CDC/IDSA COVID-19 Clinician Call

Aug. 6, 2022

Welcome & Introductions

Dana Wollins, DrPH, MGC
Vice President
Clinical Affairs & Guidelines
Infectious Diseases Society of America

- 91st in a series of calls, initiated in 2020 as a forum for information sharing among frontline clinicians caring for patients with COVID-19.
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.

Monkeypox Update: New Randomized Clinical Trial on Tecovirimat

Timothy Wilkin, MD
Assistant Dean for Clinical Research Compliance
Professor of Medicine, Weill Cornell Medical College

Confronting BA.4/BA.5: What Clinicians Can Do

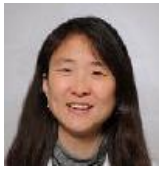
COVID-19 Situation Update

Jay Butler, MD
Deputy Director for Infectious Diseases
U.S. Centers for Disease Control and Prevention

Outpatient Therapy Update

Meg Sullivan, MD, MPH
Chief Medical Officer
Administration for Strategic Preparedness and Response
U.S. Department of Health & Human Services

Clinician-Focused Strategies to Increase Treatment & Vaccine Uptake

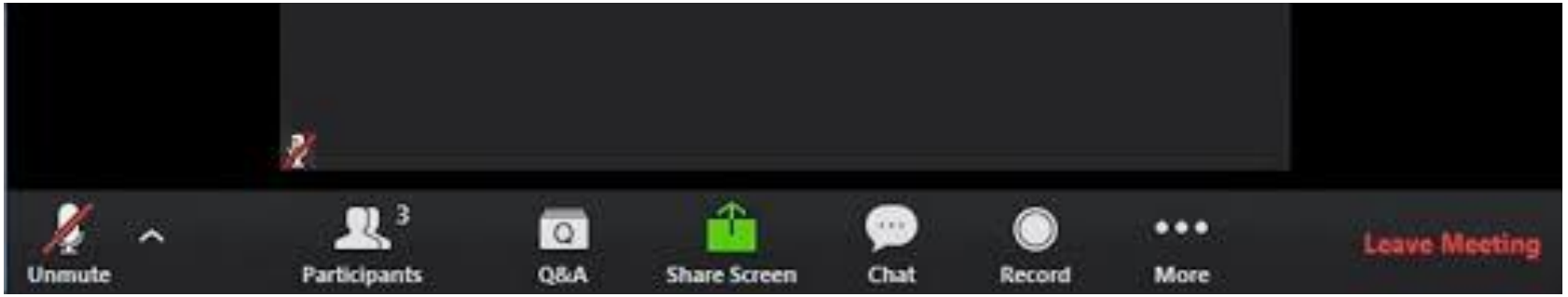


Elisa Choi, MD, FACP, FIDSA
Internal Medicine & Infectious Diseases Physician in Private Practice
Harvard Medical School Faculty
Chair, Board of Governors, American College of Physicians
CDC/IDSA COVID-19 RTLN Advisory Group Member

Valeria Cantos, MD
Assistant Professor
Division of Infectious Diseases
Emory University School of Medicine

Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button



Monkeypox Update:

New Randomized Clinical Trial on Tecovirimat for Monkeypox

Timothy Wilkin, MD

A5418

A Randomized, Placebo-Controlled, Double-Blinded Trial of the Safety and Efficacy of Tecovirimat for the Treatment of Persons with Human Monkeypox Virus Disease

Study of Tecovirimat for Human Monkeypox Virus (STOMP)

SPONSOR: NIH/AIDS CLINICAL TRIALS GROUP

Background

We are experiencing multicountry outbreak of human monkeypox virus (HMPXV)

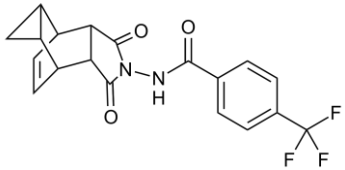
Disease is often spread sexually with rectal, genital and oral ulcers occurring commonly

Pain due to proctitis is a new feature and particularly common

Tecovirimat is a promising treatment for HMPXV disease

- Indicated for the treatment of human smallpox disease
- Works by inhibiting viral p37 protein (highly conserved in orthopoxviruses) and blocks its interaction with cellular Rab9 GTPase and TIP47, preventing the formation of egress-competent enveloped virions
- Safety and efficacy data are lacking for HMPXV

Tecovirimat is being used through CDC EA-IND and community demand for treatment is high



Other tecovirimat studies for HMPXV

PALM-007: randomized, double-blind, controlled trial of tecovirimat for HMPXV to be conducted in the Democratic Republic of Congo (n=450)

- Patients hospitalized for duration of treatment; different clade than current epidemic

PLATINUM: a randomized, double-blind controlled trial of tecovirimat for HMPXV to be conducted in the UK (n=500)

- Conducted remotely

Canadian trial (details unknown)

WHO/ANRS trial: 6 yrs and old; platform trial; time to complete resolution

All trials are evaluating same dose of tecovirimat, sampling of various compartments for HMPXV

- Unique features of A5418 rectal sampling, cross-over to tecovirimat for progression or severe pain, 2:1 allocation ratio, enrollment of presumptive HMPXV, earlier in course of disease, structure pain assessment

Study Summary

Design and Sample size	2:1 Randomized, Blinded, Placebo-controlled (n=530) Intensively sampled subset (n=100) Open label for children, persons with pregnancy or severe disease, severe immune suppression or severe skin disease (n≅250)
Study Population	Symptomatic HMPXV infection (greater than 3 kg)
Design	Superiority
1^0 Outcome	Time to clinical resolution
Duration	57 days
Enrollment period	8 weeks
Agent	Weight based oral Tecovirimat

Hypothesis

Tecovirimat will lead to faster clinical resolution of HMPXV disease compared to placebo.

1^0 Objective

To compare time to clinical resolution between people with HMPXV randomized to tecovirimat or placebo.

and endpoint

Clinical resolution is when all skin lesions are scabbed over, desquamated, or healed and all visible mucosal lesions healed

Step 1: daily self skin checks and photographs

Step 2: participant reports clinical resolution

Step 3: video visit to confirm clinical resolution

Step 4: confirmation at in person visit

A5418 Population Eligibility

Outpatients (> 3 kg) with:

- **Confirmed or presumptive** disease (oral, rectal, or skin lesion)
  - Presumptive diagnosis with compatible skin or mucosal lesions or proctitis in cisgender men or transgender women with sexual contact with 1 or more cismen or transwomen in 14 days prior to symptom onset or people with exposure to another person with known HMPXV.
- Onset of symptoms of HMPXV infection ≤14 days prior to randomization,
- At least one active, (not yet scabbed) skin lesion, mouth lesion or proctitis with or without visible ulcers

Randomization restricted to those 18 years or older without one of the following conditions

Those with severe disease (ocular involvement, hospitalization, deep lesions requiring surgical intervention, potentially disfiguring lesions on the face), pregnant and breastfeeding people, and those with severe immunodeficiency, severe inflammatory skin conditions, children are in open-label cohort.

Key 2^0 Objectives

To compare **pain scores** between randomized arms.

To compare rates of **progression to severe HMPX disease** between randomized arms.

To compare **clearance of HMPXV** between randomized arms in various compartments including blood, skin lesions, oropharynx, rectum, and genital secretions.

To compare time to **complete lesion healing** between randomized arms.

To compare **participant-reported outcomes** including adherence and EQ-5D-5L between randomized arms.

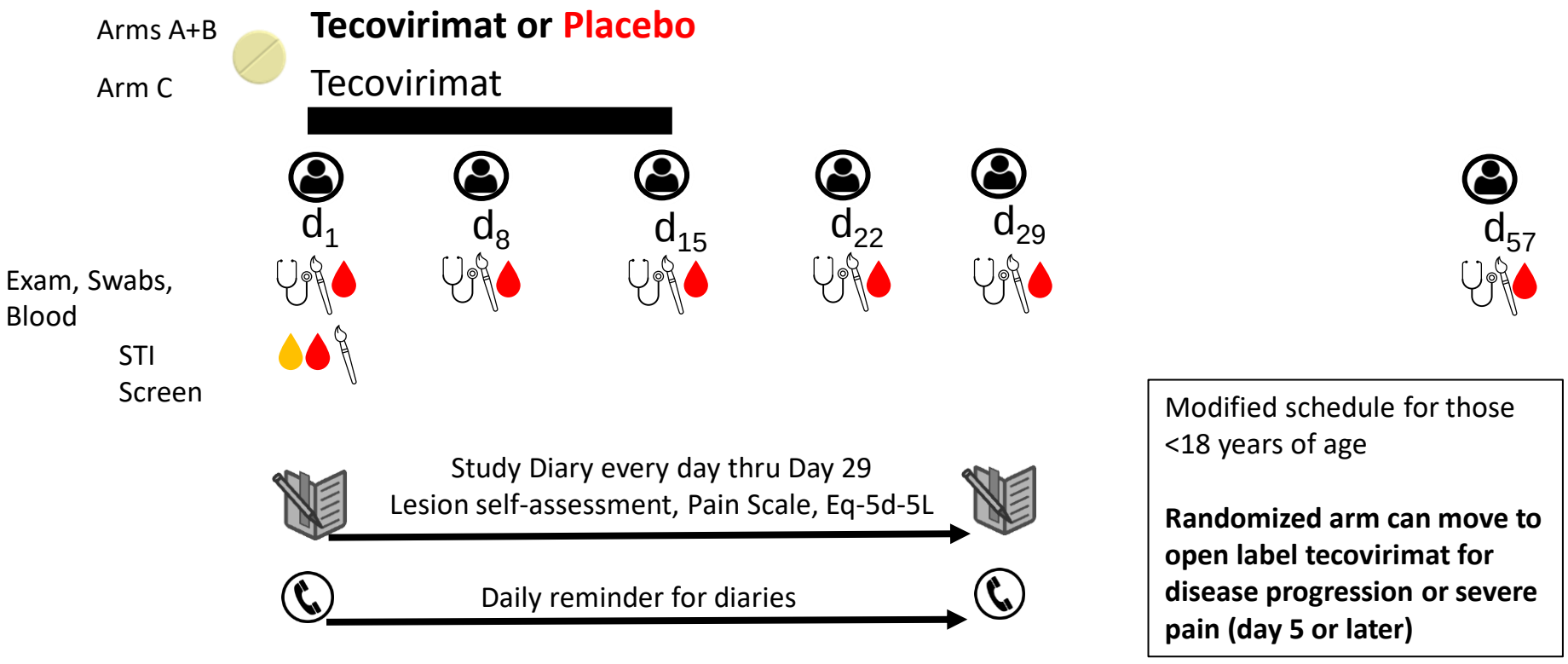
To evaluate the **safety** of tecovirimat as compared to placebo.

To describe time to lesion resolution, pain, clearance of HMPXV, time to complete lesion healing, participant-reported outcomes, and safety of tecovirimat in participants who receive **open-label tecovirimat**

To determine the **steady-state tecovirimat $AUC_{0\text{-}12h}$ and C_{12}** in children less than 18 years of age.

To evaluate the **safety profile of 14 days of tecovirimat in children** less than 18 years of age.

Schedule of Evaluations



Modified schedule for those <18 years of age

Randomized arm can move to open label tecovirimat for disease progression or severe pain (day 5 or later)

Timeline

1st protocol team meeting: 21JUL2022

Rough draft to FDA: 25JUL2022

Near final draft for FDA pre-review: 02AUG2022

DAIDS CSRC review: 04AUG2022

Submission to FDA/IRB: 11AUG2022

1st person/1st visit: 19SEP2022

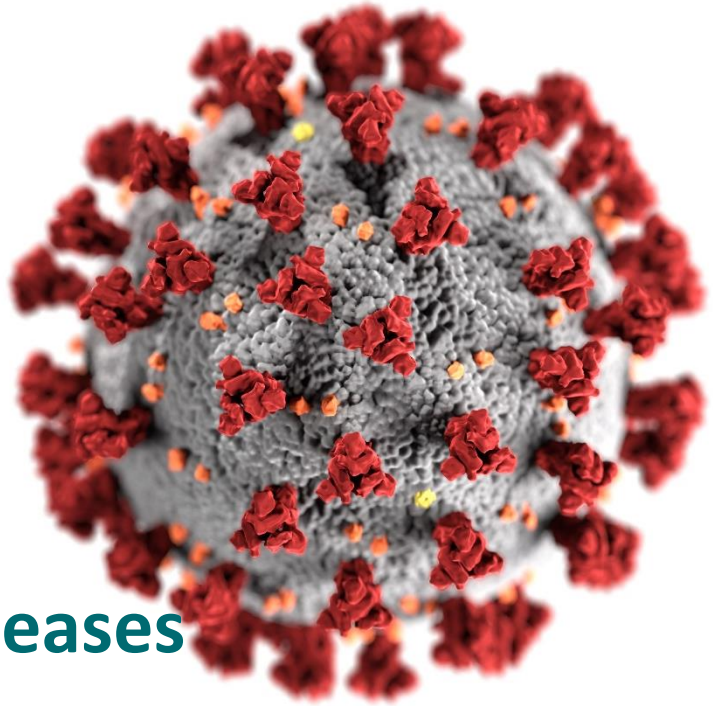
COVID-19 Situation Update

Jay Butler, MD

IDSA Clinician Call

Jay Butler, MD, FIDSA

Deputy Director for Infectious Diseases



August 6, 2022

cdc.gov/coronavirus

COVID-19 Situation Update

COVID-19 Update

Daily Update for the United States

Cases
New Cases (Daily Avg)
117,350

Case Trends

Jul 2022 Aug 2022

Deaths
New Deaths (Daily Avg)
377

Death Trends

Jul 2022 Aug 2022

Hospitalizations
New Admissions (Daily Avg)
6,113

Admission Trends

Jul 2022 Aug 2022

Vaccinations
% First Booster Dose
34.4%

People Age 5+

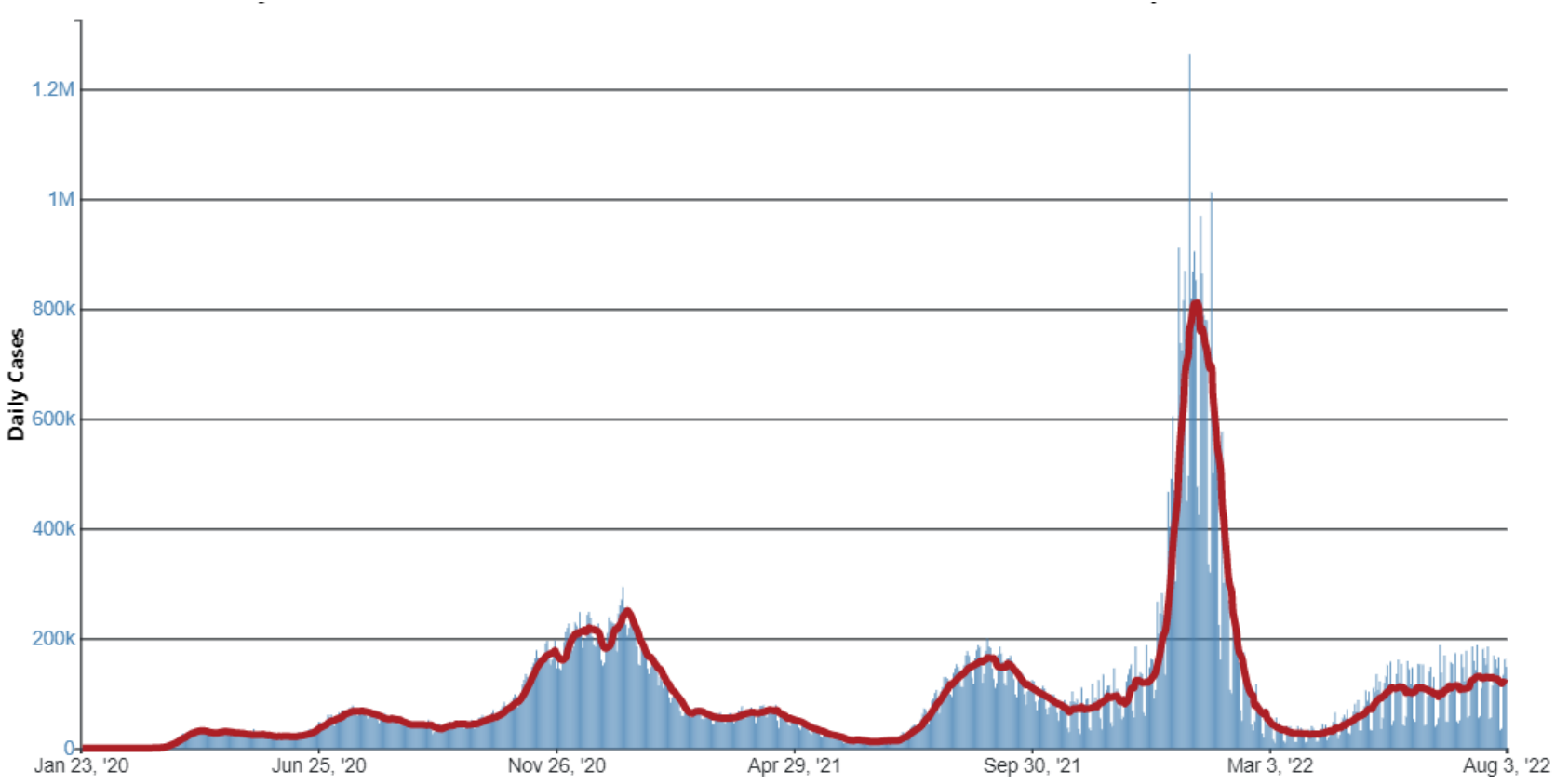
Total Cases	Total Deaths	Current Hospitalizations	Total First Booster Dose
91,676,264	1,027,370	37,113	107,490,375

CDC | Data as of: August 4, 2022 4:21 PM ET. Posted: August 4, 2022 5:32 PM ET

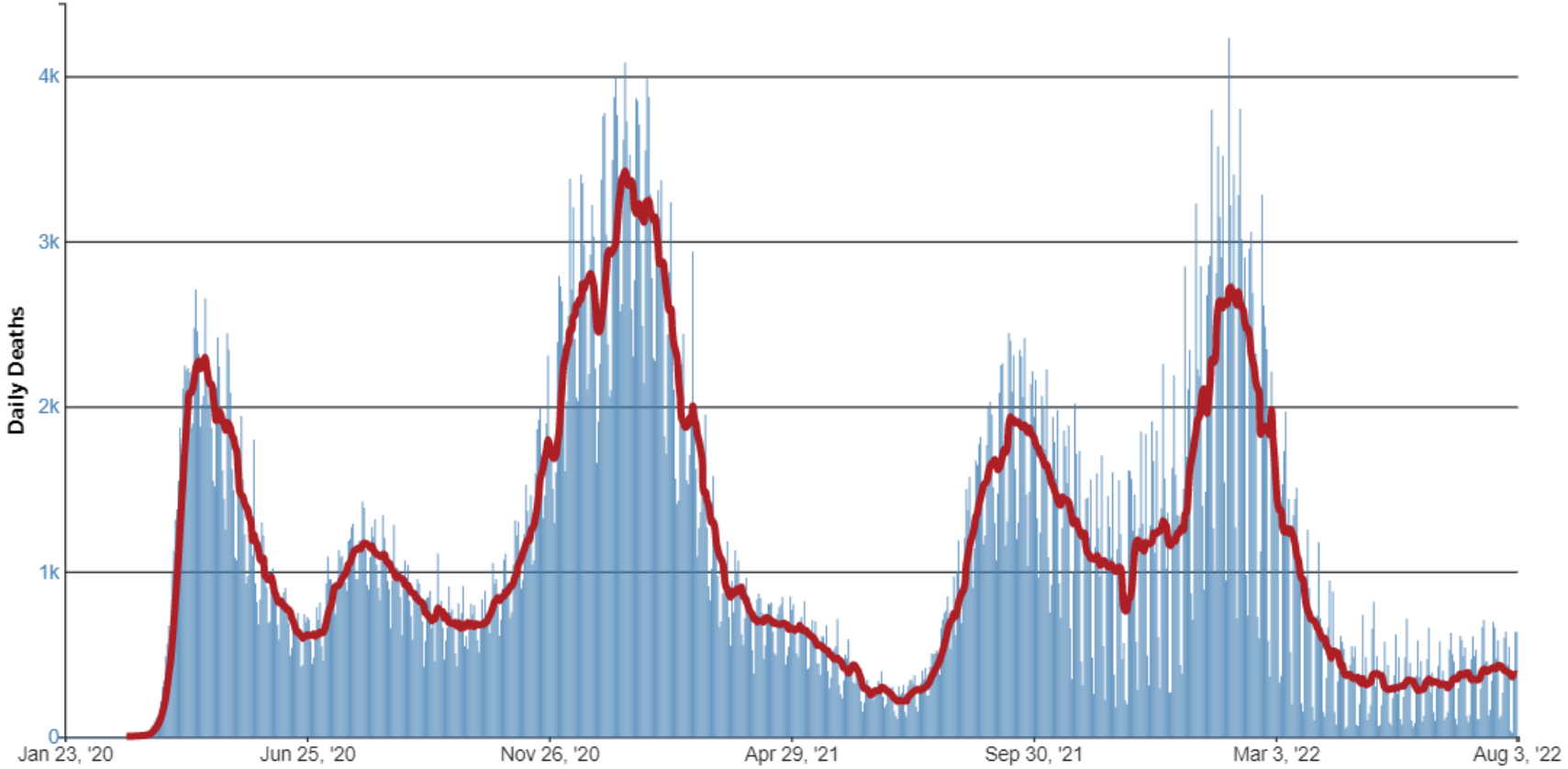
Time period: 7 day moving average (July 29 – August 4)

Source: CDC COVID Data Tracker: Home

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



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



New Admissions of Patients with Confirmed COVID-19, United States

Aug 01, 2020 - Aug 02, 2022

United States | All Ages

5,078,893
Total Admissions
Aug 01, 2020 - Aug 02, 2022

6,112
Current 7-Day Average
Jul 27, 2022 - Aug 02, 2022

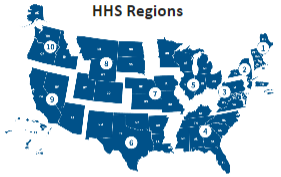
6,396
Prior 7-Day Average
Jul 20, 2022 - Jul 26, 2022

21,525
Peak 7-Day Average
Jan 09, 2022 - Jan 15, 2022

-4.4%
Percent change from prior 7-day avg. of Jul 20, 2022 - Jul 26, 2022

-71.6%
Percent change from peak 7-day avg. of Jan 09, 2022 - Jan 15, 2022

HHS Regions

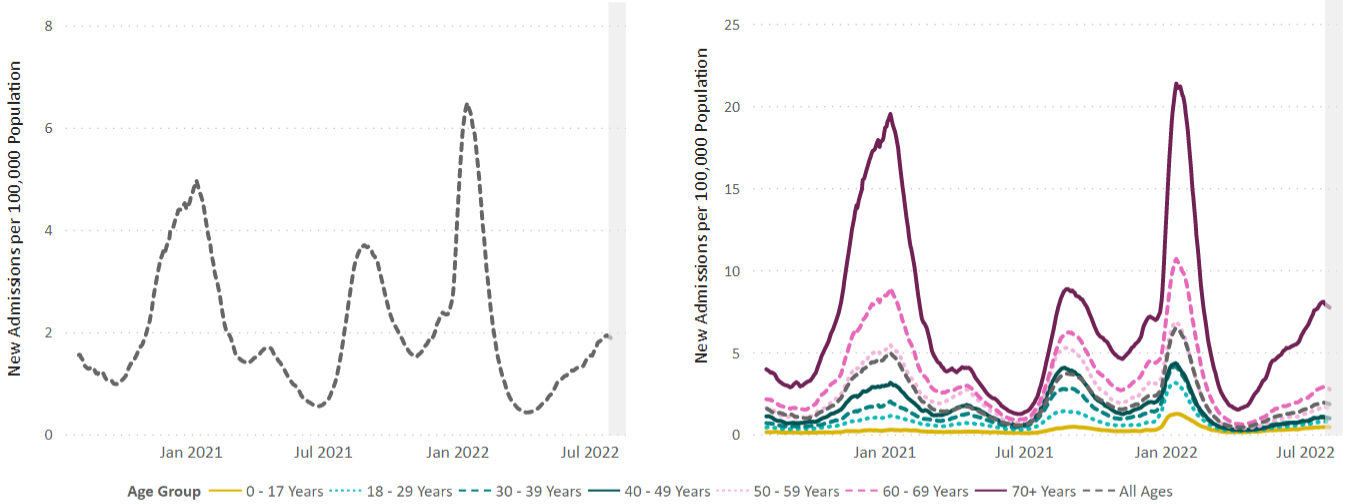


By Jurisdiction and Age Group | By Jurisdiction

Select a Jurisdiction: United States

Select an Age Group: All Ages

United States | All Ages

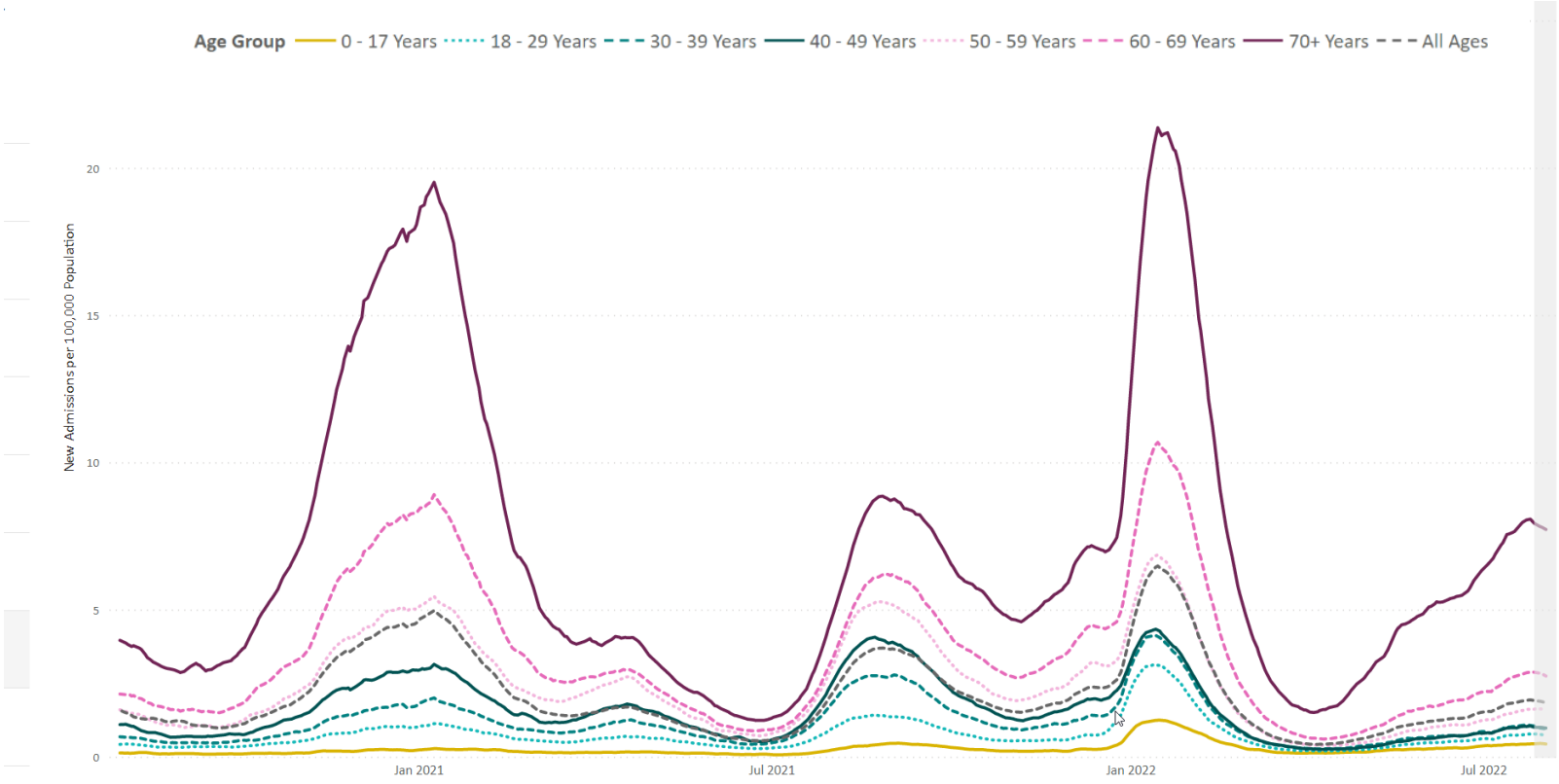


Based on reporting from all hospitals (N=5,300). Due to potential reporting delays, data reported in the most recent 7 days (as represented by the shaded bar) should be interpreted with caution.
Small shifts in historic data may occur due to changes in the CMS Provider of Services file, which is used 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. Note that the above graphs are often shown on different scales. Data prior to August 1, 2020 are unavailable.

Last Updated: Aug 04, 2022

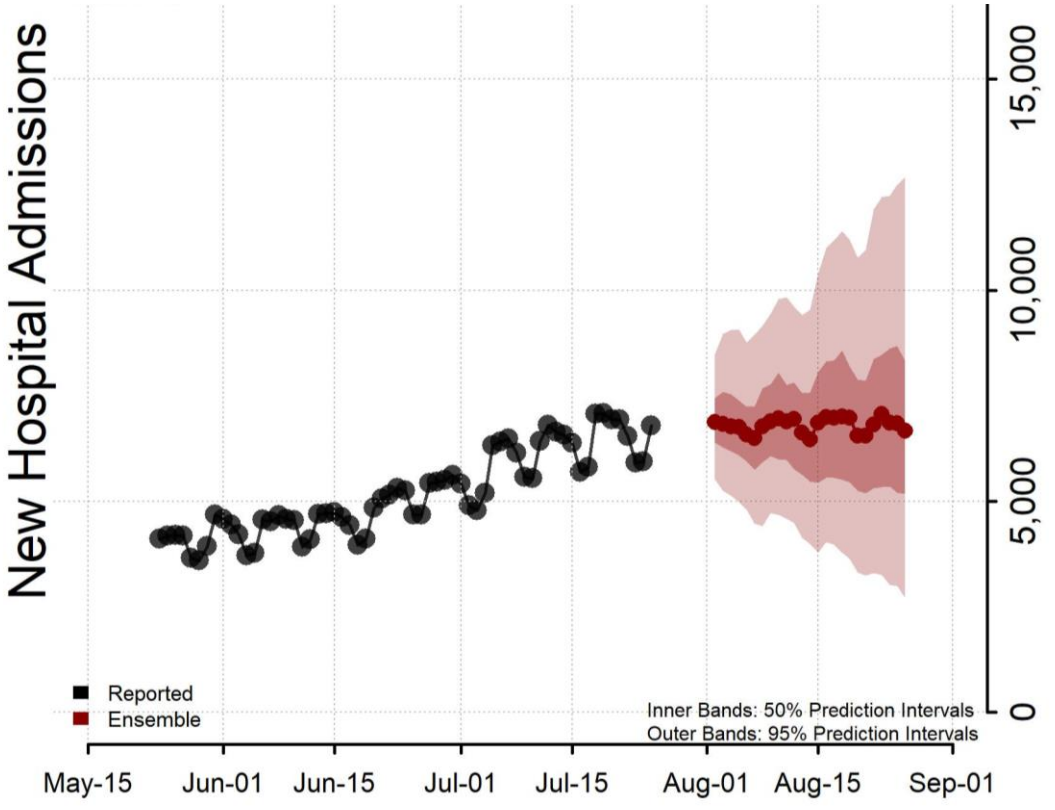
Unified Hospital Dataset, White House COVID-19 Team, Data Strategy and Execution Workgroup

New Admissions of Patients with Confirmed COVID-19, United States, Aug 1, 2020- Aug 2, 2022

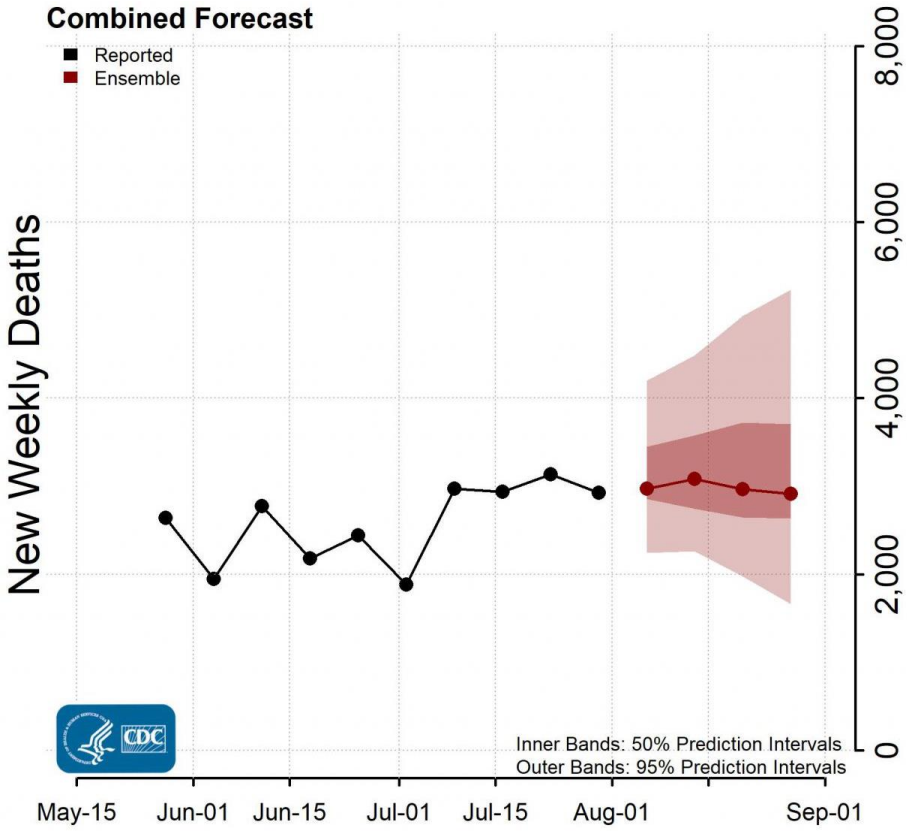


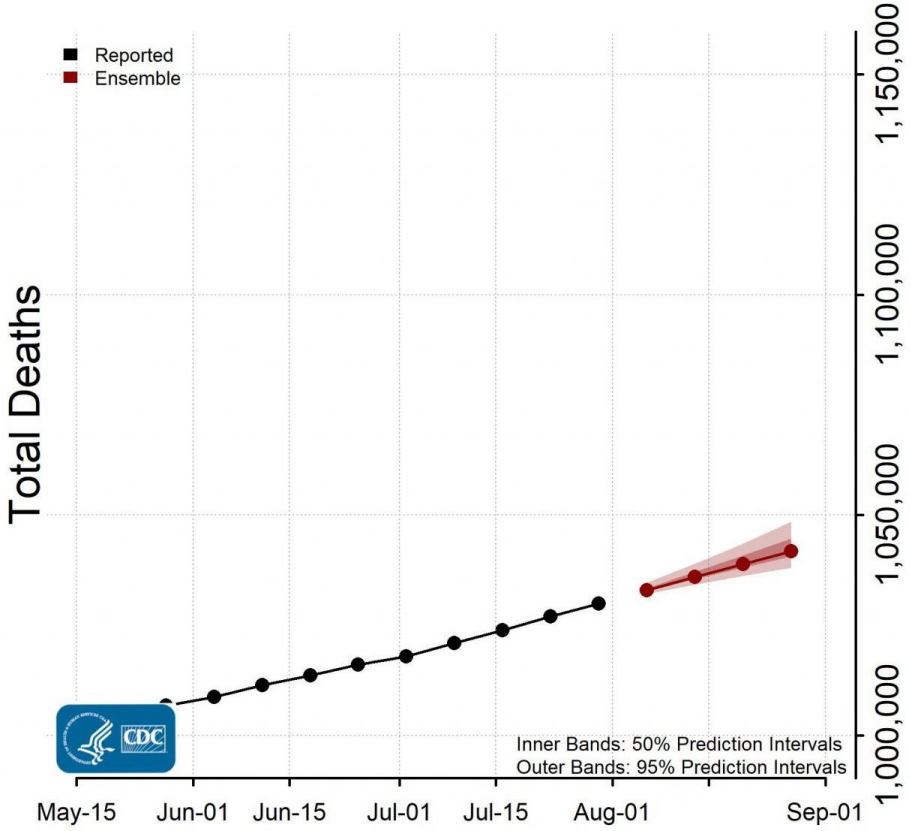
https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions

National Forecast New Hospitalization Admissions



National Forecast - Deaths



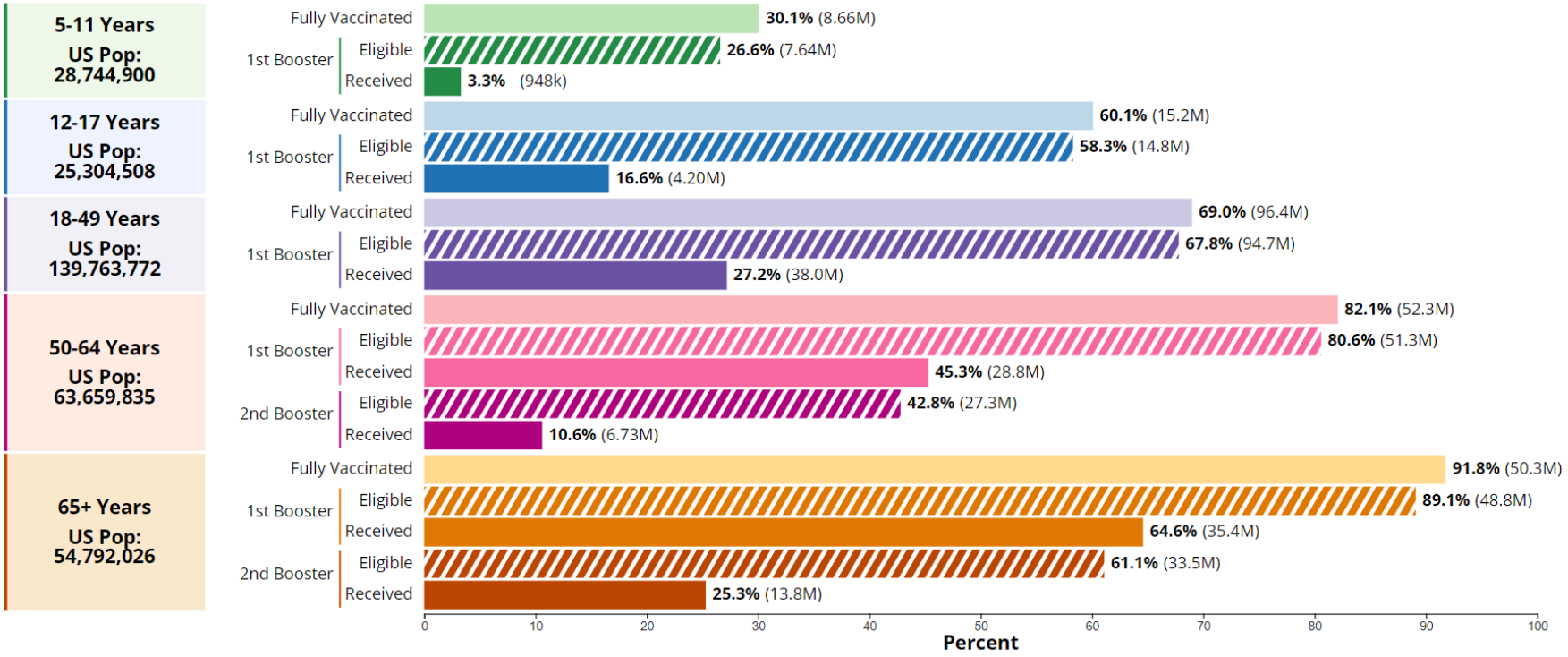


Role of Clinicians to Prevent the Spread of COVID-19

- Vaccination
- Stay aware of COVID-19 community levels
- Continue to educate patients
- Stay up-to-date on guidance
- Protect yourselves

COVID-19 Vaccines

Primary Series Completion, Booster Dose Eligibility, and Booster Dose Receipt by Age, United States



https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-additional-dose-totalpop

Bivalent Booster Vaccines with Omicron BA.4/5 Component

FDA U.S. FOOD & DRUG ADMINISTRATION

Update: COVID-19 Vaccine Booster Composition

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June 30, 2022

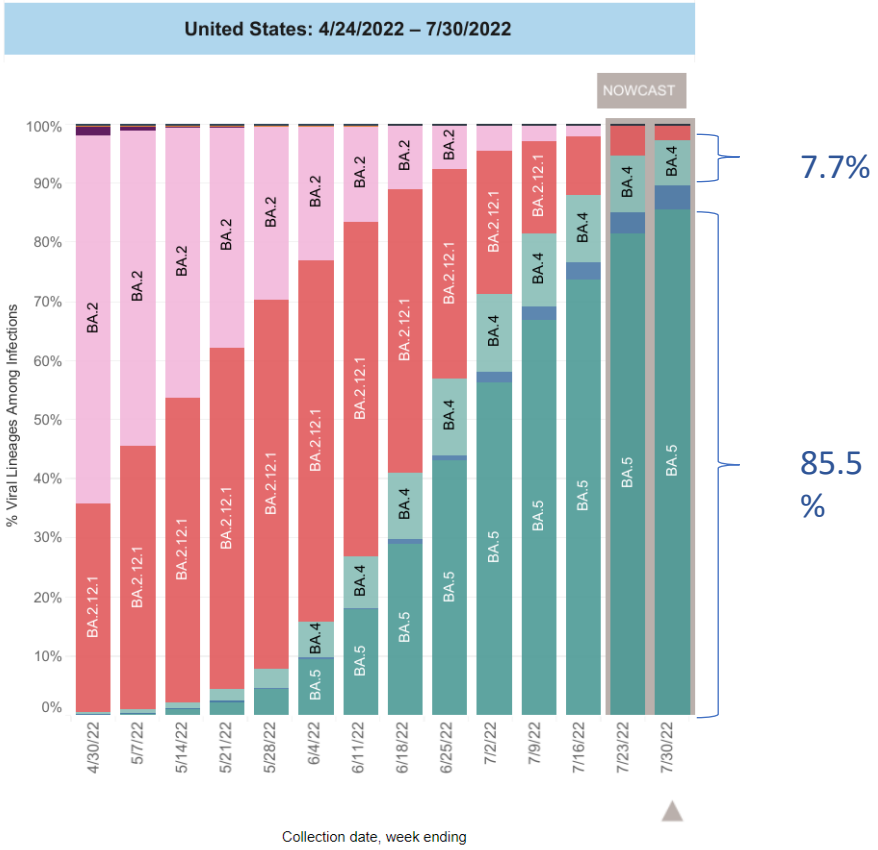
FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) held a virtual meeting on June 28, 2022, to publicly discuss whether a change to the current vaccine strain composition of COVID-19 vaccine booster doses is necessary for the 2022 fall and winter seasons.

A majority of the committee voted in favor of including a SARS-CoV-2 Omicron component in COVID-19 vaccines that would be used for booster doses in the U.S. beginning in fall 2022. In consideration of the committee's vote and the discussion that took place about the specific SARS-CoV-2 variant to include, and considering the totality of the available evidence, FDA has advised vaccine manufacturers seeking to update their COVID-19 vaccines that they should develop modified vaccines that add an Omicron BA.4/5 component to their current vaccine compositions to create two component (bivalent) booster vaccines.

We expect this coming year, when these modified booster vaccines will be introduced, to be a transitional period. Therefore, we have not advised manufacturers to change the vaccine for primary vaccination, since a primary series with this vaccine provides a base of protection against serious outcomes of COVID-19 caused by circulating strains of SARS-CoV-2.

Additional Information

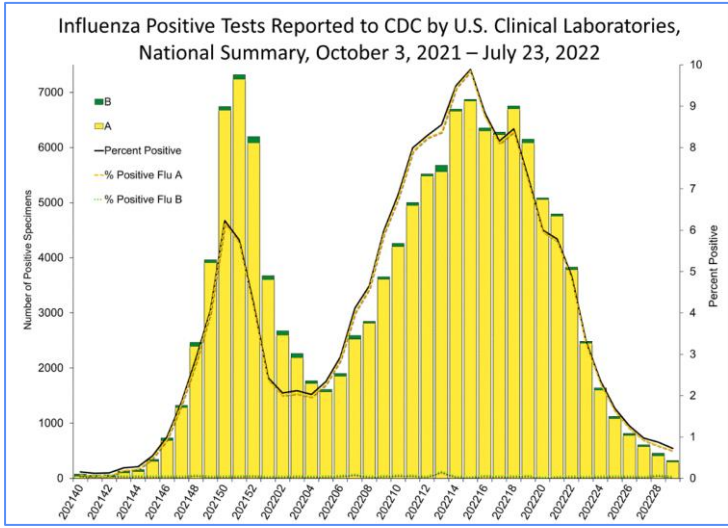
- Memorandum Re: Fall 2022 COVID-19 Vaccine Strain Composition Selection Recommendation



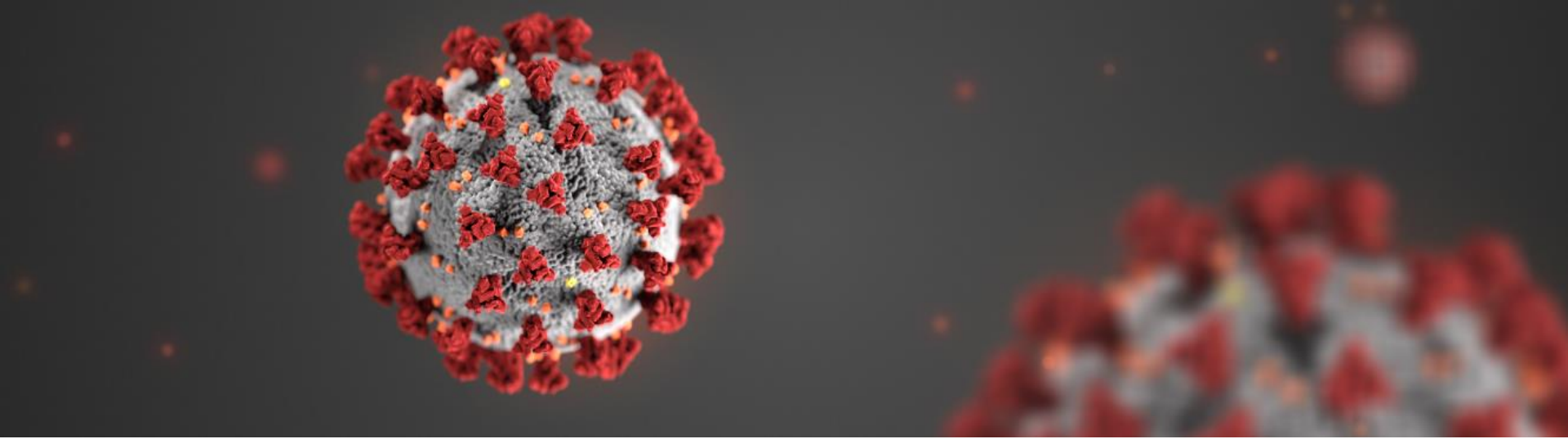
https://covid.cdc.gov/covid-data-tracker/#variant-proportions

2022-2023 Influenza Season Outlook

- Seasonal influenza activity for the past two seasons was low
- It's not possible to predict which influenza virus is going to be predominant or the timing or intensity of a season
- Many countries are seeing differences in the timing of flu epidemics, and high levels of co-circulation with COVID-19 are again a possibility



- Monitoring for co-circulation of both influenza and SARS-CoV-2 is essential
- CDC is monitoring current global influenza activity and continues to enhance our infrastructure domestically to prepare for whatever situation might arise



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

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Outpatient Therapy Update

Meg Sullivan, MD, MPH

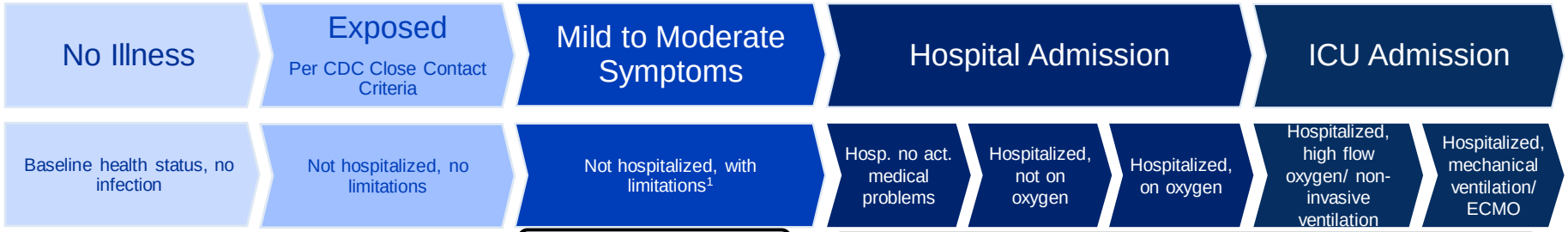
ASPR Administration for Strategic Preparedness & Response

COVID-19 Therapeutics Current Landscape

Meg Sullivan, MD, MPH
Chief Medical Officer
Administration for Strategic Preparedness & Response

August 6,2022

Current Landscape: COVID-19 Preventative Agents & Treatments



Veklury® (remdesivir, Gilead)

Please see NIH Current Inpatient Therapies (https://www.covid19treatmentguidelines.nih.gov/therapies/)

COVID-19 VACCINES

Monoclonal Antibodies for PrEP

- Evusheld (tixagevimab + cilgavimab, AZ)

None currently authorized for use in any US state or territory.

Oral Antivirals

- **Paxlovid (nirmatrelvir + ritonavir, Pfizer) – Preferred**
- Lagevrio (molnupiravir, Merck) – **Alternative**

Monoclonal Antibodies for Treatment

- Bebtelovimab (Lilly) – **Alternative**

[1] Therapeutic Management of Nonhospitalized Adults With COVID-19
[2] Therapeutic Management of Hospitalized Adults With COVID-19

Utilization Summary of Products Distributed by USG

- December 17, 2021 – July 31, 2022
- Based on 93% of sites reporting as of July 31, 2022
- Product specific national administration data for the above timeframe
- State and territorial specific data now publicly available and updated weekly
- https://aspr.hhs.gov/COVID-19/Therapeutics/orders/Pages/default.aspx

Total for all open distribution channels		
Therapeutic (currently in use)	Courses Ordered	Courses Administered
Paxlovid[1]	6,238,027	3,361,548
Lagevrio	2,284,405	512,688
Bebtelovimab	627,536	383,515
Evusheld (300mg doses)	808,008	415,053

[1]Paxlovid + renal Paxlovid

Updates: Evusheld

Evusheld Access Update

- New call line for Evusheld product and ordering information: **1-833-EVUSHLD** (833-388-7453)

- Additional pathway established for **small volume ordering**:
  - For individual providers seeking small quantities of product (1-3 patient courses)
  - OrderEvusheld.com

- Evusheld is **available at some Federal Pharmacy Partner locations**:
  - Albertsons, including Albertsons, Acme, Jewel-Osco, Pavilions, Randalls, Safeway, Star Market, and Vons
  - CPESN
  - Hy-Vee, including Amber Specialty Pharmacy
  - Managed Healthcare Associates (MHA), including Thrifty White

- Locator tool updates: Central Partners are encouraged to **update information for Evusheld providers** so that accurate information is reflected in the COVID-19 Therapeutics Locator tool.

Evusheld Fact Sheet Update on Repeat Dosing

- The repeat dosage of EVUSHELD in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) is **300 mg of tixagevimab and 300 mg of cilgavimab** administered every 6 months, refer to Table 1 below. Repeat dosing should be timed from the date of the most recent EVUSHELD dose.

Table 1 Dosage of 300 mg of Tixagevimab and 300 mg of Cilgavimab

EVUSHELD* (tixagevimab co-packaged with cilgavimab)	Antibody dose	Number of vials needed	Volume to withdraw from vial(s)
	tixagevimab 300 mg	2 vials	3 mL
	cilgavimab 300 mg	2 vials	3 mL

* 300 mg of tixagevimab and 300 mg of cilgavimab are to be administered as separate, consecutive intramuscular injections

Table 2 Dosage of 150 mg of Tixagevimab and 150 mg of Cilgavimab

EVUSHELD* (tixagevimab co-packaged with cilgavimab)	Antibody dose	Number of vials needed	Volume to withdraw from vial
	tixagevimab 150 mg	1 vial	1.5 mL
	cilgavimab 150 mg	1 vial	1.5 mL

* 150 mg of tixagevimab and 150 mg of cilgavimab are to be administered as separate, consecutive intramuscular injections

Updates: Paxlovid

CDC Interim Clinical Considerations for COVID-19 Treatment in Outpatients

What You Need to Know:

- There is strong scientific evidence that antiviral treatment of outpatients at risk for severe COVID-19 reduces their risk of hospitalization and death.
- The antiviral drugs **Paxlovid (ritonavir-boosted nirmatrelvir)** and **Veklury (remdesivir)**[1] are the preferred treatments for eligible adult and pediatric patients with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progression to severe COVID-19.
- Clinicians should consider COVID-19 treatment in non-hospitalized patients who meet all of the following:
  - Test positive for SARS-CoV-2 (with PCR or antigen test, including at-home tests)
  - Have symptoms consistent with mild-to-moderate COVID-19. People with mild COVID-19 experience symptoms such as fever, sore throat, cough, or headache that do not affect the lungs and breathing. People with moderate illness have symptoms that affect the lungs like shortness of breath or difficulty breathing.
  - Are within 5 days of symptom onset for Paxlovid or 7 days of symptom onset for Veklury
  - Have one or more risk factors for severe COVID-19

See: Interim Clinical Considerations for Covid-19 Treatment in Outpatients

CDC Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19

- Risk factors for severe COVID-19 include:
  - **Age over 50 years, with risk increasing substantially at age ≥ 65 years**
  - **Being unvaccinated or not being up to date on COVID-19 vaccinations**
  - **Specific medical conditions and behaviors**
- Some people from racial and ethnic minority groups are at risk of being disproportionately affected by COVID-19 due to many factors, including limited access to vaccines and healthcare. Healthcare providers can consider these factors when evaluating the risk for severe COVID-19 and use of outpatient therapeutics.

See: Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals

CDC MMWR: Kaiser Permanente Southern California Paxlovid and Hospitalizations

June 24, 2022 – CDC Morbidity and Mortality Weekly Report (MMWR) COVID-19-related hospital admissions and emergency department (ED) encounters after Paxlovid treatment. Kaiser Permanente Southern California, December 23, 2021 - May 21, 2022

Demographics:

- 5,287 patients ≥ 12 years received 5-day Paxlovid treatment.
- Median age was 61.
- 92% had received at least one COVID-19 vaccine dose; 72.5% received at least 3 doses, 8% unvaccinated.

Key Findings:

- 6 hospitalizations and 39 ED encounters related to SARS-CoV-2 infection.
- Hospitalizations and ED encounters for COVID-19 related illness 5-15 days after Paxlovid dispensation occurred **<1%** of all patients.
- When administered as an early-stage treatment, Paxlovid might prevent COVID-19–related hospitalization among persons with mild to moderate COVID-19 cases who are at risk for progression to severe disease.

For more information see, Hospitalization and Emergency Department Encounters for COVID-19 After Paxlovid Treatment — California, December 2021–May 2022

Paxlovid: Clinical Trial and Observational Data

- The benefit of a 5-day treatment course of Paxlovid was demonstrated in the clinical trial that supported the EUA. This study showed that among non-hospitalized, unvaccinated patients at high risk of progression to severe disease, treatment with **Paxlovid reduced the risk of hospitalization or death by 88%.**

- Observational data, including vaccinated patients, from Israel[1], United States[2], and Hong Kong[3] is consistent with benefit in high-risk patients:
  - **67% reduction in hospitalizations and 81% reduction in deaths compared to the untreated** for patients over 65[1]
  - **45% reduction in hospitalization and greater reductions for obese or unvaccinated patients** among adult patients[2]
  - **75% reduction in death compared to non-users**[3].

References:
- [1]Ronza Najjar-Debbiny et al. *Clinical Infectious Diseases*, 2022;, ciac443, https://doi.org/10.1093/cid/ciac443
- [2]Scott Dryden-Peterson et al. medRxiv 2022.06.14.22276393; doi: https://doi.org/10.1101/2022.06.14.22276393
- [3]Carlos K.H. et al. medRxiv 2022.05.19.22275291; doi: https://doi.org/10.1101/2022.05.19.22275291

Paxlovid Access Update

- In our continued efforts to increase oral antiviral dispensing in vulnerable areas, a new initiative was launched to pre-position Paxlovid in areas of high social vulnerability
  - Goal is to pre-position Paxlovid at provider sites (EDs, physician offices, clinics/urgent cares) in areas of the country that are most vulnerable to COVID-19
  - Beginning August 1 2022, emails were sent to nearly 9000 providers to invite a one-time distribution request of 20 courses of Paxlovid
    - Targeted outreach to sites in counties/parishes with high SVI and low dispensing rates of oral antivirals
- Effort intended to make product more readily available to quickly treat patients in vulnerable communities where they are engaging providers

CDC Health Advisory
COVID-19 Rebound After Paxlovid Treatment

- The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to update healthcare providers, public health departments, and the public on the potential for recurrence of COVID-19 or “COVID-19 rebound.”

- **Paxlovid continues to be recommended for early-stage treatment of mild to moderate COVID-19 among persons at high risk for progression to severe disease**.
- Paxlovid treatment helps prevent hospitalization and death due to COVID-19. COVID-19 rebound has been reported to occur between 2 and 8 days after initial recovery and is characterized by a recurrence of COVID-19 symptoms or a new positive viral test after having tested negative.
- **A brief return of symptoms may be part of the natural history of SARS-CoV-2 (the virus that causes COVID-19) infection in some persons, independent of treatment with Paxlovid and regardless of vaccination status**.
- Limited information currently available from case reports suggests that persons treated with Paxlovid who experience COVID-19 rebound have had mild illness; there are no reports of severe disease.

COVID-19 Rebound After Paxlovid Treatment (cdc.gov)

EUA Update
Pharmacists Authorized to Prescribe Paxlovid Under Certain Conditions

July 6, 2022 – FDA authorized state-licensed pharmacists to prescribe Paxlovid, with certain limitations.

- State-licensed pharmacist may prescribe PAXLOVID for individual patient when:
  - Sufficient information is available to **assess renal and hepatic function**, such as through access to health records < 12 months old or consultation with HCP in established provider-patient relationship with the individual patient **AND**
  - Sufficient information is available to obtain comprehensive list of medications that patient is taking to **assess potential drug interaction**, such as through access to healthcare records, patient reporting of medical history, or consultation with HCP in established provider-patient relationship with the individual patient

- Pharmacists should refer an individual patient for clinical evaluation, if any of following:
  - Sufficient information is not available to assess renal and hepatic function.
  - Sufficient information is not available to assess for a potential drug interaction.
  - Modification of other medications is needed due to a potential drug interaction.
  - Paxlovid is not an appropriate therapeutic option based on the current Fact Sheet for Healthcare Providers or due to potential drug interactions for which recommended monitoring would not be feasible.

EUA Update (cont'd)
Pharmacists Authorized to Prescribe Paxlovid Under Certain Conditions

- Patients should provide sufficient information to determine eligibility
  - Health records less than 12 months old, including reports of most recent blood work to review for kidney or liver problems
    - Alternatively, the pharmacist may consult with the patient's current health care provider
  - A list of medications they are taking, including over the counter medications, to screen for potential harmful interactions
- Individual pharmacies will be reviewing the EUA update and deciding whether this mechanism will be implemented for their pharmacists
- Implementation will take time, is not expected to be universal at all pharmacies, and is not available for all patients
  - Going to primary care physicians, T2T locations, and other centers of primary care are still the best options for individuals to receive a prescription for COVID-19 therapeutics

Fact Sheet for Healthcare Providers for Paxlovid (nirmatrelvir and ritonavir)

Updates: Bebtelovimab

Bebtelovimab Transition to Commercial Availability

June 29, 2022 - U.S. Department of Health and Human Services, in coordination with the U.S. Department of Defense, purchased an additional **150,000** doses of bebtelovimab.

- The total U.S. government purchase of bebtelovimab is now **750,000** doses.
- Bebtelovimab is authorized for patients for whom alternative FDA approved or authorized COVID-19 treatment options are not accessible or clinically appropriate
- Distribution of USG supply is expected through the week of August 15th at full threshold and August 22nd at lower threshold
  - Stock out projections are dependent on ordering activity in coming weeks
  - Lilly/USG are working together to support the availability of bebtelovimab without disruption as USG supply ends
    - Bebtelovimab is on track to be commercially available for purchase **starting the week of Aug 15th**
    - States/territories and providers will be eligible to purchase directly through Amerisource Bergen; Lilly is not planning state-specific procurement contracts
    - We will continue to update with additional details as they become available
- As commercial product becomes available, consider leveraging USG supply to fill in gaps for the under and uninsured within your jurisdictions

Updates: Lagevrio

Lagevrio (molnupiravir) Authorization

- Lagevrio (molnupiravir) has been authorized by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing who are at high-risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 outpatient treatment options approved or authorized by FDA are not accessible or clinically appropriate.
- Not authorized for:
  - Patients less than 18 years of age
  - Initiation of treatment in patients requiring hospitalization due to COVID-19
  - Use longer than 5 consecutive days
- Lagevrio (molnupiravir) may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which Lagevrio (molnupiravir) belongs (i.e., anti-infectives).

For more information, FDA Lagevrio Fact Sheet for Providers

Equity and Access

Equity Remains a Top Priority

- Established two additional pathways for product access in vulnerable communities.

- USG focused on enhanced outreach and education efforts
  - Developing grassroots campaign
  - Targeted social media content
  - Updated digital content, including product videos
  - Digital Toolkit for providers and patients
  - Webinars with U.S. Surgeon General
  - Starting this week, targeted outreach and product placement to providers sites in high SVI areas with low dispensing

- States/Territories encouraged to amplify where product is sent in their areas
  - Utilize provider communication networks
  - Post receiving sites on state and local health department websites
  - Partner with hospital associations for message amplification
  - Enlist support of public information officers

CDC MMWR:
Dispensing of OAVs for COVID-19 by Zip Code Vulnerability Index

- June 21, 2022: CDC Morbidity and Mortality Weekly Report (MMWR) released highlighting the dispensing of oral antiviral drugs for the treatment of COVID-19 by Zip Code over December 23, 2021 - May 21, 2022
- MMWR Summary
  - There was a substantial increase in the number of dispensing sites located throughout the country, concurrent with new initiatives (eg, T2T, LTC, pharmacy programs)
  - At end of study period, 47% of dispensing sites were located in high-vulnerability zip codes
  - Despite the increase in the number of oral antivirals dispensed during the study period, population-adjusted dispensing rates in high-vulnerability zip codes were substantially lower than those in medium- and low-vulnerability zip codes (using equitable distribution index, EDI)
  - Timely administration of oral antivirals depends on multiple factors, including adequate drug supply and distribution; acceptance of the therapy by health care providers and the public; and patient access to testing, prescriptions, and drug dispensing sites
- USG remains actively focused on improving access and equity; your partnership is needed
- Jurisdictions now have access to EDI dashboard within Tiberius

On the Web:
aspr.hhs.gov

Facebook:
facebook.com/ASPRgov

Twitter:
twitter.com/ASPRgov

Twitter: Dawn O'Connell
twitter.com/HHS_ASPR

Instagram:
instagram.com/ASPRgov/

YouTube::
youtube.com/c/ASPRgov

Flickr:
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LinkedIn:
linkedin.com/showcase/hhs-aspr/

ASPR Administration for Strategic Preparedness & Response

APPENDIX SLIDES

Evusheld Remains Readily Available for Use!

- FDA authorized extension to the shelf-life **from 18 months to 24 month** for specific lots of the refrigerated AstraZeneca monoclonal antibody therapy, Evusheld.
- Evusheld is effective and can protect some of the most vulnerable in our communities from COVID-19.
- The USG continues targeted outreach and education efforts to help inform providers and empower patients.
- There is still ample supply of Evusheld; providers are encouraged to prescribe Evusheld for eligible patients.
- **NOTE: Lot #AZ220049 expires on August 31, 2022** and will not have an extended expiration date. We ask that sites use this product in the next few weeks.

Extended Expiry Dating for Evusheld (Tixagevimab Co-Packaged with Cilgavimab) Authorized under EUA 104

Co-Pack Lot Numbers	Labeled Co-Pack Expiration Dates	Extended Co-Pack Expiration Dates
AZ210059	Jul 2022	Jan 31, 2023
AZ210062	Jul 2022	Jan 31, 2023
AZ210065	Jun 2022	Dec 31, 2022
AZ220033	Aug 2022	Feb 28, 2023
AZ220036	Aug 2022	Feb 28, 2023
AZ220061	Aug 2022	Feb 28, 2023
AZ220042	Jul 2022	Jan 31, 2023
AZ220053	Jul 2022	Jan 31, 2023
AZ220059	Jul 2022	Jan 31, 2023
AZ220056	Jul 2022	Jan 31, 2023

Disregard the Component Lot Numbers shared previously. The Co-Pack Lot Numbers (carton Lot Numbers) should be used to identify product affected by the expiry extension.

Paxlovid Shelf-Life Extension

- Upon EUA, Paxlovid was issued a 12-month product shelf-life
- Four lots of Paxlovid manufactured prior to the EUA issuance were labeled with a 9-month expiry
- FDA authorized extended expiration dates for these lots to reflect the 12-month product shelf-life (see Table), when stored according to the storage conditions detailed in the authorized Fact Sheet for Health Care Providers and the Letter of Authorization for Emergency Use Authorization (EUA) 105 for Paxlovid.
- This information is now posted on the FDA's website.

Lot#	Extended Expiry Date
FL4516 FL4517 FR7229	The initial 3 lots were extended from 7/31 to 10/31/22.
FR9088	4th lot was extended from 8/31 to 11/30/22

Did you know: ASPR has new name!

- **July 20, 2022 – U.S. Department of Health and Human Services Secretary Xavier Becerra announced the elevation of ASPR from a Staff Division to an Operating Division within HHS.**

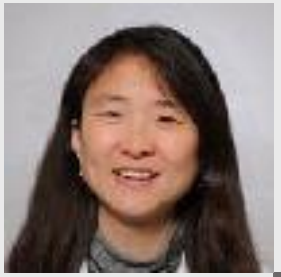
- Change allows ASPR to mobilize a coordinated national response more quickly and stably during future disasters and emergencies while equipping the organization with greater hiring and contracting capabilities.

- Places ASPR on the same level within HHS as other Operating Divisions within the department such as CDC, FDA and NIH.

New organization name:
Administration for Strategic Preparedness and Response (ASPR)

Clinician-Focused Strategies to Increase Treatment & Vaccine Uptake

Elisa Choi, MD, FACP, FIDSA
Valeria Cantos, MD



Moving past “pandemic fatigue” – Improving outpatient COVID-19 treatment and vaccines/boosters utilization

Elisa Choi, MD, FACP, FIDSA (She/Her)
Internal Medicine, Infectious Diseases
Chair, Board of Governors – American College of Physicians (ACP)
CDC/IDSA COVID-19 Real Time Learning Network Advisory Group

August 6, 2022

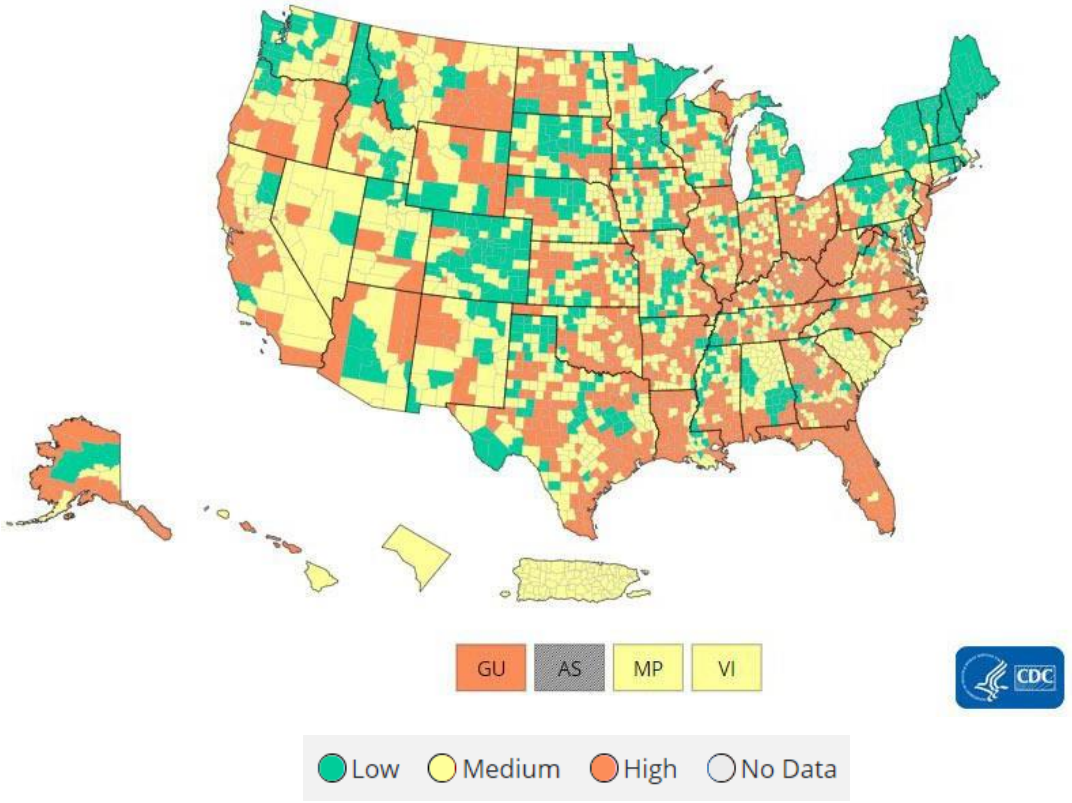
@DrElisaChoi

ACP
American College of Physicians
Leading Internal Medicine, Improving Lives

Disclosures

- No financial or IP disclosures
- Views and opinions expressed are my own and do not necessarily represent the official position or policy of organizations with which I am affiliated

U.S. COVID-19 Community Levels by County – August 4, 2022



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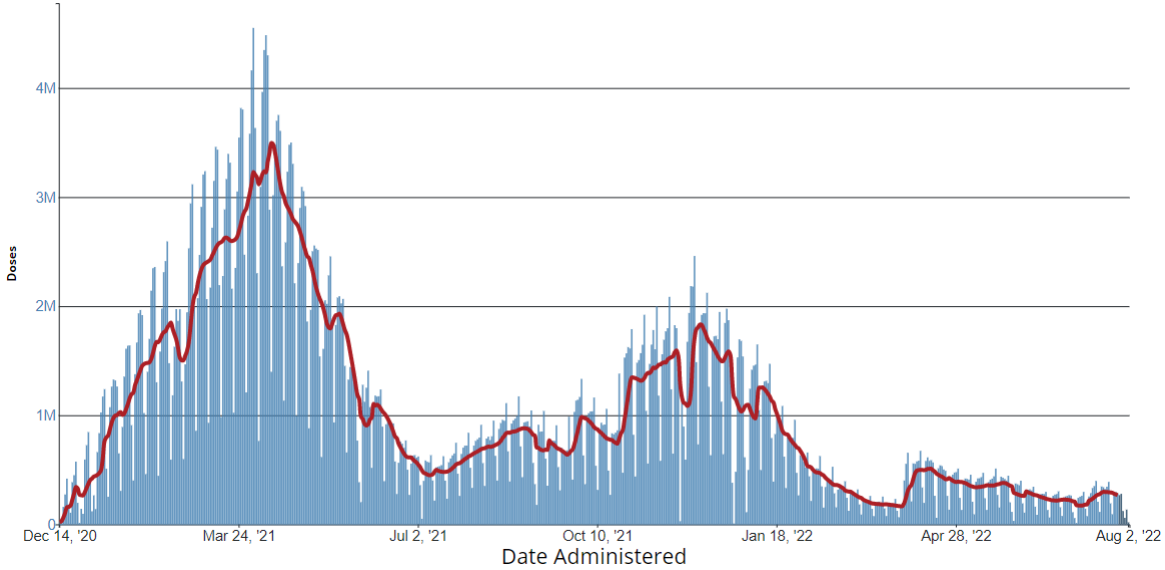
Daily Change in the Total Number of Administered COVID-19 Vaccine Doses Reported to CDC by the Date of CDC Report, United States – August 3, 2022



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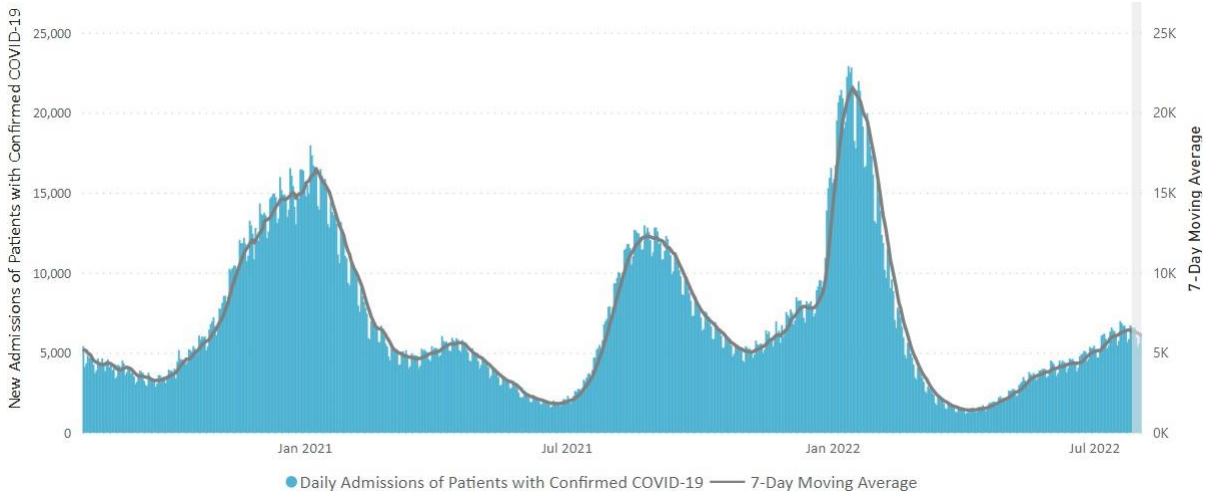
Daily Trends in Number of New COVID-19 Hospital Admissions in the United States – August 2, 2022



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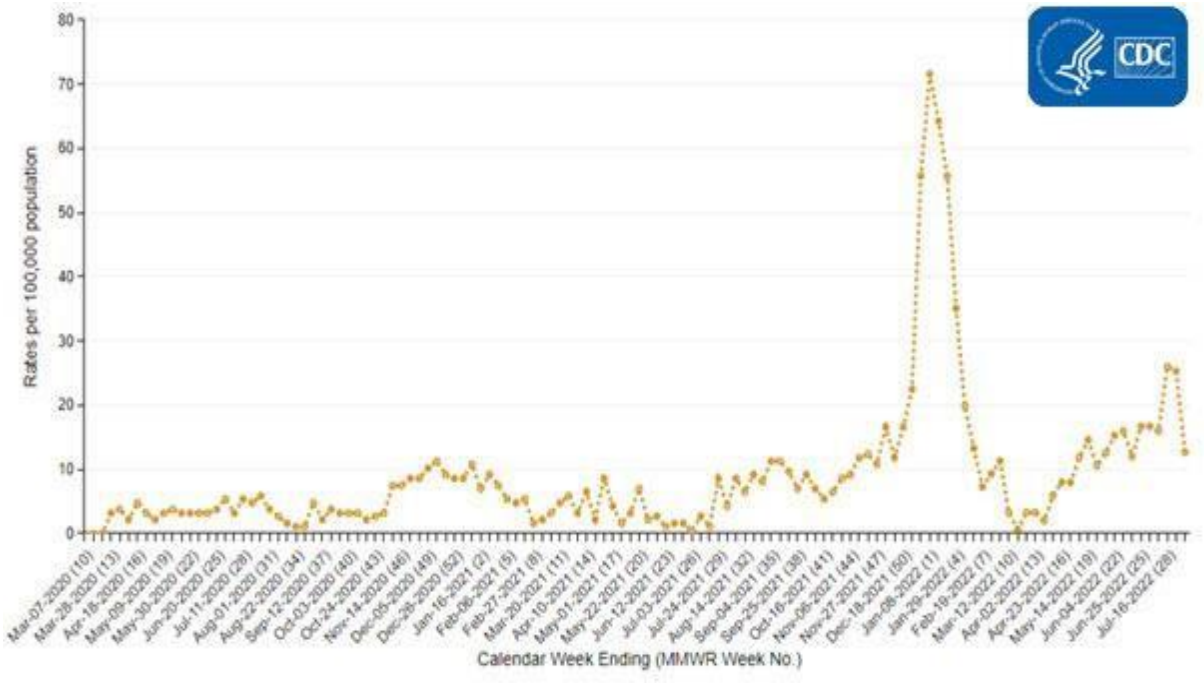
Trends in COVID-19-Associated Hospitalizations among Adults Ages ≥65 Years – July 2022



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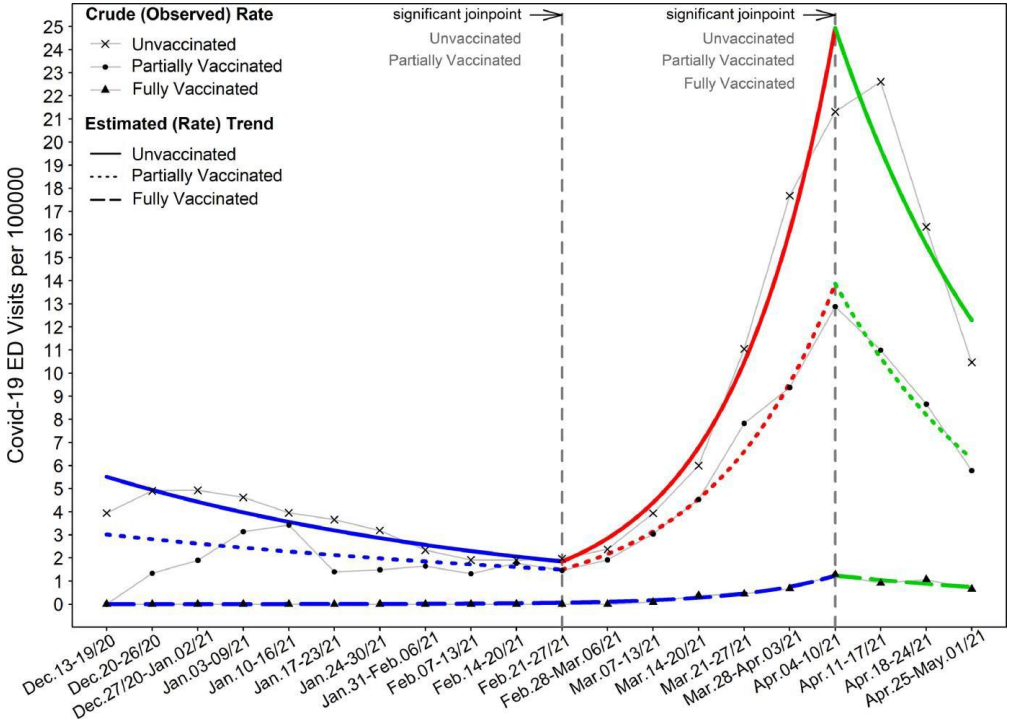
ED encounters of COVID-19 patients among vaccination groups – Lancet VOLUME 4, 100065, DECEMBER 01, 2021



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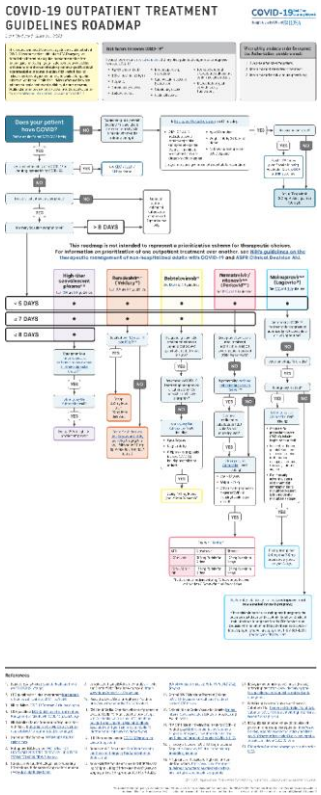
COVID-19 Outpatient Treatment Guidelines Roadmap – CDC/IDSA COVID-19 Real Time Learning Network



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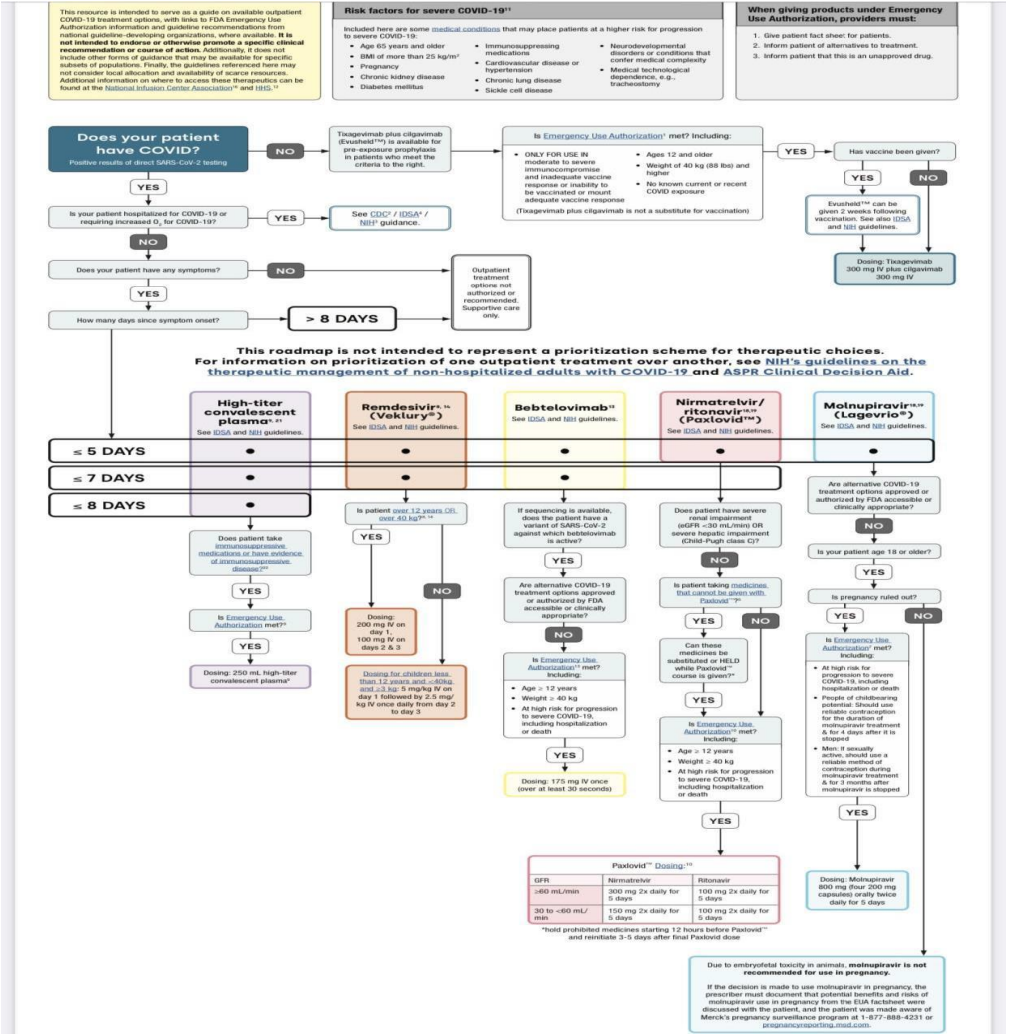
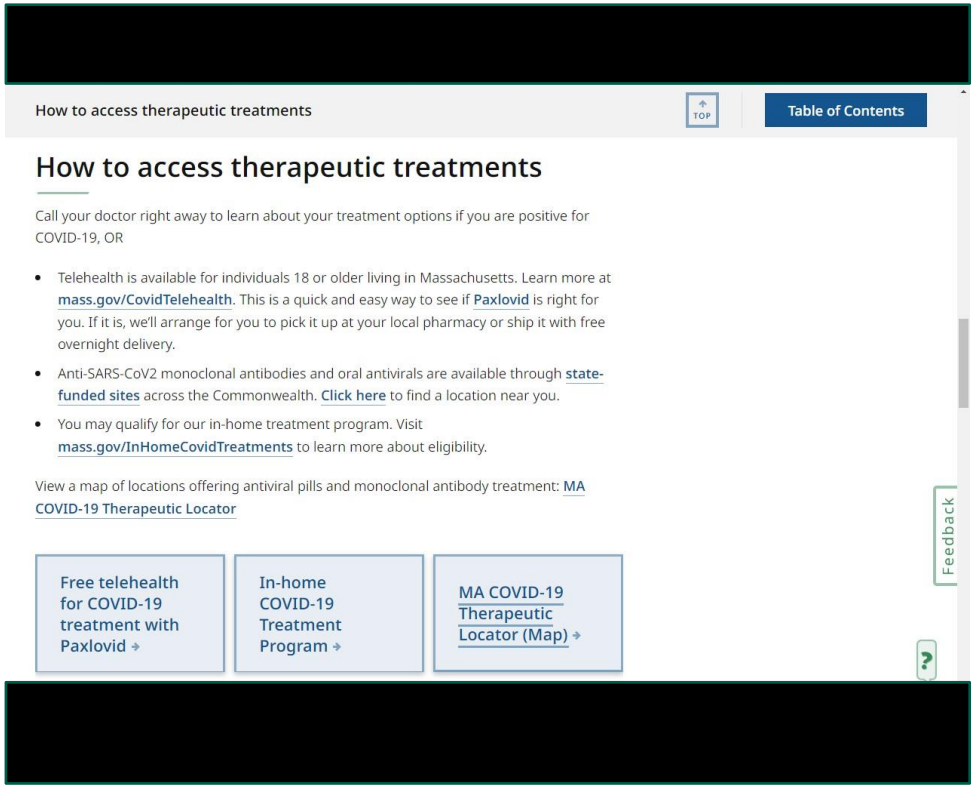
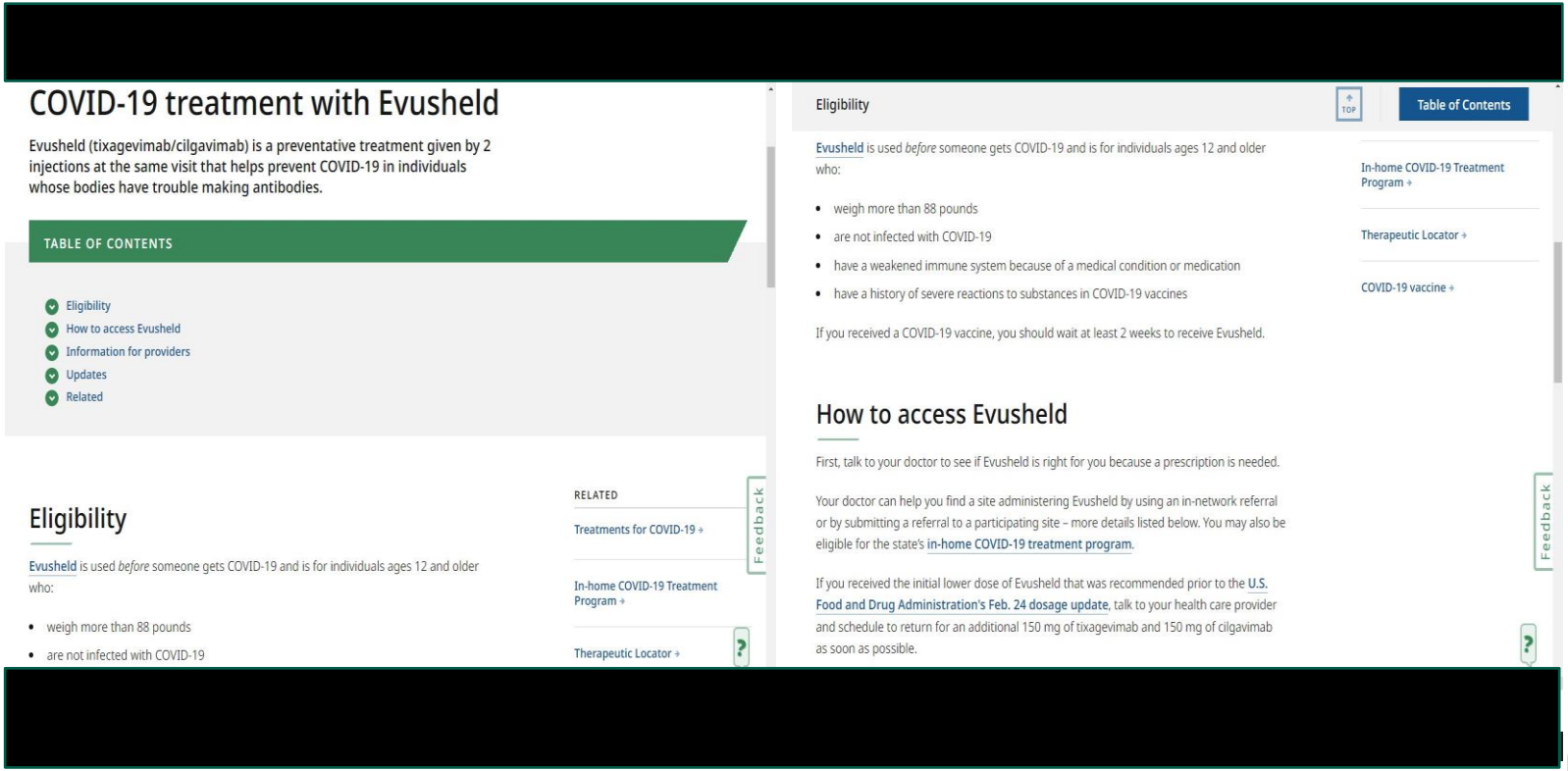
https://www.idsociety.org/covid-19-real-time-learning-network/therapeutics-and-interventions/covid-19-outpatient-treatment--guidelines-roadmap/



Public Health resources



Public Health resources



COVID-19 treatment with Evusheld

Evusheld (tixagevimab/cilgavimab) is a preventative treatment given by 2 injections at the same visit that helps prevent COVID-19 in individuals whose bodies have trouble making antibodies.

TABLE OF CONTENTS

- Eligibility
- How to access Evusheld
- Information for providers
- Updates
- Related

Eligibility

Evusheld is used *before* someone gets COVID-19 and is for individuals ages 12 and older who:

- weigh more than 88 pounds
- are not infected with COVID-19

RELATED

Treatments for COVID-19 →

In-home COVID-19 Treatment Program →

Therapeutic Locator →

Feedback

Eligibility

TOP

Table of Contents

Evusheld is used *before* someone gets COVID-19 and is for individuals ages 12 and older who:

- weigh more than 88 pounds
- are not infected with COVID-19
- have a weakened immune system because of a medical condition or medication
- have a history of severe reactions to substances in COVID-19 vaccines

If you received a COVID-19 vaccine, you should wait at least 2 weeks to receive Evusheld.

In-home COVID-19 Treatment Program →

Therapeutic Locator →

COVID-19 vaccine →

How to access Evusheld

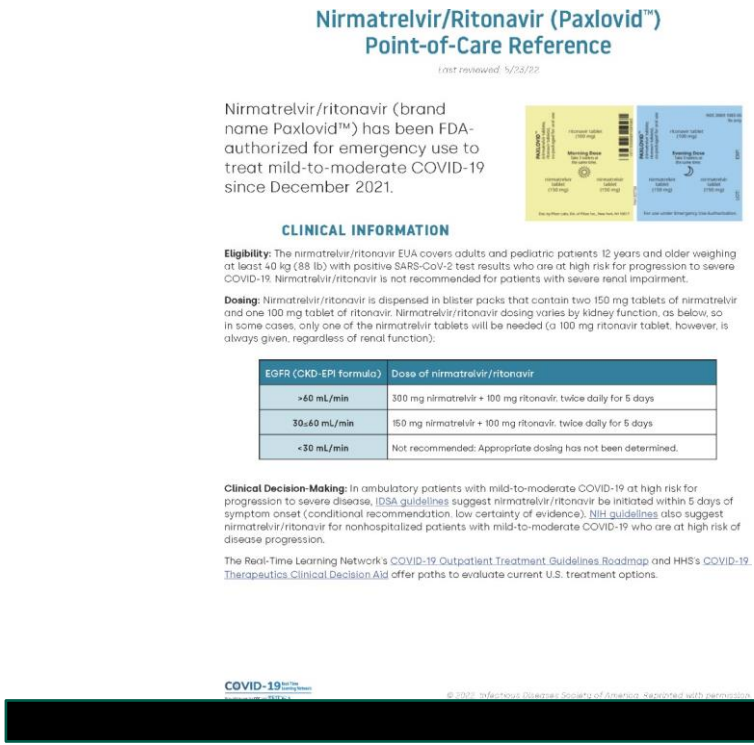
First, talk to your doctor to see if Evusheld is right for you because a prescription is needed.

Your doctor can help you find a site administering Evusheld by using an in-network referral or by submitting a referral to a participating site – more details listed below. You may also be eligible for the state's in-home COVID-19 treatment program.

If you received the initial lower dose of Evusheld that was recommended prior to the U.S. Food and Drug Administration's Feb. 24 dosage update, talk to your health care provider and schedule to return for an additional 150 mg of tixagevimab and 150 mg of cilgavimab as soon as possible.

Feedback

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



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

Last reviewed: 5/23/22

Nirmatrelvir/ritonavir (brand name Paxlovid™) has been FDA-authorized for emergency use to treat mild-to-moderate COVID-19 since December 2021.

CLINICAL INFORMATION

Eligibility: The nirmatrelvir/ritonavir EUA covers adults and pediatric patients 12 years and older weighing at least 40 kg (88 lb) with positive SARS-CoV-2 test results who are at high risk for progression to severe COVID-19. Nirmatrelvir/ritonavir is not recommended for patients with severe renal impairment.

Dosing: Nirmatrelvir/ritonavir is dispensed in blister packs that contain two 150 mg tablets of nirmatrelvir and one 100 mg tablet of ritonavir. Nirmatrelvir/ritonavir dosing varies by kidney function, as below, so in some cases, only one of the nirmatrelvir tablets will be needed (a 100 mg ritonavir tablet, however, is always given, regardless of renal function):

EGFR (CKD-EPI formula)	Dose of nirmatrelvir/ritonavir
>60 mL/min	300 mg nirmatrelvir + 100 mg ritonavir, twice daily for 5 days
30–60 mL/min	150 mg nirmatrelvir + 100 mg ritonavir, twice daily for 5 days
<30 mL/min	Not recommended: Appropriate dosing has not been determined.

Clinical Decision-Making: In ambulatory patients with mild-to-moderate COVID-19 at high risk for progression to severe disease, IDSA guidelines suggest nirmatrelvir/ritonavir be initiated within 5 days of symptom onset (conditional recommendation, low certainty of evidence). NIH guidelines also suggest nirmatrelvir/ritonavir for nonhospitalized patients with mild-to-moderate COVID-19 who are at high risk of disease progression.

The Real-Time Learning Network's COVID-19 Outpatient Treatment Guidelines Roadmap and HHS's COVID-19 Therapeutics Clinical Decision Aid offer paths to evaluate current U.S. treatment options.

COVID-19

[redacted]

https://www.idsociety.org/covid-19-real-time-learning-network/therapeutics-and-interventions/nirmatrelvir-ritonavir-paxlovid-point-of-care-reference/

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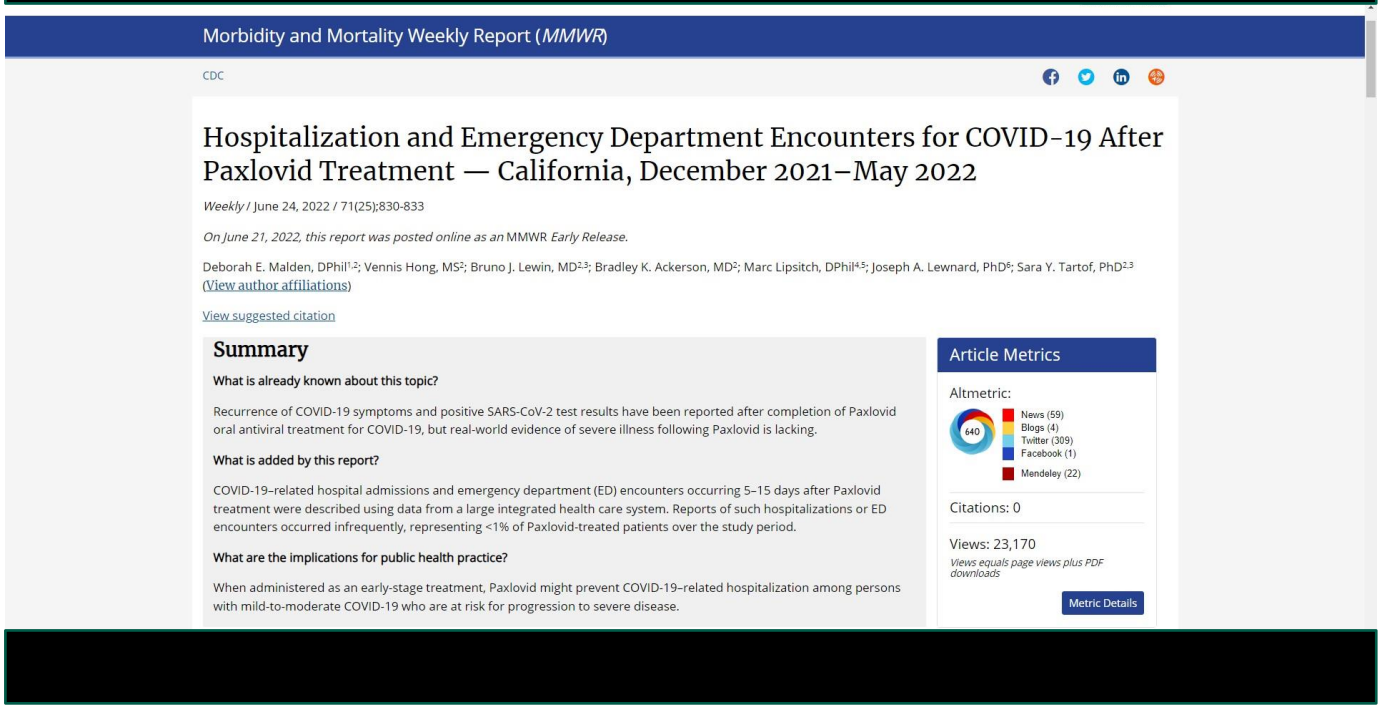
Hospitalization and Emergency Department Encounters for COVID-19 After Paxlovid Treatment — California, December 2021–May 2022

[redacted]



Morbidity and Mortality Weekly Report (*MMWR*)

CDC

Hospitalization and Emergency Department Encounters for COVID-19 After Paxlovid Treatment — California, December 2021–May 2022

Weekly / June 24, 2022 / 71(25);830-833

On June 21, 2022, this report was posted online as an MMWR *Early Release.*

Deborah E. Malden, DPhil[1,2]; Vennis Hong, MS[2]; Bruno J. Lewin, MD[2,3]; Bradley K. Ackerson, MD[2]; Marc Lipsitch, DPhil[4,5]; Joseph A. Lewnard, PhD[6]; Sara Y. Tartof, PhD[2,3] (View author affiliations)

View suggested citation

Summary

What is already known about this topic?

Recurrence of COVID-19 symptoms and positive SARS-CoV-2 test results have been reported after completion of Paxlovid oral antiviral treatment for COVID-19, but real-world evidence of severe illness following Paxlovid is lacking.

What is added by this report?

COVID-19–related hospital admissions and emergency department (ED) encounters occurring 5–15 days after Paxlovid treatment were described using data from a large integrated health care system. Reports of such hospitalizations or ED encounters occurred infrequently, representing <1% of Paxlovid-treated patients over the study period.

What are the implications for public health practice?

When administered as an early-stage treatment, Paxlovid might prevent COVID-19–related hospitalization among persons with mild-to-moderate COVID-19 who are at risk for progression to severe disease.

Article Metrics

Altmetric:

640

News (59)
Blogs (4)
Twitter (309)
Facebook (1)
Mendeley (22)

Citations: 0

Views: 23,170

Views equals page views plus PDF downloads

Metric Details

[redacted]

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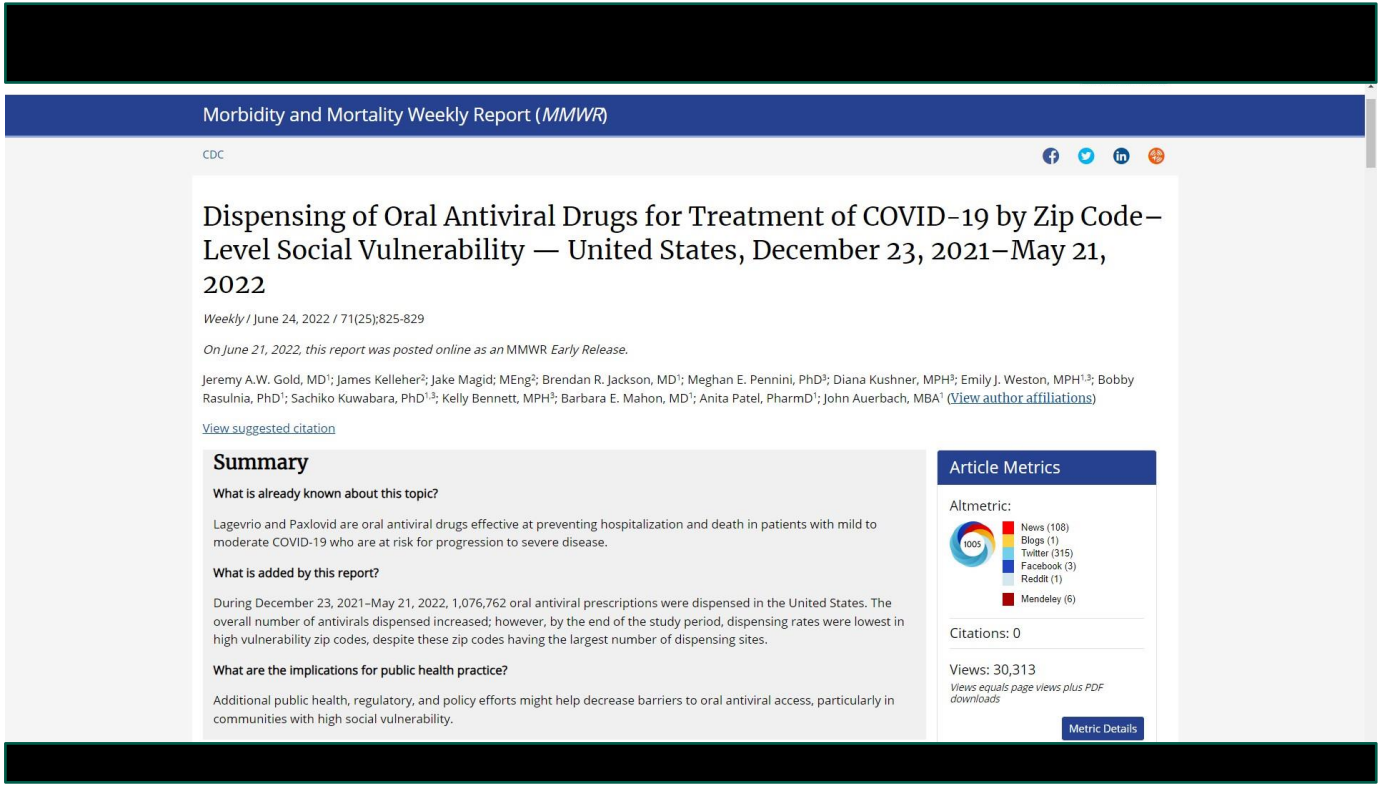
Dispensing of Oral Antiviral Drugs for Treatment of COVID-19 by Zip Code–Level Social Vulnerability — United States, December 23, 2021–May 21, 2022



Morbidity and Mortality Weekly Report (*MMWR*)

CDC

Dispensing of Oral Antiviral Drugs for Treatment of COVID-19 by Zip Code–Level Social Vulnerability — United States, December 23, 2021–May 21, 2022

Weekly / June 24, 2022 / 71(25);825-829

On June 21, 2022, this report was posted online as an MMWR *Early Release.*

Jeremy A.W. Gold, MD[1]; James Kelleher[2]; Jake Magid; MEng[2]; Brendan R. Jackson, MD[1]; Meghan E. Pennini, PhD[3]; Diana Kushner, MPH[3]; Emily J. Weston, MPH[1,3]; Bobby Rasulnia, PhD[1]; Sachiko Kuwabara, PhD[1,3]; Kelly Bennett, MPH[3]; Barbara E. Mahon, MD[1]; Anita Patel, PharmD[1]; John Auerbach, MBA[1] (View author affiliations)

View suggested citation

Summary

What is already known about this topic?

Lagevrio and Paxlovid are oral antiviral drugs effective at preventing hospitalization and death in patients with mild to moderate COVID-19 who are at risk for progression to severe disease.

What is added by this report?

During December 23, 2021–May 21, 2022, 1,076,762 oral antiviral prescriptions were dispensed in the United States. The overall number of antivirals dispensed increased; however, by the end of the study period, dispensing rates were lowest in high vulnerability zip codes, despite these zip codes having the largest number of dispensing sites.

What are the implications for public health practice?

Additional public health, regulatory, and policy efforts might help decrease barriers to oral antiviral access, particularly in communities with high social vulnerability.

Article Metrics

Altmetric:

1005

News (108)
Blogs (1)
Twitter (315)
Facebook (3)
Reddit (1)
Mendeley (6)

Citations: 0

Views: 30,313

Views equals page views plus PDF downloads

Metric Details

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Molnupiravir Quick Point-of-Care Reference

Molnupiravir Quick Point-of-Care Reference

Last reviewed: 5/23/22

Molnupiravir has been FDA-authorized for emergency use to treat mild-to-moderate COVID-19 among nonhospitalized, nonpregnant adults since December 2021.

CLINICAL INFORMATION

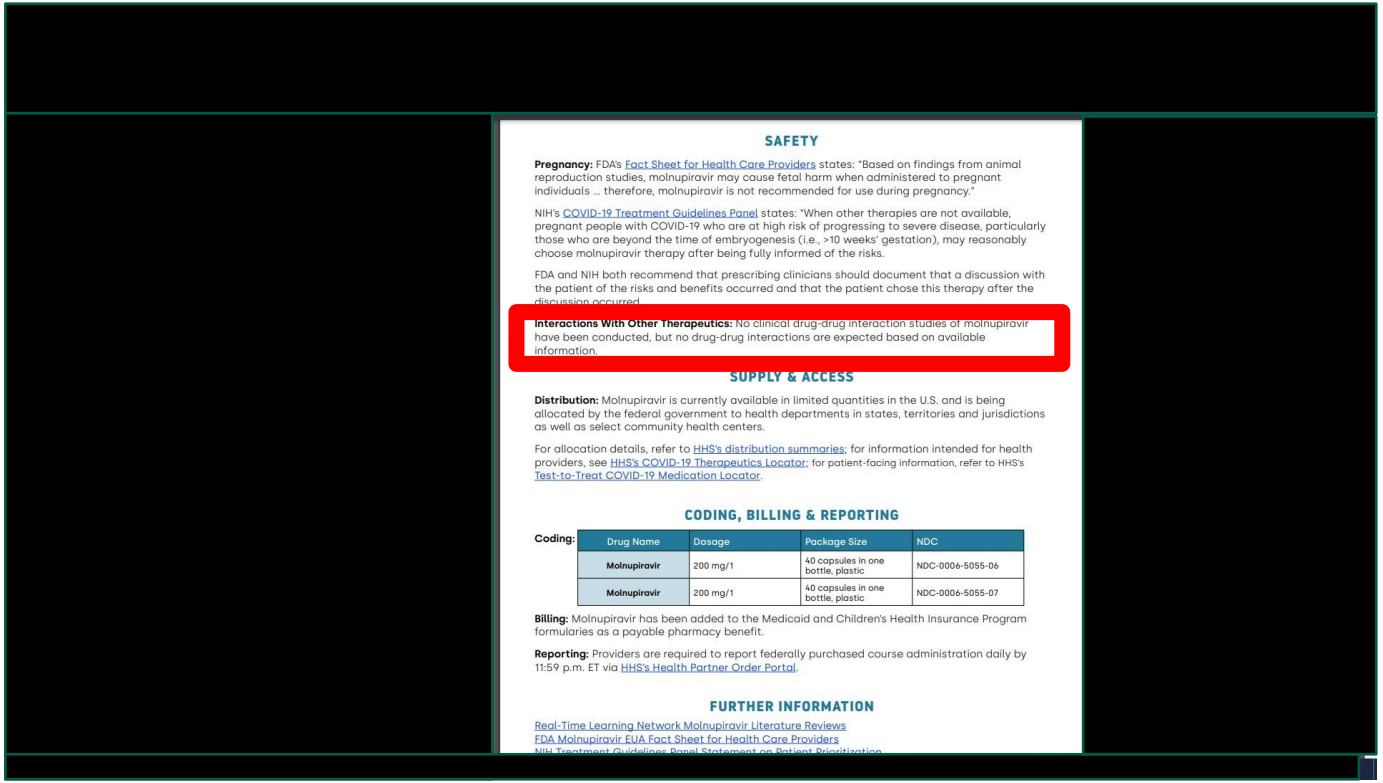
Eligibility: The molnupiravir EUA covers adults 18 years of age and older who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate. If it is decided to give molnupiravir, treatment should begin as soon as possible after diagnosis and within 5 days of symptom onset.

Dosing: A course of molnupiravir consists of 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days.

Clinical Decision-Making: In ambulatory adult patients with mild-to-moderate COVID-19 at high risk for progression to severe disease who have no other treatment options, IDSA guidelines suggest molnupiravir be initiated within 5 days of symptom onset (conditional recommendation, low certainty of evidence). NIH guidelines also suggest molnupiravir only when other antiviral options cannot be used (class CIII recommendation).

The Real-Time Learning Network's COVID-19 Outpatient Treatment Guidelines Roadmap and HHS's COVID-19 Therapeutics Clinical Decision Aid offer paths to evaluate current U.S. treatment options.

Molnupiravir Quick Point-of-Care Reference



SAFETY

Pregnancy: FDA's Fact Sheet for Health Care Providers states: "Based on findings from animal reproduction studies, molnupiravir may cause fetal harm when administered to pregnant individuals … therefore, molnupiravir is not recommended for use during pregnancy."

NIH's COVID-19 Treatment Guidelines Panel states: "When other therapies are not available, pregnant people with COVID-19 who are at high risk of progressing to severe disease, particularly those who are beyond the time of embryogenesis (i.e., >10 weeks' gestation), may reasonably choose molnupiravir therapy after being fully informed of the risks.

FDA and NIH both recommend that prescribing clinicians should document that a discussion with the patient of the risks and benefits occurred and that the patient chose this therapy after the discussion occurred.

Interactions With Other Therapeutics: No clinical drug-drug interaction studies of molnupiravir have been conducted, but no drug-drug interactions are expected based on available information.

SUPPLY & ACCESS

Distribution: Molnupiravir is currently available in limited quantities in the U.S. and is being allocated by the federal government to health departments in states, territories and jurisdictions as well as select community health centers.

For allocation details, refer to HHS's distribution summaries; for information intended for health providers, see HHS's COVID-19 Therapeutics Locator; for patient-facing information, refer to HHS's Test-to-Treat COVID-19 Medication Locator.

CODING, BILLING & REPORTING

Coding:

Drug Name	Dosage	Package Size	NDC
Molnupiravir	200 mg/1	40 capsules in one bottle, plastic	NDC-0006-5055-06
Molnupiravir	200 mg/1	40 capsules in one bottle, plastic	NDC-0006-5055-07

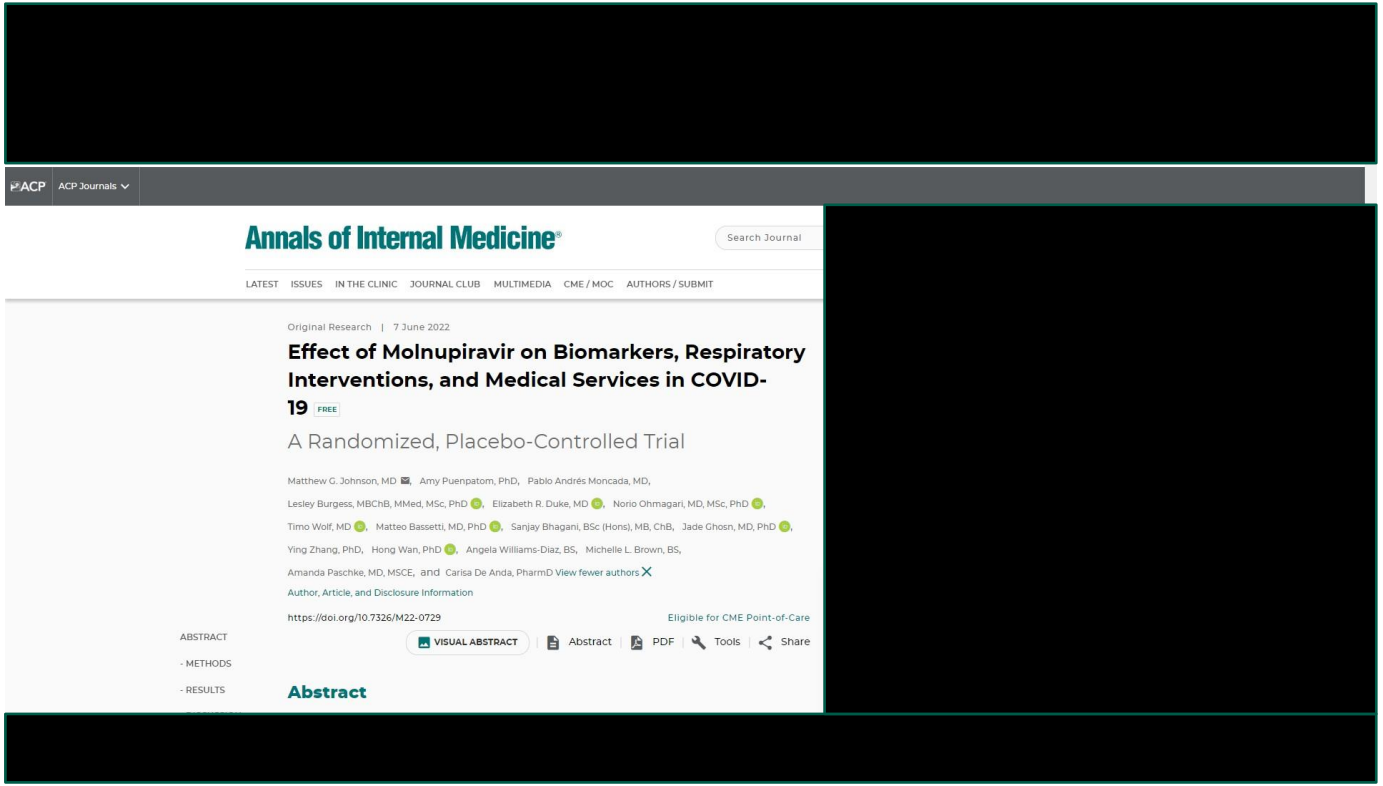
Billing: Molnupiravir has been added to the Medicaid and Children's Health Insurance Program formularies as a payable pharmacy benefit.

Reporting: Providers are required to report federally purchased course administration daily by 11:59 p.m. ET via HHS's Health Partner Order Portal.

FURTHER INFORMATION

Real-Time Learning Network Molnupiravir Literature Reviews
FDA Molnupiravir EUA Fact Sheet for Health Care Providers
NIH Treatment Guidelines Panel Statement on Patient Prioritization

Effect of Molnupiravir on Biomarkers, Respiratory Interventions, and Medical Services in COVID-19 – 7 June 2022 Annals of Internal Medicine



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COVID-19 “antivirals” virtual visits

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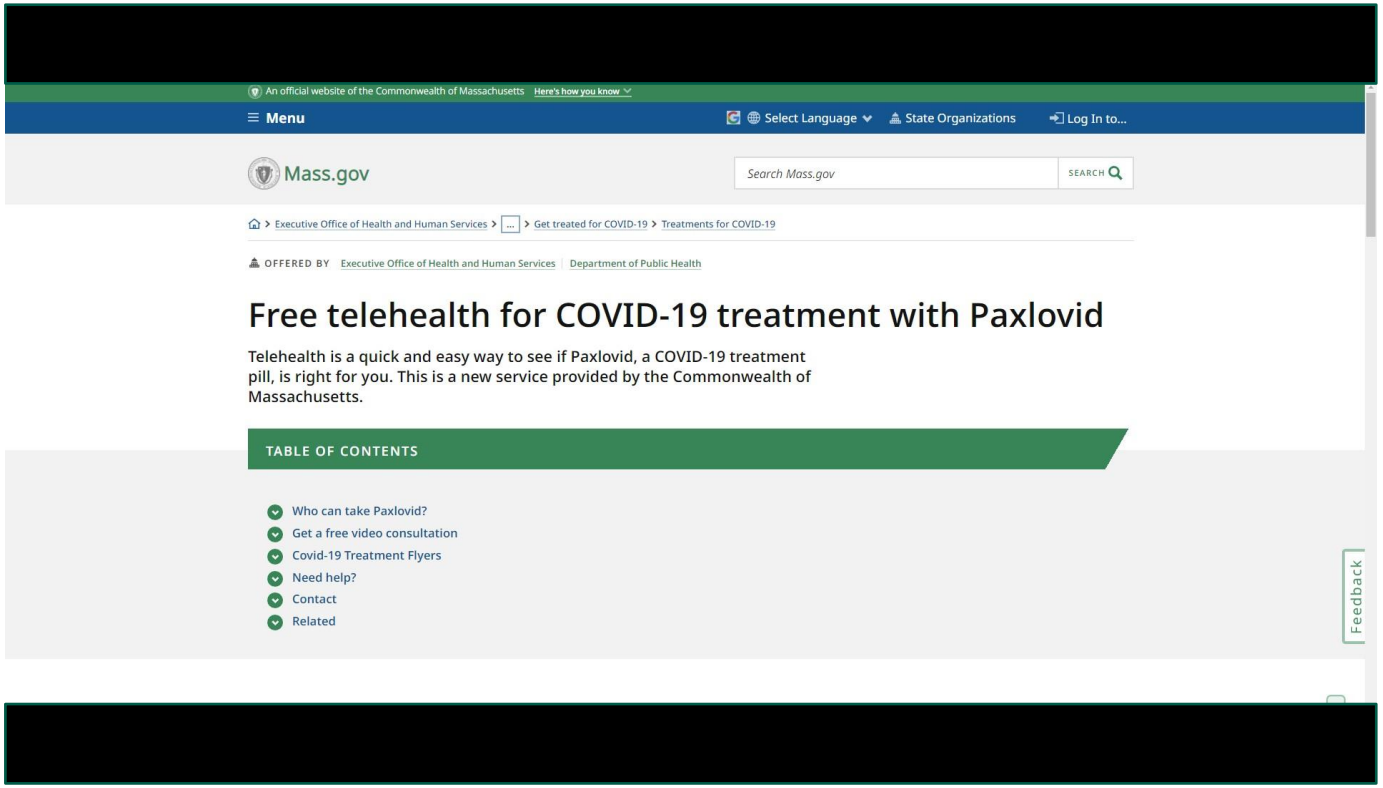
“Free telehealth for COVID-19 treatment with Paxlovid”



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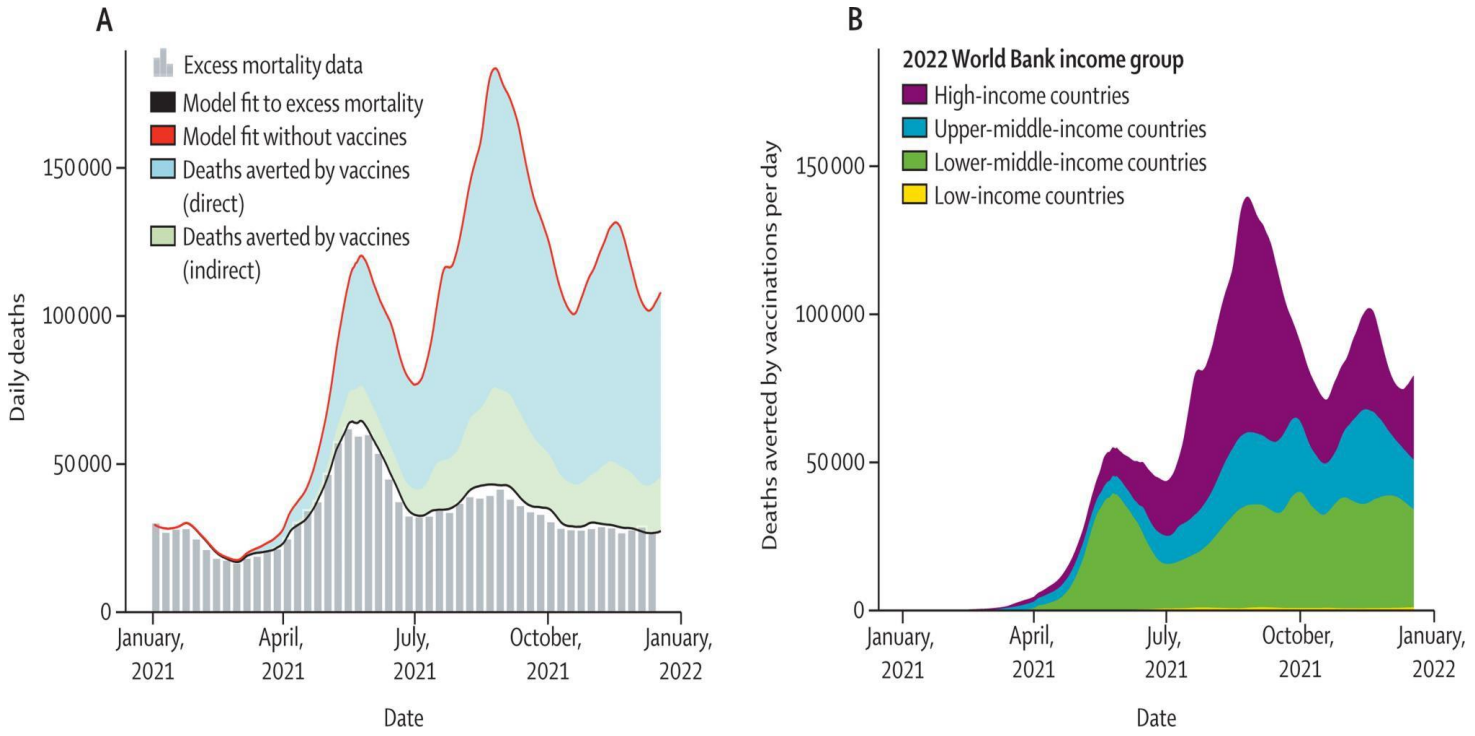
Global COVID-19 deaths averted due to vaccination based on excess mortality – Lancet ID

June 23, 2022 (DOI:https://doi.org/10.1016/S1473-3099(22)00320-6)



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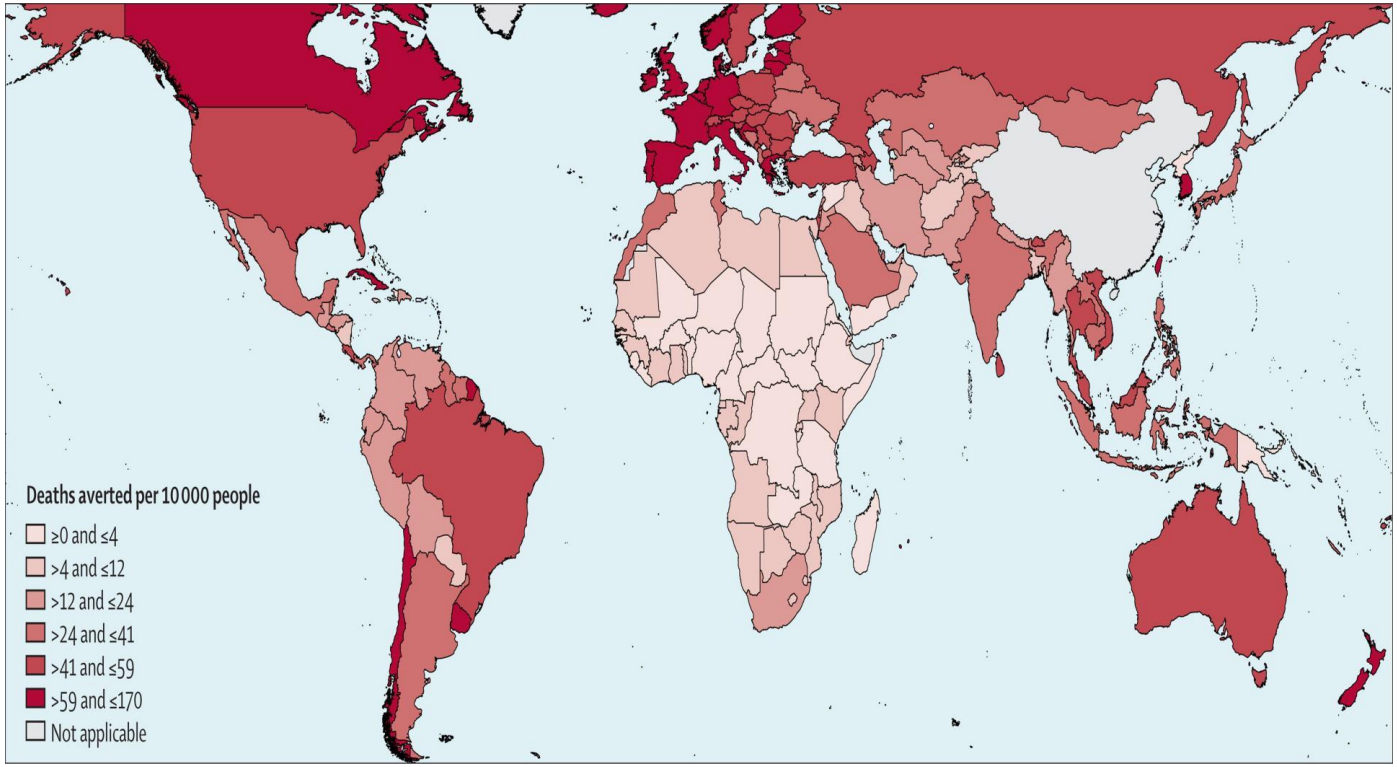
Median deaths averted by vaccinations per 10 000 people by country in the first year of COVID-19 vaccination - Lancet ID June 23, 2022 (DOI:https://doi.org/10.1016/S1473-3099(22)00320-6)



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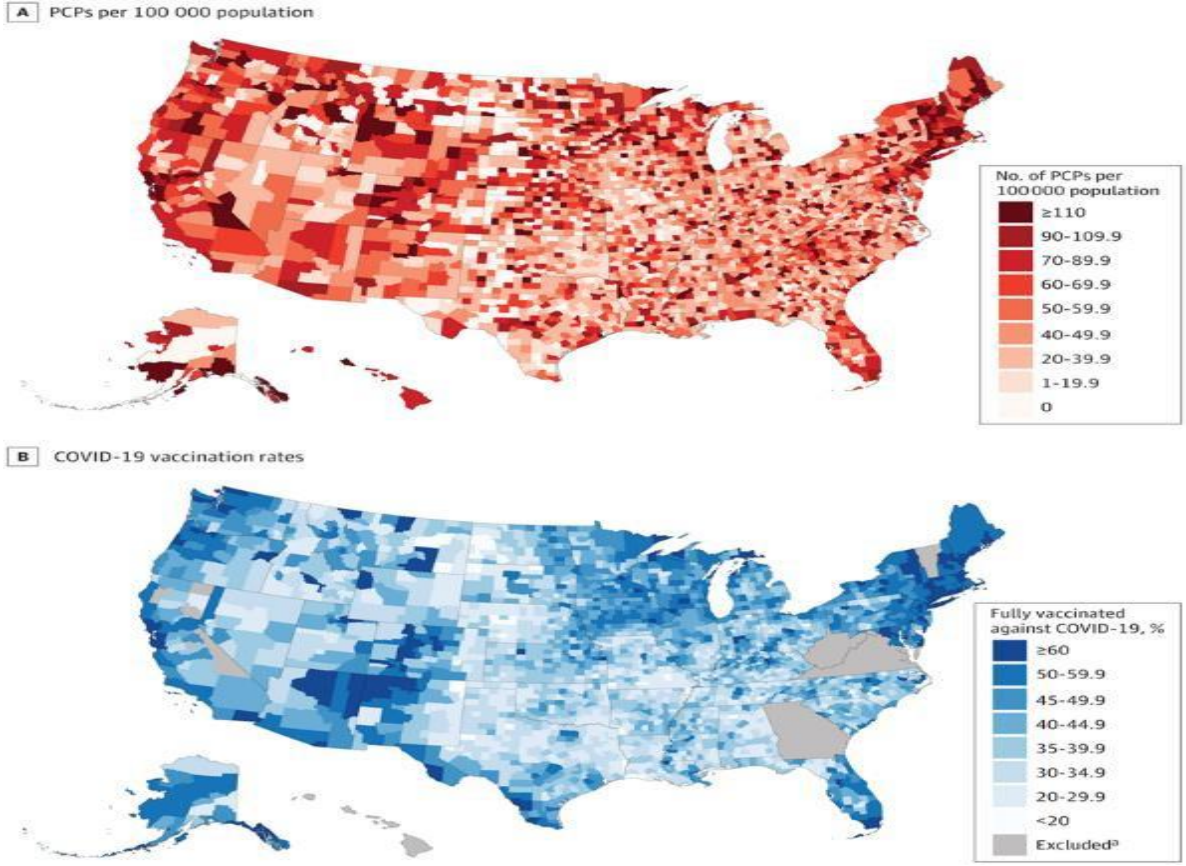
Number of Primary Care Physicians (PCPs) per 100 000 Population and COVID-19 Vaccination Rates Across US Counties - *JAMA Netw Open.* 2022;5(2):e2147920. doi:10.1001/jamanetworkopen.2021.47920



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Report of Health Care Provider Recommendation for COVID-19 Vaccination Among Adults, by Recipient COVID-19 Vaccination Status and Attitudes — United States, April–September 2021

CDC

Report of Health Care Provider Recommendation for COVID-19 Vaccination Among Adults, by Recipient COVID-19 Vaccination Status and Attitudes — United States, April–September 2021

Weekly / December 17, 2021 / 70(50);1723–1730

Kimberly H. Nguyen, DrPH[1]; David Yankey, PhD[1]; Peng-jun Lu, MD[1]; Jennifer L. Kriss, PhD[1]; Noel T. Brewer, PhD[2]; Hilda Razzaghi, PhD[1]; Mehreen Meghani, MPH[1]; Brian J. Manns, PharmD[1]; James T. Lee, MD[1]; James A. Singleton, PhD[1] (View author affiliations)

View suggested citation

Summary

What is already known about this topic?

COVID-19 vaccination is critical to controlling the COVID-19 pandemic; health care providers play an important role in achieving high vaccination coverage.

What is added by this report?

Adults who reported a provider COVID-19 vaccination recommendation were more likely to have been vaccinated, to be concerned about COVID-19, to have confidence that COVID-19 vaccines are important and safe, and to perceive that family and friends had been vaccinated.

What are the implications for public health practice?

A health care provider recommendation for COVID-19 vaccines at every visit could increase coverage and confidence in vaccines, particularly among groups with lower COVID-19 vaccination coverage, including younger adults, racial/ethnic minorities, and rural residents.

Article Metrics

Altmetric:

129

News (8)
Blogs (1)
Twitter (97)
Facebook (3)
Mendeley (37)

Citations: 9

Views: 7,212

Views equals page views plus PDF downloads

Metric Details

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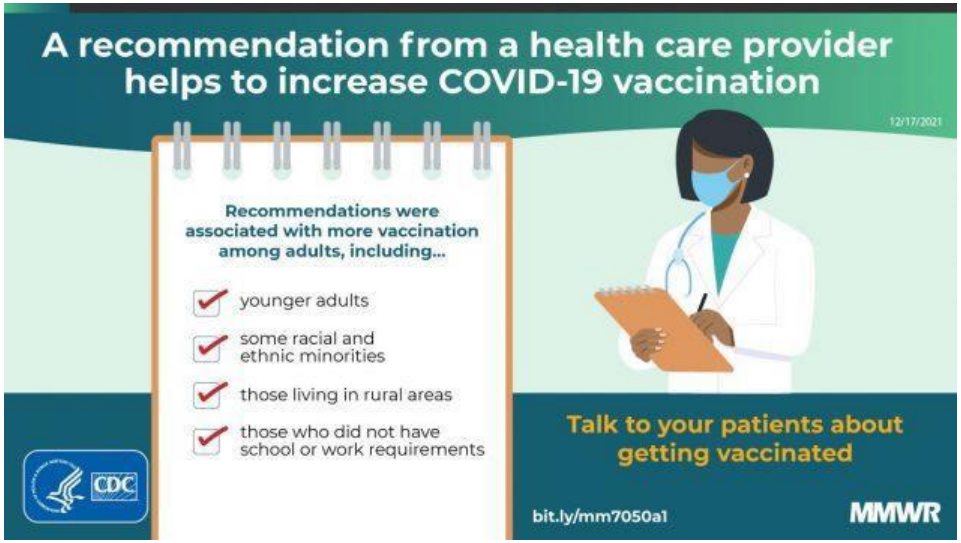
Report of Health Care Provider Recommendation for COVID-19 Vaccination Among Adults, by Recipient COVID-19 Vaccination Status and Attitudes — United States, April–September 2021



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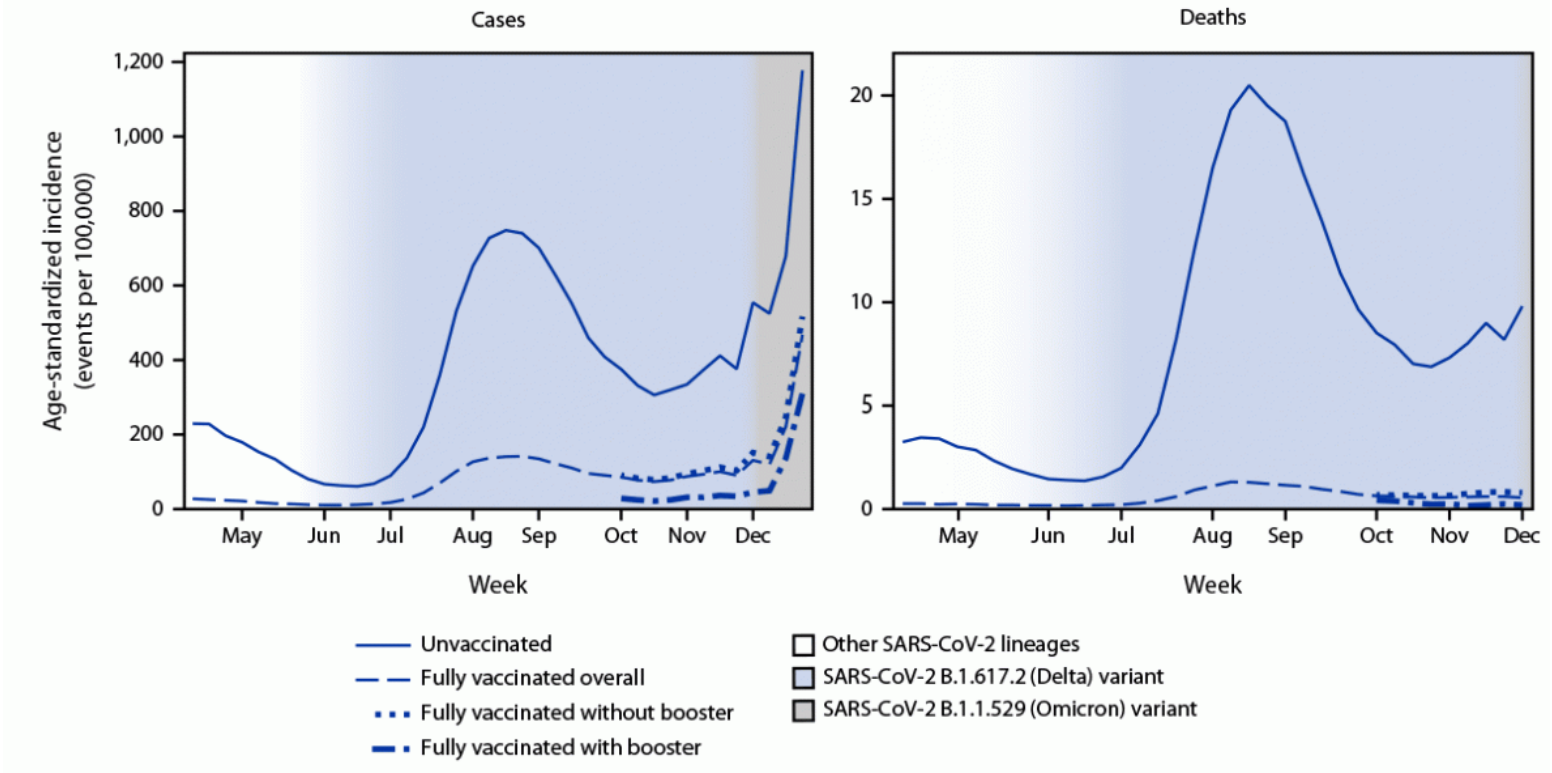
COVID-19 cases (April 4–December 25, 2021) and deaths (April 4–December 4, 2021)



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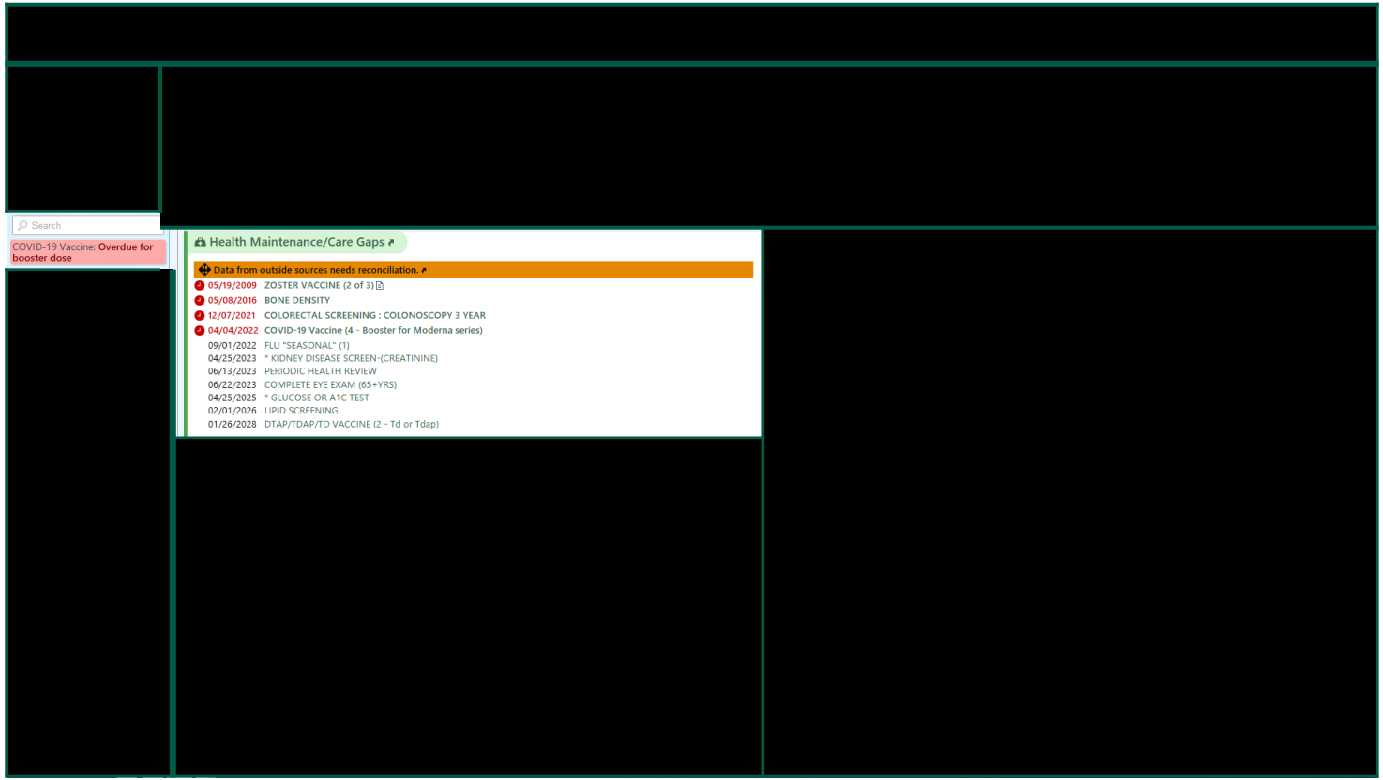
EHR & Vaccines/Boosters



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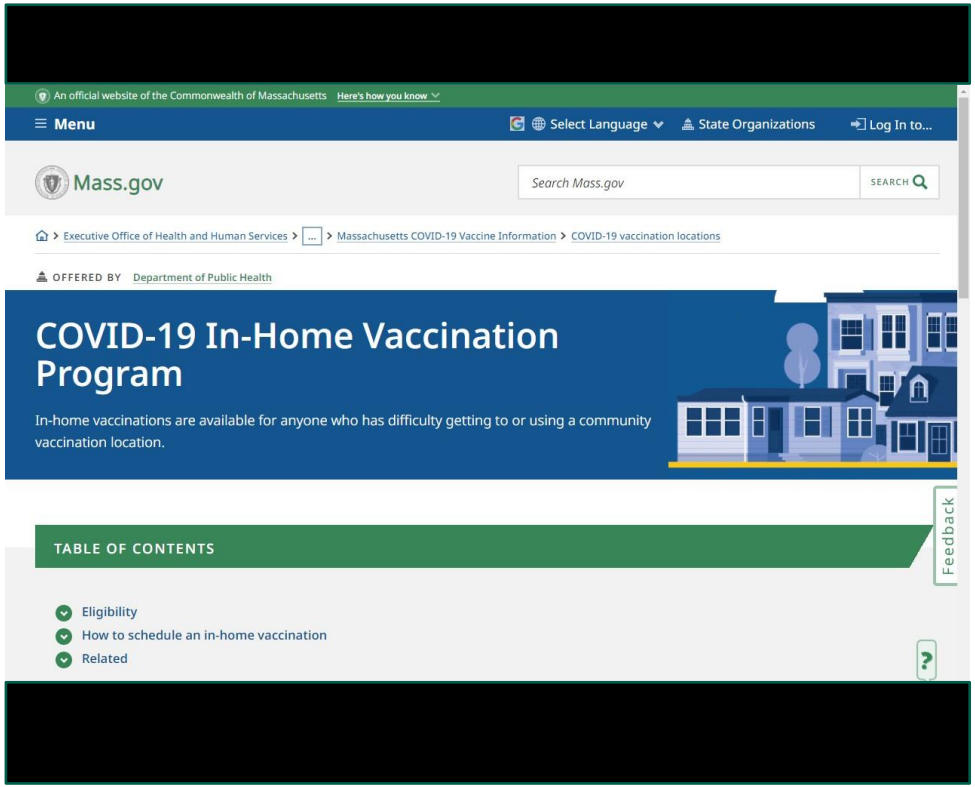
COVID-19 In-Home Vaccination Program



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How to effectively address misinformation

(https://www.cdc.gov/vaccines/covid-19/health-departments/addressing-vaccine-misinformation.html)

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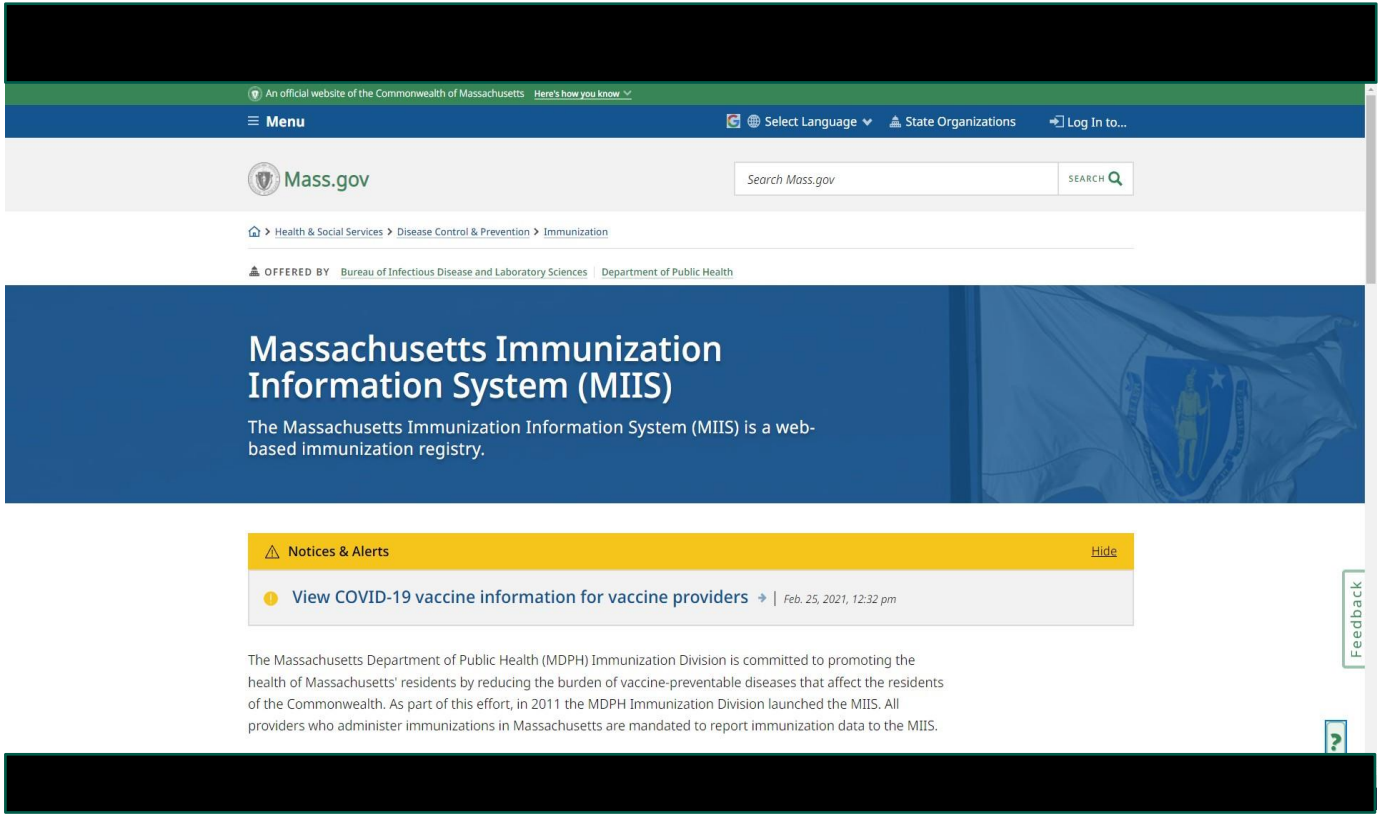
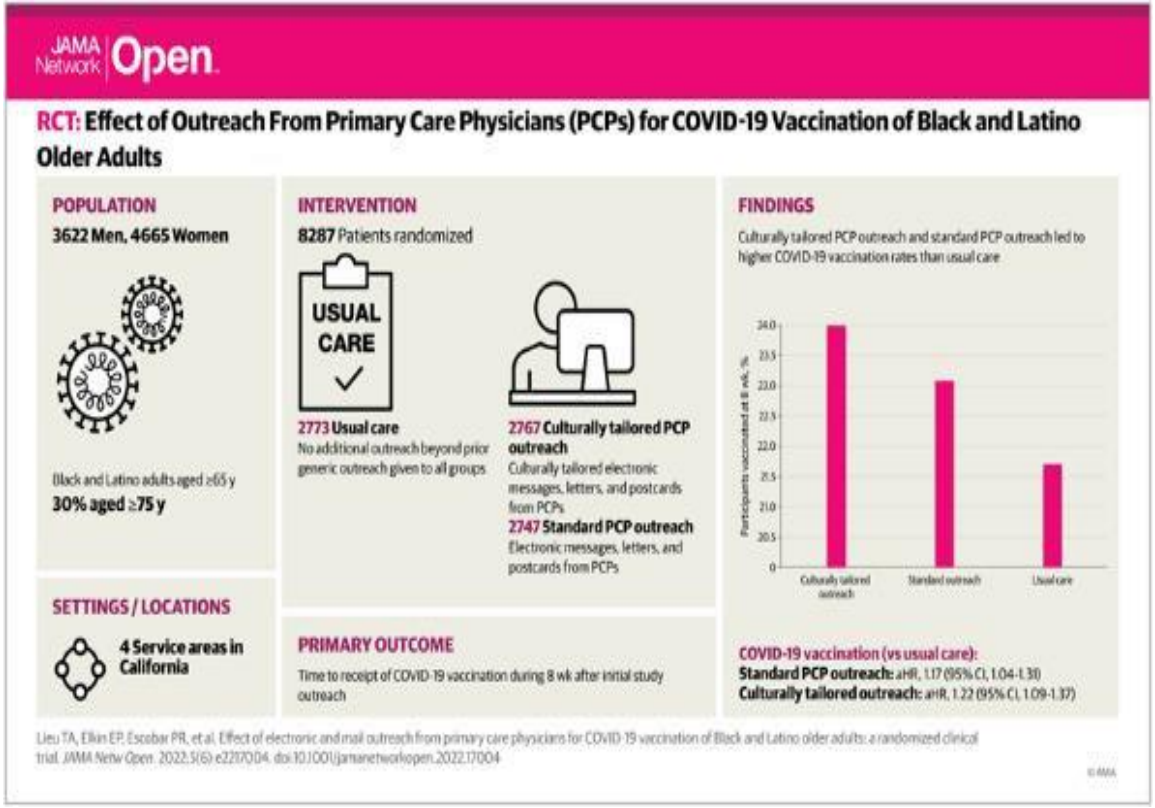
Massachusetts Immunization Information System (MIIS)



Effect of Outreach From Primary Care Physicians (PCPs) for COVID-19 Vaccination of Black and Latino Older Adults



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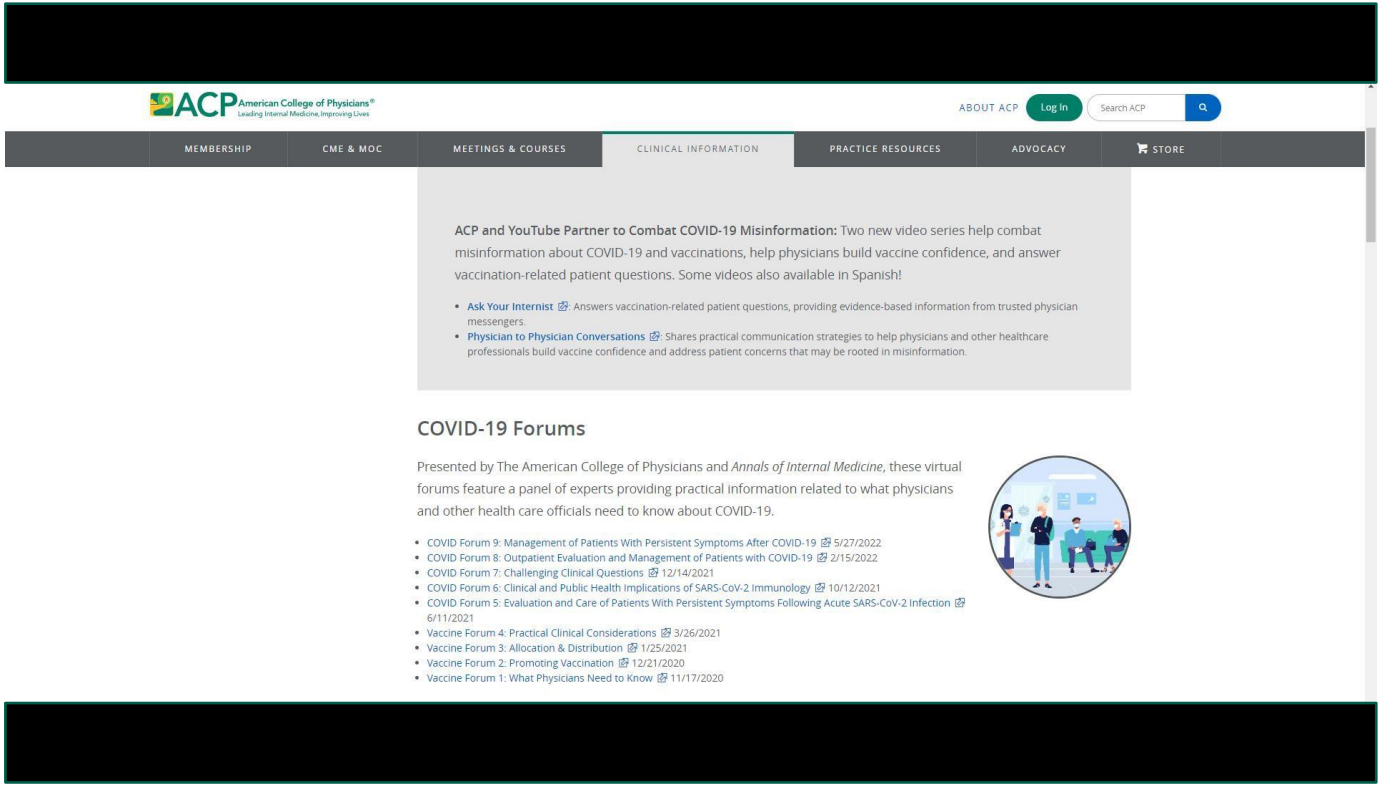
COVID-19 Resources – American College of Physicians (ACP)



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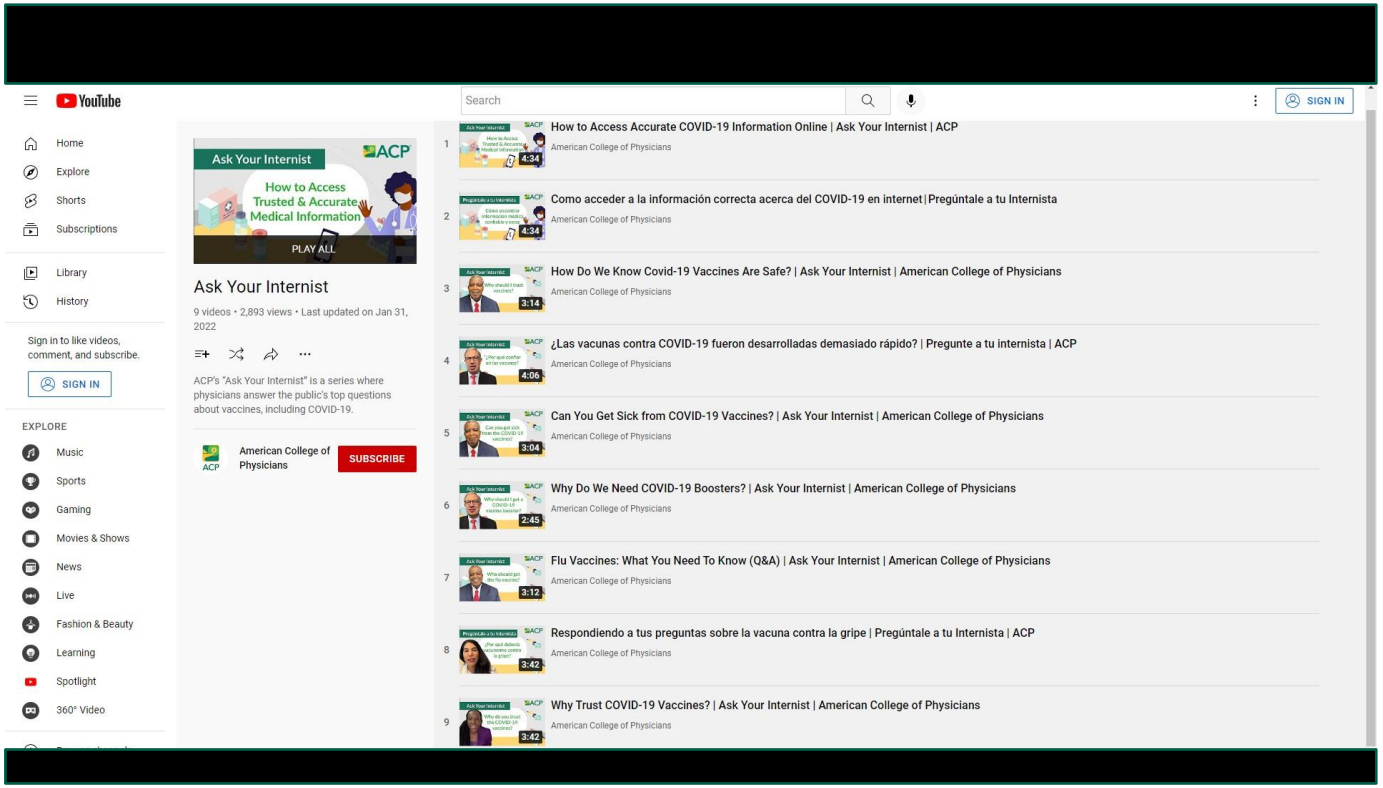
COVID-19 Resources – “Ask Your Internist” You Tube (ACP)



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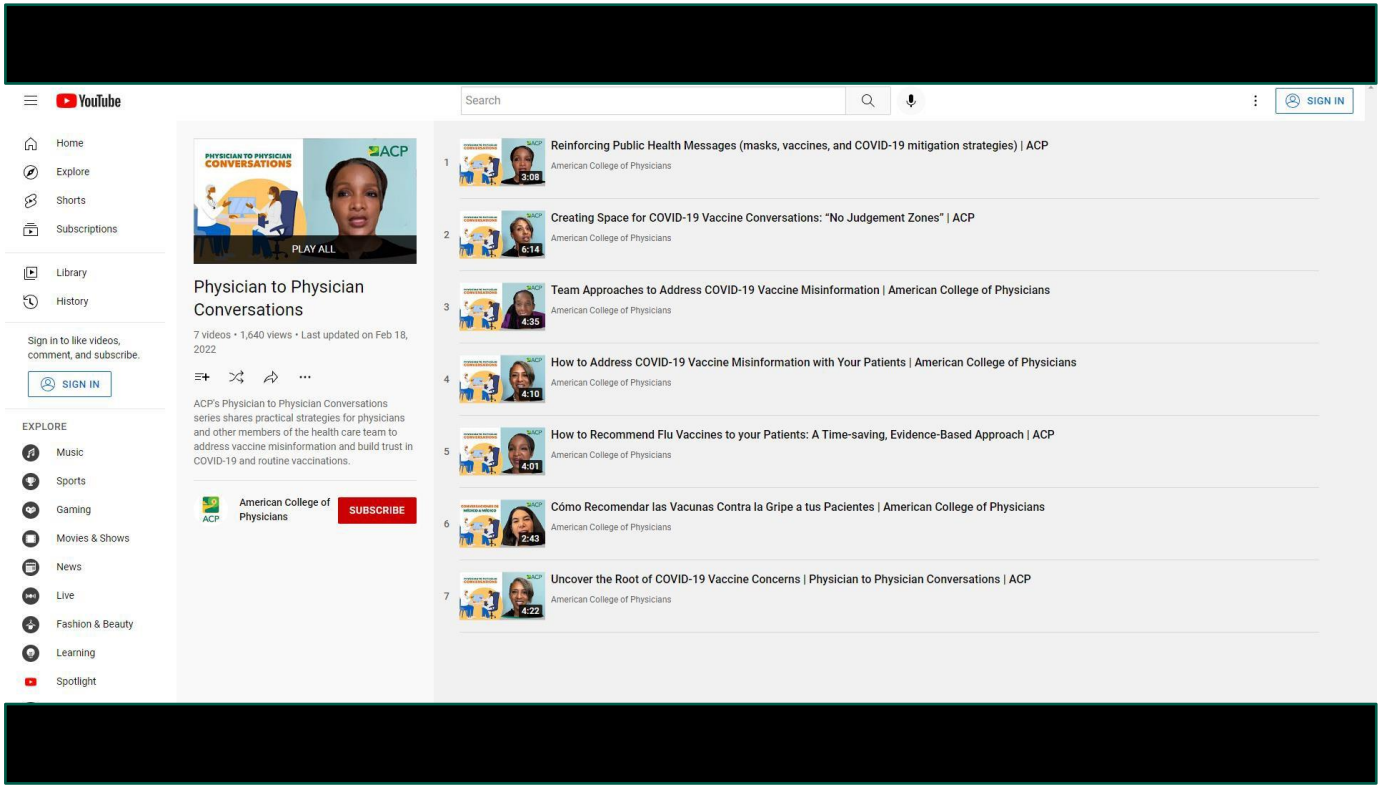
COVID-19 Resources – “Physician to Physician” You Tube (ACP)



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Summary (1)

- COVID-19 Therapeutics ➔ access to outpatient treatments

- Primary care and team based care
- population health approaches
- public health resources
- telemedicine platforms
- pharmacy/pharmacists partnership

Summary (2)

- COVID-19 Vaccinations ➔ "Treatment is not a substitute for vaccination"

- Primary care physicians & clinicians – trusted "vaccine ambassadors"
- "talk COVID-19 vaccines" at every opportunity/visit
- Rebut "waiting for better vaccine"
- focus on vaccine success vs. severe COVID-19
- Prioritize vaccine ambivalent, minoritized communities, limited English proficiency
- combat misinformation/disinformation with resources & data
- "An ounce of prevention is worth a pound of cure." – Benjamin Franklin ➔ well-fitted masks, physical distancing
- **COVID-19 vaccines = "death prevention"**

References (1)

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- CDC Data Tracker Weekly Review: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html
- **COVID-19 Outpatient Treatment Guidelines Roadmap – CDC/IDSA COVID-19 Real Time Learning Network:**
- **https://www.idsociety.org/covid-19-real-time-learning-network/therapeutics-and-interventions/covid-19-outpatient-treatment--guidelines-roadmap/**
- **https://www.idsociety.org/globalassets/covid-19-real-time-learning-network/outpatientroadmap-v10.pdf**
- "Vaccination reduces need for emergency care in breakthrough COVID-19 infections: A multicenter cohort study": https://www.thelancet.com/journals/lanam/article/PIIS2667-193X(21)00061-2/fulltext
- Nirmatrelvir/Ritonavir (Paxlovid™) Point-of-Care Reference: https://www.idsociety.org/covid-19-real-time-learning-network/therapeutics-and-interventions/nirmatrelvir-ritonavir-paxlovid-point-of-care-reference/
- Molnupiravir Quick Point-of-Care Reference: https://www.idsociety.org/globalassets/covid-19-real-time-learning-network/molnupiravir-reference-v4.pdf
- Hospitalization and Emergency Department Encounters for COVID-19 After Paxlovid Treatment — California, December 2021–May 2022: https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e2.htm
- Dispensing of Oral Antiviral Drugs for Treatment of COVID-19 by Zip Code–Level Social Vulnerability — United States, December 23, 2021–May 21, 2022: https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e1.htm#:~:text=Overall%2C%20during%20December%2023%2C%202021,(287.4)%20vulnerability%20zip%20codes
- Effect of Molnupiravir on Biomarkers, Respiratory Interventions, and Medical Services in COVID-19 – 7 June 2022 Annals of Internal Medicine: https://www.acpjournals.org/doi/10.7326/M22-0729

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- Report of Health Care Provider Recommendation for COVID-19 Vaccination Among Adults, by Recipient COVID-19 Vaccination Status and Attitudes — United States, April–September 2021: https://www.cdc.gov/mmwr/volumes/70/wr/mm7050a1.htm
- Effect of Outreach From Primary Care Physicians (PCPs) for COVID-19 Vaccination of Black and Latino Older Adults: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2793497
- **COVID-19 Resources (COVID-19 Forums w/ Annals of Internal Medicine) – American College of Physicians (ACP): https://www.acponline.org/clinical-information/clinical-resources-products/coronavirus-disease-2019-covid-19-information-for-internists/coronavirus-vaccine-resources**
- **COVID-19 Resources – "Ask Your Internist" You Tube (ACP): https://www.youtube.com/playlist?list=PL8cWWG6tbv1PkCWMz8o43xGJ2rpBxRBXa**
- **COVID-19 Resources – "Physician to Physician" You Tube (ACP): https://www.youtube.com/playlist?list=PL8cWWG6tbv1PgMvhDWS2em9RbbyXb9vvn**

On a positive note…

- “We’ll observe how the burdens braved by humankind
  Are also the moments that make us humans kind;
  Let each morning find us courageous, brought closer;
  Heeding the light before the fight is over.
  When this ends, we’ll smile sweetly, finally seeing
  In testing times, we became the best of beings.”
- *April 2020 -* Amanda Gorman - ‘The Miracle of Morning’
- https://www.youtube.com/watch?v=XOieGJl6g4s

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Thank you

- **Elisa Choi, MD, FACP, FIDSA (She/Her)**
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- **Instagram**: **@drelisachoi**
- **Facebook: Dr. Elisa Choi, MD, FACP, FIDSA - https://www.facebook.com/DrElisaChoi/**

- **CDC/IDSA COVID-19 Real Time Learning Network:**
- https://www.idsociety.org/covid-19-real-time-learning-network/
- **Twitter: @RealTimeCOVID19**

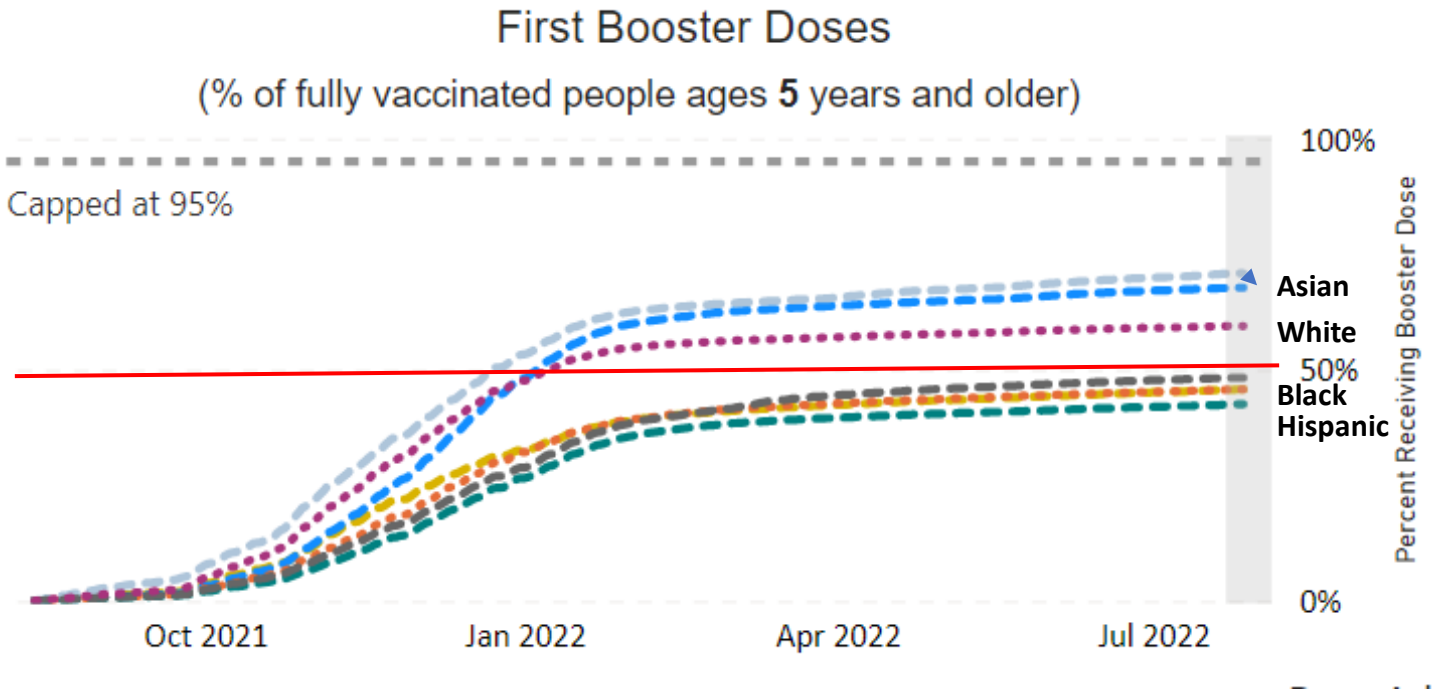
Optimizing COVID-19 booster and new therapeutics uptake among minoritized communities: Lessons Learned

Valeria Cantos, MD

Assistant Professor

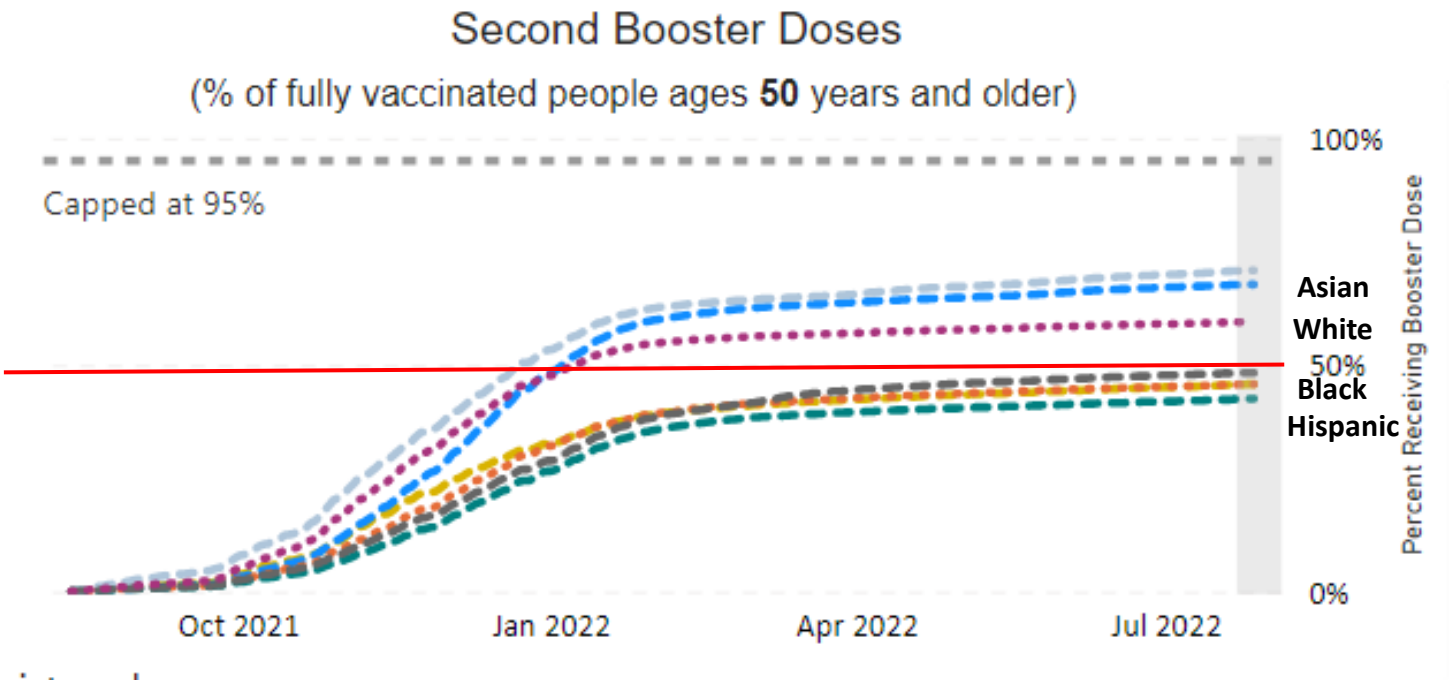
Division of Infectious Diseases, Emory University

COVID-19 Vaccine First Booster Uptake by Race/Ethnicity



Source: CDC COVID Data Tracker

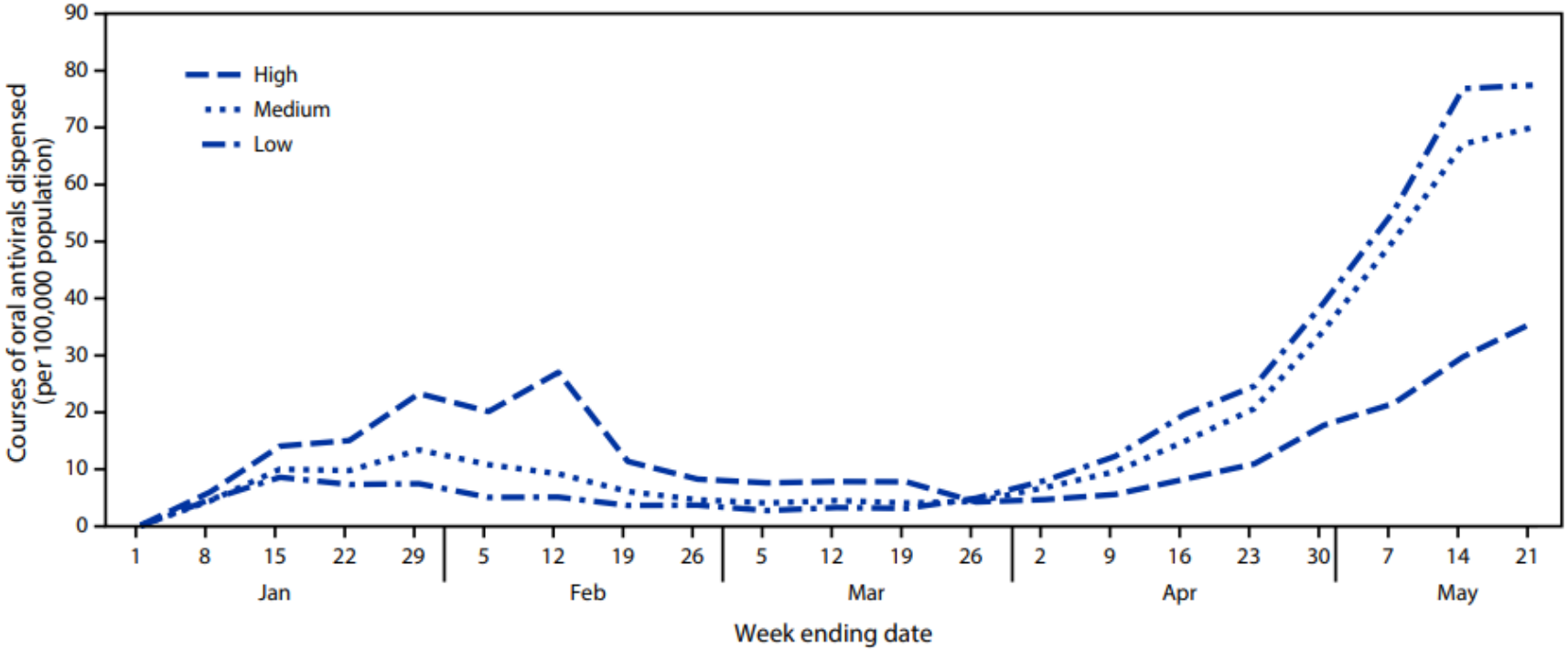
COVID-19 Vaccine Second Booster Uptake by Race/Ethnicity



Source: CDC COVID Data Tracker

Inequities in medication prescription

FIGURE 3. Courses of oral COVID-19 antiviral therapy dispensed per 100,000 persons, by week and zip code social vulnerability level — United States, December 26, 2021–May 21, 2022*



It’s been 2.5 years…

Clinicians are **TIRED**

- Increased workload
- Staff shortages and turnover
- Juggling alternative childcare during school closings
- Recurring cycles of COVID-19 aurges with new variants

Burnout, compassion fatigue, depression, anxiety, PTSD

It’s been 2.5 years…

Patients are **TIRED**

- Continuing financial struggles
- Pandemic fatigue
- Ever changing guidelines and recommendations
- Limited awareness of COVID-19 oral antivirals

“How many more shots will I have to take?”

“Do I really need a booster?”

During clinic visits

- Acknowledge patients' (and your own) hardships and fatigue
- Provide easy to understand information about benefits of boosters, regardless of reason for visit → optimize opportunity for vaccination at every visit
- Avoid shame, blame, scare techniques
- Focus on allowing patients to live their lives, while including risk reduction language
- Include in clinic template notes reminders about COVID-19 vaccination status and due dates for boosters
- Intentionally reach out to patients who belong to minoritized groups to provide direct information about boosters and therapeutics

Sources: Fiscella K, et al, JAMA Health Forum, 2022; WHO

Clinic leadership

- Organize provider's COVID-19 updates to standardize knowledge
- Track equitable distribution of boosters and therapeutics through the EMR and/or pharmacy orders and make adjustments to process as needed
- **Hire staff that belong to minoritized communities (including in leadership positions)**
- Foster a safe space environment for minoritized communities
  - Honest & visible messaging of not sharing personal health information with immigration authorities
- Make all patient-facing content available in their preferred language

Sources: Fiscella K, et al, JAMA Health Forum, 2022; WHO

With the community…

- **Connect with local trusted CBOs** to create community awareness, indications and mortality benefits of COVID-19 boosters and oral antivirals
- Culturally and linguistically appropriate information
- Important to include ACCESS guidance

COVID 19 y la Comunidad Latina: Preguntas y Respuestas

2.3K views · 2 years ago

COVID-19 Vaccines and the Latino Community

760 views · a year ago

Tu salud, tu familia, tú decides: Las vacunas de refuerzo o boosters

986 views · 38 weeks ago

Source: Fiscella K, et al, JAMA Health Forum, 2022

With the community…

- Learn from **YOUR** local minoritized communities
- Understand the main motivators and barriers of the communities you care for related to vaccine uptake

- Limited access to information
- Difficulties with online content
- Limited transportation
- Inability to miss work to attend visits
- Language barriers with clinic staff and providers
- Fear of deportation when accessing services

With the community….

Advocacy: use your privilege as a HCW to shine a light on inequities and advocate for change at the clinic, community, state and federal level

Q&A/
Discussion

Selected Resources

COVID-19 Update: Dr. Butler

- https://covid.cdc.gov/covid-data-tracker/#datatracker-home
- https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions
- https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-additional-dose-totalpop
- https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Outpatient Therapy Update: Dr. Sullivan

- https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/
- https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/hospitalized-adults--therapeutic-management/
- https://www.covid19treatmentguidelines.nih.gov/therapies/
- https://aspr.hhs.gov/COVID-19/Therapeutics/orders/Pages/default.aspx
- https://app.smartsheet.com/b/form/21e4312a2985457f982bb2738cf82744
- https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/
- https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/
- https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html
- https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/outpatient-treatment-overview.html
- https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

Selected Resources

Outpatient Therapy Update Cont.: Dr. Sullivan

- https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e2.htm?s_cid=mm7125e2_w
- https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7125e2-H.pdf
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- https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Paxlovid/Pages/default.aspx
- https://www.fda.gov/media/155050/download
- https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e1.htm?s_cid=mm7125e1_e&ACSTrackingID=USCDC-921_DM84696&ACSTrackingLabel=This%20Week%20in%20MMWR%20-%20Vol.%2071%2C%20June%2024%2C%202022&deliveryName=USCDC-921_DM84696
- https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension#COVIDtherapeutics
- https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-28June2022.aspx
- https://www.fda.gov/media/155050/download
- https://www.fda.gov/media/155049/download
- https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension#COVIDtherapeutics

Selected Resources

Clinician-Focused Strategies to Increase Treatment & Vaccine Uptake: Dr Choi

- https://www.thelancet.com/journals/lanam/issue/vol4nonull/PIIS2667-193X(21)X0005-1
- https://www.idsociety.org/covid-19-real-time-learning-network/therapeutics-and-interventions/covid-19-outpatient-treatment--guidelines-roadmap/
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- https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00320-6/fulltext
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- https://www.cdc.gov/vaccines/covid-19/health-departments/addressing-vaccine-misinformation.html)

Program Links:

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

THANK YOU

We want to hear from you!

Please complete the post-call survey.

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

-- library of all past calls available --

Contact Us:

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