



CDC/IDSA COVID-19 Clinician Call

May 1, 2021

Welcome & Introduction

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

- 64th 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.

TODAY'S TOPICS:

1. Update on SARS-CoV-2 Variants

2. Vaccine Q&A

Update on SARS-CoV-2 Variants



Natalie J. Thornburg, PhD

Respiratory Virus Immunology Team Lead
Division of Viral Diseases
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention



Walter Orenstein, MD, DSc (Hon)

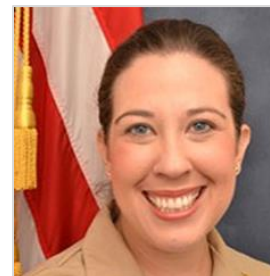
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Vaccine Q&A



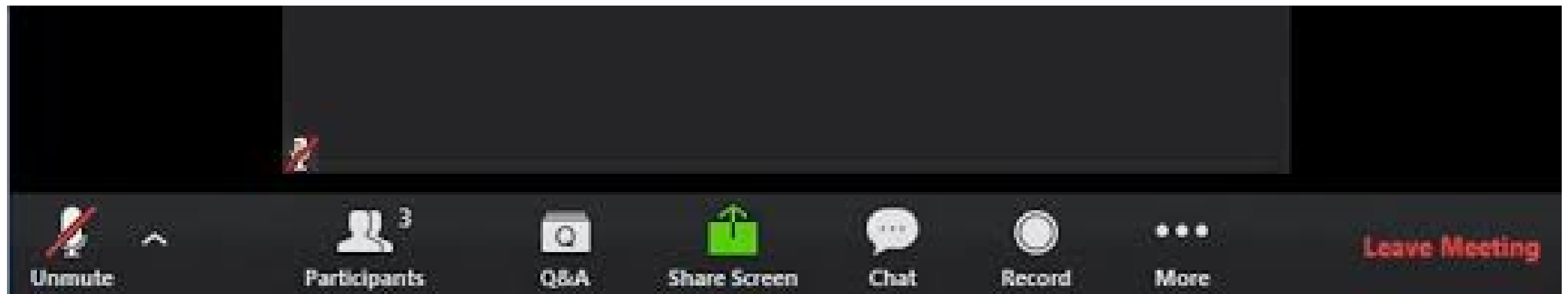
Sara Oliver, MD, MSPH

LCDR, U.S. Public Health Service
Co-Lead, COVID-19 Work Group of the Advisory Committee on
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Question?
Use the "Q&A" Button



Comment?
Use the "Chat" Button



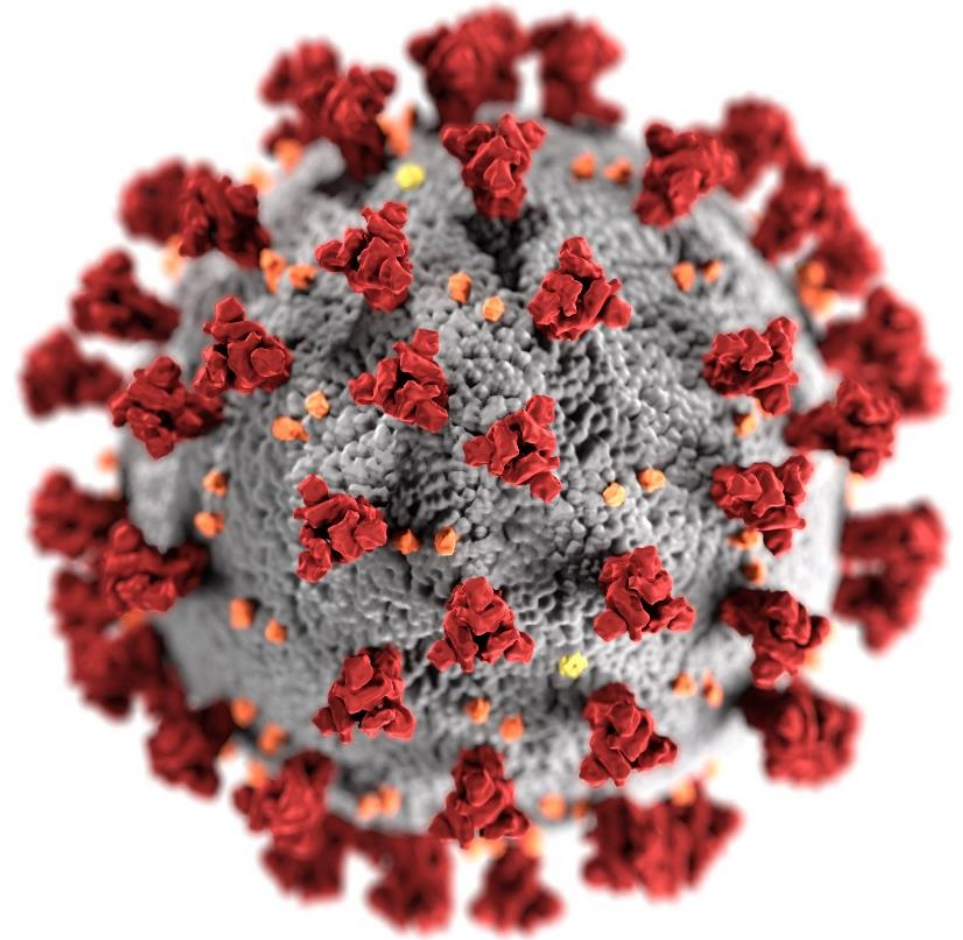
Emergence of SARS-CoV-2 viral variants

Natalie Thornburg, PhD

Lead respiratory virus immunology

CDC/IDSA COVID-19 Clinician Call

5/1/2021

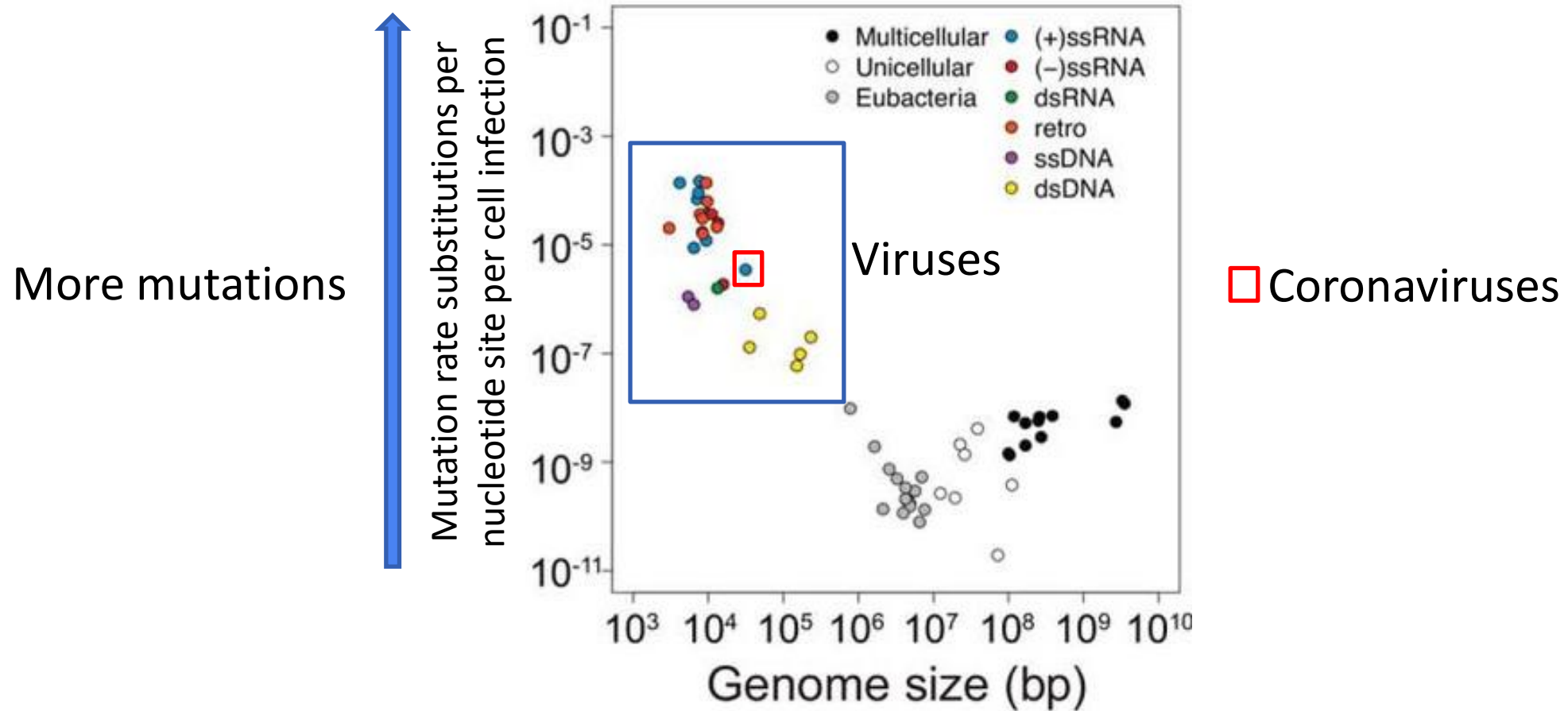


cdc.gov/coronavirus

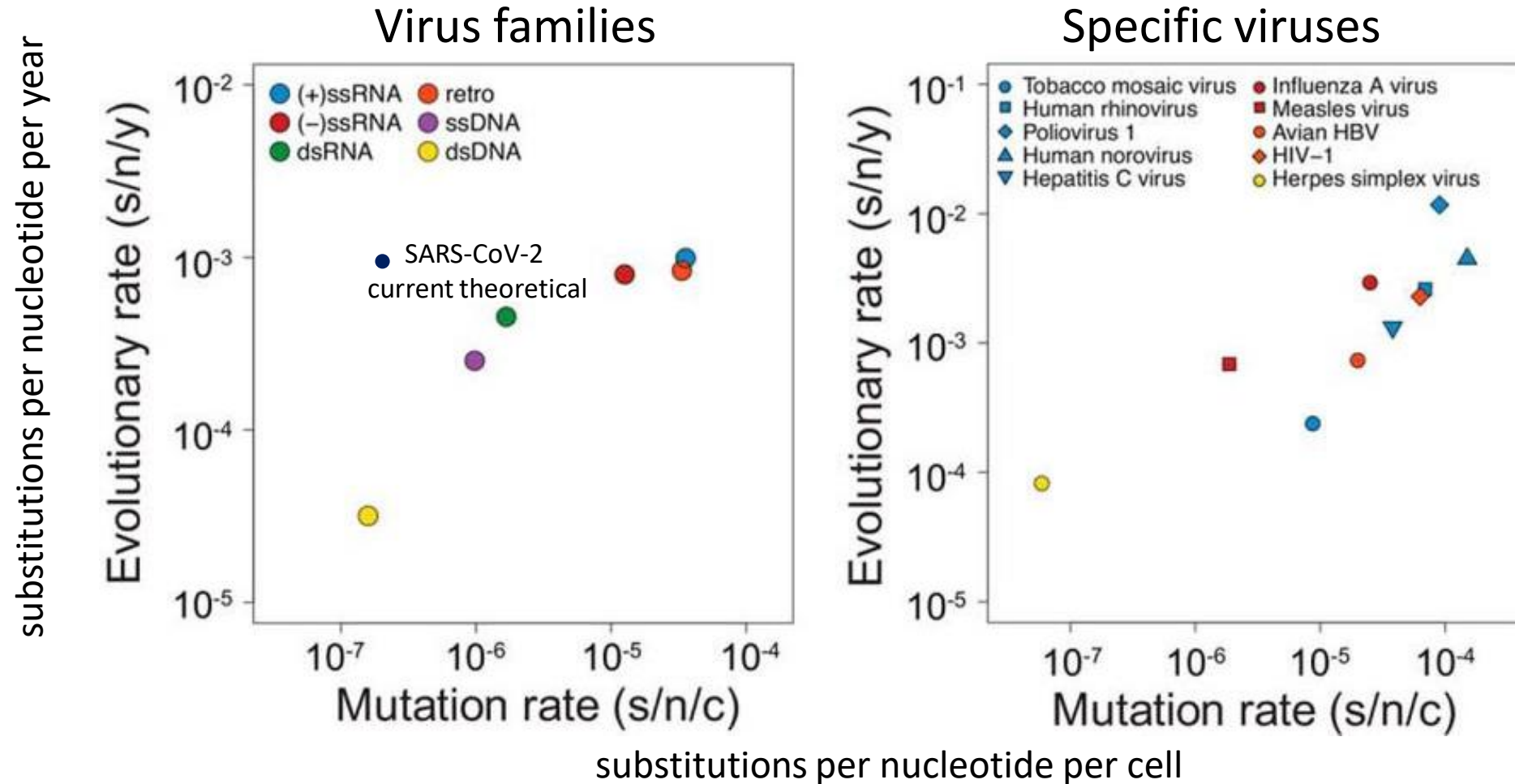
Emergence of variants is complicated. Potential contributors include:

- Inherent rate of mutation
- Fitness advantage
- Immune pressure or lack thereof
- Intermediate hosts
- Total number of infections
- Founder effect

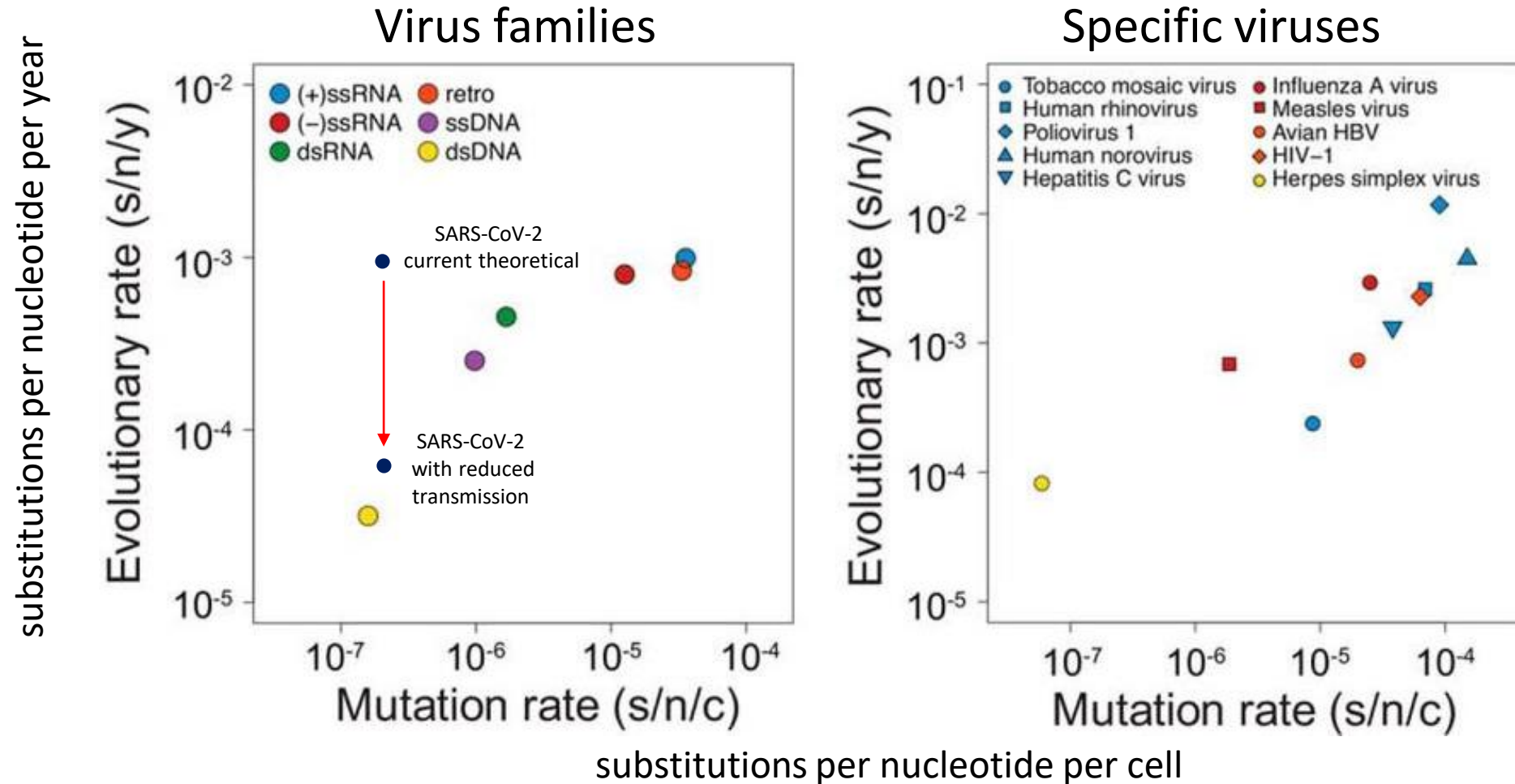
Mutation rates are dependent upon genome size and genomic makeup



In the real world, number of infections affects the evolutionary rate



In the real world, number of infections affects the evolutionary rate



Context under which current variants emerged

- No immune pressure
- High transmission
- Superspreading events
- No herd immunity – could have emerged from immune compromised persons with persistent infections

Variant Classifications

- The SARS-CoV-2 Interagency Group (SIG) established variant classifications
 - Each variant class includes possible attributes of lower classes; variant status might escalate or deescalate based on scientific evidence
- **Variant of Interest:** contains specific genetic markers associated with changes to receptor binding, reduced neutralization by antibodies generated against previous infection or vaccination, reduced efficacy of treatments, potential diagnostic impact, or predicted increase in transmissibility or disease severity
- **Variant of Concern:** evidence of an increase in transmissibility, more severe disease (increased hospitalizations or deaths), significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures
- **Variant of High Consequence:** clear evidence that prevention measures or medical countermeasures (MCMs) have significantly reduced effectiveness relative to previously circulating variants

Variants of Interest

Name (Pango lineage)	Spike Substitution	Name (Nextstrain)	First Detected	Predicted Attributes
B.1.526	(L5F*), T95I, D253G, (S477N*), (E484K*), D614G, (A701V*)	20C/S:484K	New York - November 2020	<ul style="list-style-type: none"> Reduced susceptibility to the combination of bamlanivimab and etesevimab monoclonal antibody treatment; however, the clinical implications of this are not known. Alternative monoclonal antibody treatments are available. Reduced neutralization by convalescent and post-vaccination sera
B.1.525	A67V, Δ69/70, Δ144, E484K, D614G, Q677H, F888L	20A/S:484K	United Kingdom/Nigeria - December 2020	<ul style="list-style-type: none"> Potential reduction in neutralization by monoclonal antibody treatments Potential reduction in neutralization by convalescent and post-vaccination sera
P.2	E484K, (F565L*), D614G, V1176F	20J	Brazil - April 2020	<ul style="list-style-type: none"> Potential reduction in neutralization by monoclonal antibody treatments Potential reduction in neutralization by convalescent and post-vaccination sera
B.1.526.1	D80G, Δ144, F157S, L452R, D614G, (T791I*), (T859N*), D950H	20C	United States (NY) - October 2020	<ul style="list-style-type: none"> Potential reduction in neutralization by some EUA monoclonal antibody treatments Potential reduction in neutralization by convalescent and post-vaccination sera

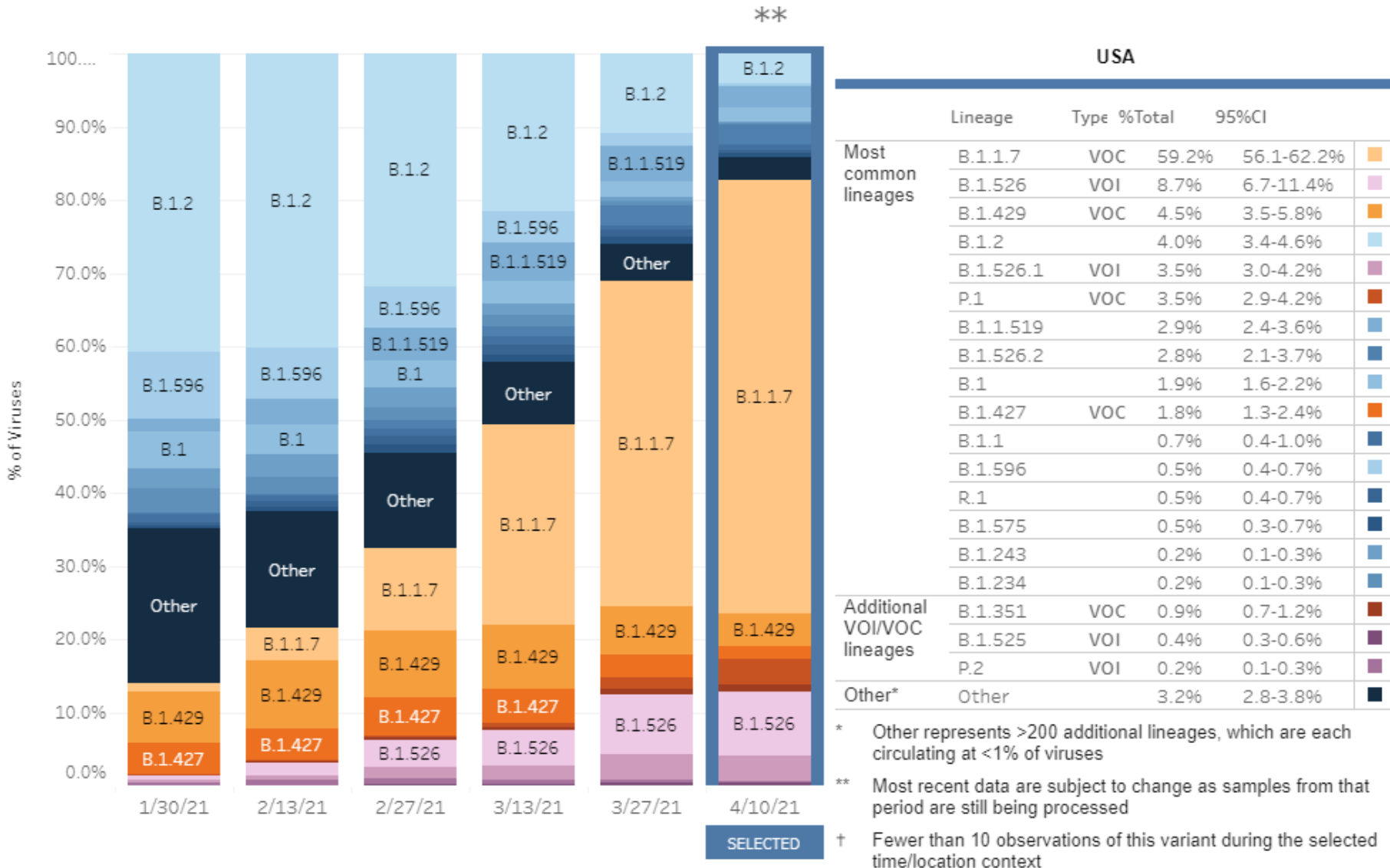
Variants of Concern

Name (Pango lineage)	Spike Substitutions	Name (Nextstrain)	First Detected	Known Attributes
B.1.1.7	Δ69/70, Δ144Y,(E484K*), (S494P*), N501Y, A570D, D614G, P681H, T716I, S982A, D1118, (K1191N*)	20I/501Y.V1	UK	<ul style="list-style-type: none"> ~50% increased transmission Potential increased severity based on hospitalizations and case fatality rate No impact on susceptibility to EUA monoclonal antibody therapeutics Minimal impact on neutralization by convalescent and post-vaccination sera
P.1	L18F, T20N, P26S, D138Y, R190S, K417T, E484K, N501Y, D614G, H655Y, T1027I	20J/501Y.V3	Japan/ Brazil	<ul style="list-style-type: none"> Significant decrease in susceptibility to the combination of bamlanivimab and etesevimab monoclonal antibody treatment, but other EUA monoclonal antibody treatments are available Reduced neutralization by convalescent and post-vaccination sera
B.1.351	D80A, D215G, Δ241/242/243, K417N, E484K, N501Y, D614G, A701V	20H/501.V2	South Africa	<ul style="list-style-type: none"> ~50% increased transmission Significant decrease in susceptibility to the combination of bamlanivimab and etesevimab monoclonal antibody treatment, but other EUA monoclonal antibody treatments are available Moderate reduction on neutralization by convalescent and post-vaccination sera
B.1.427	L452R, D614G	20C/S:452R	US CA	<ul style="list-style-type: none"> ~20% increased transmissibility Modest decrease in susceptibility to the combination of bamlanivimab and etesevimab; however, the clinical implications of this decrease are not known. Alternative monoclonal antibody treatments are available. Reduced neutralization by convalescent and post-vaccination sera
B.1.429	S13I, W152C, L452R, D614G	20C/S:452R	US CA	<ul style="list-style-type: none"> ~20% increased transmissibility Modest decrease in susceptibility to the combination of bamlanivimab and etesevimab; however, the clinical implications of this decrease are not known. Alternative monoclonal antibody treatments are available. Reduced neutralization by convalescent and post-vaccination sera

When we see mutations arise consistently in multiple lineages, it can indicate that they emerged early or provide a fitness advantage



National Prevalence of SARS-CoV-2 Variants



Prevalence of B.1.1.7 is estimated at 59.2%

Small decrease in prevalence of B.1.427 and B.1.429

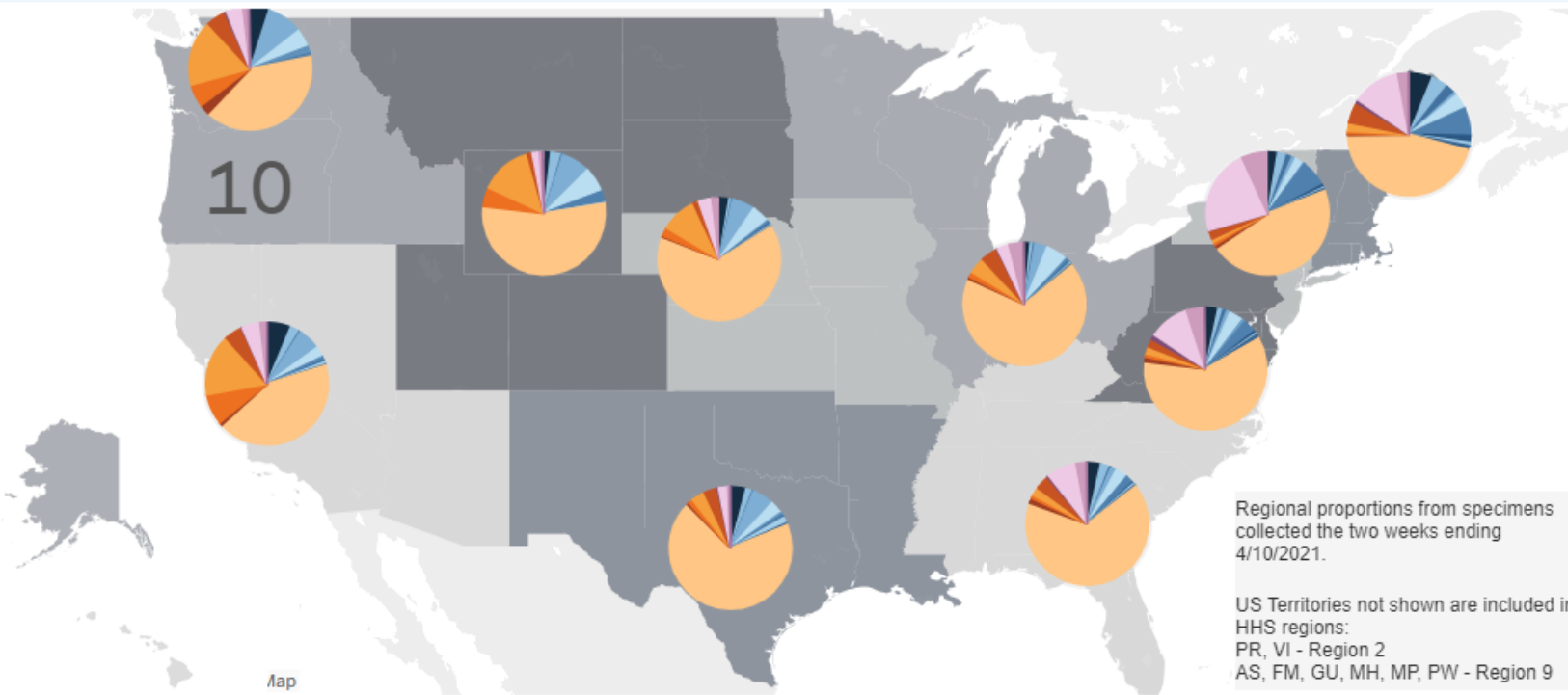
Small increase in B.1.526

Prevalence of P.1 increased from 1.6 to 3.5%,

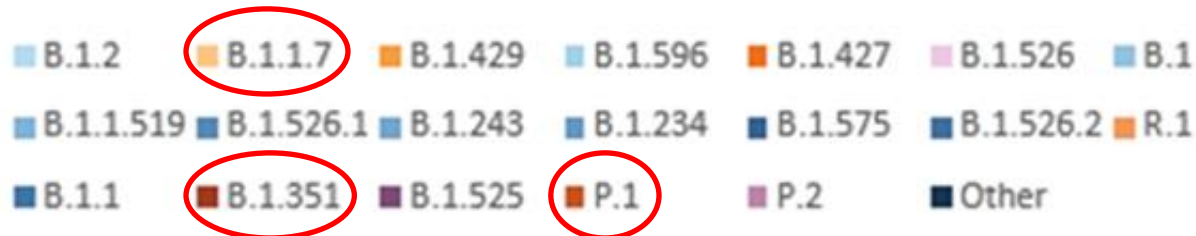
B.1.351 remained <1%

Regional Prevalence of SARS-CoV-2 Variants

United States: 3/28/2021 – 4/10/2021



Updated April 27, 2021

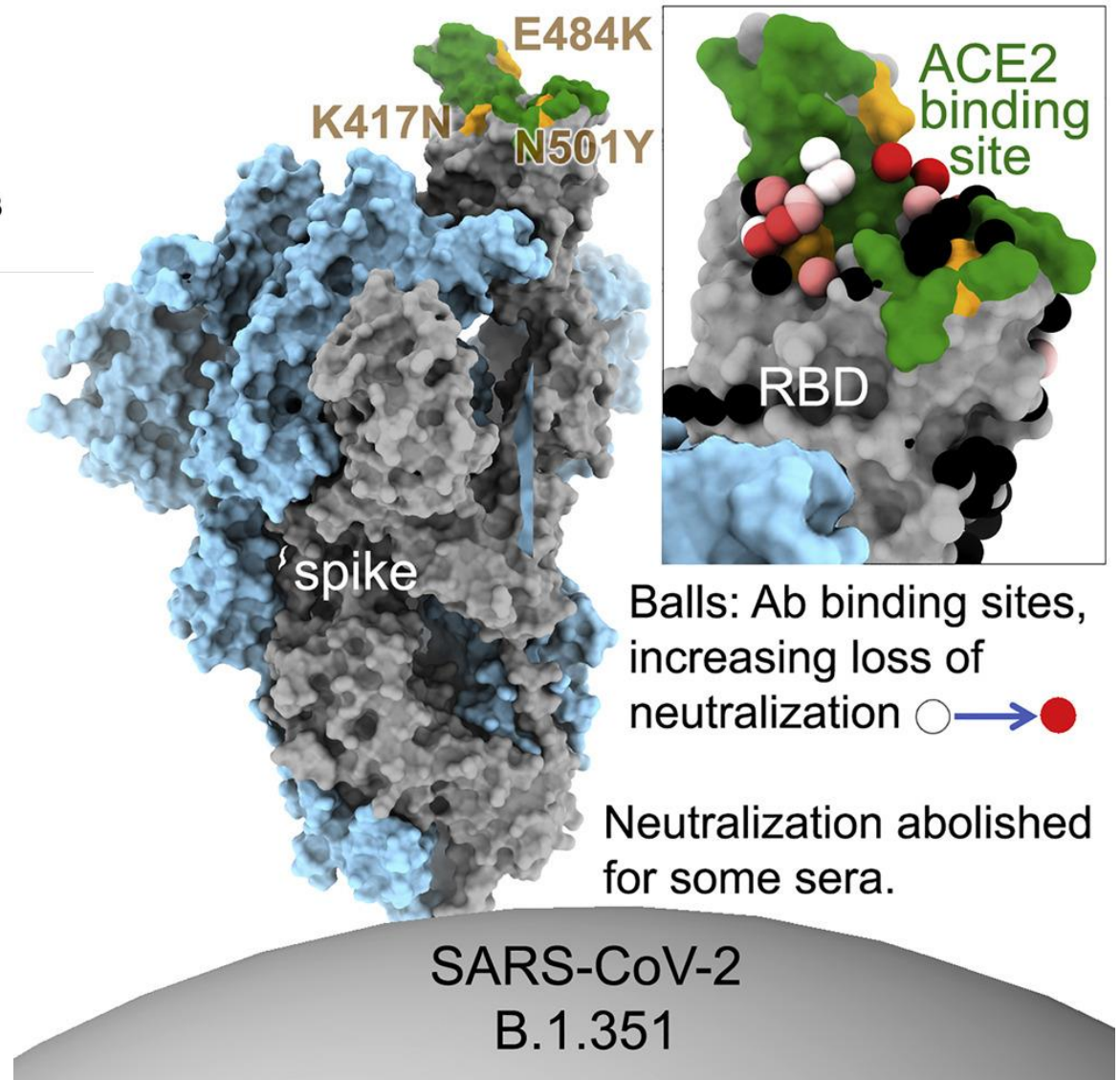
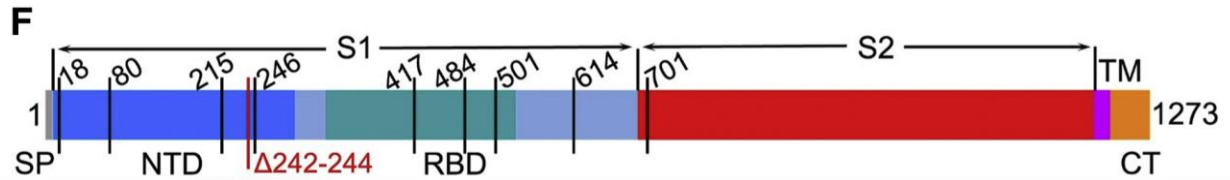


Estimated weighted prevalence of B.1.1.7 increasing in all HHS Regions and is greater than 50% in all HHS Regions except 1, 9, and 10

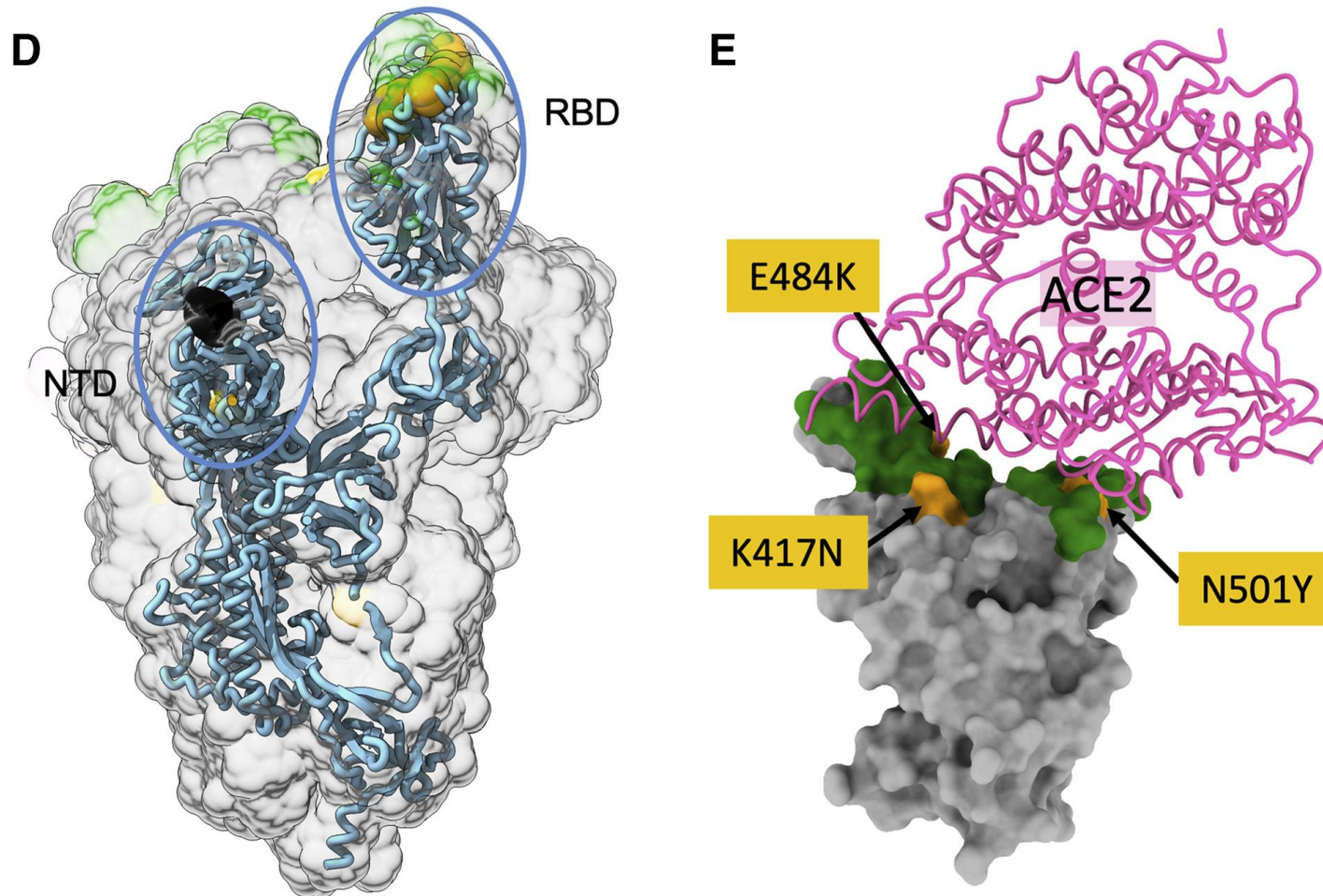
P1 increased in all HHS regions

B.1.351 remained <1%

Key residues in variants with reduced neutralization around edge of RBD



Key mutations present in variants with reduced neutralization around edge of ACE2 binding pocket



Unique features of coronavirus that make vaccine considerations different than influenza

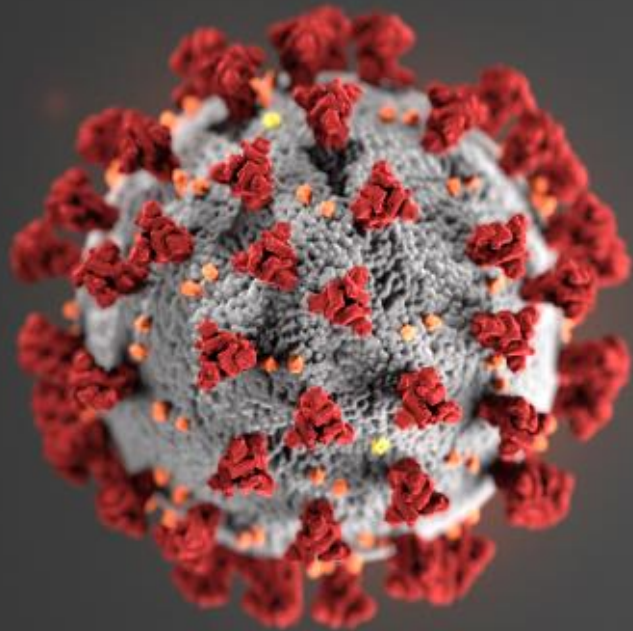
- SARS-CoV-2 is one virus; Influenza is really 3-4 viruses
- Influenza viruses have segmented genome
- Coronaviruses have proofreading capability, and much lower rate of mutation
- SARS-CoV-2 uses a protein receptor, not sialic acid

Considerations for future variant emergence

- Lower transmission = fewer cells to pass through = fewer opportunities for variants to emerge
- As more people are vaccinated, there will be immune pressure / possible escape
- Herd immunity
 - Lower transmission
 - Immune compromised individuals protected by the herd

Links

- [Surveillance for SARS-CoV-2 Variants | CDC](#)
- [National SARS-CoV-2 Genomic Surveillance Dashboard | CDC](#)
- [Variant Proportions in the U.S.](#)
- [SARS-CoV-2 Variants of Concern | CDC](#)



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.



Assessing Vaccine Effectiveness of COVID-19 Vaccines against Viral Variants

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IDSA Clinician Call – COVID-19
May 1, 2021



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Disclosures

Member, Moderna Scientific Advisory Board (SAB) – COVID-19 Vaccine

Why do VE studies?

- Evaluate real-world performance of vaccines
 - Cold chain
 - Timing and completeness of dosing schedule
 - Vaccine co-administration
 - Different epidemiology (e.g., rotavirus example)
- Address gaps in evidence of vaccine efficacy from clinical trials
 - Outcomes of interest (e.g. severe disease, death, symptomatic or asymptomatic infection, transmission)
 - Subpopulations at risk (e.g., HCWs, elderly, persons living with HIV)
 - Duration of protection from vaccines
 - Variants of Concern
- Updates to regulatory and policy making bodies
 - Provide post-authorization confirmation of VE of conditionally-approved products
 - Provide data on products that do not have FDA/EMA authorization or WHO PQ

Number of cases expected in a 100% susceptible population after 10 generations depending upon the Basic Reproduction Number (R_0)

R_0	Number of Cases in 10 th Generation
2.0	1024
2.5	9537
3.0	59,049
4.0	1,048,756

Source for R_0 values: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html#five-scenarios> (accessed 4-30-21)

Equation and Curves to Estimate Vaccine Effectiveness with the Screening Method

Bull WHO 1985: 63 (6): 1055-1068

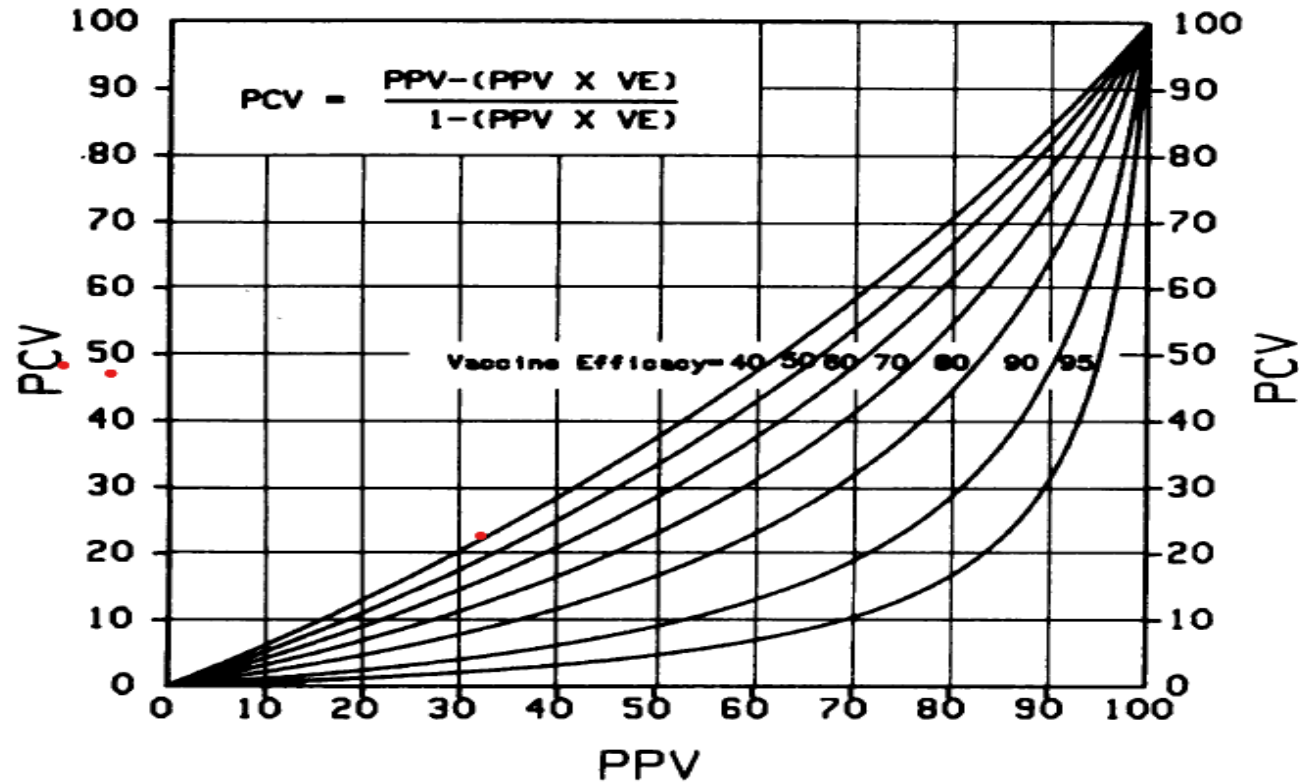


Fig. 1. The relationship between the percentage of cases vaccinated (PCV) and the percentage of the population vaccinated (PPV) for seven different percentage values of vaccine efficacy (VE).

Types of Potential Studies for Observational Studies of COVID-19 Vaccine Effectiveness

- Cohort Studies
 - Traditional Case-Control Studies
 - Test-Negative Case-Control Studies
 - Screening Method
 - Regression Discontinuity Design
-
- For accurate determination of vaccine effectiveness it is critical to determine vaccination status accurately

Test-Negative Design

- Strengths
 - Minimize bias of differences in healthcare seeking behavior of vaccinees and non-vaccinees. Also all cases and controls seek care for comparable illnesses
 - All cases and controls seek care at same facilities potentially decreasing differences in access to vaccines in different communities
 - Vaccination status usually obtained before results of laboratory tests available
 - Test sensitivity and specificity if high should minimize misclassification
- Weaknesses
 - HCWs may be less likely to test vaccinees
 - Will vaccination status ascertainment be accurate?
 - Will tests used be sensitive and specific? Should specific tests be recommended?
 - If tests are done early in illness, test positive patients may be more likely to seek care later as clinical illness intensifies (e.g., should cases in hospital be limited to those tested after hospitalization?)
 - Will vaccinees be more likely to have underlying illnesses which are exacerbated with respiratory illness of different causes leading to increase in vaccination of non-COVID cases?

Do viral genome changes threaten VE?

- Prospective platforms for general adult population will collect specimens from cases, where possible, for whole genome sequencing
 - Will not be performed in real time
 - May not be powered for variant-specific VE assessments of less common strains
- A separate team in the vaccine evaluation unit dedicated to assessing vaccine breakthrough cases
 - In particular a collaboration with the Emerging Infections Program comparing the frequency of variants among vaccinated and unvaccinated persons may shed light
- Work is part of broader CDC efforts to monitor the impact of SARS-CoV-2 variants



Adult COVID-19 VE assessments: Studies in red will characterize strains

VE priority	Prospective data collection	Electronic health record (EHR) and claims analyses (coordination across US government)
Immediate priority		
Does vaccine work as expected to prevent symptomatic disease?	Test-negative design case-control among healthcare personnel	
Subsequent priorities		
Older adults, including residents of long-term care facilities (LTCF)	Case-control among adults ≥65 years (COVID-NET linked to CMS); National Healthcare Safety Network; Outbreaks	CMS cohort (FDA, CMS) EHR datasets (CDC, VA, FDA)
Infection and transmission	Prospective longitudinal cohort among healthcare personnel & frontline workers; transmissibility evaluation in LTCF and other congregate settings; case-ascertained household cohorts for transmission	
Severe disease/hospitalization	Test-negative design (for adults and children); conventional case-control using hospitalized controls; screening method	EHR datasets (CDC, VA, FDA): Retrospective cohort or test-negative design
Non-severe disease	Test-negative design among outpatients	Potentially using EHR datasets
Those with key underlying conditions (e.g., immunocompromised)	Captured in above studies	CMS (FDA,CMS); EHR datasets (CDC, VA, FDA)
Disproportionately affected racial/ethnic groups	Captured in above studies; test-negative design in American Indian/Alaska Native population	CMS (FDA, CMS); EHR datasets (CDC, VA, FDA); Exploring IHS EHR (IHS)
Strain-specific VE	Captured in above studies (for studies with sequencing of samples)—likely only powered for predominant strains	
Vaccine impact	Ecologic analyses of disease incidence/seroprevalence and vaccine coverage; comparisons of expected vaccine impact from models with observed impact; Estimates of burden averted	

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Early Release / Vol. 70

April 28, 2021

Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Among Hospitalized Adults Aged ≥ 65 Years — United States, January–March 2021

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TABLE. Characteristics of adults aged ≥ 65 years with COVID-19–like illness* tested for SARS-CoV-2 infection, by COVID-19 case status[†] — 24 medical centers in 14 states,[§] January–March 2021

Characteristic	Case status, no. (column %)			p-value
	Total (N = 417)	Case-patients (n = 187)	Control participants (n = 230)	
SARS-CoV-2 vaccination status[†]				
Unvaccinated	287 (69)	146 (78)	141 (61)	<0.01
Single-dose vaccinated <14 days before illness onset	49 (12)	22 (12)	27 (12)	
Partially vaccinated	62 (15)	18 (10)	44 (19)	
Fully vaccinated	19 (5)	1 (0.5)	18 (8)	
Vaccine type, if vaccinated (missing = 11)				
Pfizer-BioNTech	63 (53)	15 (42)	48 (58)	0.10
Moderna	56 (47)	21 (58)	35 (42)	
Admission characteristic				
Days from illness onset to admission, median (IQR)	3 (1–6)	4 (1–7)	2 (0–4)	<0.01
Days from illness onset to SARS-CoV-2 testing, median (IQR)	2 (0–4)	3 (0–5)	1 (0–4)	<0.01

COVID Vaccines and Variants: Where Are We Headed?

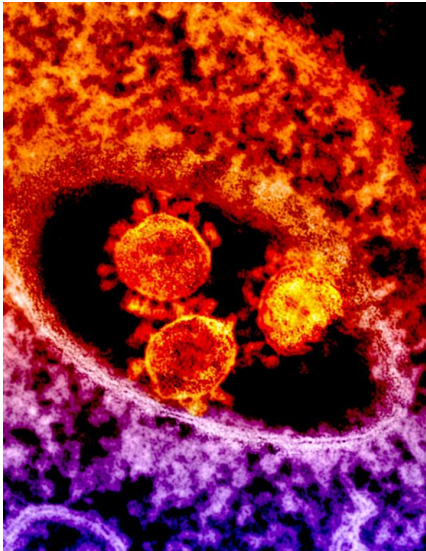
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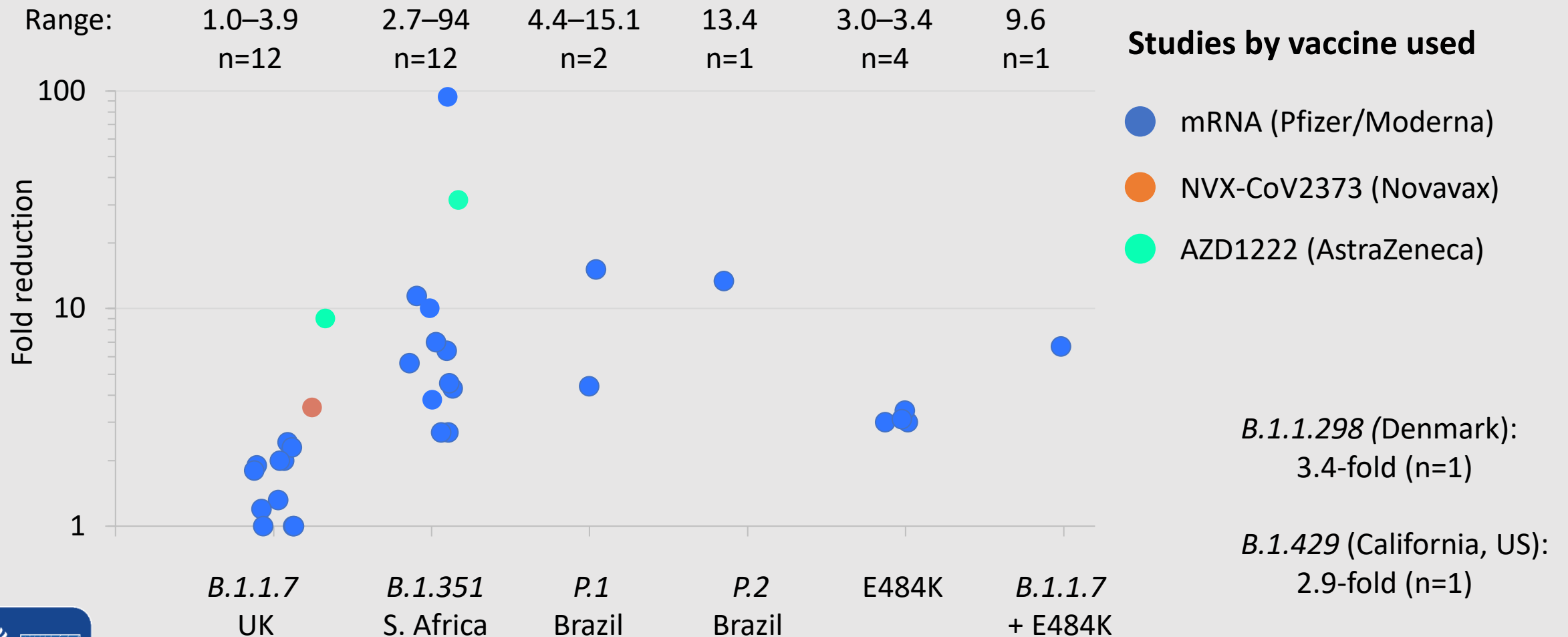
Division of Infectious Diseases

Department of Pediatrics

Vanderbilt University Medical Center



Reduced Neutralization Activity of Vaccinee Sera Relative to Wildtype/Dominant Strain by Study (n=19)



PFIZER AND BIONTECH CONFIRM HIGH EFFICACY AND NO SERIOUS SAFETY CONCERNS THROUGH UP TO SIX MONTHS FOLLOWING SECOND DOSE IN UPDATED TOPLINE ANALYSIS OF LANDMARK COVID-19 VACCINE STUDY

Thursday, April 01, 2021 - 06:45am

- *Analysis of 927 confirmed symptomatic cases of COVID-19 demonstrates BNT162b2 is highly effective with 91.3% vaccine efficacy observed against COVID-19, measured seven days through up to six months after the second dose*
- *Vaccine was 100% effective in preventing severe disease as defined by the U.S. Centers for Disease Control and Prevention and 95.3% effective in preventing severe disease as defined by the U.S. Food and Drug Administration*
- *Vaccine was 100% effective in preventing COVID-19 cases in South Africa, where the B.1.351 lineage is prevalent*
- *Vaccine safety now evaluated in more than 44,000 participants 16 years of age and older, with more than 12,000 vaccinated participants having at least six months follow-up after their second dose*
- *The companies plan to share these results with worldwide regulatory agencies soon*

ORIGINAL ARTICLE

Efficacy of the ChAdOx1 nCoV-19 Covid-19 Vaccine against the B.1.351 Variant

Table 2. Vaccine Efficacy against Mild-to-Moderate Symptomatic Covid-19 Confirmed by Nucleic Acid Amplification Test.*

End Point	Baseline Serologic Status†	Total No. of Cases	Placebo no./total no. (%)	Incidence Risk per 1000 person-yr (person-days)	Vaccine no./total no. (%)	Incidence Risk per 1000 person-yr (person-days)	Vaccine Efficacy‡ % (95% CI)
Mild-to-moderate illness with onset >14 days after second injection	Seronegative	42	23/717 (3.2)	93.6 (89,714)	19/750 (2.5)	73.1 (94,881)	21.9 (-49.9 to 59.8)
Mild-to-moderate illness associated with B.1.351 variant with onset >14 days after second injection	Seronegative	39	20/714 (2.8)	81.6 (89,448)	19/750 (2.5)	73.1 (94,881)	10.4 (-76.8 to 54.8)
Mild-to-moderate illness with onset >14 days after second injection, regardless of baseline serostatus	Any	46	24/865 (2.8)	81.9 (106,898)	22/884 (2.5)	73.2 (109,659)	10.6 (-66.4 to 52.2)
Mild-to-moderate illness with onset >14 days after one dose until October 31, 2020, a proxy for non-B.1.351 variant infection	Overall	15	12/938 (1.3)	31.1 (140,774)	3/944 (0.3)	7.6 (143,140)	75.4 (8.9 to 95.5)

This article was published on March 16, 2021, and updated on April 5, 2021, at NEJM.org.

Johnson & Johnson Ad 26 Vectored Vaccine

Table 8: Summary of Vaccine Efficacy against Moderate to Severe/Critical and Severe/Critical COVID-19 for Countries With >100 Reported Moderate to Severe/Critical Cases

		Severity	
		Moderate to Severe/Critical Point estimate (95% CI)	Severe/Critical Point estimate (95% CI)
	Onset		
US	at least 14 days after vaccination	74.4% (65.0; 81.6)	78.0% (33.1; 94.6)
	at least 28 days after vaccination	72.0% (58.2; 81.7)	85.9% (-9.4; 99.7)
Brazil	at least 14 days after vaccination	66.2% (51.0; 77.1)	81.9% (17.0; 98.1)
	at least 28 days after vaccination	68.1% (48.8; 80.7)	87.6% (7.8; 99.7)
South Africa	at least 14 days after vaccination	52.0% (30.3; 67.4)	73.1% (40.0; 89.4)
	at least 28 days after vaccination	64.0% (41.2; 78.7)	81.7% (46.2; 95.4)

Covid-19: Novavax vaccine efficacy is 86% against UK variant and 60% against South African variant

Cite this as: *BMJ* 2021;372:n296
<http://dx.doi.org/10.1136/bmj.n296>
 Published: 01 February 2021

Table 2. Vaccine Efficacy Against Symptomatic Covid-19 at Least 7 Days After the Second Dose (Day 28)

Population/Baseline Anti-Spike IgG Serostatus	No. of Cases	NVX-CoV2373*		Placebo		VE (95% CI)
		n/N (%)†	(95% CI)	n/N (%)†	(95% CI)	
All Participants						
Baseline seronegative	44	15/1357 (1.1)	(0.6, 1.8)	29/1327 (2.2)	(1.5, 3.1)	49.4%‡ (6.1, 72.8)
Baseline seropositive	19	6/500 (1.2)	(0.4, 2.6)	13/514 (2.5)	(1.4, 4.3)	52.6% (-23.8, 81.8)
Regardless of baseline serostatus	63	21/1857 (1.1)	(0.7, 1.7)	42/1841 (2.3)	(1.6, 3.1)	50.4% (16.6, 70.5)
Participants Without HIV						
Baseline seronegative	38	11/1281 (0.90)	(0.43, 1.5)	27/1255 (2.2)	(1.4, 3.1)	60.1% (19.9, 80.1)
Baseline seropositive	19	6/467 (1.29)	(0.47, 2.8)	13/484 (2.7)	(1.4, 4.5)	52.2% (-24.8, 81.7)
Regardless of baseline serostatus	57	17/1748 (0.97)	(0.57, 1.6)	40/1739 (2.3)	(1.6, 3.1)	57.7% (25.7, 75.9)

Abbreviations: CI = confidence interval; Covid-19 = coronavirus 2 disease 2019; HIV = human immunodeficiency virus; N = number of participants; n = number of participants

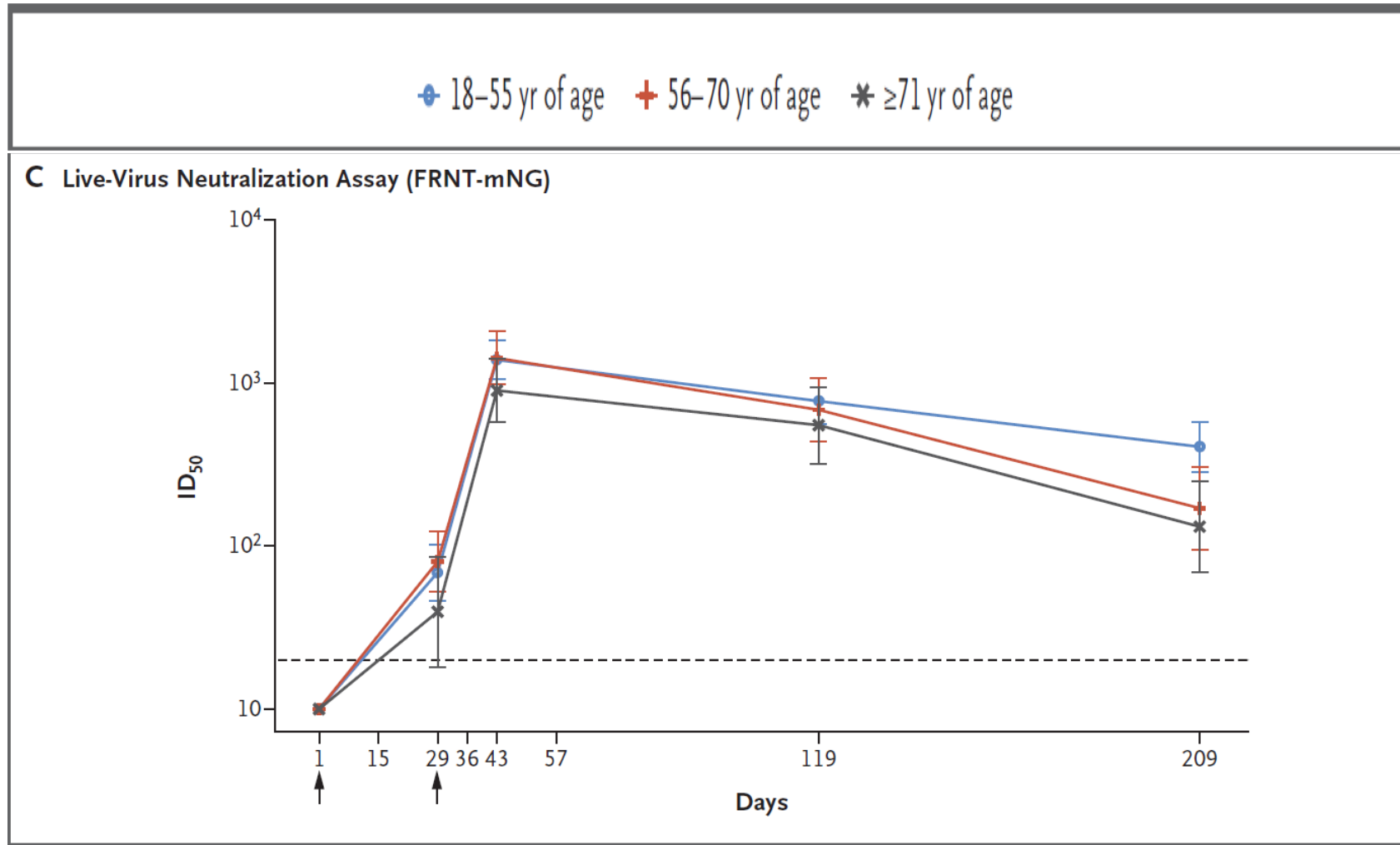
with NAAT-confirmed Covid-19; NAAT = nucleic acid amplification test; PP-EFF = per-protocol efficacy; VE = vaccine efficacy.

*Includes 50 µg Matrix-M1.

Shinde et al. Medrx posted March 3 2021

†Percentage of participants with Covid-19 calculated as $n/N \times 100$.

Antibody Persistence through 6 Months after the Second Dose of mRNA-1273 Vaccine for Covid-19



This letter was published on April 6, 2021, at NEJM.org.

Conclusions

- Widespread immunization should be implemented to reduce the generation of variants
- Immune responses to the variants will differ among the vaccines and the vaccinees (particularly those who were naturally infected)
- For some variants these immunologic differences may not impact effectiveness, but for other variants they will
- Strains associated with vaccine breakthroughs should be sequenced
- Waning immunity will need to be assessed and boosters offered to maintain protection

VACCINE Q&A

Sara Oliver, MD, MSPH

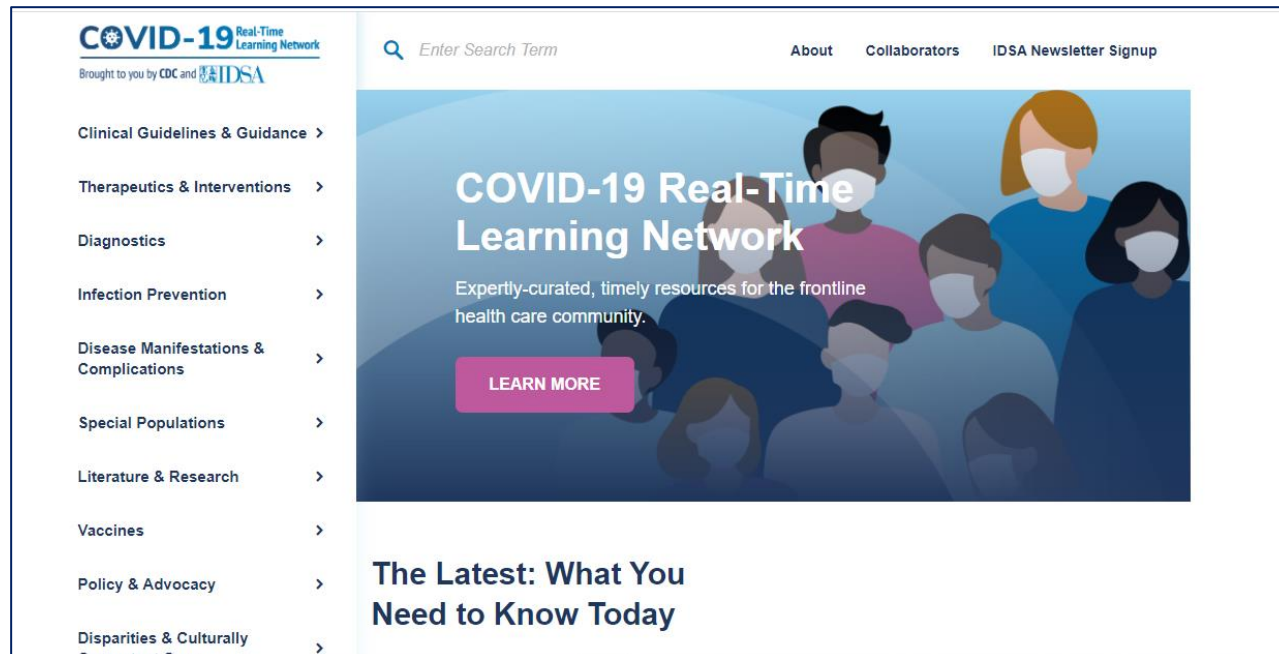
LCDR, U.S. Public Health Service
Co-Lead, COVID-19 Work Group of the
Advisory Committee on Immunization
Practices
Centers for Disease Control and
Prevention



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

@RealTimeCOVID19

#RealTimeCOVID19

CDC-IDSA Partnership: Clinical Management Call Support

FOR WHOM?

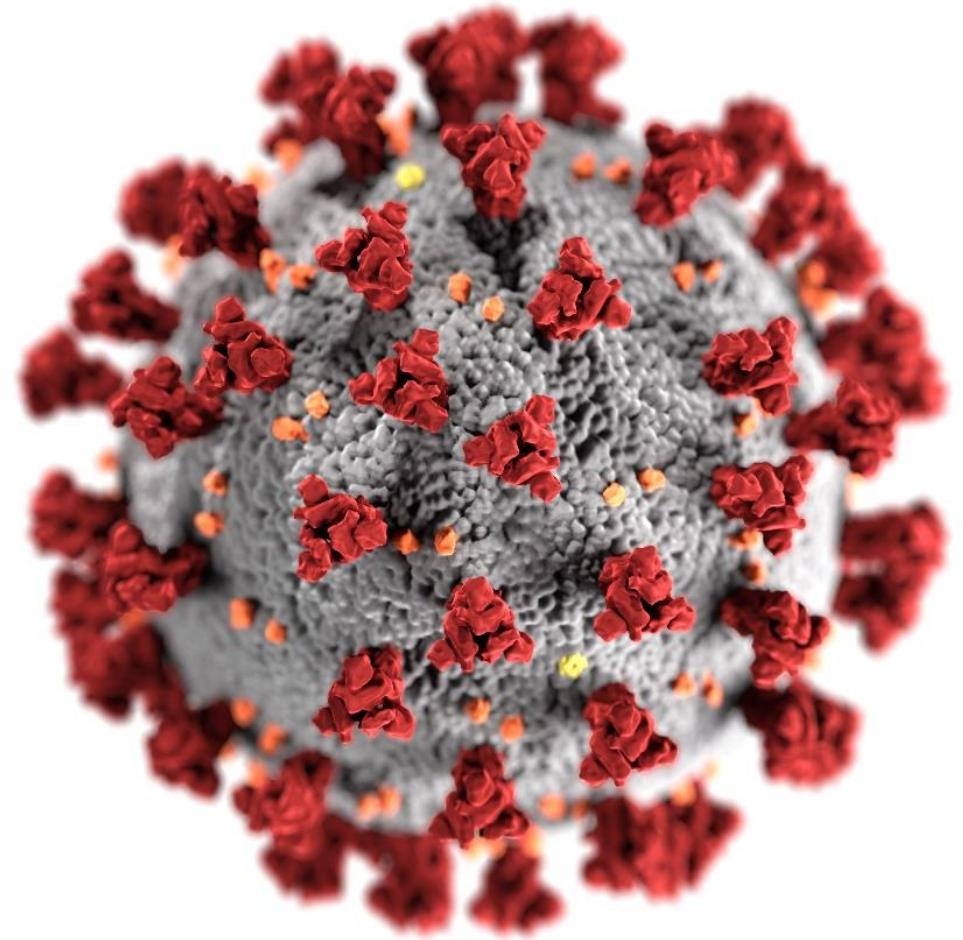
- Clinicians who have questions about the clinical management of COVID-19

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



idweek.org
Virtual Conference



Save the Date
Sept. 29 – Oct. 3, 2021

Attend, Learn & Collaborate.

Advancing Science, Improving Care

Important Dates:

- Registration Opens – mid-May
- Abstract Submission Deadline – June 9
- Case Submission Deadline – June 9

Continue the
conversation on Twitter

@RealTimeCOVID19
#RealTimeCOVID19



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

Next Call: **Sat., May 8**

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

Contact Us:

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