



Covid-19 Update: Vaccines, Testing and Therapeutics and a new variant

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

1 December 2021



WINTER
IS
COMING

with new variants

Agenda

- ❖ Current Pandemic data
- ❖ Vaccine Updates
- ❖ Boosters and Pediatric vaccines
- ❖ Covid Therapeutics
- ❖ Testing and the role of PCPs in oral antiviral therapeutics
- ❖ Long Covid
- ❖ End game for the pandemic
- ❖ Special Guest – Dr. David Blythe, State Epidemiologist
 - ❖ New and emerging variants

Daily COVID-19 Report

Data reported as of 12/1/2021 for data through 11/30/2021

587,285
cases cumulative

15,060,973
tests cumulative

16.0
7-day avg. case rate

7,397
total hospital census

10,987
deaths cumulative

1,142
cases reported yesterday

33,888
tests reported yesterday

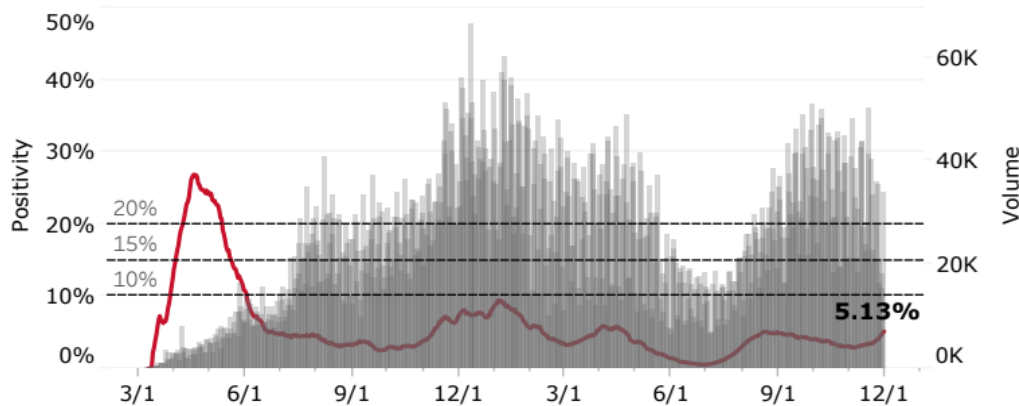
5.13%
7-day avg. positivity

320
change in total hospital census

14
deaths reported yesterday

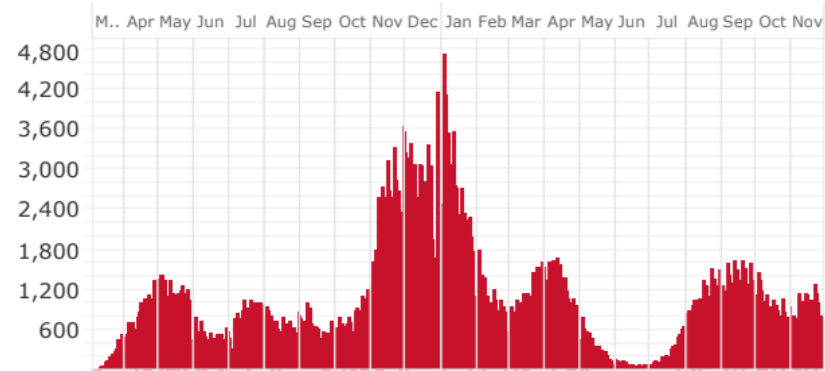
7-Day Avg. Percent Positivity and Total Testing Volume

Since 3/1/20

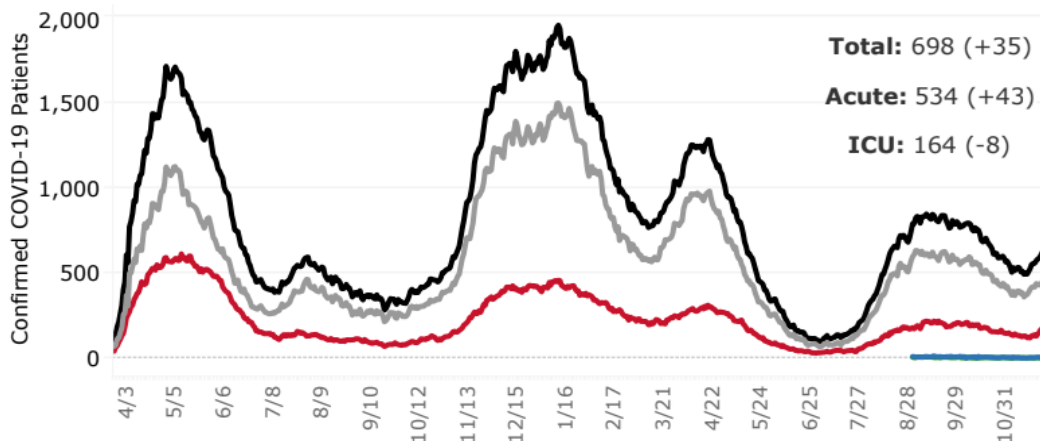


Daily New Cases

by Specimen Collection Date

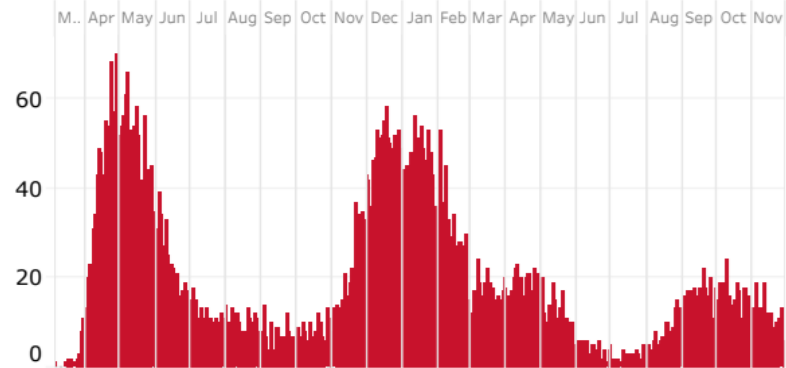


Statewide Acute/ICU Beds Occupied by COVID Patients



Daily Deaths

Confirmed and Probable



Case rate calculated as total confirmed cases per 100,000 population using the 2019 Maryland Population estimates from the Maryland Department of Planning, March 2020.

Primary Care and Vaccines

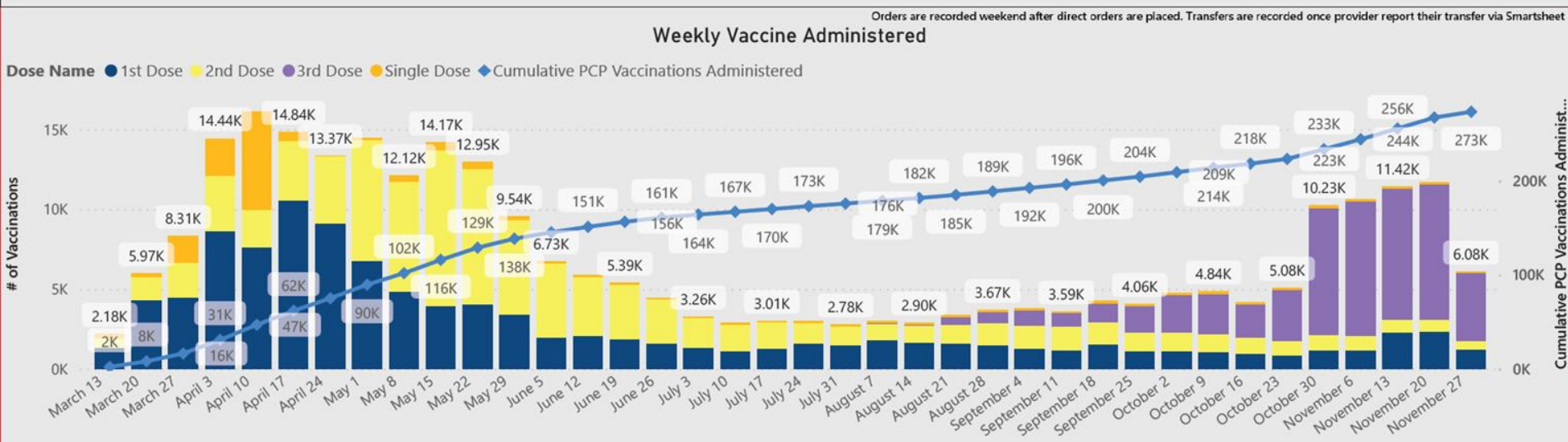
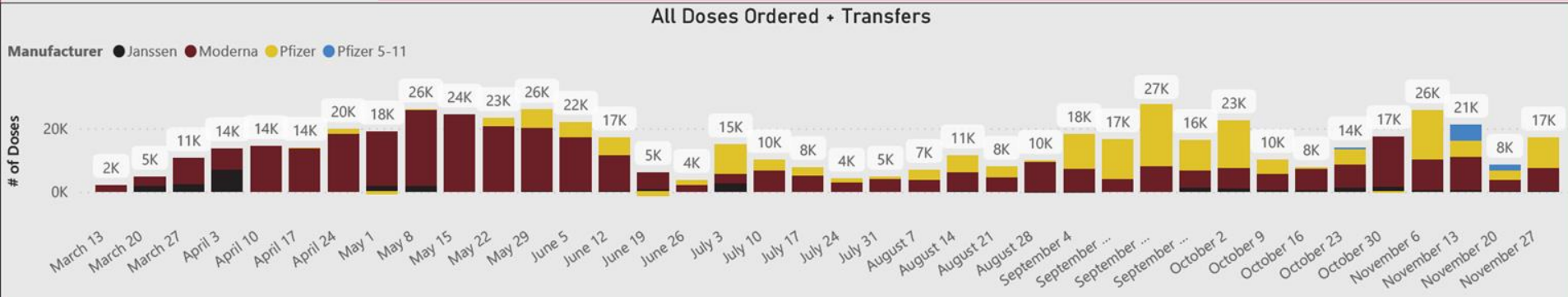
Cumulative Doses Administered

273,286

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

- ❖ 88.9% of Marylanders 18+ have received at least one vaccine dose
- ❖ 468 primary care practices are involved in the Primary Care Vaccine Program

Primary Care and Vaccines



We are excited to acknowledge the top 5 MDPCP practices and CTOs for Covid-19 vaccination efforts!

Practices

1. M Rita Ghosh MD, PC - **96.90%**
2. Dr. Luis A. Casas, M.D. - **95.42%**
3. Holy Cross Health, Inc. (Russell Ave) - **94.60%**
4. Charlestown Medical Center - **94.53%**
5. Doctors Saba, Koltz and Walters - **94.44%**

CTOs

1. Holy Cross Health, Inc.- **92.18%**
2. PHS Doctors CTO - **88.80%**
3. Greater Baltimore Health Alliance Physicians, LLC - **87.86%**
4. Ascension Saint Agnes Community Health Partners - **87.53%**
5. University of Maryland Care Transformation Organization, LLC - **86.67%**



Note: percentages represent percent of MDPCP beneficiaries fully vaccinated

We are excited to acknowledge the top 5 MDPCP practices and CTOs for accomplishing the biggest improvement in vaccinating their unvaccinated patients in the last week!

Practices

1. Clinical Outcome Improvement Medicine, LLC - **1.44%**
2. Precision Health Care, LLC. - **1.10%**
3. Tahmina K. Ahmed M.D., PC - **0.94%**
4. Raman Tul, M.D., PC - **0.87%**
5. Primary Medicine, LLC (Walker Ave) - **0.86%**

CTOs

1. HCD International - **0.28%**
2. Ascension Saint Agnes Community Health Partners - **0.24%**
3. Peninsula Regional Clinically Integrated Network - **0.22%**
4. Netrin Accountable Care, LLC - **0.21%**
5. PHS Doctors CTO - **0.20%**



Note: percentages represent percent increase of MDPCP beneficiaries fully vaccinated

COVID-19 Triple Play Strategy

❖ Early detection is key



❖ Triple Play:

➤ Vaccines

➤ Testing


➤ Therapeutics

❖ [COVID-19 Triple Play Strategy Guide](#)



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. With the winter holidays around the corner, 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


- 1**
 - Order COVID-19 vaccines on Thursdays between 8:00-4:00PM
 - Fill out 5-11 Pediatric vaccine surveys during state allocation phase
 - 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

- 2**
 - 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

- 3**
 - Refer eligible patients for monoclonal antibody treatment
 - Refer in [CRISP](#) or use this [referral form](#)
 - Prepare for the roll out of Molnupiravir, which will be [reviewed by the FDA](#) on 11/30, by ordering Point-of-Care tests to rapidly diagnose



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

Page 1

Boosters

WHO IS ELIGIBLE FOR A BOOSTER?

What did you get?	When can you get a booster?	Who is eligible for a booster?
Pfizer	6 months after 2nd dose	18 years and older
Moderna		
Johnson & Johnson	2 months after single dose	



Call 855-MDGOVAX or visit covidvax.maryland.gov to schedule your booster appointment.



❖ [COVID-19 Vaccine Booster Guide for PCPs](#)

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

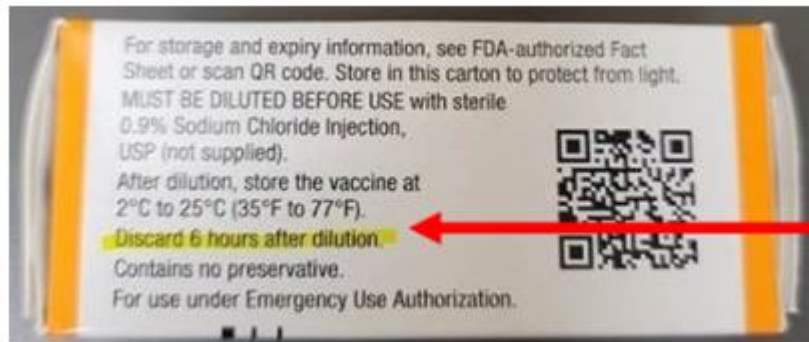
5-11 Yr Old Pediatric Pfizer Vaccine

- ❖ Two dose regimen, dose 2 can be administered 21 days after dose 1
- ❖ Different product from 12+
- ❖ Will require reconstitution
- ❖ Allocation
 - Current: State-based allocation
 - Future: Direct ordering
 - Providers will need to manage 2nd dose appointments through supply provided; **no separate allocation for 2nd doses**
- ❖ MDH [Toolkit](#) for 5-11 Pediatric Pfizer Vaccine
 - Password: 5+Vaccine

Pediatric Vaccines

- ❖ In Maryland, 76.6% of 12-17-year-olds have received at least 1 dose, compared to 60% nationally
- ❖ As of November 29:
 - 108,637 (21.8%) of Maryland's 5-11-year-olds have received a 1st dose
 - Doses have been administered in all 24 jurisdictions

Update: Correction to Pfizer Label



Should read "Discard 12 hours after dilution"

- ❖ The Pfizer Pediatric 5-11 orange vial labels were printed before the FDA EUA was released
 - Labels state, "discard 6 hours after dilution"
- ❖ The 10/29 FDA EUA states can be used up to **12 hours** after dilution

5-11 Pfizer Ordering

- ❖ Until further notice, 5-11 vaccine requests will be collected from providers in a weekly allocation survey
 - Sent to providers in ImmuNet (VFC and non-VFC)
 - Minimum of 100 dose requests
- ❖ Next allocation timeline
 - Allocation survey scheduled to go live on 12/3
- ❖ [Survey](#) for current pediatric Pfizer 5-11 records
 - Due Fri, 12/3 at 3PM

***Additional information in
appendix***

Covid Therapeutics

Timing is critical → the sooner the better

- ❖ Monoclonal Antibodies
 - IV infusion or Subq injection
 - Treatment
 - Post Exposure Prophylaxis
- ❖ Oral Antivirals- soon
 - Treatment
- ❖ Long acting IM Prophylaxis- soon
 - Prophylaxis for immunocompromised

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

Monoclonal Antibody Treatment: Post-exposure Prophylaxis

- ❖ Who is eligible for post-exposure prophylaxis?
 - Individuals with significant medical condition(s) who have no Covid-19 symptoms, but have been exposed in the past four days to a known or suspected case of COVID-19 and are in one of the following categories:
 - ✓ Are not fully vaccinated
 - ✓ Are vaccinated but not expected to have an adequate immune response to the vaccine
 - ✓ Are in a congregate living situation such as a nursing home or prison

***Additional information in
appendix***

mAbs Infusions Overview

Total mAbs Infusions **Total mAbs Inventory**

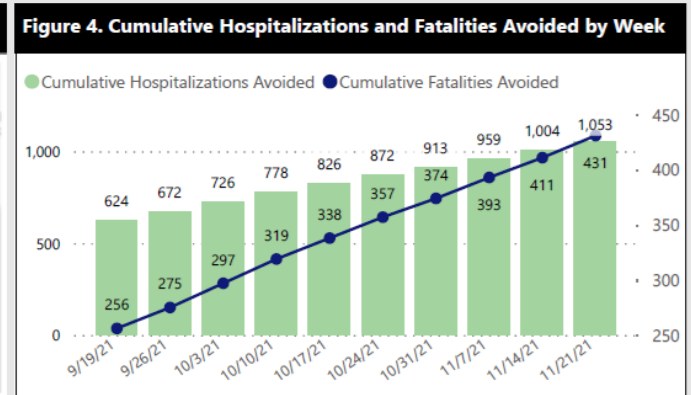
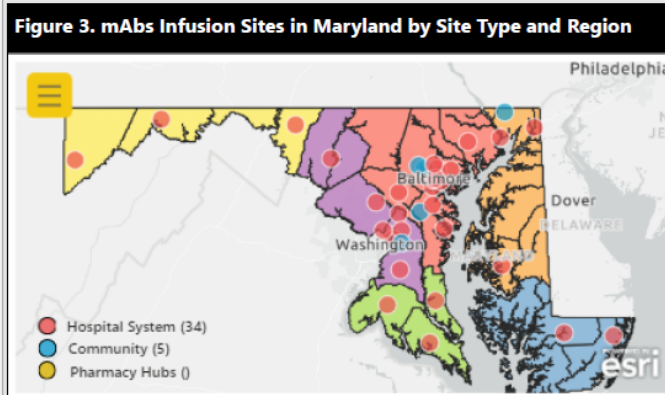
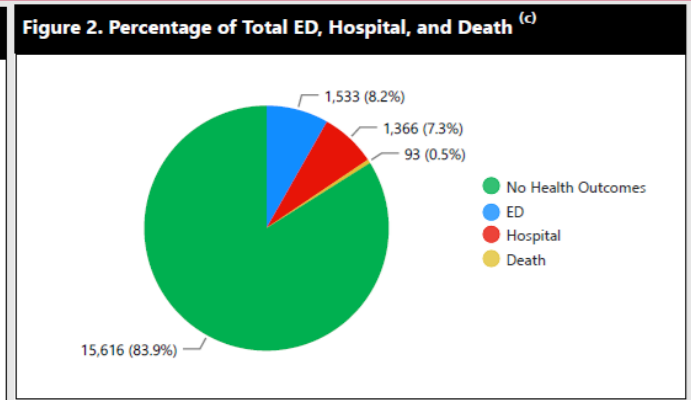
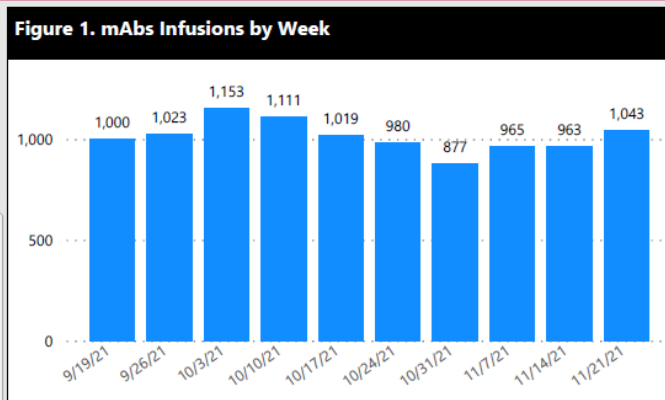
22,425 **7,062**

Change Last Week **Change Last Week**

+1043 **-69**

Statewide Impact

Cumulative Hospitalizations Avoided	1,053
Change Last Week	+49
Cumulative Fatalities Avoided	431
Change Last Week	+20
Cumulative mAbs Allocation Utilization Rate	78%
Change Last Week	+4%
% Eligible Infused (a)	60%
Change Last Week	+1%
% Eligible and Symptomatic Infused (a)	100%
Change Last Week	+2%
Cumulative PEP Infusions (b)	431
Change Last Week	+71
Cumulative mAbs Allocation	28,864
Number of mAbs Locations	39



(a) Total eligible does not include those eligible for Post-Exposure Prophylaxis (PEP). The percentage here is inflated due to infusions for PEP. These will be reported separately in future reports.
 (b) Post-Exposure Prophylaxis (PEP) infusion is mAbs infusion ASAP after known or suspected COVID-19 exposure.
 (c) The health outcome data source is obtained from CRISP and does not include those reporting manually to MDH via PROPS.

New Covid-19 Ambulatory Therapeutics

Anticipated Treatments

Drug	Treatment	Prophylaxis	FDA submission
<u>Molnupiravir</u> (Merck)	Oral drug 5d course Initiate within 5d after diagnosis Not for use in pregnancy	Studies underway	10/11/2021 submitted 11/30/2021 VRBPAC
AZD7442 (Astra-Zeneca)	N/A	Long-acting antibody (LAAB) intramuscular injection Lasts 6 months	10/5/2021 submitted
Ritonavir (<i>Paxlovid</i> ; Pfizer)	Oral drug 5d course Initiate within 3d after diagnosis	Possible	11/5/2021 Studies halted, EUA submission plans announced

Antiviral Treatment: Molnupiravir

- ❖ Molnupiravir - Merck and Ridgeback Biotherapeutics' oral antiviral treatment
 - Phase 3 trial indicates a reduction in risk of hospitalization or death by around 30% in high risk unvaccinated Covid patients
- ❖ Initial study data
 - 6.8% of patients treated were hospitalized within 29 days
 - 9.7% of placebo patients were hospitalized or died by day 29
 - 1 deaths among treated patients and 9 deaths among placebo patients by day 29
- ❖ Current status and next steps
 - FDA AMDAC endorsed an EUA for Molnupiravir on 11/30
 - The FDA will review AMDAC's endorsement and provide an authorization
 - The CDC will provide a final recommendation

Antiviral Treatment: Paxlovid

- ❖ Paxlovid - Pfizer oral antiviral treatment
- ❖ Initial study data
 - Paxlovid appears to cut the risk of hospitalization and death by 89%
 - 0.8% of patients treated were hospitalized within 28 days
 - 7.0% of placebo patients were hospitalized or died within 28 days
- ❖ Plans for next steps
 - Pfizer has submitted data to the FDA to consider an EUA for Paxlovid

AstraZeneca - Prophylactic long acting mAb

- ❖ Long-acting antibody combination intended to prevent Covid via IM injection
- ❖ Currently, AstraZeneca is seeking an emergency use authorization from the FDA for antibody therapy
- ❖ Supporting data:
 - A late-stage trial indicated a 77% reduction in people developing Covid symptoms
 - Trials have indicated that this therapy could offer up to 12 months of protection

Point-of-Care Testing

- ❖ PCPs will be essential to the rollout of new oral antiviral therapies
 - Eligible patients need to be diagnosed within 5 days of the onset of symptoms
- ❖ Providers will be able to send Rx for antivirals to selected pharmacy partners

Key to early diagnosis: [Point-of-Care Testing](#)

Call to Action: Prepare your practice by [requesting point-of-care tests](#) and be ready to conduct prerequisite tests for all eligible patients

Long Covid

- ❖ Three main categories of Long Covid
 - Severe Long Covid
 - ✓ Increased time in hospital, severe adverse effects
 - ✓ Multiorgan effects
 - ✓ Increased potential for autoimmune conditions
 - Extended Recovery Long Covid
 - ✓ Longer time to recovery
 - ✓ Ongoing symptoms particularly lethargy
 - Mysterious Long Covid
- ❖ Resources
 - CDC [Caring for People with Post-COVID Conditions](#)

Flu Season Is Here

- ❖ Timeline
 - Occurs in the fall and winter
 - Most of the time the flu peaks in between December and February
- ❖ Flu vaccines recommended for all individuals that are 6 months old and older
- ❖ [Patients who visit medical offices](#) after patients with influenza-like illnesses are more likely to show signs of influenza-like illness within the following two weeks than non-exposed patients
- ❖ CDC FAQs for the 2021 – 2022 season are [here](#)

Will it ever be truly “over”

❖ End games - and Herd Immunity

- Eradication- smallpox- none now
- Elimination- measles- near complete vaccine herd immunity
- Containment- flu- natural immunity plus vaccine



“Everything will be okay in the end. If it’s not okay, it’s not the end.”

- John Lennon

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*

Future Webinars

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

Regular Wednesday Covid-19 Updates occur every other week:

- ❖ Wednesday, 12/15, 5:00 PM-6:30 PM
 - Registration link [here](#)
- ❖ Wednesday, 1/5, 5:00 PM-6:30PM
 - Registration link [here](#)

Announcements

- ❖ BHA/MedChi Behavioral Health Webinar, “Coping with the Behavioral Health Impact of the Pandemic”
 - Thurs, 12/9 at 5:00 PM
 - Registration link is [here](#)
- ❖ **Open enrollment is live for Maryland Health Connection -** Additional information is in the Appendix of this slide deck
- ❖ Pfizer COVID-19 trainings
 - Thurs, 12/2 @ 12-1PM
 - ✓ [Attendee link](#), Password: fgZsgRpf379
 - Fri, 12/3 @ 12-1PM
 - ✓ [Attendee link](#), Password: rkMHiiMB223
- ❖ [COVID-19 Triple Play Strategy Guide](#)

Guest Speaker: Dr. David Blythe

- ❖ Maryland Department of Health
State Epidemiologist
- ❖ Director of Infectious Disease
Epidemiology and Outbreak
Response Bureau
- ❖ Served as an Epidemic Intelligence
Service (EIS) Officer with the Centers
for Disease Control and Prevention





Coronavirus Disease 2019 (COVID-19) Update

Infectious Disease Epidemiology and Outbreak Response Bureau

December 1, 2021

The information in this presentation is current as of December 1, 2021, unless otherwise noted, and subject to change.

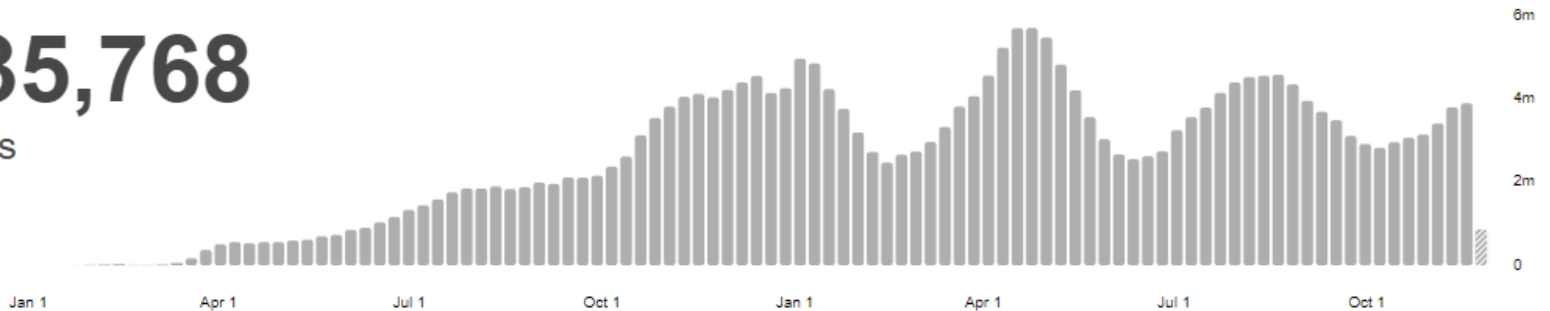
Worldwide: COVID-19

Global Situation



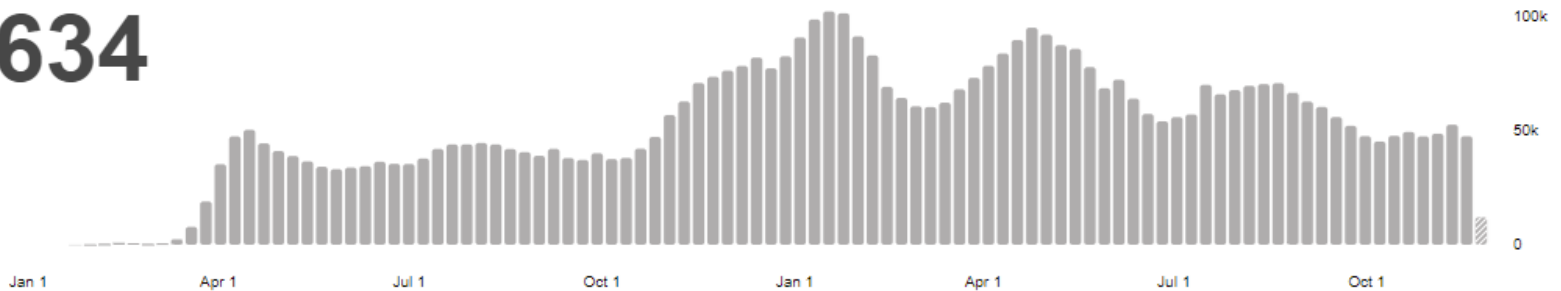
261,435,768

confirmed cases



5,207,634

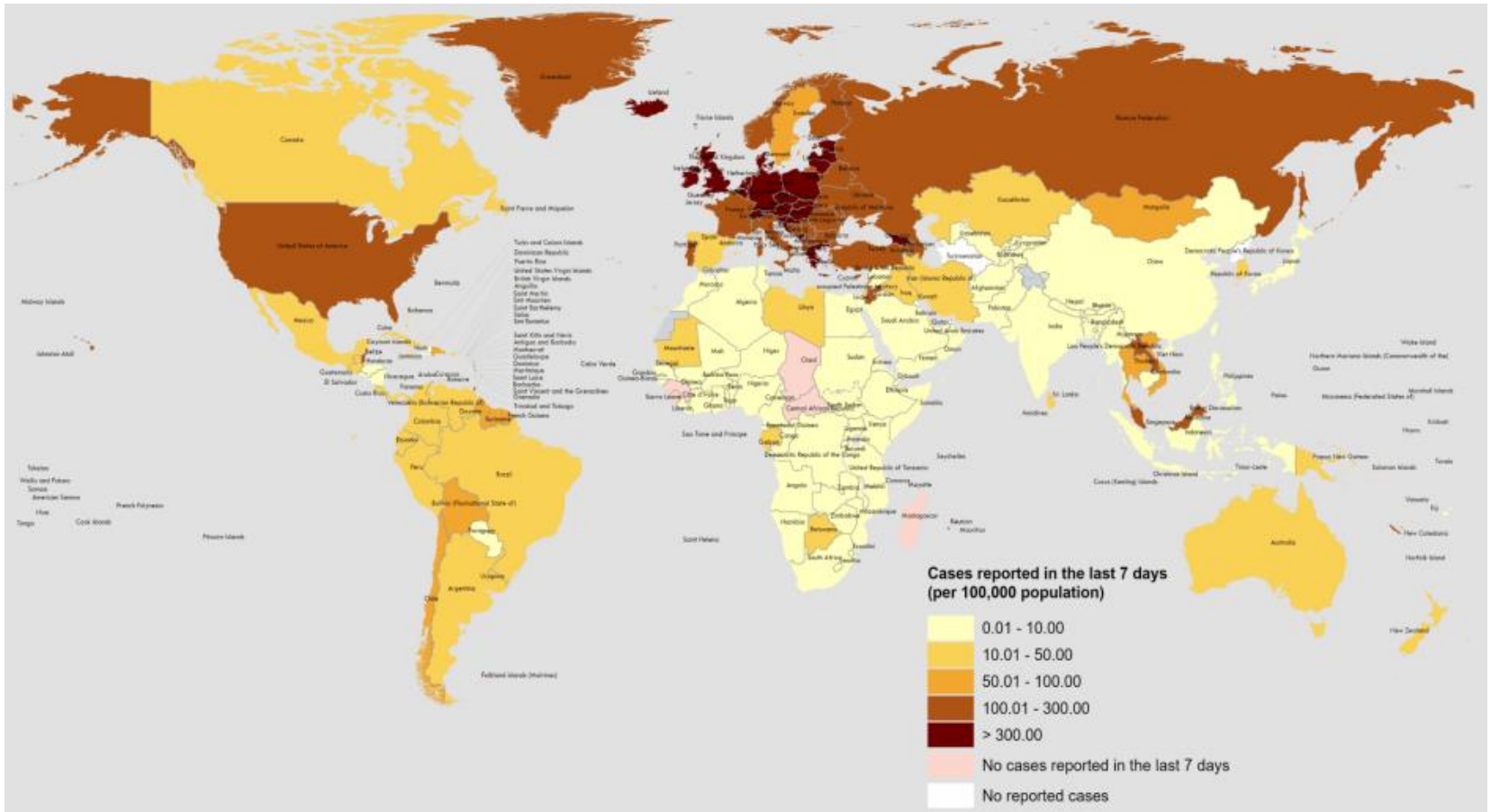
deaths



Source: World Health Organization
Data may be incomplete for the current day or week.

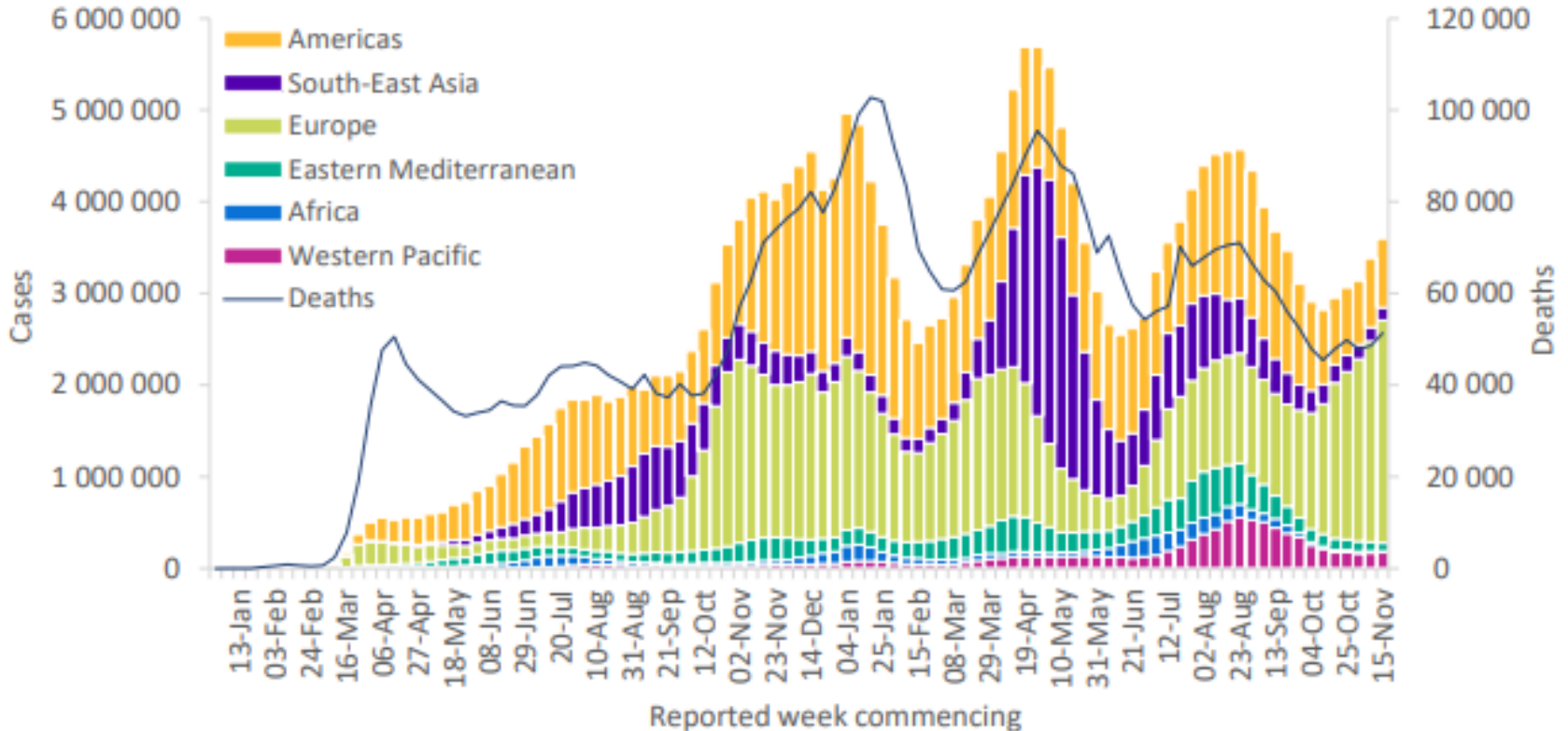


Worldwide: COVID-19 Case Rate



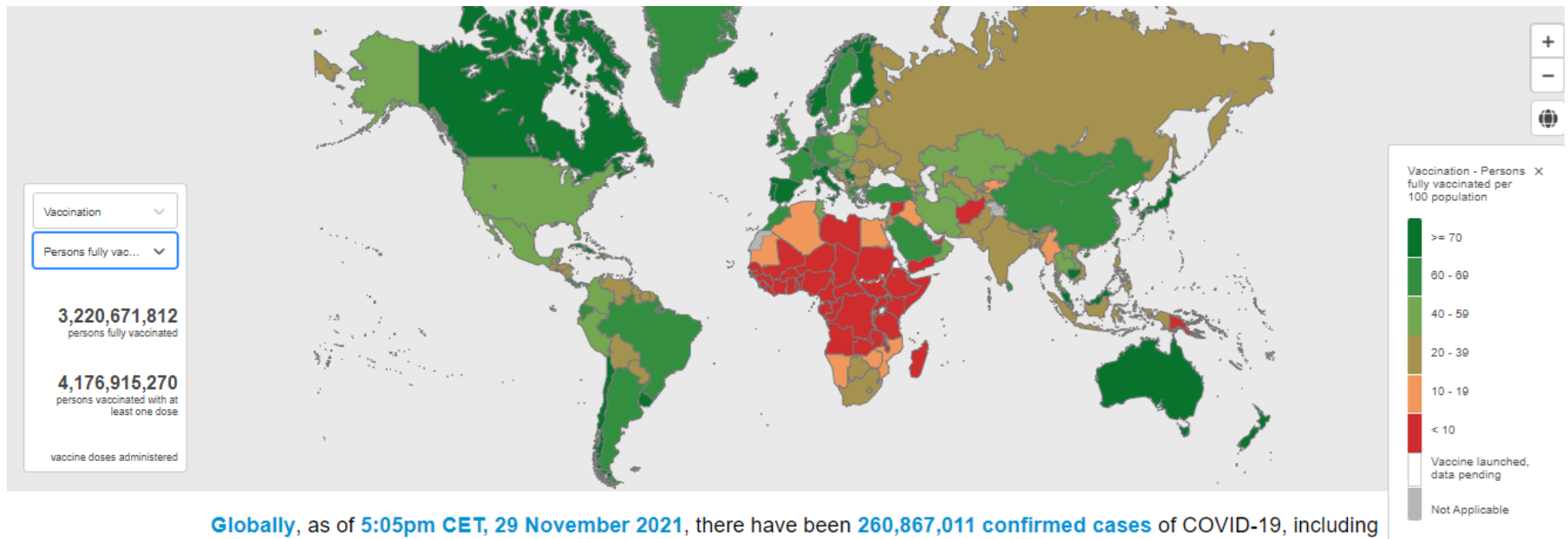
Worldwide: COVID-19

Figure 1. COVID-19 cases reported weekly by WHO Region, and global deaths, as of 21 November 2021**



**See Annex 2: Data, table, and figure notes

Worldwide: COVID-19 Vaccinations



Globally, as of 5:05pm CET, 29 November 2021, there have been 260,867,011 confirmed cases of COVID-19, including 5,200,267 deaths, reported to WHO. As of 29 November 2021, a total of 7,772,799,316 vaccine doses have been

U.S.: COVID-19



COVID Data Tracker

Cases Total 48,160,971

Last 30 Days

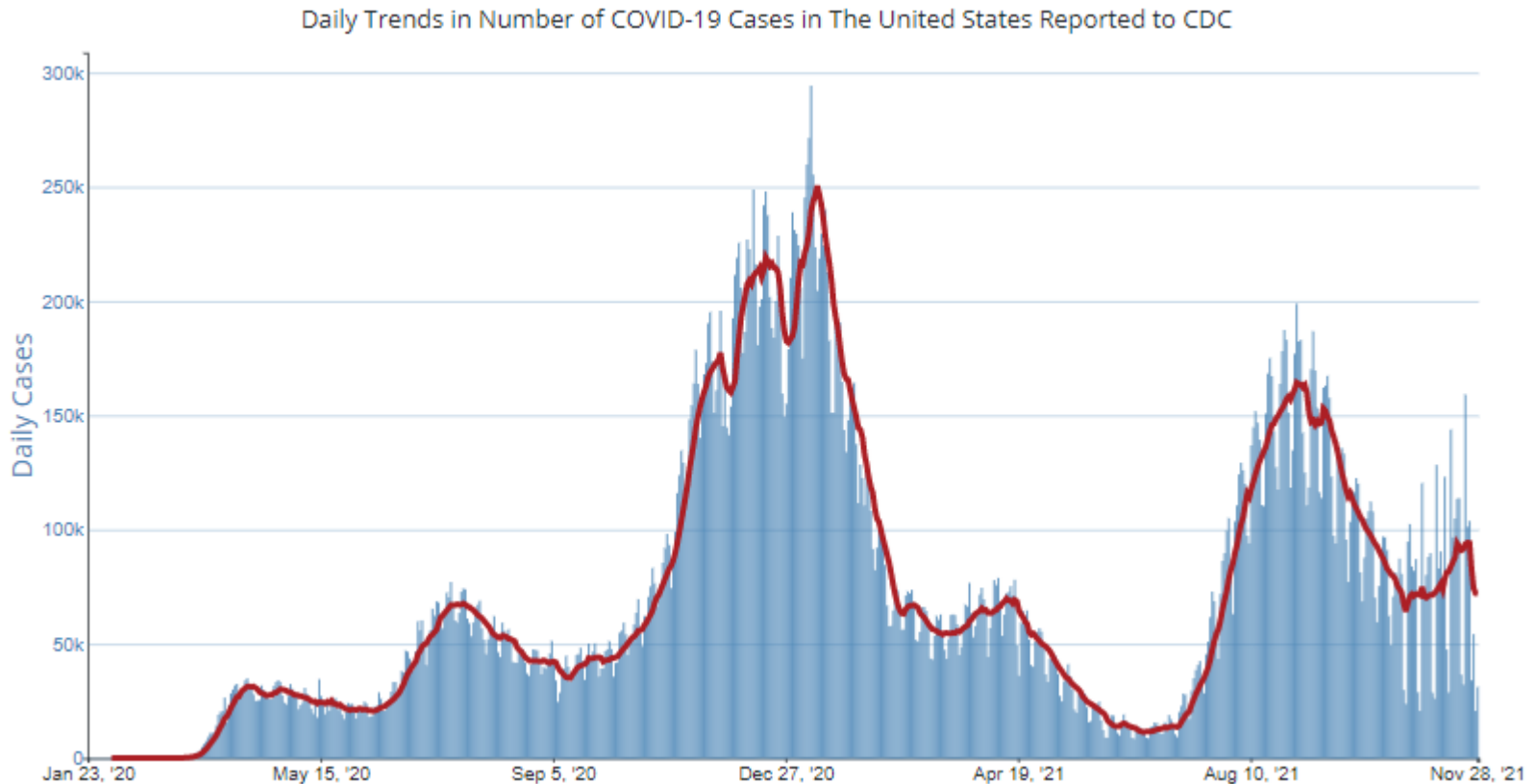
Deaths Total 776,703

Last 30 Days

74.5% of People 5+ with At Least
One Vaccination

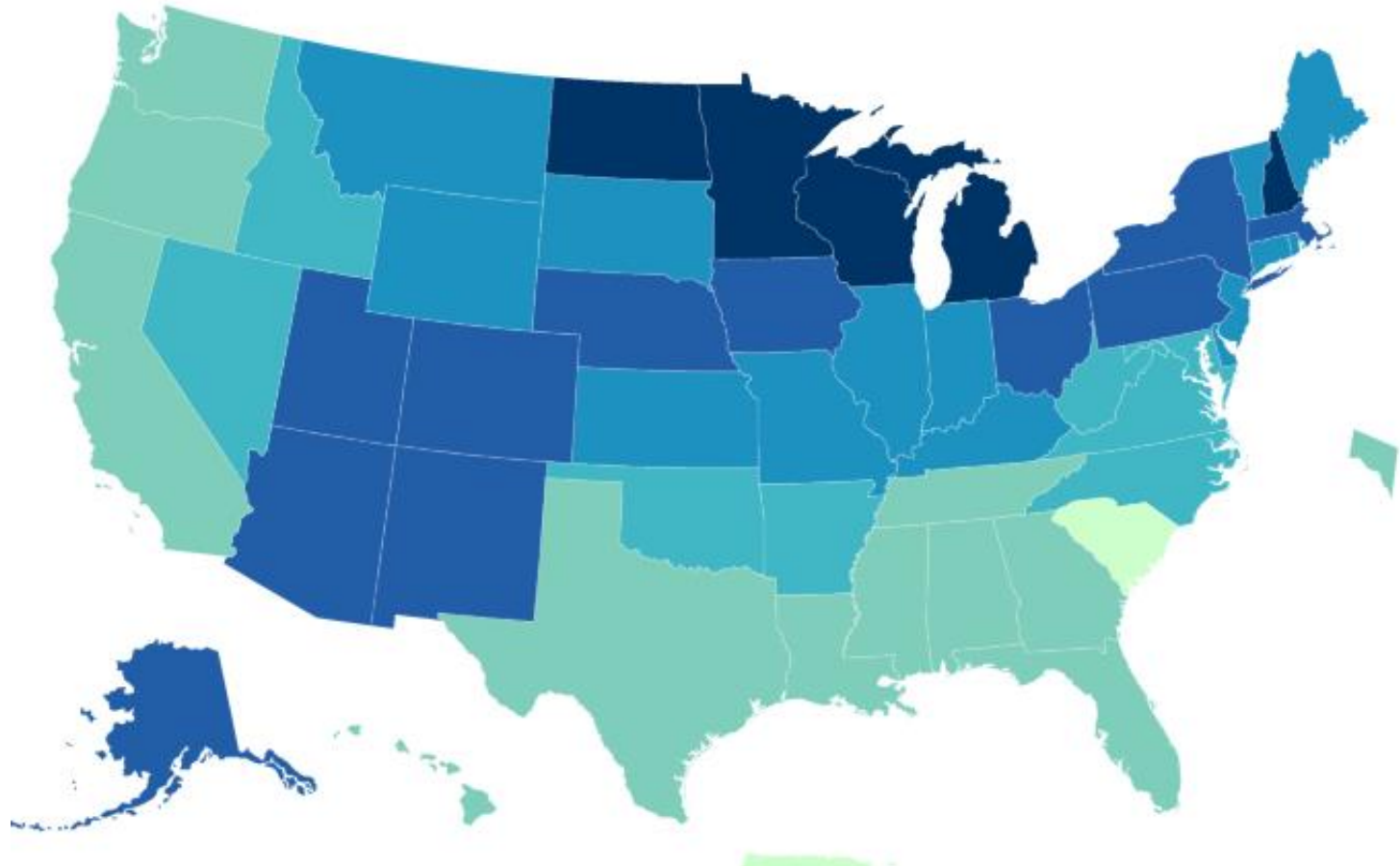
Community High
Transmission

U.S.: COVID-19 Cases



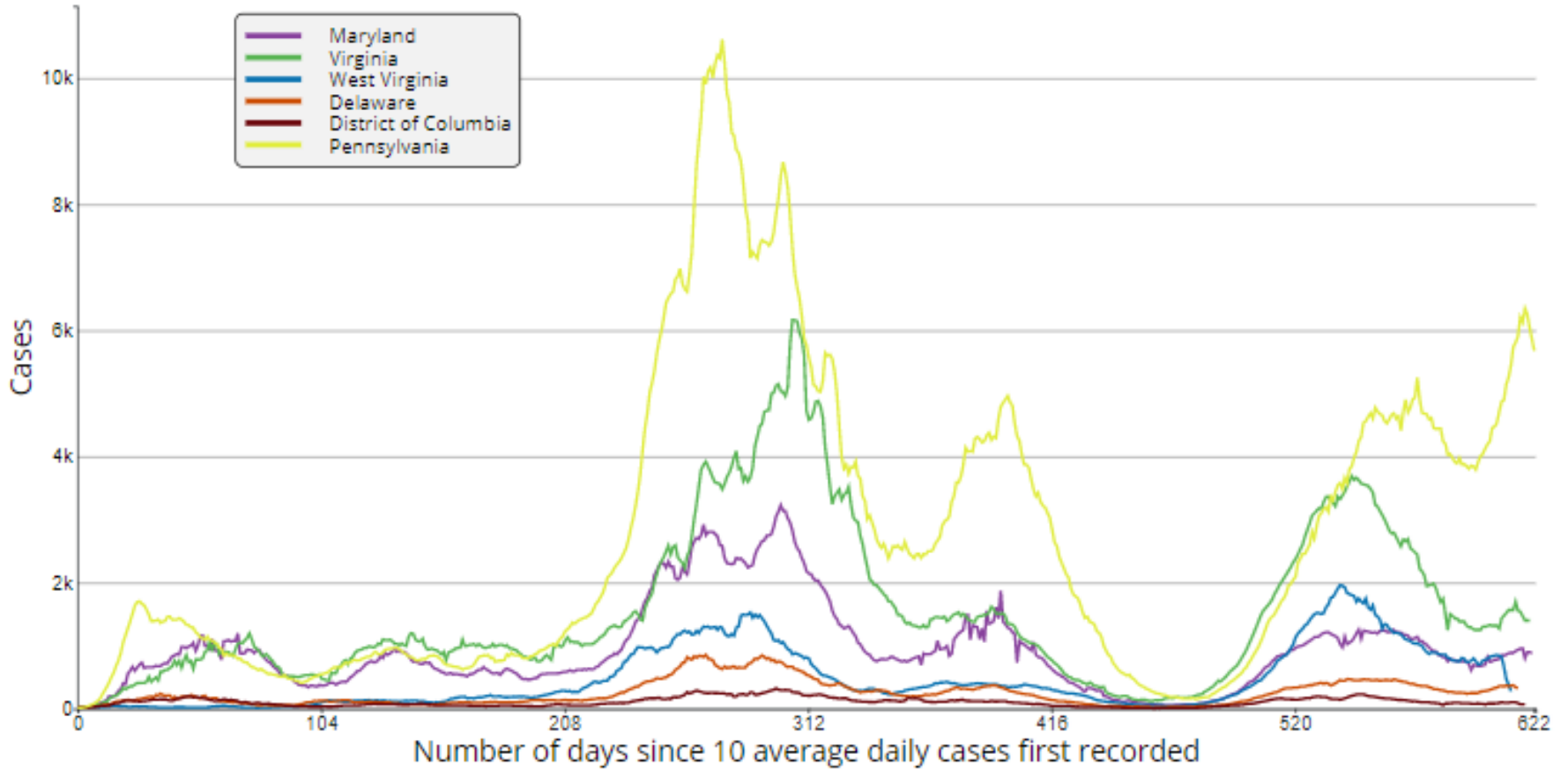
US COVID-19 7-Day Case Rate per 100,000, by State/Territory

US COVID-19 7-Day Case Rate per 100,000, by State/Territory



New cases of Covid-19, reported to CDC, in MD, VA, WV, DE, DC, and PA

Seven-day moving average of new cases by number of days since 10 average daily cases first recorded



U.S.: COVID-19 Hospitalizations

New Admissions of Patients with Confirmed COVID-19, United States
Aug 01, 2020 - Nov 26, 2021



3,389,760

Total Admissions

Aug 01, 2020 - Nov 26, 2021

5,592

Current 7-Day Average

Nov 20, 2021 - Nov 26, 2021

5,789

Prior 7-Day Average

Nov 13, 2021 - Nov 19, 2021

16,478

Peak 7-Day Average

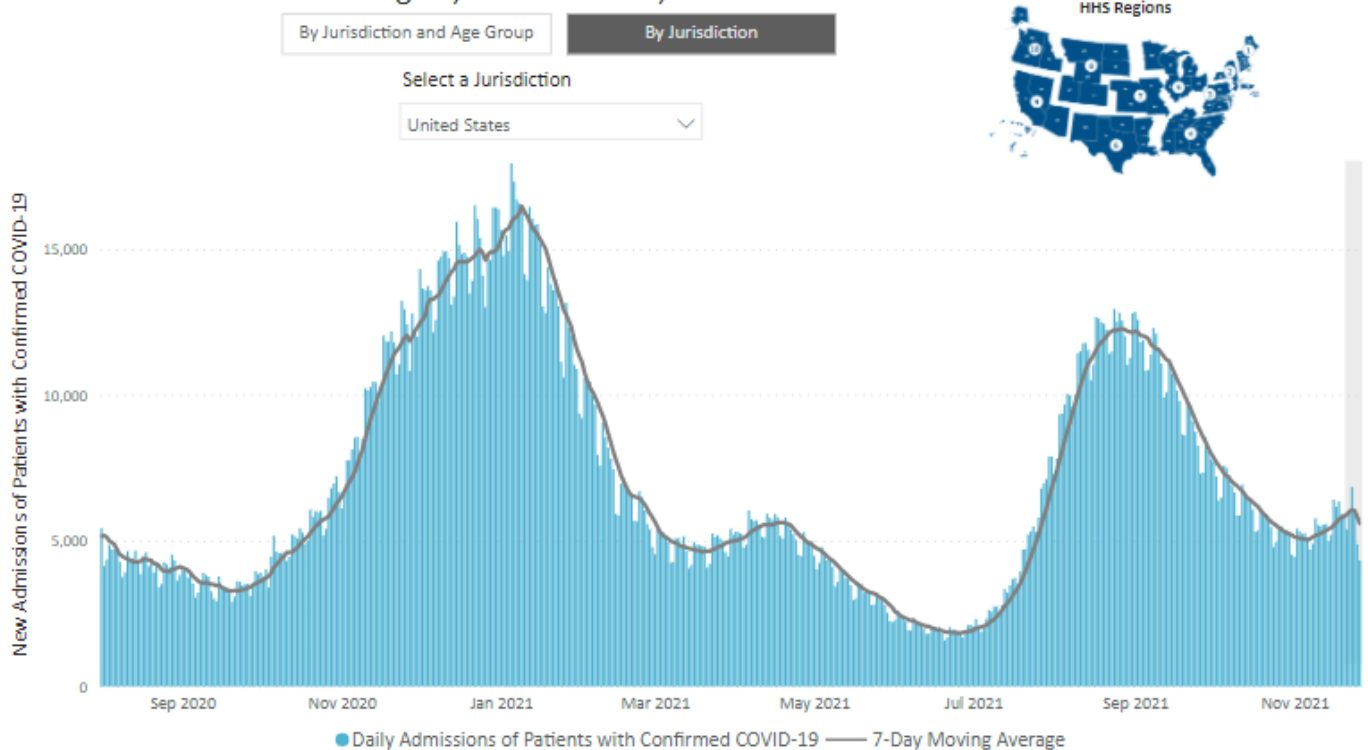
Jan 03, 2021 - Jan 09, 2021

-3.4%

Percent change from prior 7-day avg. of Nov 13, 2021 - Nov 19, 2021

-66.1%

Percent change from peak 7-day avg. of Jan 03, 2021 - Jan 09, 2021



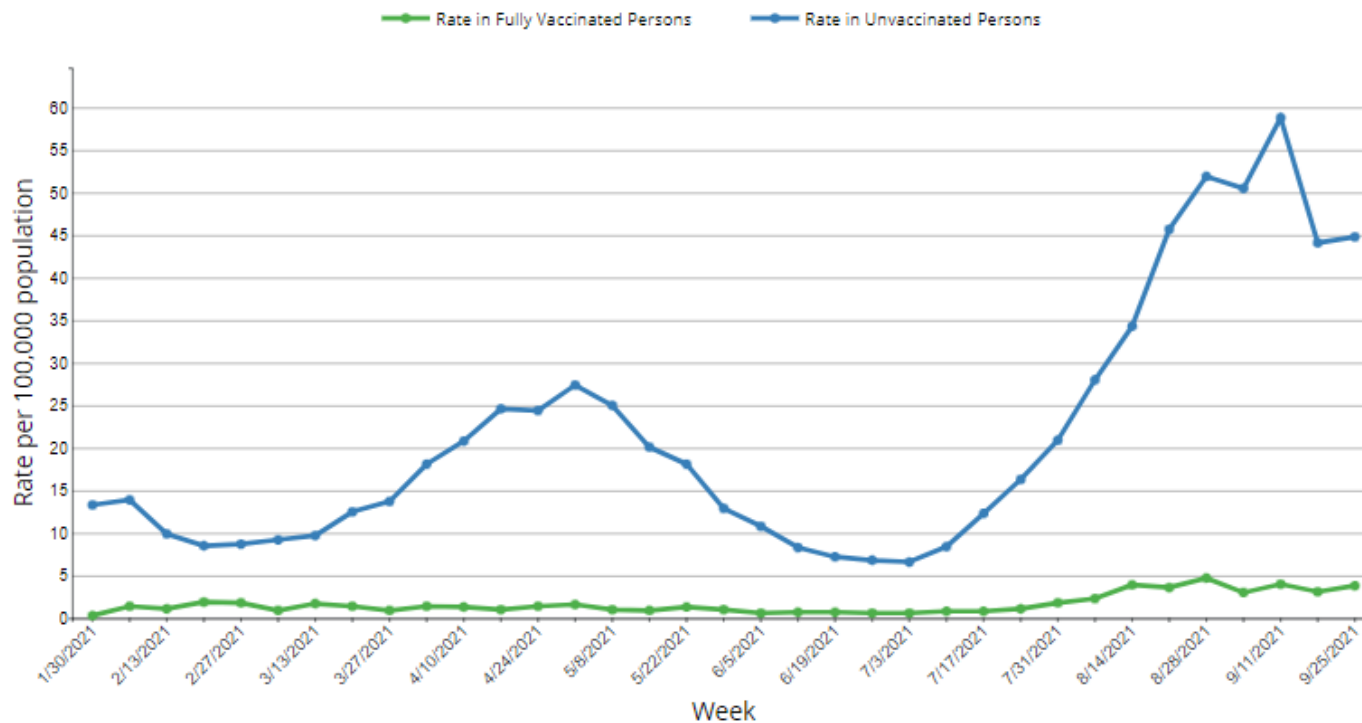
Based on reporting from all hospitals (N=5,259). Due to potential reporting delays, data reported in the most recent 7 days (as represented by the shaded bar) should be interpreted with caution.

Small shifts in historic data may occur due to changes in the CMS Provider of Services file, which is used to identify the cohort of included hospitals. Data since December 1, 2020 have had error correction methodology applied. Data prior to this date may have anomalies that are still being resolved. Data prior to August 1, 2020 are unavailable.



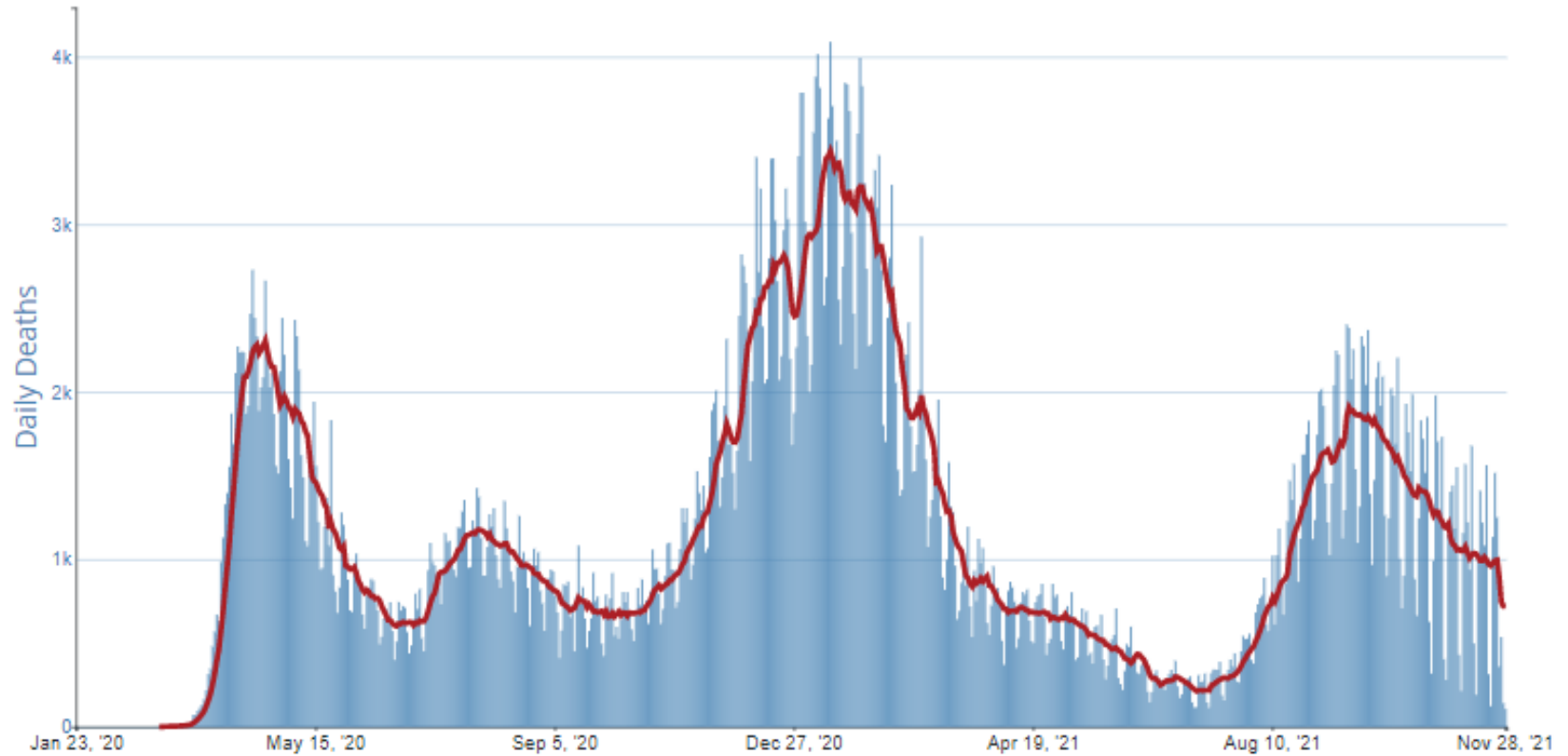
U.S.: COVID-19 Hospitalizations

Age-Adjusted Rates of COVID-19-Associated Hospitalizations by Vaccine Status in Adults Aged ≥ 18 Years, January–September 2021



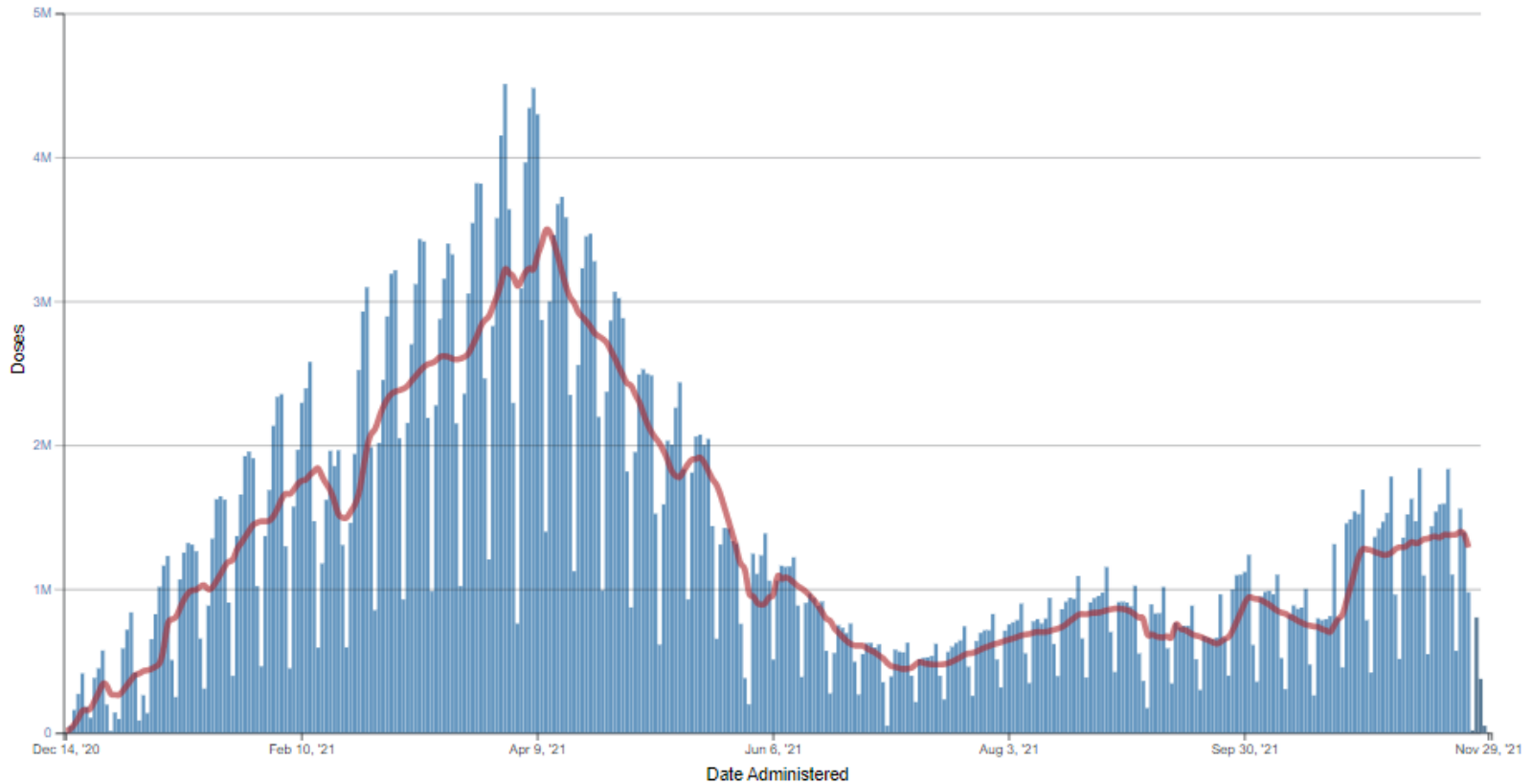
U.S.: COVID-19 Deaths

Daily Trends in Number of COVID-19 Deaths in The United States Reported to CDC

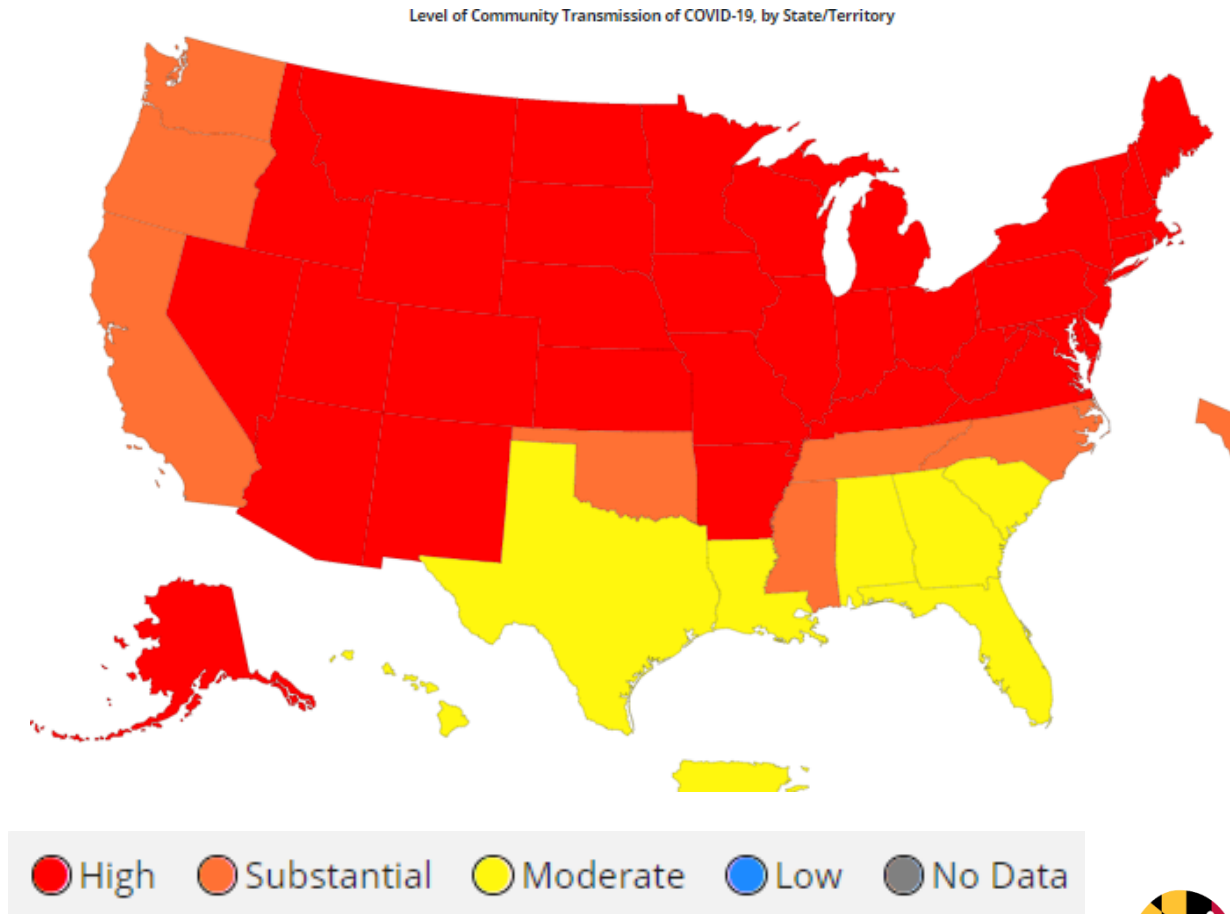


U.S.: COVID-19 Vaccinations

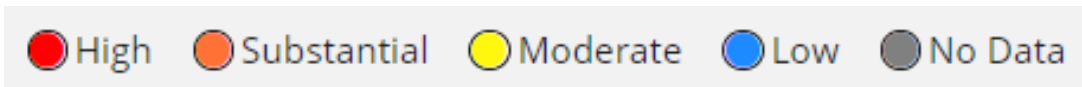
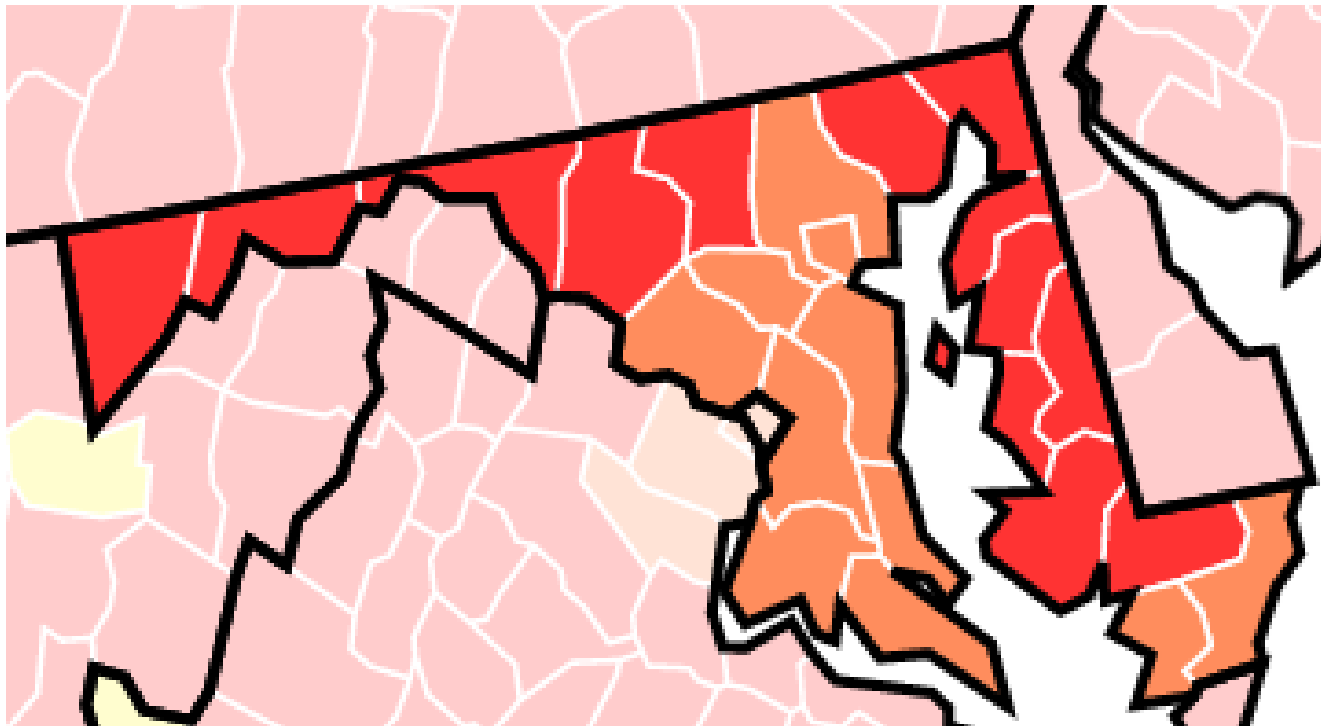
Daily Count of Total Doses Administered and Reported to CDC by Date Administered, United States



U.S.: COVID-19 Community Transmission



Maryland: COVID-19 Community Transmission



COVID-19 Variants



Maryland: COVID-19

Maryland COVID-19 Data Dashboard

Confirmed Cases

587,285

24hr Change: +1,142

Persons Tested Negative

4,614,759

24hr Change: +5,799

Testing Volume

15,060,973

24hr Change: +33,888

Testing % Positive

5.13%

24hr Change: 0.09

Confirmed Deaths

10,987

24hr Change: +14

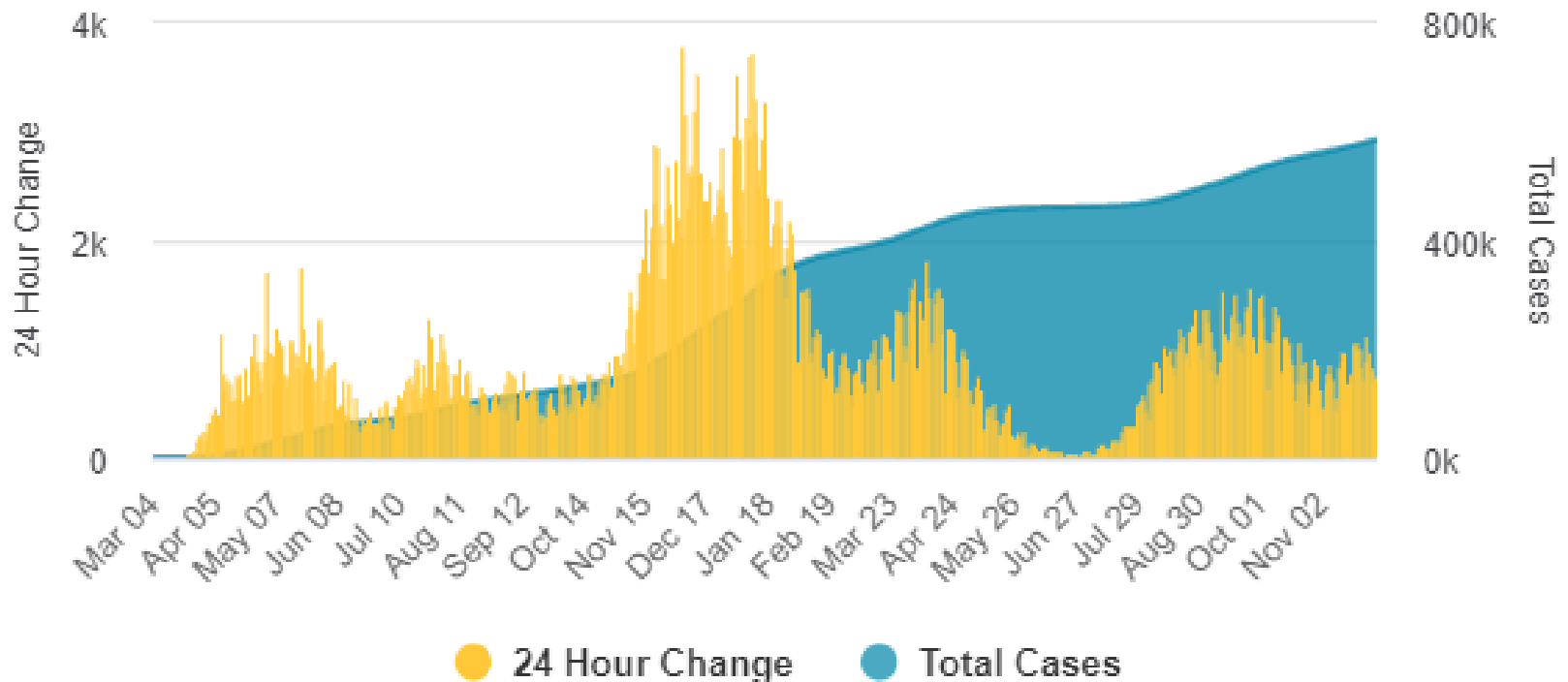
Currently Hospitalized

698

24hr Change: 35

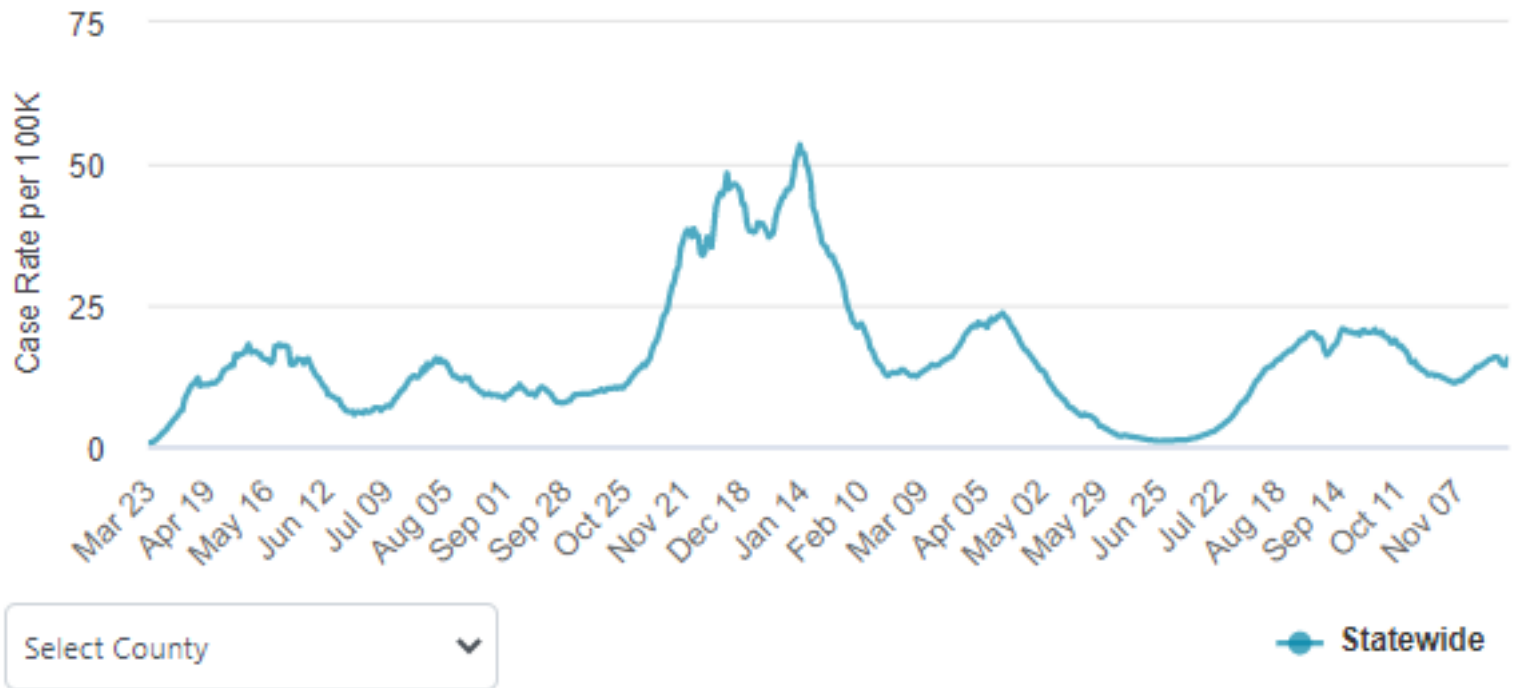
Maryland: COVID-19 Confirmed Cases

Confirmed Cases, Total over Time



Maryland: COVID-19 Case Rate

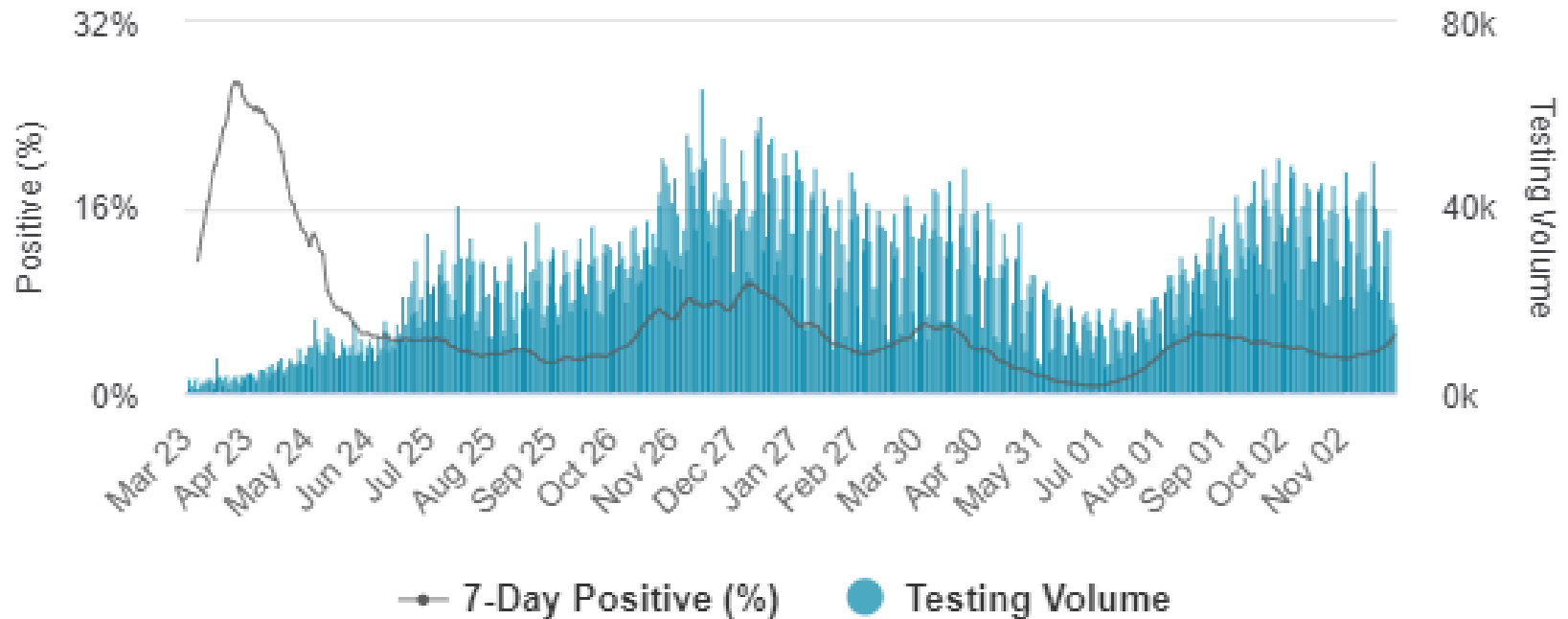
7 Day Moving Average Case Rate per 100K by Jurisdiction - [Full Screen View](#)



Maryland: COVID-19 % Positive Rate

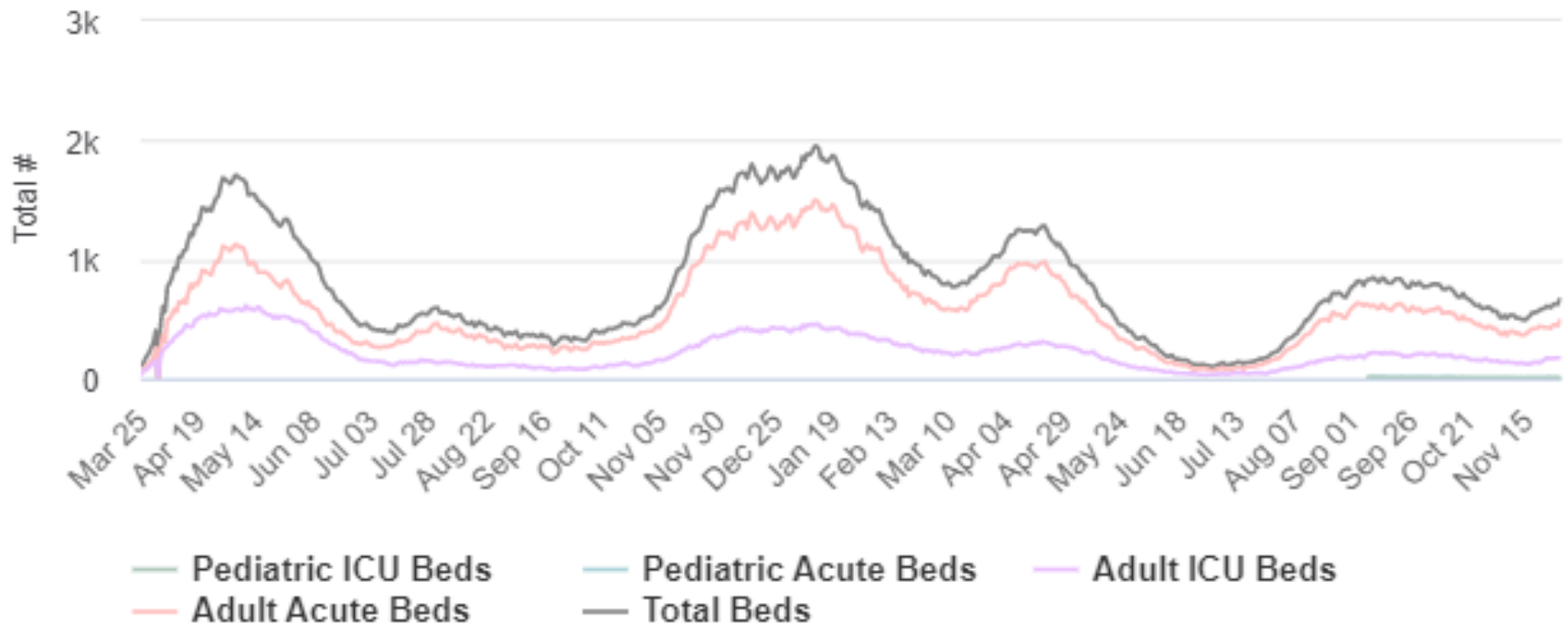
Testing Volume, Tests per Day and Percent Positive Rate (7-Day Avg)

- Methodology



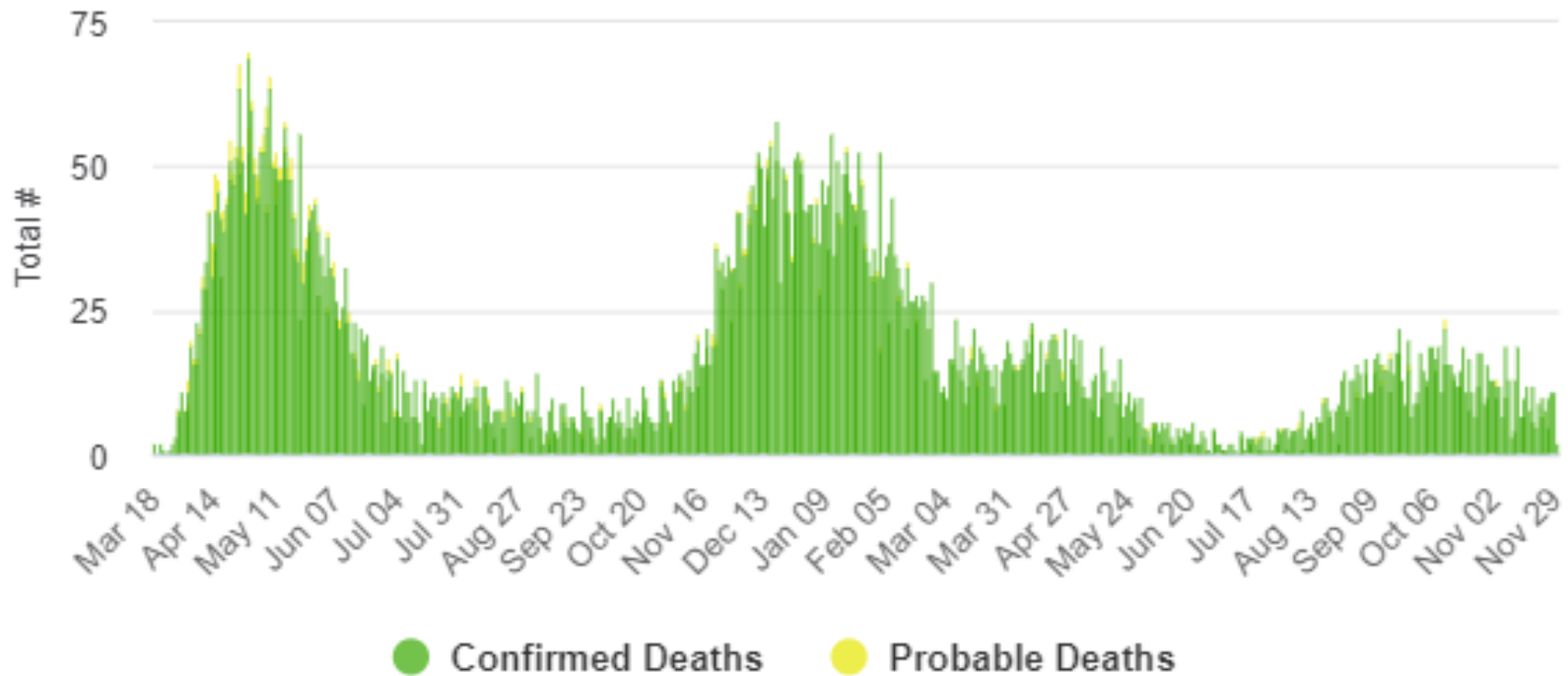
Maryland: COVID-19 Hospitalizations

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



Maryland: COVID-19 Deaths

Confirmed and Probable Deaths, Totals by Date of Death



Maryland: COVID-19 Vaccinations

CDC: 18+ Population with at Least One Dose

88.9%

Source: CDC Covid Data Tracker

Fully Vaccinated
4,099,736

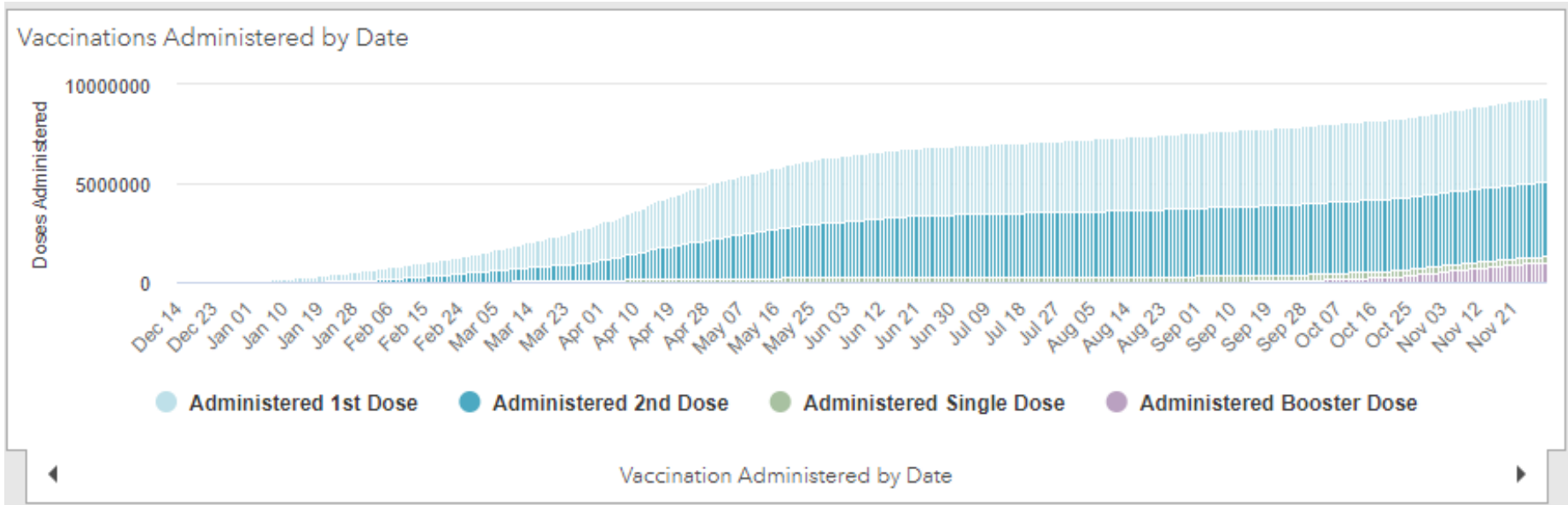
Doses Administered
9,395,285

All Doses Administered

Vaccinations by Dose

Doses Distributed
12,182,700

Maryland: COVID-19 Vaccinations



Omicron Variant

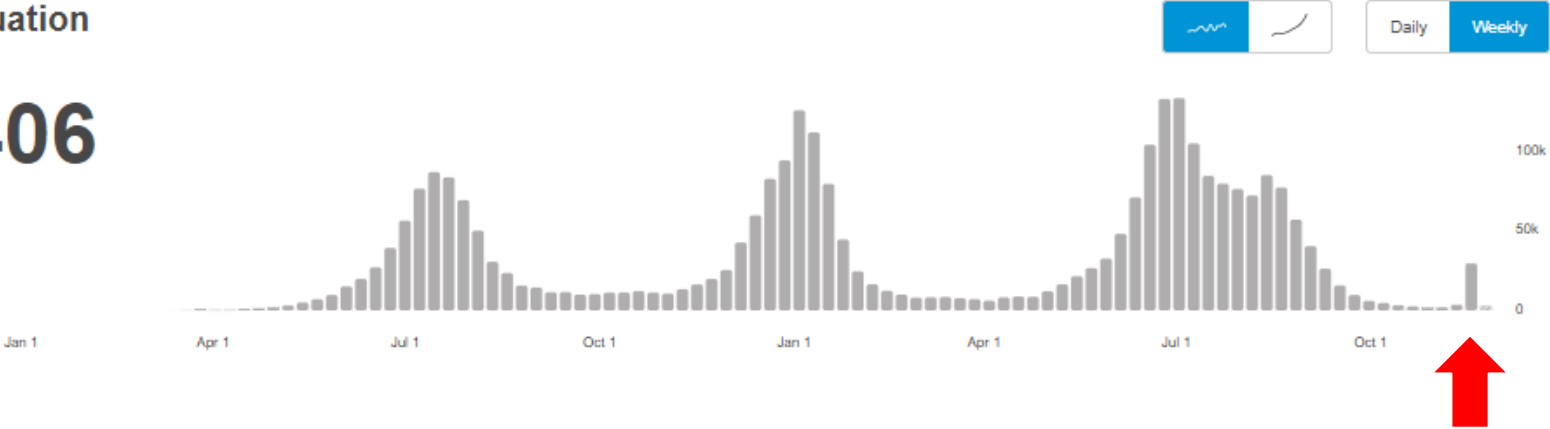
Background

- 11/26/21: WHO designated B.1.1.529 (Omicron) a Variant of Concern
- First known confirmed B.1.1.529 infection was from a specimen collected on 11/9/21 in South Africa
 - In recent weeks, infections in South Africa have increased steeply, coinciding with the detection of B.1.1.529 variant.
- Confirmed cases have now also been reported in multiple countries, including Botswana, UK, Germany, Israel, Hong Kong, Italy, Belgium, Czech Republic, Netherlands, Portugal, Canada, Australia

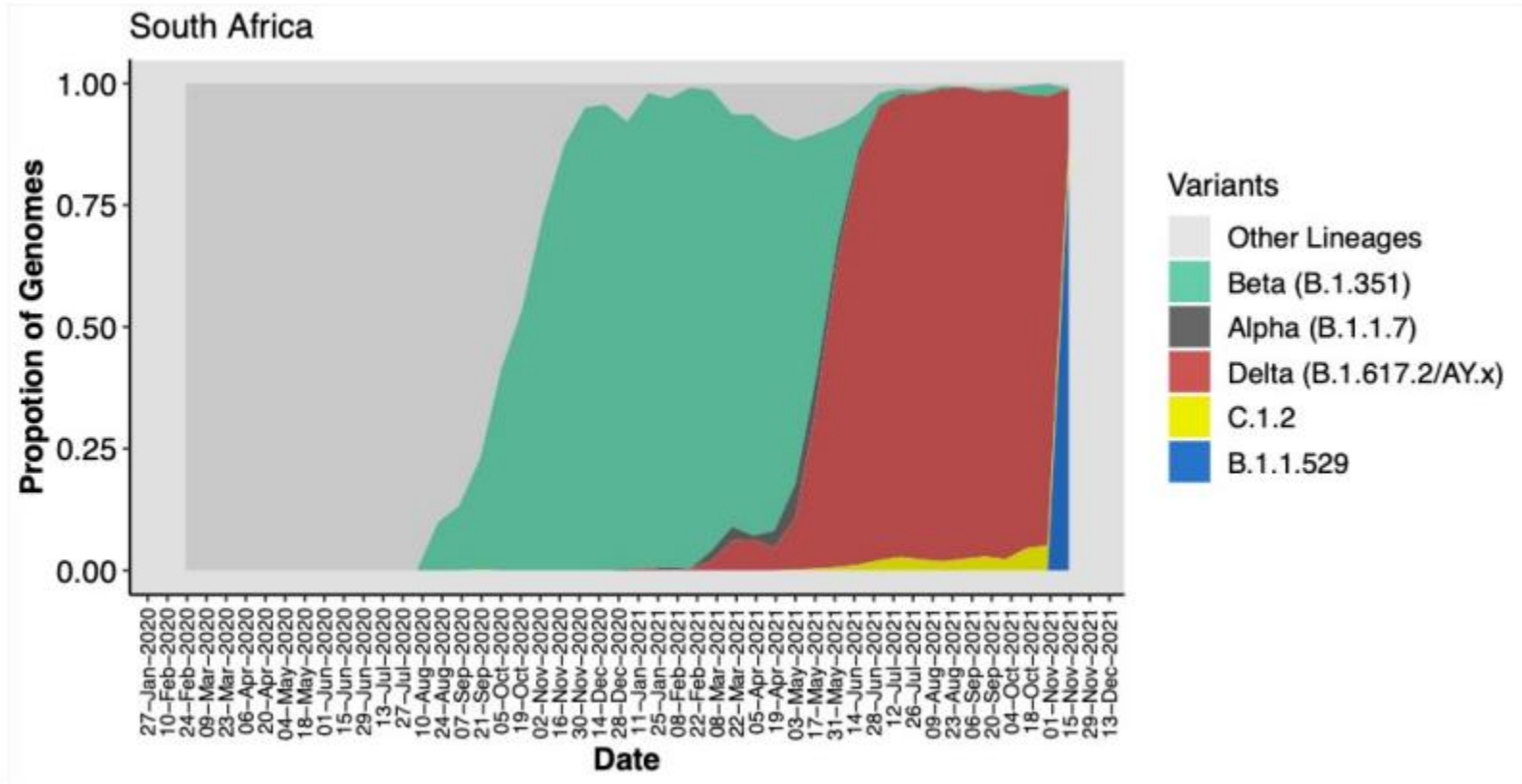
South Africa

South Africa Situation

2,961,406
confirmed cases



South Africa



6 https://www.krisp.org.za/manuscripts/25Nov2021_B.1.1.529_Media.pdf

Impact of Omicron

- Transmissibility
 - Unclear if more transmissible
 - Rising cases in areas of South Africa affected by this variant; unknown if due to Omicron
- Disease Severity
 - Not known
- Re-infection
 - Preliminary evidence suggests there may be an increased risk of reinfection with Omicron, as compared to other variants of concern, but information is limited

<https://www.who.int/news/item/28-11-2021-update-on-omicron>

Impact of Omicron

- Vaccine Efficacy
 - Laboratory neutralizing tests with serum from vaccinated individuals pending
- Testing
 - The widely used PCR tests continue to detect infection. Studies ongoing to determine whether there is any impact on rapid antigen detection tests.
- Treatment
 - Corticosteroids and IL6 Receptor Blockers will still be effective
 - Monoclonal Antibody – not known

<https://www.who.int/news/item/28-11-2021-update-on-omicron>

U.S. Travel Orders

- Effective 11/29/21, by Presidential Proclamation, U.S. has suspended the entry into the U.S., as immigrants or nonimmigrants, of noncitizens who were physically present within the following countries during the 14-day period preceding their entry or attempted entry into the U.S:
 - South Africa, Botswana, Zimbabwe, Namibia, Lesotho, Eswatini, Mozambique, Malawi
- Not applicable to U.S. citizens or permanent residents, certain non-citizen family members, and a small number of other individuals who meet specified exceptions

<https://www.whitehouse.gov/briefing-room/presidential-actions/2021/11/26/a-proclamation-on-suspension-of-entry-as-immigrants-and-nonimmigrants-of-certain-additional-persons-who-pose-a-risk-of-transmitting-coronavirus-disease-2019/>

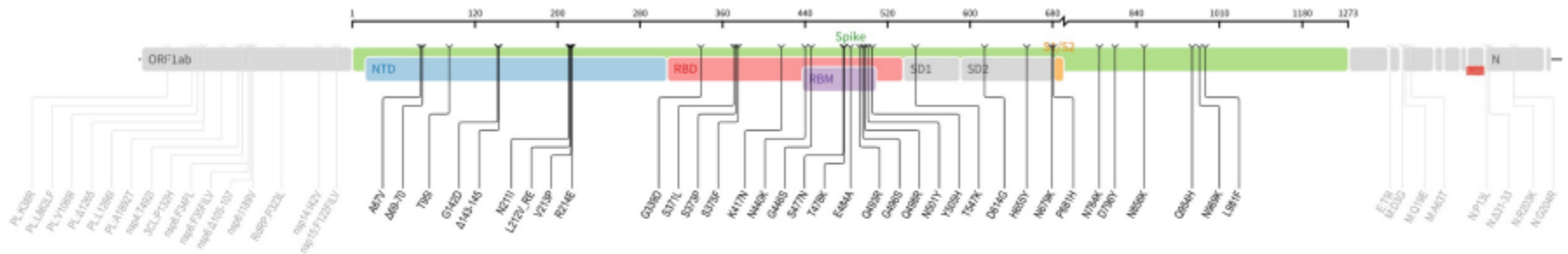
Omicron Variant

- High number of mutations across entire genome
- >30 mutations in the spike protein, some similar to Delta and Alpha; some are new
- Some known mutations have been associated with:
 - Increased transmissibility
 - Immune evasion
 - Resistance to neutralizing antibodies (natural and vaccine-induced immunity) and treatment monoclonal Ab
- Testing
 - S gene dropout: Several labs have indicated that for one widely used PCR test, one of the three target genes is not detected

<https://www.who.int/news/item/28-11-2021->

65 [update-on-omicron](https://www.who.int/news/item/28-11-2021-)

B.1.1.529 – potential impact of mutations



- Multiple RBD and NTD mutations associated **with resistance to neutralizing antibodies** (and therapeutic monoclonal antibodies)
- Cluster of mutations (H655Y + N679K + P681H) adjacent to S1/S2 furin cleavage site – **associated with more efficient cell entry → enhanced transmissibility**
- nsp6 deletion ($\Delta 105-107$) – similar to deletion to Alpha, Beta, Gamma, Lambda – may be associated with **evasion of innate immunity (interferon antagonism) → could also enhance transmissibility**
- R203K+G204R mutations in nucleocapsid - seen in Alpha, Gamma, Lambda – associated with **increased infectivity**

<https://www.krisp.org.za/manuscripts/25Nov2>

021 B.1.1.529 Media.pdf

Thank you

Question and Answer Session

Appendix

Pediatric Covid Updates

COVID-19 Vaccination Planning Update

Resources



How to Find Vaccine for 5-11 year olds

- Current covidLINK vaccination site finder: <https://coronavirus.maryland.gov/pages/vaccine>
- Search for providers administering to children 5-11

COVID-19 5-11 Vaccination Sites

Find address or place

15 mi

1 50

COVID-19 Vaccination Site Locator 5-11

You will need to contact the clinic as indicated to schedule an appointment. Please confirm vaccine availability when making your appointment.
Inclement weather may impact appointments and scheduling. Please contact the provider to confirm availability.

- Mass Vaccination Sites
- Hospital / Clinic Locations
- Pharmacy
- Local Health Department
- Primary Care or Urgent Care

Search for an address to locate COVID-19 vaccination sites. If you don't know the

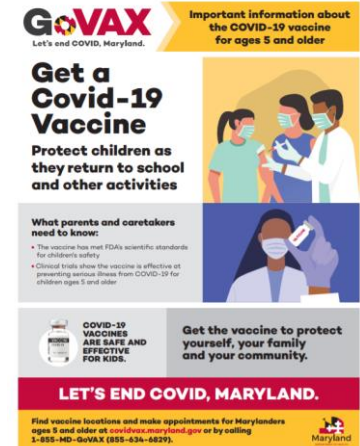
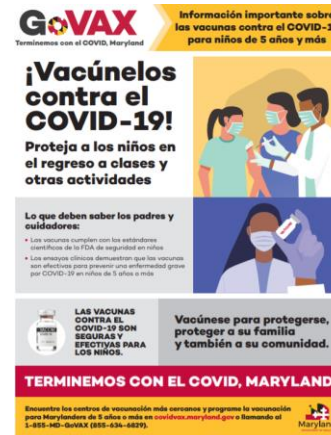
Facebook Twitter LinkedIn Email RSS

Earthstar Geographics | County of Prince William, VA | Esri | HERE | DeLorme | Mapbox | OpenStreetMap contributors | Imagery © Mapbox | © 2021 Maryland Department of Health | Powered by Esri



5-11 Vaccine Communication Toolkit

- ❖ The MDH Office of Communications has created a 5-11 Vaccine Communications toolkit, including FAQ, flyers, customizable clinic announcements, social media content, and videos
- ❖ Resources available in multiple languages
- ❖ Access the toolkit at <https://bit.ly/2ZSE82s> (password: 5+Vaccine)
- ❖ Contact: maureen.regan@maryland.gov



Appendix

Monoclonal Antibody Treatment Information and Resources

Monoclonal Antibodies Updates

- ❖ Currently available from USG by allocation to each state (100,000 doses national/week)
 - Maryland receiving 1414 doses this week
- ❖ Subcutaneous administration available for Regeneron
 - Post Exposure Prophylaxis for unvaccinated , high risk
 - Expanded patient qualifications – clinical judgment
 - Bam-Etes and Regeneron for PEP
 - HHS Protect registration and reporting required

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

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

Self-Referral Options for Patients

- ❖ Patients should coordinate with their respective physician or care provider before contacting a location to schedule an appointment.
- ❖ Patients without a healthcare provider, contact [eVisit](#) to schedule a virtual appointment or complete a [self-referral form](#).
 - Eligible patient(s) will be referred to an infusion site for treatment.
- ❖ For those without internet access or a healthcare provider, they may contact the **MDH-supported monoclonal antibody call center** at **410-649-6122** (Monday – Friday from 8 a.m. to 5 p.m) and speak to a clinician to review eligibility.
 - *Odenton VFD, City of Praise Ministries, and [MDmAbs](#) also accept direct patient contact to determine eligibility and/or schedule treatment

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). 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 people (e.g., not fully vaccinated or immunocompromised) who are at high-risk for progression to severe COVID-19.

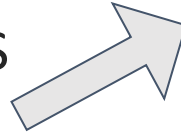
Determine Eligibility for Monoclonal Antibody Treatment for Patients	
Track 1 - Active COVID-19 Infection	Track 2 - Post-Exposure Prophylaxis
1. Is the patient 12 years of age or older weighing at least 88 pounds? If NO , STOP ; YES , proceed to number 2.	1. Is the patient 12 years of age or older weighing 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.	

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 (coughing or sneezing, for example). See this website for additional details: <https://www.cdc.gov/coronavirus/2019-nCoV/faq-close-contact-exposure.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/vaccines/imz/011/>
⁴For further information as what qualifies an individual as high risk please see slide 19 of the Monoclonal Antibody Clinical Implementation Guide available at: <https://www.dhs.gov/emergency-use/COVID-19/monoclonal-antibody-clinical-implementation-guide>



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>)

Appendix

Maryland's Official Health Insurance Marketplace: Open Enrollment Information

What's New with Maryland Health Connection

November 2021



Maryland's Official Health Insurance Marketplace

Open Enrollment
November 1, 2021

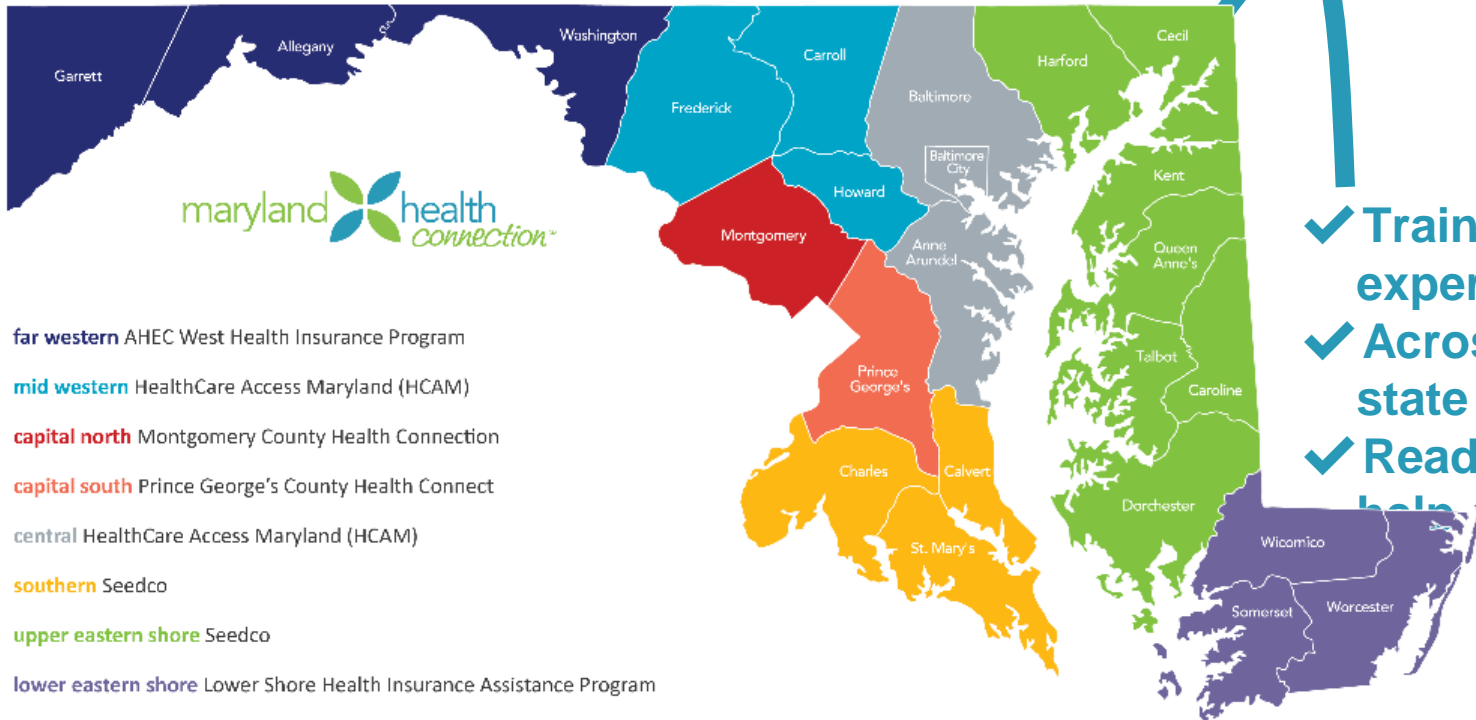
—
January 15, 2022,
to be covered for
2022



www.MarylandHealthConnection.gov

www.MarylandHealthConnection.gov/es

Where to Find Help



- ✓ Trained experts
- ✓ Across the state
- ✓ Ready to help

The Only Place to Get Financial Help

Maryland Health Connection is the only place Marylanders can get financial help to pay for their health plan. In fact, **9 out of 10 who enroll get savings.**



More Savings for More Marylanders

Did you know the **American Rescue Plan** includes big savings for health insurance?

- For the **uninsured**, it's worth checking out the 2022 health plan options – there are now new, bigger savings.
- If someone **didn't qualify for savings before** they should take another look because, for the first time, there are savings available for Marylanders with higher incomes.

Did you know Maryland has **new discounts for young adults** ages 19-34? They're new for 2022 health plans!



TheSocialPressKit.com/MarylandConnect

Visit our **Social Press Kit** for ready-to-post graphics to share on your social media channels, messaging to share with your community, and more.

Variety of messages and languages

CAMPAIGN
Enrollment for Health Coverage

HASHTAGS
#GetCoveredMD

DESCRIPTION
Use this toolkit to promote enrollment. Click to share messages quickly on social media, or download and adapt as you see fit. Don't forget to follow us @MarylandConnect and tag us in your posts!

Open Enrollment Period - English
Coronavirus Special Enrollment Period - English and Spanish
COVID-19 Public Health Resources - English and Spanish
Other Special Enrollment Period - English and Spanish

FACEBOOK POSTS

Coronavirus PSA - English
In response to the coronavirus emergency, Marylanders can now enroll in quality, affordable health plans through @MarylandConnect. Don't wait! Learn more at MarylandHealthConnection.gov/coronavirus-sep/ #GetCoveredMD

Coronavirus SEP 1
In response to the coronavirus emergency, Marylanders can now enroll in quality, affordable health plans through @MarylandConnect. Don't wait! Learn more at MarylandHealthConnection.gov/coronavirus-sep/ #GetCoveredMD

Coronavirus SEP 2
A special enrollment is available NOW! In response to the coronavirus emergency, you can sign up for health coverage through @MarylandConnect, the state's official health insurance marketplace. Visit MarylandHealthConnection.gov, the "Enroll MHC" mobile app, or call 1-800-642-8572

Easy to post videos and graphics Already written text (you can adapt)

Enrollment ends
January 15.

#GetCoveredMD



@MarylandConnec

t

Appendix

Resources and Links

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](#)

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 videochat 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/>)