AETC AIDS Education & Training Center Program Northeast/Caribbean

Weill Cornell Medicine

# COVID-19 Update: Viral Variants, Vaccines and More

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September 22, 2021

# Disclosures

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# Disclosures

- Research support to Weill Cornell Medicine:
  - Gilead Sciences
  - Regeneron
- Consultant:
  - Enzychem (DSMB* member)
  - ReAlta Life Sciences
  - Regeneron
  - Sobi (DSMB* member)



* Data Safety Monitoring Board for a clinical trial

# Overview

- Current epidemiology
- SARS-CoV-2 variants
- Treatment
- Vaccines
- Considerations for People with HIV

# Global Epidemiology (as of 9/12/21)

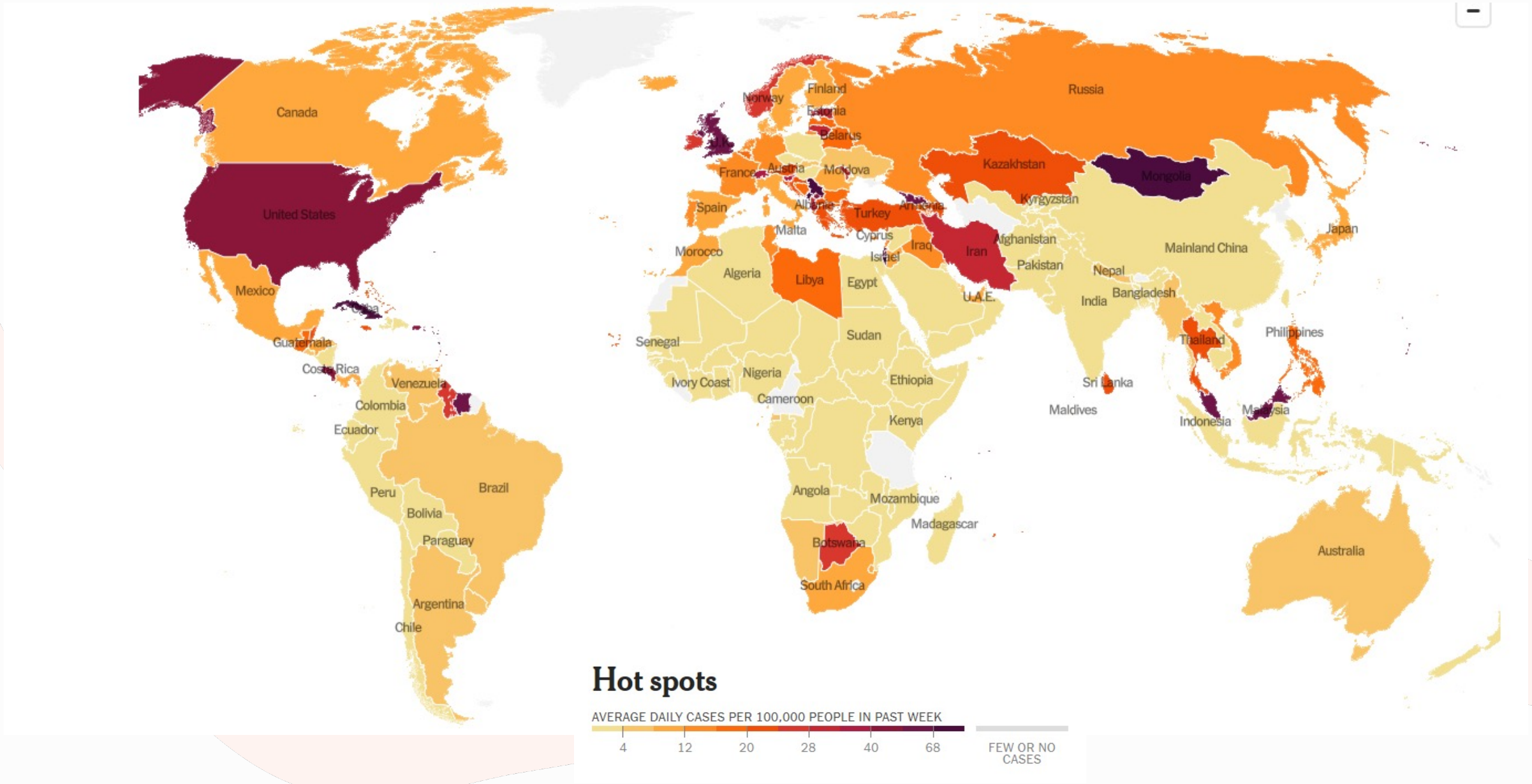
- 224 million cases  4.6 million deaths
- 5.7 billion vaccine doses administered

- Top 3 Countries:

| | Cases: | Deaths: |
|---|---|---|
| U.S.: | 40.9 M | **660,000** |
| India: | 33.2 M | 442,000 |
| Brazil: | 20.9 M | 586,000 |

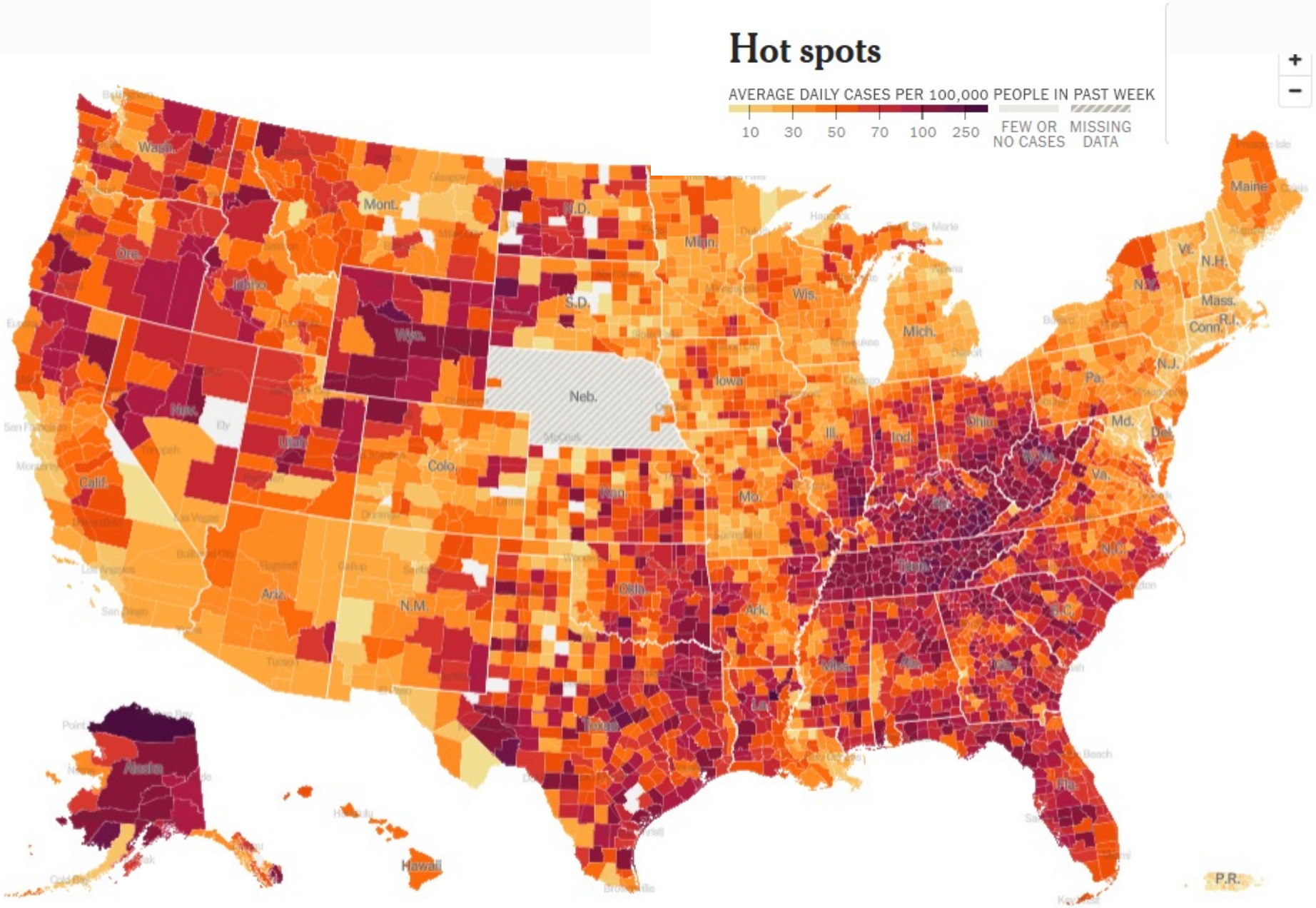


Sources: Johns Hopkins University and NY Times

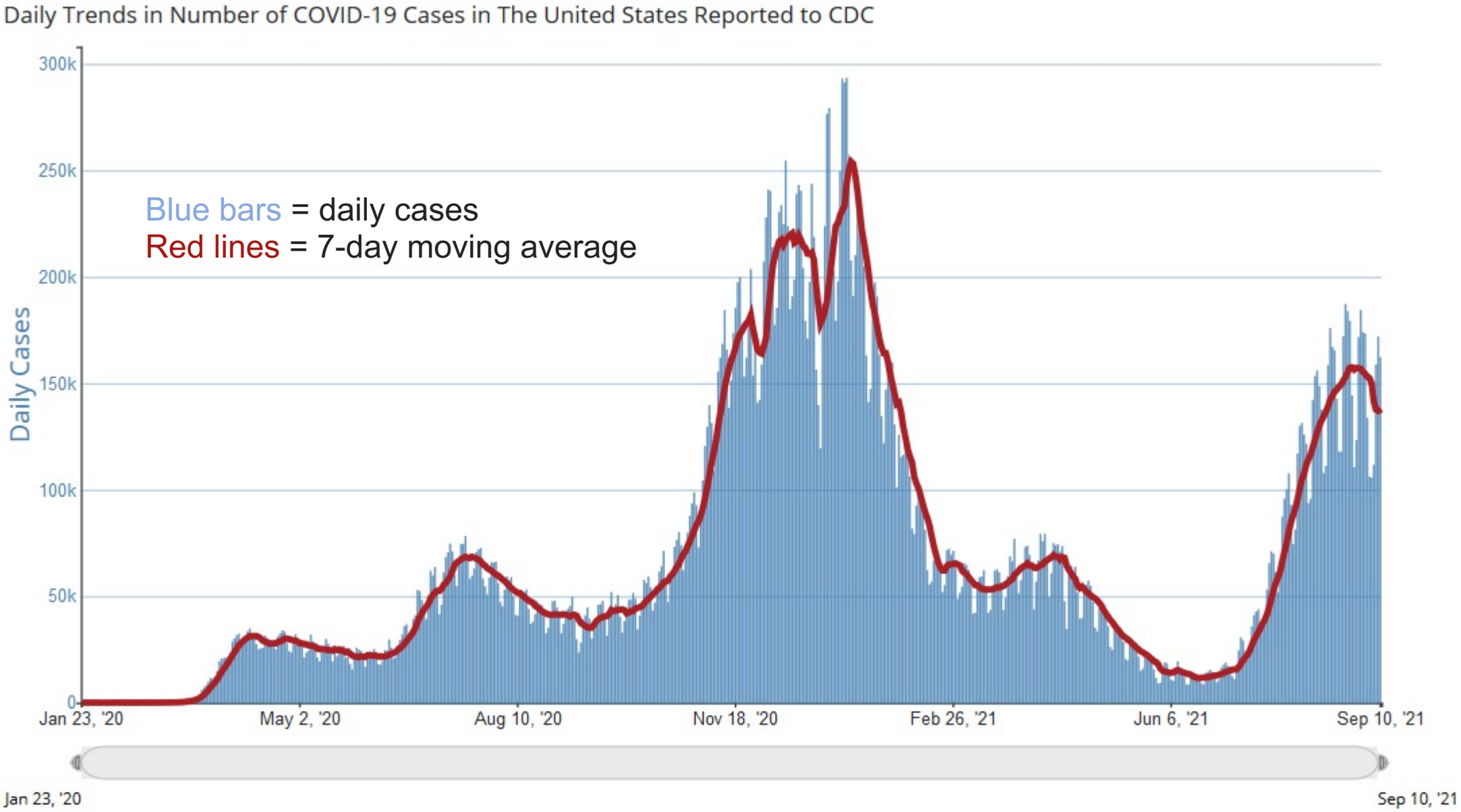





https://www.nytimes.com/interactive/2021/world/covid-cases.html accessed (9/12/21)

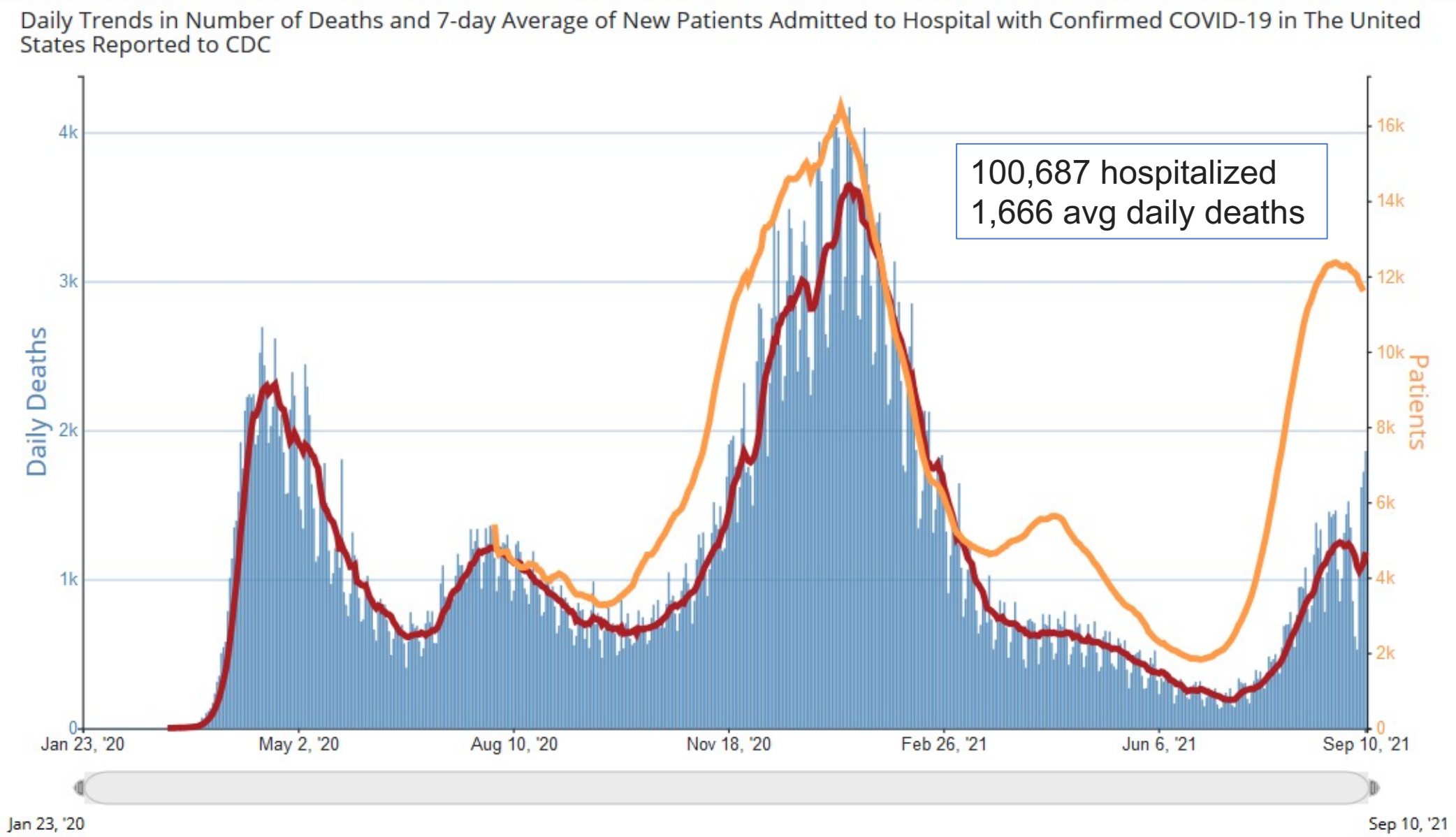



https://www.nytimes.com/interactive/2021/us/covid-cases.html (accessed 9/12/21)






https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases (accessed 9/12/21)




https://covid.cdc.gov/covid-data-tracker/#trends_dailydeaths_newhospitaladmissions (accessed 9/12/21)

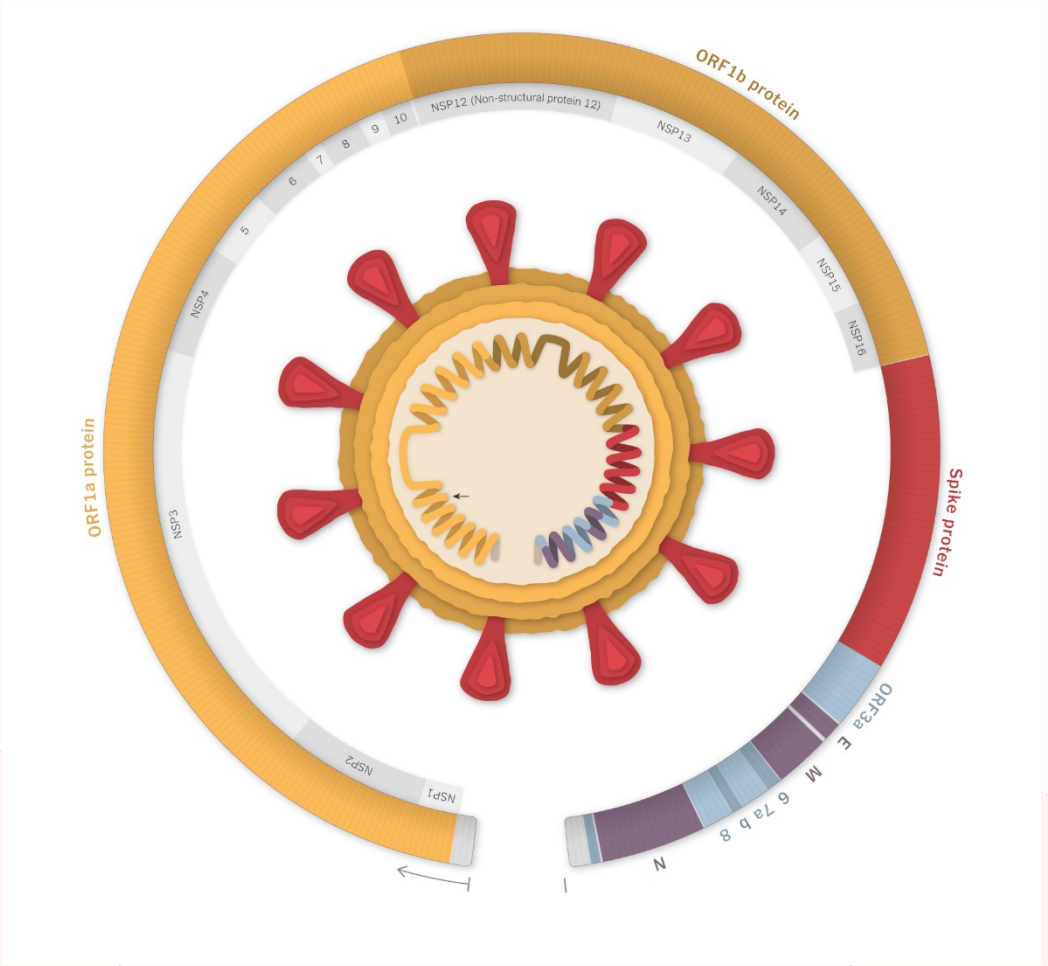

A street in Bolton, UK, where cases of COVID-19 caused by the B.1.617.2 variant have been identified. Credit: Hollie Adams/Bloomberg/Getty



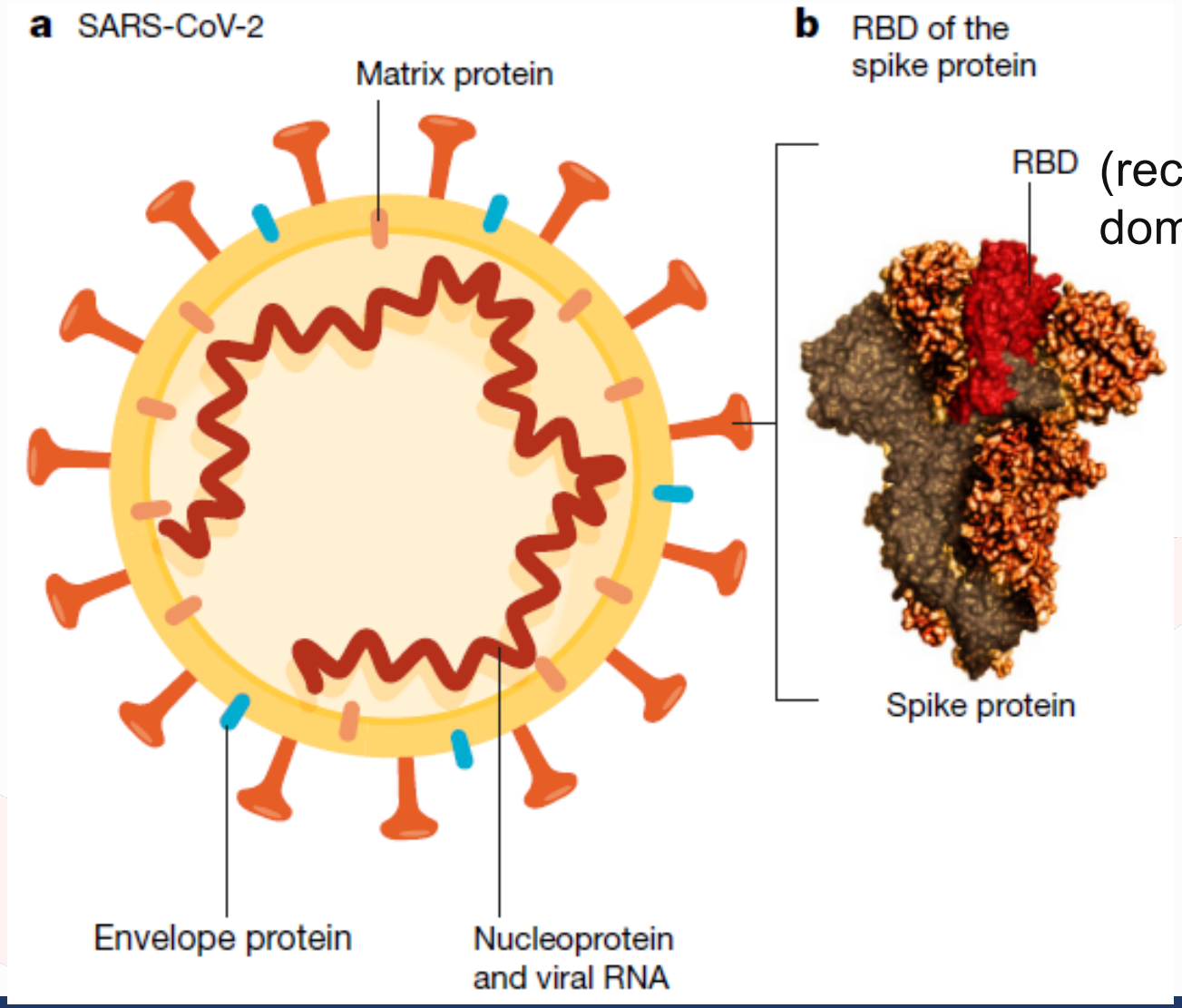
https://www.nature.com/articles/d41586-021-01390-4

# SARS-CoV-2 Variants

- Arise as natural consequence of viral replication with errors/mutations



# COVID-19 Structure

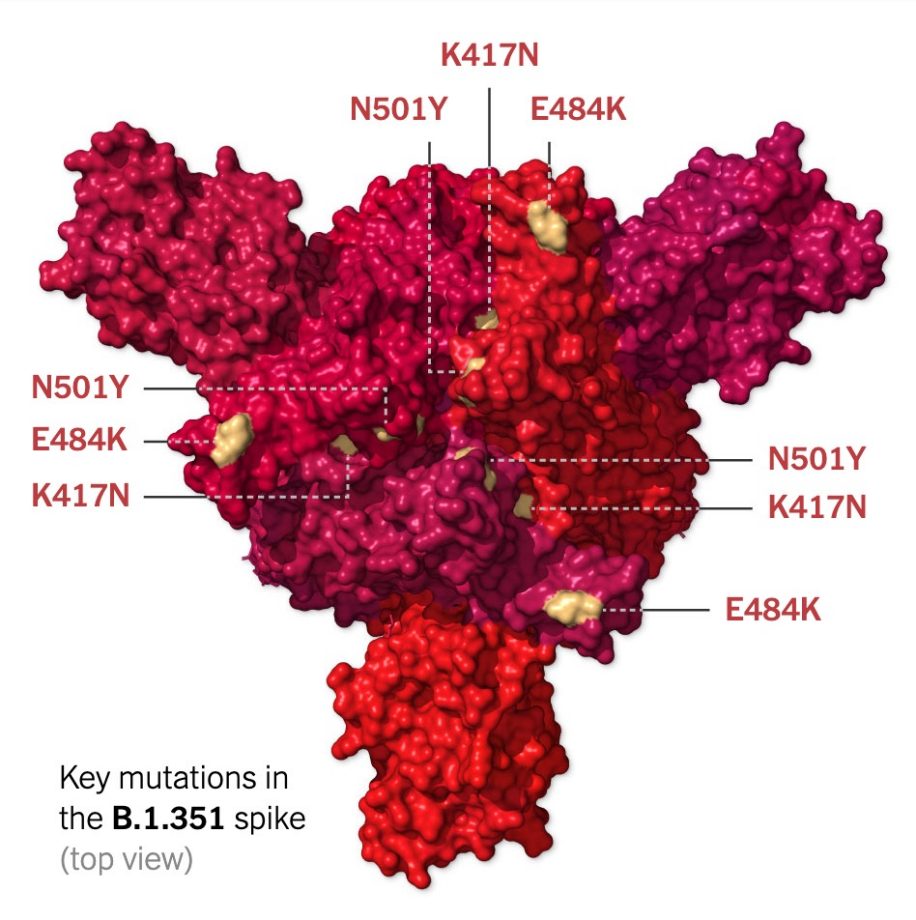





Krammer Nature 2020;586:516-527 and Annavajhala Nature (epub 8/24/21)

# Key Mutations, B.1.351 (β) (courtesy of J Faragon)

- Mutations near the tip of the spike protein include:
- — **N501Y**, which helps the virus latch on more tightly to human cells. This mutation also appears in the B.1.1.7 and P.1 lineages.
- — **K417N**, which also helps the virus bind more tightly to human cells.
- — **E484K**, which may help the virus evade some kinds of antibodies.






https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html. Accessed 3/3/21; https://www.nytimes.com/interactive/2021/health/coronavirus-variant-tracker.html#B1351; Accessed 3/3/21

# U.S. SARS-CoV-2 Interagency Group's Classification Scheme:

- **Variant of interest (VOI):** Has genetic markers associated with changes to receptor binding, ↓neutralization by antibodies, ↓efficacy of treatments, potential diagnostic impact, or predicted ↑transmissibility or disease severity.
  - e.g. eta, iota, kappa
- **Variant of concern (VOC):** Evidence of ↑transmissibility, ↑severe disease (hospitalizations/deaths), significant ↓neutralization by antibodies, ↓ effectiveness of treatments or vaccines, or diagnostic detection failures.
  - e.g. alpha, beta, gamma, delta
- **Variant of high consequence (VOHC):** Clear evidence that prevention measures or medical countermeasures (MCMs) have significantly ↓ effectiveness relative to previously circulating variants.
  - e.g. none

# New WHO Variant Nomenclature

| New name | Pangolin lineage | Earliest documented sample |
|---|---|---|
| Alpha | B.1.1.7 | United Kingdom, Sep 2020 |
| Beta | B.1.351 | South Africa, May 2020 |
| Gamma | P.1 | Brazil, Nov 2020 |
| Delta | B.1.617.2 | India, Oct 2020 |
| Epsilon | B.1.427/B.1.429 | California/US, March 2020 |
| Zeta | P.2 | Brazil, April 2020 |
| Eta | B.1.525 | Multiple countries, Dec 2020 |
| Theta | P.3 | Philippines, Jan 2021 |
| Iota | B.1.526 | New York/US, Nov 2020 |
| Kappa | B.1.617.1 | India, Oct 2020 |

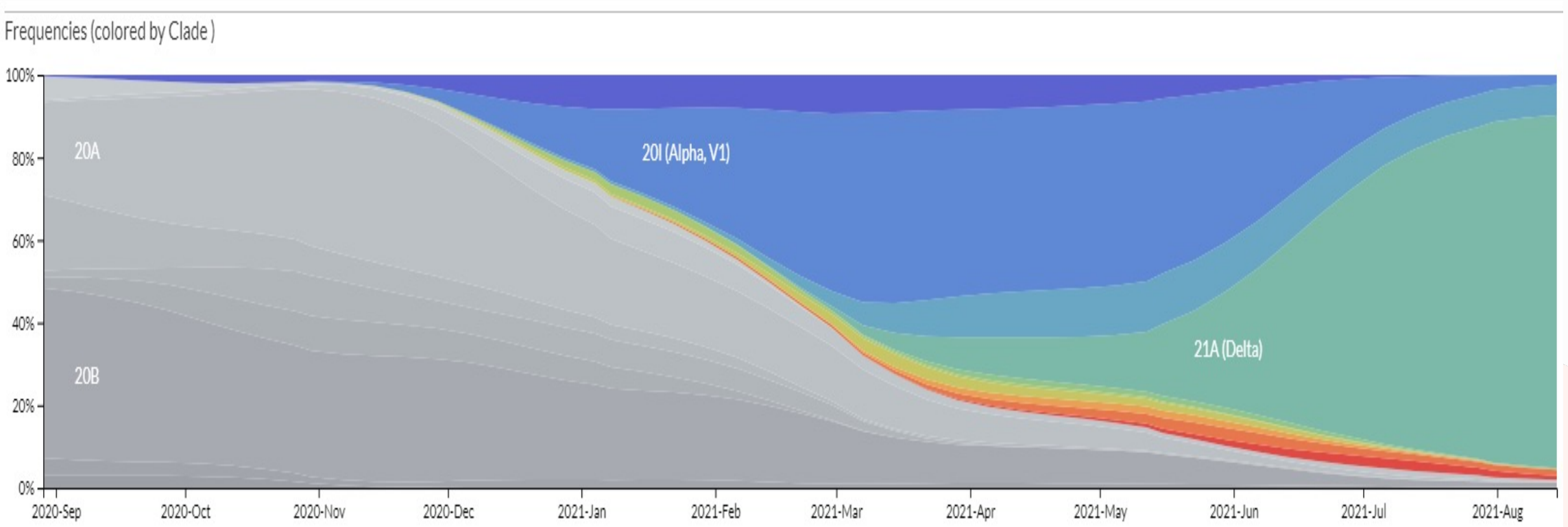
Variants of concern

Adapted from https://www.who.int/en/activities/tracking-SARS-CoV-2-variants

# Variants of Concern

| | Alpha (B.1.1.7) | Beta (B1.351) | Gamma (P.1) | Delta (B.1.617.2) |
|---|---|---|---|---|
| # of spike mutations | 10-13 | 10 | 11 | > 12 |
| Receptor binding domain mutations | N501Y | K417N<br>E484K<br>N501Y | K417N<br>E484K<br>N501Y | E484K<br>L452R |
| **Transmissibility** | ↑ 50% | ↑ 50% | | ↑ 60% vs. alpha<br>↑ 2X from original |
| **Disease severity** | ? ↑ risk of death | no effect | may cause severe disease in those with prior COVID | ? ↑ |
| **Monoclonal Abs** | No effect | ↓ susceptibility to BAM + ETE | ↓ susceptibility to BAM + ETE | potential ↓ susceptibility (?) |
| **Vaccines (U.S.)** | No effect | No effect | No effect | Modest ↓ effect |

# SARS-CoV-2 Variants: Global (Sept 2021)




3%
alpha

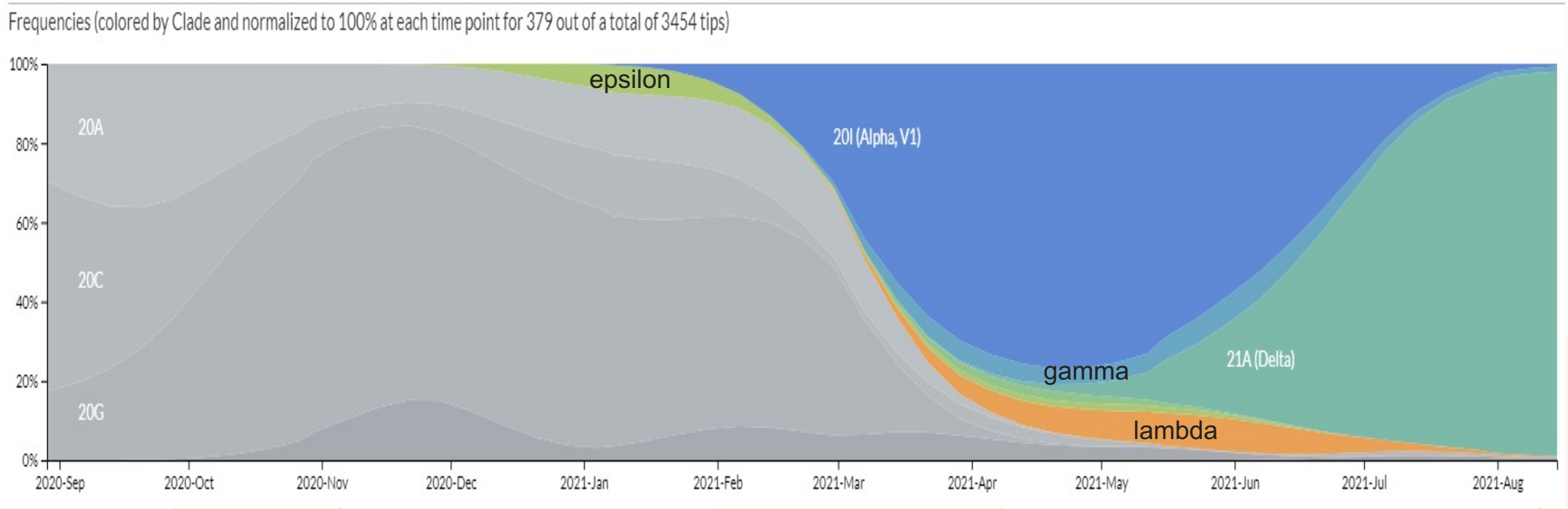
4%
gamma

88%
delta

1%
lambda

1%
mu

# SARS-CoV-2 Variants: U.S. (Sept 2021)




**97%**
**delta**

# Delta Variant: Highly Transmissible & a Particular Threat for the Unvaccinated

- **Highly transmissible -- more than 2x as transmissible as previous variants**
- **Some data suggest it may cause more severe illness than prior variants in unvaccinated people**
  - Pts with Delta more likely to be hospitalized than pts with alpha or wild-type viruses (Canada/Scotland).
  - Vast majority of hospitalizations and deaths in unvaccinated people.
- **Unvaccinated people remain the greatest concern**
  - More likely to get infected and transmit the virus.
  - Fully vaccinated people get COVID-19 infections less often.
  - ALL people infected with the Delta variant can transmit the virus to others.



https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant

# The Delta variant spreads easily in indoor spaces when people are unmasked and unvaccinated

**Occasionally unmasked adult infected with Delta variant worked for 2 days**

unvaccinated

**12 of 24 kids infected**

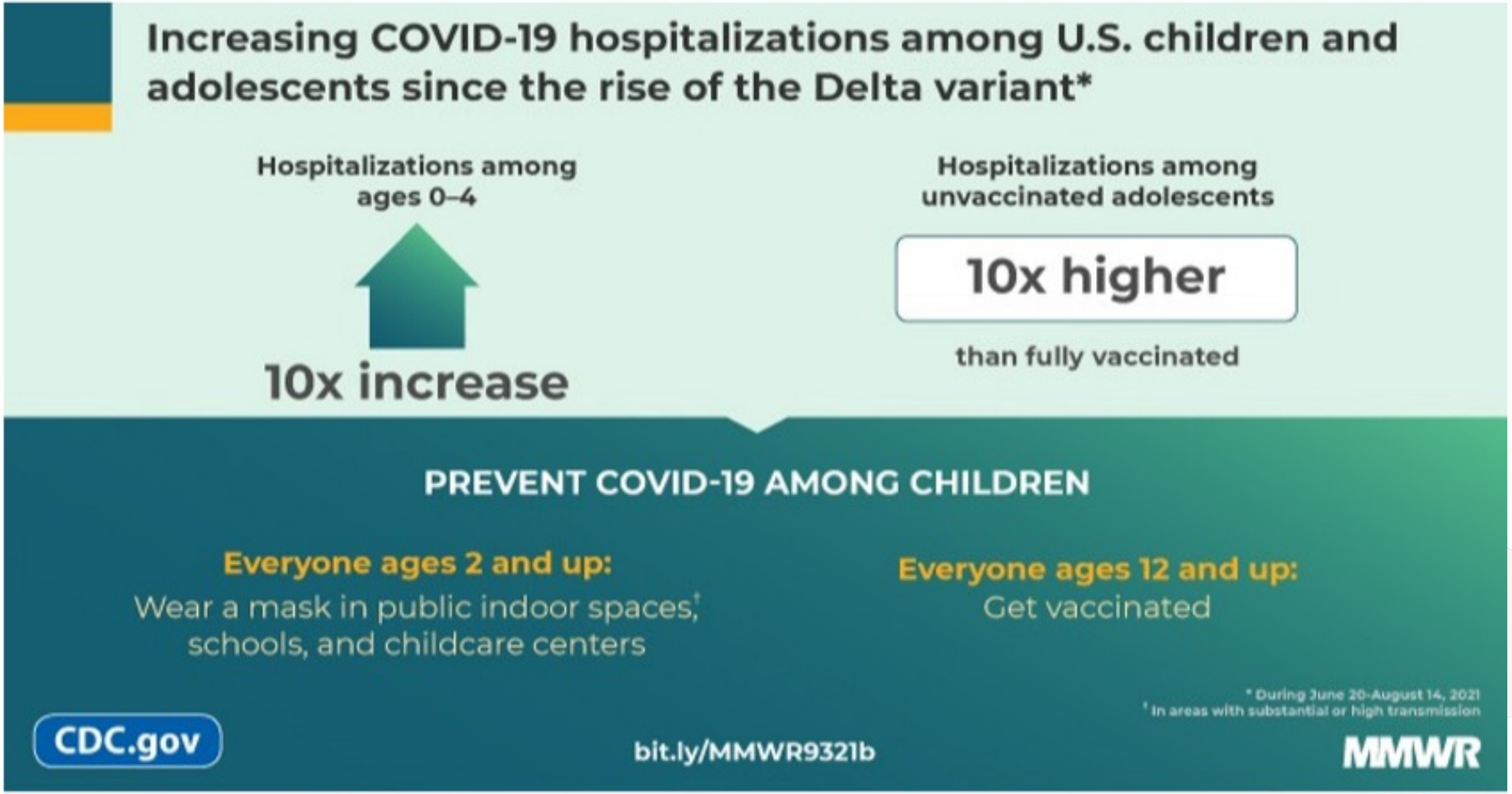
## Schools can help stop spread by ensuring everyone:

- **Wears masks correctly** in indoor spaces
- **Gets vaccinated**, if eligible
- **Stays home** if having symptoms
- **Tests routinely**

CDC.gov

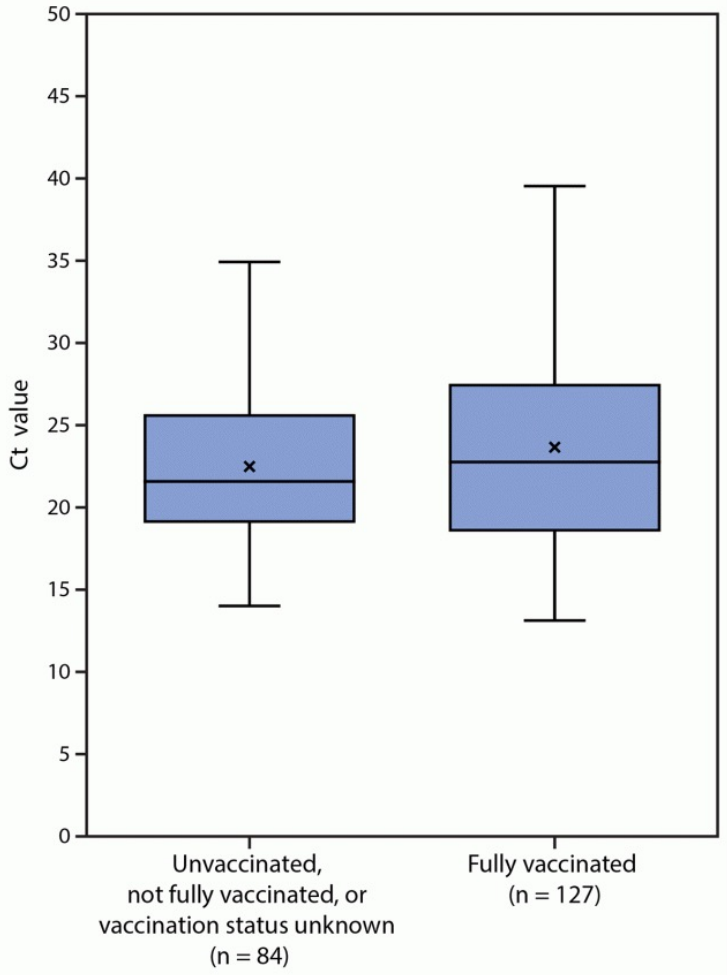
bit.ly/MMWR82721b

MMWR


Increasing COVID-19 hospitalizations among U.S. children and adolescents since the rise of the Delta variant*
Hospitalizations among ages 0–4
10x increase
Hospitalizations among unvaccinated adolescents
10x higher
than fully vaccinated
PREVENT COVID-19 AMONG CHILDREN
Everyone ages 2 and up:
Wear a mask in public indoor spaces,† schools, and childcare centers
Everyone ages 12 and up:
Get vaccinated
* During June 20–August 14, 2021
† In areas with substantial or high transmission
CDC.gov
bit.ly/MMWR9321b
MMWR

# Outbreak that Led to the CDC's Indoor Masking Recommendation Regardless of Vaccination Status

- July 2021, multiple large public events in Barnstable County, MA
- 469 COVID cases among MA residents who traveled there July 3-17
  - 90% delta in 133 samples tested
  - 346 (74%) in fully vaccinated
- Cycle thresholds similar among those fully vaccinated vs not vaccinated

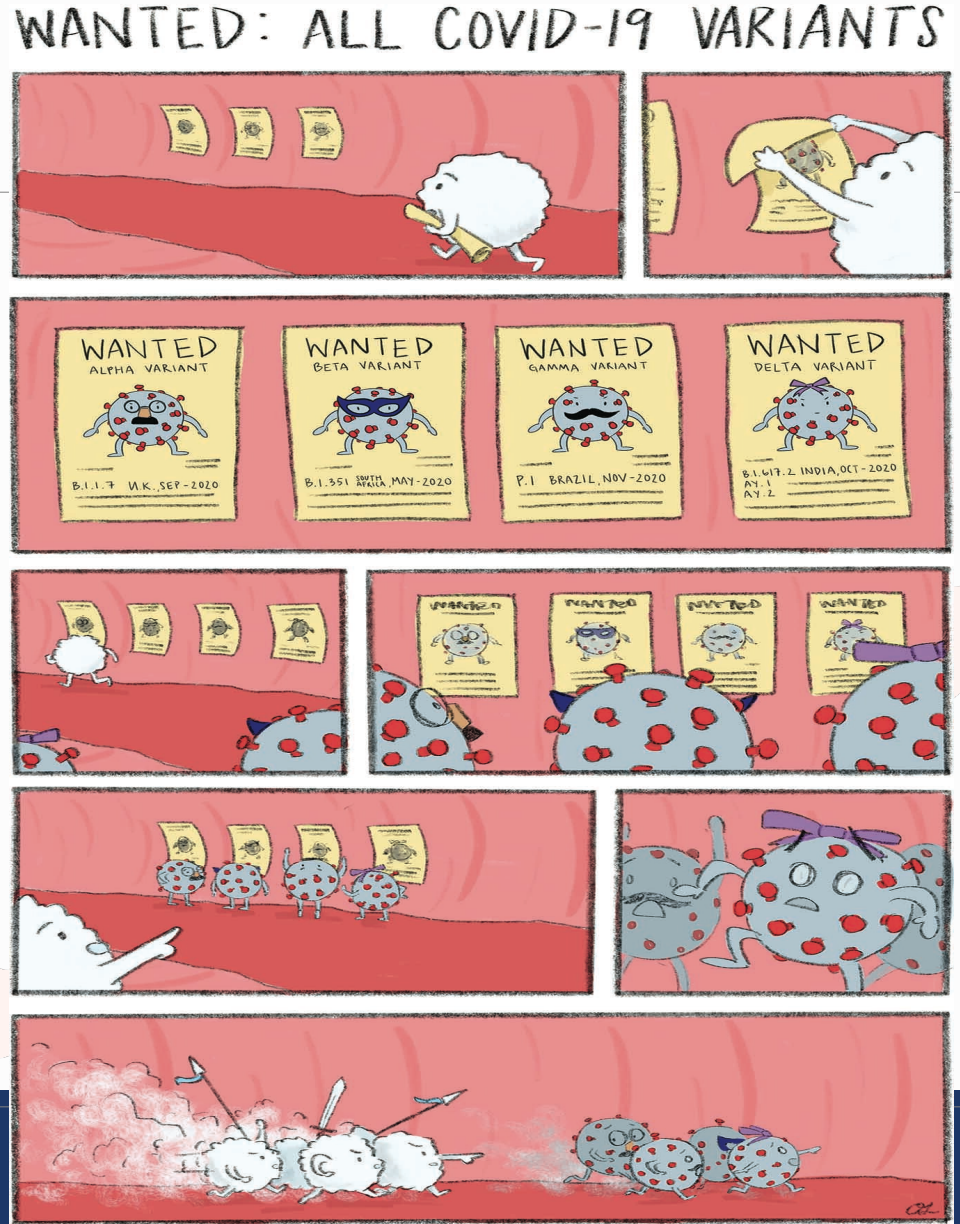


Annals of Internal Medicine®

Ann Intern Med. Published online: 31 August 2021doi:10.7326/G21-0048



**From: Annals Graphic Medicine - Wanted: All COVID-19 Variants**



# Current Vaccines Protect Against Delta

- **Vaccinated people appear to spread the virus for a shorter time**
  - For prior variants, lower amounts of viral RNA were found in samples taken from fully vaccinated people with COVID-19 infection than from unvaccinated people.
  - For people with Delta, similar amounts of viral RNA have been found among both unvaccinated and fully vaccinated people.
  - Viral RNA may ↓ faster in fully vaccinated people.
    - Transmit for less time.
- **Vaccines in the US are highly effective, including against the Delta variant**



https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant

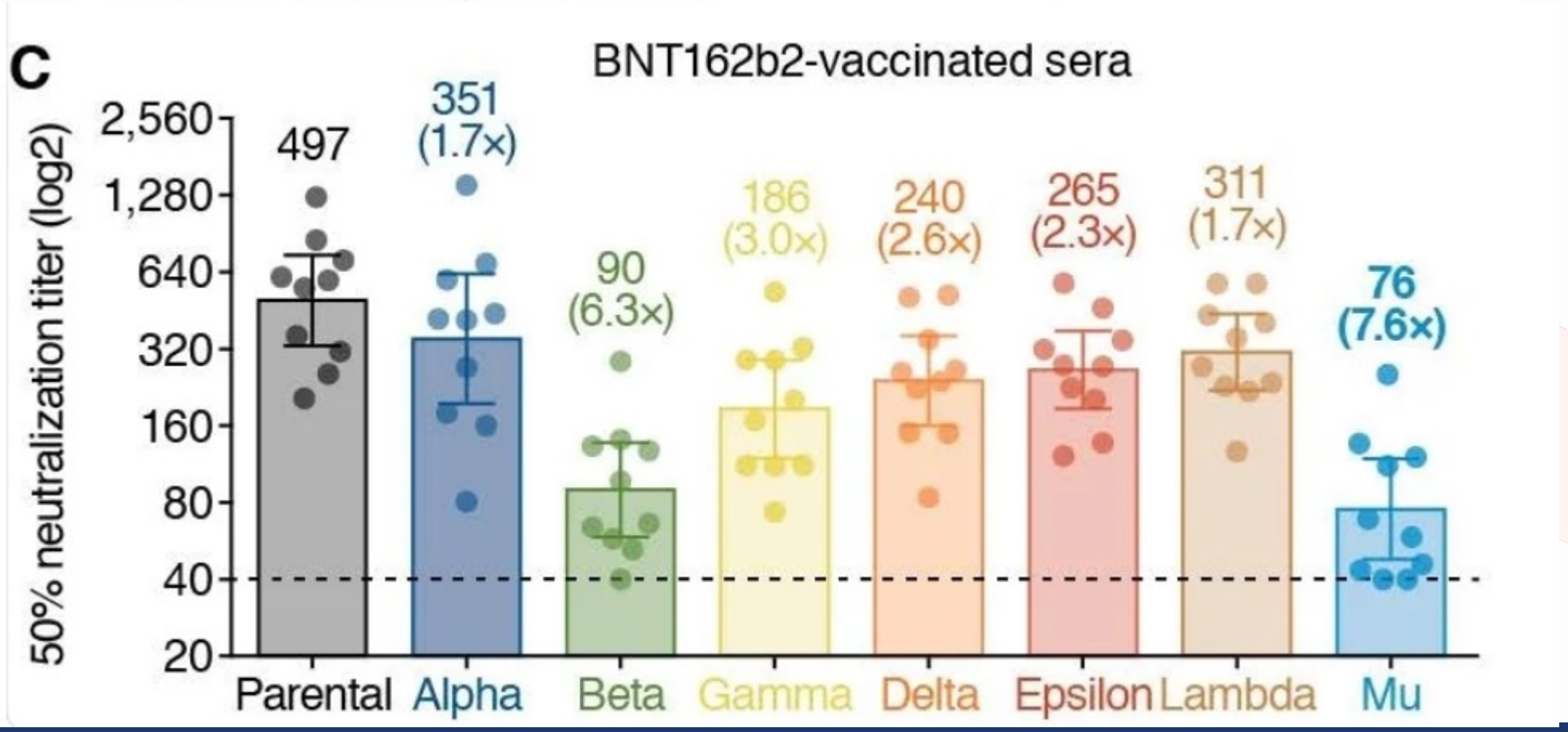

After Delta became the most common variant,* fully vaccinated people had reduced risk† of...
INFECTION
5X
HOSPITALIZATION
>10X
DEATH
>10X
Vaccination offers strong protection against COVID-19
CDC.gov
bit.ly/MMWR91021
* June 20-July 17, 2021
† Compared with people not fully vaccinated
MMWR

# Mu: Low Prevalence Variant of Interest

- B.1.621
- Detected in Colombia in Jan 2021—WHO Variant of interest 8/30/21
- E484K mutation
- ? Less transmissible than delta
- Prevalence thought to be < 0.5% of infections in the U.S.

**Ineffective neutralization of the SARS-CoV-2 Mu variant by convalescent and vaccine sera**

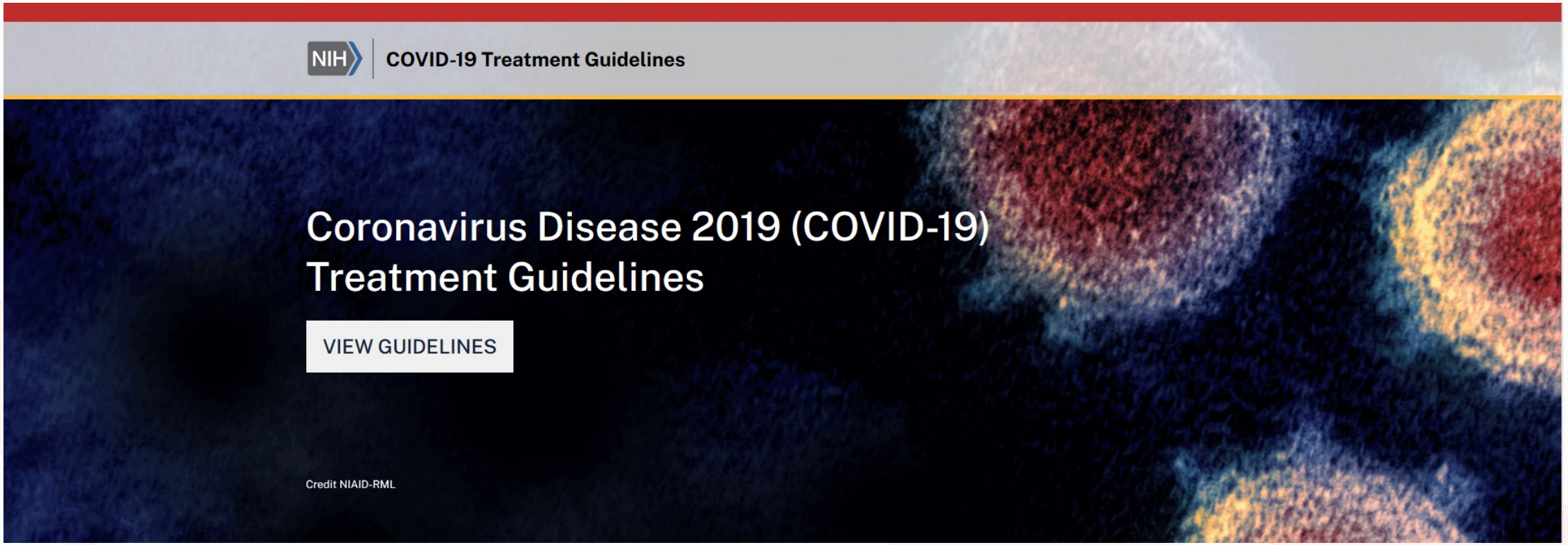
Keiya Uriu[1#], Izumi Kimura[1#], Kotaro Shirakawa[2], Akifumi Takaori-Kondo[2], Taka-aki Nakada[3], Atsushi Kaneda[3], The Genotype to Phenotype Japan (G2P-Japan) Consortium, So Nakagawa[4], Kei Sato[1*]






bioRxiv preprint doi: https://doi.org/10.1101/2021.09.06.459005; posted 9/7/21 NOT PEER REVIEWED

# COVID-19 Treatment Recommendations





Co-Chairs

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| Roy M. Gulick, MD | Weill Cornell Medicine, New York, NY |
| H. Clifford Lane, MD | National Institutes of Health, Bethesda, MD |
| Henry Masur, MD | National Institutes of Health, Bethesda, MD |

# COVID-19 Treatment

- For inpatients with COVID-19:
  - 1 FDA-approved drug: **remdesivir**
  - 3 drugs demonstrated to ↓ mortality: **dexamethasone, tocilizumab,** and **bariticinib**
  - EUAs for **baricitinib** and **convalescent plasma**

- For outpatients with COVID-19: no approved therapies
  - 3 **monoclonal antibodies** demonstrated to ↓ disease progression (available by EUAs)
    - **bamlanivimab + etesivimab (BAM + ETE)**
    - **casirivimab + imdevimab (CAS + IMD)**
    - **sotrovimab (SOT)**

- Additional candidate treatments: antivirals, immunomodulators, antithrombotics, ARDS and cellular therapies

# Monoclonal Antibodies for Outpatients

- The Panel recommends using one of the following anti-SARS-CoV-2 monoclonal antibodies, listed in alphabetical order, to treat non-hospitalized patients with **mild to moderate COVID-19 who are at high risk of clinical progression**, as defined by the EUA criteria:

  - **Casirivimab plus imdevimab; or**
  - **Sotrovimab**

•~70-85% relative reduction in hospitalizations/death

•Recommends against bamlanivimab + etesevimab because Gamma and Beta variants have reduced susceptibility

• Start as soon as possible and within 10 days of symptom onset

The following medical conditions or other factors may place adults and pediatric patients (age 12-17 years and weighing at least 40 kg) at higher risk for progression to severe COVID-19:

- Older age (for example, age ≥65 years of age)
- Obesity or being overweight (for example, BMI >25 kg/m$^2$, or if age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm)
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Sickle cell disease

Updated by FDA 5/14/21

- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19))

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of [redacted] under the EUA is not limited to the medical conditions or factors listed above. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID, see the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Healthcare providers should consider the benefit-risk for an individual patient.

# Estimated number of outpatient ivermectin prescriptions dispensed from retail pharmacies — United States


**Ivermectin is an unproven therapy and should not be used outside of a clinical trial**

# COVID-19 Prevention

- Handwashing, masks, social distancing, droplet precautions, PPE

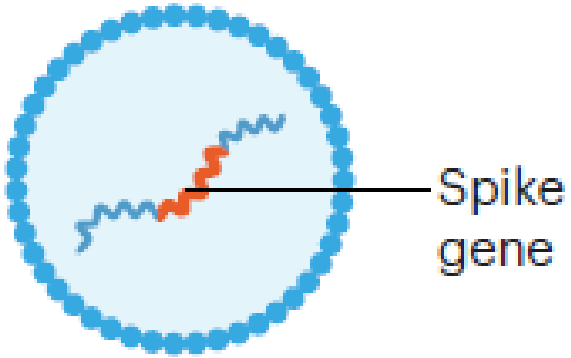
- **Pre-Exposure (PrEP)**
  - 1 FDA-approved vaccine for COVID-19: **Pfizer (Comirnaty®)**
  - 2 FDA EUAs for vaccines, **Moderna** and **J+J**
  - Additional dose of Pfizer/Moderna recommended for moderate/severe immunocompromised patients
  - Emerging data for monoclonal antibodies

- **Post-Exposure (PEP)**
  - 1 FDA EUA: **casirivimab** + **imdevimab** (CAS + IMD)
- Additional candidate preventatives: antivirals, antibodies, vaccines

# COVID-19 Vaccines: Current Approaches

## RNA Vaccines

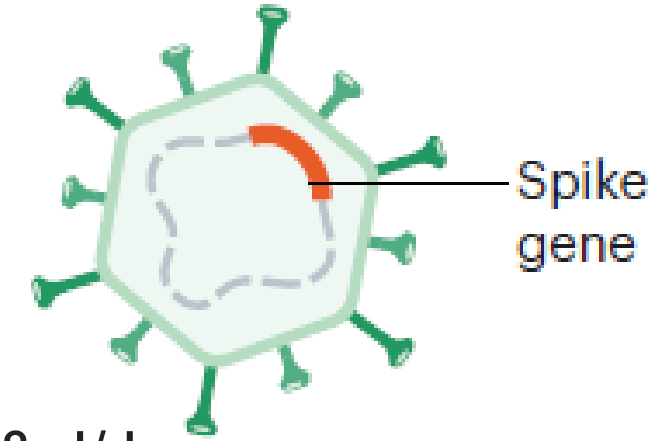
RNA vaccines consist of RNA encoding the spike protein and are typically packaged in LNPs (Lipid nanoparticles)




Pfizer-BioNTech (BNT162b2; Comirnaty®)
Moderna (mRNA-1273)

## Viral Vector Vaccines

Replication-incompetent vector vaccines cannot propagate in the cells of the vaccinated individual but express the spike protein within them




J & J/Janssen
AstraZeneca/Oxford

## Protein Subunit Vaccines

Recombinant spike-protein-based vaccines

Novavax



Adapated from: Krammer Nature 2020;586:516-527.

# General Considerations for COVID-19 Vaccines

IM Administration:

| Vaccine | Dose | Dose volume | Number doses/series | Interval between doses |
|---|---|---|---|---|
| **Pfizer-BioNTech** | 30 µg | 0.3 ml | 2 | 3 weeks (21 days) |
| **Moderna** | 100 µg | 0.5 ml | 2 | 1 month (28 days) |
| **Janssen** | $5\times10^{10}$ viral particles | 0.5 ml | 1 | N/A |

- COVID-19 vaccines are not currently interchangeable
  - CDC update (1/21): “except in exceptional situations”
- Antibody testing not recommended (before/after)
- Observation period – 15 minutes
  - 30-minute with a history of anaphylaxis (due to any cause)

# COVID-19 Vaccines: Side Effects

- **Most common:** pain at injection site, fatigue, headache, myalgias
  - ↑ after vax #2; 1/4 had fever/chills after #2
- **Axillary / cervical lymphadenopathy**
- **Dermal filler inflammation**
- **Myocarditis / pericarditis:** rare (~1/100,000)
  - adolescent/young adults; more common in men
  - mild; most recover fully
- **Clotting events:** rare (<1/100,000)
  - more common in women <50 years old
  - cerebral venous sinus and splanchnic


A 72 year-old who signed up to test Moderna's Covid vaccine was struck by lightning 28 days after getting a dose of the real vaccine (Pictures: Getty/AP)

**A volunteer who signed up for Moderna's coronavirus vaccine trial was struck by lightning 28 days after receiving the injection.**

# COVID-19 Vaccines: Side Effects

- **Guillain-Barre syndrome:** rare (~1/125,000)
  - only with J+J, not mRNA vaccines
- **Anaphylaxis:** very rare (1/200,000-280,000)
  - related to PEG/polysorbate(?)
  - more common in women, 80-86% had history of allergies, 24% had history of anaphylaxis
  - most within 15 minutes (one outlier at 20 hours)

# Modest Reduction of Vaccine Efficacy Against Delta After Receipt of 2 Doses

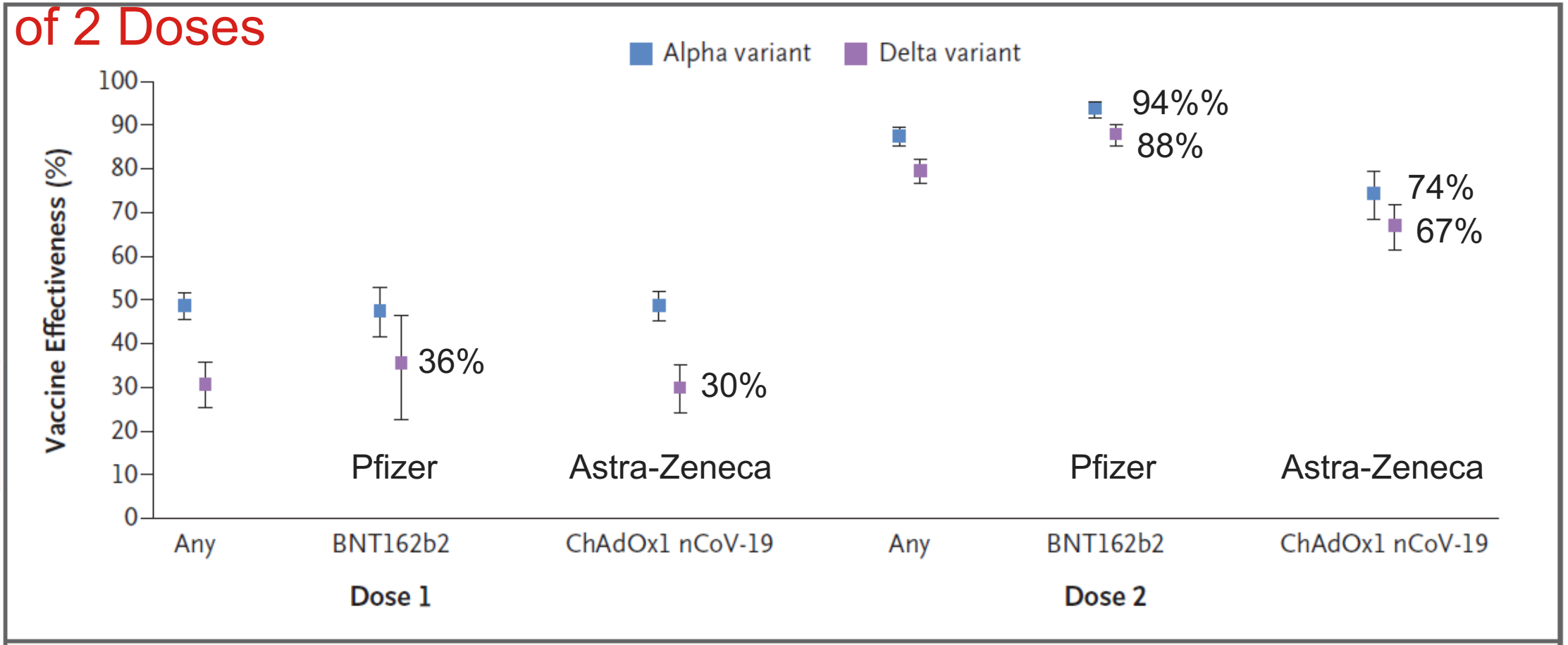



**Figure 1. Vaccine Effectiveness against the Alpha and Delta Variants, According to Dose and Vaccine Type.**

Shown is the effectiveness of one dose and two doses of the BNT162b2 and ChAdOx1 nCoV-19 vaccines, or either vaccine ("any"), against symptomatic disease with the B.1.1.7 (alpha) or B.1.617.2 (delta) variant of the severe acute respiratory syndrome coronavirus 2. I bars indicate 95% confidence intervals.

# Modest Reduction in Vaccine Effectiveness Over Time

- 4,136 HCW, first responders, essential + frontline workers in 6 U.S. states: AZ, FL, MN, OR, TX, UT
- Followed from 12/20-8/21
- Tested weekly for SARS-CoV-2 X 35 weeks
- Results:
  - Overall, **80%** effective in preventing SARS-CoV-2 infection (both symptomatic and asymptomatic) in fully vaccinated
    - 2 weeks-4 months after vax: 85% effective (95% CI 68, 93)
    - 4 months-5 months after vax: 81% effective (95% CI 34, 95)
    - After 5 months after vax: 73% effective (95% CI 49, 86)
    - Pre-delta / delta variant predominance: 91% / 66% effectiveness

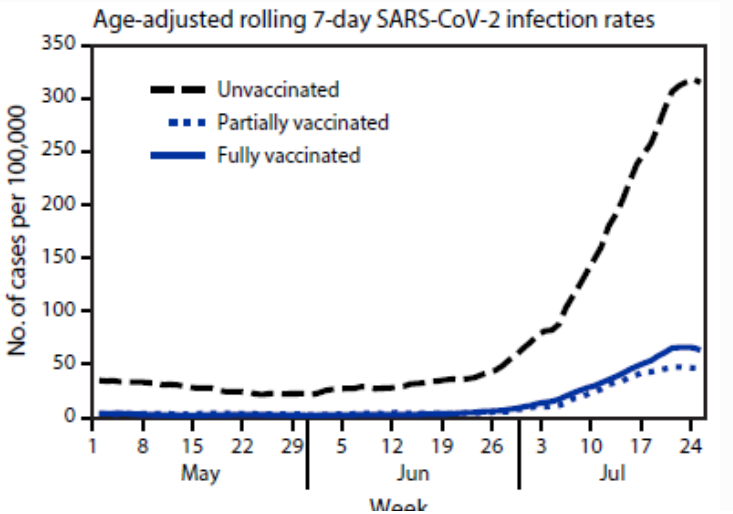


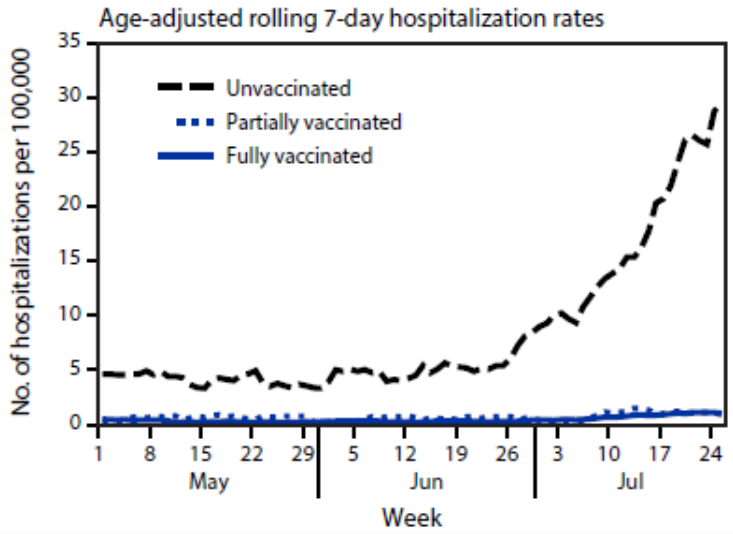
Fowlkes A et al, MMWR Morb Mortal Wkly Rep 2021;70:1167-1169.

# Vaccination Protects Against Severe COVID-19 Including Delta

- Los Angeles Country Department of Public Health data
- 5/1/21→7/25/21; delta variant >87% of cases
- % fully vaccinated 27%→51%
- 43,127 reported SARS-CoV-2 infections in people ≥16 yo
  - 30,801 (71%) unvaccinated
  - 1,431 (3.3%) partially vaccinated
  - 10,895 (25%) fully-vaccinated

| Cases: | Hospitalized | ICU | Mech Vent | Death |
|---|---|---|---|---|
| Unvaccinated | 7.6% | 1.5% | 0.5% | 0.6% |
| Partially Vax | 6.2% | 1.0% | 0.3% | 0.5% |
| Fully Vax | 3.2% | 0.5% | 0.2% | 0.2% |

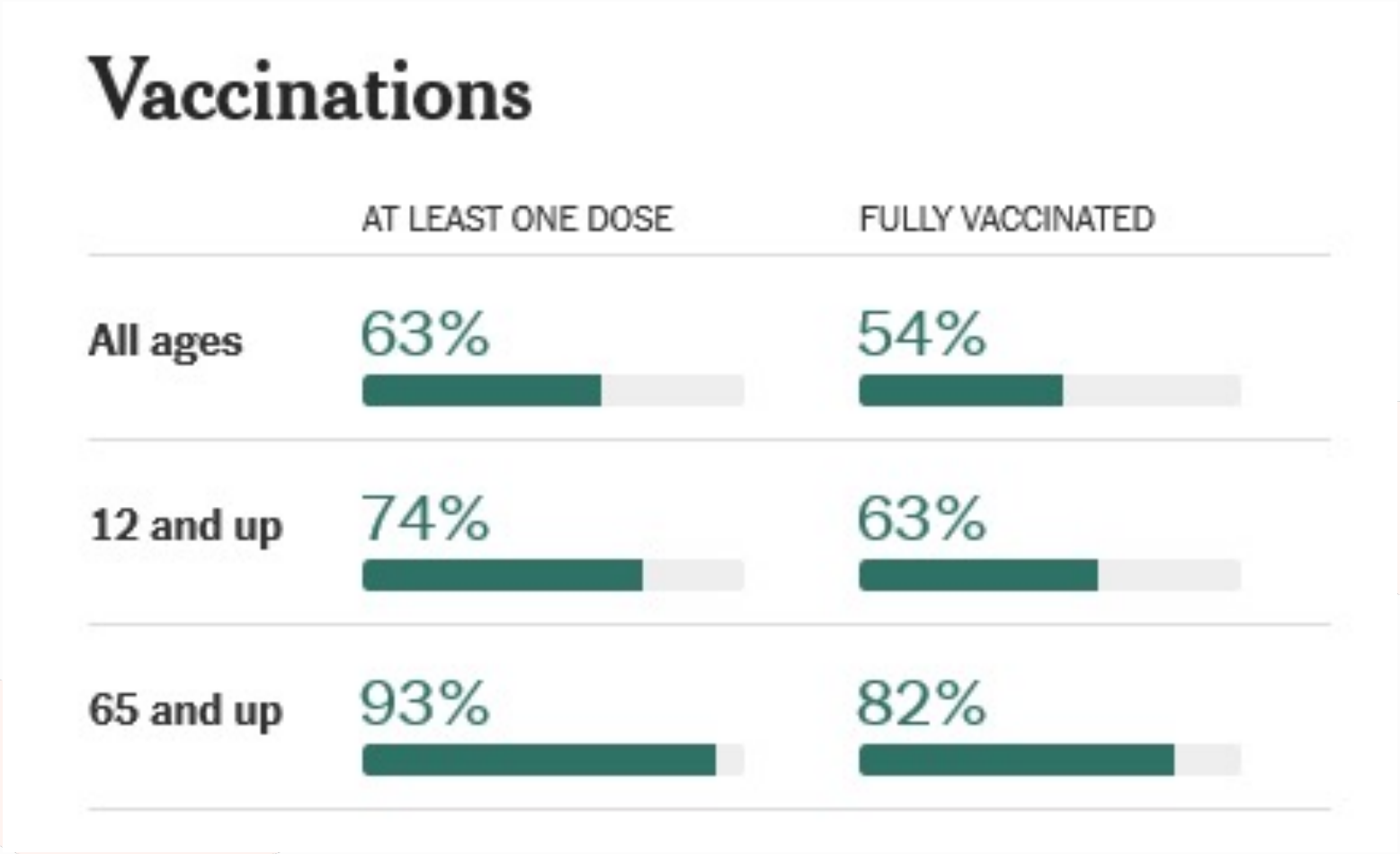





Griffin JB et al, MMWR Morb Mortal Wkly Rep 2021;70:1170–1176.

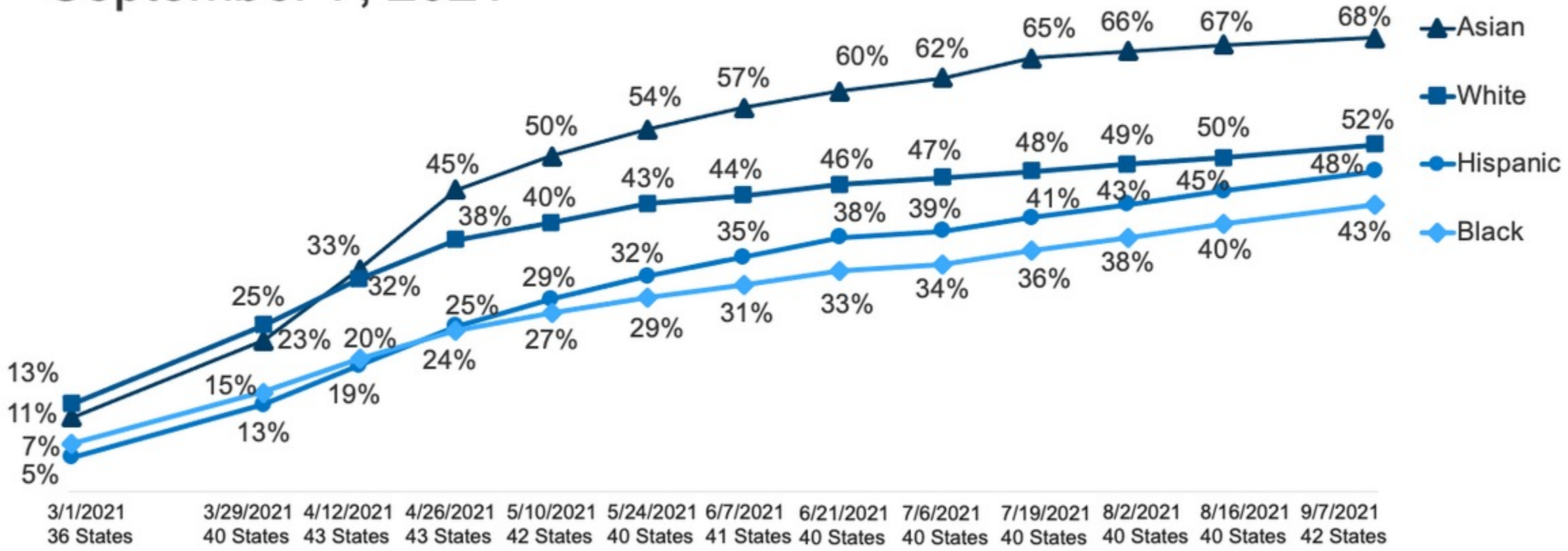
# Vaccination Rates Remain Suboptimal in the U.S.






https://www.nytimes.com/interactive/2021/us/covid-cases.html

# Percent of Total Population that Has Received at Least One COVID-19 Vaccine Dose by Race/Ethnicity, March 1 to September 7, 2021




KFF

SOURCE: Vaccination data based on KFF analysis of publicly available data on state websites; total population data used to calculate rates based on KFF analysis of 2019 American Community Survey data.

# Percent of Total Population that has Received a COVID-19 Vaccine Dose by Race/Ethnicity, Selected States, September 7, 2021

| | White | Black | | | Hispanic | | | Asian | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Percent Vaccinated | Percent Vaccinated | White to Black Ratio | Percentage Points from White | Percent Vaccinated | White to Hispanic Ratio | Percentage Points from White | Percent Vaccinated | White to Asian Ratio | Percentage Points from White |
| Total (42 States) | 52% | 43% | 1.2 | −9 | 48% | 1.1 | −4 | 68% | 0.8 | 16 |
| New York | 56% | 45% | 1.2 | −11 | 58% | 1.0 | 3 | 86% | 0.6 | 30 |

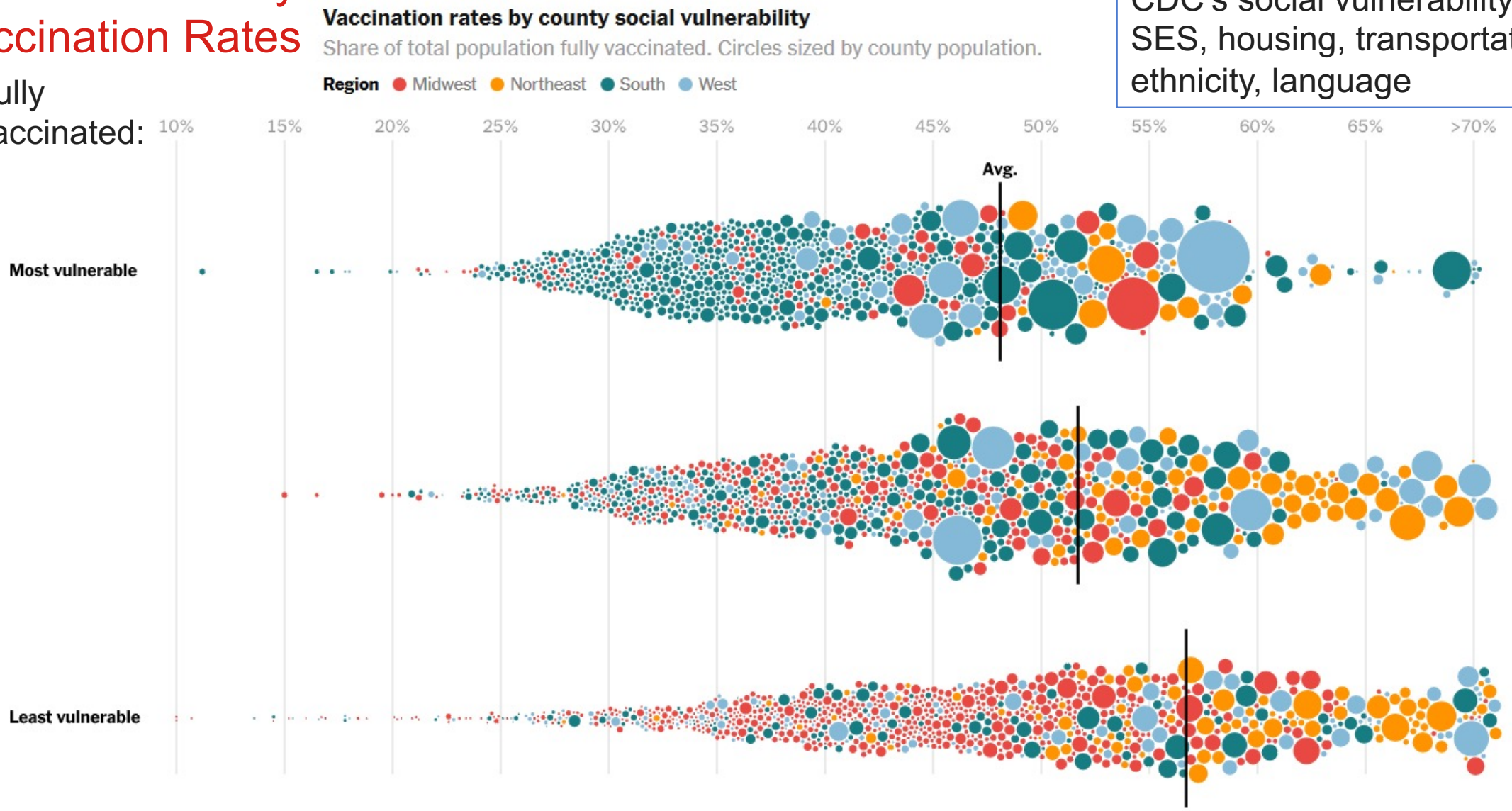


https://www.kff.org/coronavirus-covid-19/issue-brief/latest-data-on-covid-19-vaccinations-race-ethnicity/

# The Most Socially Vulnerable Counties Have Lower Vaccination Rates

CDC's social vulnerability index: SES, housing, transportation, race, ethnicity, language

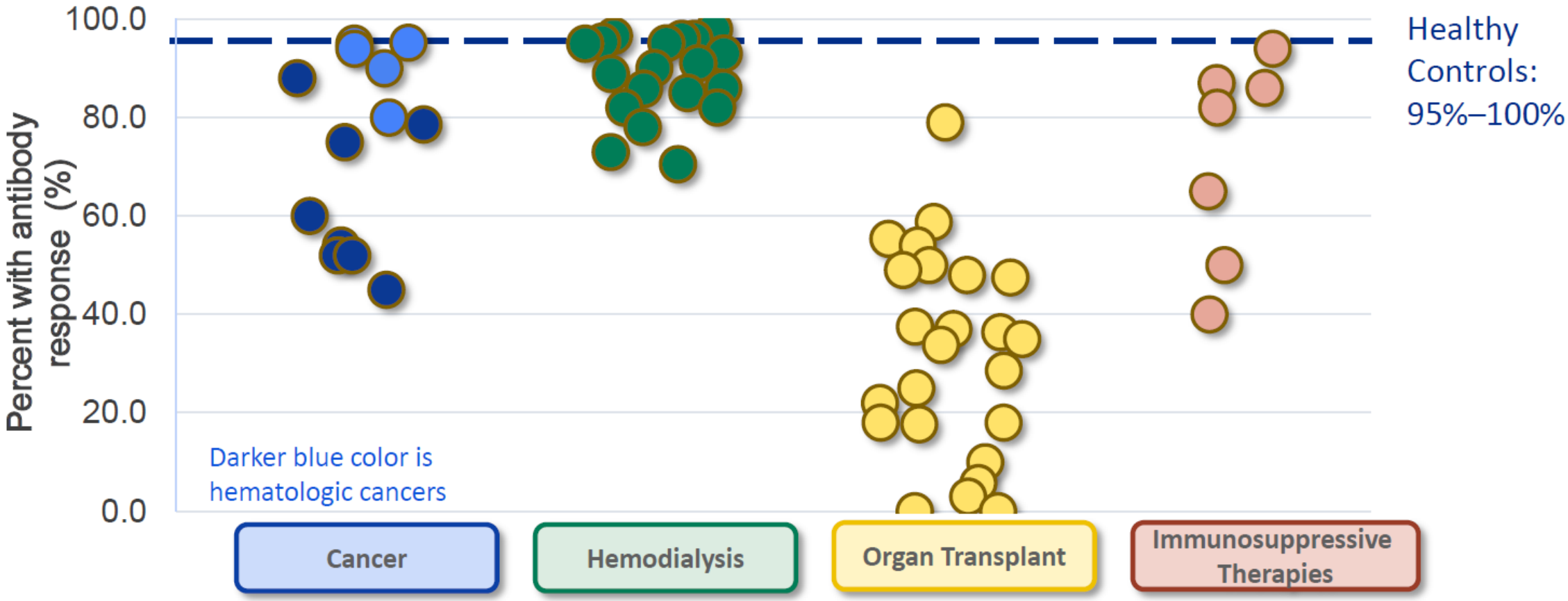
Fully vaccinated:



# 3rd Doses vs Boosters

- 3rd dose = identical to 1st two doses (mRNA vaccines)
  - Indicated for certain immunocompromised patients to try to generate a good response (≥ 28 days after 2nd dose)
- Booster shot = additional dose given after protection from original doses has begun to wane (FDA approval pending)

# Percent of subjects with antibody response after two mRNA COVID-19 vaccine doses by immunocompromising condition and study (n=63)




Studies that compared response after 1st and 2nd dose demonstrated less robust response after dose 1

Antibody measurement and threshold levels vary by study protocol

CDC ACIP 8/13/21

# Moderately and severely immunocompromised people*

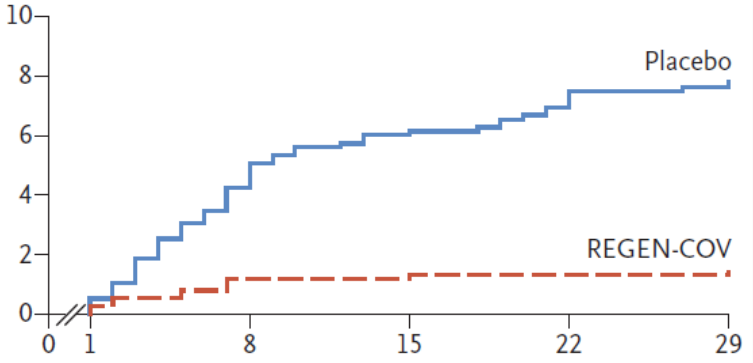
- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection

HIVMA: many experts consider CD4 < 200 or ≤14%

- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory

# SQ Casirivimab/Imdevimab (C/I) for PEP

- Phase 3 randomized, placebo-controlled, study in household contacts with SARS-CoV-2 infection (N=1505 seronegative for SARS-CoV-2 Ab; 30% high-risk groups)
- Study Rx: C/I (1200 mg sq) or placebo
- Results
  - 1° endpoint: symptomatic COVID-19 by d 28
    - 1.5% (11/753) C/I vs. 7.8% (59/752) pbo (RR 0.17; 95% CI, 0.09–0.33; p<0.001)
  - 2° endpoints:
    - symptomatic + asymptomatic infections: 4.8% C/I vs. 14.2% pbo (p<0.001)
    - VL >10,000 cps/ml (infected): 1.6% C/I vs. 11.3% pbo (p<0.001)
- Conclusion: C/I prevented (and abrogated) infection






O'Brien MP, NEJM (epub 8/4/21)

# NIH Guidelines (8/17/21) : Cas/Imd for PEP

- Recommend **casirivimab 600 mg + imdevimab 600 mg** SQ **(AI)** or IV **(BIII)** as PEP for people who are at **high risk for progression** to severe COVID-19 who have the following:

- ***Vaccination Status:***
  - **Not fully vaccinated** *OR* **fully vaccinated, but not expected to mount an adequate immune response** (e.g., those with immunocompromising conditions, including those who are taking immunosuppressive medications)

**AND**

- ***Exposure History:***

  - Had a **recent exposure** to an individual with SARS-CoV-2 infection; *OR*
  - At **high risk of exposure** to an individual with SARS-CoV-2 infection because of recent occurrence in other individuals in the **same institutional setting** (e.g., nursing homes, prisons)

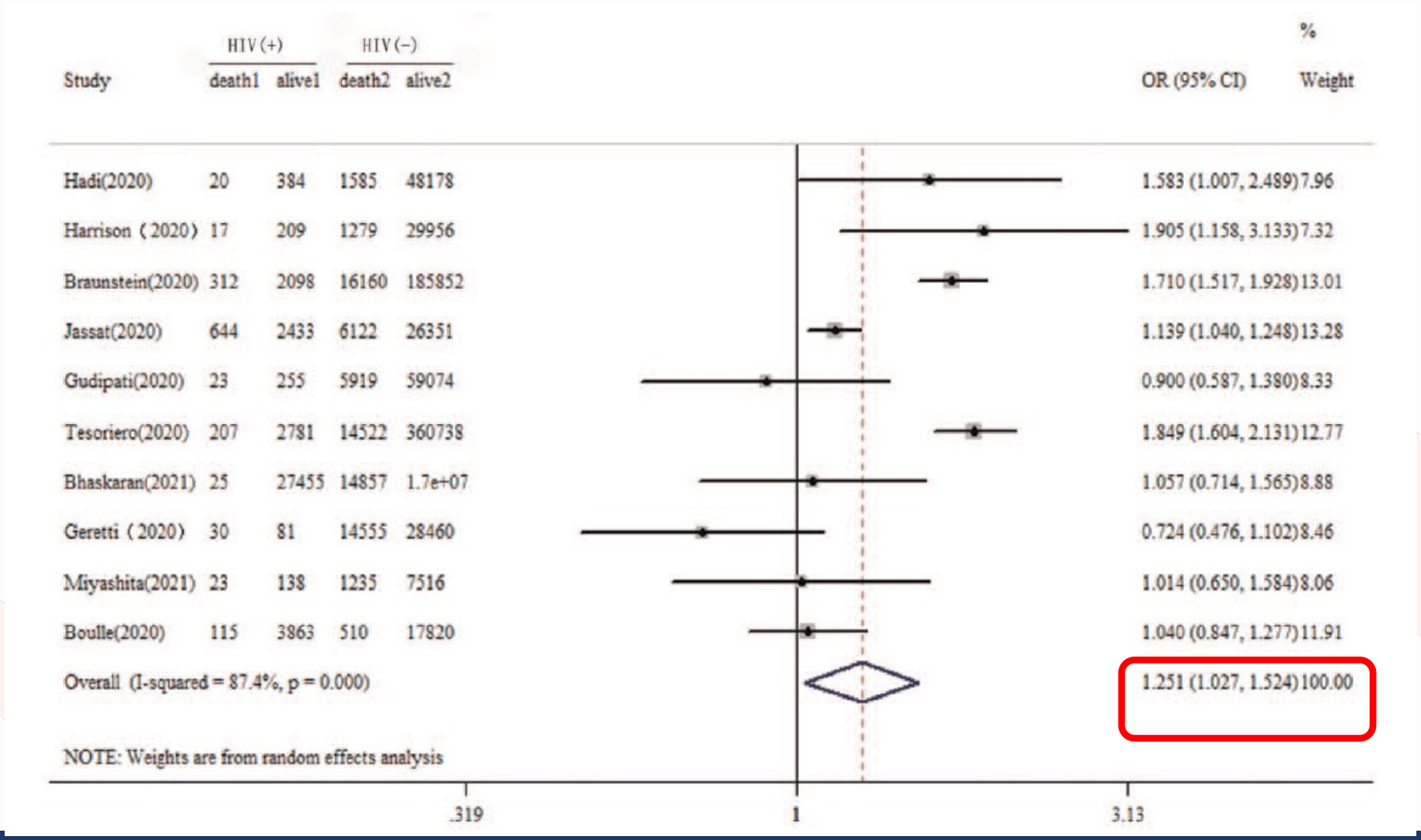
# Considerations for PWH: Risk of infection

- Systematic review/meta-analysis:  24% higher risk of acquisition[1]
- VA study: PWH had 36% higher chance of being tested for SARS-CoV-2 though rates of positivity similar (~10%)[2]
- Role of social determinants of health
- Unclear if TDF/FTC confers protection



[1]Ssentongo P, *Sci Rep 2021*;11:6283. [2] Park LS, et al, AIDS 2020: 23rd International AIDS Conference Virtual. July 6-10, 2020. Abstract LBPEC23.

# COVID-19 Mortality in PWH May Be Increased




U.S. subset: 1.520 (1.252, 1.845)

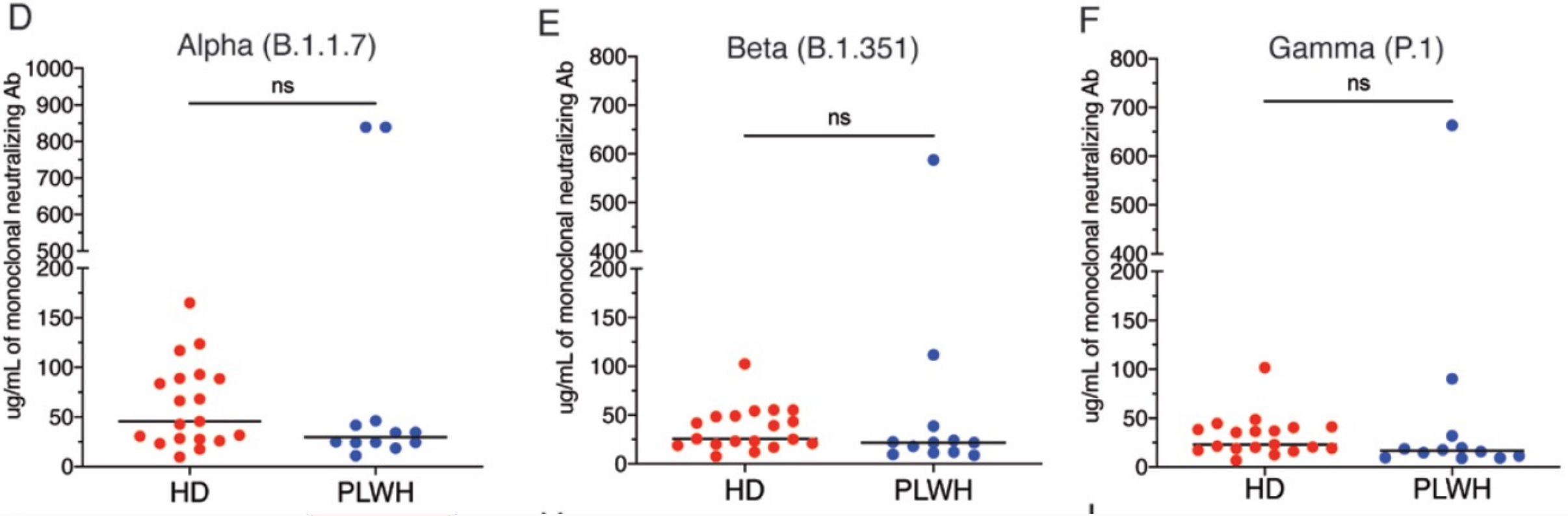
Dong Y, Medicine 2021;100:26

# Considerations for PWH:  Management

- Same as general population
  - No role for changing ART
- Attention to mental health, substance use, intimate partner violence, child abuse

# mRNA Vaccines Appear Safe and Immunogenic in PWH: Preliminary Data

- No specific safety concerns (n = 14—5 Pfizer, 9 Moderna)[1]
- Antibody responses in small study of PWH on ART (9/12 suppressed; 3 with low level viremia; median CD4 913 (649-1678) similar to controls without HIV[2]






[1]Ruddy JA, AIDS 2021; [2]Woldemeskel BA, Clin Infect Dis 2021 [online ahead of pub]

# Summary

- Incidence of SARS-CoV-2 infection and severe COVID-19 remain high
- Delta variant predominates
  - Being fully vaccinated protects against severe disease from Delta
- Monoclonal antibodies reduce hospitalization/death in outpatients
  - Post-exposure prophylaxis with C/I is efficacious
- Vaccination rates remain suboptimal in the U.S. and disparities exist
- PWH may be at higher risk of severe COVID-19 and should be vaccinated
  - 3rd dose may be indicated for untreated/uncontrolled HIV and CD4 < 200

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