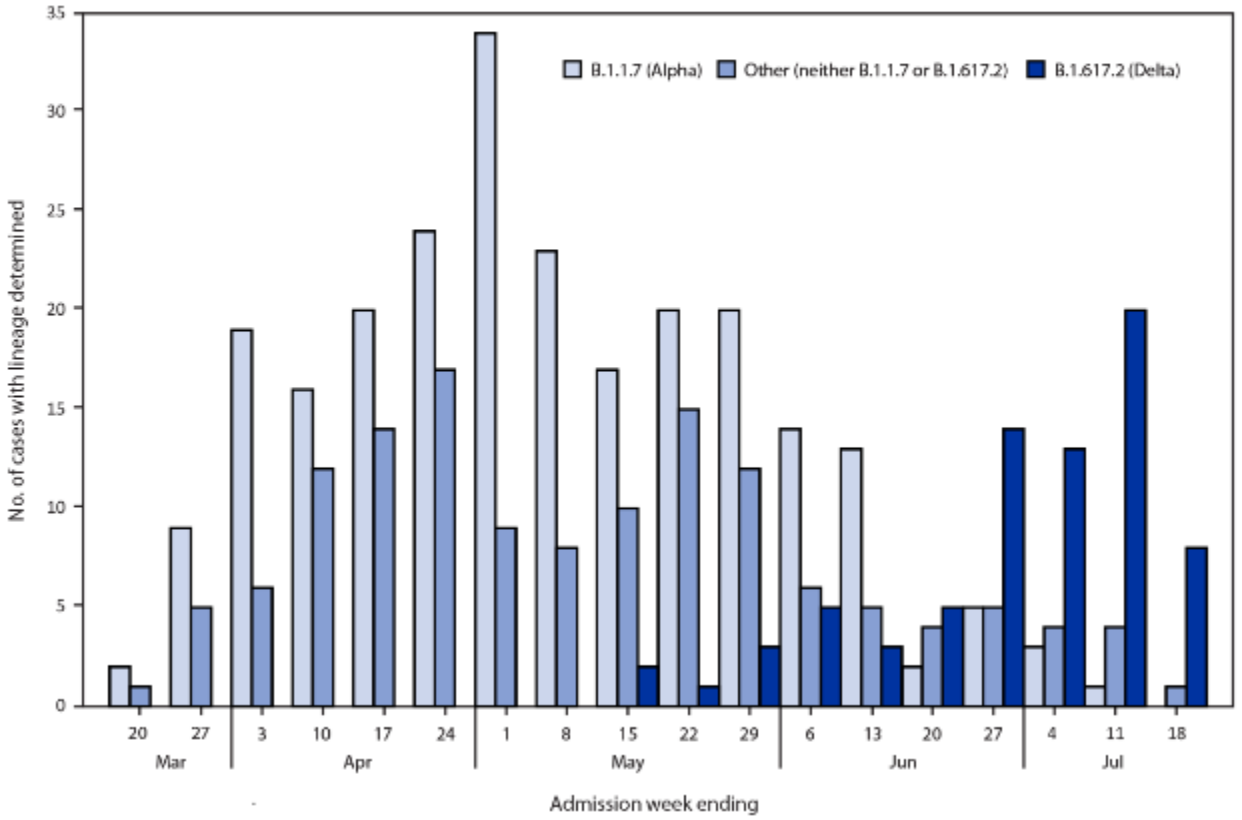
Morbidity and Mortality Weekly Report (*MMWR*)

Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults — United States, March–July 2021

FIGURE 1. Whole genome sequencing lineage determination among adults hospitalized with COVID-19 — 21 academic medical centers in 18 states,*† March–July 2021



- Among 1,129 patients who received 2 doses of a mRNA vaccine, **no decline in vaccine effectiveness against COVID-19 hospitalization was observed over 24 weeks.**
- Vaccine effectiveness was 86% 2-12 weeks after vaccination and 84% at 13-24 weeks. Vaccine effectiveness was sustained among groups at risk for severe COVID-19.
- Protection against severe COVID-19 resulting in hospitalization was sustained through 24 weeks after vaccination with mRNA COVID-19 vaccines.
- To reduce their risk for hospitalization, all eligible persons should be offered COVID-19 vaccination.
- Continued monitoring of VE against infection and severe disease is needed as the elapsed time since vaccination increases and new SARS-CoV-2 variants emerge.

https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e2.htm

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Morbidity and Mortality Weekly Report (*MMWR*)

CDC

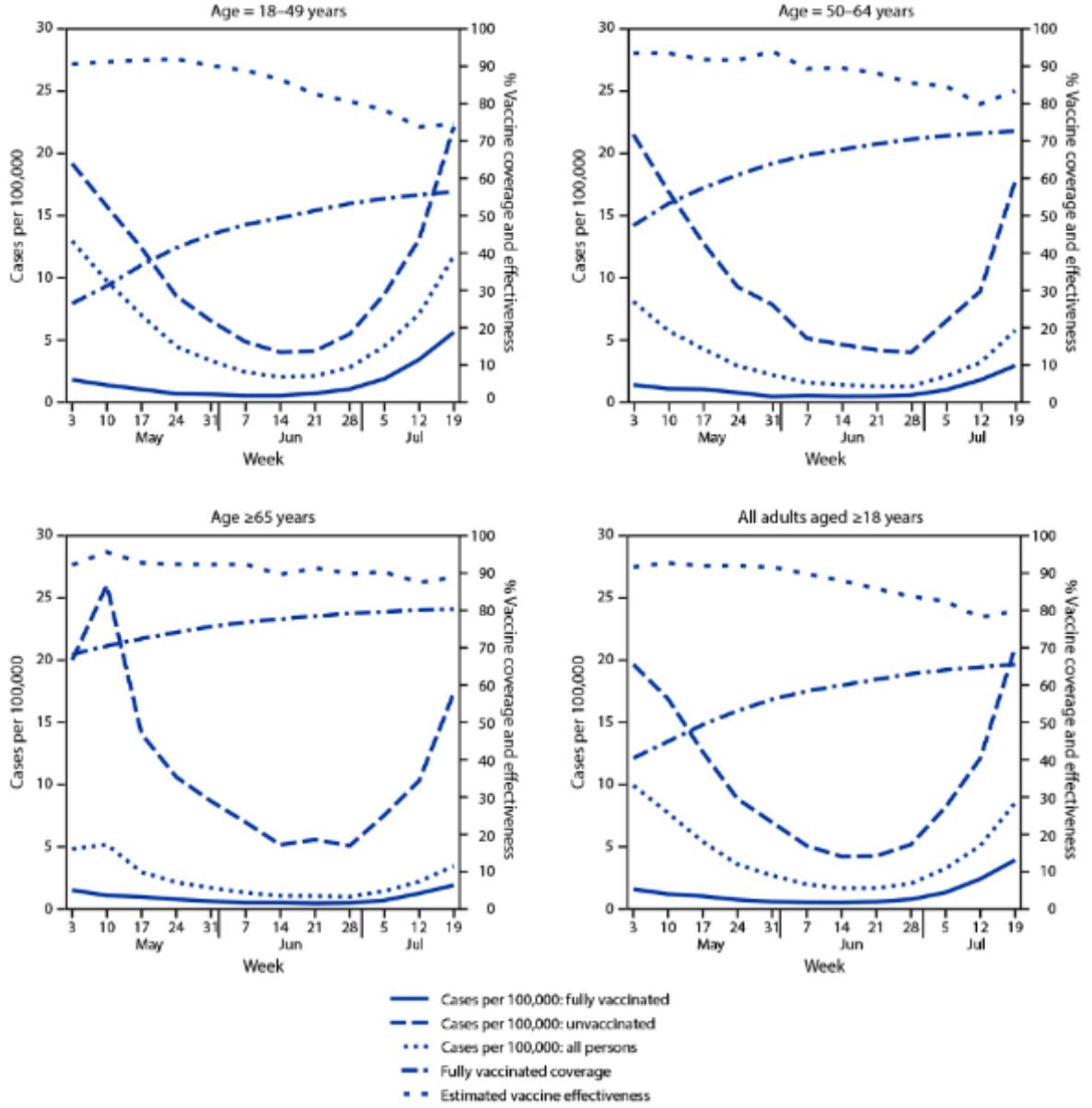
New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021

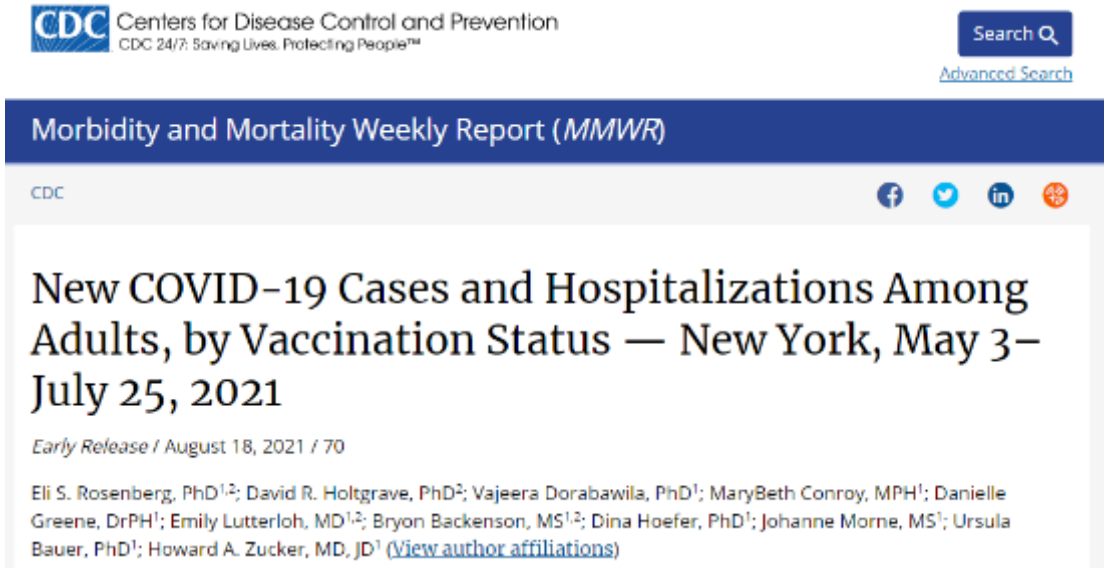
Early Release / August 18, 2021 / 70

Eli S. Rosenberg, PhD[1,2]; David R. Holtgrave, PhD[2]; Vajeera Dorabawila, PhD[1]; MaryBeth Conroy, MPH[1]; Danielle Greene, DrPH[1]; Emily Lutterloh, MD[1,2]; Bryon Backenson, MS[1,2]; Dina Hoefer, PhD[1]; Johanne Morne, MS[1]; Ursula Bauer, PhD[1]; Howard A. Zucker, MD, JD[1] (View author affiliations)

- During May 3-July 25, 2021, the overall age-adjusted vaccine effectiveness **against hospitalization** in New York was relatively stable (91.9%-95.3%).
- The overall age-adjusted vaccine effectiveness **against infection** for all New York adults declined from 91.7% to 79.8%.
- These findings support the implementation of multicomponent approach to controlling the pandemic, centered on vaccination, as well as other prevention strategies such as masking and physical distancing.

FIGURE 1. New COVID-19 cases among fully vaccinated and unvaccinated adults, vaccine coverage, and estimated vaccine effectiveness, by age — New York, May 3–July 25, 2021





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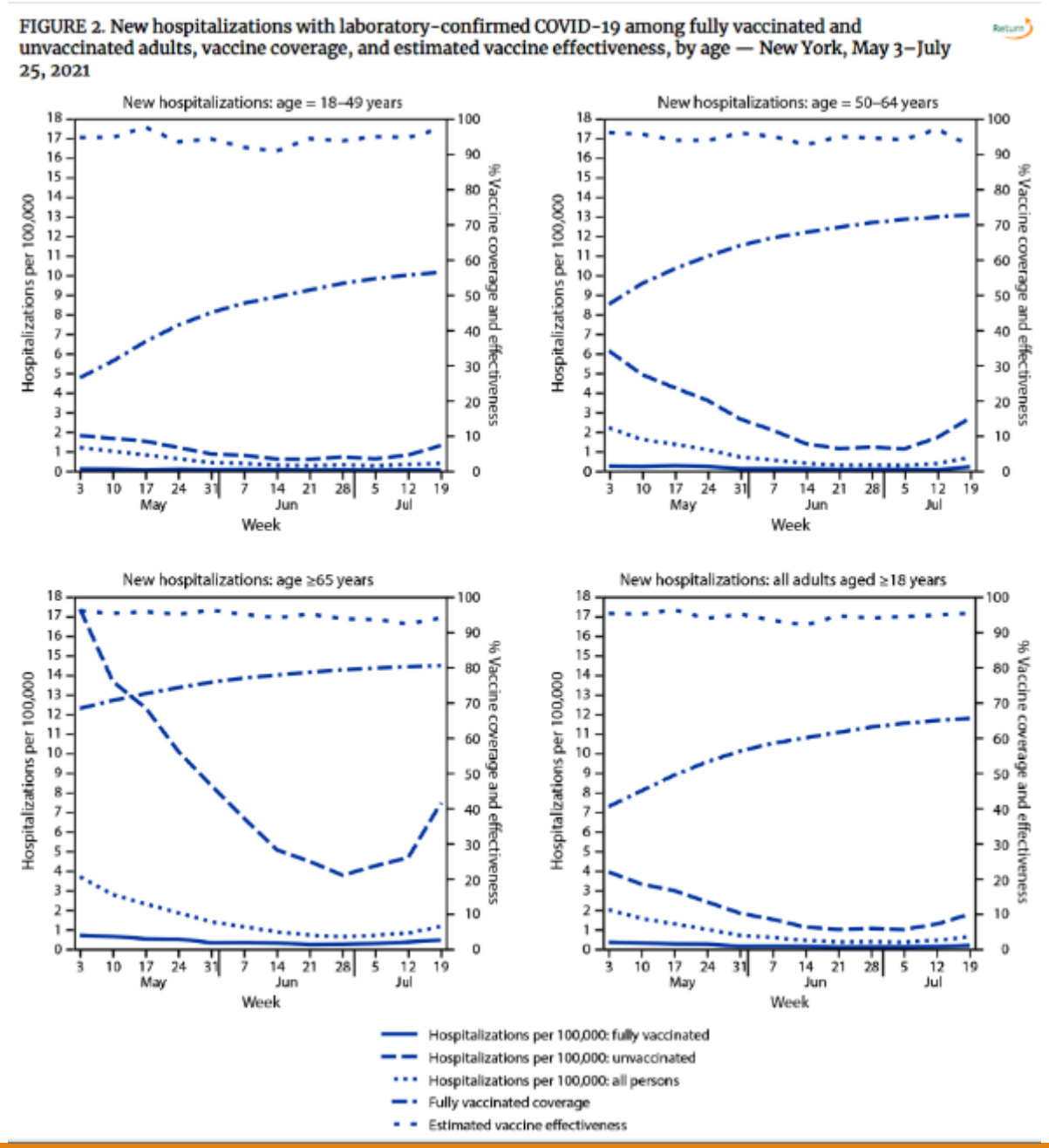
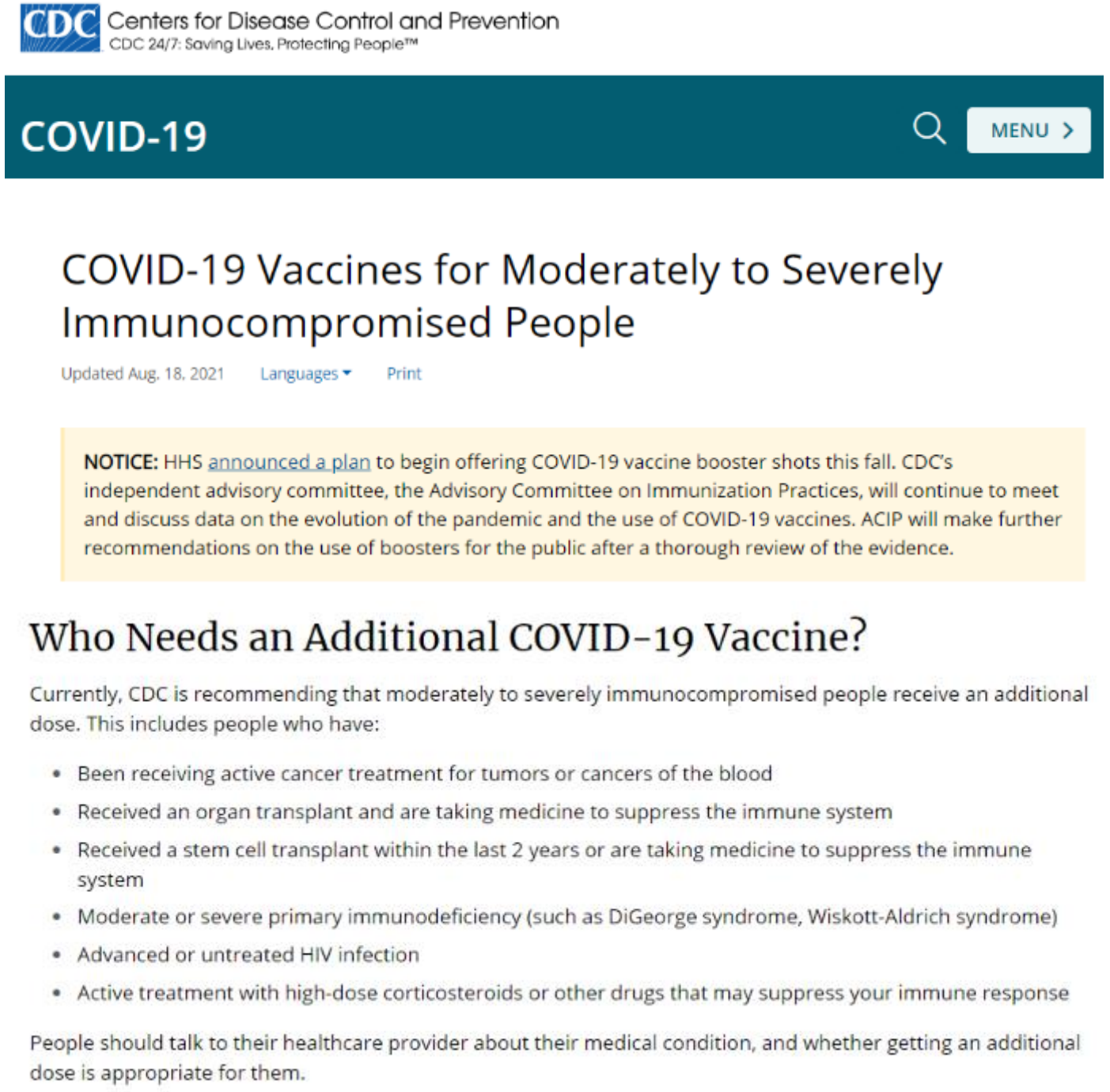


Additional Doses for Immuno-compromised

FDA 8/12/2021

ACIP 8/13/2021

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html



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COVID-19 MENU

COVID-19 Vaccines for Moderately to Severely Immunocompromised People

Updated Aug. 18, 2021 Languages Print

NOTICE: HHS announced a plan to begin offering COVID-19 vaccine booster shots this fall. CDC's independent advisory committee, the Advisory Committee on Immunization Practices, will continue to meet and discuss data on the evolution of the pandemic and the use of COVID-19 vaccines. ACIP will make further recommendations on the use of boosters for the public after a thorough review of the evidence.

Who Needs an Additional COVID-19 Vaccine?

Currently, CDC is recommending that moderately to severely immunocompromised people receive an additional dose. This includes people who have:

- Been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response

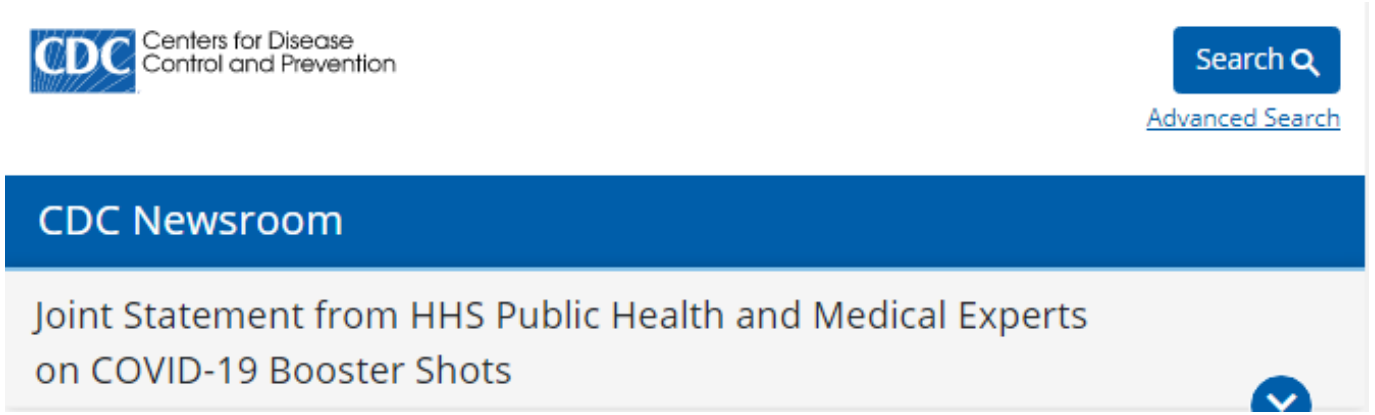
People should talk to their healthcare provider about their medical condition, and whether getting an additional dose is appropriate for them.

BOOSTERS

CDC/DHHS 8/18/2021

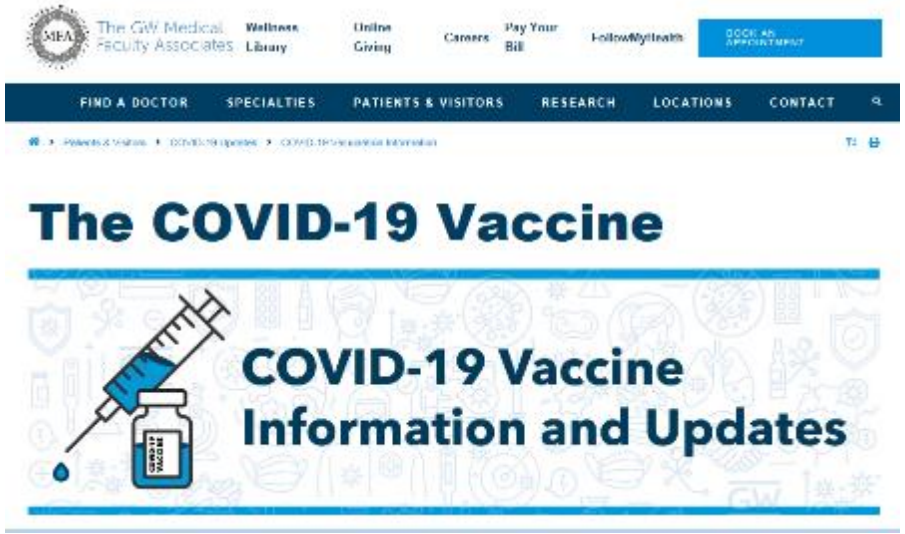
Who, What, When, Why, How?

https://www.cdc.gov/media/releases/2021/s0818-covid-19-booster-shots.html



- “Vaccines … continue to be remarkably effective in reducing risk of severe disease, hospitalization, and death, even against the widely circulating Delta variant.”
- “Protection against SARS-CoV-2 infection begins to decrease over time following the initial doses of vaccination, and in association with the dominance of the Delta variant, we are starting to see evidence of reduced protection against mild and moderate disease.”
- “Current protection against severe disease, hospitalization, and death could diminish in the months ahead, especially among those who are at higher risk or were vaccinated during the earlier phases of the vaccination rollout. For that reason, we conclude that a booster shot will be needed to maximize vaccine-induced protection and prolong its durability.”
- “We have developed a plan to begin offering these booster shots this fall subject to FDA conducting an independent evaluation and determination of the safety and effectiveness of a third dose of the Pfizer and Moderna mRNA vaccines.”
- “We are prepared to offer booster shots for all Americans beginning the week of September 20 and starting 8 months after an individual’s second dose.”

GW Updates: Additional Doses of Vaccine



https://www.gwdocs.com/patients-visitors/covid-19-updates/covid-19-vaccination-information/

COVID Vaccine Update

Based on the recently updated FDA and CDC guidance, the GW MFA COVID-19 vaccine clinic is offering additional doses of mRNA vaccine to immunocompromised patients who meet CDC ACIP criteria or upon the recommendation of their physician. We anticipate further federal guidance on vaccine "booster" doses for additional categories of previously vaccinated people in the near future, and will be updating our practice accordingly.

All individuals ages 12+, are now eligible to get a COVID Vaccine at our vaccine clinic that is operated by The GW Medical Faculty Associates. There is no appointment required; walk-ups are welcome from 7:30 a.m. to 3:30 p.m, however, if you would prefer to schedule an appointment ahead of time online please click here. For individuals under the age of 18, a parent or legal guardian must be present. We are pleased to be able to offer both DC and non-DC residents the opportunity to be vaccinated in DC.

Vaccination Location & Eligibility Information

Eligibility Information: All individuals 12+ (both DC and non-DC residents) are now welcome to walk-up to our vaccination clinic.

Walk-In Hours: Monday - Friday, 7:30 a.m. to 3:30 p.m.

PRE-SCHEDULE YOUR VACCINATION APPOINTMENT

Beginning July 6, 2021, we are now vaccines at the following location:

The GW Medical Faculty Associates

2300 M Street, NW

First Floor

Washington, DC 20037

GW FAQ Re: Additional Doses of Vaccine

- **Q: Who qualifies for additional vaccines currently?**
  A: GW criteria are consistent with CDC ACIP guidance:

  - Transplant (solid organ or BMT within last 2 years)
  - Major primary immunodeficiency
  - Advanced HIV/AIDS (CD4 <200)
  - Cancer undergoing active treatment
  - High-dose steroids or biologic immunosuppressive medications for autoimmune disease

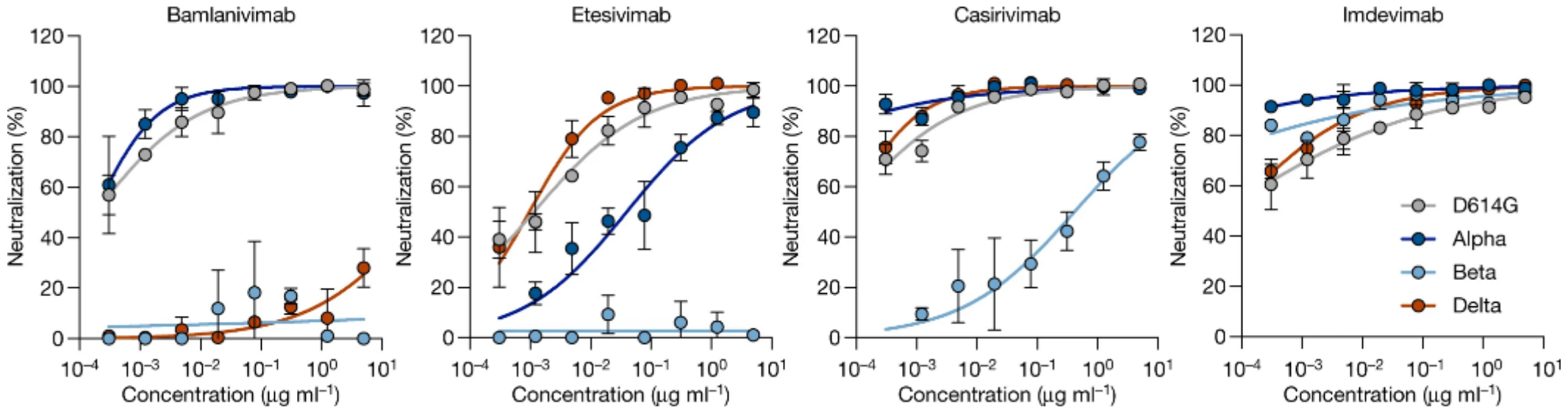
  Other condition or unsure: individual discussion with physician

- **Q: When will booster shots for everyone else be available?**
  A: Per the Federal Government, after Sept. 20th with further details to follow.

GW FAQ Re: Additional Doses of Vaccine

- **Q: How to order 3rd dose for a qualifying patient?**
  A: No physician order required at this time. Refer patient to any convenient vaccination location and self-report that they qualify. Process may be smoothest at GW MFA Vaccine Clinic (2300 M Street NW, 7:30-3:30). Appointments available on website though not required.
- **Q: Can vaccines be mixed?**
  A: Per ACIP, if possible use the same (Pfizer or Moderna) vaccine product for third dose as for the original series. However, if not available or don't know, can use either mRNA vaccine.
- **Q: What about eligible people who got J&J?**
  A: Data on J&J-vaccinated people is under review, wait for updates. If a very high-risk patient clinical judgment / shared decision may be to vaccinate now rather than wait.
- **Q: Will there be more side effects with additional or booster doses?**
  A: Not much data on this yet but plausible; counsel patients accordingly.
- **Q: Will 3rd doses for immunocompromised have a significant effect on Delta epidemiology?**
  A: Likely not, but will have significant clinical effects on individuals and their households.

From last week: Monoclonals vs. Delta



- Bamlanivimab/etesevimab: poor performance against earlier VOC, no longer offered.
- Casirivimab/imdevimab: maintains efficacy against VOC including Delta. Available.
- Sotrovimab also available. (Not part of this study.)

https://www.nature.com/articles/s41586-021-03777-9