

Covid-19 Update: The Final Push Vaccines, Boosters, Testing and Monoclonal Antibodies

Maryland Department of Health Maryland Primary Care Program Program Management Office

20 October 2021



A Chronological List of Every Triple Play in Major League Baseball History

MLB #	Date	Inn	LG	Fielding Team	HA	Batting Team	Men On	Scored
1.	05-13-1876	5	NL	Mutuals	at	Dark Blues	1-2-3	4-3-4
2.	06-29-1876	6	NL	Brown Stockings	VS	Mutuals	1-3	6-3-5
3.	09-13-1876	9	NL	Athletics	VS	Red Stockings	1-2	5-4-3
4.	07-14-1877	7	NL	Red Caps	at	Brown Stockings	1-2	4-3-4
5.	07-14-1877	8	NL	Dark Blues	at	White Stockings	1-2	4-3-5
<mark>6</mark> .	08-01-1877	5	NL	Grays	VS	Brown Stockings	<mark>1-2-</mark> 3	9-1-2-3-6-2-2
7.	05-08-1878	8	NL	Grays	VS	Red Caps	1-3	8-8-4

We Can Win This Game With A Triple Play

Push vaccines

- > The last hesitant unvaccinated- accounting for deaths
- ➤ 5-11-year-old
- ➤ Boosters for all
- Third doses for the immunocompromised
- Monoclonal antibodies
 - ➤ All eligible positive cases
 - All unimmunized contacts
- Testing
 - ➤ Primary care offices
 - > Schools
 - ➤ Businesses
 - ➤ Home testing and more



Agenda

- Current Pandemic data
- Vaccine Updates
- Monoclonal antibodies
- Testing
- Third doses and boosters
- Variants
- End game for the pandemic
- Guest Presentation: Health Outcomes, Housing and Zip Codes



Daily COVID-19 Report

Data reported as of 10/20/2021 for data through 10/19/2021



13,722,165 tests cumulative

14.1

7-day avq. case rate

7,297 total hospital census 10,526 deaths cumulative

717 cases reported yesterday

29,212

3.36% 7-day avg. positivity

4,800

4,200 3,600

3,000

2,400

1,800

1,200

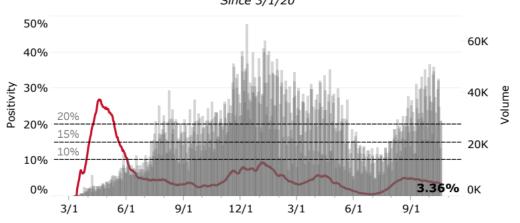
600

349 change in total hospital census

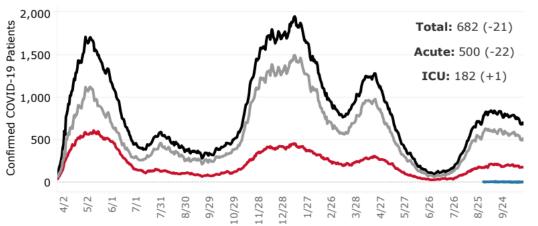
tests reported vesterday

deaths reported yesterday

7-Day Avg. Percent Positivity and Total Testing Volume Since 3/1/20



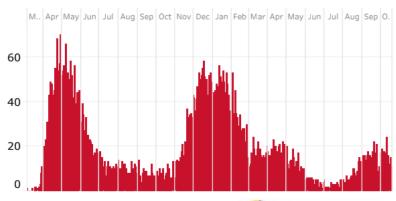
Statewide Acute/ICU Beds Occupied by COVID Patients



by Specimen Collection Date Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug S..

Daily New Cases

Daily Deaths Confirmed and Probable



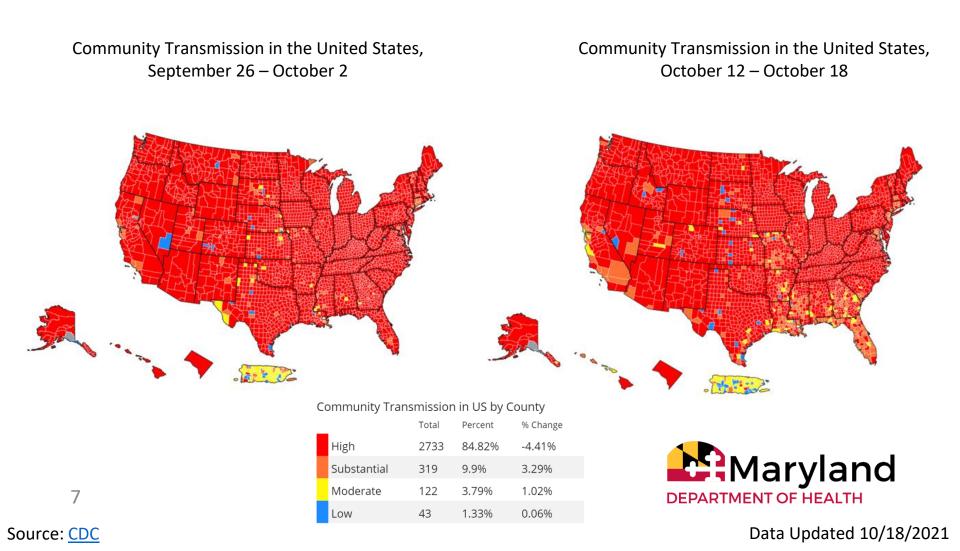
Case rate calculated as total confirmed cases per 100,000 population using the 2019 Maryland Population estimates from the Marvland Department of Planning, March 2020.



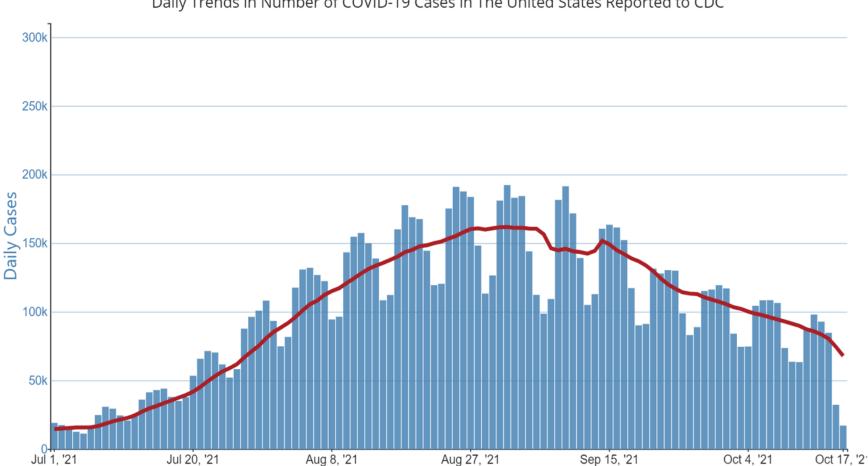
Overview of Current Pandemic Trends in the United States New reported cases

All time Last 90 days			
	7-day average		
200,000 cases			24
100,000		h	
	1	0001	in. Oct.
Feb. 2020 Jun.	Oct. Feb. 2	2021 Jt	in. Oct
Feb. 2020 Jun. Tests Feb. 2020 Oct. 2021	Hospitalized	Deaths Deaths Act. 2021 Feb. 2020	In. Oct
Tests	Hospitalized	Deaths	M
Tests	Hospitalized	Deaths	Oct. 202
Tests Feb. 2020 Oct. 2021	Hospitalized Feb. 2020 OC DAILY AVG. ON OCT. 17	Deaths Deaths Act. 2021 Feb. 2020 14-DAY CHANGE	Oct. 202 TOTAL REPORTED
Tests Feb. 2020 Oct. 2021	Hospitalized Feb. 2020 DAILY AVG. ON OCT. 17 83,576	Deaths Deaths Deaths Feb. 2020 14-DAY CHANGE -22%	Oct. 202 TOTAL REPORTED
Tests Feb. 2020 Oct. 2021 Cases Tests	Hospitalized Feb. 2020 DAILY AVG. ON OCT. 17 83,576 1,433,920	Deaths Deaths Deaths Feb. 2020 14-DAY CHANGE -22% -18%	Oct. 202 TOTAL REPORTED

US Community Transmission



Daily Trends in Number of COVID-19 Cases in the United States Reported to CDC

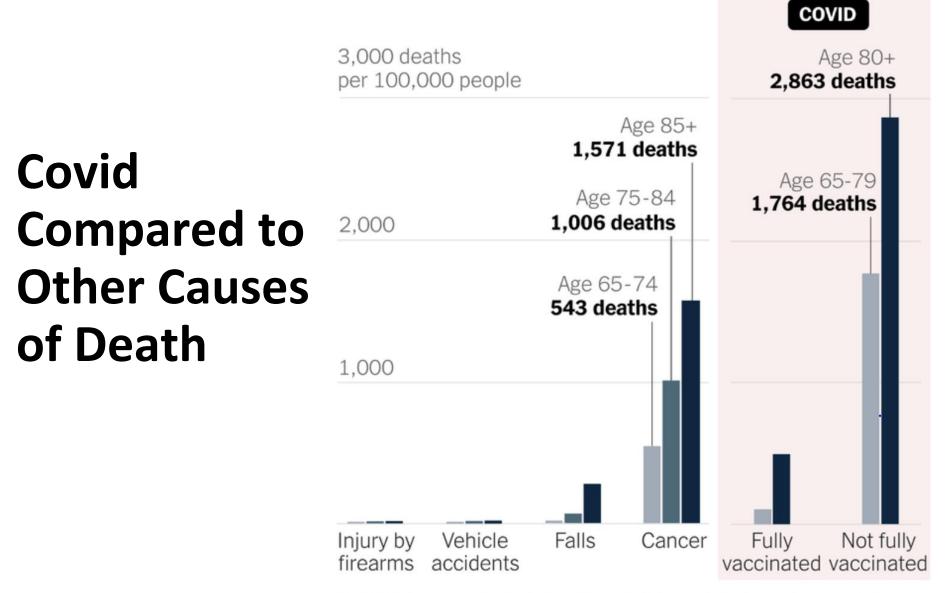


Daily Trends in Number of COVID-19 Cases in The United States Reported to CDC

Source: <u>CDC</u>

Data Updated 10/18/2021

Rate of death among older Americans



Covid data is an annualized rate from the week of Aug. 29 to Sept. 4, and is a sample from 16 U.S. jurisdictions. Data for other causes is from 2019. Source: Centers for Disease Control and Prevention

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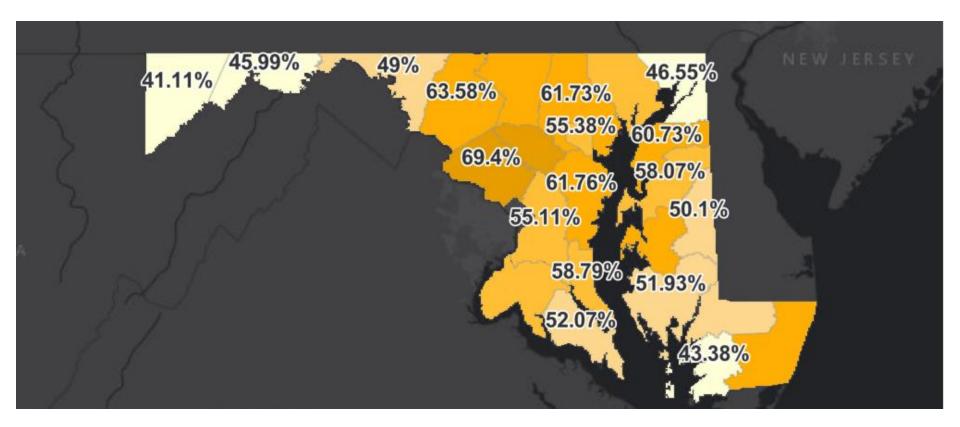
Source: NY Times

Vaccines

- The first and most important out in the triple play
- Primary Care providers are the key players in completing this part of the play



Proportion Vaccinated by County

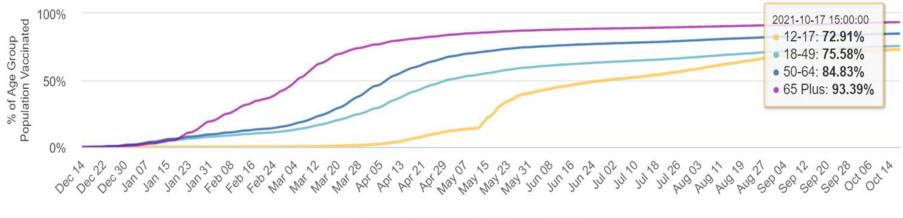




Source: Maryland Department of Health

Proportion Received At Least One Dose by Age in Maryland

Percent of Age Group Population - Received at Least One Dose



--- 12-17 --- 18-49 --- 50-64 --- 65 Plus



Source: Maryland Department of Health

Unvaccinated Hesitant Populations

Unvaccinated communities in the U.S. include:

- Pregnant individuals
- Individuals with one or more disability
- Areas with higher Social Vulnerability Index (SVI)
- Areas with higher Area Deprivation Index (ADI)
- Rural areas (MD: Western Maryland, Eastern Shore)
- Younger age groups
- Influenced by ideologies and misinformation
- ✤ Risk
 - NPR: Unvaccinated people are 11x more likely to die from Covid



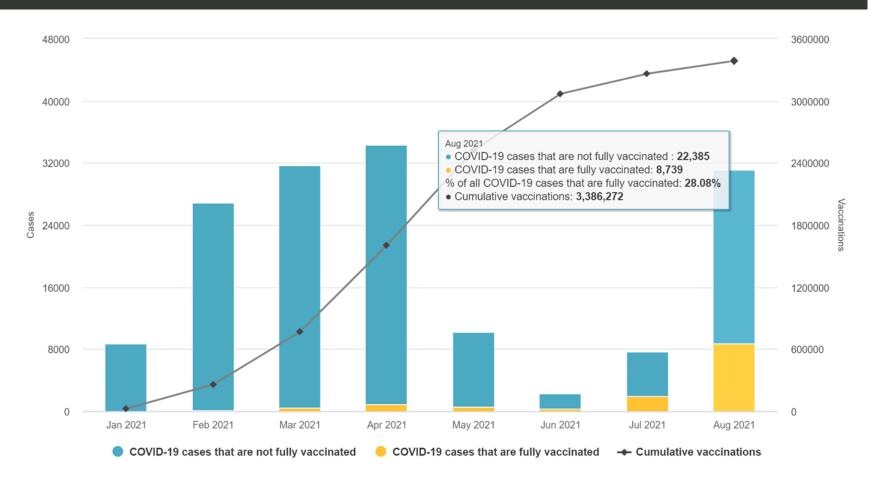
Pregnant Individuals

- CDC issued an urgent health advisory encouraging pregnant individuals to obtain a Covid vaccine
 - Only 34% of pregnant individuals are vaccinated
 - As of 10/18, there have been over 131,000 confirmed Covid cases among pregnant individuals
 - Pregnant individuals with Covid have an increased risk of:
 - ✓ Hospitalization
 - Death from Covid
 - ✓ Adverse pregnancy outcomes
- GoVAX Fast Facts brochure



Maryland Cases by Vaccination Status

COVID-19 Cases by Vaccination Status



Source: Maryland Department of Health

Primary Care and Vaccines

Cumulative Doses Administered



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

- S5.3% of Marylanders 18+ have received at least one vaccine dose
- 448 primary care practices are involved in the Primary Care Vaccine Program



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

Practices

- Charlestown Medical Center -92.92%
- 2. Linda M. Lang, M.D., LLC **92.59%**
- Doctors Saba, Koltz and Walters -92.45%
- 4. Dr. Luis A. Casas, M.D. 92.31%
- Dorchester Family Medicine -92.27%

CTOs

- 1. Holy Cross Health, Inc. **88.75%**
- 2. PHS Doctors CTO 86.20%
- 3. Greater Baltimore Health Alliance Physicians, LLC - **85.22%**
- 4. Ascension Saint Agnes Community Health Partners - **85.20%**
- University of Maryland Care Transformation Organization, LLC -84.24%



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

- Manchester Medical Center, LLC -1.71%
- Frederick Health Medical Group, Myersville - 1.52%
- MedStar Union Memorial Adult Medicine Center - 1.44%
- 4. Petek Donmez, M.D., PC **1.36%**
- 5. Doctors Community Practices Laurel - **1.33%**

CTOs

- 1. Holy Cross Health, Inc. 0.37%
- Western Maryland Physician Network, LLC
 0.29%
- 3. Management Solutions, LLC 0.26%
- 4. HCD International 0.25%
- 5. Netrin Accountable Care, LLC 0.23%



Note: percentages represent percent increase of MDPCP beneficiaries fully vaccinated

Third Doses - Completing Initial Series for Immunocompromised Individuals

- Approved and authorized by the <u>FDA</u> and <u>CDC</u>
 - mRNA for moderately to severely immunocompromised people
 - At least 28 days after second dose
 - > Supporting data:
 - Studies have indicated that fully vaccinated immunocompromised people have accounted for a large proportion of hospitalized "<u>breakthrough cases</u>"
 - Additional data and clinical considerations



Immunocompromised Individuals

- The CDC defines immunocompromised individuals as the following:
 - Been receiving active cancer treatment for tumors or cancers of the blood
 - Received an organ transplant and are taking medicine to suppress the immune system
 - Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
 - Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
 - Advanced or untreated HIV infection
 - Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response
 - People should talk to their healthcare provider about their medical condition, and whether getting an additional dose is appropriate for them



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Boosters

- Applies to Pfizer only at this time
- At least six months after 2nd dose

Pfizer Eligibility:

- 65 years and older
- Age 18+ who live in <u>long-term care settings</u>
- Age 18+ who have <u>underlying medical conditions</u>
- Age 18+ who work in <u>high-risk settings</u>
- Age 18+ who live in <u>high-risk settings</u>



On The Horizon: Other Boosters

Moderna and J&J

- > 10/21 <u>ACIP meeting</u> on VRBPAC recommendations
- ACIP recommendations & CDC final recommendations
- Likely timeframes
 - Moderna: 6 months after last dose
 - ➤ J & J: 2 months after last dose
- Approximately 100 million additional people would be eligible for boosters
- Other likelihoods:
 - > Mix and match possible
- ²² > Moderna booster half dose



On The Horizon: Pediatric Vaccines

- Pfizer vaccine for 5-11-year-olds
 - ➤ What we know:
 - Lower dose not interchangeable with adult dose do not stockpile current Pfizer inventory for 5-11
 - 5-11 vaccines will have an orange lid and orange border (age will be marked in red on label)
 - ➤ What is likely:
 - 100 doses in shipment boxes (initial minimum 300 doses only first week)
 - 2 dose regimen, 21 days apart
 - 180,000 doses initial 3 weeks
 - Initial state-based allocation, followed by direct ordering
- Recommendations
 - > 10/26 FDA VRBPAC meeting on 5-11-year-olds Pfizer primary series



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On The Horizon: Pediatric Vaccines

Storage

- ➤ Ultracold until expiration
- Refrigerator for 10 weeks
- Storage time is cumulative (count ultracold and refrigeration)
- ➤ May <u>NOT</u> be stored in regular freezer
- > Will still be delivered on dry ice
- Ordering and allocation
 - > For the initial roll out: a large, pro-rata/pre-order
 - Plenty of vaccine, limitations in distribution capacity
 - 1170 orders paused first week (10/29-11/4)
 - ➤ Pre-ordering (Week 0) in 3 waves
 - > Delivery will differ depending on wave



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On The Horizon: Pediatric Vaccines

Ordering and allocation

- Receive confirmation of order AFTER the EUA authorization
- Vaccines that are pre-positioned may not be administered until ACIP recommendation
- Week 0 only: minimum order for providers is 300 doses; 100 doses minimum order Week 1 and thereafter
- Providers will need to manage 2nd dose appointments through supply provided; no separate allocation for 2nd doses

Additional information in appendix



Pfizer-BioNTech COVID-19 Vaccines PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

Description	Current Adult/Adolescent Formulation (1170 and 450 packs)	Future Pediatric Formulation	
	Dilute Prior to Use	Dilute Prior to Use	
Age Group	12 years and older	5 to <12 years**	
	PURPLE	ORANGE	
Vial Cap Color			
Dose	30 mcg	10 mcg	
Injection Volume	0.3 mL	0.2 mL	
Fill Volume (before dilution)	0.45 mL	1.3 mL	
Amount of Diluent* Needed per Vial	1.8 mL	1.3 mL	
Doses per Vial	6 doses per vial (after dilution)	10 doses per vial (after dilution)	
Storage Conditions			
ULT Freezer (-90°C to -60°C)	9 months	6 months	
Freezer (-25°C to -15°C)	2 weeks	N/A	
Refrigerator (2°C to 8°C)	1 month	10 weeks	

Q: Can the current adult/adolescent formulation (purple cap) be used to vaccinate children 5 to <12 years old once the vaccine is authorized for this age group?

A: No. For children under 12 years of age, you cannot use the current formulation and will need to use the future pediatric (orange cap) formulation.

Purple Cap – Adult/Adolescent: Authorized only for aged 12 years and older



Orange Cap – Pediatric: Future authorization for aged 5to 12 years. A separate vaccine formulation specific for a 10mcg dose will be introduced.



<u>NOTE</u>: Use of the current adult/adolescent formulation (purple cap) to prepare doses for children 5 to <12 years would result in an injection volume for the 10mcg dose of 0.1mL, which is both generally considered too small for typical IM injections and has not been studied.

*Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS

**The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 5 to <12 years old

For Official Use Only - DO NOT DISTRIBUTE

Pfizer Ordering in ImmuNet

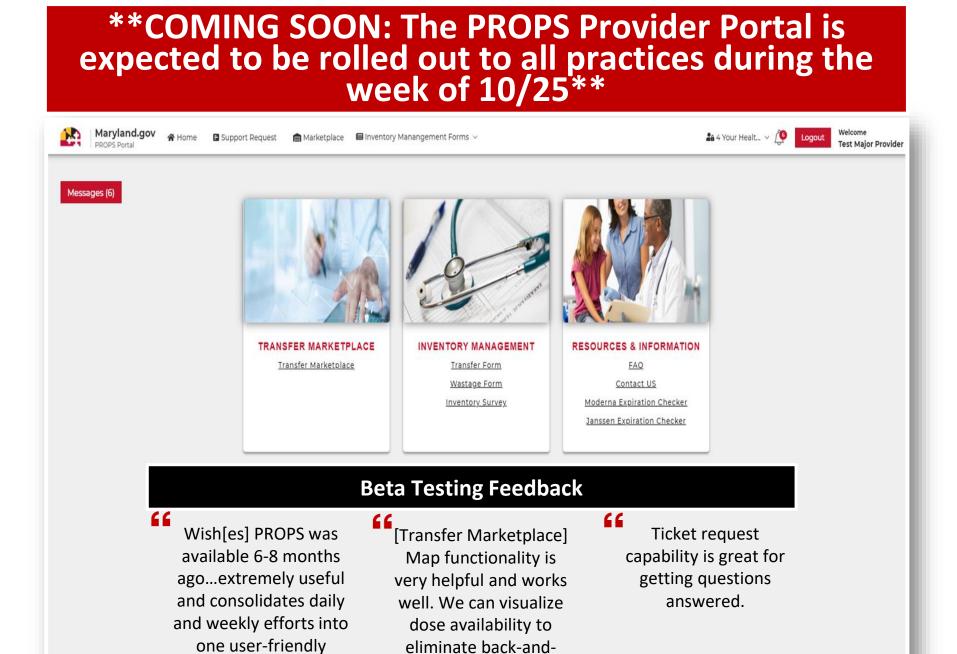
- Due to pediatric Pfizer vaccine rollout, there will be a freeze on fulfilling and shipping the 12+ Pfizer vaccine orders that are made on 10/28
 - What does this mean?
 - Orders for any COVID-19 vaccine can be placed on 10/28 in ImmuNet during the normally scheduled ordering window
 - ✓ Orders from 10/28 will be delayed in shipping and can be expected to arrive the week of 11/8



Hub and Spoke Vaccine Delivery

- For adult Pfizer vaccine
- For Adolescent Pfizer vaccine
- New portal (PROPS) coming soon!
- LHDs and others serve as hubs
- Pediatricians and other primary care are spokes





forth.

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platform.

Monoclonal Antibody Therapy

- Second out in the triple play
- Primary care providers are on second base
- Prevent deaths, prevents hospitalizations
- Sadly, many hospitalized and die without benefit of this therapy



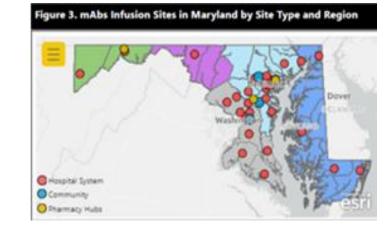
Monoclonal Antibodies Updates The Only Outpatient Covid-19 Therapy

- Currently available from USG by allocation to each state (150,000 doses national/week)
 - > Maryland receiving 1984 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



Map of Treatment Locations

- MAb treatments are offered across the state, and certain sites are able to offer home infusion across multiple counties
- Access is not equitably distributed: Western and Eastern have fewer providers offering treatment





Patient Facing Resources

Website

- Landing page-- general page highlighted at Governor's 9/30 press conference
- 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

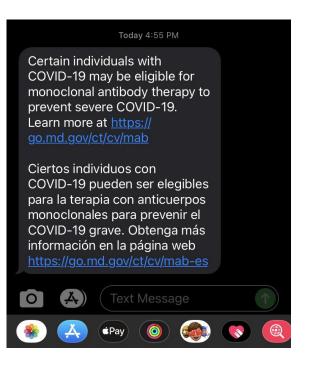
- Patients should coordinate with their respective physician or care provider before contacting a location to schedule an appointment.
- Patients without a healthcare provider, contact <u>eVisit</u> to schedule a virtual appointment or complete a <u>self-referral form</u>.
 - Eligible patient(s) will 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 <u>MDmAbs</u> also accept direct patient contact to determine eligibility and/or schedule treatment



Contact Tracing Initiative Pre-Call Text

- Automated text message sent to all cases (age 18 and above), newly reported to contact tracing, typically prior to the first outbound call
- Implemented 10/9/2021
- Text links to the new mAb landing page promoted in Governor's September 30th press conference

~2,700 texts sent from 10/9-10/14





Contact Tracing Initiative

Script for Cases and Exposures

- Script read to all interviewed cases and exposed contacts during contact tracing interview
- Content from resource material sent to interviewed cases and exposed contacts at the conclusion of their contact tracing interview

"Before we end the call, I have information about a treatment that you might qualify for called monoclonal antibody treatment. The treatment is available for COVID patients with symptoms, and for post-exposure prophylaxis (to help prevent disease) in people who were exposed to COVID-19.

"It can help reduce symptoms and keep you from needing to go to the hospital. This treatment is available to those at high risk of becoming seriously ill from COVID-19, including people over 12-years-old with certain chronic medical conditions, and those who are not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination. If you are interested, we recommend that you talk to your doctor immediately. There is no cost to receive this treatment.

"If you don't have a doctor you can still access monoclonal antibody treatment by calling 410-649-6122 for a consultation or by visiting http://umms.org/BCCInfusion to fill out a self-referral form."



Provider-Facing Resources

- Webinars- over 100
- Clinician Letters
 - "Checklist" to assist providers in determining patient eligibility for mAbs.
- Ease in making referral
 - Option 1: <u>CRISP eREFERRAL for</u> <u>Monoclonal Antibody Infusion</u>
 - Option 2: <u>Maryland Referral Form for</u> <u>Monoclonal Antibody Infusion</u> <u>Treatment</u> (Updating to include sites where PEP is available)
 - Some sites allow patients to selfrefer for evaluation (listed on referral materials)



Monoclonal Antibody Checklist

e Maryland Department of Hiadh (MDH) provides this clinical criteria sheeklists as a resource for reforing or administering model and holds (model). These according the products and introduced model Emergency Use Authorization (EUA) imministentian and Detervinity, EEG/EVCVV, and Sattrutturinity. Moneclonal antibodies are currently indicated for two purposes that in dividuals with artice (COVD1P4 and as a post-exposure prophytical in vulnerable persons (e.g., not fully vaccinated or munocompromised) who are at high-risk for progression to severe COVID-19.

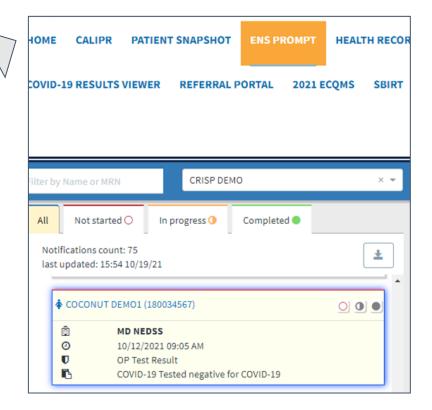
Determine Eligibility for Monoclonal Antibody Treatment for Patients			
Track 2 - Post-Exposure Prophylaxis			
 Is the patient 12 years of age or older weighing at least 88 pounds? If NO, STOP; YES, proceed to number 2. 			
 Does the patient meet high-risk exposure criteria as defined by CDC Quarantine and Isolation guidance?² If NO, Proceed to Number 3; YES, proceed to number 4. 			
 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. 			
 Is the individual <u>NOT</u> fully vaccinated?¹ If NO (individual is fully vaccinated), Proceed to Number 5; YES (individual is not fully vaccinated), proceed to number 6. 			
 Is the individual anticipated to <u>NOT</u> 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 coponer occurred within the past 96 hours, patient meets eligibility criteria, proceed with administration or referral. Detections who meet eligibility criteria cab to referred to facilities geographically speed across Maryland for equitable access. To refer a patient, please use the CRISP platform <u>effertral Tool</u> or the Maryland Department of Health (MDH) <u>Maryland Referral Ferral</u> .			

² seconda via antenized la port-osse prophysical absolutions and a low portunation of product of which we have a construct we have a start the portunation of th



Practice mAb Referral Workflow

- 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 <u>mAb</u> <u>eligibility</u>
- 3) For eligible patients, call the patient to recommend mAb treatment
 - a) See this <u>patient-facing website</u>
- 4) Refer the patient to mAb treatment through <u>CRISP</u> or
- ³⁸ <u>externally</u>





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 etesevimab ¹ (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	
Sotrovimab ³ (Glaxo Smith Kline)	Dose: sotrovimab 500mg Route: Intravenous Post-administration monitoring: 60 minutes	N/A	

*** Based on the most currently available data, <u>bamlanivimab and etesevimab are now authorized</u> 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)

² Fact Sheet for Health Care Providers Emergency Use Authorization of REGEN-COVTM (casirivimab and imdevimab) (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)

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



Testing

- The final out and the game winner to restore normality and a robust economy
- Primary care close the deal with onsite testing and making sure the ball isn't dropped for all other results



Why is Testing Important

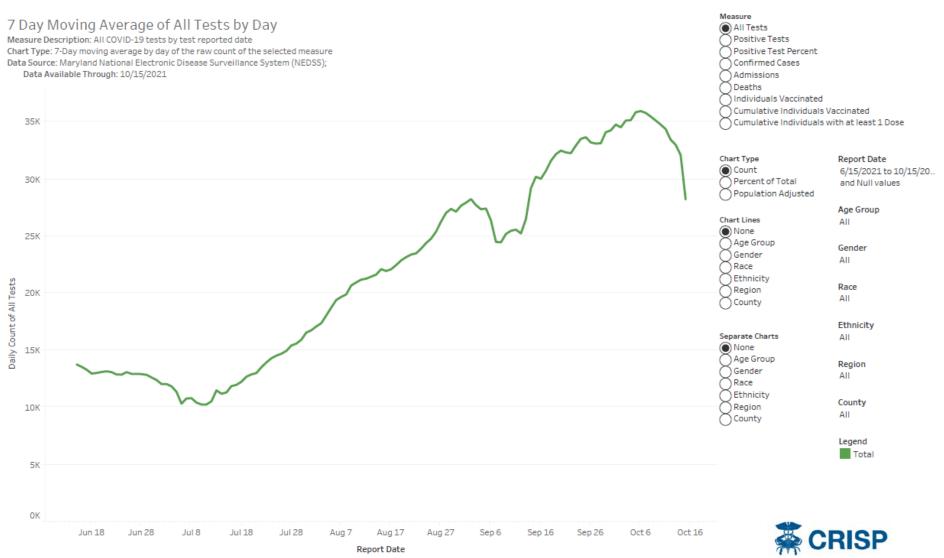
- Identify those that can spread Covid-19
- Return to work
- Return to school
- Contact tracing
- This information will facilitate the containment of spread and the opening of the economy
- Identify those eligible for monoclonal therapy



COVID-19 Data Explorer

This report allows you to view 6 different measures for the group according to the Chart Lines selection. Use the Separate Charts selector to view view multiple charts at once. The chart type determines the presentation of the measure. Daily data points are 7-day moving averages of selected measure. Population adjusted measures use 2019 Population Estimates grouped by Age Group, Gender, Race, Ethnicity, and County.

As with all reports, do not distribute this information publicly.



Primary Care POC testing

- MDH is expanding the use of point-of-care testing
- MDH guidance for point-of care testing
 - ➤ Rapid point-of-care testing toolkit
 - Point-of-care testing through MDPCP request form
 - Abbott BinaxNOW <u>getting started guide</u>



Schools, Masks and Other Controversies

- As of October 13, there were Covid outbreaks in 160 K-12 Maryland schools
 - More Information about # of outbreak-associated cases in schools available <u>here</u>

New: Mask mandate for public schools in Maryland

- On September 14, the Maryland State Board of Education and Department of Education gained approval for this statewide masking requirement
- This <u>emergency regulation</u> will remain in effect for 180 days
- Several school districts employing testing protocols
 - Screening
 - Symptomatic
- Contact tracing is variable



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 <u>here</u>



The Landscape of Primary Care

Despite the negative impacts of the pandemic, relationships between clinicians and patients are mutually and positively reinforcing during this time

A September survey of primary care providers revealed:

- > 74% have experienced a turnover in staff
- 56% report the health of patients with previously well managed chronic conditions has become worse
- Despite the difficulty, joy in the workplace is still of note
 - 88% report the ability to get to know patients over time is one of the most rewarding things about their job
 - 82% say relationships with patients help to overcome miscommunication and confusion about COVID-19



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.
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- 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 <u>this evaluation</u> after each webinar. MedChi will then be in contact with the certificate



Announcements

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:

- November 3, 2021 (5:00 pm 6:30 pm)
 - Registration link: <u>https://attendee.gotowebinar.com/register/1219509446457832972</u>
- November 17, 2021 (5:00 pm 6:30 pm)
 - Registration link: <u>https://attendee.gotowebinar.com/register/8498858063986174988</u>

Guest Speakers: Baltimore Integrated Complex Care at Home (ICCH)

- Nancy Eldridge, CEO of National Well Home Network
- Tracey Oliver-Keyser, Senior Vice President of the Office of Resident Services at the Housing Authority of Baltimore City
- Kristi Poehlmann, MSN, APRN, A-GNPC-C, Practicing Primary Care Provider and Consultant for National Well Home Network
- Stefani Hartsfield, Consultant, National Well Home Network



BALTIMORE INTEGRATED COMPLEX CARE AT HOME (ICCH)

Extending Primary Care Into the Home





Our Vision

There is a great urgency to reach people experiencing systemic health disparities. A better coordinated, more participatory system that links health care to where people live is essential.





Population Health Building Blocks

Create extenders into the community for Primary Care Practices

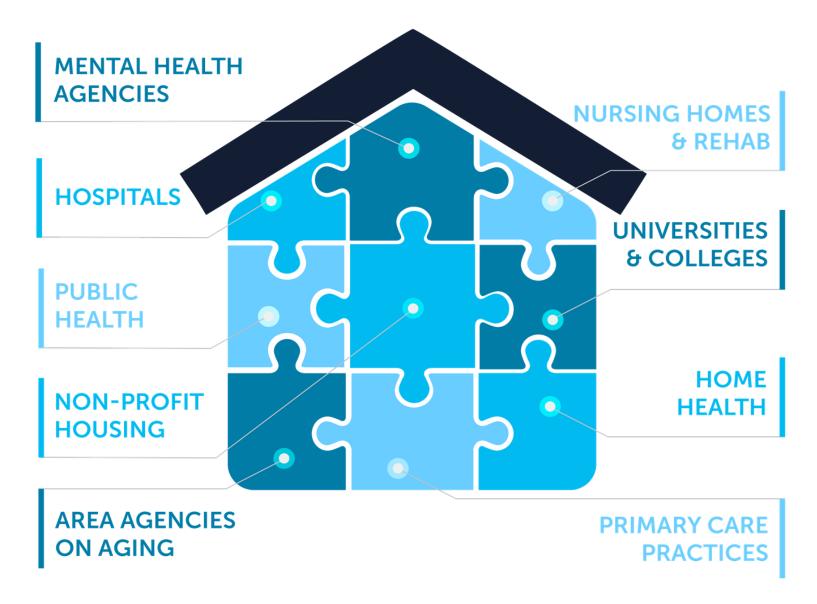
Harness the housing workforce to expand primary care reach

Embed teams where complex care patients live in publicly assisted housing and surrounding neighborhoods

Create the community-level partnerships needed to access all programs and avoid duplication

Trusting relationships and empowerment lead to the motivation for healthy behaviors



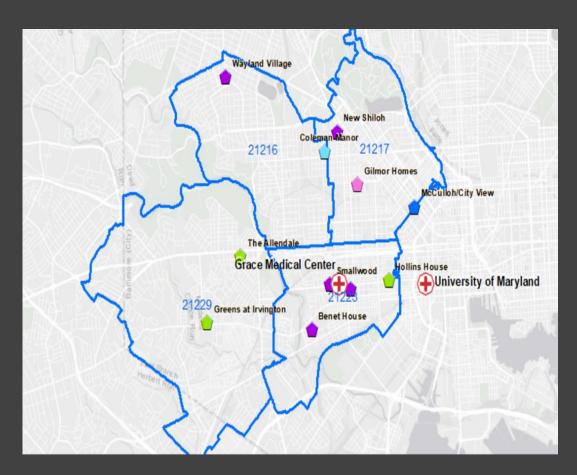




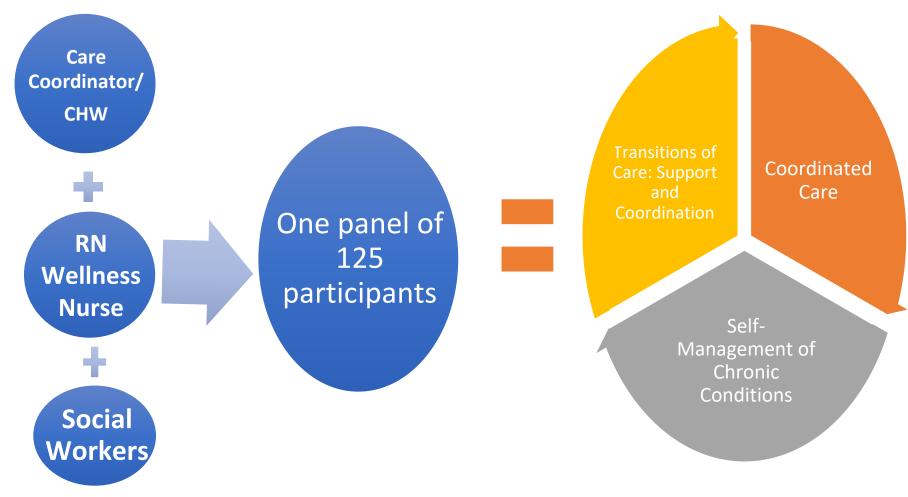
West Baltimore Housing Sites



- INTEGRATED COMPLEX CARE AT HOME: POWERED BY SASH™
- 5 owners
- 11 sites
- 1,677 units



Core of the ICCH Care Team



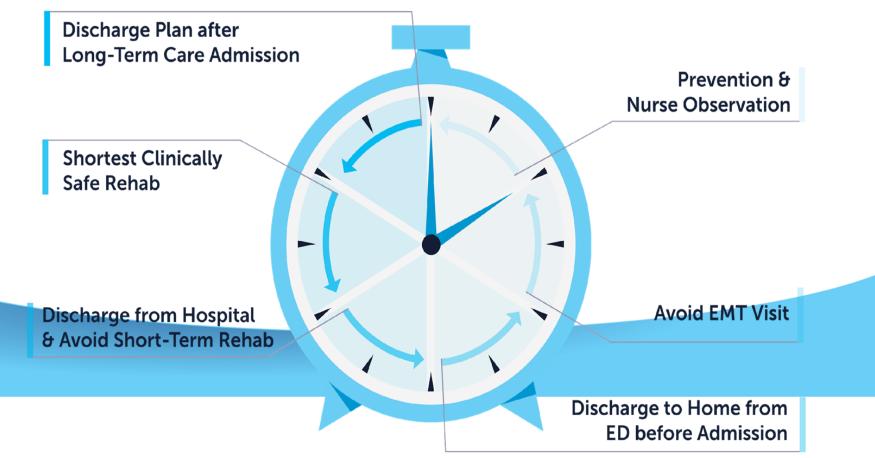
Housing Organization as Host and Hub

WHAT DO THE CARE TEAMS DO?





The Six Interruptors to Nursing Home Stays





Managing Chronic Conditions During COVID

Betty

- 78 years old
- 1 cat for company
- Loves to knit
- Diabetes, poorly controlled & hypertension
- Anxiety
- Family lives out of state

An estimated 41% of U.S. adults had delayed or avoided medical care by June 30, 2020, because of concerns about COVID-19.

(CDC, Sept. 2020)



SASH™ - A System That Works

problem, is so efficient and makes you Know you have an advocate to rely on. This has been proven again with a friend in trouble who called me for a decision about whether to call the ambulance to go to the ER or not. I immediately called Jen, and she has handled it from there. We have a wonderful nurse, Jodi, who comes right over to solve a health issue. you can tell she is concerned, and cares about you. She also taught TaiChi free of charge, Som Kudos to our SASH team.

- Betty made a plan with the care team
- Avoided potential high cost utilization
- Anxiety coaching / breathing mindfulness
- Avoided ulcer exacerbation
- Betty is healthy, and feels like she has people she can trust when she doesn't know what to do.



Medications...A Value Add Example

Home based medication reconciliation with an RN is vital to integrated care.





Cultural Impacts in Multiple Urban Settings

- Feeling Safe
 - Racial disparities in COVID-19 impact, PPE, media
- Medical system disparities and inconsistent understanding of disease
- Re-traumatization and support of embedded team
- Importance of faith
- Access to resources
- Cultural Baseline
- Creating a "New Normal"

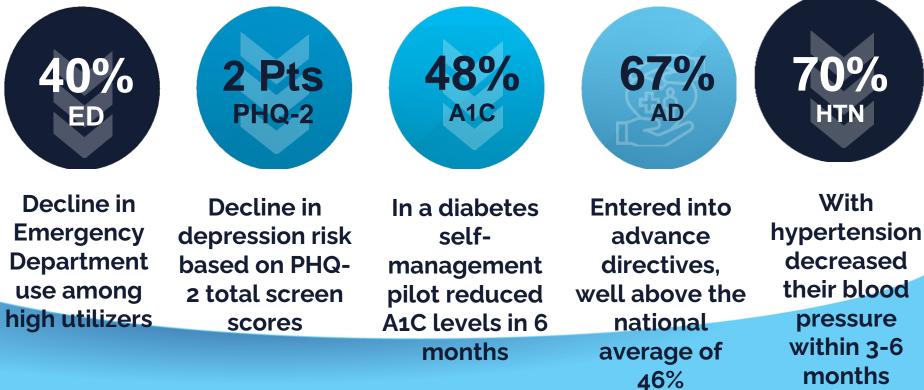








Improved Health Outcomes





Demonstrated Cost Savings \$1450 per year

Reduction in rate of growth Medicare expenditures for every urban-area SASH[™] participant

\$400/person per year

Reduction in rate of growth of Medicaid expenditures for institutional long-term care



For More Information



<u>nancy.eldridge@wellhome.org</u> <u>https://www.wellhome.org/</u>

October 20, 2021

Question and Answer Session



Appendix

Additional Pediatrics Information



COVID-19 Vaccination Planning Update

Pfizer Vaccine: 12+



For Official Use Only - DO NOT DISTRIBUTE

COVID-19 Vaccination Planning Update

12+ Pfizer Vaccine: Packaging and Handling Updates

- Current 1170 packaging and storage will remain in effect until further notice
 - New packaging will not begin shipping until the 1170 vaccine stock has been depleted, expected mid-Nov
 - **NOTE:** 1170 will be paused 10/29-11/4 to focus on 5-11
- New packaging will have a grey lid and the label will have a grey border (current packaging purple lid)
 Ages will be marked in red on label
- New 12+ doses will <u>not</u> require reconstitution
 - No diluent will be included in the ancillary kit



12+ Pfizer Vaccination Planning Update (cont'd)

- Storage
 - Ultracold until expiration
 - Refrigerator for 10 weeks
 - Storage time is cumulative (count ultracold *and* refrigeration)
 - May <u>NOT</u> be stored in regular freezer
 - Will still be delivered on dry ice
- Packaging size 2 options
 - 10 Pack 60 doses
 - 25 pack 150 doses phased out
- Still have 6-hour limit once punctured.
 - Pfizer has submitted data to FDA for a 12-hour limit



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COVID-19 Vaccination Planning Update

Pfizer Vaccine: 5-11 years



COVID-19 Vaccination Planning Update 5-11 Pfizer Vaccine: Packaging and Handling

- Will have an **orange** lid and **orange** border around the label.
 - Ages will be marked in **red** on label.
- **Different** product from 12+
 - New NDC code
 - Cannot use 12+ interchangeably do not stockpile
 current Pfizer for 5-11
 - o ⅓ dose of 12+ (10 mcg)
 - Based on age, not weight (even if age changes between shots)
 - o 21 days between 1st and 2nd dose



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COVID-19 Vaccination Planning Update

5-11 Pfizer Vaccine: Packaging and Handling

• Shipping container

- New product: single-use shipping container
- Meant to store product for 3 days
- Recipients asked to return temperature logger (NOT the shipper)
- Destroy shipper as part of local site procedures; do **not** use for storage
- Do not use multi use/med shippers to store peds vax
- 10 dose vials in cartons of 10 vials each (100 doses)
 - Dimension information forthcoming



COVID-19 Vaccination Planning Update 5-11 Pfizer Vaccine: Packaging and Handling

- Will require reconstitution.
 - Diluent and mixing syringes will be included in ancillary kit
- Storage
 - Ultracold until expiration
 - Refrigerator for **10 weeks**
 - Storage time is cumulative (count ultracold and refrigeration)
 - May **<u>NOT</u>** be stored in regular freezer
 - Will still be delivered on dry ice
- Ancillary kits included needles, syringes, diluent alcohol swabs, limited PPE, shot cards; ship at the same time as the vaccine
 Maryland
 DEPARTMENT OF HEALTH

Pfizer-BioNTech COVID-19 Vaccines PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

Description	Current Adult/Adolescent Formulation (1170 and 450 packs)	Future Pediatric Formulation
	Dilute Prior to Use	Dilute Prior to Use
Age Group	12 years and older	5 to <12 years**
	PURPLE	ORANGE
Vial Cap Color		
Dose	30 mcg	10 mcg
Injection Volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 mL
Amount of Diluent* Needed per Vial	1.8 mL	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	10 doses per vial (after dilution)
Storage Conditions		
ULT Freezer (-90°C to -60°C)	9 months	6 months
Freezer (-25°C to -15°C)	2 weeks	N/A
Refrigerator (2°C to 8°C)	1 month	10 weeks

Q: Can the current adult/adolescent formulation (purple cap) be used to vaccinate children 5 to <12 years old once the vaccine is authorized for this age group?

A: No. For children under 12 years of age, you cannot use the current formulation and will need to use the future pediatric (orange cap) formulation.

Purple Cap – Adult/Adolescent: Authorized only for aged 12 years and older



Orange Cap – Pediatric: Future authorization for aged 5to 12 years. A separate vaccine formulation specific for a 10mcg dose will be introduced.



<u>NOTE</u>: Use of the current adult/adolescent formulation (purple cap) to prepare doses for children 5 to <12 years would result in an injection volume for the 10mcg dose of 0.1mL, which is both generally considered too small for typical IM injections and has not been studied.

*Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS

**The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 5 to <12 years old

COVID-19 Vaccination Planning Update

Pfizer Vaccine: 5-11 years Ordering/Allocations



COVID-19 Vaccination Planning Update 5-11 Pfizer Vaccine: Ordering and Allocation

- For the initial roll out: a large, pro-rata/pre-order
 Plenty of vaccine, limitations in distribution capacity
 1170 orders paused first week (10/29-11/4)
- Pre-ordering (Week 0) in 3 waves
 - o 10/20, 10/22, and 10/24
 - o 40%, 30%, 30% ordering caps
 - Allocation assessments sent 10/15, due 10/18
- Delivery:
 - 1-5 business days after EUA approval (Wave 1)
 - 2-7 days after EUA approval (Wave 2)
 - 5-9 business days after EUA approval (Wave 3)



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5-11 Pfizer Vaccine: Ordering & Allocation (cont'd)

- Receive confirmation of order AFTER the EUA authorization
- Week 0 only: minimum order for providers is 300 doses; 100 doses minimum order Week 1 and thereafter
- Providers will need to manage 2nd dose appointments through supply provided; no separate allocation for 2nd doses



5-11 Pfizer Vaccine: Ordering & Allocation (cont'd)

Reallocation

- From Pfizer: no limit on number of transfers as long as cold chain is maintained
- New redistribution guidance will be released
- Pfizer is offering training to providers twice a week (Tuesdays and Thursdays)



5-11 Pfizer Vaccine: Ordering & Allocation (cont'd)

- Pharmacies participating in the federal retail program will be able to order vaccine to select pharmacy locations
 - The pharmacy allocation will be much smaller than the state's
 - PREP act allows pharmacists to administer vaccine to children as young as 3 years old
 - Anticipated ordering in Wave 2
- Small quantities allocated for other federal entities



COVID-19 Vaccination Planning Update Additional Notes

- Providers receiving doses in Week 1 should be prepared to provide "shots in arms" immediately upon ACIP recommendation
- Vaccines that are pre-positioned may not be administered until ACIP recommendation
- After Week 1, allocations will continue until further notice



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 <u>Moderna vaccine storage</u>



Covid-19 mAb Treatment Criteria

Patient Criteria

- Use clinical judgment
- ➢ Have BMI >= 35
- Have chronic kidney disease
- Have diabetes
- > Are currently receiving immunosuppressive treatment
- Are >= 65 years old
- Are >=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 >=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

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Scheduling In-Office Appointments

Patient calls in for an appointment

- Reception screens patient on the phone using the <u>pre-visit screening template</u>
- 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 <u>list of resources</u> 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 <u>Senior Call Check Program</u>



Food Resources

- Nutrition: Inform patients that children can receive three free meals/day at sites listed on:
 - Maryland Summer Meals
 - Montgomery County
 - Prince Georges County
 - Charles County
 - Frederick County

Howard County

- Anne Arundel County
- St. Mary's County
- Harford 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 (<u>https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-community-faith-organizations.html</u>)
- Mass Gatherings and Large Community Events (<u>https://www.cdc.gov/coronavirus/2019-ncov/community/mass-gatherings-ready-for-covid-19.html</u>)
- Non-Pharmaceutical Interventions for Specific Groups (<u>https://www.cdc.gov/nonpharmaceutical-interventions/index.html</u>)



Resources and References

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

