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.
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

**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

**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)**

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 Updates from IDSA’s COVID-19 Rapid Guidelines Panel**

**Treatment Supply & Distribution Update**

**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
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)
BA.2 now the predominant sublineage in many countries

BA.2 is gradually increasing in the United States


- **Omicron**
  - BA.1
  - B.1.1.529
  - US Class: VOC
  - %Total: 73.7%
  - 95%PI: 70.1-77.0%

- **BA.2**
  - US Class: VOC
  - %Total: 11.6%
  - 95%PI: 9.8-13.8%

- **Delta**
  - B.1.617.2
  - US Class: VOC
  - %Total: 0.0%

- **Other**
  - US Class: Other*
  - %Total: 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 is also aggregated with B.1.1.529, as it currently cannot be reliably called in each region.

https://covid.cdc.gov/covid-data-tracker/#variant-proportions
BA.2 is gradually increasing in the United States
U.S. COVID-19 cases are declining
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

<table>
<thead>
<tr>
<th></th>
<th>Hospital admission(^b)</th>
<th>Adjusted odds ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N (%)</td>
<td></td>
</tr>
<tr>
<td>N=95,470</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SGTF (BA.1 proxy)</td>
<td>2,965/87,194 (3.4)</td>
<td>Ref</td>
</tr>
<tr>
<td>S-gene positive (BA.2 proxy)</td>
<td>295/8,276 (3.6)</td>
<td>0.96 (0.85-1.09)</td>
</tr>
</tbody>
</table>

Hospitalization:

Severe disease, among those hospitalized:

<table>
<thead>
<tr>
<th></th>
<th>Severe disease(^a)</th>
<th>Adjusted odds ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N (%)</td>
<td></td>
</tr>
<tr>
<td>N=3,058</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SGTF (BA.1 proxy)</td>
<td>929/2776 (33.5)</td>
<td>Ref</td>
</tr>
<tr>
<td>S-gene positive (BA.2 proxy)</td>
<td>86/282 (30.5)</td>
<td>0.91 (0.68-1.22)</td>
</tr>
</tbody>
</table>

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

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)

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

*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.


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

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

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

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

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

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

Antibody evasion properties of SARS-CoV-2 Omicron sublineages, Iketani et al. bioRxiv (Preprint February 9, 2022)
For more information, contact CDC
1-800-CDC-INFO (232-4636)

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

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

**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 IC₅₀ values relative to D614G of neutralization of Omicron variants, as well as point mutants unique to BA.2.
**mAb in vitro Data**

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

<table>
<thead>
<tr>
<th>Monoclonal Antibody or Antiviral Drug</th>
<th>hCoV-19/Japan/UT-NCD1288-2N/2022 (Omicron/BA.2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tested Value</td>
</tr>
<tr>
<td>Neutralization activity of monoclonal antibody†</td>
<td></td>
</tr>
<tr>
<td>LY-CoV016, etesevimab</td>
<td>&gt;50,000 ng/ml</td>
</tr>
<tr>
<td>LY-CoV555, bamlanivimab</td>
<td>&gt;50,000 ng/ml</td>
</tr>
<tr>
<td>REGN10987, imdevimab</td>
<td>68.65±8.84 ng/ml</td>
</tr>
<tr>
<td>REGN10933, casirivimab</td>
<td>1666.19±771.77 ng/ml</td>
</tr>
<tr>
<td>COV2-2196, tixagevimab</td>
<td>395.78±62.37 ng/ml</td>
</tr>
<tr>
<td>COV2-2130, cilgavimab</td>
<td>4.44±2.72 ng/ml</td>
</tr>
<tr>
<td>S309, sotrovimab precursor</td>
<td>1359.05±269.23 ng/ml</td>
</tr>
<tr>
<td>LY-CoV016 plus LY-CoV555</td>
<td>&gt;10,000 ng/ml</td>
</tr>
<tr>
<td>REGN10987 plus REGN10933</td>
<td>222.59±64.47 ng/ml</td>
</tr>
<tr>
<td>COV2-2196 plus COV2-2130</td>
<td>14.48±2.04 ng/ml</td>
</tr>
<tr>
<td>Viral susceptibility to drug‡</td>
<td></td>
</tr>
<tr>
<td>GS-441524§</td>
<td>2.85±0.31 μM</td>
</tr>
<tr>
<td>EIDD-1931¶</td>
<td>0.67±0.22 μM</td>
</tr>
<tr>
<td>PF-07321332¶</td>
<td>6.76±0.69 μM</td>
</tr>
</tbody>
</table>
### Table S2: Efficacy of Monoclonal Antibodies and Antiviral Drugs against SARS-CoV-2 Variants in Vitro.

<table>
<thead>
<tr>
<th>Monoclonal Antibody or Antiviral Drug</th>
<th>SARS-CoV-2/UT-NC002-1T/Human/2020/Tokyo (An ancestral strain/A)</th>
<th>SARS-CoV-2/UT-HP127-1N/Human/2021/Tokyo (Alpha/B.1.1.7)</th>
<th>SARS-CoV-2/UT-HP1542/2021 (BetaB.1.351)</th>
<th>hCoV-19/USA/MDD-HP053021 (Gamma/P.1)</th>
<th>hCoV-19/USA/WI-UW-5250/2021 (Delta/B.1.617.2)</th>
<th>hCoV-19/Japan/NCS928-2N/2021 (Omicron/BA.1)</th>
<th>hCoV-19/Japan/NCS928-1N/2021 (Omicron/BA.1)</th>
<th>hCoV-18/Japan/UT-NCD1285-2N/2022 (Omicron/BA.2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutralization activity of monoclonal antibody — ng/ml†</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LY-CoV016, etesevimab</td>
<td>18.19 ± 9.10</td>
<td>150.38 ± 63.51</td>
<td>&gt;50,000</td>
<td>&gt;50,000</td>
<td>15.37 ± 9.78</td>
<td>&gt;50,000</td>
<td>&gt;50,000</td>
<td>&gt;50,000</td>
</tr>
<tr>
<td>LY-CoV555, barlanimab</td>
<td>4.89 ± 1.43</td>
<td>2.86 ± 1.30</td>
<td>9564.88 ± 826.53</td>
<td>1601.85 ± 866.02</td>
<td>641.73 ± 324.79</td>
<td>&gt;50,000</td>
<td>&gt;50,000</td>
<td>&gt;50,000</td>
</tr>
<tr>
<td>REGN10987, imdevimab</td>
<td>3.05 ± 0.93</td>
<td>1.87 ± 1.60</td>
<td>2.17 ± 1.30</td>
<td>1.04 ± 0.68</td>
<td>3.95 ± 1.78</td>
<td>&gt;50,000</td>
<td>&gt;50,000</td>
<td>88.65 ± 8.84</td>
</tr>
<tr>
<td>REGN10933, casirivimab</td>
<td>2.79 ± 1.87</td>
<td>2.74 ± 1.84</td>
<td>757.13 ± 267.91</td>
<td>187.89 ± 128.88</td>
<td>2.69 ± 1.78</td>
<td>1411.70 ± 1782.13</td>
<td>1198.94 ± 2604.70</td>
<td>1696.19 ± 771.77</td>
</tr>
<tr>
<td>COV2-2196, bgxevimab</td>
<td>1.92 ± 0.28</td>
<td>1.34 ± 0.67</td>
<td>18.98 ± 1.42</td>
<td>6.56 ± 1.56</td>
<td>4.05 ± 2.60</td>
<td>1299.94 ± 406.58</td>
<td>880.47 ± 68.08</td>
<td>395.78 ± 62.37</td>
</tr>
<tr>
<td>COV2-2130, alqevimab</td>
<td>7.70 ± 2.20</td>
<td>3.60 ± 1.62</td>
<td>10.03 ± 3.05</td>
<td>4.00 ± 2.70</td>
<td>12.76 ± 2.93</td>
<td>443.87 ± 167.96</td>
<td>13568.20 ± 4616.86</td>
<td>4.44 ± 2.72</td>
</tr>
<tr>
<td>S309, sotrovimab precursor</td>
<td>27.33 ± 3.24</td>
<td>44.91 ± 22.78</td>
<td>100.98 ± 22.27</td>
<td>28.38 ± 1.86</td>
<td>111.43 ± 58.22</td>
<td>373.47 ± 159.49</td>
<td>384.52 ± 65.98</td>
<td>1359.05 ± 269.23</td>
</tr>
<tr>
<td>LY-CoV018 plus LY-CoV555</td>
<td>12.60 ± 1.91</td>
<td>15.26 ± 3.98</td>
<td>&gt;10,000</td>
<td>2545.04 ± 625.72</td>
<td>10.28 ± 3.33</td>
<td>&gt;10,000</td>
<td>&gt;10,000</td>
<td>&gt;10,000</td>
</tr>
<tr>
<td>REGN10987 plus REGN10933</td>
<td>3.53 ± 0.88</td>
<td>1.55 ± 0.78</td>
<td>5.18 ± 1.45</td>
<td>2.11 ± 0.48</td>
<td>1.91 ± 0.79</td>
<td>&gt;10,000</td>
<td>&gt;10,000</td>
<td>222.59 ± 64.47</td>
</tr>
<tr>
<td>COV2-2196 plus COV2-2130</td>
<td>3.42 ± 0.92</td>
<td>1.94 ± 0.34</td>
<td>10.30 ± 1.17</td>
<td>1.79 ± 0.87</td>
<td>5.50 ± 2.75</td>
<td>255.86 ± 45.31</td>
<td>1374.90 ± 14.47</td>
<td>14.48 ± 2.04</td>
</tr>
<tr>
<td>Viral susceptibility to drug — μM†</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GS-441524</td>
<td>1.04 ± 0.32</td>
<td>0.83 ± 0.19</td>
<td>0.63 ± 0.20</td>
<td>0.91 ± 0.33</td>
<td>1.12 ± 0.20</td>
<td>1.28 ± 0.42</td>
<td>1.63 ± 0.30</td>
<td>2.85 ± 0.31</td>
</tr>
<tr>
<td>EIDD-1901</td>
<td>0.51 ± 0.14</td>
<td>0.95 ± 0.17</td>
<td>0.60 ± 0.21</td>
<td>0.41 ± 0.13</td>
<td>0.63 ± 0.41</td>
<td>0.43 ± 0.08</td>
<td>1.09 ± 0.13</td>
<td>0.67 ± 0.22</td>
</tr>
<tr>
<td>PF-0732/3322</td>
<td>3.59 ± 0.96</td>
<td>4.23 ± 1.04</td>
<td>2.03 ± 0.96</td>
<td>4.57 ± 1.14</td>
<td>3.90 ± 0.50</td>
<td>4.26 ± 0.36</td>
<td>3.83 ± 0.42</td>
<td>6.78 ± 0.69</td>
</tr>
</tbody>
</table>
Other Factors

• PK/PD of the mAb at the dose used
  • Sotrovimab (500mg IV) serum concentrations
    • geometric mean C (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
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
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.
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
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
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.
Two initial questions

• Does he warrant treatment for COVID-19?
• Where does CCP fit into the therapeutic lineup
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
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
### Risks for poor COVID-19 outcomes in people with cancer

Grivas et al, Annals of Oncology 2021

<table>
<thead>
<tr>
<th></th>
<th>COVID-19 severity OR (95% CI)</th>
<th>30-day mortality OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, per decade</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age &lt;40 years</td>
<td>0.91 (0.72-1.15)</td>
<td>0.58 (0.35-0.97)</td>
</tr>
<tr>
<td>Age &gt;40 years</td>
<td>1.38 (1.31-1.45)</td>
<td>1.75 (1.59-1.93)</td>
</tr>
<tr>
<td><strong>Sex, male versus female</strong></td>
<td>1.47 (1.31-1.65)</td>
<td>1.46 (1.20-1.77)</td>
</tr>
<tr>
<td><strong>Race and ethnicity, versus non-Hispanic white</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic black</td>
<td>1.46 (1.27-1.68)</td>
<td>1.38 (1.09-1.75)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1.38 (1.16-1.64)</td>
<td>1.31 (0.96-1.80)</td>
</tr>
<tr>
<td>Other</td>
<td>1.27 (1.05-1.53)</td>
<td>0.97 (0.70-1.36)</td>
</tr>
<tr>
<td><strong>Type of malignancy, versus solid tumor</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematological neoplasm</td>
<td>1.70 (1.46-1.99)</td>
<td>1.44 (1.10-1.87)</td>
</tr>
<tr>
<td>Multiple**</td>
<td>1.21 (1.01-1.44)</td>
<td>1.30 (1.00-1.70)</td>
</tr>
<tr>
<td><strong>Cancer status, versus remission or no evidence of disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active and responding</td>
<td>0.84 (0.67-1.04)</td>
<td>0.79 (0.52-1.18)</td>
</tr>
<tr>
<td>Active and stable</td>
<td>0.97 (0.81-1.16)</td>
<td>1.06 (0.77-1.44)</td>
</tr>
<tr>
<td>Active and progressing</td>
<td>2.19 (1.80-2.67)</td>
<td>2.88 (2.13-3.90)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1.93 (1.55-2.41)</td>
<td>2.19 (1.56-3.07)</td>
</tr>
<tr>
<td><strong>Modality of active anticancer therapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cytotoxic chemotherapy, yes versus no</td>
<td>1.28 (1.04-1.58)</td>
<td>1.61 (1.15-2.24)</td>
</tr>
<tr>
<td>Immunotherapy, yes versus no</td>
<td>0.86 (0.64-1.16)</td>
<td>0.91 (0.56-1.47)</td>
</tr>
<tr>
<td>Targeted therapy, yes versus no</td>
<td>1.09 (0.87-1.36)</td>
<td>0.90 (0.63-1.31)</td>
</tr>
<tr>
<td>Endocrine therapy, yes versus no</td>
<td>0.79 (0.61-1.03)</td>
<td>0.68 (0.43-1.09)</td>
</tr>
<tr>
<td>Locoregional therapy, yes versus no</td>
<td>1.18 (0.93-1.50)</td>
<td>0.96 (0.65-1.42)</td>
</tr>
<tr>
<td>Other, yes versus no</td>
<td>0.97 (0.47-2.00)</td>
<td>1.31 (0.44-3.94)</td>
</tr>
</tbody>
</table>
Seroconversion in immune compromised patients (after 2 doses of vaccine)

<table>
<thead>
<tr>
<th>Condition</th>
<th>RR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organ transplant</td>
<td>0.39</td>
<td>(0.32 to 0.46)</td>
</tr>
<tr>
<td>Heme malignancy</td>
<td>0.63</td>
<td>(0.57 to 0.69)</td>
</tr>
<tr>
<td>Immune disease</td>
<td>0.75</td>
<td>(0.69 to 0.82)</td>
</tr>
<tr>
<td>Solid tumor cancer</td>
<td>0.90</td>
<td>(0.88 to 0.93)</td>
</tr>
<tr>
<td>HIV</td>
<td>1.00</td>
<td>(0.98 to 1.01)</td>
</tr>
</tbody>
</table>

Lee et al BMJ. 2022
### Outpatient options authorized for treatment of COVID-19

<table>
<thead>
<tr>
<th>Medication</th>
<th>Route</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>mAb</td>
<td>IV/IM/SQ</td>
<td>Potential for resistant variants</td>
</tr>
<tr>
<td>Nirmatrelvir and ritonavir</td>
<td>PO</td>
<td>Drug interactions with ritonavir</td>
</tr>
<tr>
<td>Molnupiravir</td>
<td>PO</td>
<td>Efficacy questions and fetal harm</td>
</tr>
<tr>
<td>Remdesivir</td>
<td>IV</td>
<td>Need for 3 days of IV</td>
</tr>
<tr>
<td>Convalescent plasma</td>
<td>IV</td>
<td>Blood product</td>
</tr>
</tbody>
</table>
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.
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.

Convalescent plasma contains antibodies that neutralize SARS-CoV-2

Klein et al. JCI 2020
Timing, timing, timing

Cevik M et al *BMJ* 2020
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

![Graph showing overall survival probability over time for recipients and non-recipients of convalescent plasma. Log-rank test P < .001.]

<table>
<thead>
<tr>
<th>Variable</th>
<th>HR (95% CI) for death within 30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall population</td>
<td></td>
</tr>
<tr>
<td>No. of events/No. of patients at risk (%)</td>
<td>223/966 (23.1)</td>
</tr>
<tr>
<td>Convalescent plasma</td>
<td>19/143 (13.3)</td>
</tr>
<tr>
<td>No convalescent plasma</td>
<td>204/823 (24.8)</td>
</tr>
<tr>
<td>Crude analysisa</td>
<td>0.47 (0.30-0.76)</td>
</tr>
<tr>
<td>Multivariable analysisb</td>
<td>0.60 (0.37-0.97)</td>
</tr>
<tr>
<td>Propensity score matchingc</td>
<td>0.52 (0.29-0.92)</td>
</tr>
</tbody>
</table>

Thompson, MA et al JAMA Oncol. 2021
Use of convalescent plasma in COVID-19 patients with immunosuppression

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

Change on the WHO Clinical Progression Scale

\[
R^2 = 0.54, \quad p = 0.003
\]
Patients recently treated for B-lymphoid malignancies show increased risk of severe COVID-19

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Multivariable AOR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study populations (ref = Patients with nonrecently treated B-lymphoid malignancies)</strong></td>
<td></td>
</tr>
<tr>
<td>Nonrecently treated control population</td>
<td>1.16 (0.90-1.49)</td>
</tr>
<tr>
<td>Recently treated control population</td>
<td>0.75 (0.61-0.93)</td>
</tr>
<tr>
<td>Patients recently treated for B-lymphoid malignancies</td>
<td>2.30 (1.58-3.36)</td>
</tr>
</tbody>
</table>

**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)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Multivariable AOR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study populations (ref = Patients with nonrecently treated B-lymphoid malignancies)</strong></td>
<td></td>
</tr>
<tr>
<td>Nonrecently treated control population</td>
<td>0.82 (0.61-1.10)</td>
</tr>
<tr>
<td>Recently treated control population</td>
<td>0.92 (0.63-1.34)</td>
</tr>
<tr>
<td>Patients recently treated for B-lymphoid malignancies</td>
<td>1.34 (0.85-2.11)</td>
</tr>
</tbody>
</table>
## What is high titer?

<table>
<thead>
<tr>
<th>Manufacturer (listed alphabetically)</th>
<th>Assay</th>
<th>Previous Qualifying Result</th>
<th>Revised Qualifying Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott</td>
<td>AdviseDx SARS-CoV-2 IgG II (ARCHITECT and Alinity i)</td>
<td>≥ 840 AU/ml</td>
<td>≥ 1280 AU/ml</td>
</tr>
<tr>
<td>Diasorin</td>
<td>LIAISON SARS-CoV-2 TrimericS IgG</td>
<td>≥ 52 AU/mL</td>
<td>≥ 87 AU/mL</td>
</tr>
<tr>
<td>GenScript</td>
<td>cPass SARS-CoV-2 Neutralization Antibody Detection Kit</td>
<td>Inhibition ≥ 68%</td>
<td>Inhibition ≥ 80%</td>
</tr>
<tr>
<td>Kantaro</td>
<td>COVID-SeroKlr, Kantaro Semi-Quantitative SARS-CoV-2 IgG Antibody Kit</td>
<td>Spike ELISA &gt; 47 AU/mL</td>
<td>Spike ELISA &gt; 69 AU/mL</td>
</tr>
<tr>
<td>Ortho</td>
<td>VITROS Anti-SARS-CoV-2 IgG Quantitative Reagent Pack</td>
<td>N/A</td>
<td>&gt;200 BAU/mL</td>
</tr>
<tr>
<td>Roche</td>
<td>Elecsys Anti-SARS-CoV-2 S</td>
<td>≥ 132 U/mL</td>
<td>&gt;210 U/mL</td>
</tr>
</tbody>
</table>

[https://www.fda.gov/media/155159/download](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
Contact information

- Email: sshoham1@jhmi.edu
- Twitter: @ShohamTxID
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
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)
ACTT-2- Baricitinib + Remdesivir vs. Baricitinib

A Overall

- RDV + Baricitinib: 7 days [95% CI, 6-8]
- RDV + Placebo: 8 days [95% CI, 7-9]

RR = 1.16 [95% CI = 1.01-1.32]

### Ordinal scale severity

<table>
<thead>
<tr>
<th>Severity</th>
<th>Days</th>
<th>RR for recovery (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td></td>
<td>0.88 (0.63–1.23)</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>1.17 (0.98–1.39)</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>1.51 (1.10–2.08)</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td>1.08 (0.59–1.97)</td>
</tr>
</tbody>
</table>

- 4: Hospitalized requiring care, no O₂
- 5: Hospitalized, requiring O₂
- 6: Non-invasive ventilation or high-flow O₂
- 7: Mechanical ventilation or ECMO

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
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

COV-BARRIER-Subgroups

<table>
<thead>
<tr>
<th></th>
<th>Baricitinib group</th>
<th>Placebo group</th>
<th>Hazard ratio (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NIAID-OS score at baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>1/89 (1%)</td>
<td>4/97 (4%)</td>
<td>0.24 (0.00–2.18)</td>
<td>0.23</td>
</tr>
<tr>
<td>5</td>
<td>29/490 (6%)</td>
<td>41/472 (9%)</td>
<td>0.72 (0.45–1.16)</td>
<td>0.11</td>
</tr>
<tr>
<td>6</td>
<td>32/183 (17%)</td>
<td>55/187 (29%)</td>
<td>0.52 (0.33–0.80)</td>
<td>0.0065</td>
</tr>
<tr>
<td><strong>Systemic corticosteroid use at baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>57/612 (9%)</td>
<td>82/592 (14%)</td>
<td>0.63 (0.45–0.89)</td>
<td>0.017</td>
</tr>
<tr>
<td>No</td>
<td>5/150 (3%)</td>
<td>18/164 (11%)</td>
<td>0.28 (0.10–0.77)</td>
<td>0.011</td>
</tr>
<tr>
<td><strong>Remdesivir use at baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12/140 (9%)</td>
<td>16/147 (11%)</td>
<td>0.81 (0.38–1.73)</td>
<td>0.60</td>
</tr>
<tr>
<td>No</td>
<td>50/622 (8%)</td>
<td>84/609 (14%)</td>
<td>0.52 (0.36–0.74)</td>
<td>0.0014</td>
</tr>
</tbody>
</table>
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
• 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

https://www.recoverytrial.net/results
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%)

Mortality

Baricitinib 12%
Usual care 14%

RR 0.87 (0.77–0.98)
p=0.026

Number at risk

<table>
<thead>
<tr>
<th></th>
<th>Baricitinib</th>
<th>Usual care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>4148</td>
<td>4008</td>
</tr>
<tr>
<td>7</td>
<td>3940</td>
<td>3787</td>
</tr>
<tr>
<td>14</td>
<td>3775</td>
<td>3610</td>
</tr>
<tr>
<td>21</td>
<td>3668</td>
<td>3497</td>
</tr>
<tr>
<td>28</td>
<td>3605</td>
<td>3438</td>
</tr>
</tbody>
</table>

RECOVERY group. medRxiv preprint doi: https://doi.org/10.1101/2022.03.02.22271623;
# RECOVERY - Results

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

<table>
<thead>
<tr>
<th>Respiratory support at randomisation ($\chi^2_1 = 0.9; p=0.33$)</th>
<th>Baricitinib</th>
<th>Usual care</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>15/228 (7%)</td>
<td>19/237 (8%)</td>
<td>0.78 (0.39–1.53)</td>
</tr>
<tr>
<td>Simple oxygen</td>
<td>256/2770 (9%)</td>
<td>253/2743 (9%)</td>
<td>0.94 (0.79–1.12)</td>
</tr>
<tr>
<td>Non invasive ventilation</td>
<td>204/1016 (20%)</td>
<td>230/911 (25%)</td>
<td>0.75 (0.62–0.90)</td>
</tr>
<tr>
<td>Invasive mechanical ventilation</td>
<td>38/134 (28%)</td>
<td>44/117 (38%)</td>
<td>0.90 (0.58–1.39)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Use of corticosteroids ($\chi^2_1 = 0.7; p=0.41$)</th>
<th>Baricitinib</th>
<th>Usual care</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>487/3962 (12%)</td>
<td>523/3809 (14%)</td>
<td>0.86 (0.76–0.97)</td>
</tr>
<tr>
<td>No</td>
<td>25/183 (14%)</td>
<td>22/197 (11%)</td>
<td>1.09 (0.62–1.92)</td>
</tr>
<tr>
<td>All participants</td>
<td>513/4148 (12%)</td>
<td>546/4008 (14%)</td>
<td>0.87 (0.77–0.98) p=0.026</td>
</tr>
</tbody>
</table>
RECOVERY- Results

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

<table>
<thead>
<tr>
<th>Baseline CRP ( \chi^2 ) 0.0; p=0.93</th>
<th>Baricitinib</th>
<th>Usual care</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 60 mg/L</td>
<td>170/1465 (12%)</td>
<td>172/1358 (13%)</td>
<td>0.87 (0.70–1.07)</td>
</tr>
<tr>
<td>≥ 60 &lt;120 mg/L</td>
<td>164/1220 (13%)</td>
<td>174/1259 (14%)</td>
<td>0.92 (0.74–1.14)</td>
</tr>
<tr>
<td>≥ 120 mg/L</td>
<td>173/1405 (12%)</td>
<td>192/1347 (14%)</td>
<td>0.86 (0.70–1.05)</td>
</tr>
</tbody>
</table>

Use of tocilizumab \( \chi^2 = 1.29; p=0.53 \)

<table>
<thead>
<tr>
<th>Use</th>
<th>Baricitinib</th>
<th>Usual care</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>131/951 (14%)</td>
<td>153/921 (17%)</td>
<td>0.79 (0.63–1.00)</td>
</tr>
<tr>
<td>Within the next 24 hours</td>
<td>51/391 (13%)</td>
<td>61/365 (17%)</td>
<td>0.81 (0.56–1.18)</td>
</tr>
<tr>
<td>No</td>
<td>331/2806 (12%)</td>
<td>332/2722 (12%)</td>
<td>0.92 (0.79–1.07)</td>
</tr>
</tbody>
</table>

Use of remdesivir \( \chi^2 = 2.4; p=0.12 \)

<table>
<thead>
<tr>
<th>Use</th>
<th>Baricitinib</th>
<th>Usual care</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>84/878 (10%)</td>
<td>100/789 (13%)</td>
<td>0.71 (0.53–0.95)</td>
</tr>
<tr>
<td>No</td>
<td>429/3270 (13%)</td>
<td>446/3219 (14%)</td>
<td>0.91 (0.80–1.04)</td>
</tr>
</tbody>
</table>

All participants | 513/4148 (12%) | 546/4008 (14%) | 0.87 (0.77–0.98) |

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

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

<table>
<thead>
<tr>
<th></th>
<th>Deaths / Patients randomised (%)</th>
<th>Observed–Expected</th>
<th>Ratio of death rates, RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>JAK inhibitor</td>
<td>Control</td>
<td>(O−E)*</td>
</tr>
<tr>
<td>Murugesan***</td>
<td>0/50 (0%)</td>
<td>0/50 (0%)</td>
<td>0.0</td>
</tr>
<tr>
<td>Cao et al.***</td>
<td>0/20 (0%)</td>
<td>3/21 (14%)</td>
<td>−1.5</td>
</tr>
<tr>
<td>RUXCOVID***</td>
<td>9/287 (3%)</td>
<td>(3/145) x2** (2%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Guimarães et al.***</td>
<td>4/144 (3%)</td>
<td>8/145 (6%)</td>
<td>−2.0</td>
</tr>
<tr>
<td>COV–BARRIER (critically ill)</td>
<td>20/51 (39%)</td>
<td>29/50 (58%)</td>
<td>−4.7</td>
</tr>
<tr>
<td>RUXCOVID–DEVENT***</td>
<td>90/164 (55%)</td>
<td>(36/47) x4** (77%)</td>
<td>−7.9</td>
</tr>
<tr>
<td>ACTTT2</td>
<td>24/515 (5%)</td>
<td>37/518 (7%)</td>
<td>−6.4</td>
</tr>
<tr>
<td>COV–BARRIER</td>
<td>62/764 (8%)</td>
<td>100/761 (13%)</td>
<td>−19.2</td>
</tr>
<tr>
<td><strong>Subtotal: 8 trials</strong></td>
<td><strong>209/1995 (10%)</strong></td>
<td><strong>327/2023 (16%)</strong></td>
<td><strong>−40.7</strong></td>
</tr>
<tr>
<td>RECOVERY</td>
<td>513/4148 (12%)</td>
<td>546/4008 (14%)</td>
<td>−36.2</td>
</tr>
<tr>
<td>All trials</td>
<td>722/6143 (12%)</td>
<td>873/6031 (14%)</td>
<td>−76.9</td>
</tr>
</tbody>
</table>

Heterogeneity between RECOVERY and previous trials: $\chi^2=10.3$ (p=0.001)
Summary

• Baricitinib reduces mortality in patients with severe COVID-19
• Main role: Use in combination with glucocorticoids in patients requiring support >0₂
• Effect maintained regardless of remdesivir or tocilizumab use
• Remaining questions
  • Generalizability to other JAK inhibitors?
  • Best use vis-à-vis tocilizumab

Dosing Adjustments

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Age ≥9</th>
<th>Ages 2-8</th>
</tr>
</thead>
<tbody>
<tr>
<td>eGFR &gt;60</td>
<td>4 mg daily</td>
<td>2 mg daily</td>
</tr>
<tr>
<td>eGFR 30-59</td>
<td>2 mg daily</td>
<td>1 mg daily</td>
</tr>
<tr>
<td>eGFR 15-29</td>
<td>1 mg daily</td>
<td>Not recommended</td>
</tr>
<tr>
<td>eGFR &lt;15</td>
<td>Not recommended</td>
<td>Not recommended</td>
</tr>
<tr>
<td>ALC &lt;200</td>
<td>Consider holding until ≥200</td>
<td></td>
</tr>
<tr>
<td>ANC &lt;500</td>
<td>Consider holding until ≥500</td>
<td></td>
</tr>
</tbody>
</table>

Key adverse effects: thromboembolism, infection
Outpatient Treatment Supply & Distribution Update

Derek Eisnor, MD and Meg Sullivan, MD, MPH
COVID-19 Therapeutics Allocation & Distribution Update

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

These therapies require a prescription by a licensed and authorized provider. Patients should coordinate with their healthcare provider prior to contacting a location to receive these therapies.
### Summary of COVID-19 Preventative Agents & Therapeutics

<table>
<thead>
<tr>
<th>No Illness</th>
<th>Exposed</th>
<th>Mild to Moderate Symptoms</th>
<th>Hospital Admission</th>
<th>ICU Admission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per CDC Close Contact Criteria</td>
<td>Not hospitalized, with limitations</td>
<td>HOSP. no act. medical problems</td>
<td>Hospitalized, not on oxygen</td>
<td>Hospitalized, high flow oxygen/ non-invasive ventilation</td>
</tr>
</tbody>
</table>

#### Oral Antivirals
- **Paxlovid™** (Pfizer)
- *molnupiravir* (Merck)

#### Monoclonal Antibodies for Treatment
- casirivimab + imdevimab (RGN)**
- bamlanivimab + etesevimab (Lilly)**

#### Monoclonal Antibodies for PrEP
- tixagevimab + cilgavimab (AZ)
- casirivimab + imdevimab (RGN)**
- bamlanivimab + etesevimab (Lilly)**

#### COVID-19 VACCINES
- tixagevimab + cilgavimab (AZ)

#### Monoclonal Antibodies for PEP
- casirivimab + imdevimab (RGN)**
- bamlanivimab + etesevimab (Lilly)**

#### Therapeutic Management of Nonhospitalized Adults With COVID-19
- remdesivir
- 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/)  
## Updated EUA: EVUSHELD

### Updated EVUSHELD Dosing Requirements (tixagevimab and cilgavimab)

<table>
<thead>
<tr>
<th>Initial Dosage and Administration</th>
<th>Repeat Dosing for Patients who Previously Received 150 mg tixagevimab and 150 mg of cilgavimab</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 mg of tixagevimab and 300 mg of cilgavimab administered as two separate consecutive intramuscular injections.</td>
<td>150 mg of tixagevimab and 150 mg of cilgavimab administered as two separate intramuscular injections as soon as possible.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Onset of symptoms</th>
<th>Clinical visit and diagnostic test</th>
<th>Confirmed positive test</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 3 days post symptom onset</td>
<td>≤ 24 hours post diagnostic test</td>
<td>ASAP post positive test result</td>
<td></td>
</tr>
</tbody>
</table>

Treatment required within 5 to 10 days of symptom onset

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

Planning required for "Test and treat" models

Early administration of treatment needs fast testing turn-around and patient scheduling
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.
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, including:
  - 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

Self-Testing

CDC has updated isolation and quarantine recommendations for the public, and is revising the CDC website to reflect these changes. These recommendations do not apply to healthcare personnel and do not supersede state, local, tribal, or territorial laws, rules, and regulations.

Free At-Home COVID-19 Tests: Circle 4 free tests now so you have them when you need them.

If you test positive for COVID-19 and have one or more health conditions that increase your risk of becoming very sick, treatment may be available. Contact a health professional right away after a positive test to determine if you may be eligible, even if your symptoms are mild right now. Don't delay. Treatment must be started within the first few days to be effective.


https://www.covidtests.gov/

What if you test Positive?

A positive at-home test result means that the test found the virus, and you very likely have COVID-19.

If you test positive, follow the latest CDC guidance for isolation.

What if you test Negative?

A negative at-home test result means that the test did not find the virus, and you may have a lower risk of spreading COVID-19 to others. Check your test kit’s instructions for specific next steps. If you test negative, you should test again within a few days with at least 24 hours between tests.

If you test negative, follow the latest CDC guidance for self-testing.

https://www.cdc.gov
Increase COVID-19 Test to Treat Health Literacy

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](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=SEVPMzIQWDQyYW02KzcxVU01THluQT09](https://hhsasproea.zoomgov.com/j/1617766329?pwd=SEVPMzIQWDQyYW02KzcxVU01THluQT09)

- **Health Partners Ordering Portal (HPOP) Office Hours**
  - Thursdays (4:00-5:00PM ET)
  - [https://hhsasproea.zoomgov.com/j/1603047233?pwd=V3R4OG1LSdHZ2i0Y0NhZkUxVlxdz09](https://hhsasproea.zoomgov.com/j/1603047233?pwd=V3R4OG1LSdHZ2i0Y0NhZkUxVlxdz09)

- **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=NjFMcnJQOUEnSFhtRFFtaWltejYzZz09](https://hhsasproea.zoomgov.com/j/1617536991?pwd=NjFMcnJQOUEnSFhtRFFtaWltejYzZz09)

Questions or need the Zoom link for identified engagements?
Email us at [COVID19Therapeutics@hhs.gov](mailto: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

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
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 at no cost at a location. These “One Step 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 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) has already distributed COVID-19 treatments, including oral antivirals, to states and territories for free on a weekly basis. All qualified health 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 treatments. 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 therapies 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 and early 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 FDA under the beginning of the week of March 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, receive an appropriate prescription from a qualified health care provider, and have their prescription filled at no cost in one location. Individuals who receive COVID-19 testing results at home tests or another testing site can also go to 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 expand 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 through 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 not replace 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 replace existing program supply channels, but rather to offer additional options for states to ensure 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 healthcare providers available to provide timely and thorough assessment and discussion relevant to oral antiviral treatment options, 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 get test to the prescription when necessary.

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 1, 2023

asp.hhs.gov

Unclassified / For Public Distribution
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.

https://aspr.hhs.gov/TestToTreat/Pages/default.aspx
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
  Transmission of SARS-CoV-2 Omicron VOC subvariants BA.1 and BA.2: Evidence from Danish Households:
• Slides 17 and 18 - https://www.biorxiv.org/content/10.1101/2022.02.07.479306v1.full.pdf

Dr Shoham
• Slide 51 - https://www.fda.gov/media/155159/download

Jason Gallagher
• Slide 58 - . https://doi.org/10.1172/JCI141772
• 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 76** - [https://www.fda.gov/media/154701/download](https://www.fda.gov/media/154701/download)

  - [https://www.covidtests.gov](https://www.covidtests.gov)


- **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=dGRwZTBETjzWFliQW83TXZ5OFVnQT09](https://hhsasproea.zoomgov.com/j/1604329034?pwd=dGRwZTBETjzWFliQW83TXZ5OFVnQT09)
    - Stakeholder Call: National Health Care and Medical Orgs and Associations
      - Wednesdays (3:15-4:15PM ET) [https://hhsasproea.zoomgov.com/j/1617766329?pwd=SEVPMzI2WDQyYWo2KzcxVU01THlyUQT09](https://hhsasproea.zoomgov.com/j/1617766329?pwd=SEVPMzI2WDQyYWo2KzcxVU01THlyUQT09)
    - Health Partners Ordering Portal (HPOP) Office Hours
      - Thursdays (4:00-5:00PM ET) [https://hhsasproea.zoomgov.com/j/1603047233?pwd=V3R4OG1LSDhUZ210Y0NhZkUxVIlxOJs09](https://hhsasproea.zoomgov.com/j/1603047233?pwd=V3R4OG1LSDhUZ210Y0NhZkUxVIlxOJs09)
      - Every other Friday (12:00-1:00PM ET); Next meeting March 18 [https://hhsasproea.zoomgov.com/j/1617536991?pwd=NjFMcnJOUENuSFhtRFFtaW1eJyzZz09](https://hhsasproea.zoomgov.com/j/1617536991?pwd=NjFMcnJOUENuSFhtRFFtaW1eJyzZz09)

- **Slide 85** - Email us at COVID19Therapeutics@hhs.gov.


- **Slide 90** - [https://aspr.hhs.gov/TestToTreat/Pages/default.aspx](https://aspr.hhs.gov/TestToTreat/Pages/default.aspx)

Program Links:

- This webinar is being recorded and can be found with the slides online at https://www.idsociety.org/cliniciancalls
- EIN https://ein.idsociety.org/members/sign_up/.

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

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

cdc.gov/coronavirus
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](http://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](http://www.idsociety.org/cliniciancalls)

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