CDC/IDSA COVID-19 Clinician Call

March 12, 2022

Welcome & Introductions

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

- 86th in a series of calls, initiated by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19. This call is not intended for the media.
- 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.

COVID-19 Real-Time Learning Network
Brought to you by CDC and IDSA

In collaboration with the CDC, the EIN is surveying its members to better understand their perspectives on the use, interpretation and need for SARS-CoV-2 antibody tests in clinical practice.

--The survey link has been emailed to all EIN members; one final emailed reminder will be sent next week.

--The survey will be open until March 28, and all EIN members receive reports for every survey.

--To join the EIN, you can sign up here: https://ein.idsociety.org/members/sign_up/.

The Latest on COVID-19 Treatment; Plus Variants Update

Update on the Omicron Variant and its Sublineages

Deborah Dowell, MD, MPH
CAPT, U.S. Public Health Service
Chief Medical Officer, COVID-19 Response
U.S. Centers for Disease Control and Prevention

Treatment Updates from IDSA's COVID-19 Rapid Guidelines Panel

Monoclonal Antibody Therapies: What's In, What's Out

Lindsey R. Baden, MD
Professor of Medicine, Harvard Medical School
Director of Clinical Research, Division of Infectious Diseases, Brigham and Women's Hospital
Director, Infectious Diseases, Dana-Farber Cancer Institute

Outpatient COVID-19 Convalescent Plasma Treatment in Immunocompromised Patients

Shmuel Shoham, MD
Professor of Medicine, Division of Infectious Disease
Johns Hopkins University School of Medicine

Emerging Data on Baricitinib in Hospitalized Patients

Jason C. Gallagher, PharmD, FCCP, FIDP, FIDSA, BCPS
Clinical Professor, Temple University School of Pharmacy
Clinical Specialist, Infectious Diseases, Temple University Hospital

Mari Nakamura, MD, MPH
Medical Director, Antimicrobial Stewardship
Associate Physician in Pediatrics, Division of Infectious Diseases and
Assistant Professor of Pediatrics, Harvard Medical School

Treatment Supply & Distribution Update

COVID-19 Therapeutics Allocation & Distribution Update

Derek Eisnor, MD
Medical Officer, Division of Clinical Development
Biomedical Advanced Research & Development Authority (BARDA)
COVID-19 Allocation and Distribution Lead
Heath and Human Services
Assistant Secretary for Preparedness and Response (ASPR)

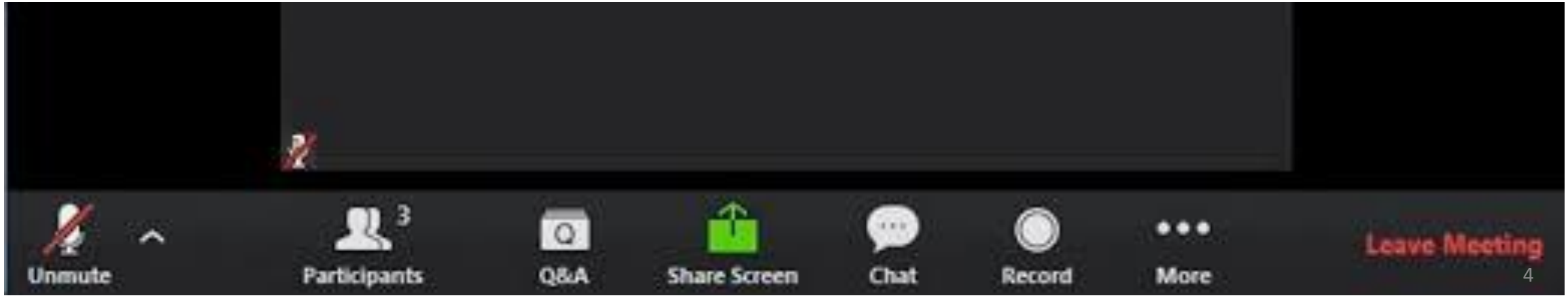
Test to Treat Initiative

Meg Sullivan, MD
Acting Chief Medical Officer
Assistant Secretary for Preparedness and Response (ASPR)

Q&A/Discussion (Full Panel)

Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button

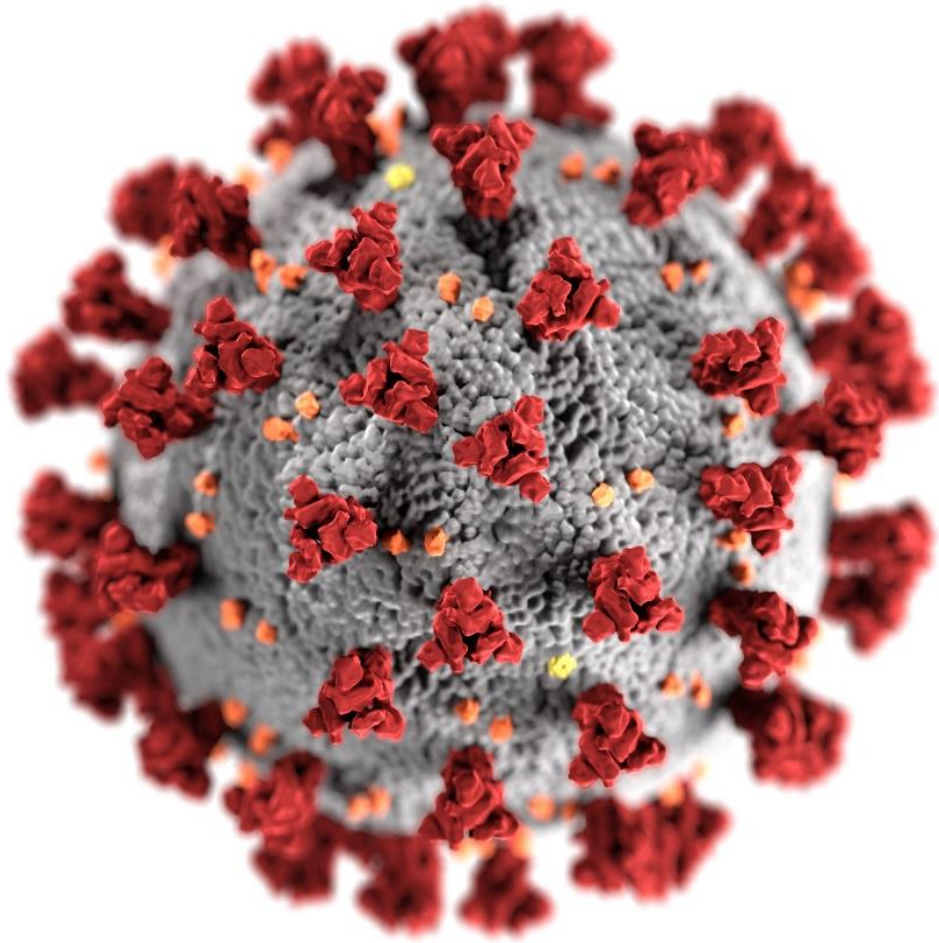


Update on the Omicron Variant and Its Sublineages

Deborah Dowell, MD, MPH

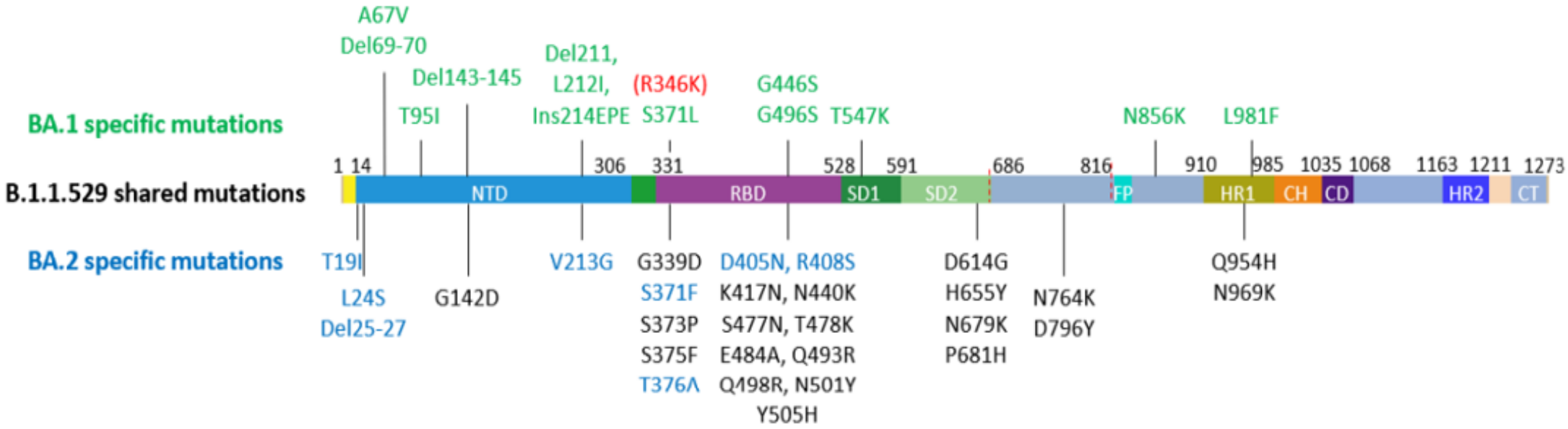
Update on the Omicron variant and its sub-lineages

Debbie Dowell, MD, MPH
Chief Medical Officer
CDC COVID-19 Response
March 12, 2022



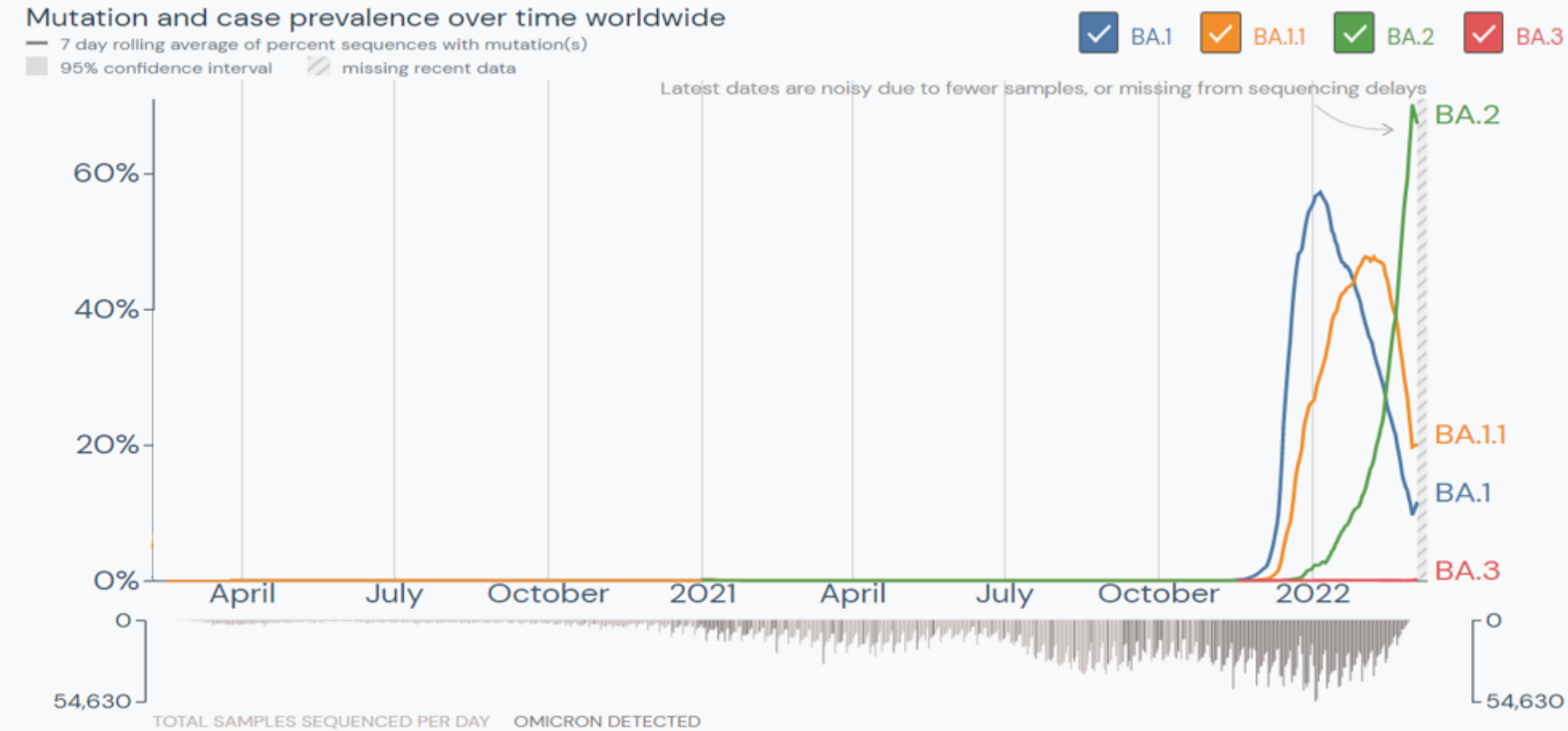
cdc.gov/coronavirus

The most common Omicron sublineages currently in circulation are BA.1, BA1.1, and BA.2



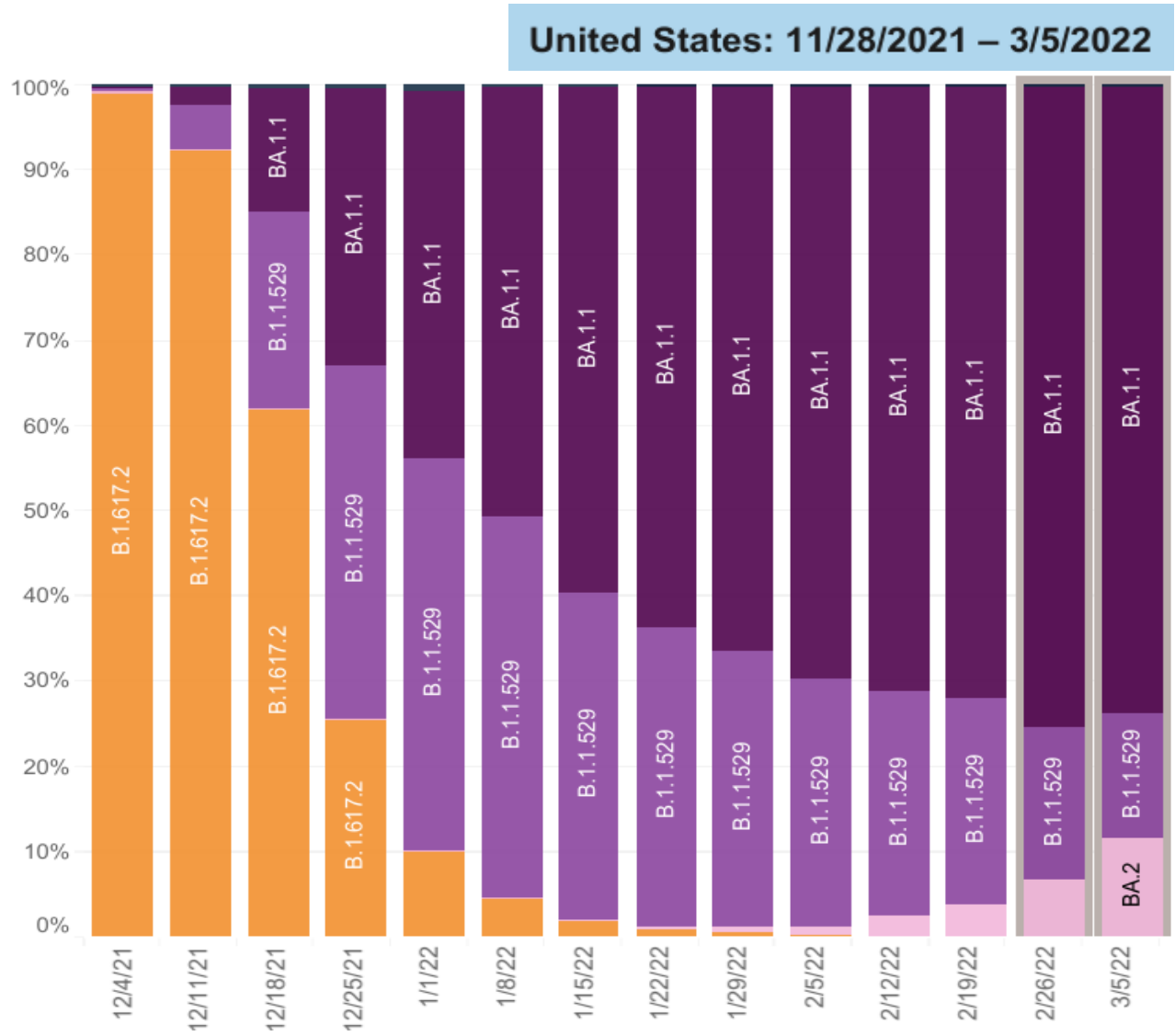
Antibody evasion properties of SARS-CoV-2 Omicron sublineages. Iketani *et al*. bioRxiv (*Preprint* February 9, 2022)[7]

BA.2 now the predominant sublineage in many countries



Omicron Variant Report. Alaa Abdel Latif, Julia L. Mullen, Manar Alkuzweny, Ginger Tsueng, Marco Cano, Emily Haag, Jerry Zhou, Mark Zeller, Emory Hufbauer, Nate Matteson, Chunlei Wu, Kristian G. Andersen, Andrew I. Su, Karthik Gangavarapu, Laura D. Hughes, and the Center for Viral Systems Biology. outbreak.info, (available at https://outbreak.info/situation-reports/omicron). Accessed 9 March 2022.

BA.2 is gradually increasing in the United States



https://covid.cdc.gov/covid-data-tracker/#variant-proportions

United States: 2/27/2022 – 3/5/2022 NOWCAST

WHO label	Lineage #	US Class	%Total	95%PI
Omicron	BA.1.1	VOC	73.7%	70.1-77.0%
	B.1.1.529	VOC	14.7%	12.4-17.4%
	BA.2	VOC	11.6%	9.8-13.6%
Delta	B.1.617.2	VOC	0.0%	0.0-0.0%
Other	Other*		0.0%	0.0-0.0%

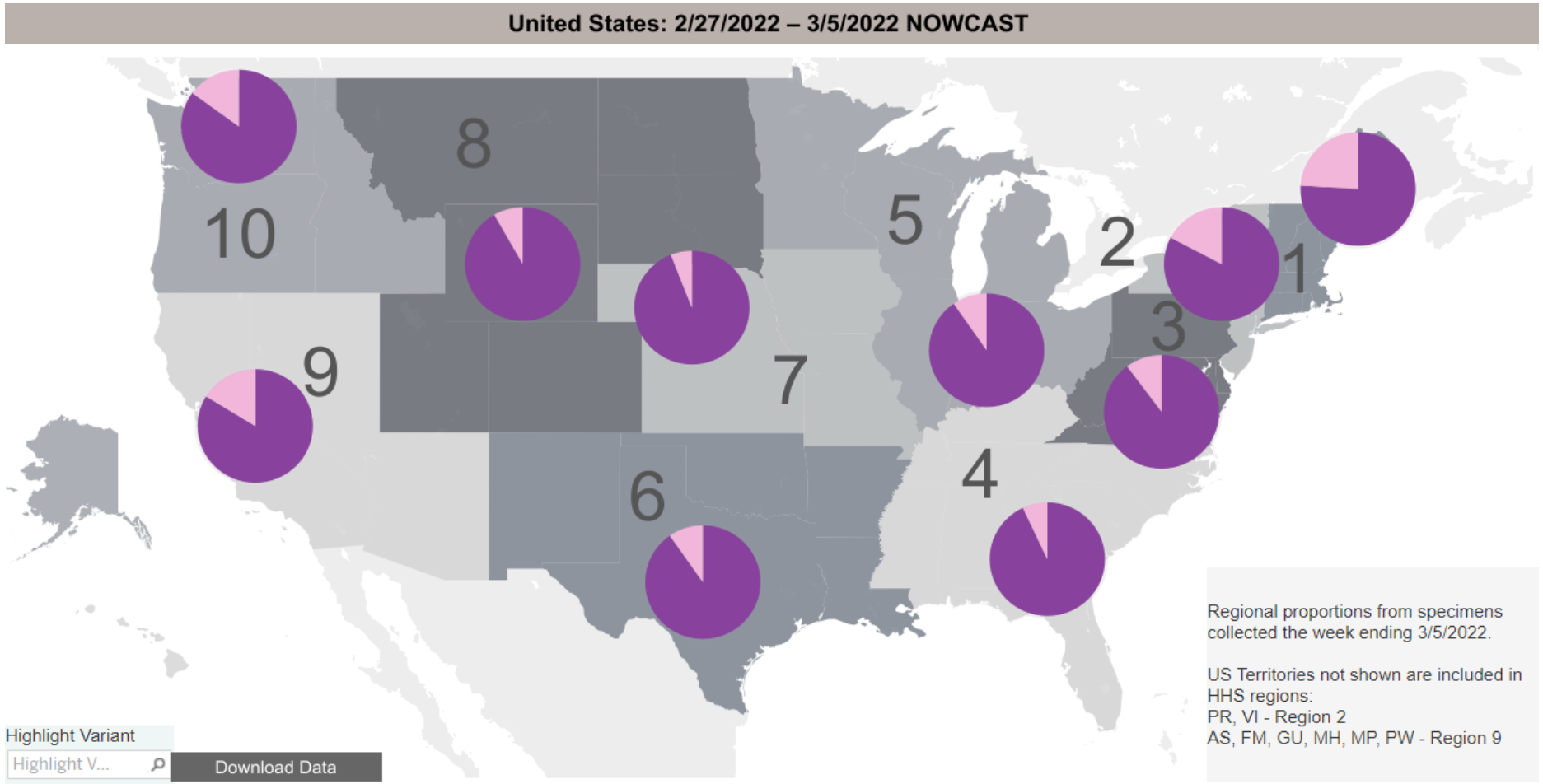
* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.

** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

AY.1-AY.133 and their sublineages are aggregated with B.1.617.2. BA.1 and BA.3 are aggregated with B.1.1.529. For regional data, BA.1.1 is also aggregated with B.1.1.529, as it currently cannot be reliably called in each region.

BA.2 is gradually increasing in the United States

4



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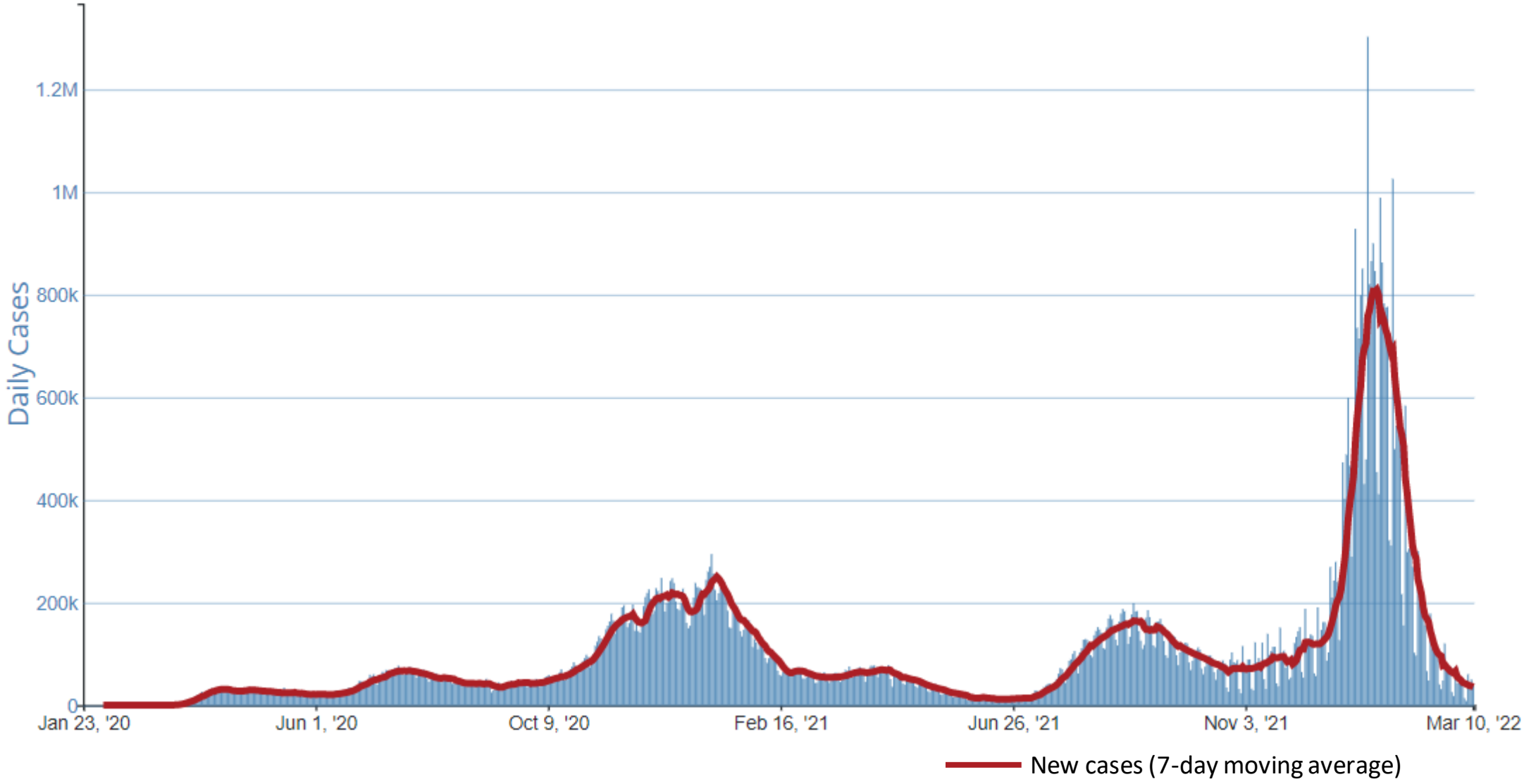
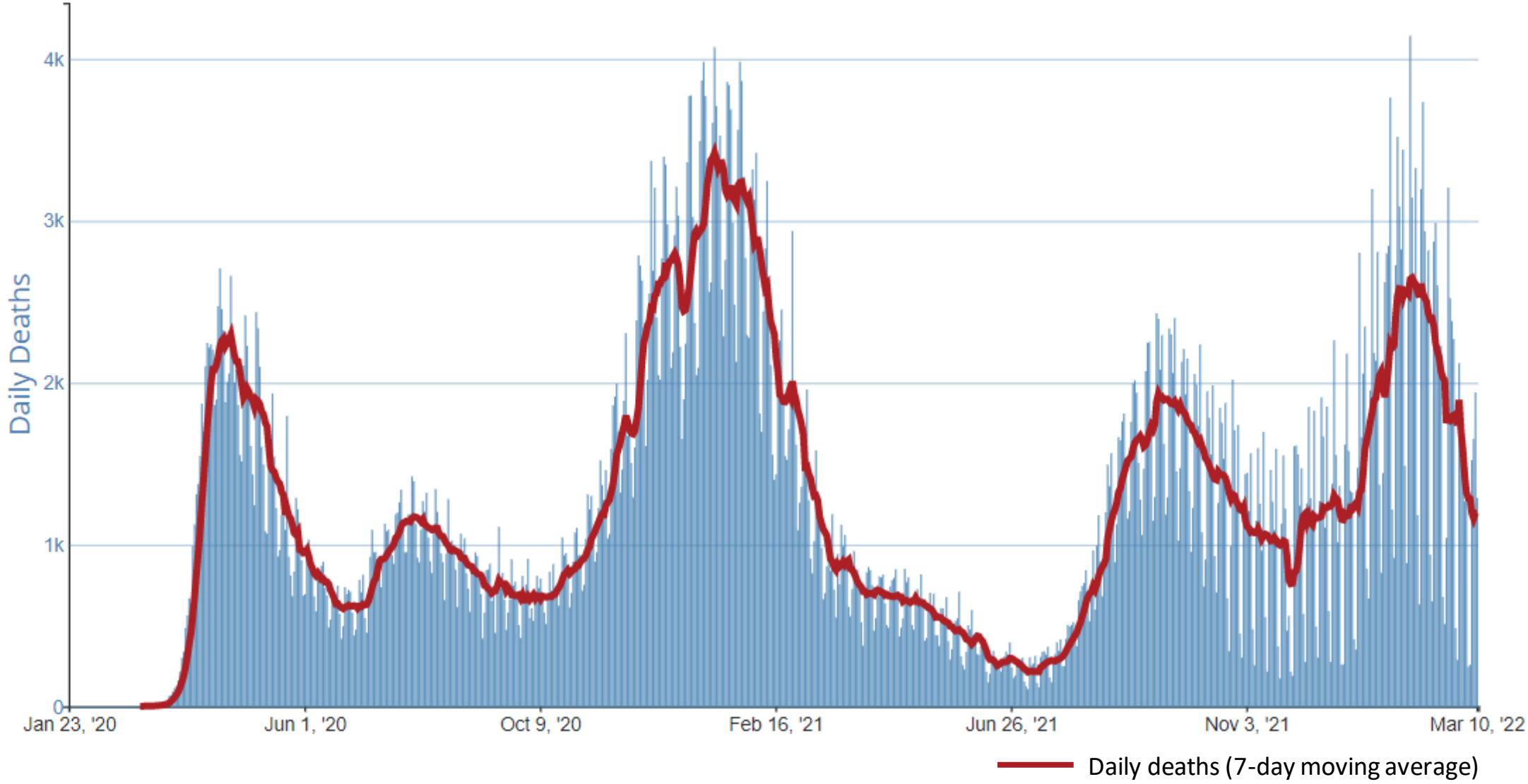
U.S. COVID-19 cases are declining



https://covid.cdc.gov/covid-data-tracker/#trends

U.S. COVID-19 deaths are decreasing but still high



https://covid.cdc.gov/covid-data-tracker/#trends

Disease severity with BA.2 and BA.1 infections appears to be similar

Hospitalization:

	Hospital admission[b] n/N (%)	Adjusted odds ratio (95% CI)
	N=95,470	
SGTF (BA.1 proxy)	2,965/87,194 (3.4)	Ref
S-gene positive (BA.2 proxy)	295/8,276 (3.6)	0.96 (0.85-1.09)

Severe disease, among those hospitalized:

	Severe disease[a] n/N (%)	Adjusted odds ratio (95% CI)
	N=3,058	
SGTF (BA.1 proxy)	929/2776 (33.5)	Ref
S-gene positive (BA.2 proxy)	86/282 (30.5)	0.91 (0.68-1.22)

Clinical severity of Omicron sub-lineage BA.2 compared to BA.1 in South Africa. Wolter *et al.* medRxiv (*Preprint* February 19, 2022).

UK Health Security Agency. SARS-CoV-2 variants of concern and variants under investigation in England Technical briefing 38. 11 March 2022. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1060337/Technical-Briefing-38-11March2022.pdf

Evidence suggests BA.2 is more transmissible than BA.1

Secondary attack rates for contacts of cases with confirmed sequenced VUI22JAN-01 and all other Omicron (VOC-21NOV-01)
(Case test dates 1 January to 14 February 2022, variant data as of 7 March 2022 and contact tracing data as of 8 March 2022)

Variant	Setting	Number of exposing cases	Number of contacts	Adjusted* secondary attack rate (95% Confidence Interval)
VOC-21NOV-01	Household	178,069	369,011	10.7% (10.6%-10.8%)
VUI-22JAN-01	Household	20,072	41,621	13.6% (13.2%-14.0%)
VOC-21NOV-01	Non-household	30,325	74,343	4.2% (4.0%-4.3%)
VUI-22JAN-01	Non-household	3,565	8,763	5.3% (4.7%-5.8%)

*Adjusted for vaccination status of the exposer and the contact (allowing for interaction with variant), age and sex of the exposer and the contact, the date (week) of positive test of the exposer and whether the contact completed contact tracing. Secondary attack rates from NHS Test and Trace should generally be considered lower bounds due to the nature of contact tracing and testing. Data provided is for contacts of cases with test dates in the period until 1 January to 14 February 2022.

UK Health Security Agency. SARS-CoV-2 variants of concern and variants under investigation in England Technical briefing 38. 11 March 2022.
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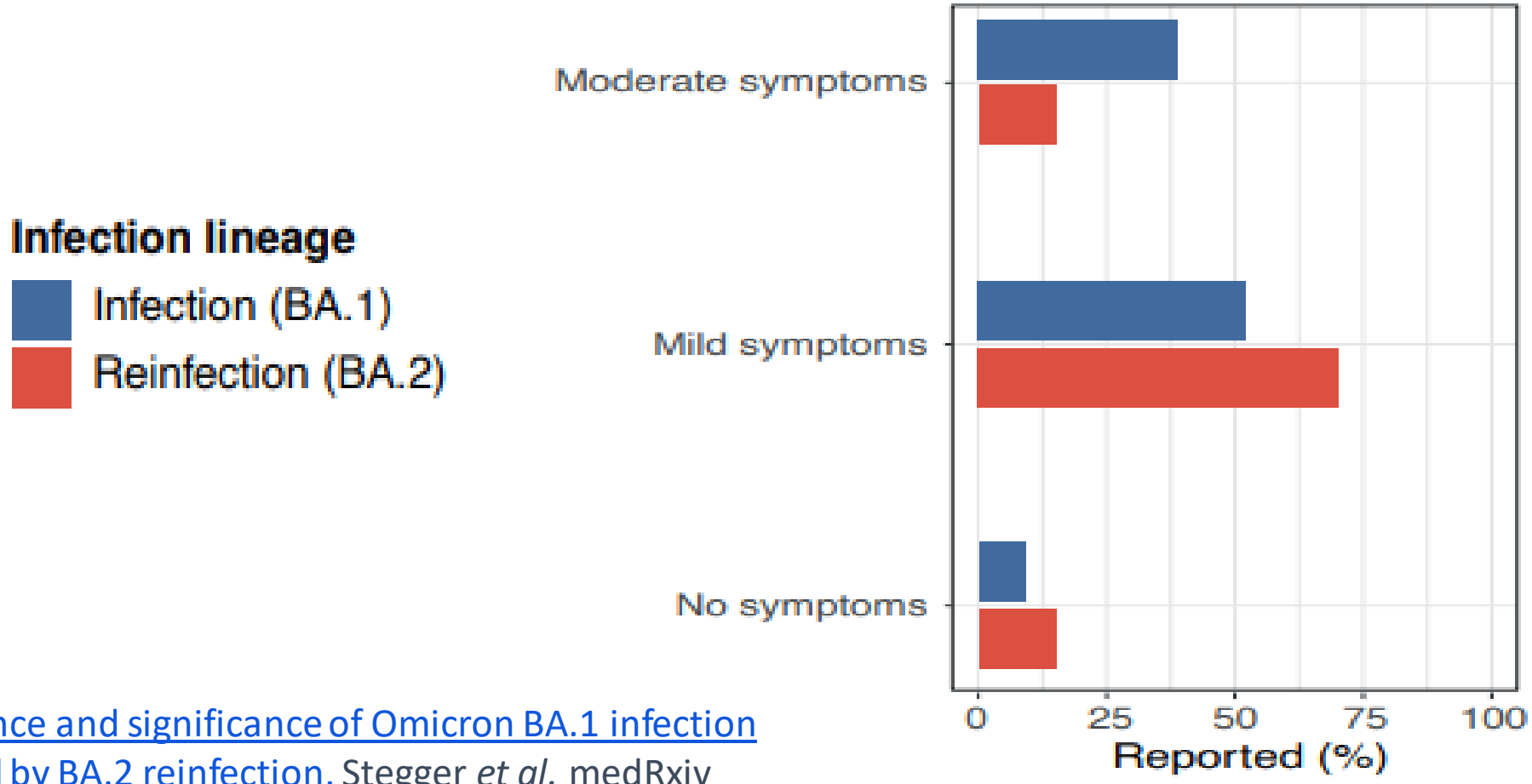
Transmission of SARS-CoV-2 Omicron VOC subvariants BA.1 and BA.2: Evidence from Danish Households: Lyngse et al, medRxiv. 3- January 2022.

Early data suggest infection with BA.1 provides protection against reinfection with BA.2



Occurrence and significance of Omicron BA.1 infection followed by BA.2 reinfection. Stegger *et al.* medRxiv (*Preprint* February 22, 2022).

Vaccine effectiveness for symptomatic infection does not appear to be reduced against BA.2 compared to BA.1

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Vaccine effectiveness against symptomatic disease (all vaccine brands combined) for BA.1 and BA.2

Dose	Interval after dose	BA.1 (VE (95% CI))	BA.2 (VE (95% CI))
2	25 weeks and over	10% (9 to 11)	18% (5 to 29)
3	2 to 4 weeks	69% (68 to 69)	74% (69 to 77)
3	5 to 9 weeks	61% (61 to 62)	67% (62 to 71)
3	10+ weeks	49% (48 to 50)	46% (37 to 53)

UK Health Security Agency. COVID-19 vaccine surveillance report Week 10 - 10 March 2022
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1060030/vaccine-surveillance-report-week-10.pdf

Lab studies suggest some changes in monoclonal antibody neutralizing activity against BA.2

Fold change in IC50 values relative to D614G of neutralization of Omicron variants

Fold change in IC_{50} relative to D614G (<3, <10, <100)	RBD mAbs												
	Class 1			Class 2				Class 3					
	CB6	Brii-196	1-20	REGN 10933	COV2-2196	LY-CoV 555	2-15	REGN 10987	COV2-2130	S309	2-7	Brii-198	LY-CoV 1404
BA.1	<428	298	<429	<2201	306	<1496	<2716	<1716	83.5	6.9	195	2.3	1.4
BA.1 + R346K	<428	135	<429	415	187	<1496	<2716	<1716	<687	4.5	82.1	<22	1.5
BA.2	<428	322	<429	<2201	680	<1496	<2716	253	1.9	27.0	7.3	10.5	1.1

Antibody evasion properties of SARS-CoV-2 Omicron sublineages. Iketani *et al.* bioRxiv (*Preprint* February 9, 2022)

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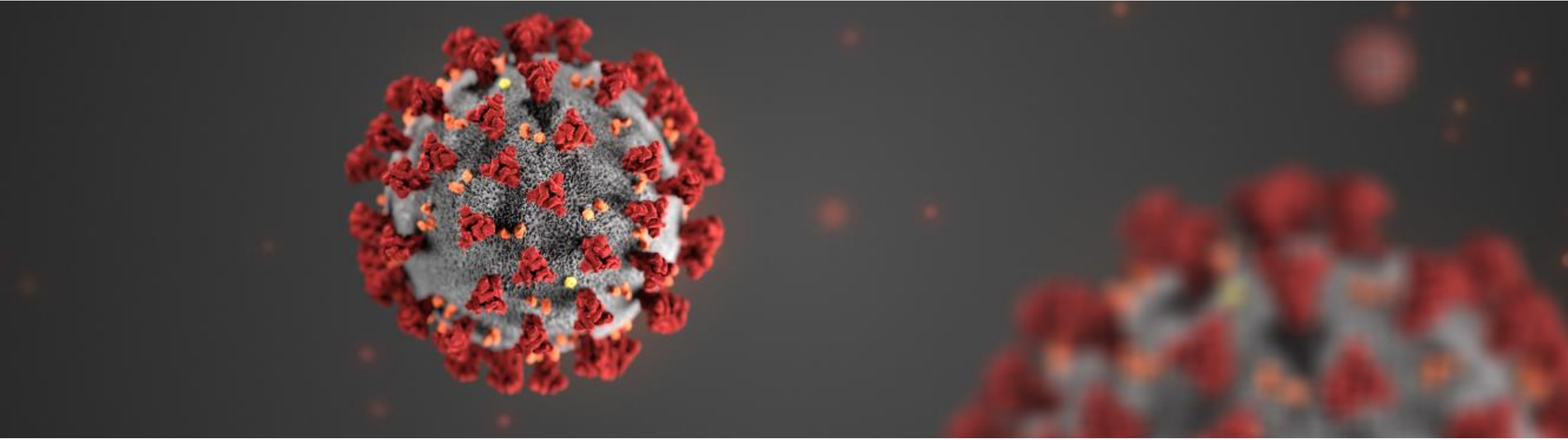


For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.

Monoclonal Antibody Therapies: What's In, What's Out

Lindsey R. Baden, MD

SARS-CoV-2 Targeting Monoclonal Antibodies (mAbs)

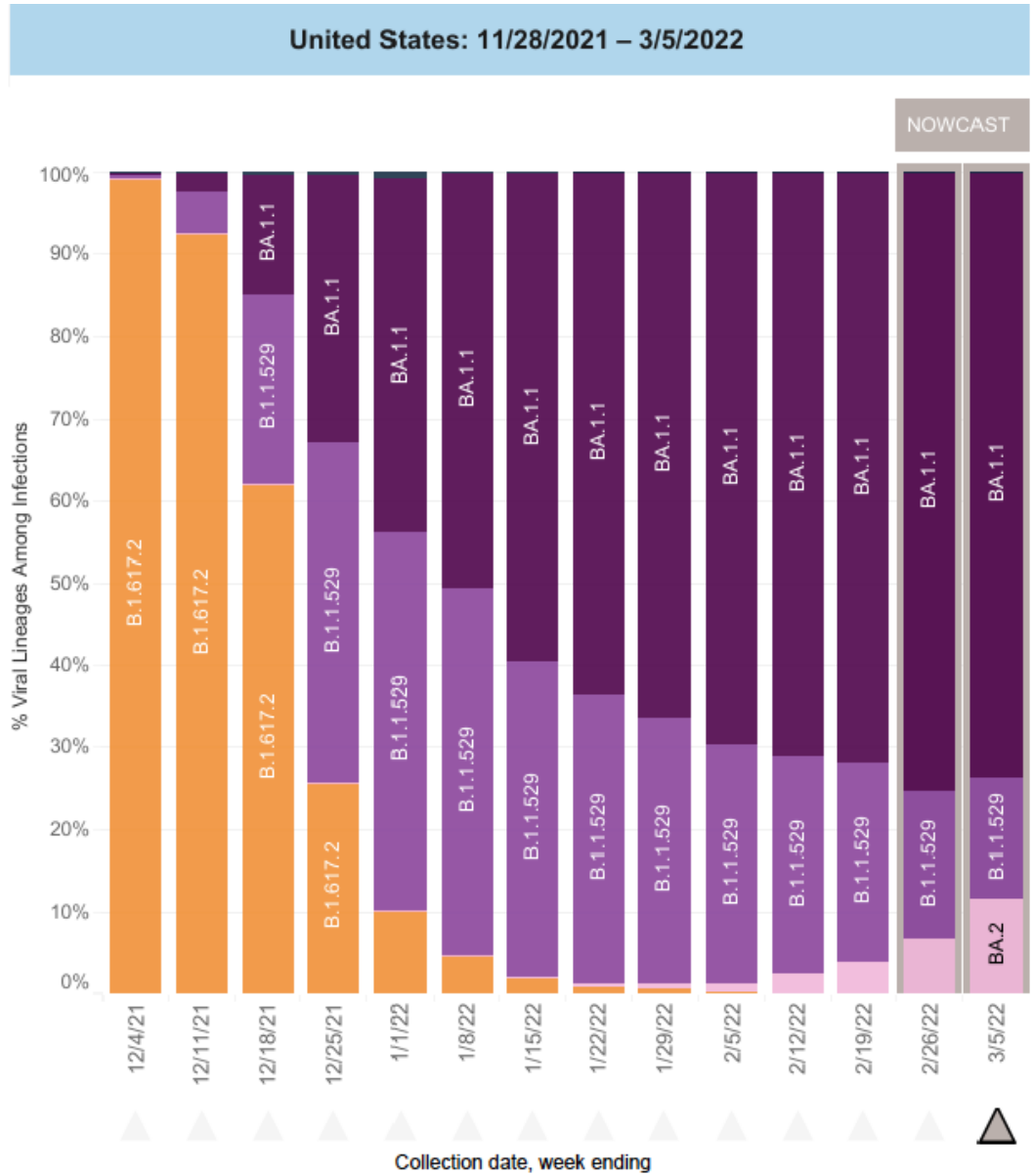
How do we move forward?

Lindsey R. Baden, MD
Brigham and Women's Hospital
Dana-Farber Cancer Institute
Harvard Medical School

Disclosures

Receive research support from NIH, Gates, Wellcome Trust for vaccine and therapeutics development including for SARS-CoV-2. Serve on multiple NIH SMC/DSMBs and the IDSA Covid-19 Treatment Guidelines Committee.

SARS-CoV-2 Variant Proportions Across United States



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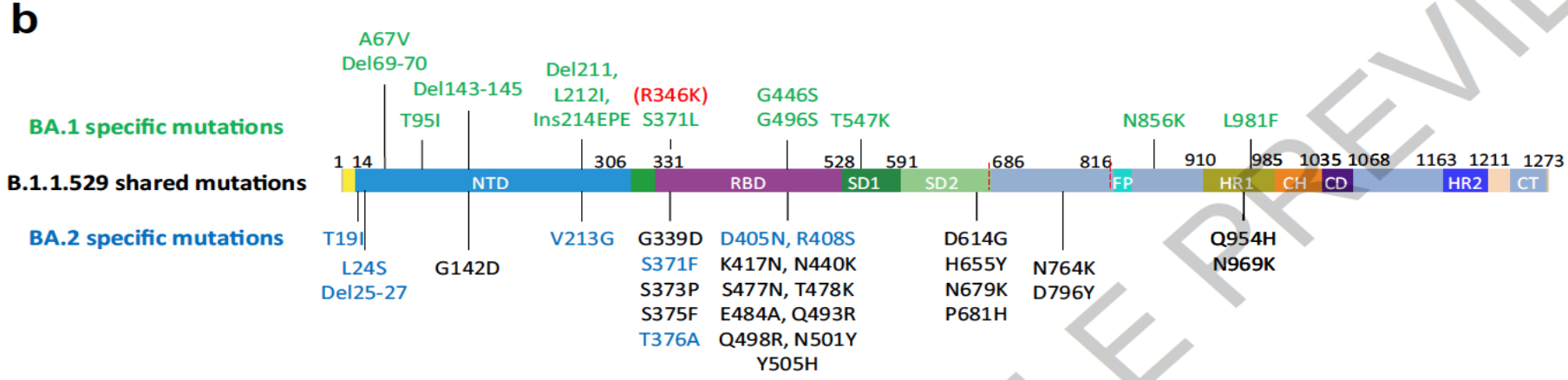
Accessed 12Mar22: Covid.cdc.gov

Omicron: Differences Between BA.1(+/-R346K) and BA.2



Fold change in IC_{50} relative to D614G	RBD mAbs													NTD mAbs					
	Class 1			Class 2				Class 3						Class 4					
	CB6	Brii-196	1-20	REGN 10933	COV2-2196	LY-CoV 555	2-15	REGN 10987	COV2-2130	S309	2-7	Brii-198	LY-CoV 1404	ADG-2	DH1047	10-40	S2X259	4-18	5-7
BA.1	<-428	-298	<-429	<-2201	-306	<-1496	<-2716	<-1716	-83.5	-6.9	-195	2.3	1.4	-11.0	-14.2	-21.1	-13.7	<-26.7	-4.1
BA.1 + R346K	<-428	-135	<-429	-415	-187	<-1496	<-2716	<-1716	<-687	-4.5	-82.1	<-22	1.5	-15.7	-7.9	-20.5	-7.5	<-26.7	-5.5
BA.2	<-428	-322	<-429	<-2201	-680	<-1496	<-2716	-253	-1.9	-27.0	-7.3	-10.5	1.1	<-555	<-58.0	<-114	<-96	<-26.7	<-171
T19I	-3.1	-4.9	-5.3	-3.7	-1.9	-2.2	-2.0	-2.1	-1.5	-1.8	-5.1	-1.6	-1.7	-1.7	-1.5	-2.7	-2.9	-6.1	-3.3
L24S	-2.9	-4.0	-4.6	-3.2	-2.4	-2.4	-2.8	-4.2	-2.1	-1.5	-2.6	-2.2	-1.6	-1.3	-1.1	-2.4	-2.0	-3.1	-1.1
Del25-27	-1.2	-2.6	-2.0	-1.3	-1.0	-1.4	-1.2	-1.3	1.0	-1.3	-2.8	2.0	-1.2	1.1	1.6	-1.8	1.1	-23.1	-16.8
V213G	-2.5	-3.1	-3.0	-3.1	-1.5	-1.1	-1.6	-2.2	-2.0	-1.2	-3.2	-1.1	-1.5	1.1	1.0	-2.0	-1.7	1.9	-2.8
S371F	-143	-126	-95.1	-27.9	-26.1	-5.1	-6.3	-86.6	-1.3	-20.5	-30.6	<-22	-2.4	-43.0	-60.9	<-114	-77.5	7.8	2.3
T376A	-1.9	-3.1	-2.5	-2.1	-1.3	-1.7	-1.3	-1.9	-1.8	1.0	-2.7	2.0	-1.7	1.1	1.1	-1.5	-2.3	1.3	-1.3
D405N	-25.6	-2.3	-2.9	-2.8	-2.1	-1.9	-1.7	-1.6	1.0	1.5	-3.1	-1.6	1.3	3.3	-1.2	-3.9	-2.2	5.6	1.5
R408S	1.4	-1.1	-1.3	-1.1	1.5	-1.6	-1.3	1.2	1.0	1.0	1.2	1.4	-1.4	-1.6	-2.1	-1.2	-3.6	1.1	-1.3

>3	<-3	<-10	<-100

Fig. 2 | BA.2 differs in resistance profile to monoclonal antibodies. a, Pseudovirus neutralization by monoclonal antibodies. Values above the LOD of 10 μg/mL are arbitrarily plotted to allow for visualization of each sample. **b,** Fold change in IC_{50} values relative to D614G of neutralization of Omicron variants, as well as point mutants unique to BA.2.

ED ARTICLE PRE E PREVIE

Iketani S et al *Nature* 28Feb22
https://doi.org/10.1038/s41586-022-04594-4

mAb *in vitro* Data

Table 1. Efficacy of Monoclonal Antibodies and Antiviral Drugs against the Omicron/BA.2 Subvariant in Vitro.*

Monoclonal Antibody or Antiviral Drug	hCoV-19/Japan/UT-NCD1288-2N/2022 (Omicron/BA.2)	
	Tested Value	Factor Increase as Compared with the Ancestral Strain
Neutralization activity of monoclonal antibody†		
LY-CoV016, etesevimab	>50,000 ng/ml	>2749
LY-CoV555, bamlanivimab	>50,000 ng/ml	>10,661
REGN10987, imdevimab	68.65±8.84 ng/ml	22.5
REGN10933, casirivimab	1666.19±771.77 ng/ml	597.2
COV2-2196, tixagevimab	395.78±62.37 ng/ml	206.1
COV2-2130, cilgavimab	4.44±2.72 ng/ml	0.6
S309, sotrovimab precursor	1359.05±269.23 ng/ml	49.7
LY-CoV016 plus LY-CoV555	>10,000 ng/ml	>794
REGN10987 plus REGN10933	222.59±64.47 ng/ml	63.1
COV2-2196 plus COV2-2130	14.48±2.04 ng/ml	4.2
Viral susceptibility to drug‡		
GS-441524§	2.85±0.31 μM	2.7
EIDD-1931¶	0.67±0.22 μM	1.3
PF-07321332‖	6.76±0.69 μM	1.9

Takashita E et al. NEJM 10Mar22

mAb *in vitro* Data

Table S2. Efficacy of Monoclonal Antibodies and Antiviral Drugs against SARS-CoV-2 Variants in Vitro.*

Monoclonal Antibody or Antiviral Drug	SARS-CoV-2 Variant							
	SARS-CoV-2/UT-NC002-1T/Human/2020/Tokyo (An ancestral strain/A)	SARS-CoV-2/UT-HP127-1Nf/Human/2021/Tokyo (Alpha/B.1.1.7)	hCoV-19/USA/MD-HP01542/2021 (Beta/B.1.351)	hCoV-19/Japan/TY7-503/2021 (Gamma/P.1)	hCoV-19/USA/WI-UW-5250/2021 (Delta/B.1.617.2)	hCoV-19/Japan/NC928-2N/2021 (Omicron/BA.1)	hCoV-19/Japan/NC929-1N/2021 (Omicron/BA.1.1)	hCoV-19/Japan/UT-NCD1288-2N/2022 (Omicron/BA.2)
Neutralization activity of monoclonal antibody — ng/ml†								
LY-CoV016, etesevimab	18.19 ± 9.10	150.38 ± 83.51	>50,000	>50,000	15.37 ± 9.78	>50,000	>50,000	>50,000
LY-CoV555, bamlanivimab	4.69 ± 1.43	2.65 ± 1.30	9554.88 ± 926.53	1601.65 ± 896.02	641.73 ± 324.79	>50,000	>50,000	>50,000
REGN10987, imdevimab	3.05 ± 0.93	1.87 ± 1.60	2.17 ± 1.30	1.04 ± 0.68	3.95 ± 1.78	>50,000	>50,000	68.65 ± 8.84
REGN10933, casirivimab	2.79 ± 1.87	2.74 ± 1.84	757.13 ± 287.91	187.69 ± 128.88	2.89 ± 1.78	14110.70 ± 1782.13	11998.94 ± 2604.70	1666.19 ± 771.77
COV2-2196, tixagevimab	1.92 ± 0.28	1.34 ± 0.67	18.98 ± 1.42	6.56 ± 1.56	4.05 ± 2.60	1299.94 ± 406.58	880.47 ± 68.08	395.78 ± 62.37
COV2-2130, cilgavimab	7.70 ± 2.20	3.60 ± 1.62	10.03 ± 3.05	4.00 ± 2.70	12.76 ± 2.93	443.87 ± 167.96	13558.20 ± 4646.95	4.44 ± 2.72
S309, sotrovimab precursor	27.33 ± 3.24	44.91 ± 22.76	100.98 ± 22.27	28.38 ± 1.86	111.43 ± 58.22	373.47 ± 159.49	384.52 ± 65.98	1359.05 ± 269.23
LY-CoV016 plus LY-CoV555	12.60 ± 1.91	15.26 ± 3.98	>10,000	2545.04 ± 625.72	10.28 ± 3.33	>10,000	>10,000	>10,000
REGN10987 plus REGN10933	3.53 ± 0.66	1.55 ± 0.78	5.18 ± 1.45	2.11 ± 0.48	1.91 ± 0.79	>10,000	>10,000	222.59 ± 64.47
COV2-2196 plus COV2-2130	3.42 ± 0.92	1.94 ± 0.34	10.30 ± 1.17	1.79 ± 0.87	5.50 ± 2.75	255.86 ± 45.31	1374.90 ± 14.47	14.48 ± 2.04
Viral susceptibility to drug — μM‡								
GS-441524§	1.04 ± 0.32	0.83 ± 0.19	0.63 ± 0.20	0.91 ± 0.33	1.12 ± 0.20	1.28 ± 0.42	1.63 ± 0.30	2.85 ± 0.31
EIDD-1931¶	0.51 ± 0.14	0.95 ± 0.17	0.60 ± 0.21	0.41 ± 0.13	0.83 ± 0.41	0.43 ± 0.08	1.09 ± 0.13	0.67 ± 0.22
PF-07321332‖	3.59 ± 0.96	4.23 ± 1.04	2.03 ± 0.96	4.57 ± 1.14	3.90 ± 0.50	4.26 ± 0.36	3.63 ± 0.42	6.76 ± 0.69

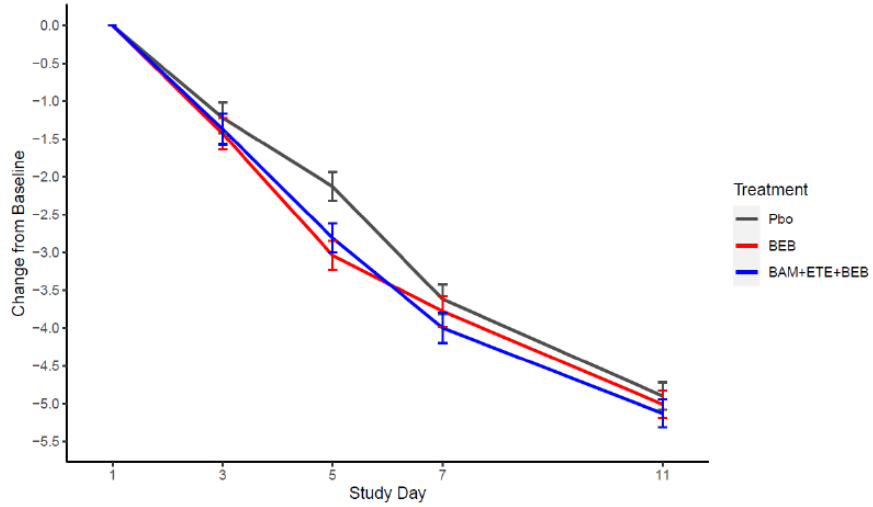
Takashita E et al. NEJM 10Mar22

Other Factors

- PK/PD of the mAb at the dose used
  - Sotrovimab (500mg IV) serum concentrations
    - geometric mean C_{max} (at the end of a 1 hr IV infusion) - 137 µg/mL (N= 129, CV% 40)
    - geometric mean Day 29 serum concentration - 34 µg/mL (N= 78, CV% 23) (ca.gsk.com)
  - Tixagevimab (300mg IM)
    - Cmax= 21.9 ug/mL, geometric mean day2= 9.5 ug/mL, day84= 15 ug/mL
  - Cilgavimab (300mg IM)
    - Cmax= 20.3 ug/mL, geometric mean day2= 9.1 ug/mL, day84= 14 ug/mL (product insert fda.gov)
  - Bebtelovimab (175mg IV)
    - Cmax= 59.8 ug/mL, geometric mean day29= 4.35 ug/mL (FDA Lilly summary review 07Jan22)

- Clinical data
  - Safety
    - For the class/platform
    - For the product
    - For the product with the VOC of interest
  - Efficacy

Figure 1: SARS-CoV-2 Normalized Viral Load Change from Baseline (Mean ± SE) by Visit of Low-Risk Adults in Trial PYAH (Arms 9-11)



Source: EUA submission on 2/4/2022

Integrate Several Lines of Evidence

- VOC
- *in vitro* activity of mAb
- PK/PD of mAb
- Clinical safety data
- Clinical efficacy data
  - In general vs against the specific VOC
  - Tempo of availability

Bebtelovimab

U.S. FOOD & DRUG ADMINISTRATION

February 11, 2022

Eli Lilly and Company
Attention: Christine Phillips, PhD, RAC
Advisor Global Regulatory Affairs - US
Lilly Corporate Center
Drop Code 2543
Indianapolis, IN 46285

RE: Emergency Use Authorization 111

- Based on the review of the data from the BLAZE-4 clinical trial (NCT04634409), a Phase 1/2 randomized, single-dose clinical trial studying bebtelovimab for the treatment of non- hospitalized patients with mild-to-moderate COVID-19, as well as available pharmacokinetic data and nonclinical viral neutralization data for Omicron and other variants of concern, it is reasonable to believe that bebtelovimab may be effective for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who are at high-risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate…

- Bebtelovimab is **not** authorized for treatment of mild-to-moderate COVID-19 in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant, based on available information including variant susceptibility to these drugs and regional variant frequency.

mAbs for Pre-Exposure Prophylaxis: Tixagevimab/cilgavimab

- **In moderately or severely immunocompromised individuals at increased risk for inadequate immune response to COVID-19 vaccine or for whom COVID-19 vaccine is not recommended due to a documented serious adverse reaction to the vaccine, the IDSA guideline panel suggests pre-exposure prophylaxis with tixagevimab/cilgavimab rather than no tixagevimab/cilgavimab.**
  - **(Conditional recommendation, Low certainty of evidence)**

Remarks:

- Dosing for tixagevimab/cilgavimab is 300 mg of tixagevimab & 300 mg of cilgavimab administered as two separate consecutive intramuscular injections once.
- Local SARS-CoV-2 variant susceptibility should be considered.

mAbs for Early Treatment: Sotrovimab…

- **Among ambulatory patients with mild to moderate COVID-19 at high risk for progression to severe disease, the IDSA guideline panel suggests ~~bamlanivimab/etesevimab~~, ~~casirivimab/imdevimab~~, or sotrovimab rather than no neutralizing antibody treatment.**
  - **(Conditional recommendation, Moderate certainty of evidence)**

Remarks:

- Dosing for sotrovimab is 500 IV once.
- Patients with mild to moderate COVID-19 who are at high risk of progression to severe disease admitted to the hospital for reasons other than COVID-19 may also receive ~~bamlanivimab/etesevimab~~, ~~casirivimab/imdevimab~~, or sotrovimab.
- Local variant susceptibility should be considered in the choice of the most appropriate neutralizing antibody therapy. Local availability of different monoclonal antibody combinations may be affected by predominance of local variants.
- There are limited data on efficacy of ~~bamlanivimab/etesevimab~~, ~~casirivimab/imdevimab~~, or sotrovimab in high-risk patients under 18 years of age.

mAbs for Early Treatment: Bebtelovimab

- Recommendation 2 (NEW: 11Mar22):
  - In ambulatory patients with mild-to-moderate COVID-19 at high risk for progression to severe disease, the IDSA guideline panel recommends bebtelovimab only in the context of a clinical trial. (Knowledge gap)

Outpatient COVID-19 Convalescent Plasma Treatment in Immunocompromised Patients

Shmuel Shoham, MD

Outpatient COVID-19 Convalescent Plasma Treatment in Immunocompromised Patients

Shmuel Shoham, MD
Professor of Medicine
Johns Hopkins University School of Medicine

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MEDICINE

Disclosures

- Funding related to CCP
  - U.S. Department of Defense (JPEO-CBRND and DHA), Bloomberg Philanthropies, State of Maryland, NIH (NIAD and NCATS), Mental Wellness Foundation, Moriah Fund, Octapharma, HealthNetwork Foundation and the Shear Family Foundation
- Other funding
  - Ansun, F2G, Zeteo
- Personal fees: Celltrion, Immunome, Adagio
- DSMB: Karyopharm, Intermountain Health, Adamis

CASE

34 year old man with history of hypertension, diabetes mellitus, end stage kidney disease for which he underwent kidney transplant in 2017

His course has been complicated by post transplant lymphoproliferative disorder for which he is receiving a rituximab based regimen.

He now presents with fevers, sore throat and cough x 2 days. SARS-CoV-2 RT-PCR testing is positive.

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Two initial questions

- Does he warrant treatment for COVID-19?
- Where does CCP fit into the therapeutic lineup

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Outcomes in SOT recipients requiring hospitalization for COVID-19

- 428 SOT recipients from >50 centers
  - 66% kidney, 15.1% liver, 11.8% heart, 6.2% lung.
  - Median age 58
  - median time post-transplant 5 years
  - Among hospitalized:
    - **78% required mechanical ventilation**
    - **20.5% died by 28 days after diagnosis**

Kates Clin Infect Dis. 2021

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Outcomes in immune compromised

- Rheumatological disease (1)
  - Risk for hospitalization RR 1.14; 95% CI 1.03–1.26
  - ICU admission RR 1.32; 95% CI 1.03–1.68
  - Acute renal failure RR 1.81; 95% CI 1.07–3.07
  - venous thromboembolism RR 1.74; 95% CI 1.23–2.45

- Immunosuppressive medications (2)
  - Inpatient death: No increase risk
  - Rituximab: Increased mortality
    - Rheumatological disease HR 1.72; 95% CI 1.10–2.69
    - cancer HR 2.57; 95% CI 1.86–3.56

1. D'Silva Arthritis Rheumatol 2021
2. Anderson Lancet Rheumatol 2022

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Risks for poor COVID-19 outcomes in people with cancer

	COVID-19 severity	30-day mortality
	OR[a] (95% CI)	OR[b] (95% CI)
Age, per decade[c]		
Age <40 years	0.91 (0.72-1.15)	0.58 (0.35-0.97)
Age >40 years	1.38 (1.31-1.45)	1.75 (1.59-1.93)
Sex, male versus female	1.47 (1.31-1.65)	1.46 (1.20-1.77)
Race and ethnicity, versus non-Hispanic white		
Non-Hispanic black	1.46 (1.27-1.68)	1.38 (1.09-1.75)
Hispanic	1.38 (1.16-1.64)	1.31 (0.96-1.80)
Other	1.27 (1.05-1.53)	0.97 (0.70-1.36)
Type of malignancy, versus solid tumor		
Hematological neoplasm	1.70 (1.46-1.99)	1.44 (1.10-1.87)
Multiple[d]	1.21 (1.01-1.44)	1.30 (1.00-1.70)
Cancer status, versus remission or no evidence of disease		
Active and responding	0.84 (0.67-1.04)	0.79 (0.52-1.18)
Active and stable	0.97 (0.81-1.16)	1.06 (0.77-1.44)
Active and progressing	2.19 (1.80-2.67)	2.88 (2.13-3.90)
Unknown	1.93 (1.55-2.41)	2.19 (1.56-3.07)
Modality of active anticancer therapy[e]		
Cytotoxic chemotherapy, yes versus no	1.28 (1.04-1.58)	1.61 (1.15-2.24)
Immunotherapy, yes versus no	0.86 (0.64-1.16)	0.91 (0.56-1.47)
Targeted therapy, yes versus no	1.09 (0.87-1.36)	0.90 (0.63-1.31)
Endocrine therapy, yes versus no	0.79 (0.61-1.03)	0.68 (0.43-1.09)
Locoregional therapy, yes versus no	1.18 (0.93-1.50)	0.96 (0.65-1.42)
Other, yes versus no	0.97 (0.47-2.00)	1.31 (0.44-3.94)

Grivas et al, Annals of Oncology 2021

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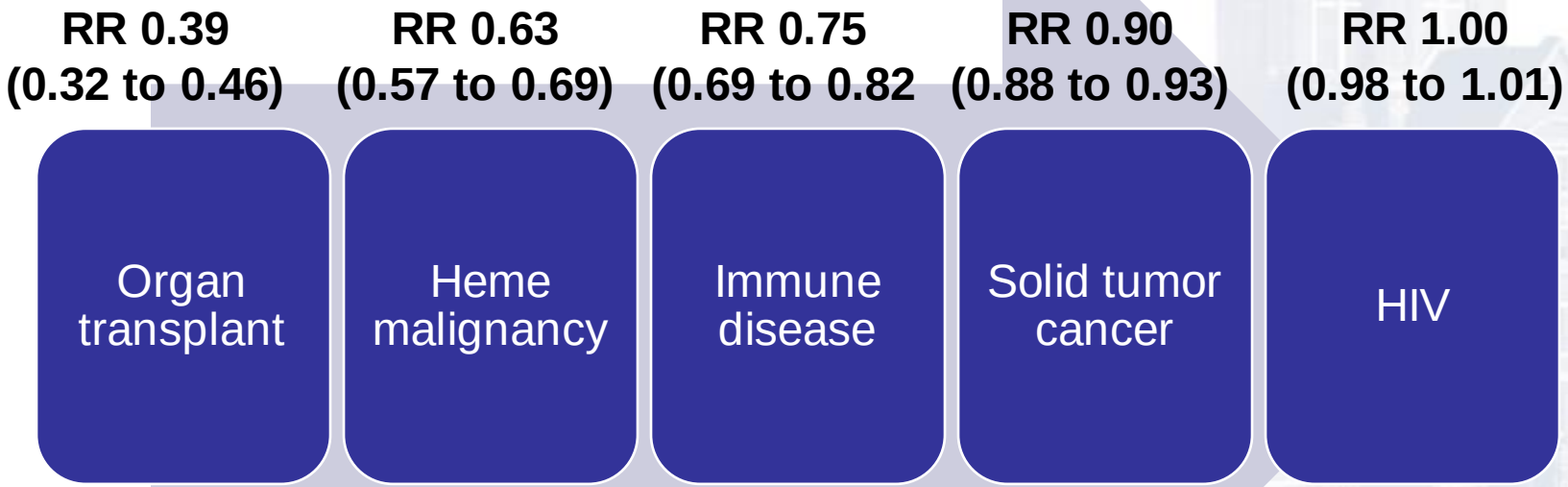
Seroconversion in immune compromised patients (after 2 doses of vaccine)



Lee et al BMJ. 2022

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Outpatient options authorized for treatment of COVID-19

Medication	Route	Comments
mAb	IV/IM/SQ	Potential for resistant variants
Nirmatrelvir and ritonavir	PO	Drug interactions with ritonavir
Molnupiravir	PO	Efficacy questions and fetal harm
Remdesivir	IV	Need for 3 days of IV
Convalescent plasma	IV	Blood product

FDA: December 28, 2021

FACT SHEET FOR HEALTH CARE PROVIDERS

EMERGENCY USE AUTHORIZATION (EUA) OF COVID-19 CONVALESCENT PLASMA FOR TREATMENT OF CORONAVIRUS DISEASE 2019 (COVID-19)

AUTHORIZED USE

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies, for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment, in either the outpatient or inpatient setting.

Clinical dosing may first consider starting with one unit of COVID-19 convalescent plasma (about 200 mL), with administration of additional convalescent plasma units based on the prescribing physician's medical judgment and the patient's clinical response.

IDSA Guideline on the Treatment and Management of COVID-19

Recommendation 2 (UPDATED): Among ambulatory patients with mild to moderate COVID-19 at high risk for progression to severe disease who have no other treatment options*, the IDSA guideline panel suggests FDA-qualified high-titer COVID-19 convalescent plasma within 8 days of symptom onset rather than no high-titer COVID-19 convalescent plasma. (Conditional recommendation, Low certainty of evidence)

Remarks:

- In the US, FDA EUA only authorizes use in patients with immunosuppressive disease or receiving immunosuppressive treatment.
- Patients, particularly those who are not immunocompromised, who place a low value on the uncertain benefits (reduction in the need for mechanical ventilation, hospitalization, and death) and a high value on avoiding possible adverse events associated with convalescent plasma would reasonably decline convalescent plasma.

https://www.idsociety.org/globalassets/idsa/practice-guidelines/covid-19/treatment/idsa-covid-19-gl-tx-and-mgmt---convalescent-plasma-2022-02-03.pdf

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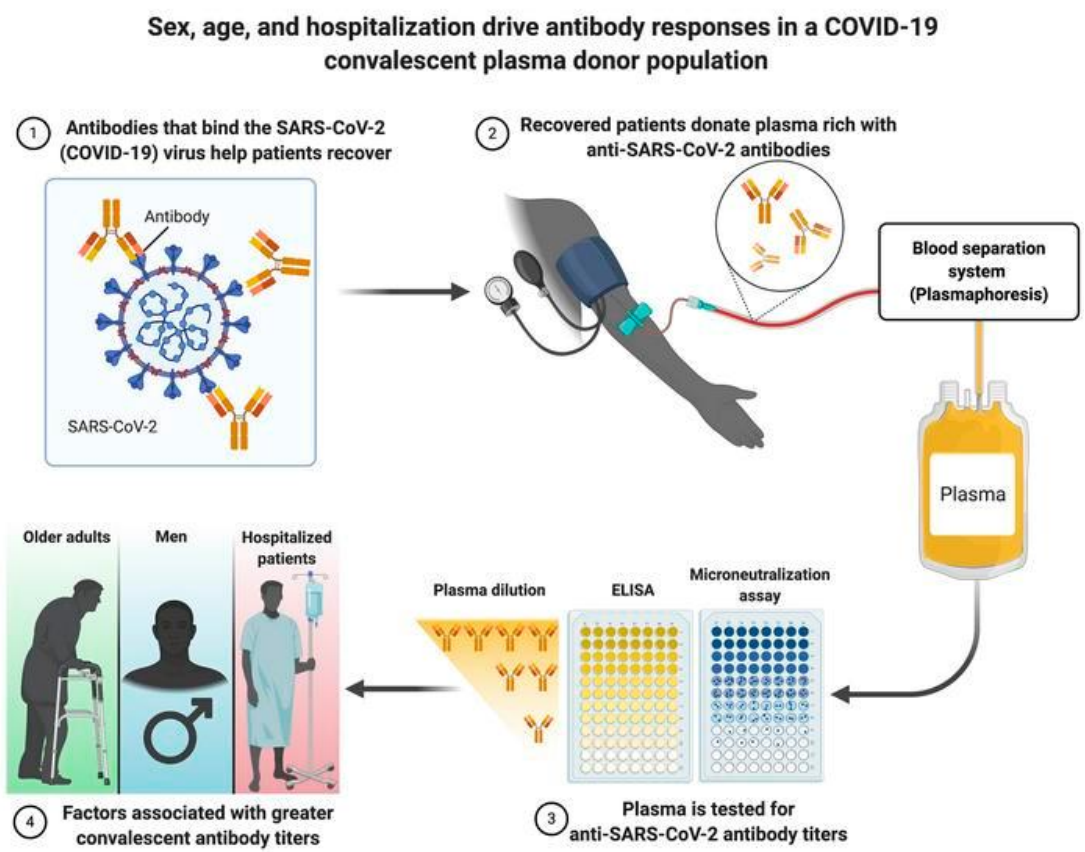
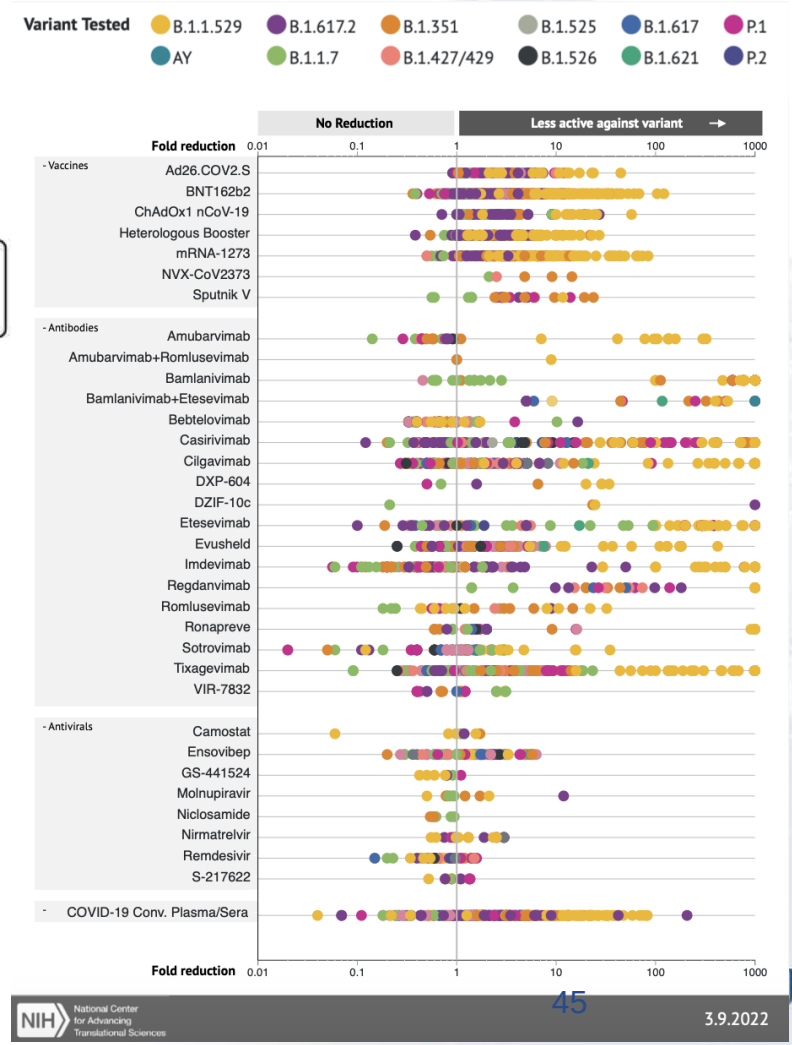
Convalescent plasma contains antibodies that neutralize SARS-CoV-2





Klein et al. JCI 2020

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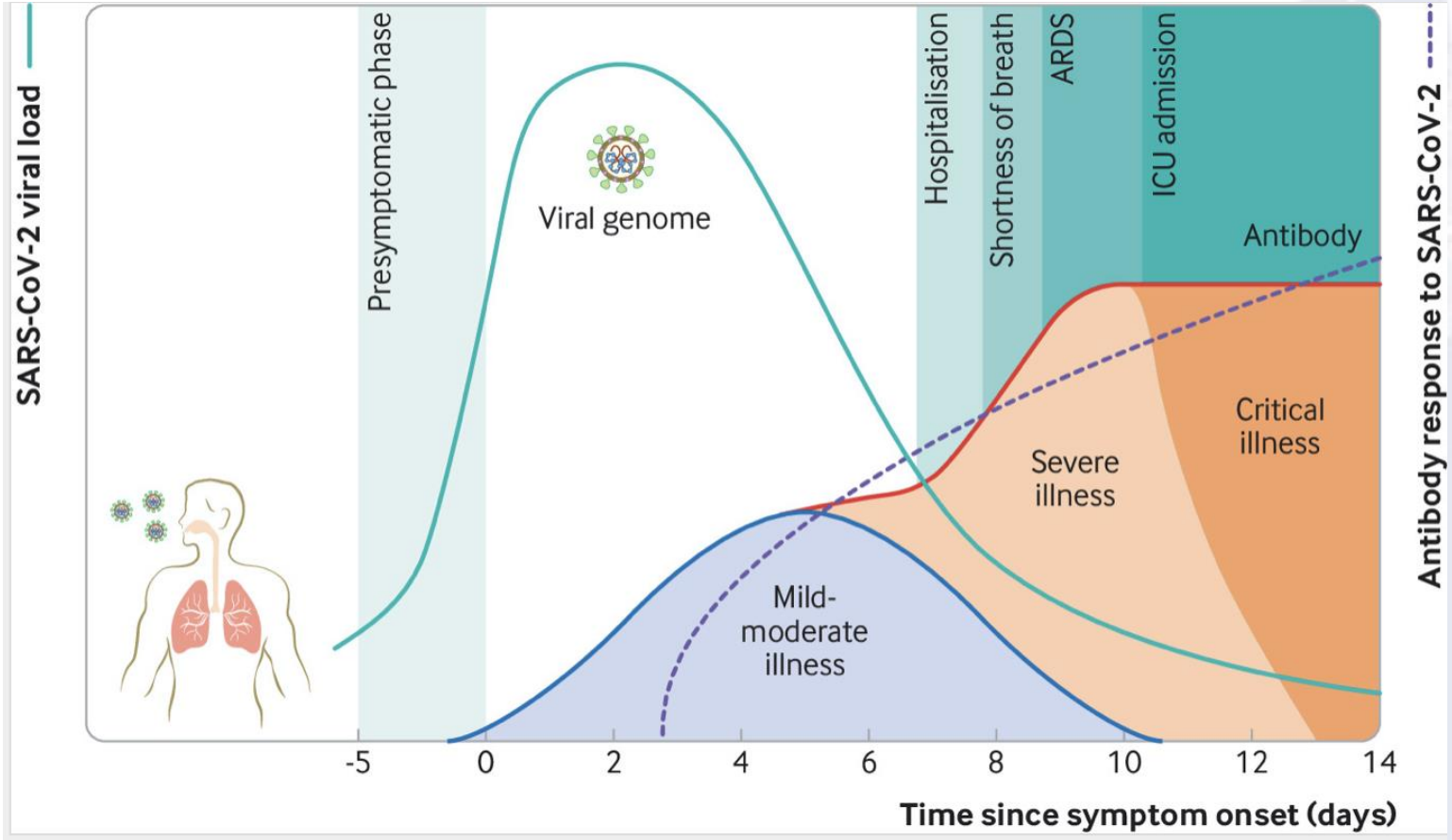
Timing, timing, timing



Cevik M et al *BMJ* 2020

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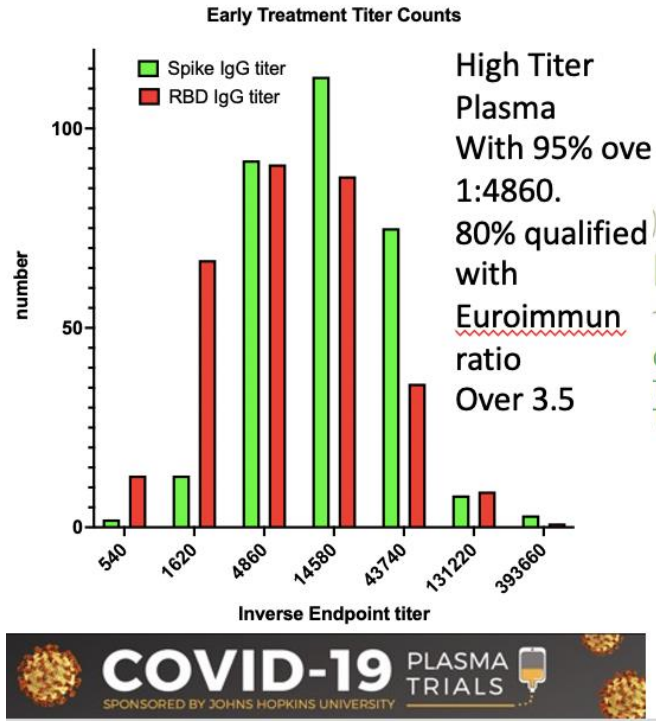
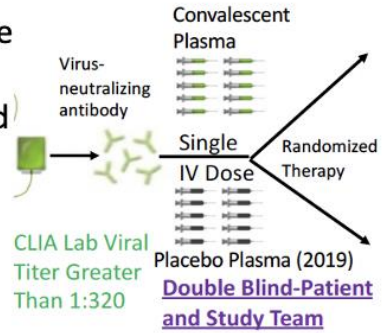
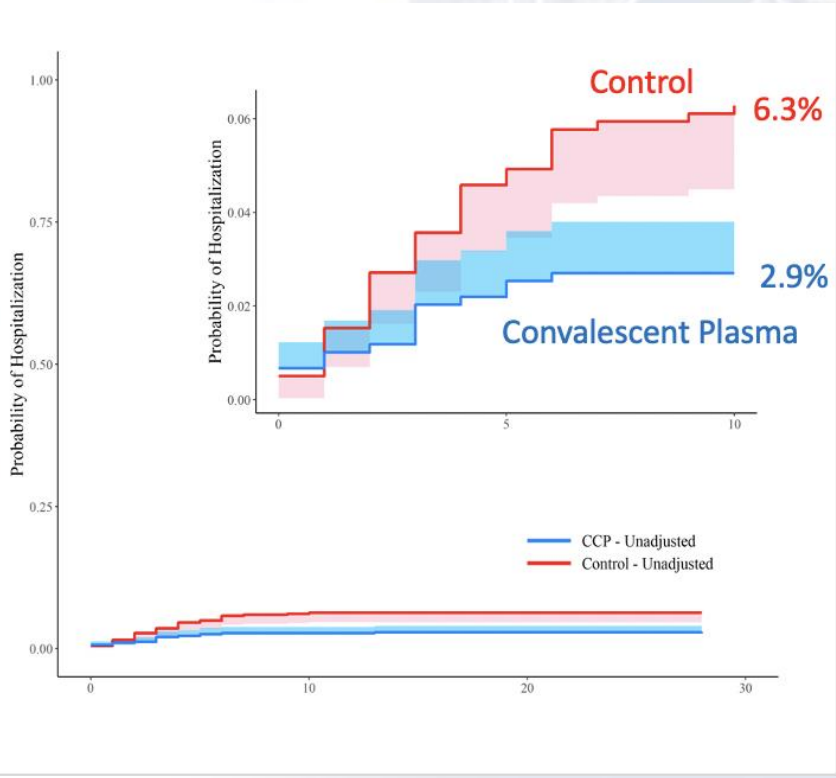
Early Outpatient Treatment with Convalescent Plasma Reduces Hospitalizations by 50%
Double Blind Randomized Control Trial at 24 USA sites with 1181 Participants Transfused
Sullivan et al MedRxiv 2022

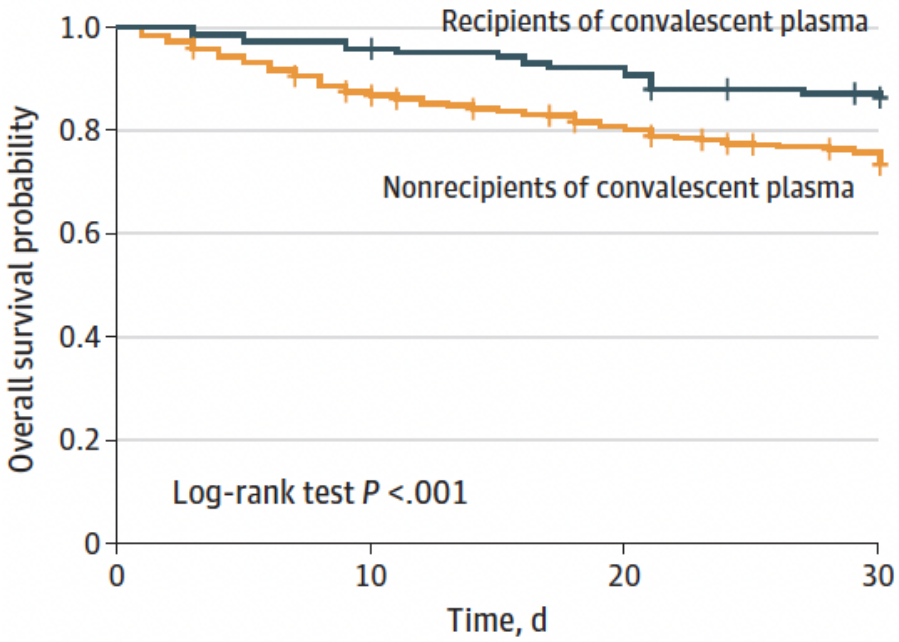
Of 1181 transfused, 37 of 589 (6.3%) control and 17 of 592 (2.9%) COVID-19 Convalescent Plasma were hospitalized for COVID-19 (relative risk, 0.46; CI= 0.733; P=0.004) corresponding to a 54% risk reduction and absolute risk difference of 3.4%.







Convalescent Plasma in Patients With Hematologic Cancers and COVID-19



Variable	HR (95% CI) for death within 30 days
Overall population	
No. of events/No. of patients at risk (%)	223/966 (23.1)
Convalescent plasma	19/143 (13.3)
No convalescent plasma	204/823 (24.8)
Crude analysis[a]	0.47 (0.30-0.76)
Multivariable analysis[b]	0.60 (0.37-0.97)
Propensity score matching[c]	0.52 (0.29-0.92)

Thompson, MA et al JAMA Oncol. 2021

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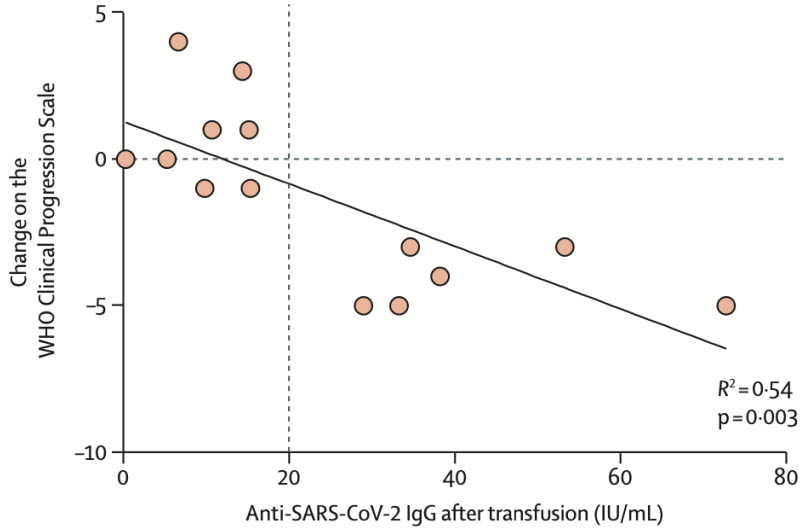
Use of convalescent plasma in COVID-19 patients with immunosuppression

Condition	No. patients	COVID-19 disease severity scale[a]	Illness onset to treatment (days)[a]	Mortality (*n*, %)[a]	Rapid improvement in supplemental oxygen (≤5 days) (*n*, %)[a]
Primary immunosuppression					
Agammaglobulinemia	15	3 (2–5)	27 (12–69)	1, 7%	3 of 6, 50%
Common variable immune deficiency	7	3 (2–5)	20 (11–28)	1, 14%	2 of 2, 100%
Secondary immunosuppression					
Hematological malignancies	150	3 (2–5)	26 (2–103)	30, 20%	37 of 55, 67%
Solid organ transplants	66	3 (2–5)	9 (2–31)	9, 14%	25 of 37, 68%



Senefeld Transfusion 2021
Rodionov Lancet Microbe 2021

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Patients recently treated for B-lymphoid malignancies show increased risk of severe COVID-19

Characteristics	Multivariable AOR (95% CI)
Study populations (ref = Patients with nonrecently treated B-lymphoid malignancies)	
Nonrecently treated control population	1.16 (0.90-1.49)
Recently treated control population	**0.75 (0.61-0.93)**
Patients recently treated for B-lymphoid malignancies	**2.30 (1.58-3.36)**

Supplement Table 9: Results of sensitivity analysis: multivariable proportional odds logistic regression with primary outcome of COVID-19 severity adjusting for convalescent plasma receipt in hospitalized patients only (N = 4840)

Characteristics	Multivariable AOR (95% CI)
Study populations (ref = Patients with nonrecently treated B-lymphoid malignancies)	
Nonrecently treated control population	0.82 (0.61-1.10)
Recently treated control population	0.92 (0.63-1.34)
Patients recently treated for B-lymphoid malignancies	1.34 (0.85-2.11)

Rubinstein Blood Cancer Discov. 2022

What is high titer?

Tests Acceptable for Use in the Manufacture of COVID-19 Convalescent Plasma with High Titers of Anti-SARS-CoV2 Antibodies			
Manufacturer (listed alphabetically)	**Assay**	**Previous Qualifying Result**	**Revised Qualifying Result**
Abbott	AdviseDx SARSCoV-2 IgG II (ARCHITECT and Alinity i)	≥ 840 AU/mL	≥ 1280 AU/mL
Diasorin	LIAISON SARS-CoV-2 TrimericS IgG	≥ 52 AU/mL	≥ 87 AU/mL
GenScript	cPass SARS-CoV-2 Neutralization Antibody Detection Kit	Inhibition ≥ 68%	Inhibition ≥ 80%
Kantaro	COVID-SeroKlir, Kantaro Semi-Quantitative SARS-CoV-2 IgG Antibody Kit	Spike ELISA > 47 AU/mL	Spike ELISA > 69 AU/mL
Ortho	VITROS Anti-SARS-CoV-2 IgG Quantitative Reagent Pack	N/A	>200 BAU/mL
Roche	Elecsys Anti-SARS-CoV-2 S	≥ 132 U/mL	>210 U/mL

https://www.fda.gov/media/155159/download

What are some scenarios for use?

- Immune compromised patient with early COVID-19 in whom other drugs are not an option
  - Not available
  - Resistance
  - Drug interactions
- Immune compromised patient with COVID-19 that fails to resolve despite other therapies

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Contact information

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- Twitter: @ShohamTxID

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Baricitinib – An Update

Jason C. Gallagher, PharmD, FCCP, FIDP, FIDSA, BCPS

Baricitinib – An Update

Jason C. Gallagher, PharmD, FCCP, FIDP, FIDSA, BCPS
Clinical Professor
Temple University

Disclosures

Dr. Gallagher has the following relevant financial relationships with commercial interests to disclose:

- Grant/Research Support: Merck
- Consultant: Astellas, Merck, Qpex, scPharmaceuticals, Shionogi, Spero
- Speakers Bureau: Astellas, Merck (both former)

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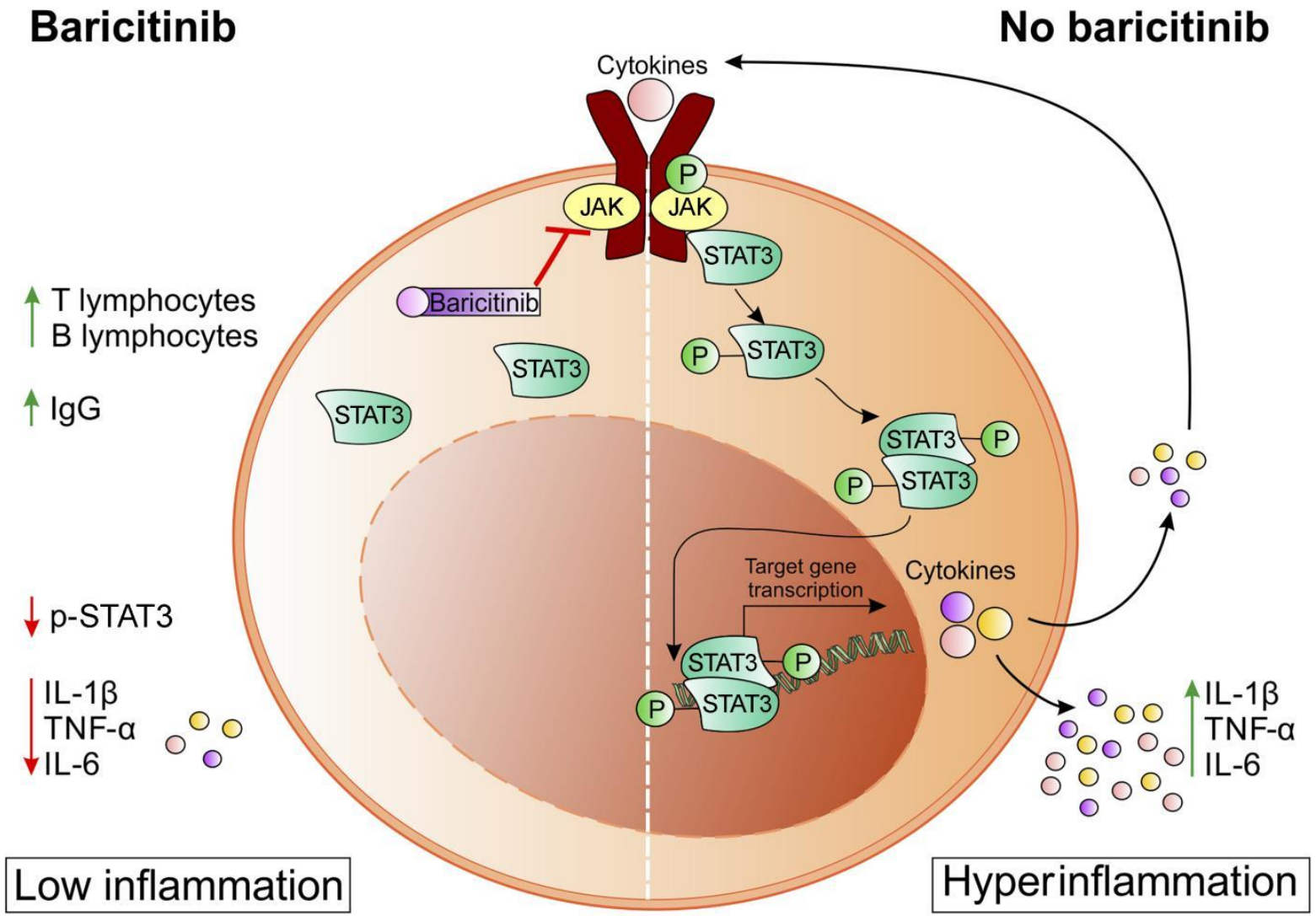
Baricitinib – It Can Do JAK (inhibition)



J Clin Invest. 2020;130(12):6409-6416. https://doi.org/10.1172/JCI141772

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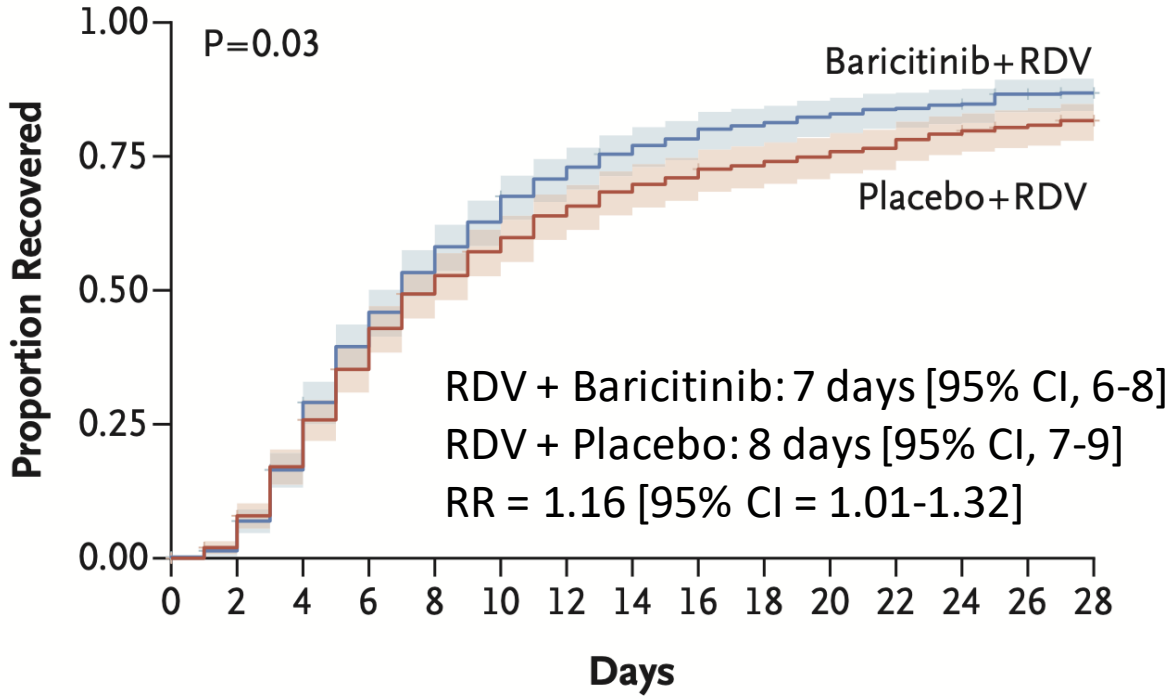
ACTT-2- Baricitinib + Remdesivir vs. Baricitinib

A Overall

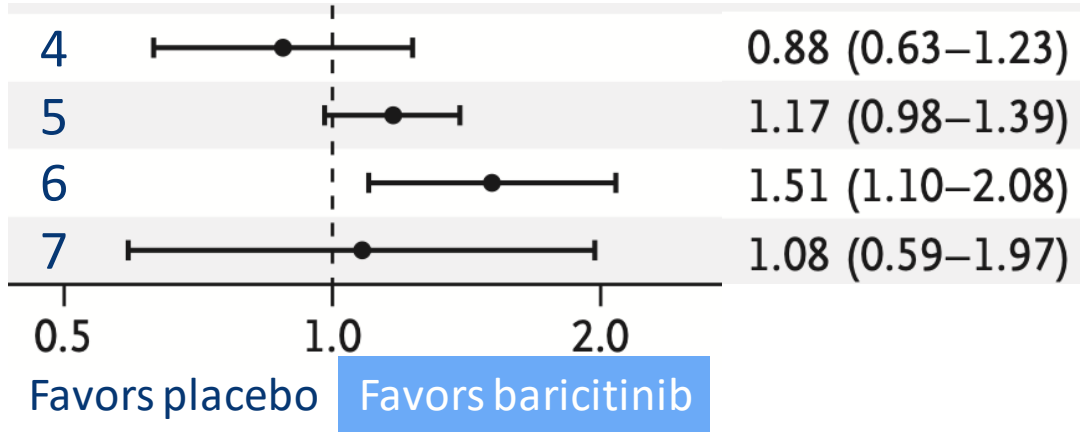


No. at Risk

Baricitinib+RDV	515	497	418	302	233	186	145	121	107	95	87	80	76	63	30
Placebo+RDV	518	495	417	322	251	211	178	156	143	131	123	115	102	92	44

Ordinal scale severity

RR for recovery (95% CI)



4	Hospitalized requiring care, no O_2
5	Hospitalized, requiring O_2
6	Non-invasive ventilation or high-flow O_2
7	Mechanical ventilation or ECMO

Kalil AC et al. *New Engl J Med* 2020. DOI: 10/1056/NEJMoa2031994

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ACTT-2- Outcomes

28-day mortality

- Baricitinib: 24 (5.1%)
- Placebo: 37 (7.8%)
- HR = 0.65 (95% CI 0.39-1.09)

Progression to death or MV

- Baricitinib: 63 (12.2%)
- Placebo: 89 (17.2%)
- RR = 0.69 (95% CI 0.50-0.95)

Median number of days on MV or ECMO (new after enrollment)

- Baricitinib: 16 days
- Placebo: 27 days
- Difference: -11 (95% CI -18.3 to -3.7)

Grade 3/4 adverse events

- Baricitinib: 207 (40.7%)
- Placebo: 238 (46.8%)

Key point – No glucocorticoid use

Kalil AC et al. *New Engl J Med* 2020. DOI: 10/1056/NEJMoa2031994

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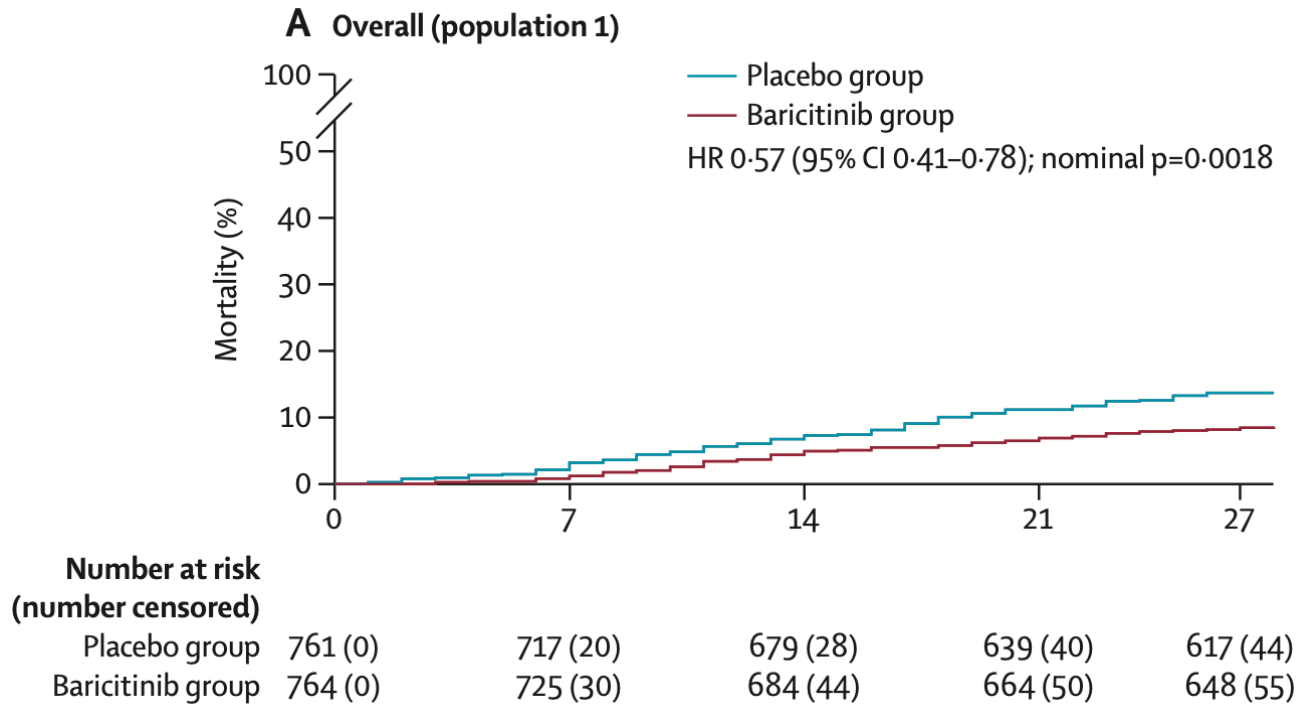
COV-BARRIER- Baricitinib + SOC vs SOC

- RCT of baricitinib added to standard of care
  - Most patients received glucocorticoids, relatively few received remdesivir (<20%)
- Patients were OS 4-6; no OS 7
- Primary outcome: progression or death at 28d
- Secondary outcome: 28d mortality, recovery time
- Primary outcome:
  - Baricitinib: 27.8%
  - Placebo: 30.5%

    OR 0.85 (0.67-1.08); p=0.18)

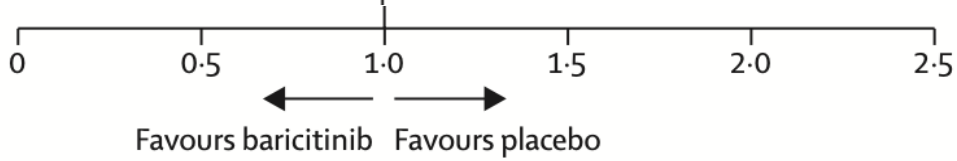
Mortality at 28 days



Marconi V et al. *Lancet Respir Med* 2021;9:1407–18

COV-BARRIER- Subgroups

	Baricitinib group	Placebo group	Hazard ratio (95% CI)	p value
NIAID-OS score at baseline				
4	1/89 (1%)	4/97 (4%)	0·24 (0·00–2·18)	0·23
5	29/490 (6%)	41/472 (9%)	0·72 (0·45–1·16)	0·11
6	32/183 (17%)	55/187 (29%)	0·52 (0·33–0·80)	0·0065
Systemic corticosteroid use at baseline				
Yes	57/612 (9%)	82/592 (14%)	0·63 (0·45–0·89)	0·017
No	5/150 (3%)	18/164 (11%)	0·28 (0·10–0·77)	0·011
Remdesivir use at baseline				
Yes	12/140 (9%)	16/147 (11%)	0·81 (0·38–1·73)	0·60
No	50/622 (8%)	84/609 (14%)	0·52 (0·36–0·74)	0·0014



Marconi V et al. *Lancet Respir Med* 2021;9:1407–18

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COV-BARRIER- Sub-study in Patients on MV or ECMO

RCT of 101 patients with OS 7

ECMO – 3 pts

baricitinib, 1

placebo

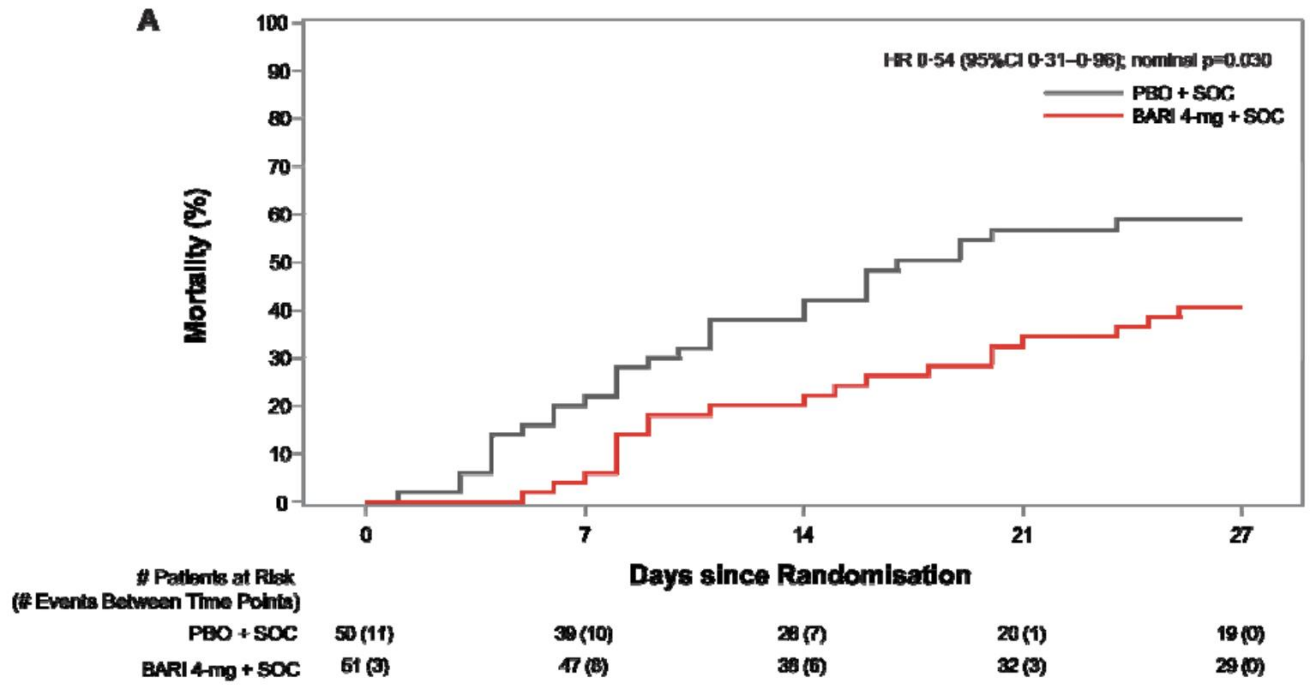
Mortality:

Baricitinib: 20/51 (39.2%)

Placebo: 29/50 (58%)

p=0.030

>80% of patients received glucocorticoids



Wesley Ely E et al. medRxiv preprint doi: https://doi.org/10.1101/2021.10.11.21263897

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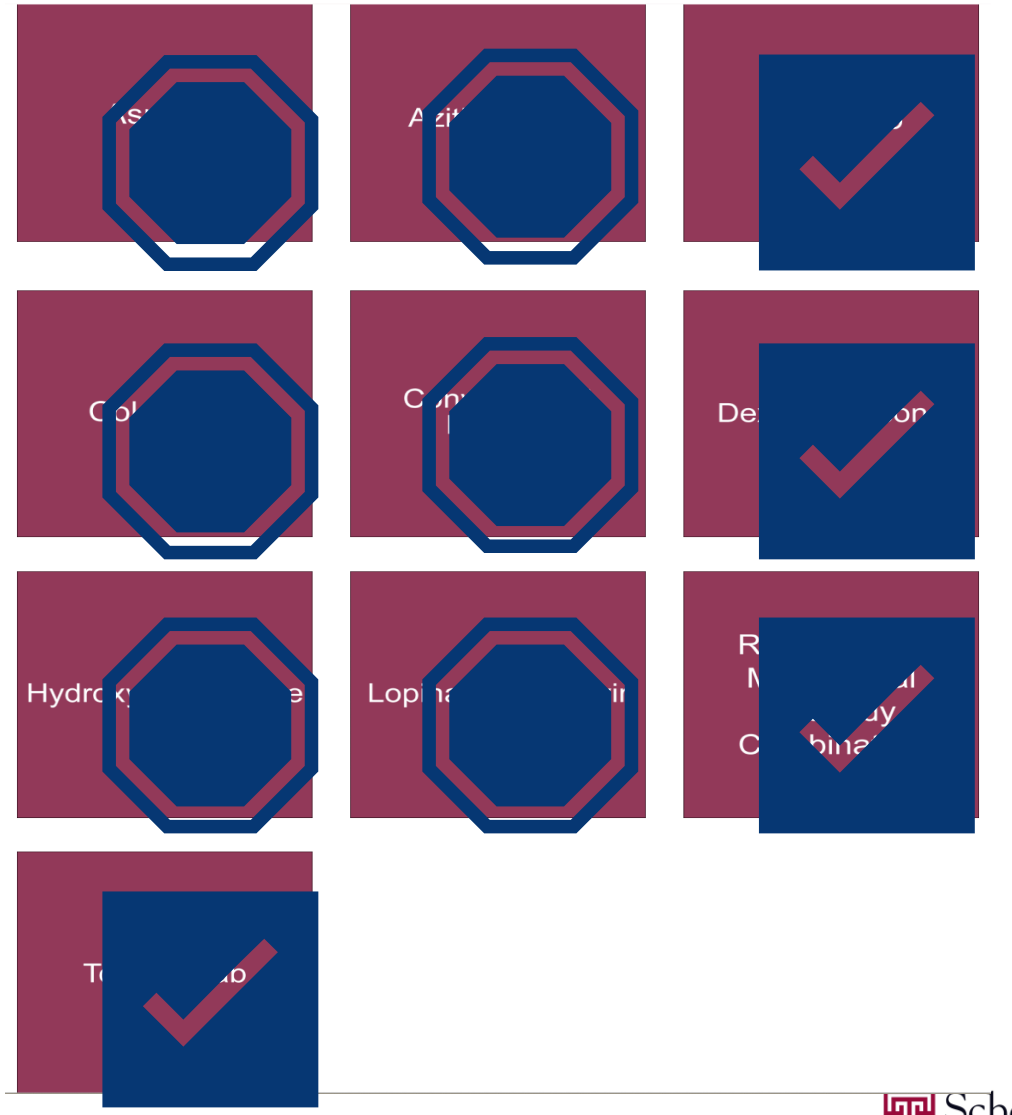
RECOVERY

- Platform, adaptive, open-label, randomized trial of multiple drugs vs. usual care
  - During baricitinib trial, other drugs were ASA, colchicine, dimethyl fumarate, casirivimab-imdevimab, empagliflozin
- Primary outcome: 28-day mortality



RECOVERY
Randomised Evaluation of COVID-19 Therapy

https://www.recoverytrial.net/results

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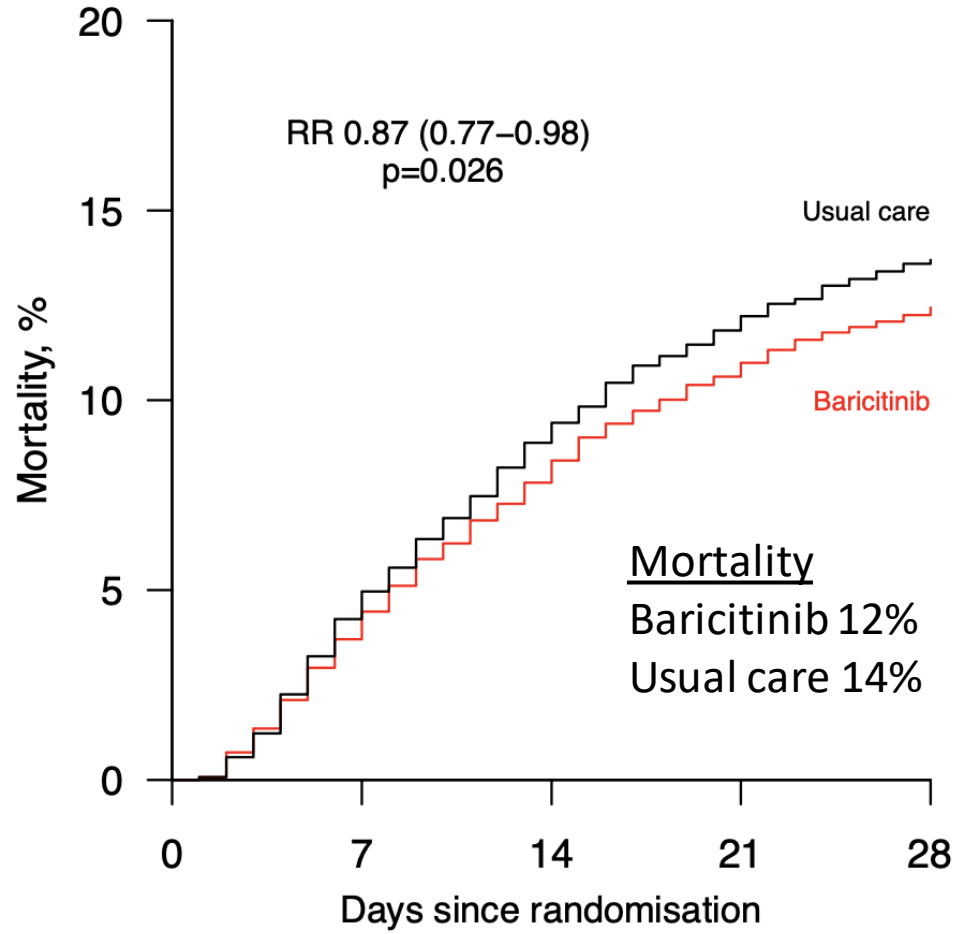
RECOVERY- Results

- 8156 patients enrolled
- Characteristics (Baricitinib; Usual care)
  - Respiratory support
    - None: 228 (5%); 237 (6%)
    - O2: 2770 (67%); 2743 (68%)
    - NIMV: 1016 (24%); 911 (23%)
    - IMV: 134 (3%); 117 (3%)
  - Vaccinated: 1755 (42%); 1665 (42%)
  - Glucocorticoids: 3962 (96%); 3809 (95%)
  - Remdesivir: 878 (21%); 789 (20%)
  - Tocilizumab: 951 (23%); 921 (23%)



Number at risk					
Baricitinib	4148	3940	3775	3668	3605
Usual care	4008	3787	3610	3497	3438

RECOVERY group. medRxiv preprint doi: https://doi.org/10.1101/2022.03.02.22271623; t

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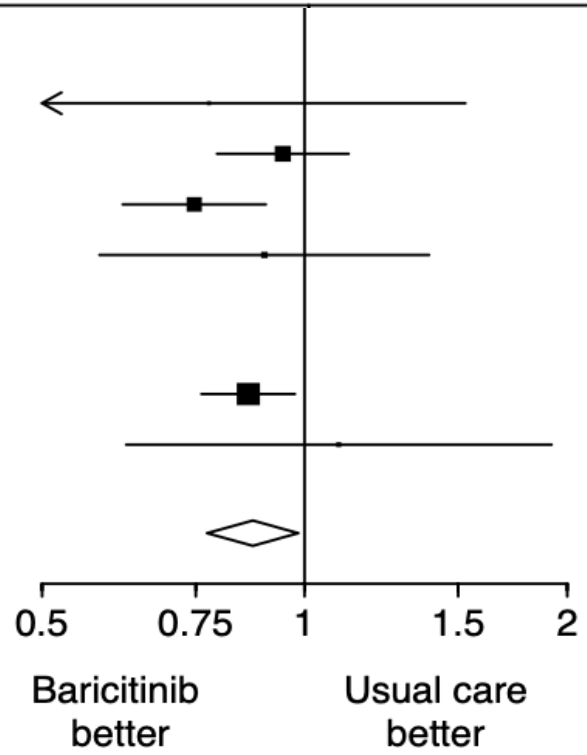
RECOVERY- Results

Figure 3: Effect of allocation to baricitinib on 28–day mortality by pre–specified baseline characteristics

	Baricitinib	Usual care	RR (95% CI)
Respiratory support at randomisation (χ^2_1= 0.9; p=0.33)			
None	15/228 (7%)	19/237 (8%)	0.78 (0.39–1.53)
Simple oxygen	256/2770 (9%)	253/2743 (9%)	0.94 (0.79–1.12)
Non invasive ventilation	204/1016 (20%)	230/911 (25%)	0.75 (0.62–0.90)
Invasive mechanical ventilation	38/134 (28%)	44/117 (38%)	0.90 (0.58–1.39)
Use of corticosteroids (χ^2_1= 0.7; p=0.41)			
Yes	487/3962 (12%)	523/3809 (14%)	0.86 (0.76–0.97)
No	25/183 (14%)	22/197 (11%)	1.09 (0.62–1.92)
All participants	**513/4148 (12%)**	**546/4008 (14%)**	**0.87 (0.77–0.98) p=0.026**



RECOVERY group. medRxiv preprint doi: https://doi.org/10.1101/2022.03.02.22271623; t

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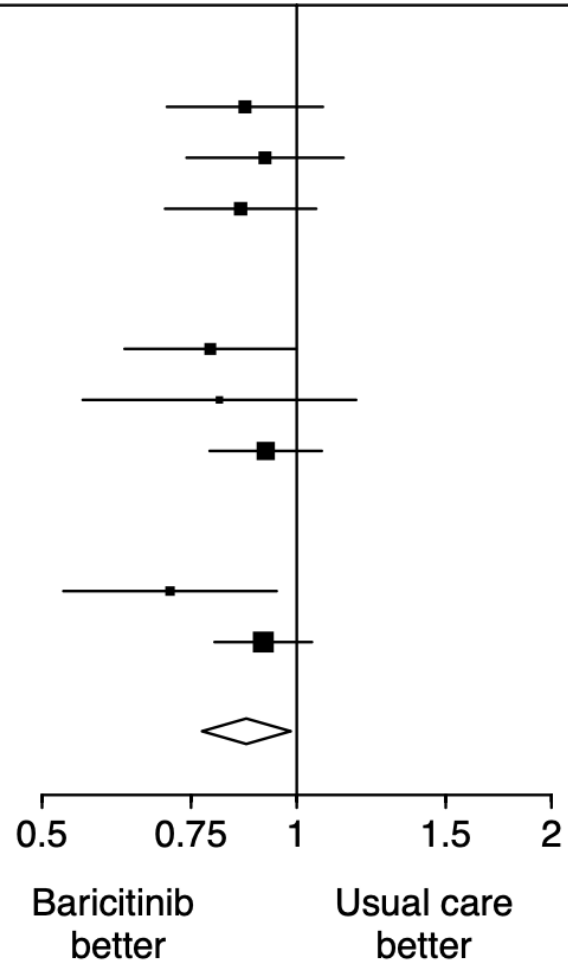
RECOVERY- Results

Webfigure 1: Effect of allocation to baricitinib on 28–day mortality by subgroups defined retrospectively

	Baricitinib	Usual care	RR (95% CI)
Baseline CRP (χ_1^2 0.0; p=0.93)			
< 60 mg/L	170/1465 (12%)	172/1358 (13%)	0.87 (0.70–1.07)
≥ 60 <120 mg/L	164/1220 (13%)	174/1259 (14%)	0.92 (0.74–1.14)
≥ 120 mg/L	173/1405 (12%)	192/1347 (14%)	0.86 (0.70–1.05)
Use of tocilizumab (χ_2^2= 1.29; p=0.53)			
Yes	131/951 (14%)	153/921 (17%)	0.79 (0.63–1.00)
Within the next 24 hours	51/391 (13%)	61/365 (17%)	0.81 (0.56–1.18)
No	331/2806 (12%)	332/2722 (12%)	0.92 (0.79–1.07)
Use of remdesivir (χ_1^2= 2.4; p=0.12)			
Yes	84/878 (10%)	100/789 (13%)	0.71 (0.53–0.95)
No	429/3270 (13%)	446/3219 (14%)	0.91 (0.80–1.04)
All participants	**513/4148 (12%)**	**546/4008 (14%)**	**0.87 (0.77–0.98) p=0.026**



RECOVERY group. medRxiv preprint doi: https://doi.org/10.1101/2022.03.02.22271623; (Supplementary data).

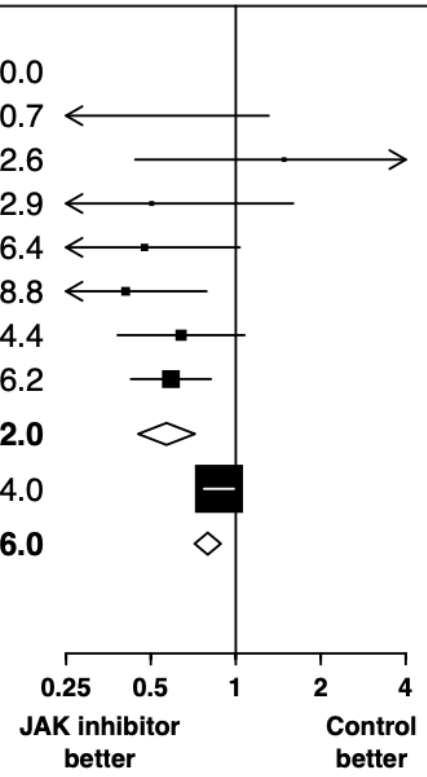
Pharmacy

RECOVERY- Results

Figure 4: JAK inhibitor vs usual care in patients hospitalised with COVID – Meta–analysis of mortality in RECOVERY and other trials

	Deaths / Patients randomised (%)		Observed–Expected		Ratio of death rates, RR (95% CI)
	JAK inhibitor	Control	(O–E)*	Var(O–E)	
Murugesan***	0/50 (0%)	0/50 (0%)	0.0	0.0	
Cao et al.***	0/20 (0%)	3/21 (14%)	–1.5	0.7	0.13 (0.01–1.31)
RUXCOVID***	9/287 (3%)	(3/145) x2** (2%)	1.0	2.6	1.48 (0.44–4.99)
Guimarães et al.***	4/144 (3%)	8/145 (6%)	–2.0	2.9	0.50 (0.16–1.60)
COV–BARRIER (critically ill)	20/51 (39%)	29/50 (58%)	–4.7	6.4	0.47 (0.22–1.03)
RUXCOVID–DEVENT***	90/164 (55%)	(36/47) x4** (77%)	–7.9	8.8	0.41 (0.21–0.79)
ACTT2	24/515 (5%)	37/518 (7%)	–6.4	14.4	0.64 (0.38–1.07)
COV–BARRIER	62/764 (8%)	100/761 (13%)	–19.2	36.2	0.59 (0.43–0.82)
Subtotal: 8 trials	**209/1995 (10%)**	**327/2023 (16%)**	**–40.7**	**72.0**	**0.57 (0.45–0.72)**
RECOVERY	513/4148 (12%)	546/4008 (14%)	–36.2	264.0	0.87 (0.77–0.98)
All trials	**722/6143 (12%)**	**873/6031 (14%)**	**–76.9**	**336.0**	**0.80 (0.71–0.89) p<0.001**

Heterogeneity between RECOVERY and previous trials: χ^2_1=10.3 (p=0.001)



RECOVERY group. medRxiv preprint doi: https://doi.org/10.1101/2022.03.02.22271623; t

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Summary

- Baricitinib reduces mortality in patients with severe COVID-19
- Main role: Use in combination with glucocorticoids in patients requiring support >0_2
- Effect maintained regardless of remdesivir or tocilizumab use
- Remaining questions
  - Generalizability to other JAK inhibitors?
  - Best use vis-à-vis tocilizumab

Dosing Adjustments

Parameter	Age ≥9	Ages 2-8
eGFR ≥60	4 mg daily	2 mg daily
eGFR 30-59	2 mg daily	1 mg daily
eGFR 15-29	1 mg daily	Not recommended
eGFR <15	Not recommended	
ALC <200	Consider holding until ≥200	
ANC <500	Consider holding until ≥500	

Key adverse effects: thromboembolism, infection

Outpatient Treatment Supply & Distribution Update

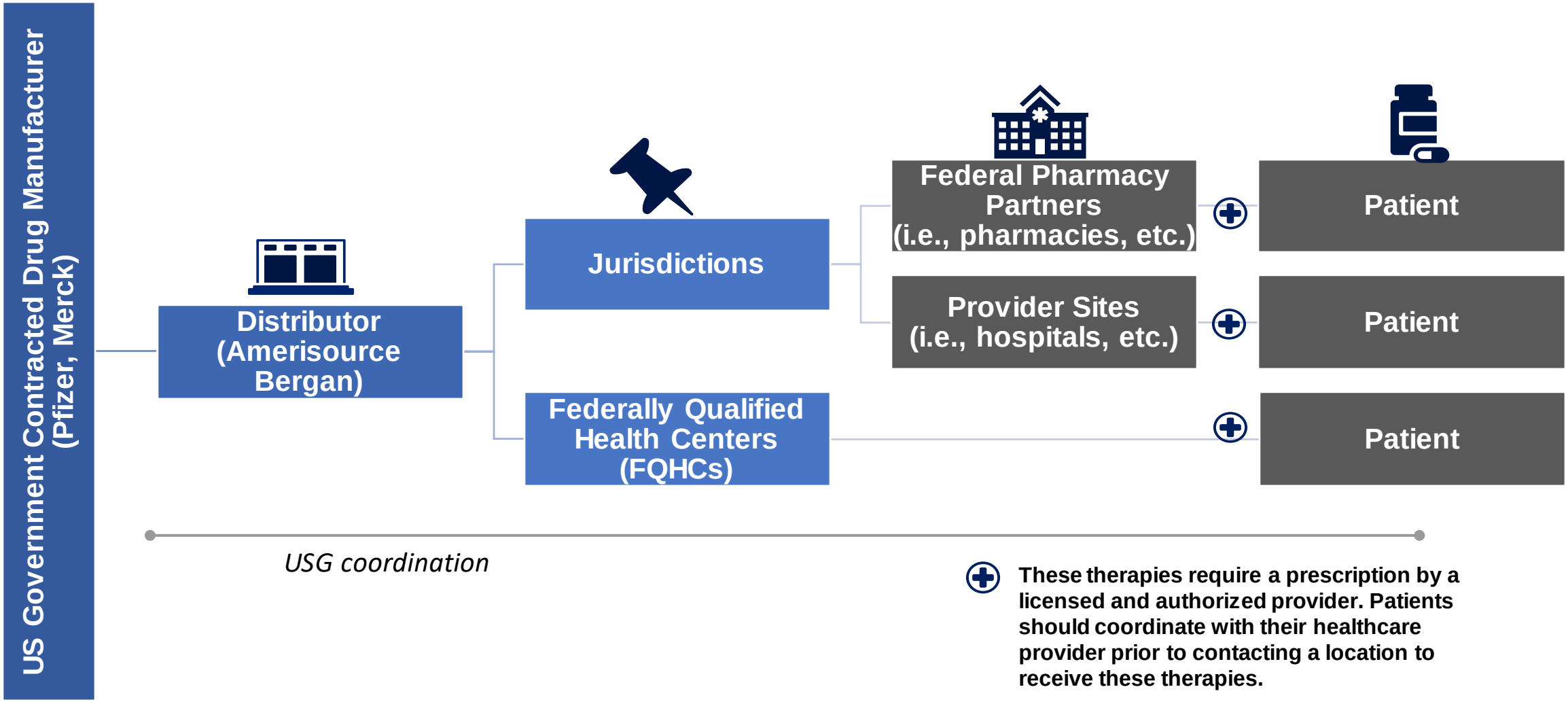
Derek Eisnor, MD and Meg Sullivan, MD, MPH

Derek Eisnor, MD
Medical Officer, Division of Clinical Development
Biomedical Advanced Research and Development Authority (BARDA)
COVID-19 Allocation and Distribution Lead
HHS ASPR

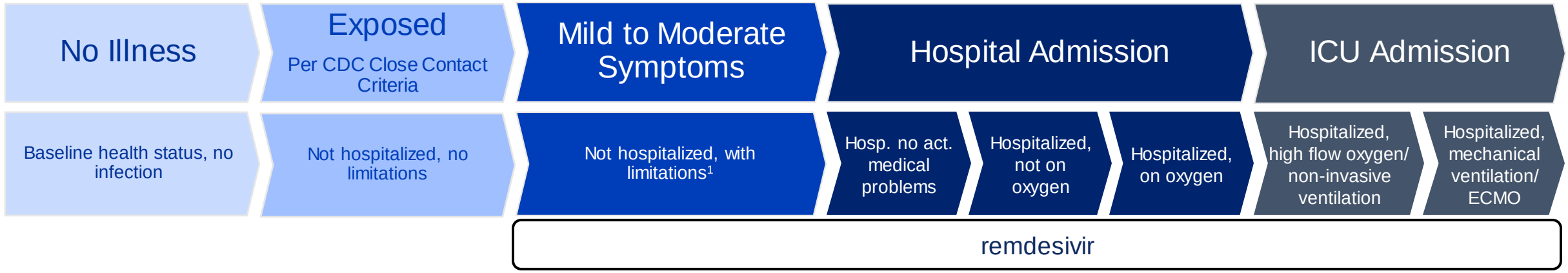
March 12, 2022

Nothing to Disclose

Oral Antiviral Dispensing: Pharmacy Partners Help Increase Access



Summary of COVID-19 Preventative Agents & Therapeutics



COVID-19 VACCINES

Monoclonal Antibodies for PrEP

- tixagevimab + cilgavimab (AZ)

Monoclonal Antibodies for PEP

- casirivimab + imdevimab (RGN)**
- bamlanivimab + etesevimab (Lilly)**

Oral Antivirals

- Paxlovid™ (Pfizer)
- molnupiravir (Merck)

Monoclonal Antibodies for Treatment

- sotrovimab (GSK/Vir)
- bebtelovimab (Lilly)
- bamlanivimab + etesevimab (Lilly)**
- casirivimab + imdevimab (RGN)**

tocilizumab

dexamethasone

baricitinib

****Not currently authorized for use anywhere in the U.S. due to the prevalence of Omicron.**

[1] NIH COVID-19 Treatment Guidelines https://www.covid19treatmentguidelines.nih.gov/about-the-guidelines/whats-new/
Therapeutic Management of Nonhospitalized Adults With COVID-19 https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/

Updated EUA: EVUSHELD

Updated EVUSHELD Dosing Requirements (tixagevimab and cilgavimab)

Initial Dosage and Administration	Repeat Dosing for Patients who Previously Received 150 mg tixagevimab and 150 mg of cilgavimab
300 mg of tixagevimab and **300 mg of cilgavimab** administered as two separate consecutive intramuscular injections.	**150 mg of tixagevimab** and **150 mg of cilgavimab** administered as two separate intrmuscular injections as soon as possible.

For more information, see *Fact Sheet for Healthcare Providers: Emergency Use Authorization For EVUSHELD (tixagevimab co-packaged with cilgavimab).*

Pathway to Treatment: Patient with Confirmed COVID-19 Infection

- Treatment likely most beneficial to patients if given **early in symptom progression**
- EUA requires administration of **treatment as soon as possible after** confirmed positive test result and within **5 to 10 days of symptom onset***
- Strong **partnership and communication** between patients and HCP to get right treatment to right patients at right time
- Fast testing turnaround needed, to efficiently **identify positive tests** and **schedule for treatment**

Example of timeline which would fulfill EUA requirements

Onset of symptoms	Clinical visit and diagnostic test	Confirmed positive test	Treatment
	≤ 3 days *post symptom onset*	***≤ 24 hours*** *post diagnostic test*	***ASAP*** *post positive test result*

Treatment required within 5 to 10 days of symptom onset *Testing sites should recommend COVID+ patients that are high risk confer with their HCP on potential suitability for Tx*

Early administration of treatment needs fast testing turn-around and patient scheduling

Planning required for "Test and treat" models

***Please reference EUA factsheet for specific treatment guidelines including recommended treatment window**

Outpatient Therapeutic Portfolio

For Planning Purposes Only – Subject to Change

	Drug Class	Allocation Cadence*	Sweep Schedule*	Allocation Feb 7	Allocation Feb 14	Planned Allocation Feb 21	Planned Allocation Feb 28	Planned Allocation Mar 7	Planned Allocation Mar 14
Paxlovid Pfizer	Oral antiviral	Transition to Weekly	N/A	100,000	0	150,000	0	125,000	125,000
Molnupiravir Merck	Oral antiviral	Transition to Weekly	N/A	400,000	+ requests	350,000 (+ requests)	+ requests	125,000 (+ requests)	125,000 (+ requests)
Sotrovimab GSK/Vir	Monoclonal for treatment	Weekly	N/A	52,250	52,250	52,250	47,000	52,250	52,250
Bebtelovimab Lilly	Monoclonal for treatment	Weekly	N/A	N/A	49,000	49,000	52,000	49,000	49,000
Evusheld AstraZeneca	Monoclonal for prevention	Transition to Monthly	N/A	50,000	50,000	50,000	50,000	200,000 (monthly allocation)	(ordering against monthly)
Bam/Ete Lilly	Monoclonal; omicron resistance	Weekly	Weekly; Saturday	Distribution pause[1]	Distribution pause[1]	Distribution pause[1]	Distribution pause[1]	Distribution pause[1]	Distribution pause[1]
REGEN-COV Regeneron	Monoclonal, omicron resistance	Weekly	Weekly; Saturday	Distribution pause[1]	Distribution pause[1]	Distribution pause[1]	Distribution pause[1]	Distribution pause[1]	Distribution pause[1]
Remdesivir Gilead	IV antiviral	Commercial Market	N/A	N/A	N/A	N/A	N/A	N/A	N/A

1. In accordance with the FDA EUA update on 1/24/2022, bam/ete and REGEN-COV distribution is paused nationally due to the high prevalence of the omicron variant. Resumption of allocation will be considered based on variant prevalence data and/or availability of patient level variant diagnostic testing.

* As disease incidence declines and incoming supply increases to better meet demand, allocation strategies may transition later in March.

Unclassified / For Public Distribution

Long-Term Care Partners Program

- **Overview**: Partnership with Pharmacy serving long-term care facilities (LTCFs) for **direct ordering of oral antivirals** up to a specific threshold at locations that provide direct access of product to the long-term care community
- Uses separate federal cache that **does not impact allocations to states/territories**
- Aids states by identifying long-term care supporting pharmacies (LTCPs) within their jurisdictions
- Identified LTCPs have ability to open order with guard rails, closely tied to utilization
- Will ensure maximum visibility by states and territories on product supplies in LTCPs and LTCFs
- Will Ensure equitable distribution of therapeutics
- Provides an efficient and flexible logistical and distribution structure to meet current and future demand for therapeutics when and where needed

Test To Treat Initiative

Meg Sullivan, MD, MPH
Acting Chief Medical Office
HHS ASPR

Test to Treat Overview

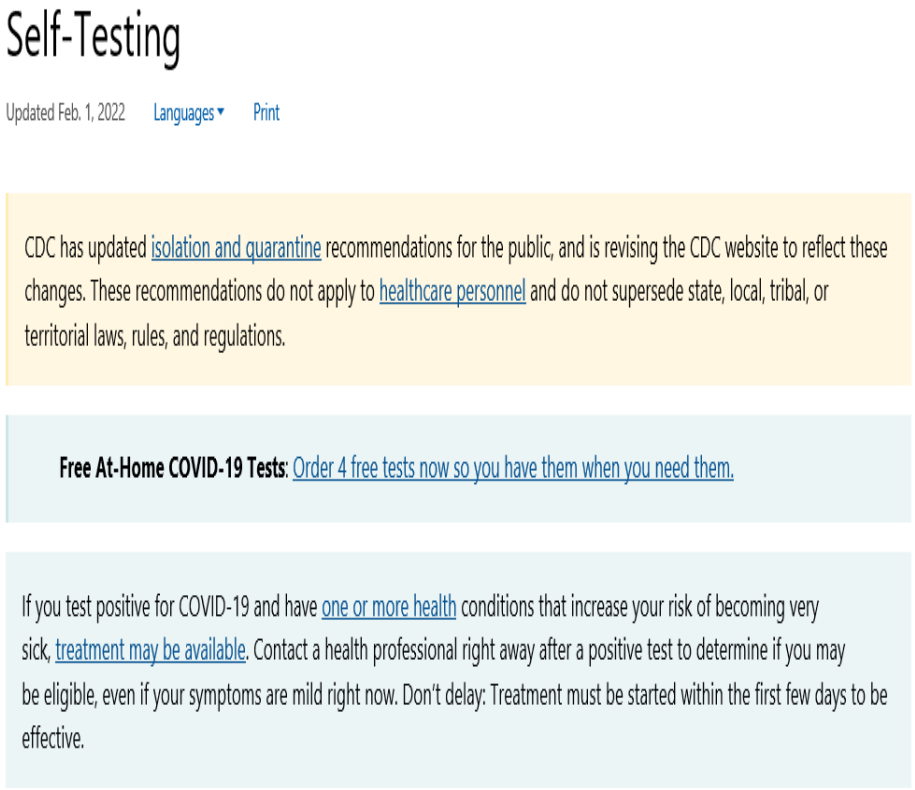
- ***Test to Treat efforts aim to address challenges with patients obtaining therapeutics, <u>including</u>:***
  - Consumer knowledge of “test to treat” guidance
  - Access to tests upon symptom onset
  - Access to healthcare provider (or treatment site for mAbs) within timeframe for treatment effectiveness
  - Provider knowledge of and comfort level with prescribing therapeutics
  - Equitable distribution of therapeutics, especially in the setting of limited supply
  - Provider/consumer locating site with medication in-stock

COVID-19 Test to Treat Strategy: Overall Goals

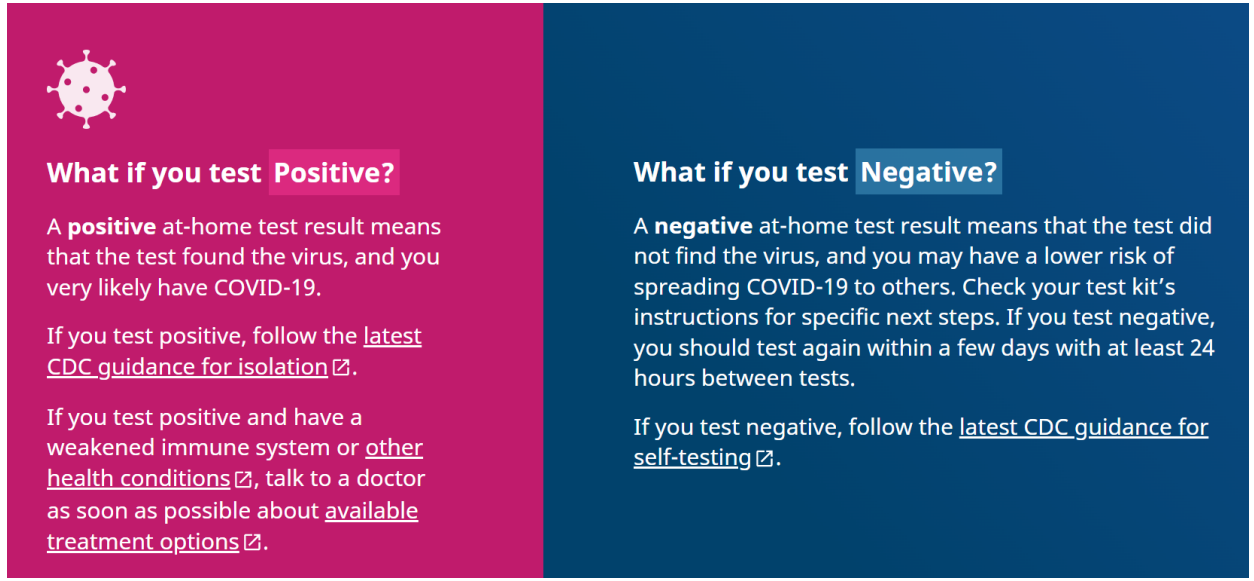
- **Increase COVID-19 test and treat health literacy.**
- **Ensure Access to Tests** for early diagnosis, with a specific focus on high-risk individuals.
- **Facilitate Rapid Linkage to Care after Positive Result**, with a specific focus on high-risk individuals.
- **Ensure Access to Therapeutics,** with a focus on equitable distribution.

Increase COVID-19 Test to Treat Health Literacy

Include Test to Treat language on testing websites

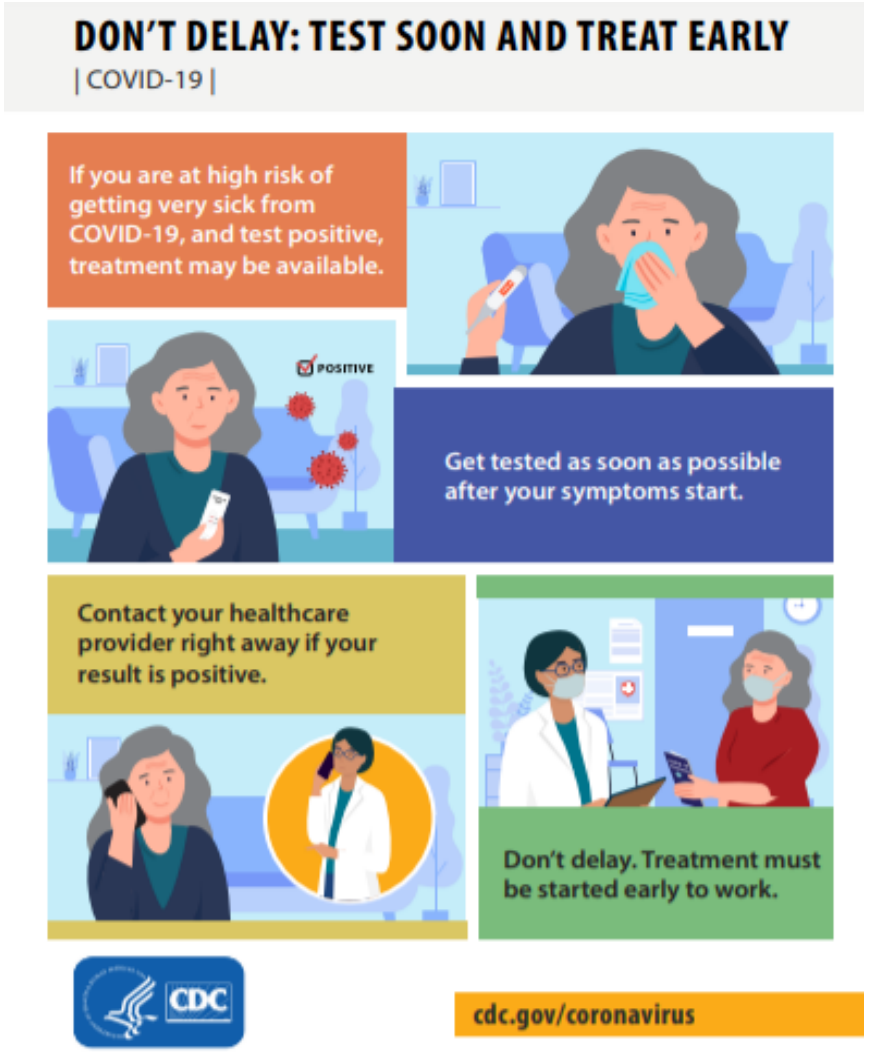


https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html



https://www.covidtests.gov/

Increase COVID-19 Test to Treat Health Literacy



https://www.cdc.gov/coronavirus/2019-ncov/downloads/communication/print-resources/Test-Soon-Treat-Early.pdf

Weekly Stakeholder Engagements

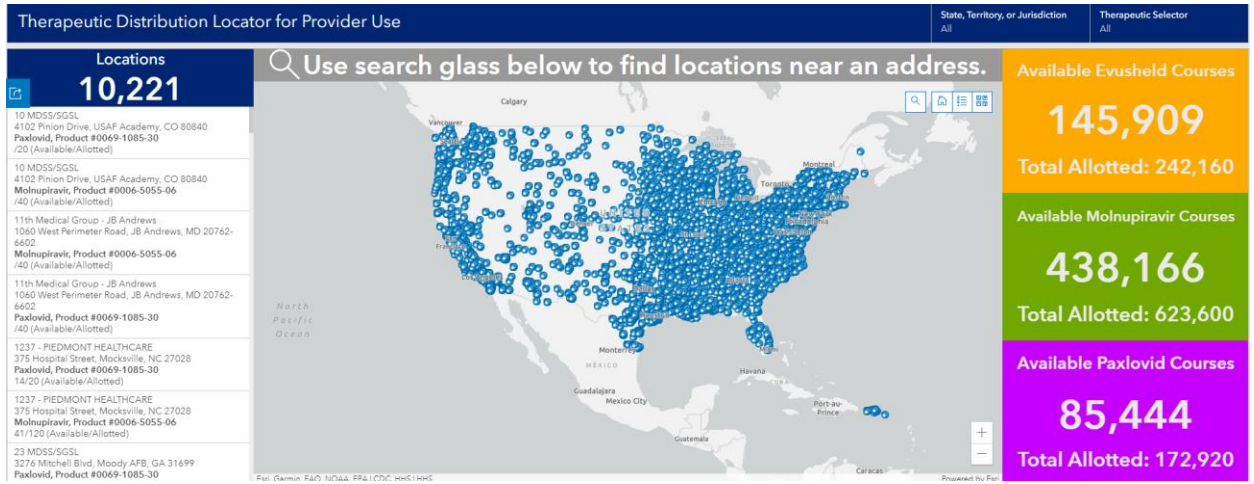
- **Office Call Sessions**: **HHS/ASPR Distribution and Administration of COVID-19 Therapeutics**
  - Tuesdays (2:00-3:00PM ET)
  https://hhsasproea.zoomgov.com/j/1604329034?pwd=dGRwZTBETTJzWFliQW83TXZSOFVNQT09
- **Stakeholder Call: Federal Retail Pharmacy Therapeutics Program (FRPTP) Participants**
  - Every other Tuesday (12:00-12:30PM ET); Next meeting March 8
- **Stakeholder Call: State and Territorial Health Officials**
  - Wednesdays (2:00-3:00PM ET)
- **Stakeholder Call: National Health Care and Medical Orgs and Associations**
  - Wednesdays (3:15-4:15PM ET)
  https://hhsasproea.zoomgov.com/j/1617766329?pwd=SEVPMzlQWDQyYWo2KzcxVU01THluQT09
- **Health Partners Ordering Portal (HPOP) Office Hours**
  - Thursdays (4:00-5:00PM ET)
  https://hhsasproea.zoomgov.com/j/1603047233?pwd=V3R4OG1LSDhUZ2I0Y0NhZkUxVlkxdz09
- **Federal COVID-19 Response: COVID-19 Therapeutics Clinical Webinar**
  - Every other Friday (12:00-1:00PM ET); Next meeting March 18
  https://hhsasproea.zoomgov.com/j/1617536991?pwd=NjFMcnJOUENuSFhtRFFtaWltejYzZz09

Questions or need the Zoom link for identified engagements?
Email us at COVID19Therapeutics@hhs.gov.

Increase COVID-19 Test and Treat Health Literacy/Ensure Access to Therapeutics

- Amplify existing resources, and develop additional resource for linkages to therapeutics for healthcare providers

https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/



Test to Treat Initiative: Enhanced Distribution Model

- Part of larger strategy to increase access to oral antivirals:
  - **Public education** campaign and enhanced patient/consumer education and messaging
  - **Provider outreach** to increase knowledge of and comfort level with prescribing therapeutics
  - Ensure **access to and preposition tests** in high priority settings & populations
  - Ensure **access to and preposition therapeutics** in high priority settings and populations
    - Continue existing process of allocation of oral antivirals to states, jurisdictions, and territories
    - Continue direct distribution of oral antivirals to HRSA-funded health centers, with expansion to additional health centers as supply increases
    - Provide direct access to medication at sites where end-to-end test to treat model can be provided and/or disease burden is high using a separate federal cache that **does not impact current partners allocations**
      - Open direct ordering pathway for pharmacy-based clinics
      - Open direct ordering pathway for Long-Term Care Pharmacies
  - Explore further opportunities for telehealth and other options for linkage to care and treatment

Pharmacy-Based Clinic Test to Treat Initiative

- **Overview:** Partnership with Pharmacy-Based Clinics for **direct ordering of oral antivirals** up to a specific threshold at locations that provide comprehensive test and treat services at that location
- Initiative will increase opportunities for successful end-to-end Test and Treat model
  - Co-locates testing, provider, and treatment in single location
  - Reduce barriers to rapid linkage to treatment for high-risk COVID-19+ individuals
- Opens additional pathway of direct ordering of oral antivirals for eligible retail health clinic locations that meet the following criteria:
  - Enrolled in Federal pharmacy partnership program (or ability to rapidly enroll)
  - Provide/offer comprehensive end-to-end test and treat services to support a seamless patient experience:
    - Rapid COVID-19 testing on-site (or evaluation of at-home testing)
    - Linkage to a clinical evaluation by licensed healthcare provider after positive result to provide prescription when appropriate
    - Co-located pharmacy able to readily dispense medication to eligible patients
  - Services available to all individuals, regardless of insurance status

ASPR Office of the Assistant Secretary for Preparedness & Response

Fact Sheet: COVID-19 Test to Treat

The Biden-Harris Administration is launching a new nationwide Test to Treat initiative that will give individuals an important new way to rapidly access free lifesaving treatment for COVID-19. In this program, people will be able to get tested and – if they are positive and treatments are appropriate for them – receive a prescription from a health care provider, and have their prescription filled all in one location. These "One-Stop Test to Treat" locations will be available at hundreds of locations nationwide, including pharmacy-based clinics, federally-qualified community health centers (FQHCs), and long-term care facilities. People will also continue to be able to be tested and treated by their own health care providers who can appropriately prescribe these oral antivirals at locations where they are being distributed.

While vaccination continues to provide the best protection against COVID-19, therapies are now available to help treat eligible people who do get sick. The Biden-Harris Administration has invested in a medicine cabinet of COVID-19 treatments, which includes two oral antiviral pills – Pfizer's Paxlovid and Merck's Molnupiravir – that can help prevent severe illness and hospitalization when taken soon after symptom onset.

The Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS) already distributes COVID-19 treatments, including oral antivirals, to states and territories for free on a weekly basis. All qualified heath care providers can prescribe these therapeutics to patients who are at increased risk for developing severe COVID-19.

Effective March 7, HHS will also begin distributing oral antiviral pills directly to participating Test to Treat pharmacy-based clinics, making more treatments available to more people in more locations. ASPR will also launch a program for long-term care pharmacies to directly order these antivirals to facilitate increased access for eligible long-term care residents who are at increased risk for developing severe COVID-19.

These pharmacy-based clinics and long-term care facilities join hundreds of FQHCs in our hardest-hit and highest-risk communities – these centers will provide access for people to get tested, receive a prescription from a health care provider if appropriate, and have their prescription filled, all at one convenient location.

Building upon the existing distribution of oral antivirals to thousands of locations across all states and territories, the Test to Treat initiative is part of a broader strategy to quickly connect eligible individuals who are at high risk of getting very sick from COVID-19 to appropriate treatments. The Department of Veterans Affairs (VA) is also connecting our nation's veterans who test positive at VA medical centers directly to treatment. For more information regarding available COVID-19 treatments, visit www.aspr.hhs.gov.

Frequently Asked Questions about the Test to Treat Initiative

What pharmacy-based clinics, health centers, and long-term care facilities have partnered with HHS as part of the Test to Treat initiative?
Some of the nation's largest pharmacy chains are participating. The participating locations have health clinics inside their stores where health care providers can prescribe these COVID-19 therapites to eligible people who need them. These oral antivirals may only be prescribed by a qualified health care provider. There are also hundreds of federally-qualified health centers already participating in our hardest-hit and highest-risk communities, with additional long-term care facilities that serve high-risk residents also coming on board.

Which treatments will participating Test to Treat locations receive?
Pharmacy-based clinics participating in the initiative are eligible to receive the oral antiviral pills from Merck (molnupiravir) and Pfizer (Paxlovid) through direct allocations from HHS/ASPR beginning the week of Mar. 7, 2022.

How does the Test to Treat program work?
Patients will be able to get tested – and if they are positive and eligible for treatment – to receive an appropriate prescription from a qualified health care provider, and have their prescription filled all in one location. Individuals who receive COVID-19 test results through at-home tests or another testing site can also utilize a Test to Treat location to receive a prescription from a qualified healthcare provider and treatment on the spot if eligible.

Will there be a Test to Treat site near me?
The initial launch of the Test to Treat initiative includes hundreds of federally-qualified health centers, pharmacy-based clinics, and long-term care facilities across the country. HHS will enroll additional sites in the coming weeks as the program launches and expands. In addition to the Test to Treat sites, states and territories will also continue to receive oral antiviral pills available for distribution throughout their jurisdictions.

How will people find Test to Treat sites as more come online?
A federal Test to Treat website is in development with anticipated launch in mid-March.

Will the Test to Treat program reduce the amount of oral antiviral treatments that a state or territory receives?
No, this program will have a separate federal supply that will not impact current state and territory allocations that are going to other sites and providers. The Test to Treat program is not intended to interfere with or supplant existing allocation protocols, but rather to offer more options for places where eligible people can quickly get needed care.

Are pharmacists themselves able to prescribe the oral antiviral pills (Paxlovid and Molnupiravir)?
No. The Test to Treat initiative includes sites that have health care providers available to provide timely and thorough assessment and discussion relevant to oral antiviral treatment option(s), consistent with FDA requirements regarding these drugs. The Test to Treat initiative does not change existing requirements for a qualified health care provider to write the prescription.

Can I get oral antivirals through my regular health care provider?
Yes. As has been the case until now, qualified health care providers will continue to be able to prescribe oral antivirals to their eligible patients who are at increased risk of developing severe COVID-19. Patients will be able to pick up those prescriptions wherever antivirals are being distributed

Can I bring at-home test results to a Test to Treat site for assessment to receive treatment?
Yes. The Test to Treat initiative does **not** require that an individual is tested at the Test to Treat site.

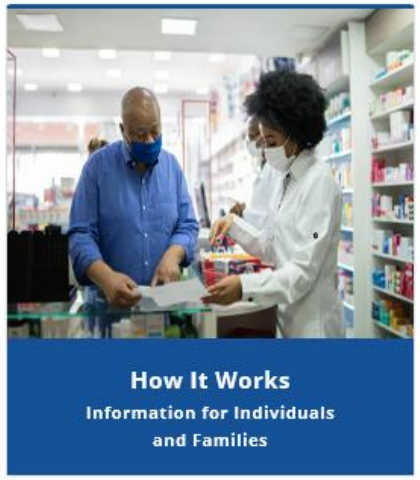
March 4, 2022

TEST TO TREAT WEBSITE

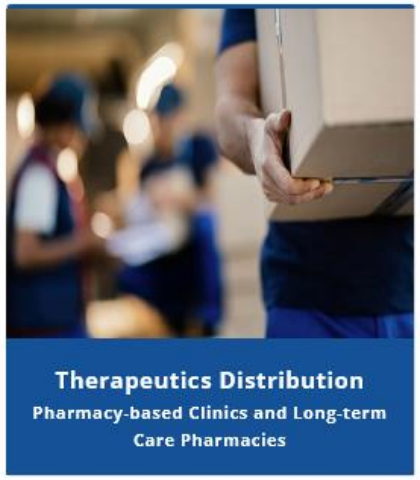
Test to Treat

Faster, Easier Access to Life-Saving COVID-19 Treatments

A newly launched nationwide Test to Treat initiative gives individuals an important way to rapidly access free lifesaving treatment for COVID-19. In this program, people are able to get tested and – if they are positive and treatments are appropriate for them – receive a prescription from a health care provider, and have their prescription filled all in one location. These "One-Stop Test to Treat" sites will be available at hundreds of locations nationwide, including pharmacy-based clinics, federally-qualified community health centers (FQHCs), and long-term care facilities. People will also continue to be able to be tested and treated by their own health care providers who can appropriately prescribe these oral antiviral pills and patients can have their prescriptions filled at locations where these antivirals are being distributed. To learn more, check out the **COVID-19 Test to Treat fact sheet**.



How It Works
Information for Individuals and Families



Therapeutics Distribution
Pharmacy-based Clinics and Long-term Care Pharmacies

Frequently Asked Questions

https://aspr.hhs.gov/TestToTreat/Pages/default.aspx

Equity Remains a Shared Responsibility

- We urge jurisdictions to put equity at center of distribution plans; consider allocating to sites that help increase product access within vulnerable communities and to priority populations

- HHS identifying about 200 HRSA-funded health centers across all 50 states to receive direct allocations of oral antiviral product
  - Separate from allocations to state and territorial health departments
  - Centers identified to date found here
  - Will further help ensure oral antivirals are available to some of the most vulnerable communities and hard-hit populations across country

- We encourage jurisdictions to amplify where product is sent in their areas
  - Utilize provider communication networks
  - Post receiving sites on state and local health department websites
  - Partner with hospital associations for message amplification
  - Enlist support of public information officers

Thank You!

COVID19Therapeutics@HHS.gov

ASPR.HHS.gov

Q&A/Discussion

Selected Resources

Dr. Dowell

- Slide 7 - https://www.biorxiv.org/content/10.1101/2022.02.07.479306v1
- Slides 9 and 10 - https://covid.cdc.gov/covid-data-tracker/#variant-proportions
- Slides 11 and 12- https://covid.cdc.gov/covid-data-tracker/#trends
- Slide 13 - https://www.medrxiv.org/content/10.1101/2022.02.17.22271030v1
  - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1060337/Technical-Briefing-38-11March2022.pdf
- Slide 14 - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1060337/Technical-Briefing-38-11March2022.pdf
  Transmission of SARS-CoV-2 Omicron VOC subvariants BA.1 and BA.2: Evidence from Danish Households:
- Slide 15 - https://www.medrxiv.org/content/10.1101/2022.02.19.22271112v1 .
- Slide 16 - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1060030/vaccine-surveillance-report-week-10.pdf
- Slides 17 and 18 - https://www.biorxiv.org/content/10.1101/2022.02.07.479306v1.full.pdf

Dr Shoham

- Slide 44 - https://www.idsociety.org/globalassets/idsa/practice-guidelines/covid-19/treatment/idsa-covid-19-gl-tx-and-mgmt---convalescent-plasma-2022-02-03.pdf
- Slide 51 - https://www.fda.gov/media/155159/download

Jason Gallagher

- Slide 58 - . https://doi.org/10.1172/JCI141772
- Slide 59 - https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html. https://ourworldindata.org/mortality-risk-covid
- Slide 64 - https://doi.org/10.1101/2021.10.11.21263897
- Slide 65 - https://www.recoverytrial.net/results
- Slides 66-69: RECOVERY group. medRxiv preprint doi: https://doi.org/10.1101/2022.03.02.22271623

Selected Resources Continued

Drs. Eisnor and Sullivan

- Slide 75 – https://www.covid19treatmentguidelines.nih.gov/about-the-guidelines/whats-new/
  - https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/
- Slide 76 - https://www.fda.gov/media/154701/download
- Slide 83 - https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html
  - https://www.covidtests.gov/
- Slide 84 - https://www.cdc.gov/coronavirus/2019-ncov/downloads/communication/print-resources/Test-Soon-Treat-Early.pdf
- Slide 85 - **Office Call Sessions**: **HHS/ASPR Distribution and Administration of COVID-19 Therapeutics**
  - Tuesdays (2:00-3:00PM ET) https://hhsasproea.zoomgov.com/j/1604329034?pwd=dGRwZTBETTJzWFliQW83TXZSOFVNQT09
  - **Stakeholder Call: National Health Care and Medical Orgs and Associations**
    - Wednesdays (3:15-4:15PM ET)
      https://hhsasproea.zoomgov.com/j/1617766329?pwd=SEVPMzlQWDQyYWo2KzcxVU01THluQT09
  - **Health Partners Ordering Portal (HPOP) Office Hours**
    - Thursdays (4:00-5:00PM ET)
      https://hhsasproea.zoomgov.com/j/1603047233?pwd=V3R4OG1LSDhUZ2I0Y0NhZkUxVlkxdz09
  - **Federal COVID-19 Response: COVID-19 Therapeutics Clinical Webinar**
    - Every other Friday (12:00-1:00PM ET); Next meeting March 18
      https://hhsasproea.zoomgov.com/j/1617536991?pwd=NjFMcnJOUENuSFhtRFFtaWltejYzZz09
- Slide 85 - Email us at COVID19Therapeutics@hhs.gov.
- Slide 86 - **https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/**
- Slide 90 - https://aspr.hhs.gov/TestToTreat/Pages/default.aspx
- Slide 91 - https://bphc.hrsa.gov/emergency-response/covid-19-therapeutics/participants

Selected Resources Continued

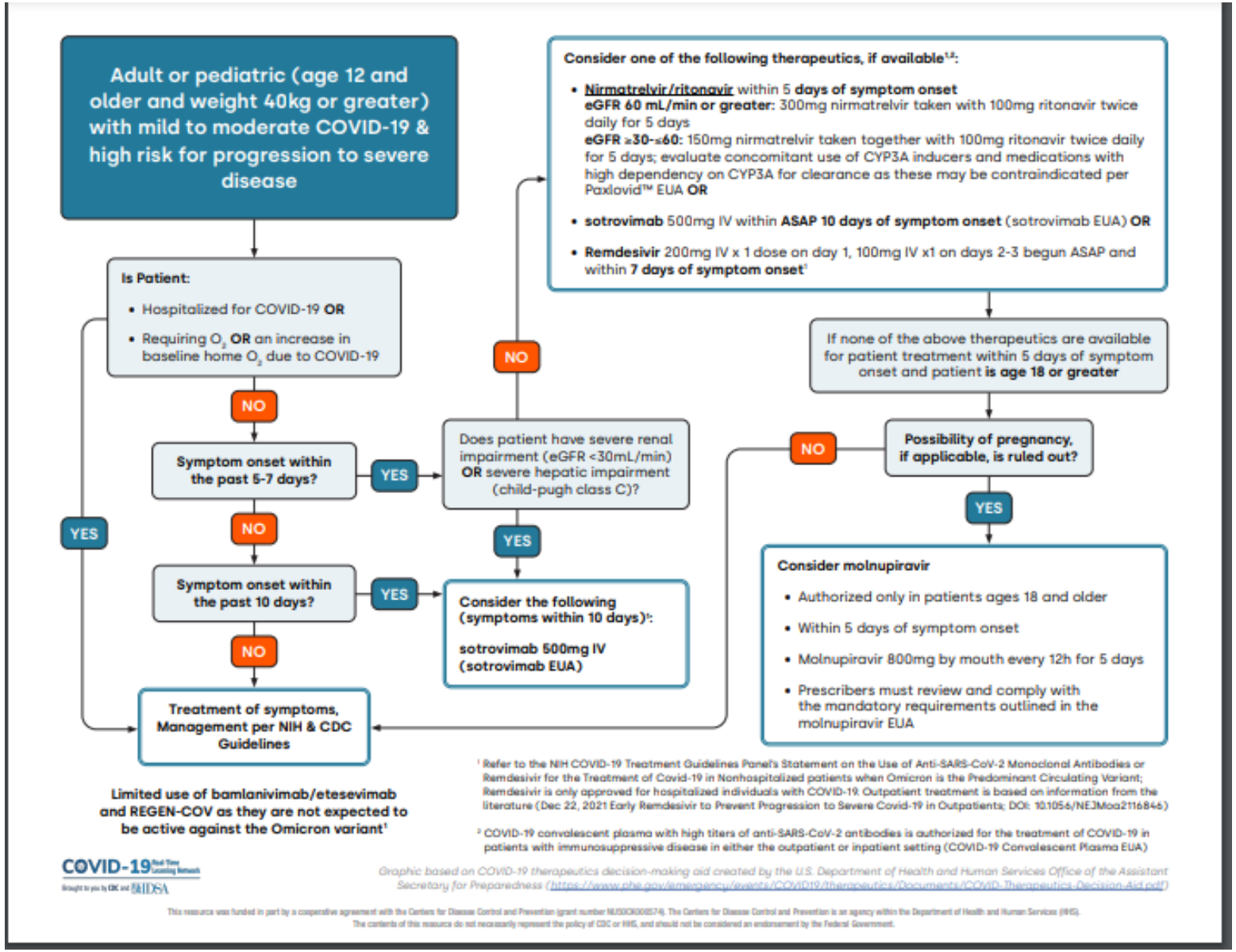
Program Links:

- This webinar is being recorded and can be found with the slides online at https://www.idsociety.org/cliniciancalls
- COVID-19 Real-Time Learning Network: https://www.idsociety.org/covid-19-real-time-learning-network/
- Vaccine FAQ: https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines-information--faq/
- EIN https://ein.idsociety.org/members/sign_up/.

- Molnupiravir Point of Care Reference: https://www.idsociety.org/globalassets/covid-19-real-time-learning-network/molnupiravir-reference-v4.pdf
- Paxlovid Point of Care Reference https://www.idsociety.org/covid-19-real-time-learning-network/nirmatrelvir-ritonavir-paxlovid-point-of-care-reference/

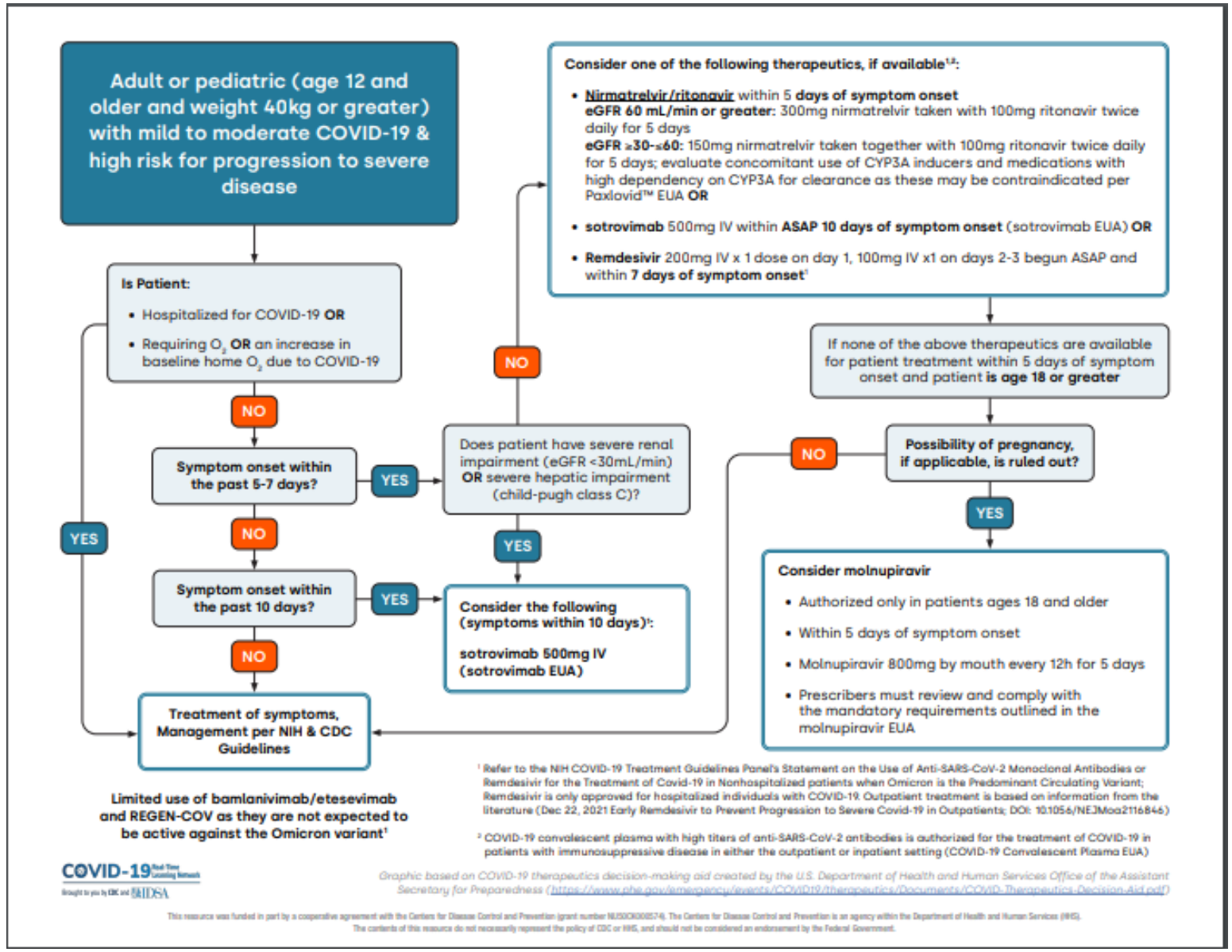
Molnupiravir Quick Point-of-Care Reference

https://www.idsociety.org/globalassets/covid-19-real-time-learning-network/molnupiravir-reference-v4.pdf



Nirmatrelvir/Ritonavir (Paxlovid™) Point-of-Care Reference

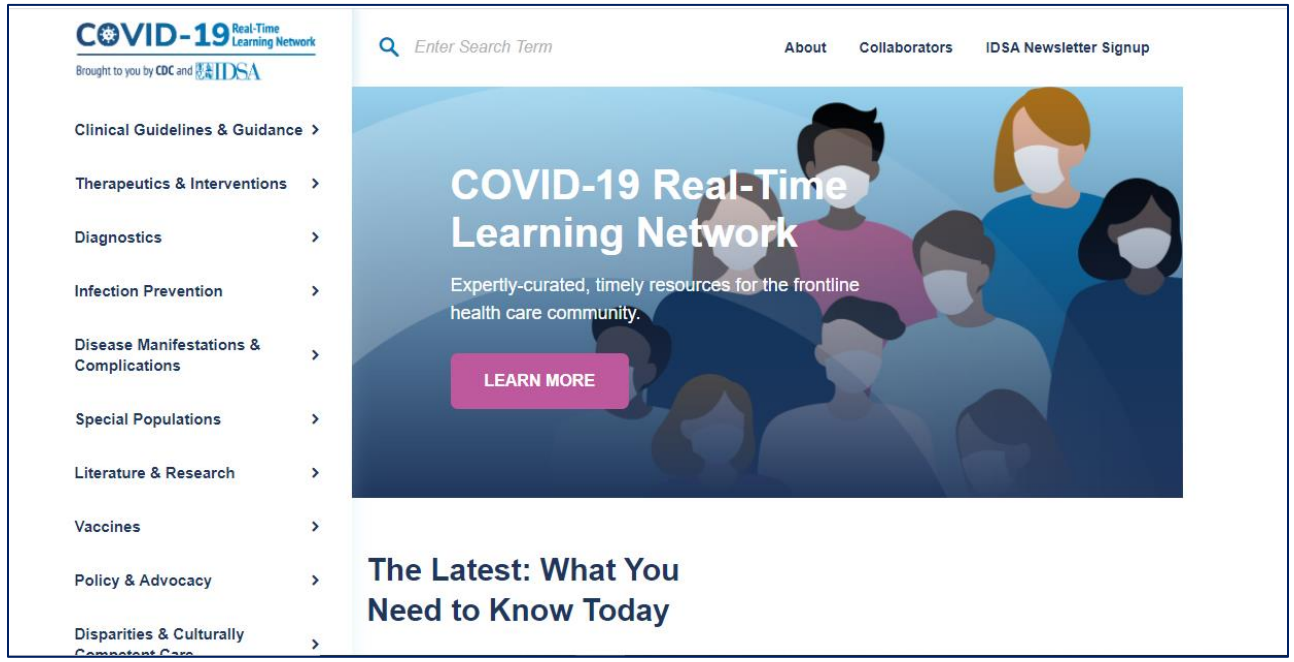
https://www.idsociety.org/globalassets/covid-19-real-time-learning-network/paxlovid-quick-point-of-care-reference-hs-v9.pdf



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 Obstetricians and Gynecologists
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?

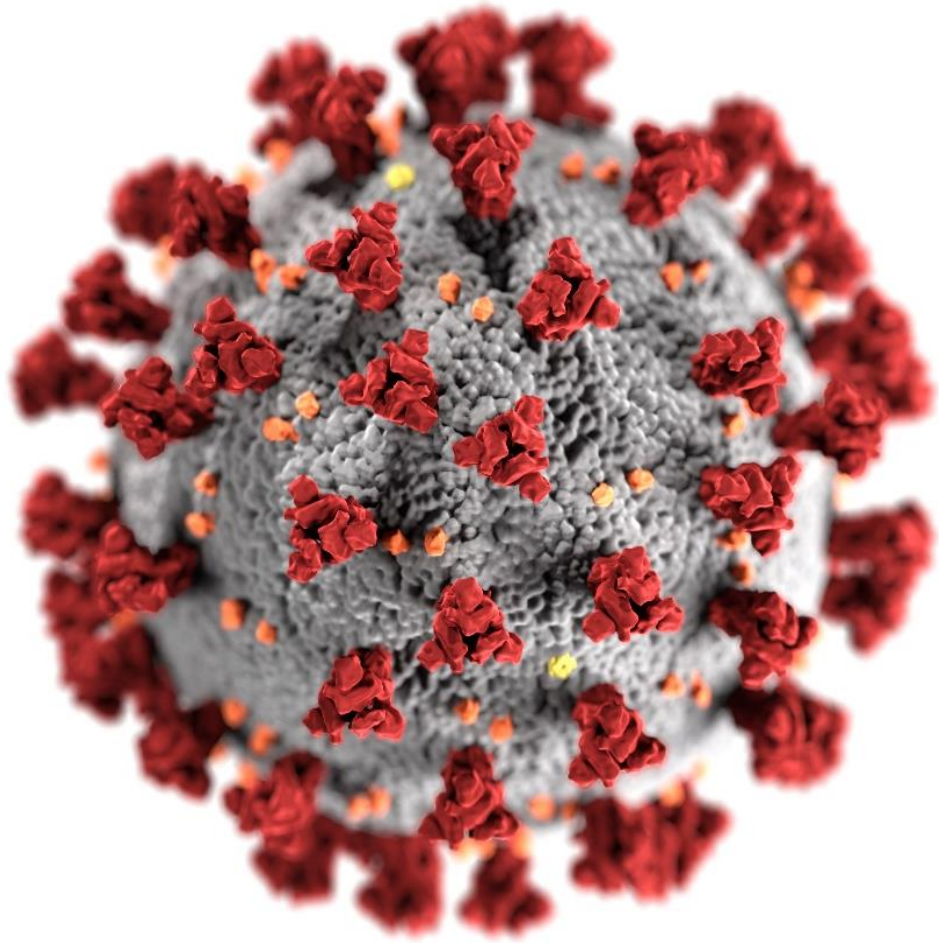
- Clinicians who have questions about the clinical management of COVID-19

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

Continue the conversation on Twitter

@RealTimeCOVID19
#RealTimeCOVID19

We want to hear from you!

Please complete the post-call survey.

Next Call

Saturday, April 9th

The Clinician Calls are moving to once a month at the same time, 3pm ET. Go to the registration page found at www.idsociety.org/cliniciancalls

for future call dates.

A recording of this call, slides and the answered Q&A will be posted at www.idsociety.org/cliniciancalls

-- library of all past calls now available --

Contact Us:

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Jide Ehimika (jehimika@idsociety.org)