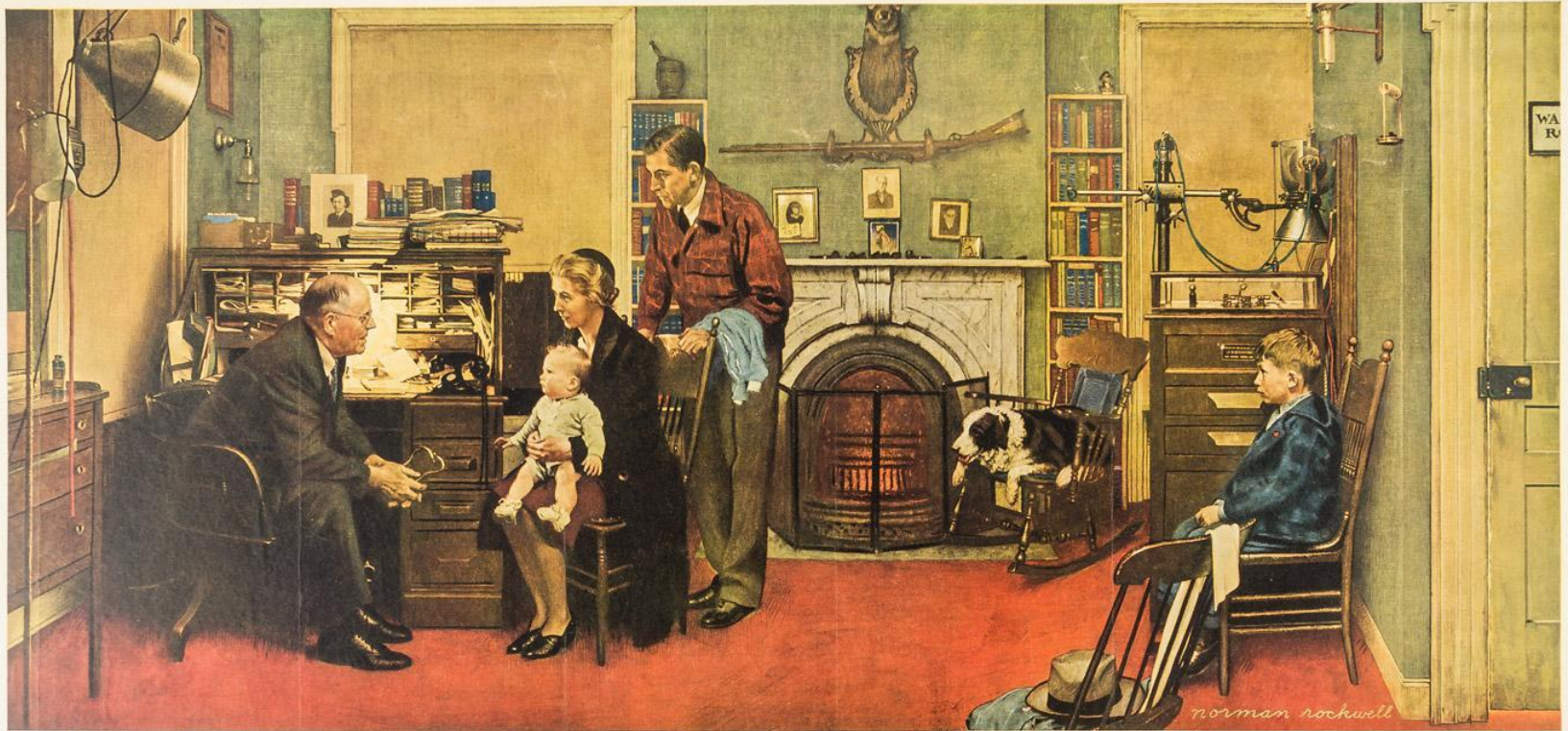




Covid-19 Update: Primary Care What Was Old is New Again

**Maryland Department of Health
Maryland Primary Care Program
Program Management Office**

9 March 2022



Norman Rockwell 1947
Dr George Russell
Arlington, Vermont

THE FAMILY DOCTOR
BY
NORMAN ROCKWELL

*To "Doc" Stephens
good luck
Sincerely, Norman Rockwell*

In a time when most people were skeptical even of shots and immunizations, Dr. Russell diligently advised patients and imparted his knowledge of good health practices. He held clinics on tuberculosis treatment, promoted the use of a district nurse resulting in better health for children, and even caught rabid dogs and transported bitten children to New York City.

Agenda

- ❖ Action Steps
- ❖ Current surge data
- ❖ The new customary care
- ❖ Vaccines and boosters
- ❖ Therapeutics
- ❖ Testing
- ❖ Health Equity and Primary Care
- ❖ Q/A

Action Steps: What you can do now

Primary Care Triple Play

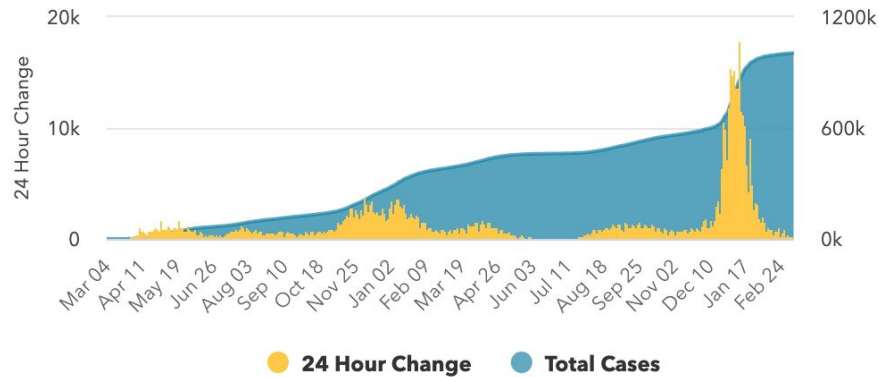
- 1) **Vaccines**: Outreach to patients who are due for boosters and schedule a **vaccine appointment**
- 2) **Testing**: **Test patients** at your practice as needed, and order free POC tests from MDH here
- 3) **Therapeutics**: Refer eligible patients to **oral antivirals and monoclonals**, as early as possible in alignment with NIH prioritization
- 4) Practice self care for yourself and your staff

Current Surge Data

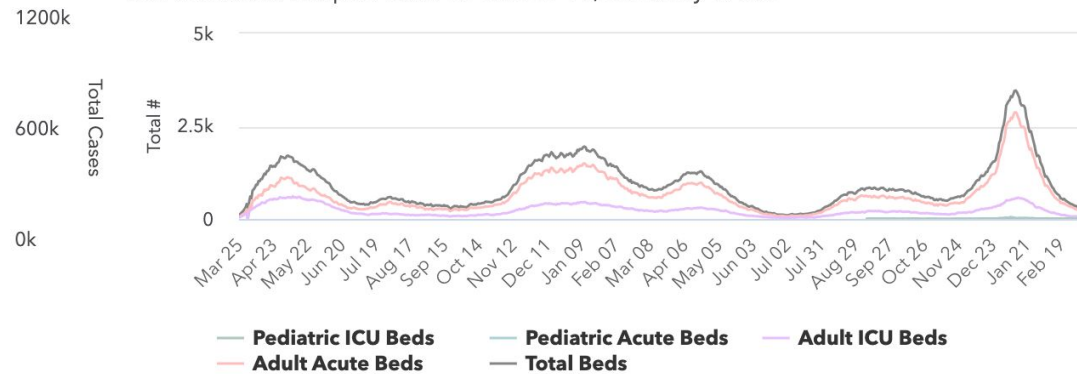
Cases and Hospitalizations in Maryland

Sustained and Rapid Decline

Confirmed Cases, Total over Time



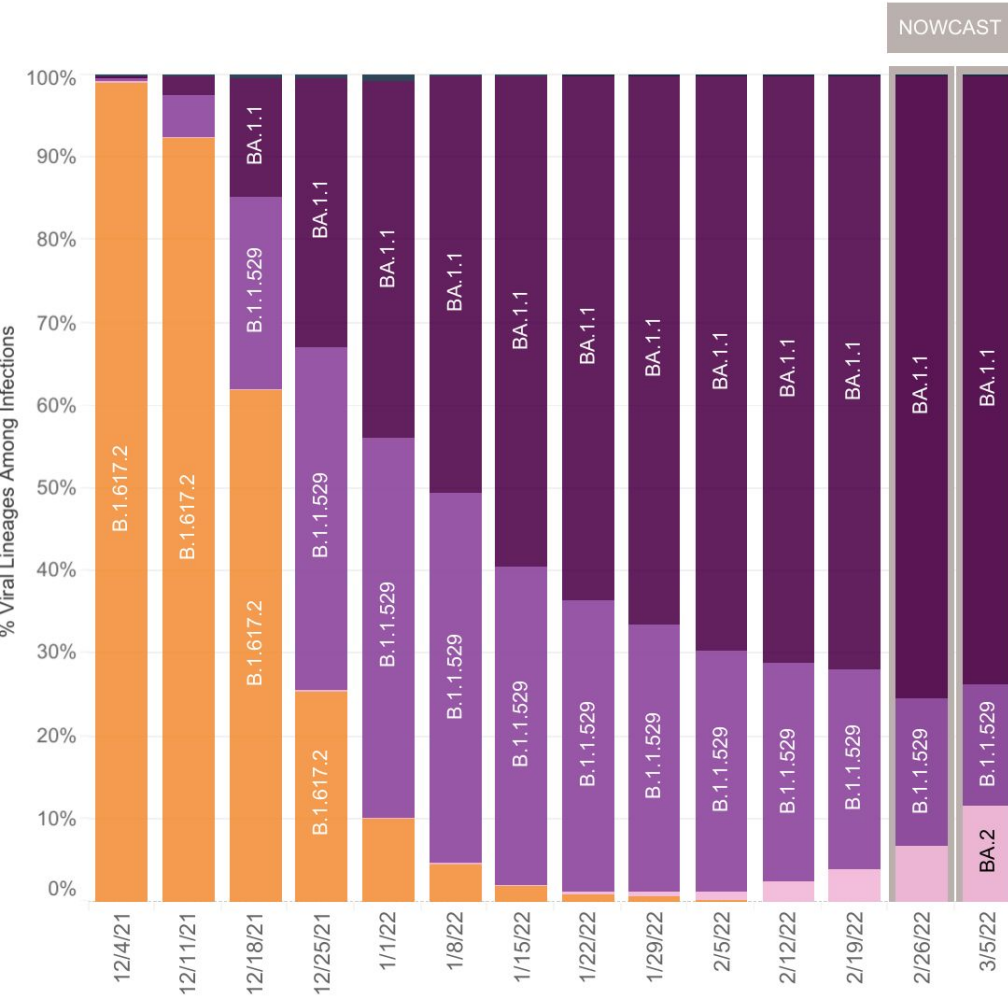
ICU and Acute Hospital Beds for COVID-19, Currently in Use



- ❖ Confirmed cases: 1,005,333 (*24hr change = +277*)
- ❖ Testing % positive: 1.60% (*24hr change = -0.01%*)
- ❖ Currently hospitalized: 284 (*24hr change = -2*)

United States: 11/28/2021 – 3/5/2022

Omicron in the U.S.



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

As of 3/6, CDC estimates the Omicron BA.2 variant makes up 11.6% of Covid cases

The New Customary Care

New Customary Care

- ❖ As pandemic posture fades we move back to the “New – Old Customary Care” with primary care at the center
 - Pent up demand for prevention and screening
 - Pent up demand for chronic disease management
 - Pent up demand to foster the provider- patient relationship
 - Pent up demand for behavioral health care
 - New demands to care for those physically and emotionally wounded by the pandemic
 - Continued demand for vaccines and boosters
 - Equitable access to care

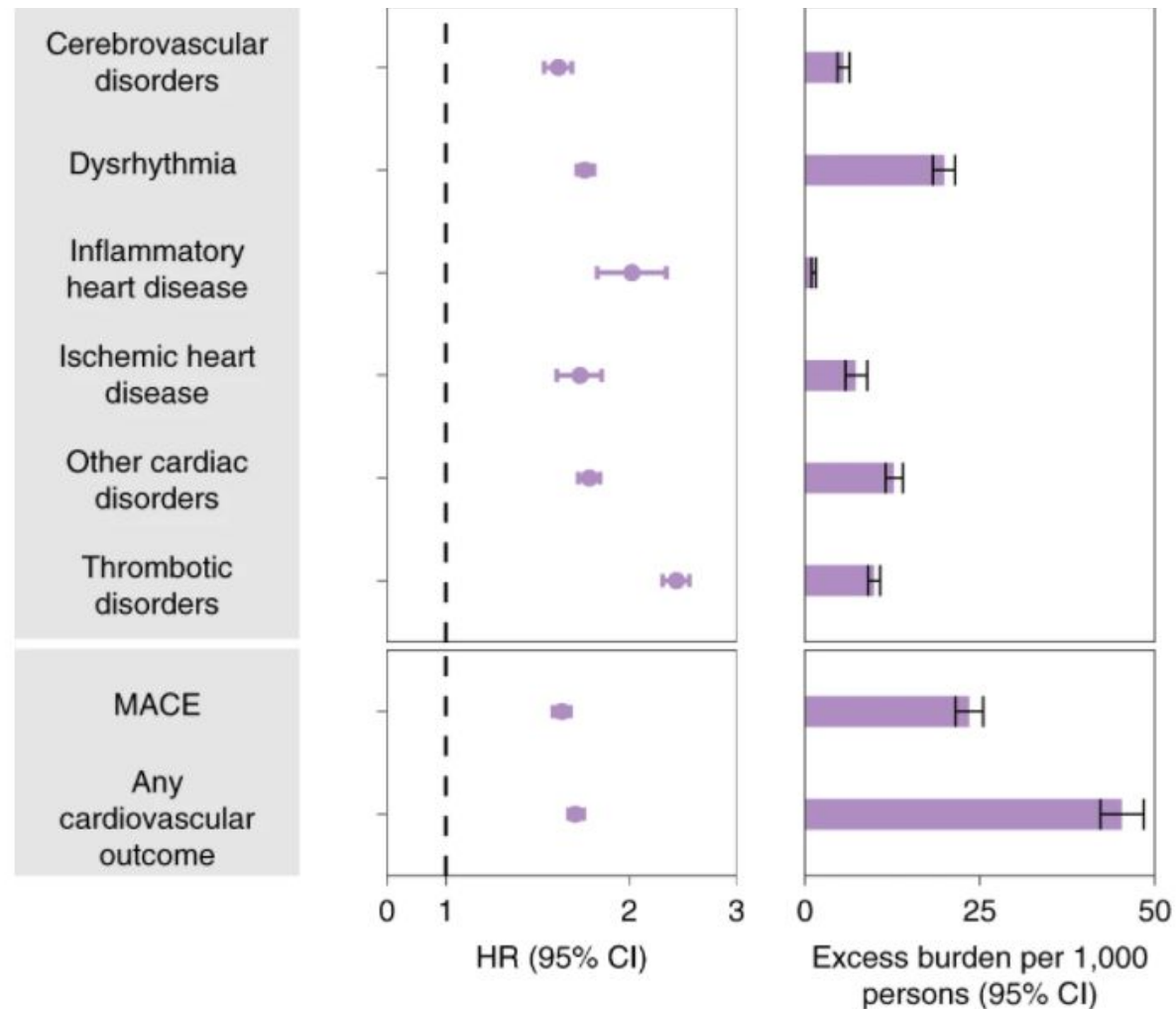
The New Door That Has Opened

- ❖ Incorporating the many lessons learned:
 - Equity needs to be intentional and data driven
 - Expanded testing access and POC tests
 - Expanded access to vaccines and rapid development of new vaccines
 - New therapeutics for infectious diseases
 - Collaboration with public health on population health and public communication

Cardiovascular Outcomes After Covid

Fig. 3: Risks and 12-month burdens of incident post-acute COVID-19 composite cardiovascular outcomes compared with the contemporary control cohort.

At the 12-month mark, compared with the contemporary control group, for every 1000 people, **COVID-19 was associated with increased incidents of all studied cardiovascular health outcomes**



Vaccines (Focus on Boosters and Pediatrics)

Francis Folger Franklin



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And Cotton Mather started inoculating people.



"In 1736 I lost one of my sons, a fine boy of four years old, by the smallpox taken in the common way. I long regretted bitterly and still regret that I had not given it to him by inoculation. This I mention for the sake of the parents who omit that operation, on the supposition that they should never forgive themselves if a child died under it; my example showing that the regret may be the same either way, and that, therefore, the safer should be chosen"

Providing and Referring for Vaccines

- ❖ Join the Maryland Primary Care Vaccine Program for now and for the future...
 - [Enroll in ImmuNet](#), [set up EHR or CSV reporting](#), and [register in ImmuNet](#)
- ❖ ImmuNet ordering now standard
- ❖ As new vaccines emerge to address new variants of coronavirus and emerging diseases, we will not likely go back to a state-based system but will rely on primary care
 - ❖ To inform patients
 - ❖ To administer vaccine
 - ❖ To track success



CDC Updated Recommendations for Immunocompromised Individuals

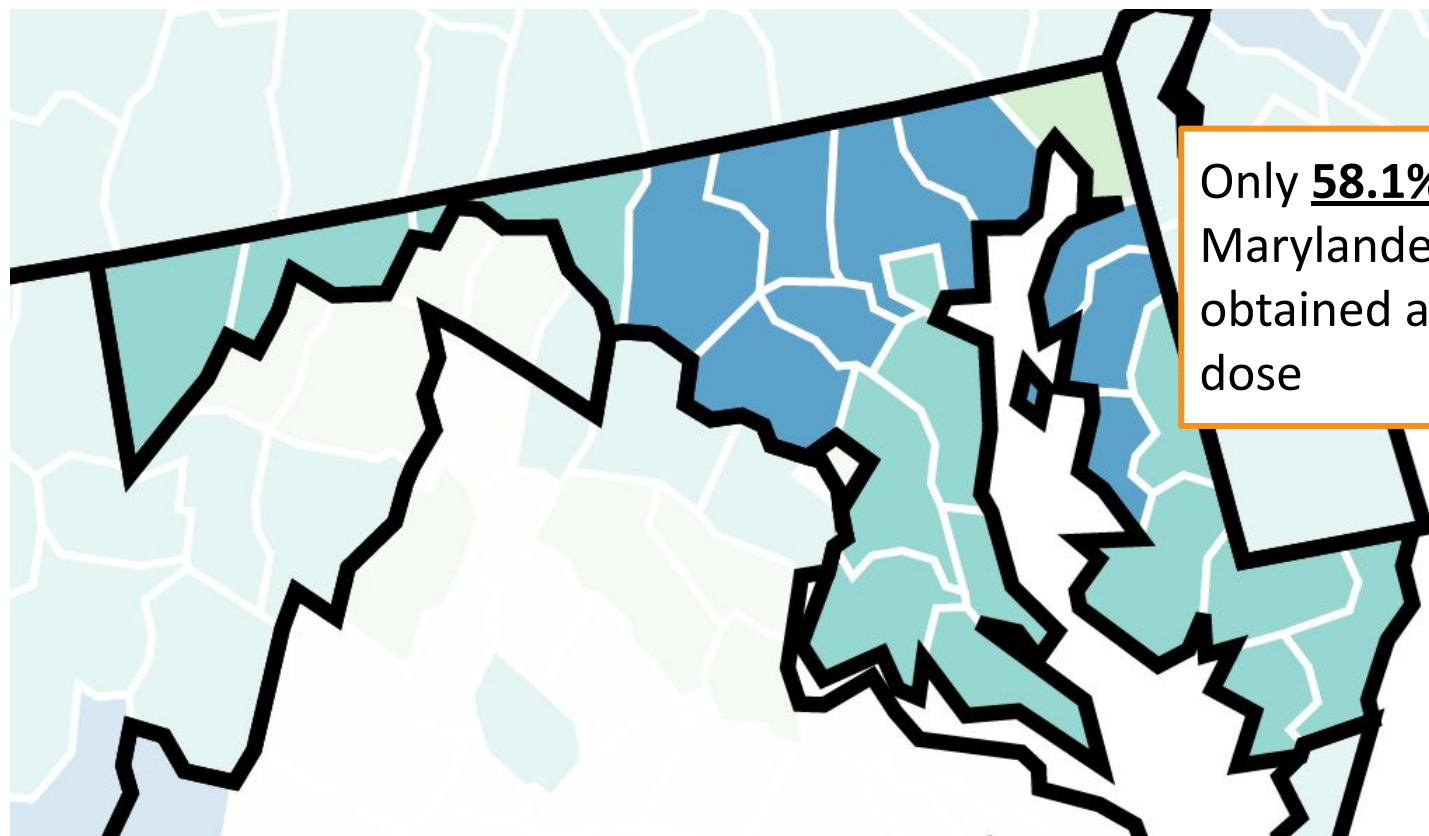
- ❖ New recommendations for immunocompromised individuals
 - Adjusted booster timelines
 - Now includes recommendations for those that obtained J&J

- ❖ More information on these recommendations and who is considered immunocompromised can be found on the [CDC website here](#)

Primary Series COVID-19 Vaccine	Age Group	Number of Doses to Complete Primary Series and Timing	Booster and Timing
Pfizer-BioNTech	12+ years	3 doses 2 nd dose given 3 weeks (21 days) after 1 st dose 3 rd dose given at least 4 weeks (28 days) after 2 nd dose	1 booster Given at least 3 months after 3 rd dose
Moderna	18+ years	3 doses 2 nd dose given 4 weeks (28 days) after 1 st dose 3 rd dose given at least 4 weeks (28 days) after 2 nd dose	1 booster Given at least 3 months after 3 rd dose

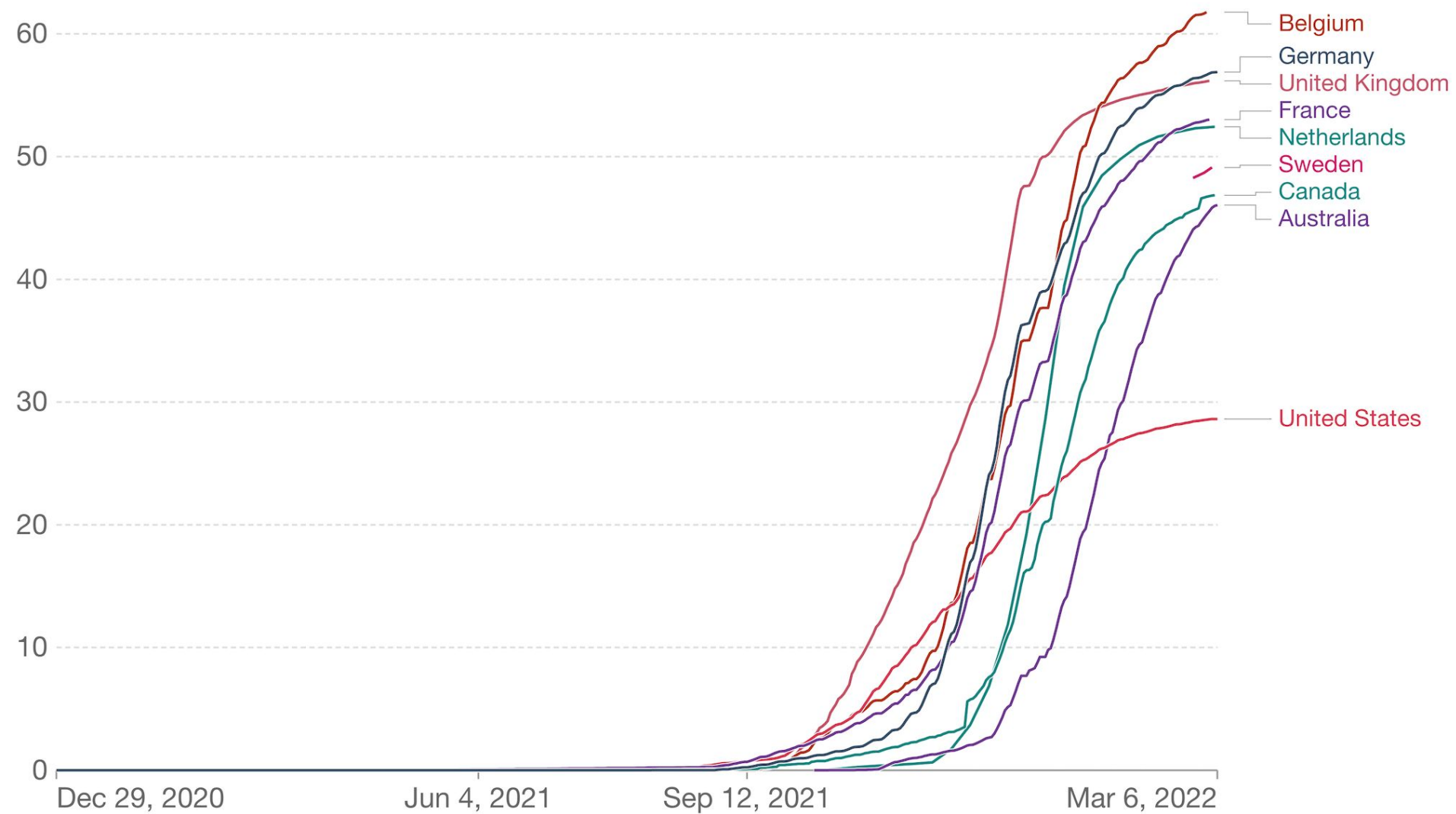
Primary Series COVID-19 Vaccine	Age Group	Number of Doses to Complete Primary Series and Timing	Booster and Timing
J&J/Janssen	18+ years	2 doses 1 st dose J&J/Janssen 2 nd dose Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) given at least 4 weeks (28 days) after 1 st dose	1 booster Either Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) in most situations given at least 2 months after 2 nd dose

Percent of Fully Vaccinated Population with a Booster Dose in Maryland

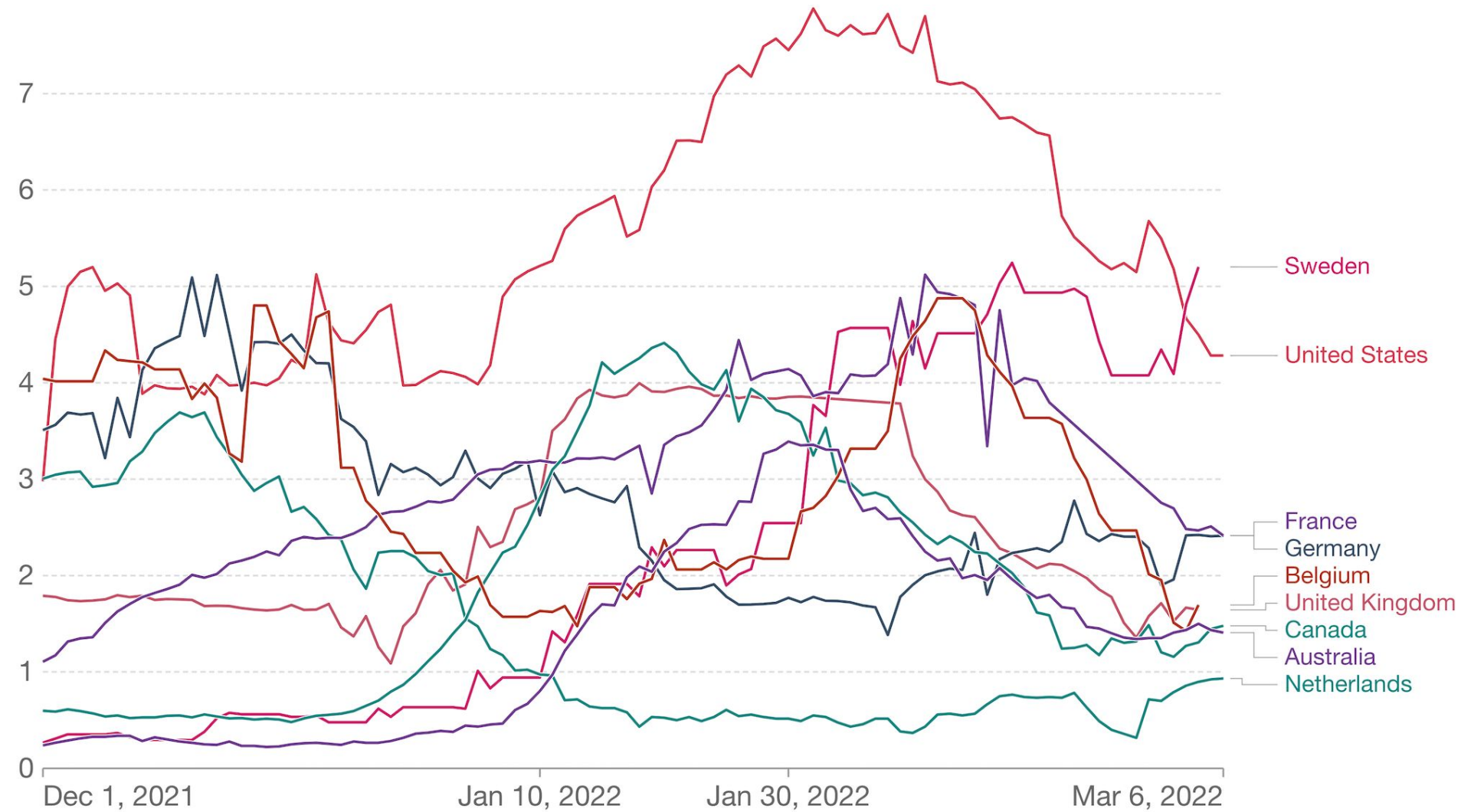


○ 0-29.9% ○ 30-39.9% ○ 40-49.9% ○ 50-69.9% ○ 70%+ ○ No Data

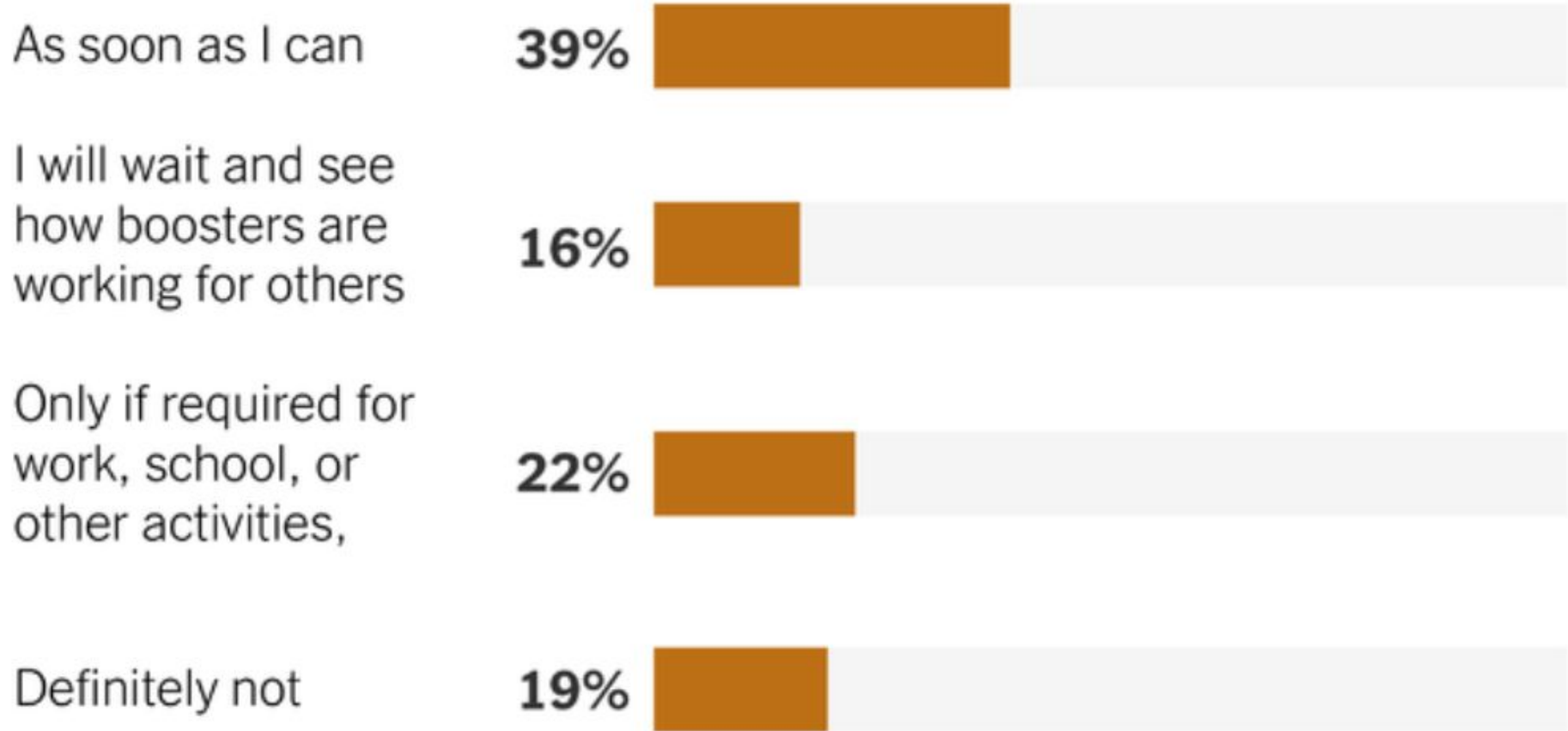
Boosters Administered by 100 People



Deaths per Million People During Omicron Variant



Will you get a booster dose?



From a survey of 530 vaccinated adults who had not already received a booster, Jan. 2022 | Source: Kaiser Family Foundation

Fully Vaccinated Population with a Booster Dose in Maryland by Age

Total boosters administered	2,199,496
% of Fully Vaccinated Population \geq 12 Years of Age with a Booster Dose	58.10%
% of Fully Vaccinated Population \geq 18 Years of Age with a Booster Dose	59.80%
% of Fully Vaccinated Population \geq 65 Years of Age with a Booster Dose	75.70%
% of Fully Vaccinated Population with a Booster Dose	58.10%

Please note that these percentages are among eligible individuals for each age bracket

Boosters

What did you get?	When are you eligible for a booster?	Who is eligible for a booster?	What should you get for your booster?
Pfizer	5 months after 2nd dose	12+	<i>Pfizer or Moderna</i>
Moderna	5 months after 2nd dose	18+	<i>Pfizer or Moderna</i>
J&J	2 months after single dose	18+	<i>Pfizer or Moderna</i>

- ❖ *Updated: [COVID-19 Vaccine Booster Guide for PCPs](#)
- ❖ ***Boosters are our best protection against Omicron and many vulnerable patients have not received boosters***

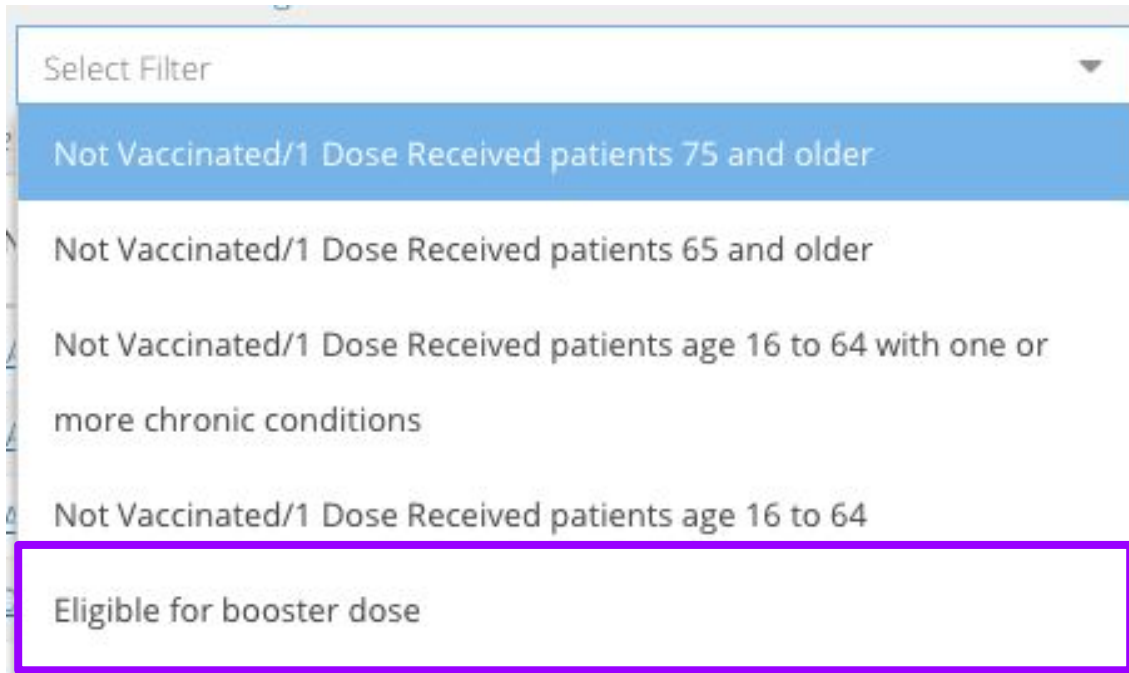
Booster Campaign

- ❖ COVID-19 vaccines remain effective, however their effectiveness against serious infection wanes over time, particularly for individuals that are 65+
- ❖ There are 60,000 MDPCP beneficiaries that are eligible for a booster dose, but have not obtained it
- ❖ Individuals that are 65+ have yet to receive a booster are:
 - 1.5 times more likely to test positive for COVID-19
 - 4.08 times more likely to be hospitalized for COVID-19
 - 4.24 times more likely to die from COVID-19
- ❖ **MDPCP is holding a booster campaign from now until March 28th to encourage increased booster uptake**

VaxCash 2.0

- ❖ [VaxCash 2.0 Promotion](#) - began 2/15
 - Weekly drawings for Marylanders that have obtained boosters (drawings are for \$500,000)
 - Promotion will continue for ten weeks and a grand prize of \$1M will be awarded on 5/3
- ❖ Use this promotion when outreaching to your patients to encourage them to get a vaccine booster dose

CRISP Booster Eligible Filter as a First Step in Data Driven Care



- ❖ Filter shows who is due for a booster who have not yet received one
- ❖ This has been updated to the new **5 month** timeline
- ❖ Use the filter to find your patients to outreach for booster doses

Note: this filter does not currently filter out deceased patients. Use the “Expired” column in the Vaccine Tracker to further filter out deceased patients. A fix for this is in the works.

Primary Care and Vaccines - A Strong Current Position

Cumulative Doses Administered

387,716

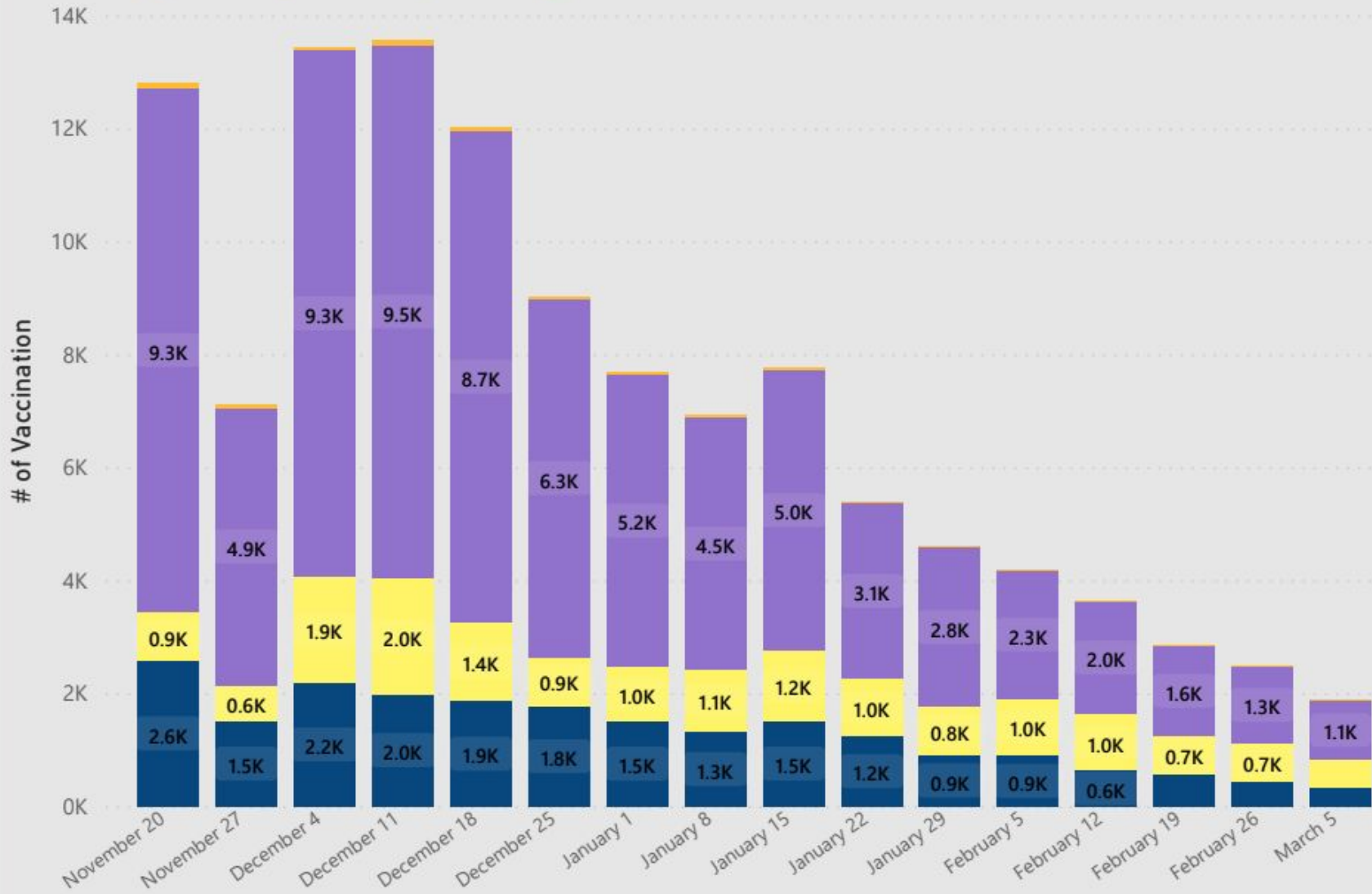
- ❖ 499 primary care practices are involved in the Primary Care Vaccine Program

Primary care providers are one of the most influential people in patients' lives and with increasing cases, we are inviting all providers to join the vaccination efforts

Primary Care and Booster Doses

Weekly Vaccine Administered

DoseName ● 1st Dose ● 2nd Dose ● 3rd Dose ● Single Dose



Pediatrics Vaccination Data

In Maryland, as of 3/8/22:

- ❖ Among 5-11-year-olds:
 - **45.6%** have received at least 1 dose
 - **39.0%** have received 2 doses
- ❖ Among 12-15-year-olds:
 - **77.3%** have received at least 1 dose
 - **71.3%** have received 2 doses
 - **68,324** 12-15 year olds in MD have received a booster
- ❖ Among 12-17-year-olds:
 - **85.4%** have received at least 1 dose
 - **75.3%** have received 2 doses
 - **45,238** 16-17 year olds in MD have received a booster

Poll Question

Therapeutics

Covid Therapeutics - Overview

Moving back to “Customary Care”

Timing is critical → the sooner the better

- ❖ Primary Care is the foundation of diagnosis and treatment for acute illness
- ❖ Rapid diagnosis of Covid-19 and/or other treatable conditions using POC tests
- ❖ Understanding the specific patient risks and benefits from the various therapies
- ❖ Prescribing or referring for the appropriate therapy in a timely manner
- ❖ Providing ongoing care for the patient and monitoring process

NIH Guidance on Outpatient Therapeutic Preferences

- 1) Paxlovid - by prescription
- 2) Sotrovimab - by referral
- 3) Remdesivir - by prescription
- 4) Molnupiravir - by prescription
- 5) ***NEW: Bebtelovimab - by referral***

[NIH guidelines link](#)

FDA Issues EUA for Lilly's Bebtelovimab

- ❖ FDA issued an [EUA](#) for Lilly's bebtelovimab — 2/11
- ❖ For treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg or ~88 lbs)
 - Positive COVID-19 test
 - High risk for progression to severe COVID-19, including hospitalization or death
 - Alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate
- ❖ NOT authorized for patients hospitalized due to COVID-19 or require oxygen therapy due to COVID-19
- ❖ Retains activity against both omicron variant and the BA.2 omicron subvariant
- ❖ Potential risk of treatment failure due to the development of viral variants that are resistant to bebtelovimab
- ❖ Daily reporting required via HPOP

Bebtelovimab Pseudotyped Data

Lineage with spike protein substitution	Country first identified	WHO nomenclature	Key substitutions tested ^a	Fold reduction in susceptibility
B.1.1.7	UK	Alpha	N501Y	no change ^b
B.1.351	South Africa	Beta	K417N + E484K + N501Y	no change ^b
P.1	Brazil	Gamma	K417T + E484K + N501Y	no change ^b
B.1.617.2/ AY.3	India	Delta	L452R + T478K	no change ^b
AY.1/ AY.2 (B.1.617.2 sublineages)	India	Delta [+K417N]	L452R + T478K + K417N	no change ^b
B.1.427/ B.1.429	USA (California)	Epsilon	L452R	no change ^b
B.1.526 ^c	USA (New York)	Iota	E484K	no change ^b
B.1.617.1	India	Kappa	L452R + E484Q	no change ^b
C.37	Peru	Lambda	L452Q + F490S	no change ^b
B.1.621	Colombia	Mu	R346K + E484K + N501Y	5.3
B.1.1.529/BA.1	South Africa	Omicron	G339D + S371L + S373P + S375F + K417N + N440K + G446S + S477N + T478K + E484A + Q493R + G496S + Q498R + N501Y + Y505H	no change ^b
BA.1.1	South Africa	Omicron [+R346K]	G339D + R346K + S371L + S373P + S375F + K417N + N440K + G446S + S477N + T478K + E484A + Q493R + G496S + Q498R + N501Y + Y505H	no change ^b
BA.2	South Africa	Omicron [BA.2]	G339D + S371F + S373P + S375F + T376A + D405N + R408S + K417N + N440K + S477N + T478K + E484A + Q493R + Q498R + N501Y + Y505H	no change ^b

^aKey substitutions occurring in the RBD of spike protein are listed. Pseudoviruses containing the full-length spike protein reflective of the consensus sequence for each of the variant lineages were tested. ^bNo change: < 5-fold reduction in susceptibility. ^cIsolates of the B.1.526 lineage harbor several spike protein amino acid substitutions, and not all isolates contain the E484K substitution (as of February 2021). VLP: virus-like particle; WHO: World Health Organization.

Table 1. Bebtelovimab pseudotyped virus-like particle neutralization data for SARS-CoV-2 Spike protein variants

Monoclonal Antibody Referrals

❖ Referral Options

- Option 1: [CRISP eREFERRAL for Monoclonal Antibody Infusion](#)
- Option 2: [Maryland Referral Form for Monoclonal Antibody Infusion Treatment](#) (Updated weekly)
- Some sites allow patients to self-refer for evaluation (listed on referral materials)



Monoclonal Antibody Checklist

The Maryland Department of Health (MDH) provides this clinical criteria checklist as a resource for referring or administering monoclonal antibodies (mAb). There are currently three products authorized under Emergency Use Authorization (EUA): [Bamlanivimab and Etesevimab](#), [REGN-COV2](#), and [Sotrovimab](#).¹ Monoclonal antibodies are currently indicated for two purposes: certain individuals with active COVID-19 and as a post-exposure prophylaxis in vulnerable persons (e.g., not fully vaccinated or immunocompromised) who are at high-risk for progression to severe COVID-19.

Determine Eligibility for Monoclonal Antibody Treatment for Patients	
Track 1 - Active COVID-19 Infection	Track 2 - Post-Exposure Prophylaxis
1. Is the patient 12 years of age or older weighing at least 88 pounds? If NO , STOP ; YES , proceed to number 2.	1. Is the patient 12 years of age or older weighing at least 88 pounds? If NO , STOP ; YES , proceed to number 2.
2. Does the patient have a positive COVID-19 PCR or antigen test result? If NO , STOP ; YES , proceed to number 3.	2. Does the patient meet high-risk exposure criteria as defined by CDC Quarantine and Isolation guidance? If NO , Proceed to Number 3 ; YES , proceed to number 4.
3. Does the COVID-19 positive patient have mild to moderate COVID-19 symptoms such as fever, cough, shortness of breath, loss of taste/smell, fatigue, nausea, vomiting, diarrhea, throat pain, congestion, myalgia, or headache? If NO , STOP ; YES , proceed to number 4.	3. Is the patient at high risk of exposure to an individual infected with COVID-19 in the same institutional setting? If NO , STOP ; YES , proceed to number 4.
4. Has it been less than 10 days since symptom onset and positive COVID-19 test result? If NO , STOP ; YES , proceed to number 5.	4. Is the individual NOT fully vaccinated? ² If NO (individual is fully vaccinated), Proceed to Number 5 ; YES (individual is not fully vaccinated), proceed to number 6.
5. Is the COVID-19 positive patient at high risk* for progression to severe COVID-19, including hospitalization or death? If NO , STOP ; YES , proceed to number 6.	5. Is the individual anticipated to NOT mount an adequate immune response to complete SARS-CoV-2 vaccination (e.g. immunocompromised or taking immunosuppressive medications)? If NO , STOP ; YES , proceed to number 6.
6. If any of the following apply, STOP ; the patient is not eligible for treatment. Otherwise, proceed to number 7. <ul style="list-style-type: none"> • Patient hospitalized for COVID-19 • Patient requires oxygen therapy due to COVID-19 • Patient requires require an increase in baseline oxygen flow rate due to COVID-19 • Patient is in imminent need of hospitalization due to COVID-19 	6. If exposure occurred within the past 96 hours, patient meets eligibility criteria; proceed with administration or referral. Patients who meet eligibility criteria can be referred to facilities geographically spread across Maryland for equitable access. To refer a patient, please use the CRISP platform eReferral Tool or the Maryland Department of Health (MDH) Maryland Referral Form .
7. Patient meets eligibility criteria; proceed with administration or referral. For referral resources see Track 2 No. 6.	

¹Sotrovimab is not authorized for post-exposure prophylactic administration and is only commercially available at this time.
²Close contact with an infected individual is defined as being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). See this website for additional details: <https://www.cdc.gov/soronets/2019/nCoV-19-at-risk-immunization.html>
³Individuals are considered to be fully vaccinated 2 weeks after their second vaccine dose in a 2-dose series (such as the Pfizer or Moderna vaccines), or 2 weeks after a single-dose vaccine (such as the Johnson & Johnson/Janssen vaccine). See this website for more details: <https://www.cdc.gov/soronets/2019/nCoV-19-at-risk-immunization.html>
⁴For further information as what qualifies an individual as high risk please see slide 39 of the Monoclonal Antibody Clinical Implementation Guide available at: https://www.dhs.gov/emergency-events/covid19/investigation-MCM/Documents/USG_COVID19-1x_Playbook.pdf



Updated Recommendations for Vaccines Post Therapeutics

- ❖ Updated recommendations from the CDC now include the recommendation that individuals who have obtained monoclonal antibodies or convalescent plasma can be vaccinated at any time
 - There is no longer a waiting period recommendation related to Covid vaccines after receiving these treatments
 - More information can be found on the [CDC website here](#)

Oral Antiviral Agents Overview

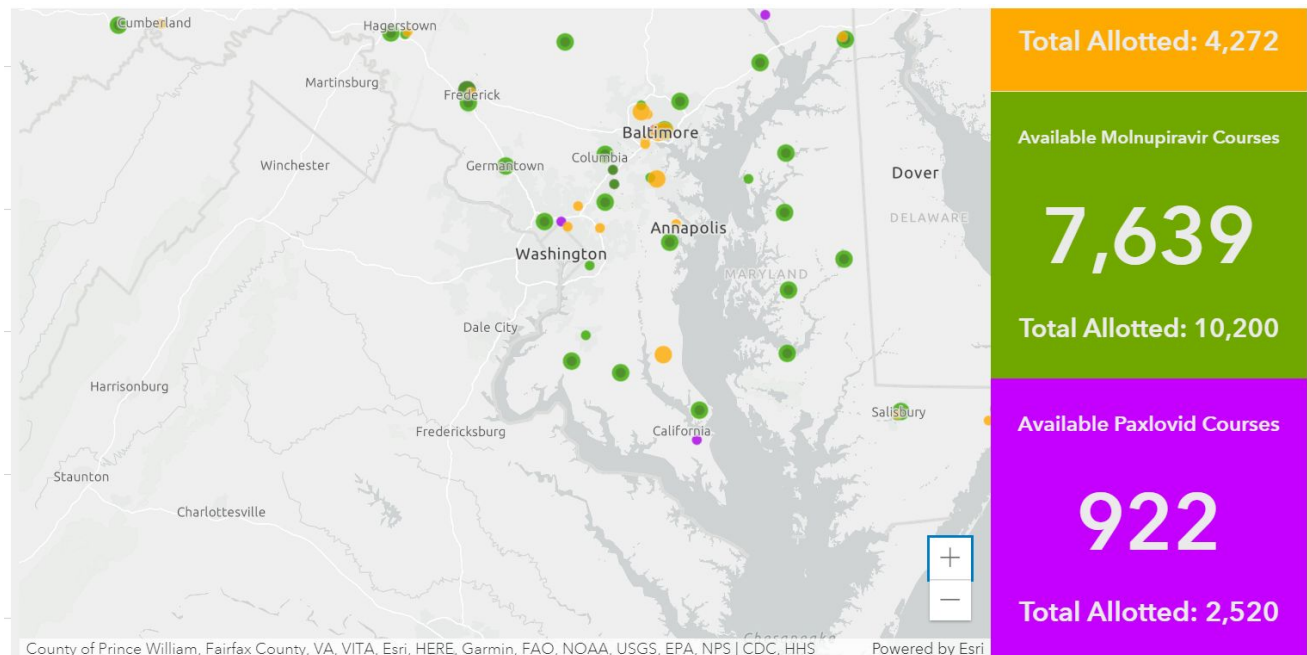
- ❖ [Paxlovid FDA EUA](#) and [Molnupiravir FDA EUA](#)
- ❖ Dedicated pharmacies across state - list provided in “Clinician Letter”
 - Prescribed medication
- ❖ Start within 5 days of symptoms - sooner the better
- ❖ Proof of positive Covid test
 - Can be any type of Covid test
- ❖ No cost to patients for treatment
 - Delivery fees may apply

Federal Test to Treat Program

- ❖ Began Tuesday, 3/8 and is in 44 CVS pharmacies across the state of Maryland
- ❖ Initially Federal Pharmacy Partners with clinics
- ❖ Institutional Pharmacies serving LTC facilities
- ❖ Open soon to Primary Care and Urgent Care
 - Direct delivery of OAVs to office
 - Requires registration on reporting in HPOPs

Oral Agent Inventory Confirmation

- ❖ Check inventory prior to ordering to ensure availability:
 - Use this [Federal Therapeutics Locator website](#) to identify where you can refer patients and the inventory available at those locations:



Paxlovid

- ❖ FDA authorized an [EUA for Paxlovid](#) on 12/22
- ❖ USG purchased 10 million courses for first half of 2022
 - 750 doses for Maryland per week – will increase around April
- ❖ Eligibility
 - Intended for mild-to-moderate Covid in **12+ adults** weighing at least 40 kilograms that test positive and are at high risk for progression to severe Covid-19
 - Medication must be initiated within 5 days of the onset of symptoms
- ❖ Study data
 - Paxlovid appears to cut the risk of hospitalization and death by 89%
- ❖ Dosage information in [FDA Fact Sheet](#)

Paxlovid Prescribing Details

- ❖ [Paxlovid Point-of-Care Reference Guide](#)
- ❖ Renal impairment adjustments
- ❖ Cautions after use regarding oral contraceptives
- ❖ Untreated or uncontrolled HIV cautions
- ❖ Medication interactions
 - Cytochrome P3A inhibitor
 - Drugs that use P3A for metabolism may be increased
 - P3A inducing drugs may reduce effectiveness of Paxlovid
 - [See Fact Sheet for Healthcare Providers](#) for full prescribing information

Molnupiravir

- ❖ FDA authorized an [EUA for Molnupiravir](#) on 12/23
- ❖ USG allocating 300,000 courses initially (3.1 million total)
 - 4,500 doses for Maryland
- ❖ Eligibility
 - Intended for mild-to-moderate Covid in **18+ adults** weighing at least 40 kilograms that test positive and are at high risk for progression to severe Covid-19
 - Medication must be initiated within 5 days of the onset of symptoms
 - *Not indicated during pregnancy*- needs post use contraception
- ❖ Study data
 - Molnupiravir appears to cut the risk of hospitalization and death by 30%

Remdesivir for Outpatient Therapy

- ❖ FDA approved for high risk ambulatory patients
- ❖ For individuals 12 years and older and weighing 40 kg or more
- ❖ Treatment
 - Remdesivir 200 mg IV on Day 1, followed by Remdesivir 100 mg IV daily on Days 2 and 3
 - Initiated as soon as possible and within 7 days of symptom onset
- ❖ Study data
 - 3 consecutive days of IV Remdesivir resulted in an 87% relative reduction in risk of hospitalization or death compared to placebo

Evusheld - Long Acting Prophylaxis

- ❖ On 2/27, the FDA issued an updated [EUA for Evusheld](#) doubling the dose
 - Requires Moderate to severe immune compromise
 - Unable to take vaccine due to severe allergy
 - IM dosing at (tbd) month intervals
- ❖ Allocation
 - Directly to hospital partners and monoclonal providers
 - Referrals expanding - Weekly updates for providers
- ❖ Data submitted to FDA to consider an EUA for treatment
- ❖ Providers interested in having Evusheld allocations - details in weekly provider Therapeutics Memo
- ❖ **Note**: Wait two weeks after Covid vaccines before giving Evusheld

Evusheld EUA Update

Updated Evusheld Dosing Requirements (tixagevimab and cilgavimab)

Updated Dosage and Administration

300 mg of tixagevimab and **300 mg of cilgavimab** administered as two separate consecutive intramuscular injections.

Repeat Dosing for Patients who Previously Received 150 mg of tixagevimab and 150 mg of cilgavimab

150 mg of tixagevimab and **150 mg of cilgavimab** administered as two separate intramuscular injections as soon as possible.



Neutralization Activity Against VOC

Across independent evaluations, **IC₅₀ values for neutralization of Omicron with TIXA/CILGA ranged from 147 to 273 ng/mL (live neutralization assay)** – within the range of neutralizing antibody titers found in individuals who have been previously infected with and recovered naturally from COVID-19¹

Subvariant	Testing Location / Analysis	Assay Type	Key Substitutions Tested	TIXA/CILGA	
				IC ₅₀ (ng/mL)	Fold Change (Reduction)
Omicron BA.1	Oxford University ^{1,2}	Live (Authentic)	All spike changes ^b	273	30-fold
Omicron BA.1	Washington University ^{a,1,3}		All spike changes ^b	147	12-fold ^c
Omicron BA.1	EVUSHELD Fact Sheet ⁴	Pseudotyped VLP	G339D+S371L+ S373P+S375F+ K417N +N440K+ G446S+ S477N+T478K+ E484A +Q493R+ G496S+Q489R+ N501Y+ Y505H	171-277	132-183-fold
Omicron BA.1.1	EVUSHELD Fact Sheet ⁴	Live (Authentic)	G339D+R346K+ S371L+ S373P+ S375F +K417N+N440K +G446S+ S477N +T478K +E484A+Q493R+ G496S +Q489R+N501Y+ Y505H	–	176-fold
Omicron BA.2	EVUSHELD Fact Sheet ⁴	Live (Authentic)	G339D+S371F+S373P+ S375F+ T376A+ D405N+ R408S +K417N+ N440K+ S477N +T478K+E484A+Q493R+Q498R +N501Y+ Y505H +H655Y+N679K+P681H +N764K	–	5.4-fold

^aTesting using parental versions of AZD8895 (COV2-2196) and AZD1061 (COV2-2130); ^bOmicron spike mutations: A67V, Δ69-70, T95I, G142D, Δ143-145, Δ211, L212I, ins214EPE, G339D, S371L, S373P, S375F, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, G496S, Q498R, N501Y, Y505H, T547K, D614G, H655Y, N679K, P681H, N764K, D796Y, N856K, Q954H, N969K, L981F; ^cFold change values reported as neutralization of B.1.1.529 in Vero-hACE2-TMPRSS2 cells.

COVID-19 = coronavirus disease 2019; hACE2 = angiotensin-converting enzyme 2; IC₅₀ = half-maximal inhibitory concentration; NA = not applicable; TIXA/CILGA = tixagevimab/cilgavimab; TMPRSS2 = Transmembrane protease, serine 2. VLP = virus-like particle; VOC = variant of concern.

1. AstraZeneca Pharmaceuticals LP press release. Published December 23, 2021; 2. Dejnirattisai W et al. *Cell*. 2022; 185(3):467-484.e15;

3. VanBlargan LA et al. Online ahead of print. *Nat Med*. 2022; 4. Fact sheet for healthcare providers. Emergency Use Authorization (EUA) of EVUSHELD™ (tixagevimab co-packaged with cilgavimab). 2022.

Evusheld Allocation and Distribution

- ❖ Encouraging referrals open to community providers for appropriate patients
- ❖ Actively adding more sites. Contact kara.stitcher@maryland.gov if interested
- ❖ Opening access to community providers to provide treatments.
- ❖ Evusheld is now available in institutional pharmacies that serve skilled nursing facilities (SNFs)

	Evusheld Allocation
12/27/2021	912
1/3/2022	888
1/10/2022	1,320
1/17/2022	1,320
1/24/2022	1,344
1/31/2022	1,340
2/7/2022	892
2/14/2022	912
3/7/22 (month)	3646

Evusheld Referral Options

Region/Site	Referral Form
Region 1: Garrett Regional Medical Center	Fax rx and supporting diagnosis information to 301-533-4102 to initiate referral.
Region 2: Meritus Medical Center	Visit website
Region 3: Hatzalah of Baltimore	Submit referral through provider referral link .
Region 3: Mercy Medical Center	Contact COVIDAntibody@mdmercy.com to refer.
Region 3: LifeBridge Health Hospitals (Sinai, Northwest, Carroll)	Submit referral through provider referral link .
Region 3: Soleil Pharmacy	Fax prescription and supporting diagnosis information to 410-582-8728 to initiate referral.
Region 5: Calvert Health Medical Center	Fax referral form attached to 410-535-8224 or send referral form to COVIDTX@calverthealthmed.org .
Multiple Regions: MedStar Health System	Contact calvin.williams@medstar.net , or glenn.w.wortmann@medstar.net to discuss referral.

Testing

Point-of-Care Tests

- ❖ [Order](#) and use point-of-care tests to rapidly diagnose symptomatic patients
- ❖ Tests can be conducted outside of a lab setting including congregate care facilities, physician offices, etc. Results typically ready in ~ 15 minutes
- ❖ Note: The FDA has updated and expanded the expiry dates for the Abbott BinaxNOW tests
 - Further information including kit lot numbers, original expiration dates, and updated expiration dates can be found [here](#)

Point-of-Care Test Reimbursement

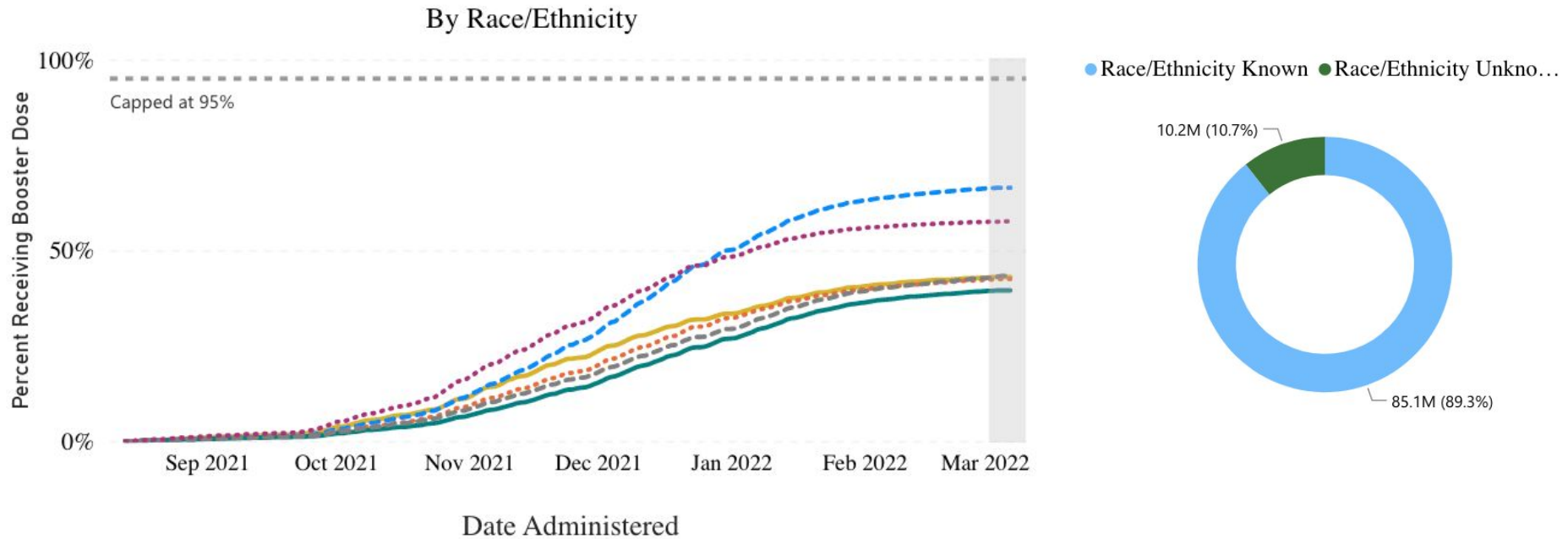
- ❖ Point-of-care tests are available for reimbursement
- ❖ Further guidance and information can be found in the MDH COVID-19 Reimbursable Laboratory Codes Fee Schedule document [here](#)
 - This document includes laboratory codes, as well as specimen collection fee information

New Testing Opportunity

- ❖ More details - soon to be announced
- ❖ Free multichannel rapid PCR testing platforms
- ❖ Required reagent cartridges
- ❖ Required reporting to MDH
- ❖ Billable services
- ❖ More information to follow
- ❖ Expressions of interest to Sherlina.holland@maryland.gov

Equity and Primary Care

Booster Vaccination Trends by Race and Ethnicity

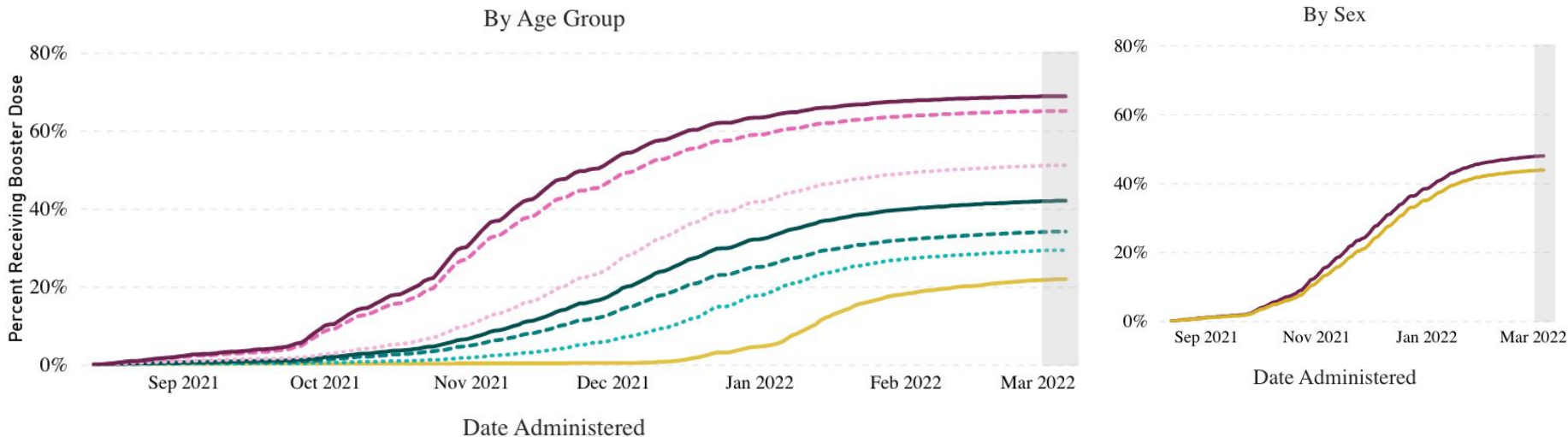


Percent of Fully Vaccinated People Receiving COVID-19 Booster Doses by Race/Ethnicity and Date Administered, United States for 12 Years and Older

August 13, 2021 – March 07, 2022

	AI/AN, NH	Asian, NH	Black, NH	Hispanic/Latino	NHOPI, NH	White, NH
Booster Dose	43.0%	66.4%	42.5%	39.5%	43.3%	57.6%

Booster Vaccination Trends by Age and Sex



Percent of Fully Vaccinated People Receiving COVID-19 Booster Doses by Age, Sex and Date Administered, United States for 12 Years and Older

August 13, 2021 – March 07, 2022

12-17 yrs 18-24 yrs 25-39 yrs 40-49 yrs 50-64 yrs 65-74 yrs 75+ yrs

Booster Dose 21.9% 29.3% 34.1% 42.0% 51.1% 65.0% 68.8%

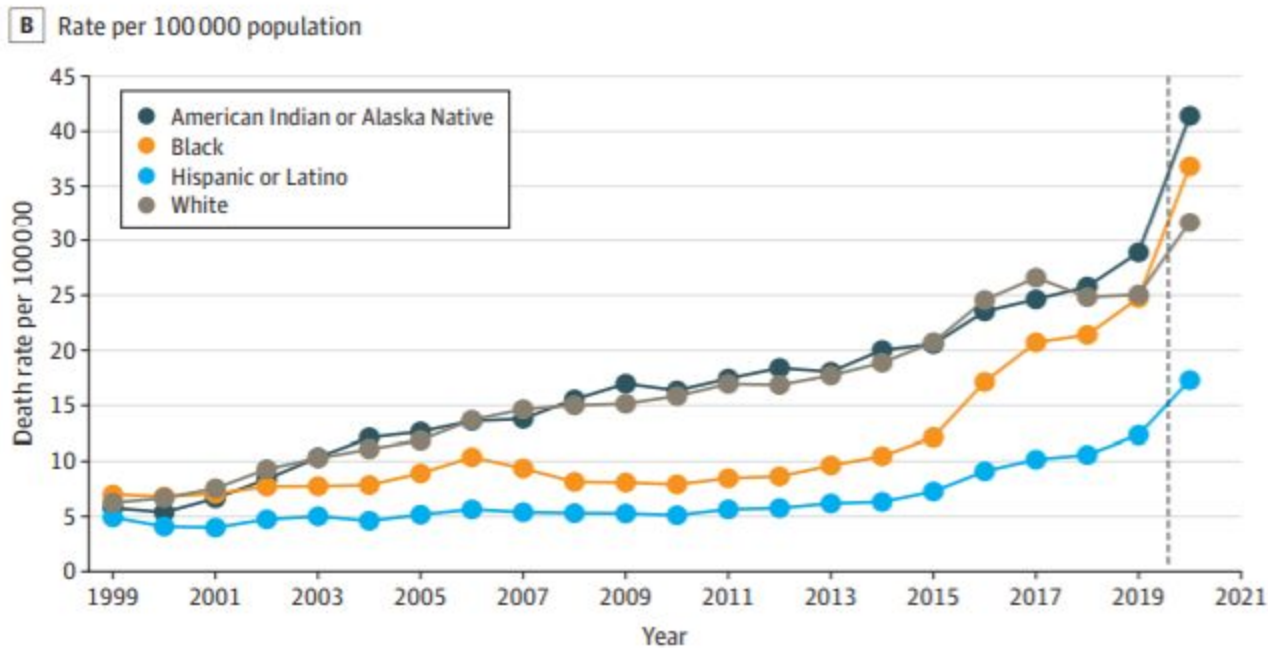
Female Male

Booster Dose 47.9% 43.8%

Source: [CDC](https://www.cdc.gov)

Updated: 3/7/2022

Racial and Ethnicity Impacts on Overdose Deaths



A, Year-to-year percent change.
 B, Drug overdose mortality per 100 000 population. The vertical dashed lines separate the COVID-19 pandemic period from prior trends.

Friedman JR, Hansen H. Evaluation of Increases in Drug Overdose Mortality Rates in the US by Race and Ethnicity Before and During the COVID-19 Pandemic. *JAMA Psychiatry*. Published online March 02, 2022. doi:10.1001/jamapsychiatry.2022.0004

Coming Soon in MDPCP: Health Equity & Digital Quality Measures Solution

- ❖ Digital Quality Measure platform linked to practice EHR that can:
 - Track quality data on a near real-time basis
 - Stratify quality reports by key socio-demographic variables to uncover disparities and focus on health equity through quality measurement
 - Easier data collection for MIPS quality measures
 - Annual specification updates implemented beginning of the performance year, earlier than currently possible through most EHR vendors

Simple platform for reporting on quality measures and tracking quality performance with an equity focus

The Future of Primary Care Includes Health Equity

- ❖ Digital quality measures
- ❖ Social needs screening
- ❖ Patient demographic collection
- ❖ Referrals for social needs

The key is using data to inform care delivery and provide an equity lens in providing care

Takeaways: Triple Play Strategy

Triple Play and Takeaways for Primary Care

- ❖ Covid isn't over but it is moving toward control
- ❖ Unlike this time last year, we now have **baseball bats**, a **better pitch**, and **protective gear**
- ❖ The **Triple Play** will lead us through Omicron and the Winter season
 - **Vaccines - including boosters**
 - **Testing - test at your practice**
 - **Therapeutics - prescribe antivirals and mAb referrals**

The COVID-19 Triple Play: Three Keys to COVID Mitigation in Primary Care



There are many strategies and a lot of information out there related to COVID-19. As we continue to face the Omicron surge, focus on three essential areas for primary care to mitigate COVID-19 -- primary care's triple play. Below you will find the three essential focus areas and related links to guide your practice.



Vaccines

- Order COVID-19 vaccines on Thursdays between 8:00-4:00PM
 - Pfizer 12+, Pfizer 5-11, Moderna 18+, and J&J 18+
- Outreach to patients to get them in for initial vaccines and **booster** dose appointments
- Refer patients to a [vaccinating site](#) or request a [mobile vaccination clinic](#) via this [form](#)



Testing

- Order free Point-of-Care tests in order to quickly diagnose patients
 - [Ordering form](#)
- Consider PCR testing for asymptomatic patients
 - Review [this webinar](#) (beginning at 5:00) for PCR testing options
- Use [this toolkit](#) to guide testing protocols and communication



Therapeutics

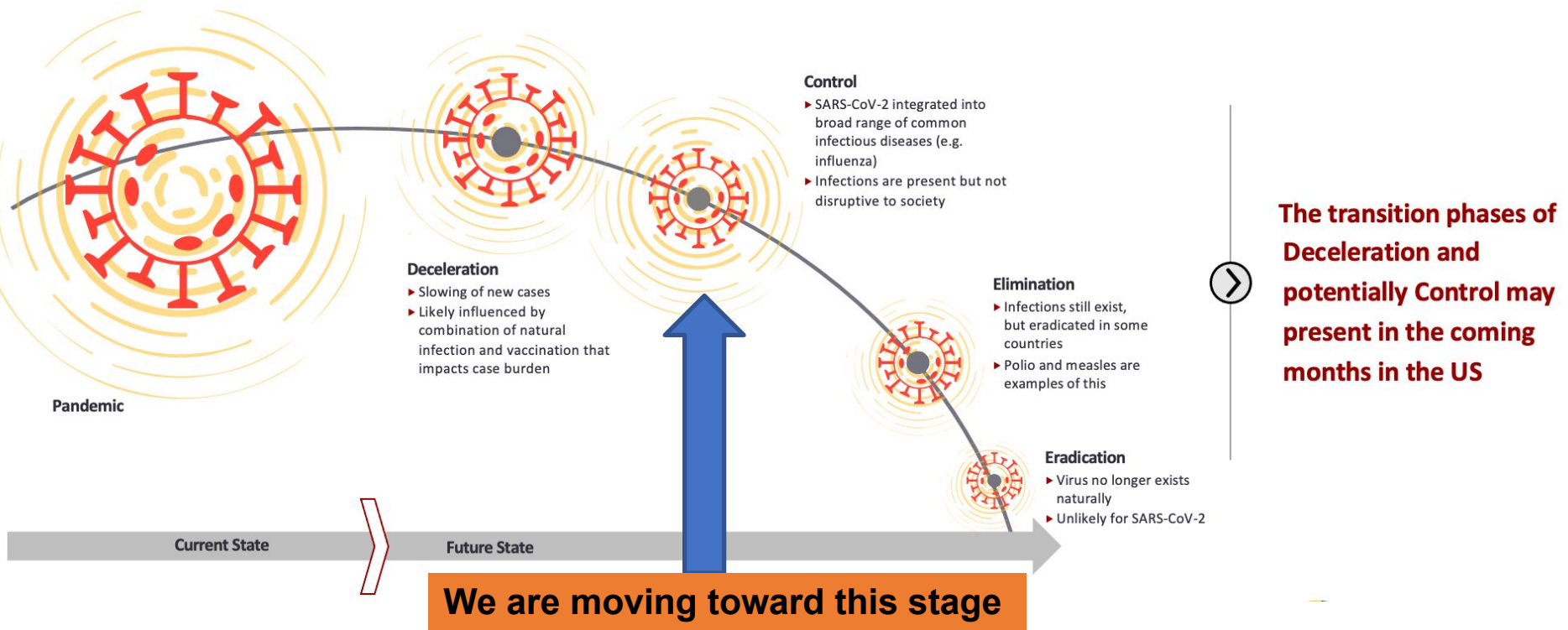
- Refer eligible patients for monoclonal antibody treatment
 - Refer in [CRISP](#) or use this [referral form](#)
- Use this [Federal Therapeutics Locator website](#) to identify where you can refer eligible patients for oral antiviral agents including Molnupiravir and Paxlovid



With this triple play, we can send COVID-19 to the dugout!

Page 1

There are proposed stages of post-pandemic transition; not all may be achievable with SARS-CoV-2



Take Care of Yourself and Your Staff

- ❖ It is not selfish to take breaks and you cannot work nonstop
- ❖ Check in on your team and talk about your feelings and experiences
- ❖ Connect with family and friends

*You have been an essential part of the Covid response
and have saved countless lives*

Thank you for all that you do!

Future Webinars

Thank you to all of our providers and their staff who have been true healthcare heroes throughout the pandemic

Our next Wednesday Covid-19 Updates will be on:

- ❖ Wednesday, 4/13, 5:00 PM - 6:30 PM
 - Registration link [here](#)

Announcements

- ❖ [Long COVID and Fatiguing Illness Recovery Program](#)
 - Monthly webinars, register [here](#)

Questions and Answers

CME

CME Accreditation and Designation

- ❖ This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of MedChi, The Maryland State Medical Society, and The Maryland Department of Health. MedChi is accredited by the ACCME to provide continuing medical education for physicians.
- ❖ MedChi designates this live webinar educational activity for a maximum of 1 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity. Contact Frank Berry at fberry@medchi.org

CME Disclosures and Evaluation

- ❖ Presenters and Planners: Howard Haft, MD, has reported no relevant financial relationships to disclose.
- ❖ MedChi CME Reviewers: The reviewers from the MedChi Committee On Scientific Activities (COSA) for this activity have reported no relevant financial relationships to disclose.
- ❖ *Attendees can receive CME credit by completing [this evaluation](#) after each webinar. MedChi will then be in contact with the certificate*

Appendix

Vaccine Resources

General Vaccine Resources

- ❖ [CDC Covid-19 Vaccination Communication Toolkit](#) - ready made materials, how to build vaccine confidence, social media messages
- ❖ [New York Times Vaccine Tracker](#) - information on every Covid vaccine in development
- ❖ [New York Times Vaccine Distribution Tracker](#) – information on the distribution of Covid vaccines in the United States
- ❖ [MDH Covidlink Vaccine Page](#) - information on vaccine priority groups in Maryland
- ❖ [CDC Vaccine Storage and Handling Toolkit](#)
- ❖ [Project ECHO Webinar](#) - webinar on vaccines and Long Term Care Facilities, relevant for primary care
- ❖ CDC [Moderna vaccine storage](#)

Outreaching to Patients

- ❖ Information and education
 - [Public Health Collaborative toolkit](#) for 5-11 Pfizer vaccines
 - [Public Health Collaborative toolkit](#) for COVID-19 boosters
 - [Public Health Collaborative messaging](#) for Omicron variant
- ❖ Communication resources
 - *New: Free Johns Hopkins University COVID Vaccine Ambassador Training
 - ✓ [Coursera link](#)
 - The National Hispanic Medical Association - [Vaccinate for All Toolkit](#) (available in [Spanish](#))
 - [Vaccine Communication & Outreach Strategies in Primary Care](#)

Stay “Up To Date” with Vaccines

- ❖ The CDC is now using the term “Up To Date” to indicate individuals that have obtained their primary COVID-19 vaccine series and any eligible booster doses
 - Examples of patients that are **up to date**:
 - 12+ patient has obtained doses 1 and 2 of Pfizer and a booster dose five months later
 - 18+ patient that is immunocompromised has obtained doses 1, 2, and 3 of Moderna and a booster dose five months later
 - Examples of patients that are **not up to date**:
 - 18+ patient has *only* obtained doses 1 and 2 of Moderna more than five months ago
- ❖ Definition of “fully vaccinated” indicates individuals that have completed the primary series

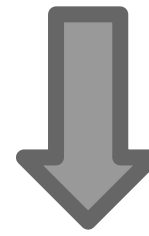
Pfizer 'Gray Cap'


- ❖ Beginning 12/23, a new Pfizer vaccine formulation will become available (Pfizer Tris-sucrose Adult Formulation)
- ❖ For all 12+ individuals
- ❖ Changes to ordering and handling:
 - They will have a gray cap
 - Will be available in smaller 300-dose configuration
 - Does not require diluent
 - May be stored at 2-8°C(36-46°F) for up to 10 weeks



Practices should use current remaining Pfizer inventory before ordering the Tris-Adult formulation

More on 'Gray Cap'



Description	Dilute Before Use	Do Not Dilute	Dilute Before Use
Age Group	12 years and older ^{1,2}	12 years and older ³	5 through 11 years ⁴ ("Age 5y to <12y" on vial label)
Vial Cap Color	Purple 	Gray 	Orange 
Dose	30 mcg	30 mcg	10 mcg
Dose Volume	0.3 mL	0.3 mL	0.2 mL
Amount of Diluent Needed per Vial*	1.8 mL	NO DILUTION	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)

- ❖ [Pfizer Vaccine Formulation/Presentation Guide](#)
- ❖ Pfizer trainings are ongoing and additional information is in the announcements section of this slide deck

Heterologous Dosing - Mixing and Matching

- ❖ The CDC has now advised that booster doses can be a different vaccine type than the primary series
 - Ex: An individual that originally obtained Moderna for doses 1 and 2, can now obtain Moderna, Pfizer, or J&J for a booster if they are eligible for a booster dose
- ❖ All Moderna booster doses are a **half dose**, regardless of the individual's primary vaccine type

Therapeutics Information and Resources

Moderate to Severe Immunocompromise

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts $<200/\text{mm}^3$, 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 prednisone or equivalent per day when administered for ≥ 2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory
- Additional information on immunocompromised classifications can be found on the [CDC website here](#)

Monoclonal Treatment Eligibility

❖ Who Qualifies for Treatment?

➤ mAb treatment is for adults and adolescents (12 and older) who:

- ✓ Recently tested positive for COVID-19
- ✓ Are within 10 days of first experiencing symptoms
- ✓ Do not need to be hospitalized for COVID-19
- ✓ Weigh at least 88 pounds

➤ Are in one of the following high-risk categories:

- ✓ Are age 55 to 64 AND have cardiovascular disease, hypertension, chronic respiratory diseases or COPD
- ✓ Have diabetes, obesity, kidney disease or other serious chronic conditions
- ✓ Are 65 years old or older
- ✓ Are pregnant
- ✓ For adolescents: high BMI, sickle cell disease, heart disease, neurodevelopmental disorders, a medical-related technological dependence, asthma or other chronic respiratory disease
- ✓ Or who have been determined by their healthcare provider to be at high risk for worsening and/or hospitalization

NIH Guidelines on Prioritization

Patient Level

- ❖ Treatment only now
 - No PEP with Sotrovimab
- ❖ Unvaccinated over vaccinated
- ❖ Other priorities to consider
 - Early in course
 - B cell abnormalities
 - Solid organ transplants
 - Severe underlying conditions

Tier	Risk Group
1	<ul style="list-style-type: none"> • Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); or • Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥ 75 years or anyone aged ≥ 65 years with additional risk factors).
2	<ul style="list-style-type: none"> • Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥ 65 years or anyone aged < 65 years with clinical risk factors)
3	<ul style="list-style-type: none"> • Vaccinated individuals at high risk of severe disease (anyone aged ≥ 75 years or anyone aged ≥ 65 years with clinical risk factors) <p>Note: Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment.</p>
4	<ul style="list-style-type: none"> • Vaccinated individuals at risk of severe disease (anyone aged ≥ 65 years or anyone aged < 65 with clinical risk factors) <p>Note: Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment.</p>

Patient Facing Resources

- ❖ Website
 - [Landing page](#)-- general page
 - [FAQ](#)-- detailed information about mAb
- ❖ Contact tracing
 - Direct text message to all contacts and people with positive tests (ages 18+) linking to Landing Page (Eng. & Sp.)
 - mAb information sent to Interviewed Cases & Exposed Contacts at conclusion of contact tracing interview
- ❖ Site Access and PEP status
 - Flyer with treatment location list, PEP information, and self-referral information

Provider-Facing Resources

- ❖ Webinars - over 100
- ❖ Clinician Letters
 - “Checklist” to assist providers in determining patient eligibility for mAbs.
- ❖ Ease in making referral
 - Option 1: [CRISP eREFERRAL for Monoclonal Antibody Infusion](#)
 - Option 2: [Maryland Referral Form for Monoclonal Antibody Infusion Treatment](#) (Updating to include sites where PEP is available)
 - Some sites allow patients to self-refer for evaluation (listed on referral materials)



Monoclonal Antibody Checklist

The Maryland Department of Health (MDH) provides this clinical criteria checklist as a resource for referring or administering monoclonal antibodies (mAb). These are currently three products authorized under Emergency Use Authorization (EUA): [Bamlanivimab and Etesimab](#), [REGN-COV2](#), and [Sotrovimab](#).¹ Monoclonal antibodies are currently indicated for two purposes: certain individuals with active COVID-19 and as a post-exposure prophylaxis in vulnerable persons (e.g., not fully vaccinated or immunocompromised) who are at high-risk for progression to severe COVID-19.

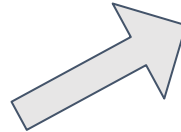
Determine Eligibility for Monoclonal Antibody Treatment for Patients	
Track 1 - Active COVID-19 Infection	Track 2 - Post-Exposure Prophylaxis
1. Is the patient 12 years of age or older weighing at least 88 pounds? If NO , STOP ; YES , proceed to number 2.	1. Is the patient 12 years of age or older weighing at least 88 pounds? If NO , STOP ; YES , proceed to number 2.
2. Does the patient have a positive COVID-19 PCR or antigen test result? If NO , STOP ; YES , proceed to number 3.	2. Does the patient meet high-risk exposure criteria as defined by CDC Quarantine and Isolation guidance? ² If NO , Proceed to Number 3 ; YES , proceed to number 4.
3. Does the COVID-19 positive patient have mild to moderate COVID-19 symptoms such as fever, cough, shortness of breath, loss of taste/smell, fatigue, nausea, vomiting, diarrhea, throat pain, congestion, myalgia, or headache? If NO , STOP ; YES , proceed to number 4.	3. Is the patient at high risk of exposure to an individual infected with COVID-19 in the same institutional setting? If NO , STOP ; YES , proceed to number 4.
4. Has it been less than 10 days since symptom onset and positive COVID-19 test result? If NO , STOP ; YES , proceed to number 5.	4. Is the individual NOT fully vaccinated? ³ If NO (individual is fully vaccinated), Proceed to Number 5 ; YES (individual is not fully vaccinated), proceed to number 6.
5. Is the COVID-19 positive patient at high risk ⁴ for progression to severe COVID-19, including hospitalization or death? If NO , STOP ; YES , proceed to number 6.	5. Is the individual anticipated to NOT mount an adequate immune response to complete SARS-CoV-2 vaccination (e.g. immunocompromised or taking immunosuppressive medications)? If NO , STOP ; YES , proceed to number 6.
6. If any of the following apply, STOP ; the patient is not eligible for treatment. Otherwise, proceed to number 7. <ul style="list-style-type: none"> • Patient hospitalized for COVID-19 • Patient requires oxygen therapy due to COVID-19 • Patient requires require an increase in baseline oxygen flow rate due to COVID-19 • Patient is in imminent need of hospitalization due to COVID-19 	6. If exposure occurred within the past 96 hours, patient meets eligibility criteria; proceed with administration or referral. Patients who meet eligibility criteria can be referred to facilities geographically spread across Maryland for equitable access. To refer a patient, please use the CRISP platform eReferral Tool or the Maryland Department of Health (MDH) Maryland Referral Form .
7. Patient meets eligibility criteria; proceed with administration or referral. For referral resources see Track 2 No. 6.	

¹ Sotrovimab is not authorized for post-exposure prophylactic administration and is only commercially available at this time.
² Close contact with an infected individual is defined as being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (greeting or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (coughing or sneezing, for example). See this website for additional details: <https://www.cdc.gov/coronavirus/2019-nCoV/faq-close-contact-exposure.html>.
³ Individuals are considered to be fully vaccinated 2 weeks after their second vaccine dose in a 2-dose series (such as the Pfizer or Moderna vaccines), or 2 weeks after a single-dose vaccine (such as the Johnson & Johnson Janssen vaccine). See this website for more details: <https://www.cdc.gov/vaccines/imz/faq.html>.
⁴ For further information as what qualifies an individual as high risk please see slide 39 of the Monoclonal Antibody Clinical Implementation Guide available at: <https://www.dhs.gov/comptroller/COVID-19/implementation/MABImplementationGuideCOVID-19-042021.pdf>.



Practice mAb Referral Workflow

- 1) Daily, go into the CRISP ENS PROMPT to [view new positive Covid-19 test results](#) for your patients
- 2) For Covid-positive patients, assess every patient for [mAb eligibility](#)
- 3) For eligible patients, call the patient to recommend mAb treatment
 - a) See this [patient-facing website](#)
- 4) Refer the patient to mAb treatment through [CRISP](#) or [externally](#)



HOME CALIPR PATIENT SNAPSHOT **ENS PROMPT** HEALTH RECORDS

COVID-19 RESULTS VIEWER REFERRAL PORTAL 2021 ECQMS SBIRT

Filter by Name or MRN CRISP DEMO

All Not started In progress Completed

Notifications count: 75
last updated: 15:54 10/19/21

COCONUT DEMO1 (180034567)

MD NEDSS
10/12/2021 09:05 AM
OP Test Result
COVID-19 Tested negative for COVID-19

Additional Monoclonal Information

Indications for Outpatient COVID-19 mAbs

Monoclonal Antibody Indications and Routes of Administration

Monoclonal Antibody	TREATMENT of Mild to Moderate COVID-19 Infection within 10 days of symptom onset in patient with high risk of progression to severe disease	POST-EXPOSURE PROPHYLAXIS for individuals who are not fully vaccinated or immunocompromised, with high risk of progression to severe disease
bamlanivimab and etesevimab¹ (Eli Lilly) ^{***}	Dose: 700 mg bamlanivimab and 1400 mg etesevimab ^{***} Route: Intravenous administration Post-administration monitoring: 60 minutes	N/A
casirivimab and imdevimab² (REGEN-COV)	Dose: casirivimab 600mg and imdevimab 600mg Route: Intravenous is preferred route, however subcutaneous injection may be utilized in situations where there would be a delay in intravenous administration Post-administration monitoring: 60 minutes	Dose: casirivimab 600mg and imdevimab 600mg Route: Intravenous or subcutaneous Post-administration monitoring: 60 minutes
Sotrovimab³ (Glaxo Smith Kline)	Dose: sotrovimab 500mg Route: Intravenous Post-administration monitoring: 60 minutes	N/A

^{***} Based on the most currently available data, [bamlanivimab and etesevimab are now authorized](https://www.fda.gov/media/151719/download) in all U.S. states, territories, and jurisdictions (9/2/21) [https://www.fda.gov/media/151719/download]

Refer to product Emergency Use Authorizations for detail on indications and administration

¹ [Fact Sheet for Health Care Providers Emergency Use Authorization of Bamlanivimab and Etesevimab](https://www.fda.gov/media/145802/download) (https://www.fda.gov/media/145802/download)

² [Fact Sheet for Health Care Providers Emergency Use Authorization of REGEN-COV™ \(casirivimab and imdevimab\)](https://www.fda.gov/media/145611/download) (https://www.fda.gov/media/145611/download)

³ [Fact Sheet for Health Care Providers Emergency Use Authorization of Sotrovimab](https://www.fda.gov/media/149534/download) (https://www.fda.gov/media/149534/download)

Paxlovid is **contraindicated** with **drugs that are highly dependent on CYP3A for clearance** and for which elevated concentrations are associated with serious and/or life-threatening reactions

- Alpha₁-adrenoreceptor antagonist: alfuzosin
- Analgesics: pethidine, piroxicam, propoxyphene
- Antianginal: ranolazine
- Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine
- Anti-gout: colchicine
- Antipsychotics: lurasidone, pimozide, clozapine
- Ergot derivatives: Dihydroergotamine, ergotamine, methylergonovine
- HMG-CoA reductase inhibitors: lovastatin, simvastatin
- PDE5 inhibitor: sildenafil (Revatio) when used for pulmonary arterial hypertension (PAH)
- Sedative/hypnotics: triazolam, oral midazolam

Paxlovid is **contraindicated** with **drugs that are potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance**. Paxlovid cannot be started immediately after discontinuation of any of the following medications due to the delayed offset of the recently discontinued CYP3A inducer

- Anticancer drugs: apalutamide
- Anticonvulsant: carbamazepine, phenobarbital, phenytoin
- Antimycobacterials: rifampin
- Herbal products: St. John's Wort

Evusheld Availability

- ❖ PCPs can contact one of the following hospitals that receives an allocation to determine if referrals are possible:

Adventist Healthcare Fort Washington Medical Center

Adventist Healthcare Takoma Park Campus

Adventist Shady Grove Medical Center

Adventist White Oak Medical Center

Atlantic General Hospital

CalvertHealth Medical Center

ChristianaCare Union

Franklin Square Hospital

Frederick Health Hospital

Garrett Regional Medical Center

85 Johns Hopkins Health System

Kaiser Permanente

Luminis Doctors Community Medical Center

Luminis Health Anne Arundel Medical Center

Mercy Medical Center

Meritus Medical Center

Sinai Hospital

Tidalhealth Peninsula Regional

UMMC

UPMC Western Maryland

National Institute of Health

Hatzalah of Baltimore

St Agnes Hospital

Adult or pediatric (age 12 and older and weight 40kg or greater) with mild to moderate COVID-19 & high risk for progression to severe disease

+

Is Patient:

- Hospitalized for COVID-19 **OR**
- Requiring O₂ **OR** an increase in baseline home O₂ due to COVID-19

No

Symptom onset within the past 5-7 days?

Yes

Does patient have severe renal impairment (eGFR <30mL/min) **OR** severe hepatic impairment (child-pugh class C)

Yes

Consider the following (symptoms within 10 days)¹:
sotrovimab 500 mg IV ([sotrovimab EUA](#))

No

Symptom onset within the past 10 days?

Yes

Treatment of symptoms, Management per NIH & CDC Guidelines

Yes

No

Consider one of the following therapeutics, if available^{1,2}:

Paxlovid within 5 days of symptom onset

eGFR 60 mL/min or greater: 300mg nirmatrelvir taken with 100mg ritonavir twice daily for 5 days

eGFR ≥30-≤60: 150mg nirmatrelvir taken together with 100mg ritonavir twice daily for 5 days; evaluate concomitant use of CYP3A inducers and medications with high dependency on CYP3A for clearance as these may be contraindicated per [Paxlovid EUA](#)

OR

sotrovimab 500 mg IV within **ASAP 10 days of symptom onset** ([sotrovimab EUA](#))

OR

Remdesivir 200mg IV x 1 dose on day 1, 100mg IV x1 on days 2-3 begun ASAP and within **7 days of symptom onset¹**

If none of the above therapeutics are available for patient treatment within 5 days of symptom onset and patient is **age 18 or greater**

No

Possibility of pregnancy, if applicable, is ruled out?

Yes

Consider molnupiravir

- Authorized only in patients ages 18 and older
- Within 5 days of symptom onset
- Molnupiravir 800mg by mouth every 12h for 5 days
- Prescribers must review and comply with the mandatory requirements outlined in [the molnupiravir EUA](#)

Limited use of bamlanivimab/etesevimab and REGEN-COV as they are not expected to be active against the Omicron variant¹

¹Refer to the [NIH COVID-19 Treatment Guidelines Panel's Statement on the Use of Anti-SARS-CoV-2 Monoclonal Antibodies or Remdesivir for the Treatment of Covid-19 in Nonhospitalized patients when Omicron is the Predominant Circulating Variant](#); Remdesivir is only approved for hospitalized individuals with COVID-19. Outpatient treatment is based on information from the literature ([Dec 22, 2021 Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients](#); DOI: 10.1056/NEJMoa2116846)

² COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease in either the outpatient or inpatient setting ([COVID-19 Convalescent Plasma EUA](#))

Testing

Refer for Testing

- ❖ Use [this toolkit](#) to guide testing protocols and communication
- ❖ Consider PCR testing for asymptomatic patients
 - Review [this webinar](#) (beginning at 51:00) for PCR testing options
- ❖ Refer patients for testing at [one of these sites](#)

New CDC Quarantine and Isolation Guidelines

New CDC Quarantine and Isolation Guidelines

If You Test Positive for COVID-19 (Isolation)

Everyone, regardless of vaccination status:

- Stay home for 5 days
- If asymptomatic after 5 days, you can leave your house
- Continue to wear a mask around others for 5 additional days
- You may test at day 5 and without symptoms:
 - If positive, continue to isolate to day 10
 - If negative, end isolation and continue to wear a mask around others until day 10

If you have a fever or other symptoms, continue to stay home until symptoms resolve

(Quarantine guidelines on next slide)



New CDC Quarantine and Isolation Guidelines

If You Were Exposed to Someone with COVID-19 (Quarantine)

If you are unvaccinated or overdue for a booster:

- Stay home for 5 days. After that continue to wear a mask around others for 5 additional days.
- If you can't quarantine you must wear a mask for 10 days.
- Test on day 5 if possible.

If you develop symptoms, get a test and stay home.

If you are vaccinated and boosted:

- Wear a mask around others for 10 days.
- Test on day 5, if possible.

If you develop symptoms, get a test and stay home

Quarantine in High-Risk Congregate Settings

High-Risk Congregate Settings:

Everyone, regardless of vaccination status:

- High-risk congregate settings that have a high risk of secondary transmission
 - Examples: Correctional facilities, detention centers, homeless shelters, and cruise ships
- Residents quarantine for 10 days regardless of vaccination and booster status
- [CDC setting-specific guidance](#)

Maryland's Official Health Insurance Marketplace: Open Enrollment Information

General Resources and Links

Available and Free PPE

- ❖ MDH has free and available PPE
 - Supplies that are available include KN95 masks and N95 masks
- ❖ To request free PPE, fill out pages 3-4 of this [PPE request form](#) and submit the information to your local Health Department contact listed on pages 1-2

Covid-19 mAb Treatment Criteria



Patient Criteria

- Use clinical judgment
- Have BMI \geq 35
- Have chronic kidney disease
- Have diabetes
- Are currently receiving immunosuppressive treatment
- Are \geq 65 years old
- Are \geq 55 years old and have
 - Cardiovascular disease, or
 - Hypertension, or
 - Chronic obstructive pulmonary disease/other chronic respiratory disease
- Are 12 – 17 years old AND have
 - BMI \geq 85th percentile for their age and gender based on CDC growth charts, or
 - Sickle cell disease, or
 - Congenital or acquired heart disease, or
 - Neurodevelopmental disorders, or
 - A medical-related technological dependence, or
 - Asthma

Scheduling In-Office Appointments

- ❖ Patient calls in for an appointment
 - Reception screens patient on the phone using the [pre-visit screening template](#)
 - Schedule in-office visits for different groups: At-risk and vulnerable patients on certain days, healthier patients on other days
 - Schedule telehealth and non-office-based care for other patients including follow-ups and patients uncomfortable with office visits

- ❖ Check In
 - Practice remote check in and limited front-desk contact
 - Consider using a triage zone outside of office or main area;
 - Or use a barrier at the front desk
 - Design your office to accommodate patients who come in specifically for Covid testing and triage, separate from patients who arrive for non-Covid related and elective procedures
 - Ensure patients and staff do not cross between Covid and non-Covid areas
 - Set aside a specific area for patients who come in for testing to wait and be triaged

Scheduling In-Office Appointments

- ❖ Checking out
 - Practice remote check out, limit front desk exposure;
 - Or use a barrier at the front desk
- ❖ If patient is paying co-pays, etc., set up credit card reader outside of the barrier
- ❖ Other workflow resources
 - [Care management workflows](#)
 - [BMJ telemedicine workflow graphics](#)
 - [CDC flowchart to identify and assess 2019 novel Coronavirus](#)
 - [CDC telephone evaluation flow chart for flu](#)
 - [CDC guidance for potential Covid-19 exposure associated with international or domestic travel](#)

CDC Guidelines for Covid Patient Management

- ❖ Healthy people can be monitored, self-isolated at home
- ❖ People at higher risk should contact healthcare providers early, even if illness is mild
- ❖ Older adults and people with severe underlying chronic medical conditions are at higher risk, need closer contact
- ❖ Emergency Department and hospitals only when needed - not for screening or low risk/minimal disease

Guidelines are important and powerful tools, but remember providers' clinical experience and judgment are key to care

Personal Protective Equipment (PPE) Sources and Requests

- ❖ Practices should initially request PPE through their usual vendors
- ❖ Practices should make their PPE requests through their local health departments
- ❖ Maryland PPE Manufacturers List – next slide
- ❖ [National and international PPE supplier list](#)
- ❖ [PPE request form](#)

Personal Protective Equipment (PPE) Sources and Requests

- ❖ Increasing Maryland's supply of PPE – one of the 4 building blocks on the Road to Recovery
- ❖ Maryland has launched the [Maryland Manufacturing Network Supplier Portal](#), an online platform that helps connect Maryland suppliers with buyers in need of critical resources
- ❖ For additional business resources during Covid-19, visit businessexpress.maryland.gov/coronavirus
- ❖ Providers may also request PPE from the non-profit ['Get Us PPE'](#)

Provider/Patient Mental Health Resources

❖ Providers

- “Helping the Helpers and Those They Serve,” a [webinar series](#) from the Maryland Department of Health Behavioral Health Administration and MedChi
- [Heroes Health Initiative](#)

❖ Patients

- [Ask Suicide-Screening Questions toolkit](#)
- CDC [list of resources](#) for coping with stress

Health Equity Resources

- ❖ [Maryland Department of Health Office of Minority Health and Health Disparities](#) (MHHD)
- ❖ Maryland Department of Health Minority Outreach and Technical Assistance Program [overview](#)
- ❖ MHHD fiscal year 2020 minority outreach and technical assistance [program information](#)
- ❖ [Description](#) of the term “health disparity”
- ❖ [Implicit bias test](#)
- ❖ “Hundreds of Days of Action as a Start to Address Hundreds of Years of Inequality” – New England Journal of Medicine [article](#) by Maulik Joshi, DrPH
- ❖ “Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine” – [discussion draft](#) for public comment by Committee on Equitable Allocation of Vaccine for the Novel Coronavirus, The National Academies of Science, Engineering, Medicine

Telehealth Resources

- ❖ [Maryland Health Care Commission Telehealth](#)
- ❖ [Maryland Health Care Commission Telehealth Readiness Assessment Tool](#)
- ❖ [U.S. Department of Health and Human Services Health Insurance Portability and Accountability Act \(HIPAA\) for Professionals](#)
- ❖ [American Telehealth Association](#)
- ❖ [Maryland Telehealth Alliance](#)
- ❖ [National Consortium of Telehealth Resource Centers](#)

Support for Patients at Home

- ❖ Food
 - Meals on Wheels
- ❖ Caregivers
 - Visiting nurses and caregivers
- ❖ Emotional support
 - Support from family
 - Phone calls and video chat to fight loneliness
 - MD Department of Aging [Senior Call Check Program](#)

Food Resources

- ❖ Nutrition: Inform patients that children can receive three free meals/day at sites listed on:
 - [Maryland Summer Meals](#) [Howard County](#)
 - [Montgomery County](#) [Anne Arundel County](#)
 - [Prince Georges County](#) [St. Mary's County](#)
 - [Charles County](#) [Harford County](#)
 - [Frederick County](#) [Calvert County](#)
- ❖ Free meals available from 42 rec centers in Baltimore
 - Call 311 for locations and to schedule pickup time

Resources for Specific Groups

- ❖ Community- and Faith-Based Organizations
(<https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-community-faith-organizations.html>)
- ❖ Mass Gatherings and Large Community Events
(<https://www.cdc.gov/coronavirus/2019-ncov/community/mass-gatherings-ready-for-covid-19.html>)
- ❖ Non-Pharmaceutical Interventions for Specific Groups
(<https://www.cdc.gov/nonpharmaceutical-interventions/index.html>)

Resources and References

- ❖ Maryland Department of Health Coronavirus Website (<https://coronavirus.maryland.gov>)
- ❖ CDC Coronavirus Website (<https://www.cdc.gov/coronavirus/2019-nCoV/index.html>)
- ❖ CDC National data on Covid-19 infection and mortality (<https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html>)
- ❖ CDC Interim Guidance for Homes and Communities (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html>)
- ❖ CDC Interim Guidance for Businesses (<https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/guidance-business-response.html>)
- ❖ CDC Interim Guidance for Childcare and Schools (<https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/guidance-for-schools.html>)
- ❖ CDC Travel Website (<https://wwwnc.cdc.gov/travel/>)

Articles

- ❖ [“Effectiveness of Mask Wearing to Control Community Spread of SARS-CoV-2”](#)
- ❖ [“COVID-19 Vaccines vs Variants—Determining How Much Immunity Is Enough”](#)
- ❖ [“SARS-CoV-2–Specific Antibodies in Breast Milk After COVID-19 Vaccination of Breastfeeding Women”](#)
- ❖ [“Maternal and Neonatal Morbidity and Mortality Among Pregnant Women With and Without COVID-19 Infection: The INTERCOVID Multinational Cohort Study”](#)
- ❖ [“Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in a Population in Lombardy, Italy”](#)
- ❖ [“Sequelae in Adults at 6 Months After COVID-19 Infection”](#)
- ❖ [“How COVID-19 Affects the Brain”](#)