CDC/IDSA COVID-19 Clinician Call

May 7, 2022

Welcome & Introductions

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

- 88th in a series of calls, initiated in 2020 by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19.
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.

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

Update: New Resources to Manage Paxlovid Drug Interactions

Carlos del Rio, MD, FIDSA
President-Elect, IDSA
Distinguished Professor of Medicine, Division of Infectious Diseases
Emory University School of Medicine
Professor of Epidemiology and Global Health
Rollins School of Public Health of Emory University

Antibody Therapy & Second Boosters: Updates and Perspectives on Protecting Our Most Vulnerable

Prevention of COVID-19 in Immunocompromised Individuals: Focus on Evusheld

Clinical Considerations & Patient Scenarios

Camille Kotton, MD, FIDSA, FAST
Clinical Director
Transplant and Immunocompromised Host Infectious Diseases
Massachusetts General Hospital

Update on Distribution & Administration

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

Operationalizing Evusheld: Keys to Success

Swana K. Thomas, PharmD, MPH
Clinical Pharmacist, Ambulatory Care
Geisinger Commonwealth School of Medicine

Monoclonal Antibody Therapy for Treatment: What are the Options?

Raymund R. Razonable, MD, FIDSA
Professor of Medicine and Vice Chair, Infectious Diseases
Mayo Clinic

Second Boosters: Who Will Benefit?

Updates and Clinical Considerations From the April 20 ACIP Meeting

Elisha Hall, PhD, RD
Lead, Clinical Guidelines, Vaccine Coordination Unit
U.S. Centers for Disease Control and Prevention

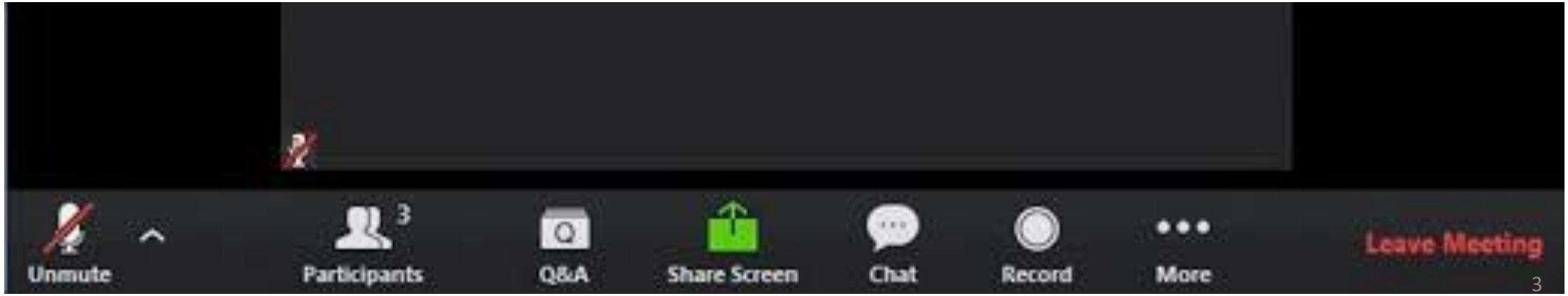
Perspectives on the Immunocompromised And People Over 50

William Schaffner, MD, FIDSA
Professor of Preventative Medicine, Department of Health Policy
Professor of Medicine, Division of Infectious Diseases
Vanderbilt University School of Medicine

Q&A/Discussion (Full Panel)

Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button



Update: New Resources to Manage Paxlovid Drug Interactions

Carlos del Rio, MD, FIDSA

New Resources to Manage Paxlovid Drug Interactions

Carlos del Rio, MD

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Overview

Overview of COVID-19

SARS-CoV-2 Testing

Prevention of SARS-CoV-2

Clinical Spectrum

Prioritization of Therapeutics

Guideline PDFs

Section Only (PDF | 278 KB)

Full Guideline (PDF | 7 MB)

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Prioritization of Anti-SARS-CoV-2 Therapies for the Treatment and Prevention of COVID-19 When There Are Logistical or Supply Constraints

Last Updated: March 24, 2022

The COVID-19 Treatment Guidelines Panel (the Panel) has recommended several therapeutic agents for the treatment and prevention of SARS-CoV-2 infection in individuals who are at high risk for progression to severe COVID-19. These anti-SARS-CoV-2 therapeutics are of greatest proven clinical benefit for nonhospitalized patients who have risk factors for progression to severe COVID-19. The risks for progression are substantially higher for those who are not vaccinated or who are vaccinated but not expected to mount an adequate immune response to the vaccine.

The Food and Drug Administration's Emergency Use Authorizations provide a broad list of medical conditions or other factors as criteria for use of anti-SARS-CoV-2 agents as treatment or pre-exposure prophylaxis (PrEP). However, at times throughout the pandemic, increased cases of COVID-19 and the emergence of new variants of concern have resulted in logistical or supply constraints that made it impossible to offer the available therapy to all eligible patients. In those situations, prioritization of therapy for those who would have benefited the most became necessary. The purpose of this section is to provide guidance on which individuals might receive the greatest benefit from anti-SARS-CoV-2 therapeutics for treatment or prevention.

ASPR Office of the Assistant Secretary for Preparedness & Response

Find Locations

Search by therapy and by zip code to find potential locations.

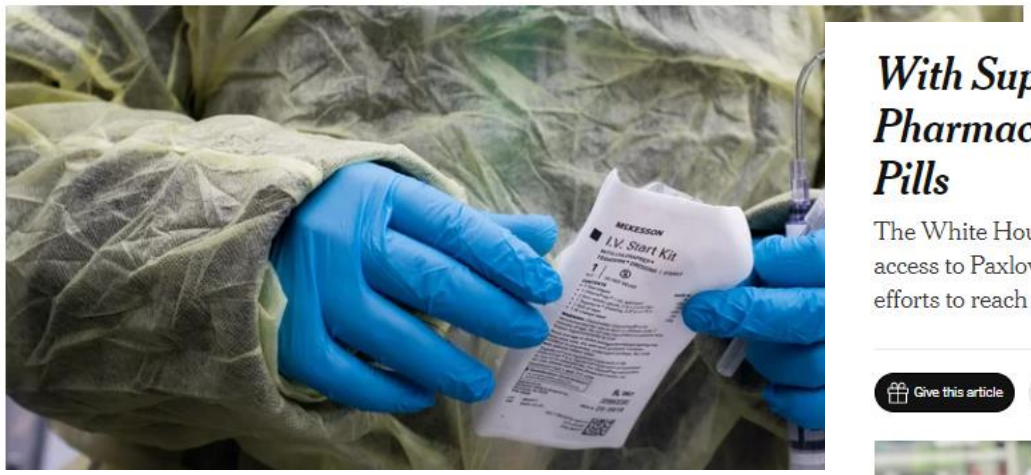
https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/

TREATMENTS

Lifesaving COVID drugs are sitting unused on pharmacy shelves, HHS data shows

March 18, 2022 · 5:00 AM ET

PIEN HUANG



Hundreds are still dying from Covid every day. Why is Paxlovid sitting on shelves?

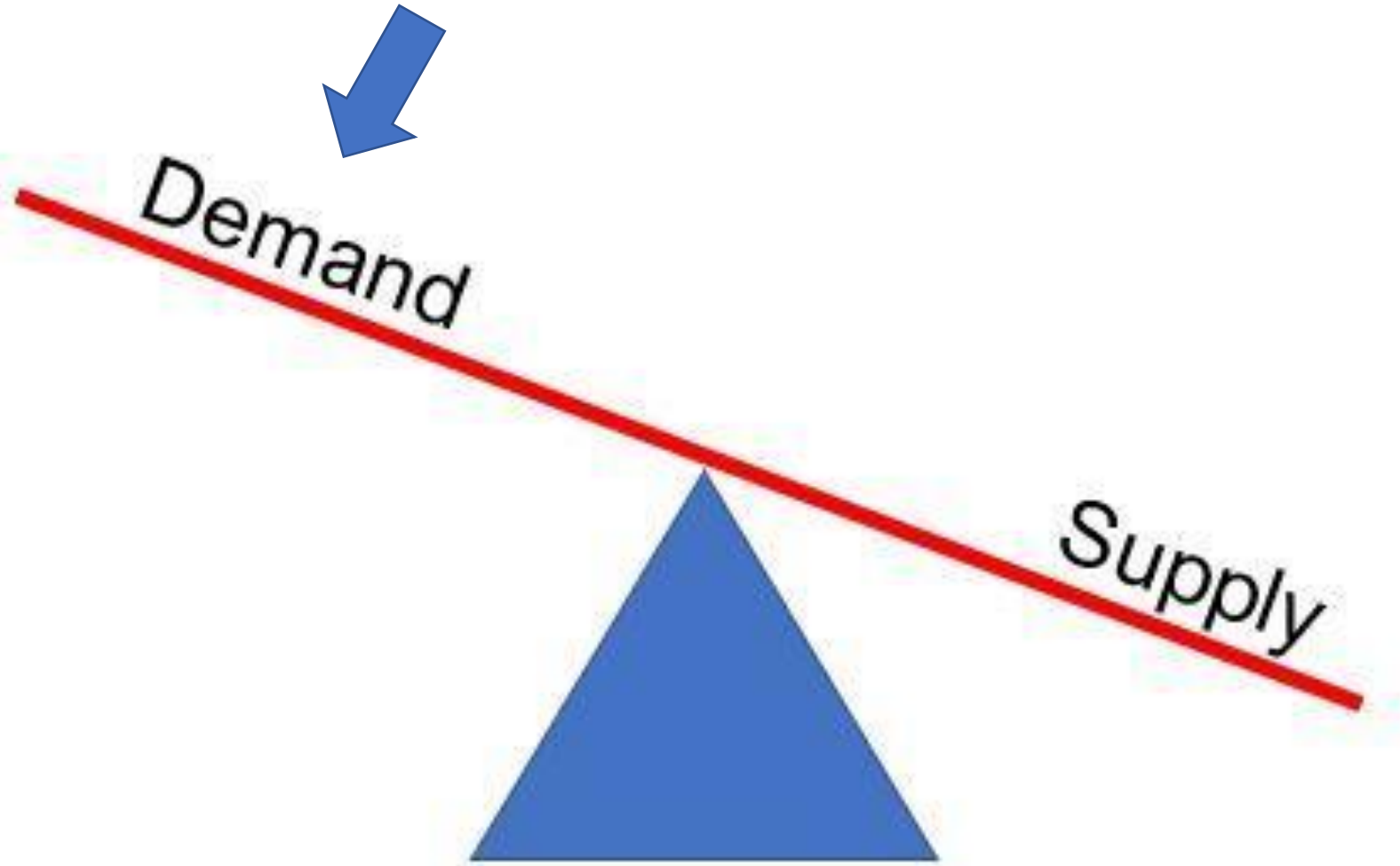
The supply of Pfizer's highly effective antiviral pill has rapidly increased, but many physicians still aren't prescribing it.

With Supply More Abundant, Pharmacies Struggle to Use Up Covid Pills

The White House on Tuesday announced new steps to expand access to Paxlovid, the Covid-19 antiviral pill. But experts say that efforts to reach at-risk Americans remain complex and inefficient.

Give this article

Adeolu Odewale, right, the owner of Demmy's Pharmacy in Greenbelt, Md., had been eager to obtain Paxlovid for his high-risk customers, but so far he has dispensed it to just seven people. Shuran Huang for The New York Times


Demand
Supply

FDA Updates on Paxlovid for Health Care Providers

News & Events for Human Drugs

CDER Conversations

Director's Corner Podcasts

From Our Perspective

Notable Approvals | Drugs

Spotlight on CDER Science

FDA authorized Paxlovid (nirmatrelvir and ritonavir) in December 2021 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) with positive results of direct SARS-CoV-2 viral testing who are also at high risk for progression to severe COVID-19, including hospitalization or death.

Paxlovid is now widely available in community pharmacies. Although the number of COVID-19 hospitalizations has decreased dramatically since early 2022, some high-risk patients are still getting sick enough to require hospital admission, and early treatment with Paxlovid and other available authorized or approved therapeutics could make a difference.

In this CDER Conversation, Dr. John Farley, director of the Office of Infectious Diseases, provides useful information that can help health care providers in decision making regarding Paxlovid, the preferred therapy for the management of non-hospitalized adults with COVID-19, according to the National Institutes of Health COVID Treatment Guidelines.

Content current as of:
05/04/2022

Regulated Product(s)
Drugs

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

This checklist is intended as an aid to support clinical decision making for prescribers. However, use of this checklist is not required to prescribe PAXLOVID under the EUA.

Medical History

- ❑ Positive SARS-CoV-2 test (Confirmation of a positive home rapid SARS-CoV-2 test result with additional direct SARS-CoV-2 viral testing is not required.)
- ❑ Age ≥ 18 years OR ≥ 12 years of age and weighing at least 40 kg
- ❑ Has one or more risk factors for progression to severe COVID-19[1] (Risk factors have changed over time, and additional risk factors [such as being unvaccinated or having not received a booster] could be considered. Healthcare providers should consider the benefit-risk for an individual patient.)
- ❑ Symptoms consistent with mild to moderate COVID-19[2]
- ❑ Symptom onset within 5 days (Prescriber is encouraged to include a note to the pharmacist in the prescription stating: Please fill prescription by [insert date]. This prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.)
- ❑ Not requiring hospitalization due to severe or critical COVID-19 at treatment initiation
- ❑ No known or suspected severe renal impairment (eGFR ≤ 30 mL/min)
  - Note that a dose reduction is required for patients with moderate renal impairment (eGFR ≥30-<60 mL/min); see the Fact Sheet for Healthcare Providers.
  - Prescriber may rely on patient history and access to the patient's health records to make an assessment regarding the likelihood of renal impairment. Providers may consider ordering a serum creatinine or calculating the estimated glomerular filtration rate (eGFR) for certain patients after assessment on a case-by-case basis based on history or exam.
- ❑ No known or suspected severe hepatic impairment (Child-Pugh Class C)
- ❑ No history of clinically significant hypersensitivity reactions [e.g., toxic epidermal necrolysis (TEN) or Stevens-Johnson syndrome] to the active ingredients (nirmatrelvir or ritonavir) or other components of the product

NOTES: _____

https://www.fda.gov/media/158165/download

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

Other Drugs with Established and Other Potentially Significant Drug Interactions with PAXLOVID (listed alphabetically by generic name)

Interaction Codes:

XXX	Coadministration of this drug with PAXLOVID is CONTRAINDICATED. For further information, refer to the Fact Sheet for Healthcare Providers and the individual Prescribing Information for the drug.
***	Coadministration of this drug with PAXLOVID should be avoided and/or holding of this drug, dose adjustment of this drug, or special monitoring is necessary. Consultation with the prescriber of the potentially interacting drug is recommended. For further information, refer to the Health Care Provider Fact Sheet and the individual Prescribing Information for the drug.

Drug	Drug Class	Interaction Code
abemaciclib	Anticancer drug	***
alfuzosin	Alpha 1-adrenoreceptor antagonist	XXX
amiodarone	Antiarrhythmic	XXX
amlodipine	Calcium channel blocker	***
apalutamide	Anticancer drug	XXX
bedaquiline	Antimycobacterial	***
bepridil	Antiarrhythmic	***
betamethasone	Systemic corticosteroid	***
bosentan	Endothelin receptor antagonist	***
budesonide	Systemic corticosteroid	***
bupropion	Antidepressant	***
carbamazepine	Anticonvulsant	XXX
ceritinib	Anticancer drug	***
ciclesonide	Systemic corticosteroid	***
clarithromycin	Anti-infective	***
clozapine	Antipsychotic	XXX
colchicine	Anti-gout	XXX
cyclosporine	Immunosuppressant	***
dabigatran	Anticoagulants	***
dasabuvir	Hepatitis C direct acting antiviral	***
dasatinib	Anticancer drug	***
dexamethasone	Systemic corticosteroid	***

Management of Drug Interactions With Nirmatrelvir/Ritonavir (Paxlovid®): Resource for Clinicians

IDSA Infectious Diseases Society of America

IDSA COVID-19 TREATMENT AND MANAGEMENT GUIDELINE PANEL ON BEHALF OF THE INFECTIOUS DISEASES SOCIETY OF AMERICA

Last Updated: May 6, 2022- *Version 1.1**

Nirmatrelvir/ritonavir has FDA Emergency Use Authorization to treat mild-to-moderate COVID-19 in patients at high risk of progression to severe disease who are ≥12 years of age and weigh ≥40 kg.

In such patients, IDSA guidelines suggest nirmatrelvir/ritonavir be initiated within 5 days of symptom onset. 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 nirmatrelvir/ritonavir. NIH guidelines also suggest nirmatrelvir/ritonavir for nonhospitalized patients with mild-to-moderate COVID-19 who are at high risk of disease progression.

Given coformulation with ritonavir as a pharmacokinetic booster, there is potential for drug interactions. The following steps can be taken to minimize the risk of drug interactions for those who are eligible and would benefit from nirmatrelvir/ritonavir treatment:

1. Obtain a complete list of the patient's current medications, including over-the-counter agents and herbal supplements.
2. Confirm that the patient is taking each medication as prescribed. If the patient is not taking a medication, discontinue the medication from their medication profile.
3. Review the FDA Paxlovid® Healthcare Provider Fact Sheet to Identify any medications that the patient is currently taking that are contraindicated with nirmatrelvir/ritonavir. If the patient is taking a contraindicated medication, prescribe alternative treatment for mild to moderate COVID-19.
4. Review potential drug interactions between nirmatrelvir/ritonavir and the patient's current medications.

   Resources:

   - Liverpool COVID-19 Interactions (covid19-druginteractions.org)
   - Paxlovid® Healthcare Provider Fact Sheet
   - PAXLOVID® Patient Eligibility Screening Checklist Tool for Prescribers (fda.gov)
   - Nirmatrelvir/Ritonavir (Paxlovid®): What Prescribers and Pharmacists Need to Know - Ontario COVID-19 Science Advisory Table (covid19-sciencetable.ca)
5. Advise the patient on dose adjustments, temporary cessation of medication(s), or clinical monitoring that is needed during and after the 5 day nirmatrelvir/ritonavir treatment.
6. If relapse occurs after initial treatment and a second course of treatment is warranted, duration of therapy should be used to guide adjustments to concomitant medications.

Among the top 100 prescribed drugs, **only two have interactions so severe that nirmatrelvir/ritonavir should be avoided altogether: rivaroxaban and salmeterol.**

Concomitant Medication	Nirmatrelvir/ Ritonavir Effect on Drug Level	Possible Effect	Recommendation During Nirmatrelvir/Ritonavir Treatment
Rivaroxaban	↑	Increased bleeding	Avoid nirmatrelvir/ritonavir
Salmeterol	↑	Increased cardiac effects	Avoid nirmatrelvir/ritonavir

The following table contains information on management of commonly prescribed medications that are known to interact with nirmatrelvir/ritonavir. This list was derived from ClinCalc's Top 200 Prescribed Medications in the United States in 2019. Please note:

- Inclusion on this list is not a contraindication to prescribe nirmatrelvir/ritonavir. Rather, additional management considerations may be necessary as shown below.
- If a drug is not on this list, it should still be checked for interactions, as it may be a less commonly prescribed medication that has interactions or is contraindicated.
- Routine lab testing for transaminases or creatinine is not needed, and clinical judgement should be used.

Concomitant Medication	Nirmatrelvir/ Ritonavir Effect on Drug Level	Possible Effect	Recommendation During Nirmatrelvir/Ritonavir Treatment
Alprazolam	↑	Excess sedation	Consider dose reduction, but do not stop if chronic use
Apixaban	↑	Increased bleeding	Dose dependent: • Apixaban 2.5 mg: Avoid nirmatrelvir/ritonavir • Apixaban 5mg or 10 mg: Reduce dose by 50% until 3 days after nirmatrelvir/ritonavir
Bupropion	↓	Decreased effects	No dose adjustment required
Buspirone	↑	Increased side effects	Reduce dose or monitor for side effects
Calcium-channel blockers (amlodipine, nifedipine)	↑	Decreased blood pressure	• Continue if tolerated based on symptoms • Reduce dose if patient has low blood pressure
Calcium-channel blockers (diltiazem, verapamil)	↑	Decreased blood pressure	• Continue if tolerated • Reduce dose if patient has low blood pressure or bradycardia
Clonazepam	↑	Excess sedation	Consider dose-reduction, but do not stop if chronic use

https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/management-of-drug-interactions-with-nirmatrelvirritonavir-paxlovid/

Prevention of COVID-19 in Immunocompromised Individuals: Focus on Evusheld

Clinical Considerations & Patient Scenarios

Camille Kotton, MD, FIDSA, FAST

Prevention of COVID-19 in Immunocompromised Individuals: Focus on Evusheld Clinical Considerations & Patient Scenarios

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Past President, Infectious Disease Section, The Transplantation Society
Councilor, The Transplantation Society
Voting Member, CDC Advisory Committee on Immunization Practice

MGH 1811
MASSACHUSETTS GENERAL HOSPITAL
TRANSPLANT CENTER

Camille Nelson Kotton, Disclosures in area of COVID-19

Company	Role	Details
Advisory Committee on Immunization Practice (ACIP) at USA CDC	Voting Member	Vaccine guidelines
Beigene	Consultant, Research	Treatments (zanubrutinib, monoclonal antibodies)
Regeneron	Research	Monoclonal antibodies

Concept: Immunocompromised Patients Likely Need More than Vaccine

Combination of <u>vaccine plus monoclonal antibody</u> may provide better coverage especially for higher risk patients

Annals of Internal Medicine IDEAS AND OPINIONS

Belt and Suspenders: Vaccines and Tixagevimab/Cilgavimab for Prevention of COVID-19 in Immunocompromised Patients

Camille N. Kotton, MD

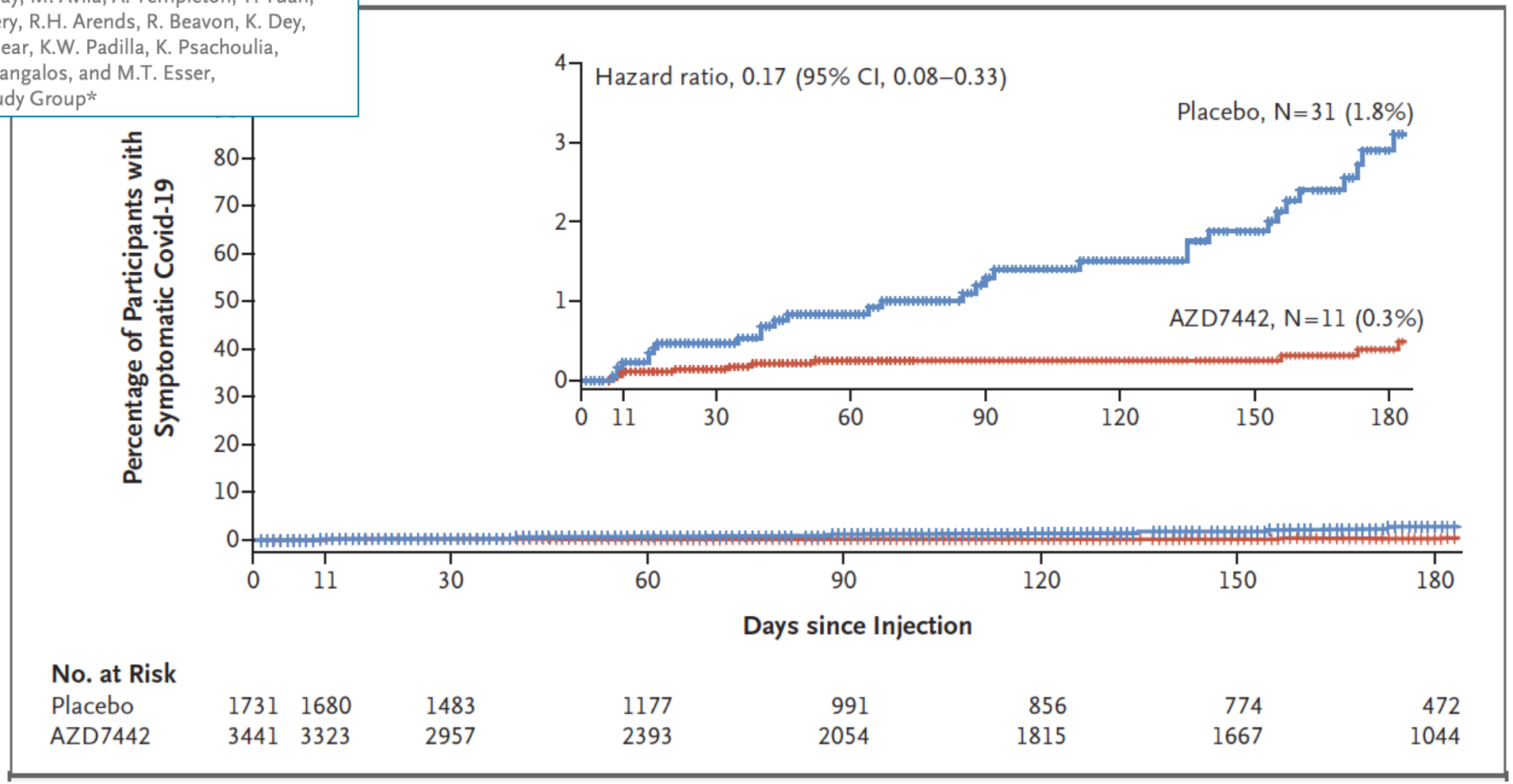
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Intramuscular AZD7442 (Tixagevimab–Cilgavimab) for Prevention of Covid-19

M.J. Levin, A. Ustianowski, S. De Wit, O. Launay, M. Avila, A. Templeton, Y. Yuan, S. Seegobin, A. Ellery, D.J. Levinson, P. Ambery, R.H. Arends, R. Beavon, K. Dey, P. Garbes, E.J. Kelly, G.C.K.W. Koh, K.A. Near, K.W. Padilla, K. Psachoulia, A. Sharbaugh, K. Streicher, M.N. Pangalos, and M.T. Esser, for the PROVENT Study Group*

- Unvaccinated, enrolled Nov 2020-March 2021, monitored 180 days
- Symptomatic Covid-19 occurred in 8 of 3441 participants (0.2%) in the AZD7442 group & 17/1731 participants (1.0%) in placebo
  - relative risk reduction, 77%
- Five cases of severe or critical Covid-19 and two Covid-19–related deaths occurred, all in the placebo group.



NEJM April 20, 2022

Prevention of SARS-CoV-2 Infection (NIH Treatment Guidelines)

Last Updated: April 29, 2022

Summary Recommendations
• The COVID-19 Treatment Guidelines Panel (the Panel) recommends COVID-19 vaccination as soon as possible for everyone who is eligible according to the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices **(AI)**.

• The Panel recommends using **tixagevimab 300 mg plus cilgavimab 300 mg (Evusheld)** administered as 2 consecutive 3-mL intramuscular injections **(BIII)** as SARS-CoV-2 pre-exposure prophylaxis (PrEP) for adults and adolescents (aged ≥12 years and weighing ≥40 kg) who do not have SARS-CoV-2 infection, who have not been recently exposed to an individual with SARS-CoV-2 infection, **AND** who:
  • Are moderately to severely immunocompromised and may have an inadequate immune response to COVID-19 vaccination; *or*
  • Are not able to be fully vaccinated with any available COVID-19 vaccines due to a history of severe adverse reactions to a COVID-19 vaccine or any of its components.

• The Food and Drug Administration Emergency Use Authorization states that individuals who received tixagevimab 150 mg plus cilgavimab 150 mg should be given a second dose as soon as possible. The specific dose of tixagevimab plus cilgavimab that an individual should receive depends on the amount of time that has passed since the first dose was administered:
  • If the initial dose was administered ≤3 months prior, the second dose should be tixagevimab 150 mg plus cilgavimab 150 mg.
  • If the initial dose was administered >3 months prior, the second dose should be tixagevimab 300 mg plus cilgavimab 300 mg.

• **Tixagevimab plus cilgavimab is not a substitute for COVID-19 vaccination and should not be used in unvaccinated individuals for whom COVID-19 vaccination is recommended.** • If supplies of tixagevimab plus cilgavimab are limited, priority for use as PrEP should be given to those who are at the highest risk for severe COVID-19. • The Panel **recommends against** the use of **bamlanivimab plus etesevimab** and **casirivimab plus imdevimab** for post-exposure prophylaxis (PEP), as the Omicron (B.1.1.529) variant and its subvariants, which are not susceptible to these agents, are currently the dominant SARS-CoV-2 variants circulating in the United States **(AIII)**.
Rating of Recommendations: A = Strong; B = Moderate; C = Weak **Rating of Evidence:** I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion

Thus far, no guidance on when to redose after full dose

https://files.covid19treatmentguidelines.nih.gov/guidelines/covid19treatmentguidelines.pdf downloaded 7 May 2022

Populations Included in the Emergency Use Authorization: tixagevimab plus cilgavimab (USA)

Active treatment for solid tumor and hematologic types of cancer

Receipt of solid organ transplant and receiving immunosuppressive therapy

Receipt of chimeric antigen receptor T-cell or hematopoietic stem cell transplant (within 2 y of transplant or receiving immunosuppression therapy)

Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott–Aldrich syndrome)

Advanced or untreated HIV infection (persons with HIV and CD4 cell counts <200 $\times 10^9$ cells/L , history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)

Active treatment with high-dose corticosteroids (i.e., ≥20 mg of prednisone or equivalent per day when administered for ≥2 wk), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents)

https://www.fda.gov/media/154701/download

Patient Prioritization for Pre-Exposure Prophylaxis (National Institutes of Health)

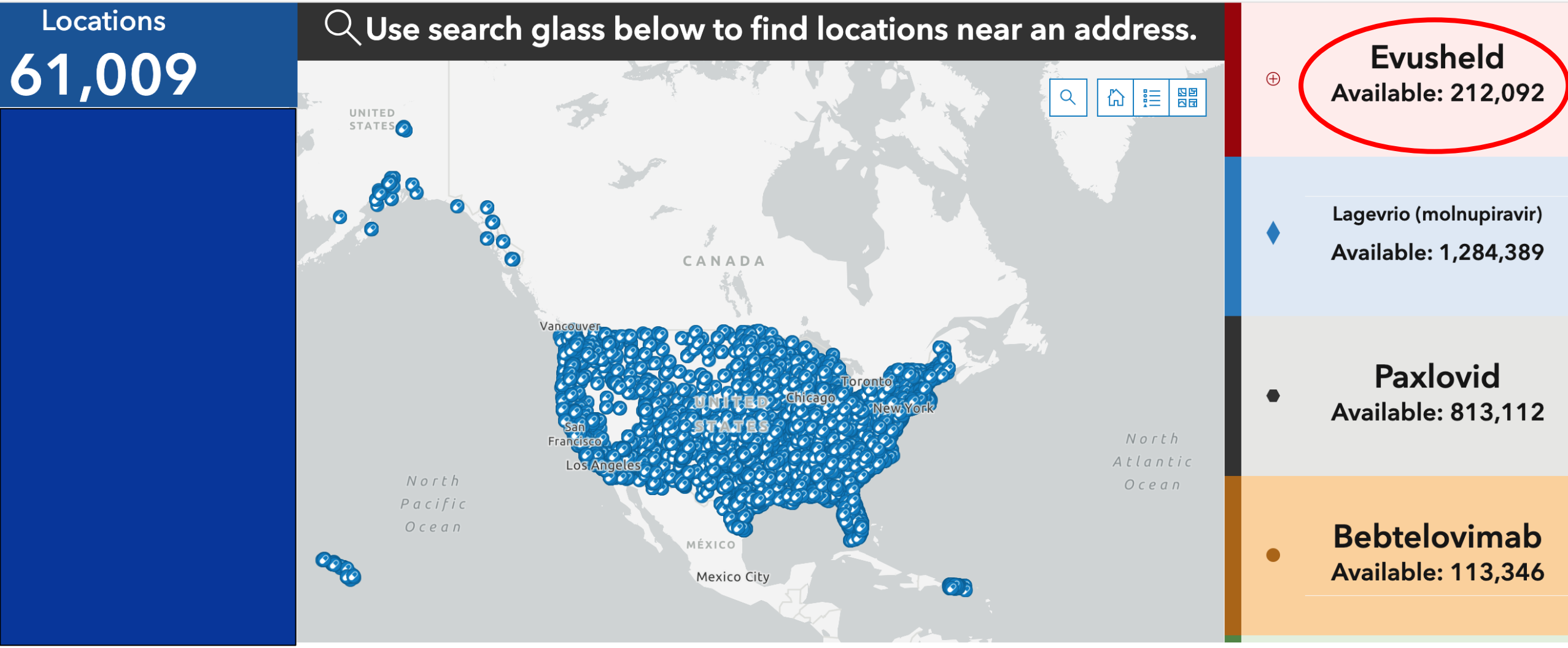
- **Patients who are within 1 year of receiving B-cell depleting therapies**
  - e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab
- **Patients receiving Bruton tyrosine kinase inhibitors**
- **Chimeric antigen receptor T cell recipients**
- **Post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication**
- **Patients with hematologic malignancies who are on active therapy**
- **Lung transplant recipients**
- **Patients who are within 1 year of receiving a solid-organ transplant (other than lung transplant)**
- **Solid-organ transplant recipients w/ recent treatment for acute rejection w/ T or B cell depleting agents**
- **Patients with severe combined immunodeficiencies**
- **Patients with untreated HIV who have a CD4 T lymphocyte cell count <50 cells/mm3**

No recommendation (FDA/CDC) that this be based on antibody titers, nor that those be trended after administration

https://files.covid19treatmentguidelines.nih.gov/guidelines/covid19treatmentguidelines.pdf

ASPR Office of the Assistant Secretary for Preparedness & Response

Rob Relyea @rrelyea (HHS ASPR data healthdata.gov)



https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/
Downloaded 7 May 2022

Contraindications and precautions to COVID-19 vaccination

CDC considers COVID-19 vaccination to be contraindicated, not recommended, or a precaution in the following situations:

Table 4. Contraindications and precautions to COVID-19 vaccination

Medical condition or history	Guidance	Recommended action(s)
History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine	Contraindication	Do not vaccinate with the same type of COVID-19 vaccine (i.e., mRNA or Janssen COVID-19 Vaccine). See Appendix E for actions and additional information.
History of a known diagnosed allergy to a component of the COVID-19 vaccine	Contraindication	
For **the Janssen COVID-19 Vaccine**, TTS following receipt of a previous Janssen COVID-19 Vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors, e.g., AstraZeneca)	Contraindication	Do not vaccinate with Janssen COVID-19 Vaccine. See Safety considerations for Janssen COVID-19 Vaccine for additional information on vaccinating this group with an mRNA COVID-19 vaccine.
For **the Janssen COVID-19 Vaccine**, history of an episode of immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic HIT	Not recommended	Do not vaccinate with Janssen COVID-19 Vaccine. These people should receive an mRNA COVID-19 vaccine.
For the **Janssen COVID-19 Vaccine**, GBS within 6 weeks after receipt of Janssen COVID-19 Vaccine	Not recommended	Do not vaccinate with Janssen COVID-19 Vaccine. These people should receive an mRNA COVID-19 vaccine.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid19-vaccination-sarscov2-infection

AMERICAN SOCIETY OF TRANSPLANTATION

Statement on Use of Monoclonal Antibody for Pre-Exposure Prophylaxis

- **Monoclonal antibody (mAb) therapy should NOT be used as a substitute for vaccination or for primary prevention strategies, including masking, social distancing, and avoidance of large indoor social gatherings.**
  - Vaccination of close contacts, including household members, continues to be an important measure to protect transplant recipients from COVID-19 infection

- Given the limited supply, centers should consider allocating AZD7442 based on stratification of individual patient risk. Risk assessments should incorporate both underlying patient risk factors for severe outcomes from COVID-19 infection as well as risk of exposure to COVID-19 infection.

Risks Associated with Severe disease[1]

- Anti-RBD seronegativity after a complete series of vaccine[2]
- Age ≥ 60
- 2 or more comorbidities[3]
- Lung transplantation
- Immunosuppression (recent B-cell depletion e.g., rituximab; T-cell depletion e.g., ATG, alemtuzumab; Belatacept use)

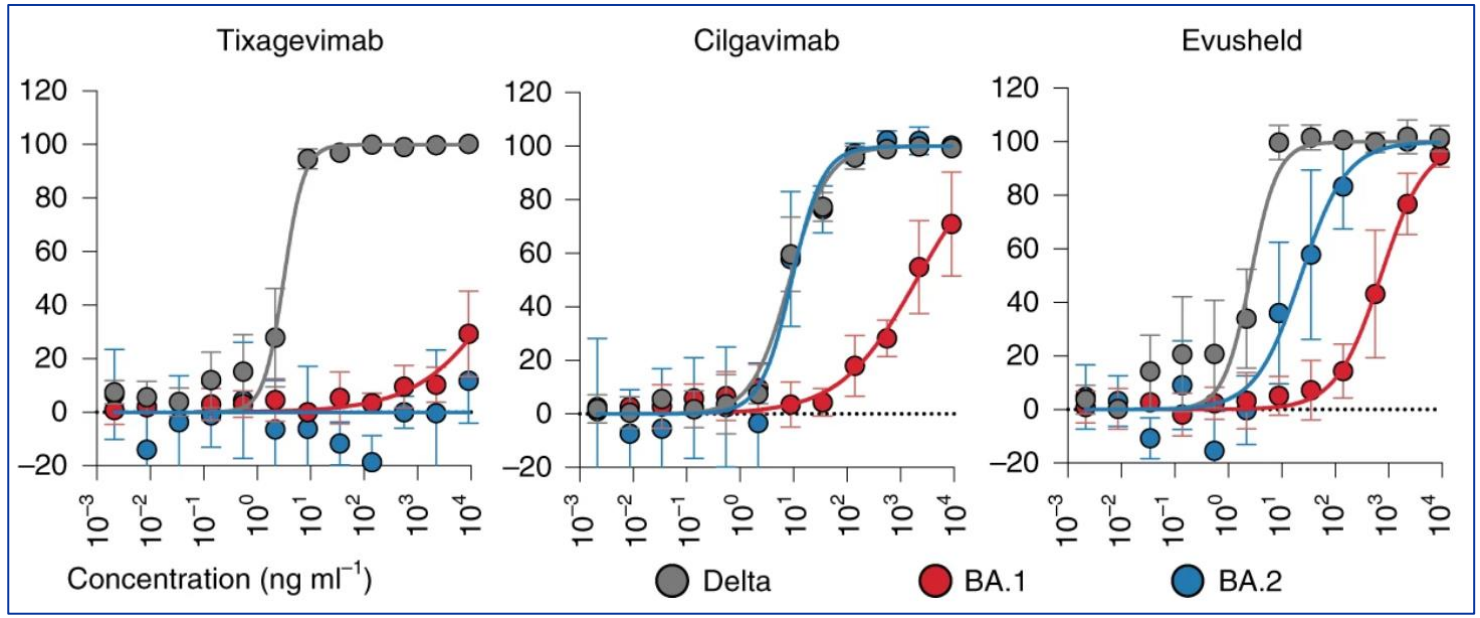
Risks Associated with Increased Exposure[4]

- High-risk occupations especially schools, day cares, health care
- Residence in a long-term care facility or other congregate setting (e.g., dormitory, prison)

https://www.myast.org/sites/default/files/AST%20Statement%20on%20Use%20of%20Monoclonal%20Antibody_Final%20Mar%209%202022.pdf

Impact of Variants is Significant for Monoclonal Antibodies

- In sera from 29 immunocompromised individuals ≤ 1 month after getting tixagevimab/cilgavimab, neutralizing titers were markedly decreased against BA.1 (344-fold) c/w BA.2 (nine-fold) compared to the Delta variant
- Possibility of resistance with BA.4/5: cilgavimab exhibits ~30x higher resistance to BA.4/5 compared to BA.2 (Yamasoba et al, medRxiv preprint, posted 3 May 2022)



Bruel, T. *et al.* Serum neutralization of SARS-CoV-2 Omicron sublineages BA.1 and BA.2 in patients receiving monoclonal antibodies. *Nat Med* (2022). March 2022 https://doi.org/10.1038/s41591-022-01792-5

Concerns for Breakthrough Infections

- 39/416 (9.4%) kidney transplant recipients who received prophylactic injections of tixagevimab/cilgavimab (150mg each) developed COVID-19. **All were vaccinated**.
  - 38/39 were symptomatic
  - 14/39 (35.9%) hospitalized
  - 3/39 admitted to intensive care unit
  - 2 died of COVID-19-related acute respiratory distress syndrome

Benotmane I. *et al*, medRxiv preprint, posted 19 March 2022, and person communication
https://www.medrxiv.org/content/10.1101/2022.03.19.22272575v1.full.pdf

4/29 immunocompromised had breakthrough infection after vaccine x 3 plus tixagevimab/cilgavimab

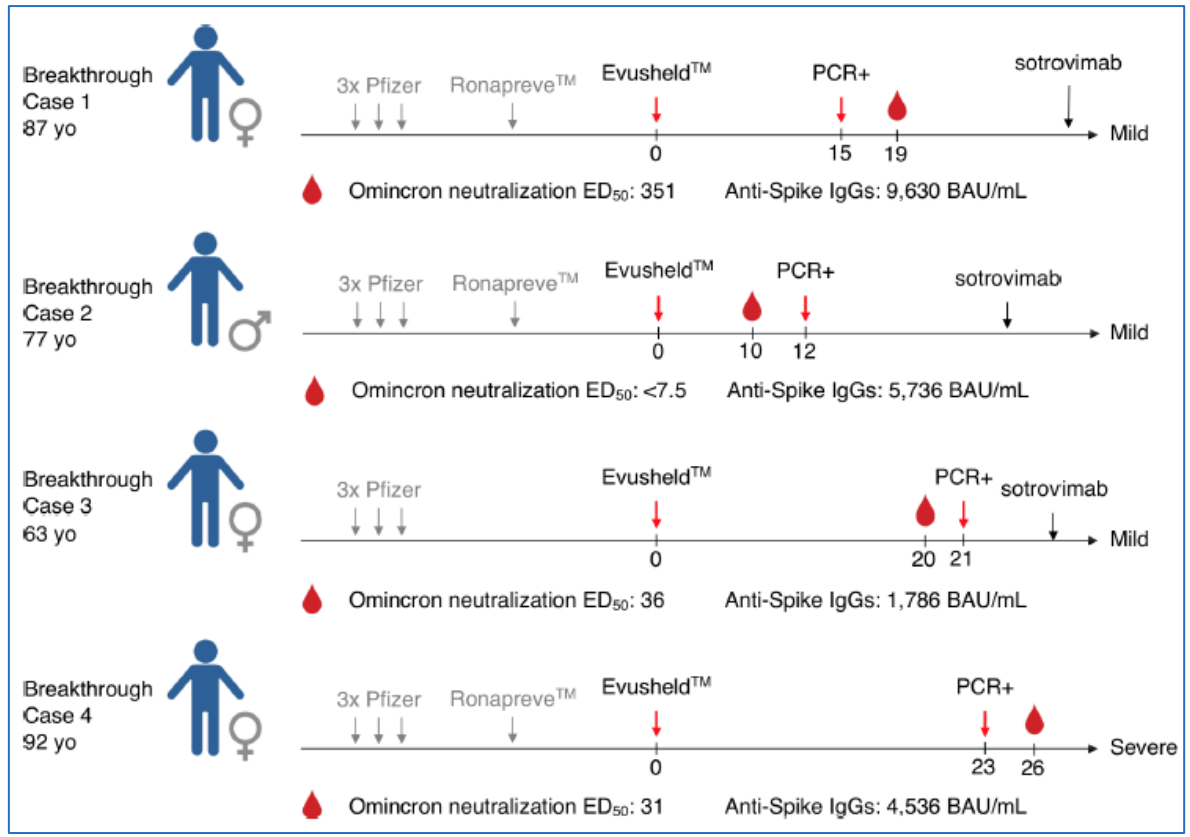


Table 3 | Summary of breakthrough cases

Case	Diagnostic	Strain*	Days after Evusheld	Anti-S (BAU ml^{-1})	Neutralization BA.1 (ED_{50})	COVID-19
1	PCR+ screening	Omicron	15	9,630	351	Mild
2	PCR+ screening	Omicron	12	5,736 } high	7,5 } low	Mild
3	PCR+ screening	Omicron	21	1,786	36	Mild
4	PCR+ sequencing	BA.1	23	4,536	31	Severe

*90% BA.1 circulating at that time

Bruel, T. *et al.* Serum neutralization of SARS-CoV-2 Omicron sublineages BA.1 and BA.2 in patients receiving monoclonal antibodies. *Nat Med* (2022). March 2022 https://doi.org/10.1038/s41591-022-01792-5

Wear a mask with the best fit, protection, and comfort for you.

N95 Respirator

NIOSH-approved

When worn correctly, respirators offer the highest level of protection and filter 95% of particles.

KN95 Respirator

Filtration varies depending on standard.

When worn correctly, KN95s provide more protection than disposable masks.

Disposable Mask

Sometimes referred to as "surgical masks" or "medical procedure masks"

Disposable masks offer more protection than cloth masks.

Cloth Mask

Non-medical, made of fabric

Layered finely woven cloth masks offer more protection.

Loosely woven cloth masks provide the least protection.

Masks and respirators should not be worn by children younger than 2 years old.

cdc.gov/coronavirus

328947-P

Passive Antibody Products

Prior guidance

Defer COVID-19 vaccination for:

- 30 days if product used for post exposure prophylaxis
- 90 days if product used for treatment
- No guidance for pre-exposure prophylaxis

Revised guidance

- No recommended deferral period
- However, tixagevimab/cilgavimab (EVUSHELD™) should be deferred for at least two weeks after vaccination

Per product EUA

Benschop, et al. (2021). The effect of anti-SARS-CoV-2 monoclonal antibody, bamlanivimab, on endogenous immune response to COVID-19 vaccination. *medRxiv*. Preprint. **doi:** https://doi.org/10.1101/2021.12.15.21267605

Clinical Vignette

- 65-year-old professor was diagnosed with Waldenstrom's macroglobulinemia in 2020, treated with plasmapheresis then ibrutinib and mavorixafor (small-molecule, selective antagonist of the CXCR4 receptor)
- He was given 5 doses of Pfizer vaccine while on therapy (3+1+1)
  - Clinical trial found no spike protein antibody response
- Has been living in complete isolation with his wife, hesitant to go for infusion
- He is briefly hospitalized for an unrelated reason
- My recommendation: **give tixagevimab/cilgavimab prior to discharge**

Clinical Vignette

- 72 year old heart transplant recipient is now 1.5 years after transplant, not vaccinated prior to transplant, on tacrolimus/mycophenolate mofetil/prednisone
- Had 3 doses mRNA vaccine for primary series then a booster (3+1)
- Absolute lymphocyte count is ~800
- No clinical COVID-19 infection
- She is asking you if she should get a second booster now or get tixagevimab/cilgavimab?
- My recommendation: **give booster then tixagevimab/cilgavimab > 2 weeks later**

Let's Utilize this Prophylactic Therapy and Optimize Administration

- Immunocompromised patients being discharged from hospital
- Use as bridge between deep immune suppression and when likely to have a more robust vaccine response, i.e. after stem cell transplant
- Focus on highly immunocompromised to ensure they get priority
- For those truly intolerant of vaccine, defined by CDC
- Adjunctive protection to primary vaccination ("belt and suspenders")
- May need to reconsider efficacy with BA.4/5 looming on horizon

Questions? ckotton@mgh.Harvard.edu

MASSACHUSETTS GENERAL HOSPITAL
TRANSPLANT CENTER

Prevention of COVID-19 in Immunocompromised Individuals: Focus on Evusheld

Update on Distribution & Administration

Derek Eisnor, MD

U.S. Department of Health and Human Services

ASPR Office of the Assistant Secretary for Preparedness & Response

Update on Evusheld

Distribution and Administration of COVID-19 Therapeutics

Derek Eisnor MD – Therapeutics Implementation Lead

HHS Coordination Operations and Response Element (H-CORE)

May 7, 2022

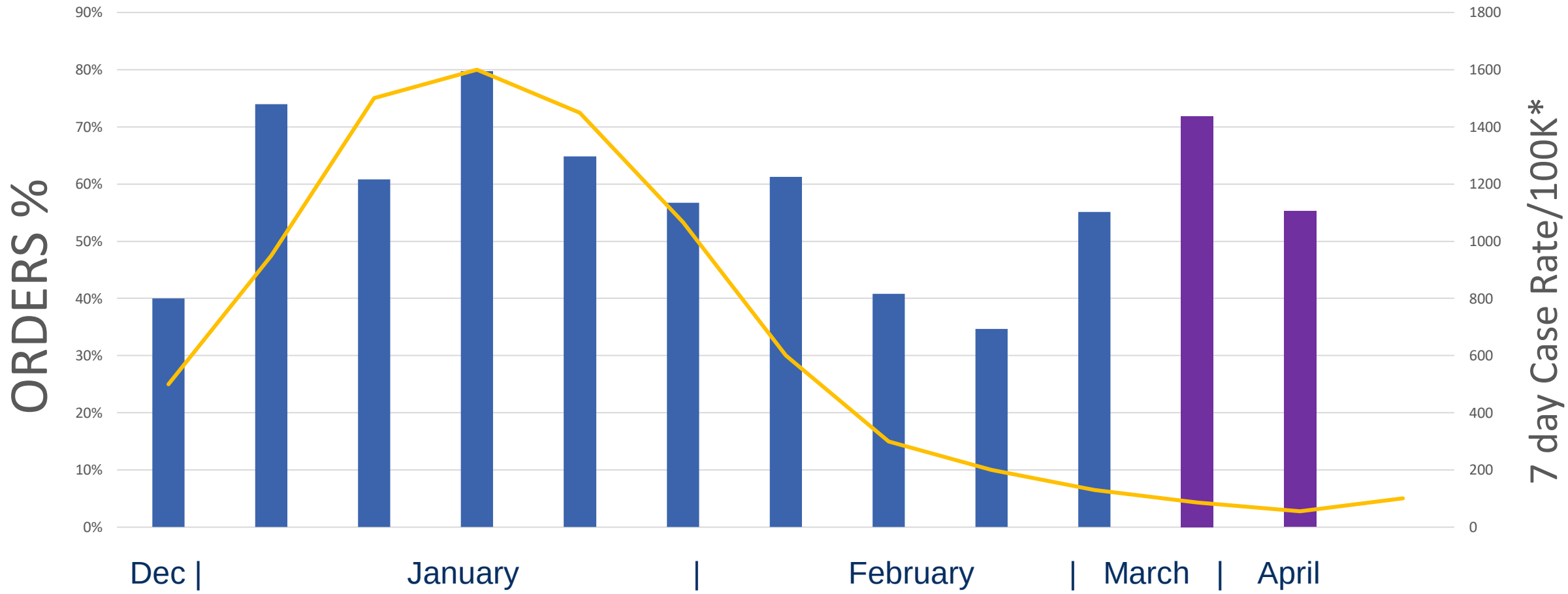
Disclosures

- Federal employee
- My opinions are my own
- No disclosures

Evusheld Threshold Distribution

- Evusheld (tixagevimab co-packaged with cilgavimab) first issue EUA 12/8/2021
- 200K courses made available to states and jurisdictions monthly
- Daily utilization reporting required per provider agreements but without enforcement
- Recent audit of high volume/low utilization sites(150) show variable reporting:
  - Sites with <50% utilization (0-47%)
  - Sites with total ordering between 500-10,000 courses to date
  - Zero utilization (no reporting): unaware or unclear who is doing reporting
  - Low utilization: major barriers in staffing and space

Ordering Trends Q1 2022 - Evusheld



*https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days

Improving Access & Awareness

- Spotlight local success stories
  - Variable resources
- Resource additional channels
  - Specialty pharmacies
  - Retail pharmacies
  - Primary care practices (TX), increasing from January
  - Telehealth
- Potential barriers
  - Provider awareness
  - Uninsured/underinsured, private payor copays (not like vaccines)
  - Provider Reimbursement
- Public awareness
  - Sponsor DTC campaign
  - Patient advocacy group outreach
  - Improved messaging

Thank you!

Prevention of COVID-19 in Immunocompromised Individuals: Focus on Evusheld

Operationalizing Evusheld: Keys to Success

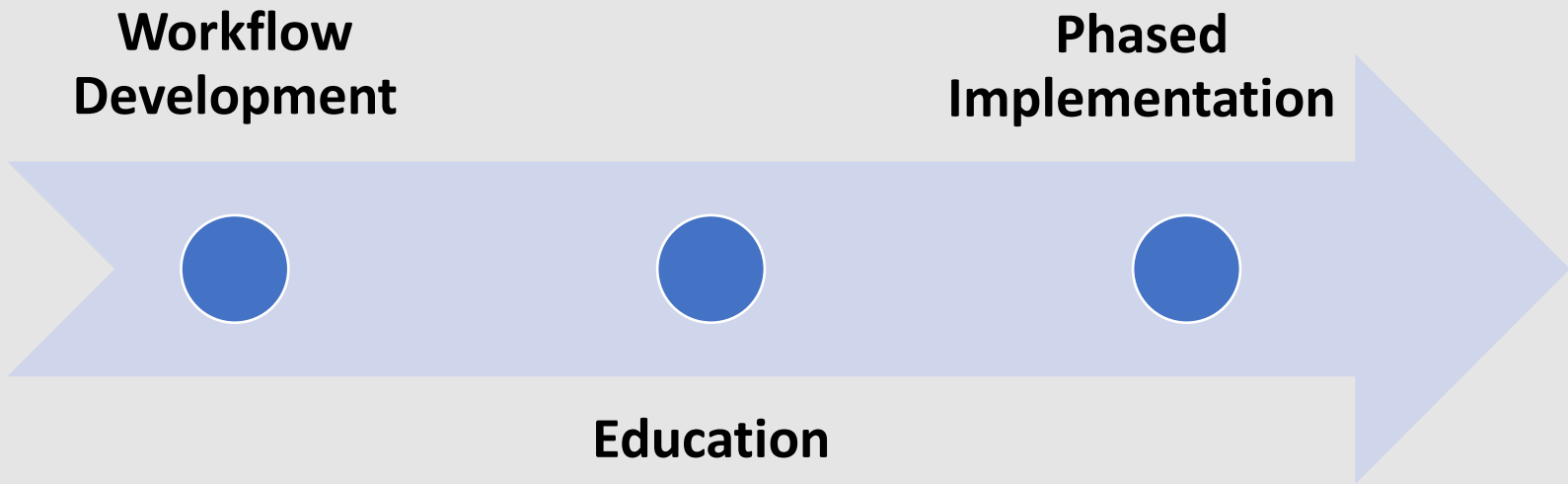
Swana K. Thomas, PharmD, MPH

Shielding Patients with Evusheld

Swana Thomas, PharmD, MPH
MTDM Ambulatory Care Pharmacist
Geisinger Rheumatology

Operationalizing Evusheld: The Process

THE GOAL



Operationalizing Evusheld: The Process

BARRIERS TO IMMPLEMENTATION

Education

- **Problem:** Lack of education on medication
- **Solution:** Specialty pharmacists embedded in clinics were tasked to educate physicians and nurses

Process

- **Problem:** No way to order medication in clinic and for individual patient
- **Solution:** Pharmacy worked with IT to
  - Develop order set for medication
  - Ensure ordering product via

Clinic Capacity

- **Problem**: Space and volume were of initial concern
- **Solution:** Enacted a *reactive* approach to target patients when in clinic and only highly immunosuppressive medications

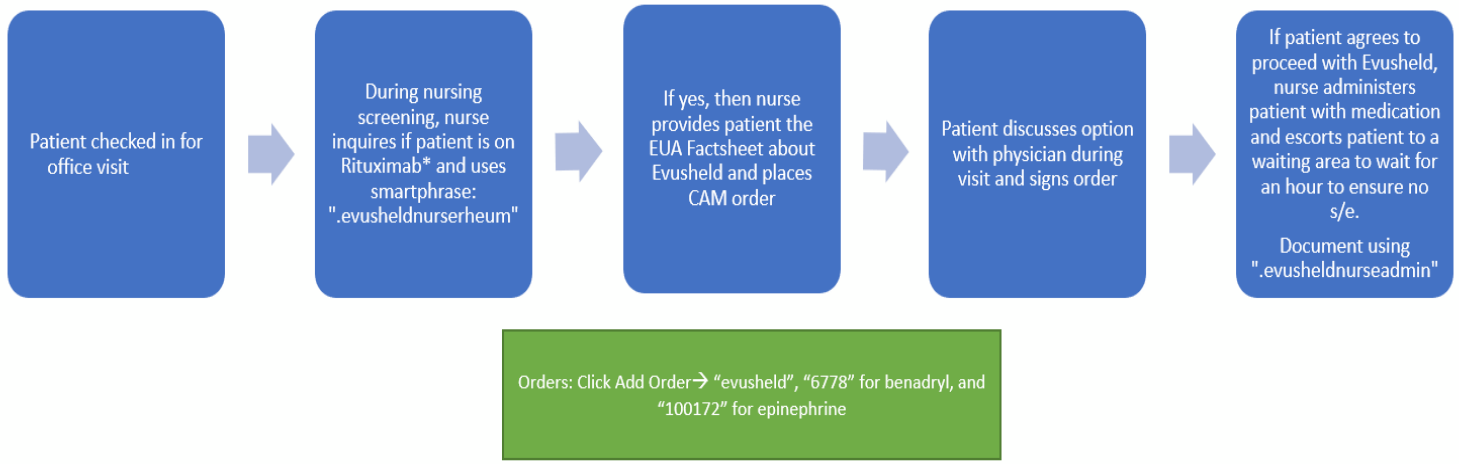
Patient Receptivity

- **Problem:** Concern of “buy-in” from patients
- **Solution:** Nurse screening tool allowed patients to understand purpose of medication, possible precautions to medication, and process of administration to alleviate any concerns

Operationalizing Evusheld: The Workflow

WORKFLOW

Patient Identified During Office Visit



Rituximab = Rituxan, Truxima, Riabni, Ruxience

Operationalizing Evusheld: The Process

SCREENING TOOL

Evusheld Medication Recommendation

The Rheumatology Department has determined that you are eligible for a medication that may help prevent COVID-19 infection if you do get exposed to the virus. This medication is called a monoclonal antibody known as EVUSHELD. Our hope is that this drug may help people like you, who are immune suppressed, in preventing COVID-19 infection for up to 6 months after the injection based on studies.

Before we get you scheduled, please allow me to review some information about this medication, as well as to verify your eligibility.

SCREENING TOOL

- Are you currently receiving Rituximab or Cytoxan infusions? {yes/no:60}
- If applicable, do you receive Plasmapheresis dose: {yes/no:60}
- If applicable, are you pregnant or lactating: {yes/no:60}
- Have you been vaccinated against COVID-19?: {yes/no:60}
- Have you been exposed to COVID-19 in the past 14 days?: {yes/no:60}
- Have you been treated against COVID-19 with monoclonal antibodies?: {yes/no:60}
- Do you have a history of bleeding disorders (ex. Thrombocytopenia, Von Willebrand Disease, Hemophilia): {yes/no:60}
- Do you have a history of Coronary Artery Disease, Heart Attack, Heart Failure, or Arrhthymias (atrial fibrillation, paroxymal atrioventricular block) : {yes/no:60}
- Has there been any history of cardiac-related conditions or events that were not mentioned? If yes, please elaborate: {yes/no:60} ***
- If not an office visit, what day/time would you like to come in for appt? (1 week from today if not in for an OV today): ***

EVUSHELD INFORMATION

- As you probably heard, because of your immunosuppressed status, you are more likely than the average person to develop a severe COVID-19 infection if you were to contract the infection.
- While we hope this drug may help prevent COVID-19 infections, we cannot say for sure whether it will or will not. This drug is still being studied in clinical trials. It is called an investigational drug. This drug is approved under what is known as an emergency use authorization.
- This drug is a 1 time medication that is given as 2 separate injections at the same time into the gluteal muscle. The injection itself takes almost no time, however we do ask that you be monitored in our clinic for at least 1 hour after the injection to monitor for side effects.
- Based on early results of trials, this drug looks relatively safe. There were some side effects identified in clinical trials in patients who received this medication. These include:
  - Allergic reactions. Allergic reactions can happen during or after injection of EVUSHELD. Tell your healthcare provider right away if you get any of the following signs and symptoms of an allergic reaction: Fever, chills, nausea, headache, shortness of breath, lower high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, dizziness and sweating. These reactions may be severe life-threatening.
  - Cardiac (heart) events. Serious cardiac adverse effects have happened, but were not common, in people who received this medication. Additionally the side effects were noted in people who did not receive this medication. In people with risk factors for cardiac events, including a history of heart attack, more people who received this medication experienced serious cardiac events than people who did not receive this medication. It is not known if these events are related to the medication or to underlying medical conditions. Contact your healthcare provider or get medical help right away if he gets any symptoms of cardiac events, including pain, pressure, or discomfort in the chest, arms, neck, back, stomach her jaw, as well as shortness of breath, feeling tired or weak, feeling sick, or swelling in your ankles or lower legs.
  - Side effects associated with intramuscular injection. The side effects of getting any medicine by intramuscular injection may include pain, bruising of the skin, soreness, swelling, and possible bleeding or infection at the injection site
  - Additional side effects. The these are not all the possible side effects of this medication. Not a lot of people have been given this medication. Serious and unexpected side effects may happen. This medication is still being studied so it is possible that all of the risks are not known at this time.
- It is possible that this medication may reduce your body's immune response to a COVID-19 vaccine. If you have received a COVID-19 vaccine, you should wait to receive this medication until least 2 weeks after vaccination.
- There are alternative options to this medication. Vaccines to prevent COVID-19 infection are approved or available under emergency use authorization. The use of this medication does not replace vaccination against COVID-19. You can say yes or no to taking this drug and it won't affect your care at Geisinger in any way.
- For more information about other medicines authorized for treatment or prevention of COVID-19, go to *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization* for more information

After reviewing screening questions, reading medication pamphlet, and discussing with provider, patient would like to proceed with Evusheld prophylactic therapy and receive injections: {yes/no:60} . **Order will be pended to physician for final review and if patient agreeable.**

Operationalizing Evusheld: The Process

ADMINISTRATION DOCUMENTATION

EVUSHELD ADMINISTRATION

Prior to Administration, the following was addressed:

- I understand that EVUSHELD is a combination of unapproved drugs authorized under the EUA (emergency use authorization) and made patient aware of this fact: {yes/no:60}
- I confirm that the patient/caregiver has been informed of the possible alternative treatments to EVUSHELD: {yes/no:60}
- I confirm that the patient/caregiver has been provided a copy of the EUA Factsheet: {yes/no:60}
- I confirm that the patient is not currently infected or has not had a recent exposure to COVID-19: {yes/no:60}
- I confirm that patient has moderate-severe immunocompromise and may not mount to an adequate response to COVID-19 vaccine or a contraindication/high risk of reaction to vaccine: {yes/no:60}

Patient has an order for EVUSHELD (tixagevimab co-packaged with cilgavimab) intramuscular injections.

Patient provided manufacturer's medication fact sheet, verbalized understanding of ordered therapy and was agreeable to proceed with injections.

Patient verbalized awareness to watch for and immediately report any shortness of breath, difficulty breathing, rash, hives, chest pain/tightness, itching, abdominal cramps/pain, dizziness, rapid heartbeat, light-headedness, flushing, nausea or vomiting, or any unusual feeling.

Patient instructed to report any adverse effects to our clinic.

Patient provided EUA documentation, including information on how to report adverse event/effects to the FDA (www.fda.gov/medwatch/report.htm)

Emergency medication was ordered by physician to be used in the event of a medical emergency

@ME@

Keys To Success

- **Collaboration with IT** to ensure that the ordering process is seamless
- **Utilizing ambulatory pharmacy** team members to educate and operationalize processes
- Implementing through a **phased approach**

Monoclonal Antibody Therapy for Treatment: What are the Options?

Raymund R. Razonable, MD, FIDSA

CDC/IDSA COVID-19 Clinician Call

Monoclonal Antibody for Treatment: What are the Options?

Raymund R. Razonable, MD

Professor of Medicine

Mayo Clinic, Rochester, MN, USA

May 7, 2022

MAYO CLINIC

@RazonableMD

Disclosures

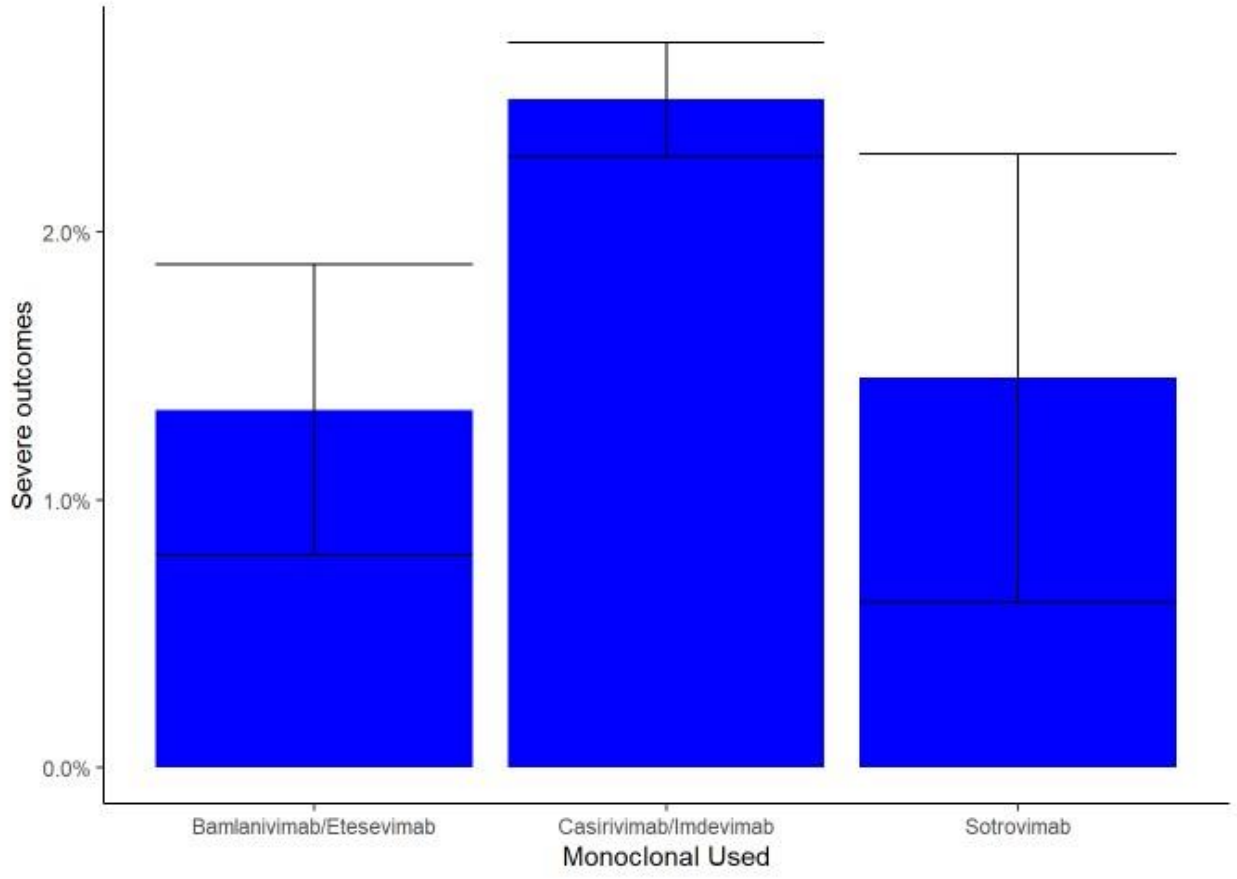
- Research grants (funds to institution): Gilead, Regeneron, Roche, nFerence
- DSMB: Novartis
- Advisory Board: Merck, Roche, Glaxo Smith Kline

- Use of anti-spike monoclonal antibodies, nirmatrelvir-ritonavir, molnupiravir are under emergency use authorization

Anti-spike Neutralizing Monoclonal Antibodies for Treatment of Mild to Moderate COVID-19 in Eligible High-Risk Persons

Antibody Product	Pre-Delta Period	Delta VOC	Omicron VOC	Omicron subvariant BA.2
Bamlanivimab-etesevimab	YES except P.1 (Gamma) and B.1.351 (Beta)	YES	X	X
Casirivimab-imdevimab	YES	YES	X	X
Sotrovimab	YES	YES	YES	X
Bebtelovimab	Not available	Not available	YES (alternative)	YES

COVID-19 Delta (n=10,775 patients)
August 1 – December 1, 2021



Real-world outcomes analysis

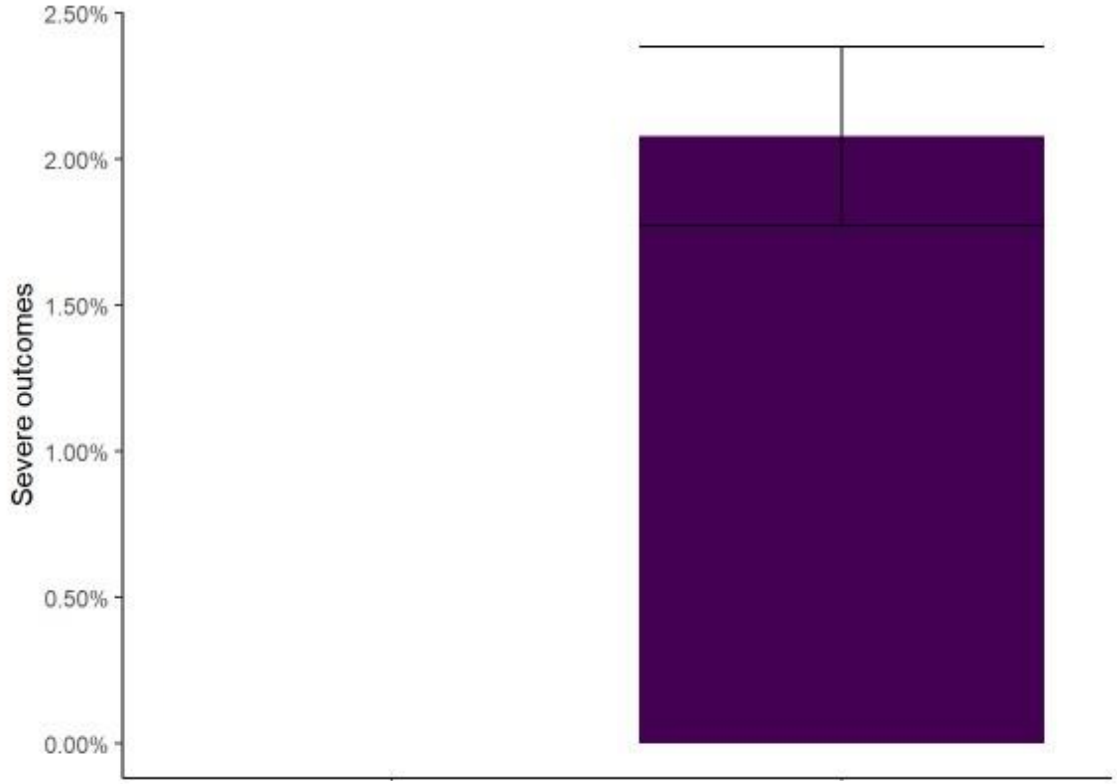
Retrospective design

Duration of follow up: 28 days

Median time to infusion: 2 days from positive test

Razonable R et al. Unpublished data (under peer-review for publication)

COVID-19 Omicron
Since January 1, 2022



Sotrovimab (n=2165)

January-March 20, 2022
Use halted by BA.2 Omicron

Duration of follow up: 28d

Scarcity of supply:
Prioritization of patients with MASS 3+ (including immune compromised patients)

Razonable R et al. Unpublished data (not peer-reviewed); MASS=Monoclonal Antibody Screening Score

Clinical Prioritization of Monoclonal Antibodies

Monoclonal Antibody Screening Score (MASS)

NNT to prevent hospitalization

MASS 1 = 225

MASS 4+ = 4

MAYO CLINIC

Bierle et al. *J Infect Disease* 2021

Monoclonal Antibodies for Immunocompromised Hosts

SOT Recipients (n=657)	CD20-depleted Patients (n=180)
Hospitalization = 8.7%	Hospitalization = 9.4%
MASS correlates with outcome	No deaths in 30 days
Vaccination is protective	1.8% persistent infection

Yetmar and Razonable 2022 (unpublished); Yetmar Z et al. *OFID* 2022

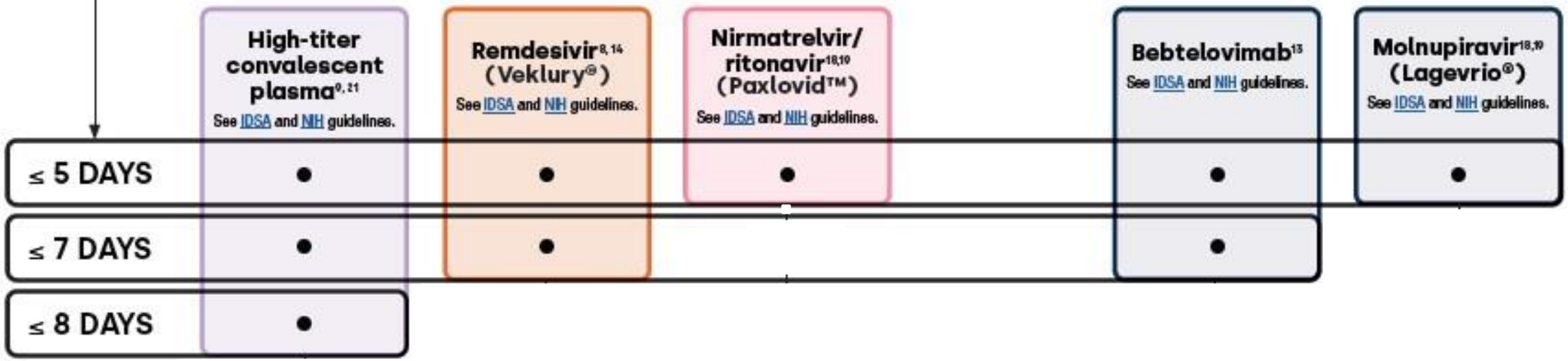
COVID-19 OUTPATIENT TREATMENT GUIDELINES ROADMAP

COVID-19 Real-Time Learning Network

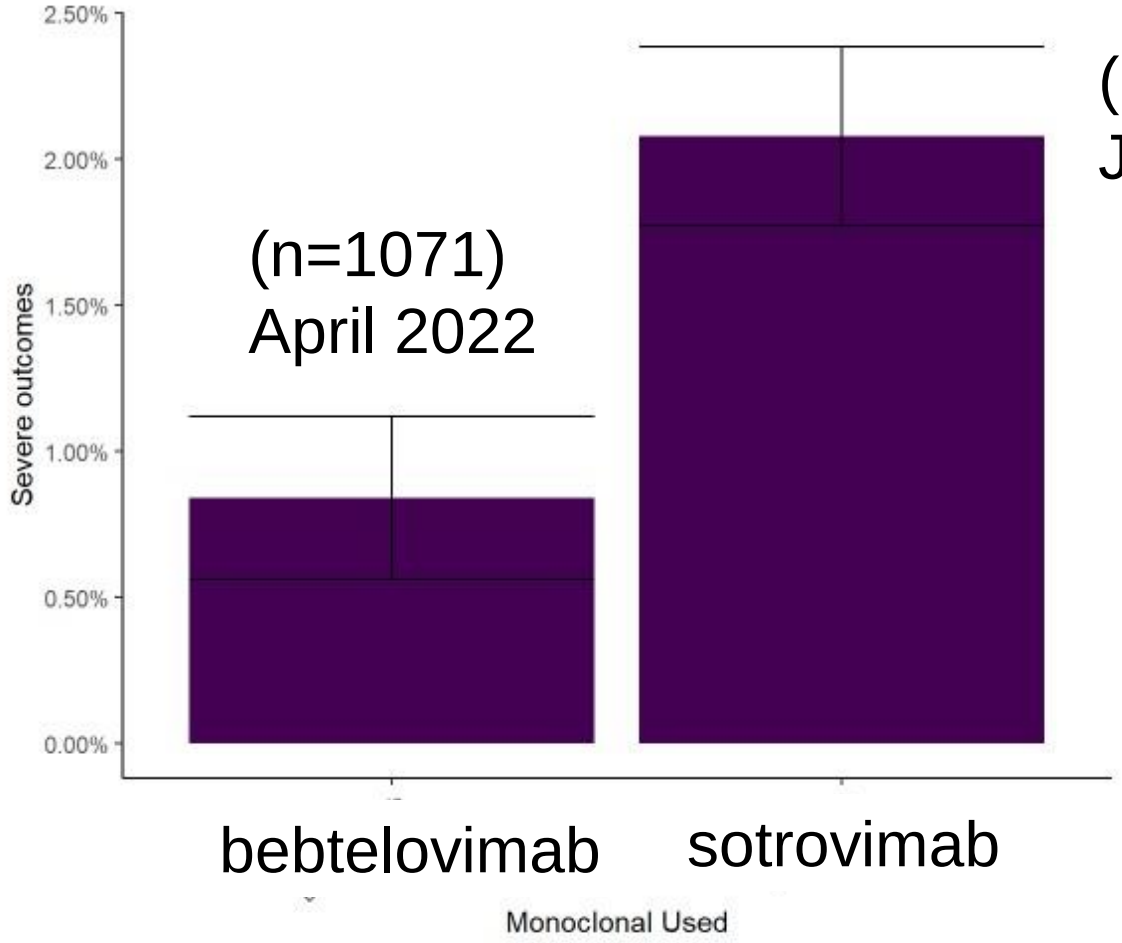
Brought to you by CDC and IDSA

Last Updated: April 5, 2022

Mild to moderate COVID-19 in eligible high-risk patient



COVID-19 Omicron (n=3236 patients)
January 1 – April 22, 2022



(n=2165)
January-March 2022

Duration of follow up:
Patients treated with Bebtelovimab has 14-28d follow up only (data evolving)

Other options:
Nirmatrelvir-ritonavir
Remdesivir
Molnupiravir

Razonable R et al. Unpublished data (not peer-reviewed)

Omicron subvariants

- BA.2, BA.2.11, BA.2.12.1, BA.4/5 subvariants have emerged
- Spike mutations of newly emerging variants warrant evaluation of therapeutic efficacy of monoclonal antibodies
- Pseudovirus experiments (preprint)
  - Bamlanivimab, etesevimab, casirivimab, imdevimab, tixagevimab NOT functional against BA.2 and new variants
  - Bebtelovimab 2-fold more effective against BA.2 and all Omicron subvariants than parental virus
  - Sotrovimab not active against BA.2, but BA.2.11 and BA.4/5 were more sensitive than BA.2

MAYO CLINIC

Yamasoba et al. Sensitivity of novel SARS-CoV-2 Omicron subvariants, BA.2.11, BA.2.12.1, BA.4 and BA.5 To therapeutic monoclonal antibodies. bioRxiv preprint: https://doi.org/10.1101/2022.05.03.490409

Conclusions

- Monoclonal antibodies are effective treatment of mild to moderate covid-19 in outpatients : reduced mortality and severe outcomes
- Short therapeutic life-span due to emergence of variants with mutations in spike protein
- May 2022: Bebtelovimab is the only monoclonal antibody active against current Omicron variants
- Rapid evaluation of new variants against monoclonal treatments with pseudovirus experiments should be supplemented by clinical trials and real-time real-world assessment of outcomes

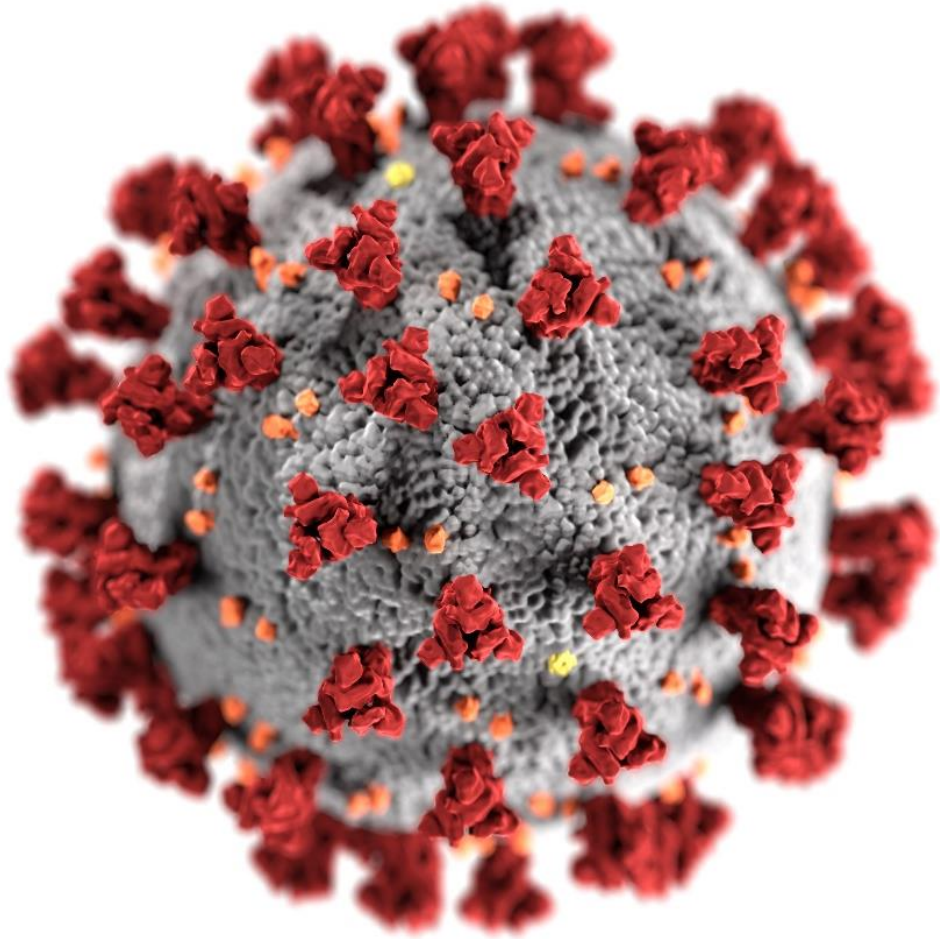
Second Busters: Who Will Benefit?

Updates and Clinical Considerations From the April 20 ACIP Meeting

Elisha Hall, PhD, RD

Updates and Clinical Considerations from the April 20 ACIP Meeting

Elisha Hall, PhD, RD
Clinical Guidelines Lead
Vaccine Coordination Unit, CDC



IDSA

May 07, 2022

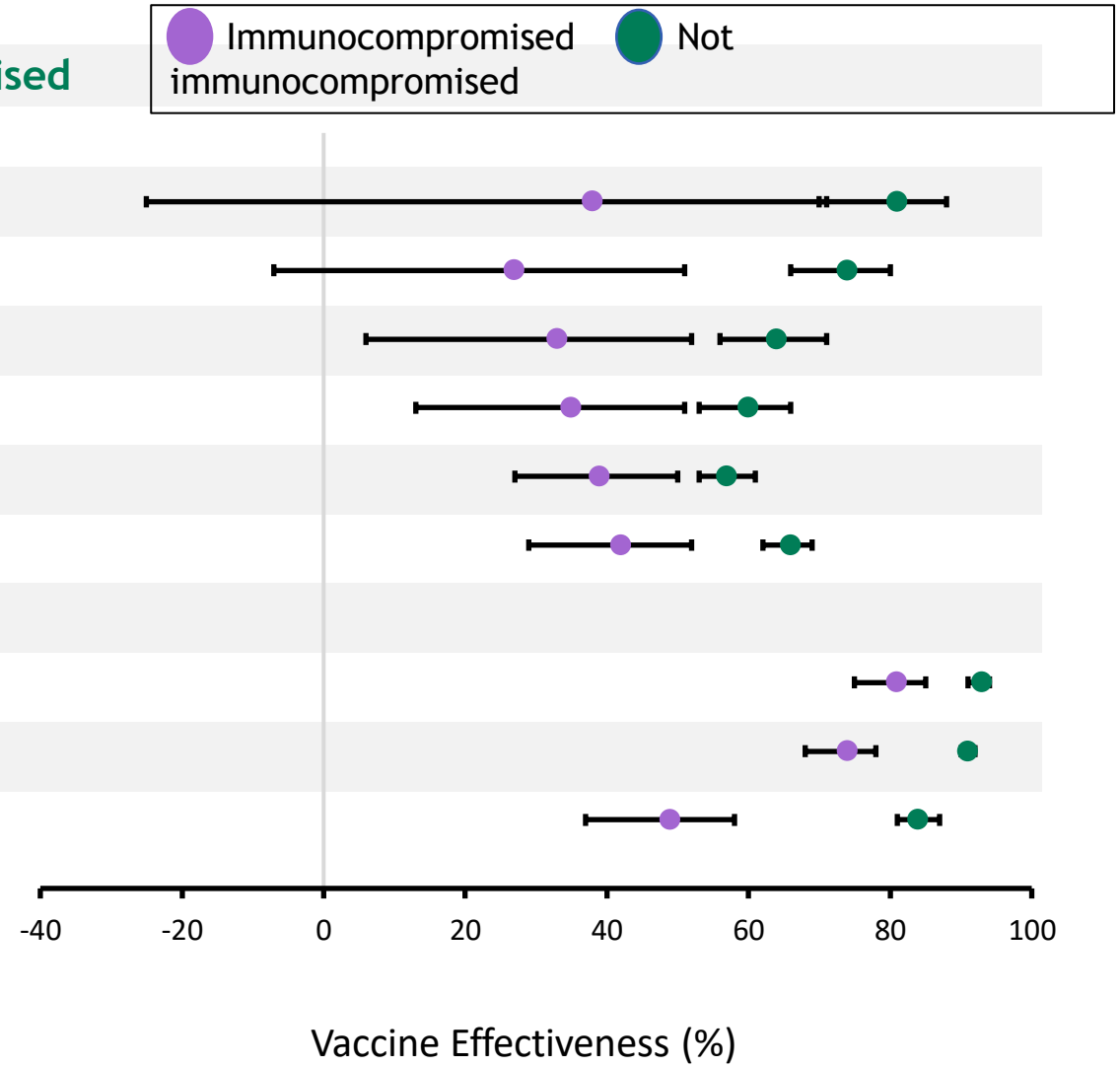
cdc.gov/coronavirus

Disclosure and Disclaimer

- Dr. Hall has no relevant relationships with commercial entities whose products are mentioned in this presentation.
- Use of trade names of vaccine products is for identification purposes and does not imply endorsement by the Centers for Disease control and Prevention (CDC)
- The findings and conclusions in this presentation are those of the presenters and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

mRNA vaccine effectiveness (VE) for hospitalization by number of doses and time since last dose receipt for adults ≥50 years, Dec 2021–Mar 2022, by immunocompromised status

	Adjusted VE% (95% CI)	
Status:	Immunocompromised	Not immunocompromised
2 doses		
14-59 days	38 (-25-71)	81 (70-88)
60-119 days	27 (-7-51)	74 (66-80)
120-179 days	33 (6-52)	64 (56-71)
180-239 days	35 (13-51)	60 (53-61)
240-299 days	39 (27-50)	57 (53-61)
300+ days	42 (29-52)	66 (62-69)
3 doses		
14-59 days	81 (75-85)	93 (91-94)
60-119 days	74 (68-78)	91 (90-92)
120-179 days	49 (37-58)	84 (81-87)



CDC, preliminary unpublished data from VISION network. Individuals with prior infections excluded. Logistic regression conditioned on calendar week and geographic area, and adjusted for age, sex, race, ethnicity, local virus circulation, respiratory or nonrespiratory underlying medical conditions, and propensity to be vaccinated

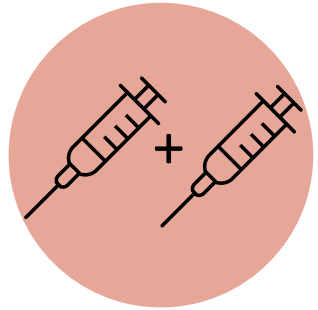
63

2nd COVID-19 Vaccine Booster Doses

- Following FDA's regulatory action on March 29, 2022, CDC updated its COVID-19 vaccination guidance that some people **may** receive a second booster dose using an mRNA COVID-19 vaccine **at least 4 months** after the first booster dose

People ages 50 years and older

People ages 12 years and older who are moderately or severely immunocompromised



People ages 18 years and older who received Janssen as both primary and booster dose

Considerations for Eligible People on Getting a 2nd Booster Dose As Soon As Possible

- Certain underlying medical conditions that increase the risk of severe COVID-19 illness
  - Moderate or severe immunocompromise
- Living with someone who is immunocompromised, at increased risk for severe disease, or who cannot be vaccinated due to age or contraindication
- Increased risk of exposure to SARS-CoV-2 through occupational, institutional, or other activities (e.g., travel or large gatherings)
- Living or working in an area where the COVID-19 community level is medium or high

Considerations for Eligible People on Waiting to Receive a 2nd Booster Dose

- Recent SARS-CoV-2 infection within the past 3 months
- Hesitancy about getting another recommended booster dose in the future, as a booster dose may be more important in the fall and/or if a variant-specific vaccine is needed.

2nd Booster Dose Product

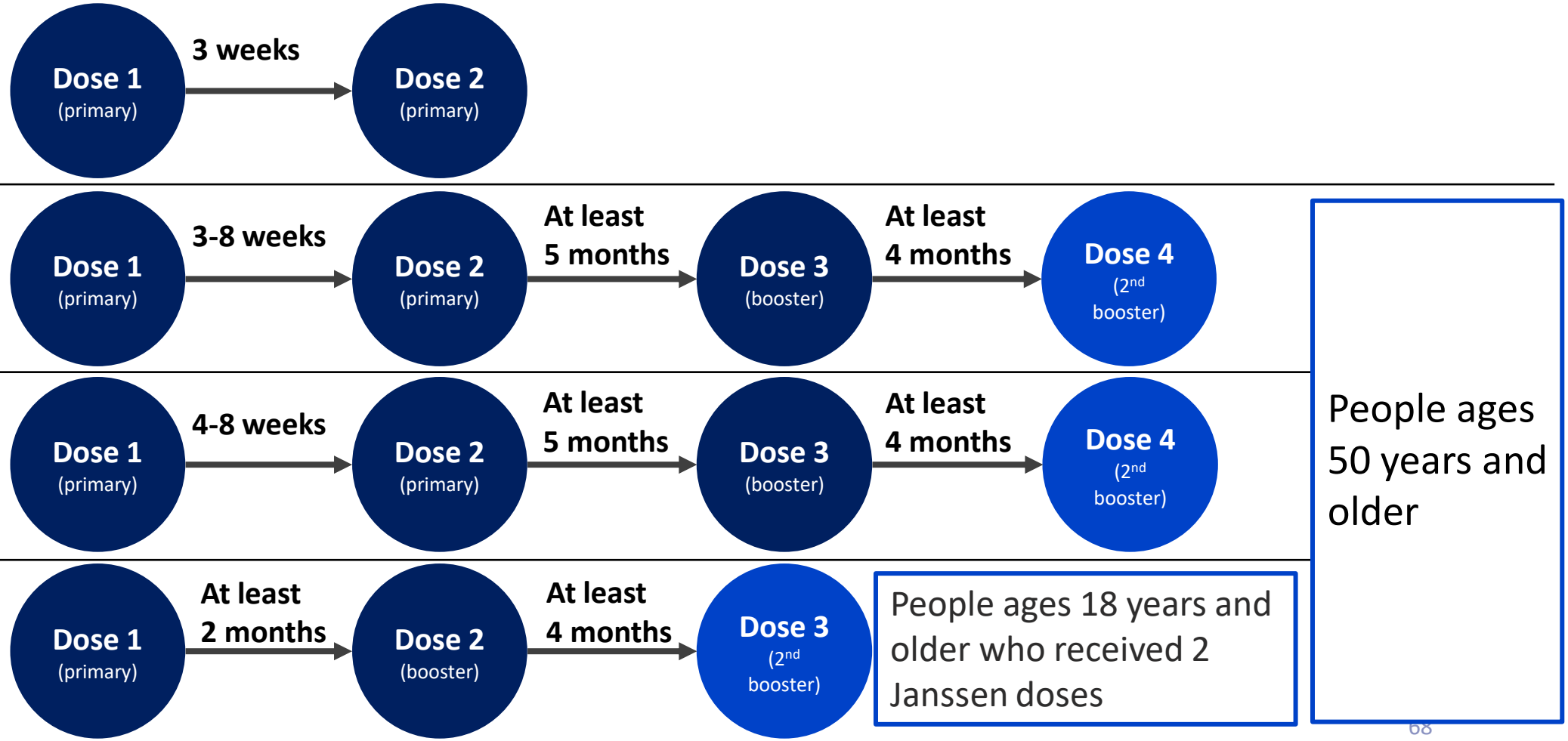
- 2nd booster dose should be an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna).
- Janssen COVID-19 Vaccine is not authorized for use as a second booster.
- Booster doses may be heterologous.
  - Eligible people ages 12–17 years can only receive Pfizer-BioNTech COVID-19 Vaccine.
- The dosage is the same as the first booster dose
  - Pfizer-BioNTech (gray or purple cap): 0.3 mL (30 mcg)
  - Moderna (red cap): 0.25 mL (50 mcg)

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

Summary of Recommendations by Primary Series Product and Age

Everyone in the age group **SHOULD** receive the dose

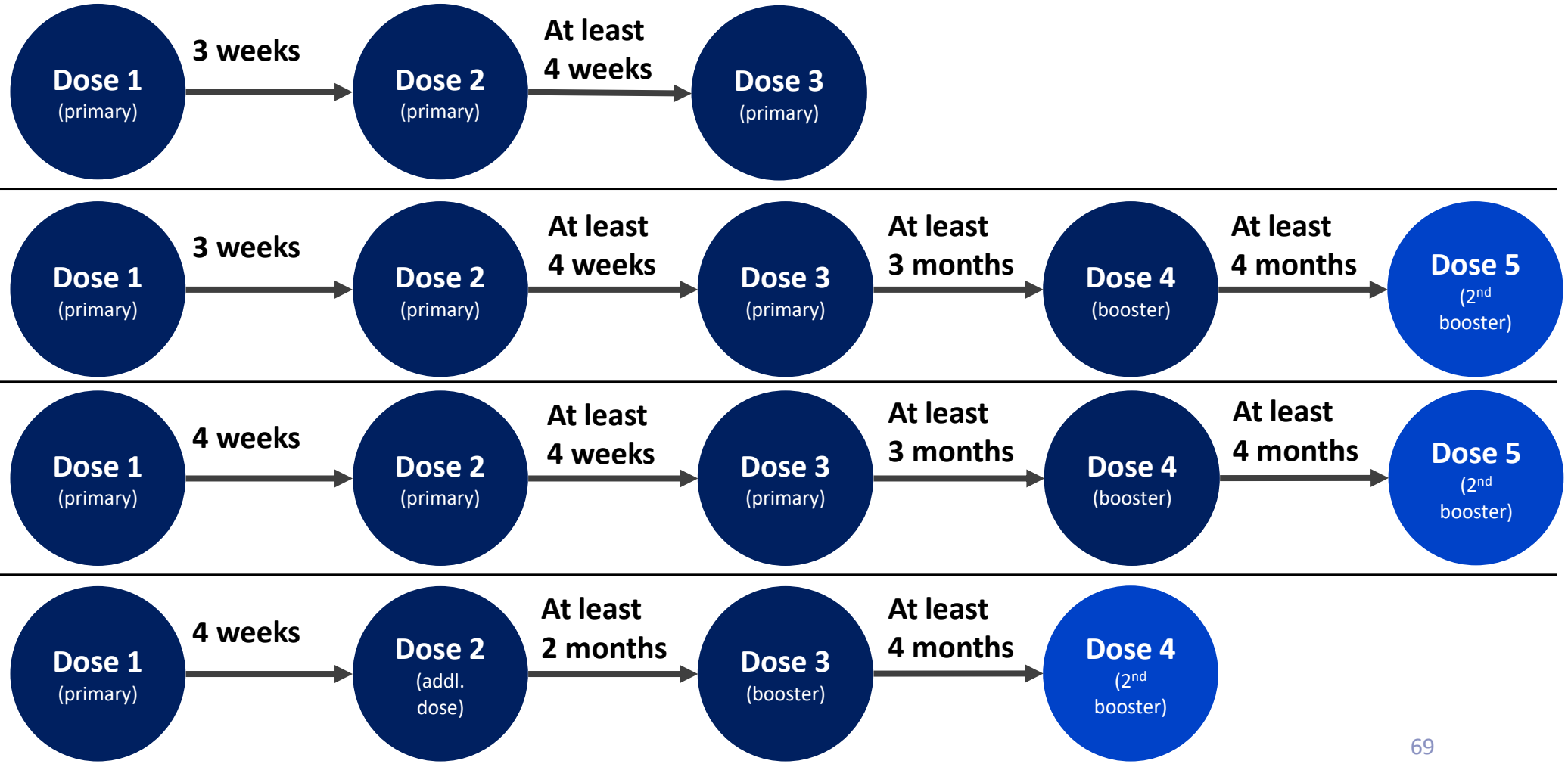
Some people in the age group **MAY** receive the dose



Summary of Recommendations by Primary Series Product and Age, Moderately or Severely Immunocompromised

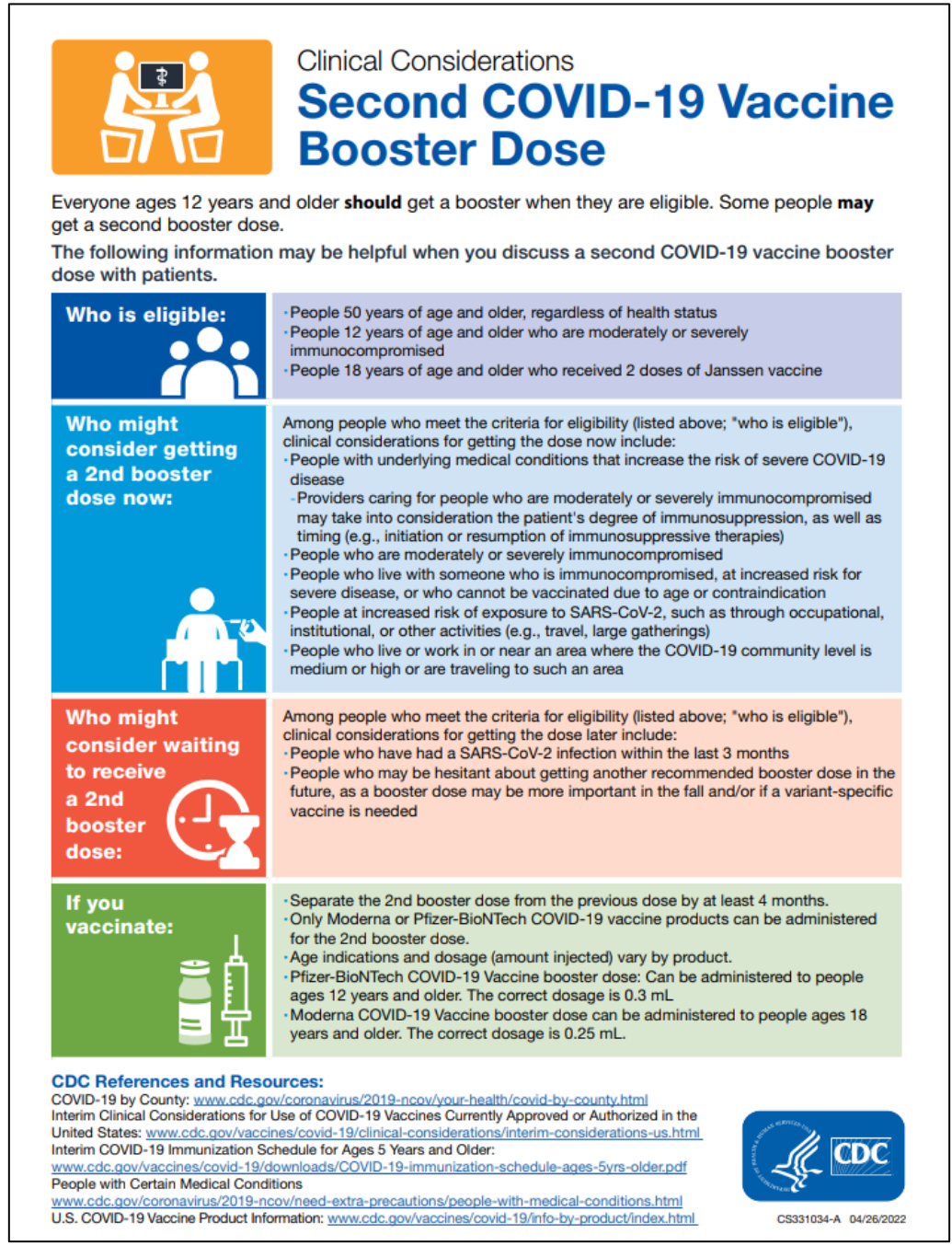
Everyone in the age group **SHOULD** receive the dose

Some people in the age group **MAY** receive the dose



For more information:

https://www.cdc.gov/vaccines/covid-19/downloads/Clinical-Considerations-Second-COVID-19-Booster-508.pdf



Clinical Considerations

Second COVID-19 Vaccine Booster Dose

Everyone ages 12 years and older **should** get a booster when they are eligible. Some people **may** get a second booster dose.

The following information may be helpful when you discuss a second COVID-19 vaccine booster dose with patients.

Who is eligible:

- People 50 years of age and older, regardless of health status
- People 12 years of age and older who are moderately or severely immunocompromised
- People 18 years of age and older who received 2 doses of Janssen vaccine

Who might consider getting a 2nd booster dose now:

Among people who meet the criteria for eligibility (listed above; "who is eligible"), clinical considerations for getting the dose now include:

- People with underlying medical conditions that increase the risk of severe COVID-19 disease
  - Providers caring for people who are moderately or severely immunocompromised may take into consideration the patient's degree of immunosuppression, as well as timing (e.g., initiation or resumption of immunosuppressive therapies)
- People who are moderately or severely immunocompromised
- People who live with someone who is immunocompromised, at increased risk for severe disease, or who cannot be vaccinated due to age or contraindication
- People at increased risk of exposure to SARS-CoV-2, such as through occupational, institutional, or other activities (e.g., travel, large gatherings)
- People who live or work in or near an area where the COVID-19 community level is medium or high or are traveling to such an area

Who might consider waiting to receive a 2nd booster dose:

Among people who meet the criteria for eligibility (listed above; "who is eligible"), clinical considerations for getting the dose later include:

- People who have had a SARS-CoV-2 infection within the last 3 months
- People who may be hesitant about getting another recommended booster dose in the future, as a booster dose may be more important in the fall and/or if a variant-specific vaccine is needed

If you vaccinate:

- Separate the 2nd booster dose from the previous dose by at least 4 months.
- Only Moderna or Pfizer-BioNTech COVID-19 vaccine products can be administered for the 2nd booster dose.
- Age indications and dosage (amount injected) vary by product.
- Pfizer-BioNTech COVID-19 Vaccine booster dose: Can be administered to people ages 12 years and older. The correct dosage is 0.3 mL
- Moderna COVID-19 Vaccine booster dose can be administered to people ages 18 years and older. The correct dosage is 0.25 mL.

CDC References and Resources:

COVID-19 by County: www.cdc.gov/coronavirus/2019-ncov/your-health/covid-by-county.html
Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
Interim COVID-19 Immunization Schedule for Ages 5 Years and Older: www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-5yrs-older.pdf
People with Certain Medical Conditions www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
U.S. COVID-19 Vaccine Product Information: www.cdc.gov/vaccines/covid-19/info-by-product/index.html

CDC

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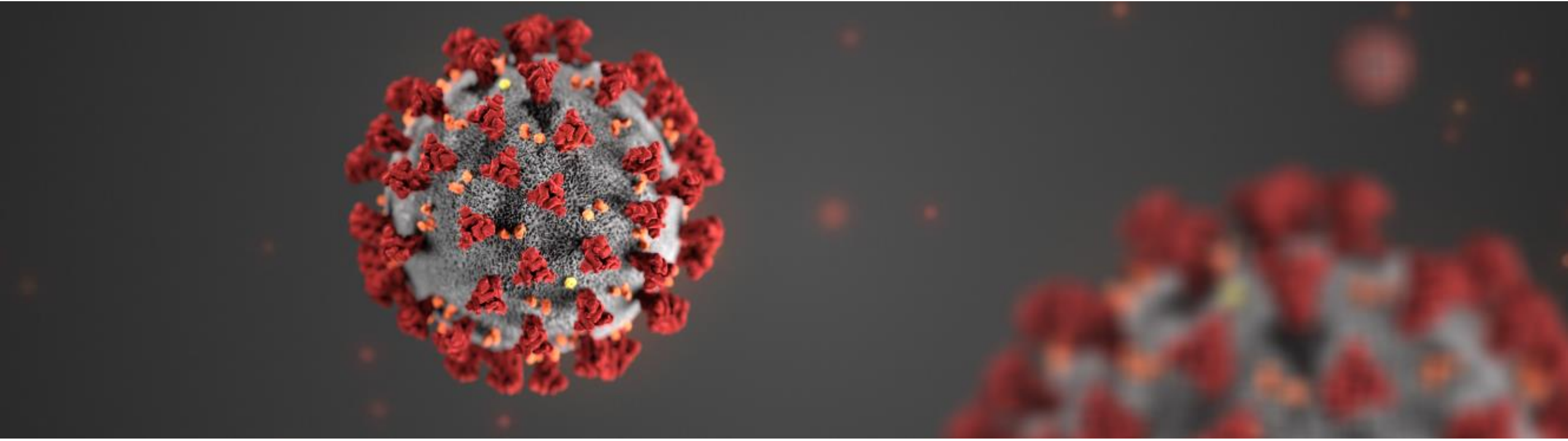


For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.

Second Busters: Who Will Benefit?

Perspectives on the Immunocompromised and People Over 50

William Schaffner, MD, FIDSA

Perspectives on the Immunocompromised and People Over 50

William Schaffner, MD

Professor of Preventive Medicine, Department of Health Policy

Professor of Medicine, Division of Infectious Diseases

Vanderbilt University Medical Center

Disclosures:

VBI Vaccines - Consultant

Where are we?

- Period of transition: PANDEMIC → ENDEMIC
- Uncertainty continues
- Mutational drift – likely

  SHIFT - ???
- Effectiveness of current vaccines against new variants
- Duration of protection from vaccines and natural infection

Vaccines are the Foundation of Prevention
Personal – Healthcare – Community

Unvaccinated: 2-3x risk of testing positive

20x risk of dying

Only 45% "up to date" with 3rd dose (1st booster)

Previews: An updated bi-valent booster likely available this fall

Recommended universally (along with separate flu vaccine)?

2nd Booster FAQ

- What does "may" receive mean?
  - "should": benefits clearly > risks → universal
  - "may": diversity of benefits/risks

- If I get a 2nd booster now, might I be eligible for another this fall? Yes

- Will repeated boosting diminish the response of the immune system? Not with mRNA vaccines

2nd COVID-19 Booster Doses

Age 50+	Risk increases with increasing age
	Medical conditions: heart, lung disease
	diabetes, obesity
	Caring for immunocompromised
	Communities with medium/high transmission
	Individual risk tolerance
Age 12+	Moderately or severely immunocompromised
Age 18+	J&J x 2

We welcome your

questions, suggestions and corrections

Q&A/Discussion

Selected Resources

Dr. del Rio

- Slide 7 - https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/
- Slide 11 - https://www.fda.gov/media/158165/download
- Slide 12 - https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/management-of-drug-interactions-with-nirmatrelvirritonavir-paxlovid/

Dr. Kotton

- Slide 18 - https://files.covid19treatmentguidelines.nih.gov/guidelines/covid19treatmentguidelines.pdf
- Slide 19 - https://www.fda.gov/media/154701/download
- Slide 20 - https://files.covid19treatmentguidelines.nih.gov/guidelines/covid19treatmentguidelines.pdf
- Slide 21- https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/
- Slide 22 - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid19-vaccination-sarscov2-infection
- Slide 23 - https://www.myast.org/sites/default/files/AST%20Statement%20on%20Use%20of%20Monoclonal%20Antibody_Final%20Mar%209%202022.pdf
- Slide 24 - https://doi.org/10.1038/s41591-022-01792-5
- Slide 25 - https://www.medrxiv.org/content/10.1101/2022.03.19.22272575v1.full.pdf
- Slide 26 - https://doi.org/10.1038/s41591-022-01792-5
- Slide 27 – https://www.cdc.gov/coronavirus

Selected Resources

Dr. Eisner

- Slide 37 - https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days

Dr. Razonable

- Slide 58 - https://doi.org/10.1101/2022.05.03.490409

Dr. Hall

- Slide 67 - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
- Slide 70 - https://www.cdc.gov/vaccines/covid-19/downloads/Clinical-Considerations-Second-COVID-19-Booster-508.pdf

Program Links:

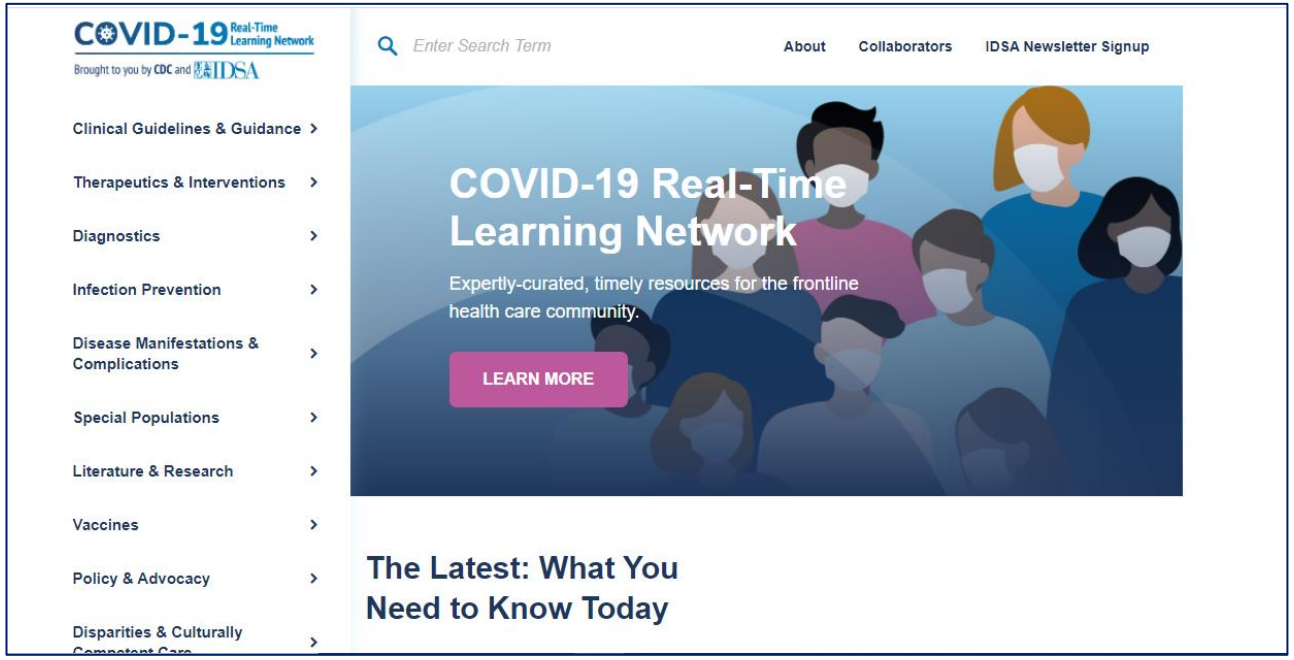
- This webinar is being recorded and can be found with the slides online at https://www.idsociety.org/cliniciancalls
- COVID-19 Real-Time Learning Network: https://www.idsociety.org/covid-19-real-time-learning-network/
- Vaccine FAQ: https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines-information--faq/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

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?

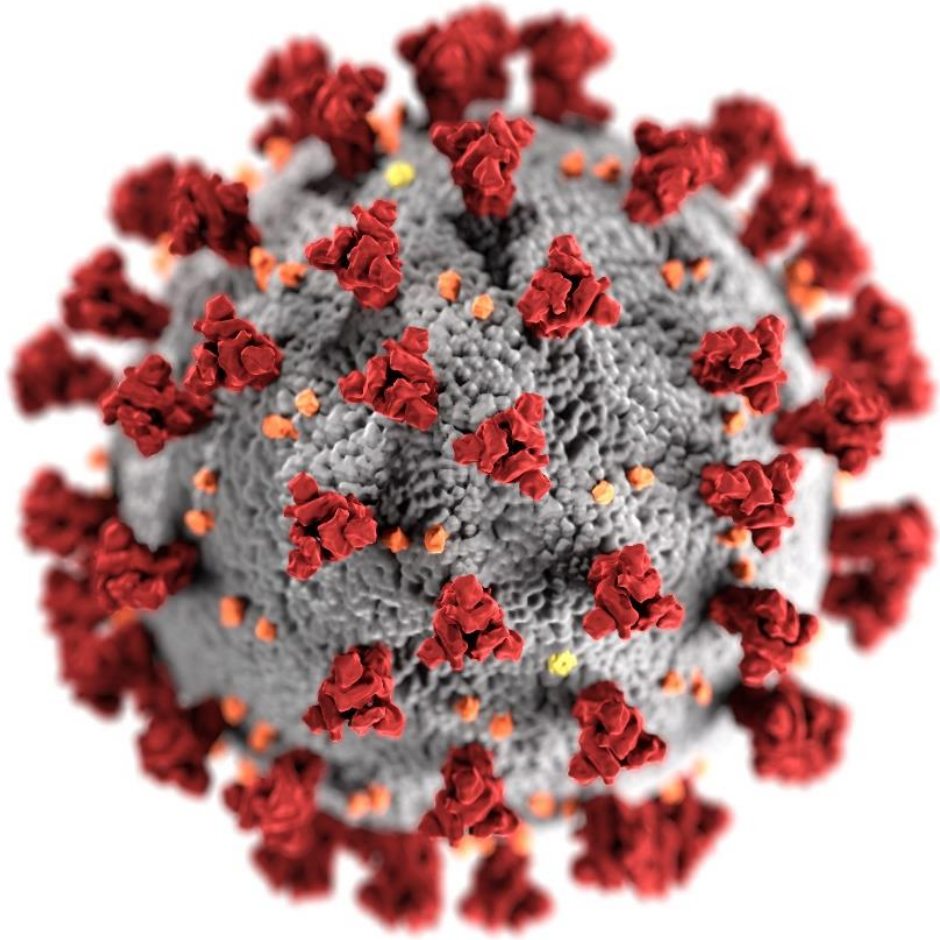
- Clinicians who have questions about the clinical management of COVID-19

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, June 11 @ 3:00 PM Eastern

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

-- library of all past calls available --

Contact Us:

Dana Wollins (dwollins@idsociety.org)
Deirdre Lewis (dlewis@idsociety.org)