CDC/IDSA Clinician Call

March 14, 2024

Welcome & Introductions

Dana Wollins, DrPH, MGC
Senior Vice President, Strategy
Infectious Diseases Society of America

- About the Clinician Call: Initiated in 2020 as a forum for information sharing among frontline clinicians caring for patients with COVID-19. Now expanded to address timely topics in infectious diseases—all from a clinical perspective.

- 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.
Updates on CDC’s New Respiratory Virus Guidance, COVID Antivirals & the Emergence of Clade I Mpox
1. Clade-1 Monkeypox Virus – Informational Update and U.S. Preparedness

Agam Rao, MD, FIDSA
CAPT, U.S. Public Health Service
Medical Officer
Poxvirus and Rabies Branch
U.S. Centers for Disease Control & Prevention

2. CDC’s New Respiratory Virus Guidance

Brendan Jackson, MD, MPH
CDR, U.S. Public Health Service
Lead, Respiratory Viruses Response
U.S. Centers for Disease Control & Prevention

3. COVID-19 Antivirals: Closing the Treatment Gap

COVID-19 Epidemiology Update
Pragna Patel, MD, MPH
Chief Medical Officer
Coronavirus & Other Respiratory Viruses Division
National Center for Immunization & Respiratory Diseases
U.S. Centers for Disease Control & Prevention

Real-World Effectiveness of COVID-19 Antivirals: The Latest Data
Therese Tripler, PhD
Scientific Program Manager
National Center for Advancing Translational Sciences
National Institutes of Health

Closing the Treatment Gap Clinical Considerations
Peter V. Chin-Hong, MD
Professor of Medicine and
Associate Dean for Regional Campus
Director, Transplant and Immunocompromised
Host Infectious Disease Program
University of California, San Francisco

4. Q&A/Discussion
Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button
Clade-1 Monkeypox Virus – Informational Update and U.S. Preparedness

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Clade I Monkeypox virus—Informational Update and U.S. Preparedness

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March 14, 2024
Global Monkeypox virus (MPXV) Clade II outbreak, 2022-present

- Associated with Clade II which is endemic in certain African countries
- First U.S. cases associated with travel
- Primarily affecting gay, bisexual, and other men who have sex with men (MSM); transgender and nonbinary persons
- Associated with person-to-person spread via close skin-to-skin contact (including sex)
- Deaths have occurred, primarily among persons with severe immunocompromise from advanced HIV
- U.S. case counts and deaths comprising more than a third of global cases
  - >32,000 U.S. cases
  - 58 U.S. deaths
Clade II MPXV: Countries historically known to be endemic
Mpx Clade II Epi-Curve—United States, 2022-present

Peak Daily Cases (7-day average):
467 cases
U.S. Clade II cases continue to occur

Peak Daily Cases (7-day average): 11 cases
ACIP recommends vaccination with the 2-dose JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox

**Persons at risk**

- 1. Gay, bisexual, and other men who have sex with men, 2. transgender people or 3. nonbinary people who, in the past 6 months, have had one of the following
  - New diagnosis of ≥ 1 sexually transmitted disease
  - More than one sex partner
  - Sex at a commercial venue
  - Sex in association with a large public event in a geographic area where mpox transmission is occurring
- Sexual partners of persons with the risks described above
- Persons who anticipate experiencing any of the above
### Mpox vaccine on routine immunization schedule

#### Table 1: Recommended Adult Immunization Schedule by Age Group, United States, 2024

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>19–26 years</th>
<th>27–49 years</th>
<th>50–64 years</th>
<th>≥65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COVID-19</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inactivated (IIV4) or</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza recombinant (rIFN4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Influenza live, attenuated</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(LAN-IV)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory Syncytial Virus</strong></td>
<td>Seasonal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(RSV)</td>
<td>administration during pregnancy. See Notes.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tetanus, diphtheria, pertussis</strong></td>
<td>1 dose Tdap</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Tdap or Td)</td>
<td>each pregnancy; 1 dose Td/Tdap for wound management (see notes)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Measles, mumps, rubella</strong></td>
<td>1 dose Tdap, then Td or Tdap booster every 10 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(MMR)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Varicella</strong> (VAR)</td>
<td>2 doses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(if born in 1995 or later)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Zoster recombinant</strong> (ZCV)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Human papillomavirus</strong> (HPV)</td>
<td>2 or 3 doses depending on age at initial vaccination or condition</td>
<td>27 through 45 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(PCV13, PCV20, PPSV23)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Pneumococcal</strong> (PCV15, PCV20, PPSV23)</td>
<td>2, 3, or 4 doses depending on vaccine</td>
<td>2, 3, or 4 doses depending on vaccine</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hepatitis A</strong> (HepA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Hepatitis B</strong> (HepB)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Meningococcal A, C, W, Y</strong></td>
<td>1 or 2 doses depending on indication, see notes for booster recommendations</td>
<td>1 or 2 doses depending on indication, see notes for booster recommendations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(MenACWY)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Meningococcal B</strong> (MenB)</td>
<td>2 or 3 doses depending on vaccine and indication, see notes for booster recommendations</td>
<td>19 through 23 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Haemophilus influenzae type b</strong> (Hib)</td>
<td>1 or 3 doses depending on indication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mpox</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of immunity**
- **Recommended vaccination for adults with an additional risk factor or another indication**
- **Recommended vaccination based on shared clinical decision-making**
- **No recommendation/Not applicable**

Overall vaccine coverage
1-dose: 40% and 2-dose: 25%

*Data reported to CDC between May 22, 2022 and January 9, 2024*
Clade I MPXV
At this time, no Clade I cases identified outside of countries known to be endemic for this MPXV clade
Clade I MPXV: Countries historically known to be endemic
Ongoing Clade I outbreak: Democratic Republic of Congo

- Identified in parts of the country without previous cases
- Some cases associated with sex; however, both genders involved
- Children most affected
**Ongoing suspected* Clade I outbreak—Democratic Republic of Congo**

<table>
<thead>
<tr>
<th>Year</th>
<th>Suspected Cases</th>
<th>Suspected Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021</td>
<td>2,497</td>
<td>68</td>
</tr>
<tr>
<td>2022</td>
<td>5,697</td>
<td>234</td>
</tr>
<tr>
<td>2023</td>
<td>14,626</td>
<td>654</td>
</tr>
<tr>
<td>2024 Total (Week 9)*</td>
<td>3,576 (+365)</td>
<td>265 (+25)</td>
</tr>
</tbody>
</table>

*Most cases are based on clinical suspicion; only a fraction of cases are laboratory-confirmed

§ Preliminary data for weeks 1-9 and subject to change. Note cases numbers reported in previous epi weeks may increase or decrease in the current week’s data. This can result in changes in the cumulative number of cases reported. Additional investigation is underway.
<table>
<thead>
<tr>
<th>Ways in which both clades are similar</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical presentation</strong></td>
</tr>
<tr>
<td>Firm, deep-seated, sometimes umbilicated lesions; presents along a clinical continuum (mild to severe)</td>
</tr>
<tr>
<td><strong>Transmission of virus</strong></td>
</tr>
<tr>
<td>Contact with skin lesions, fomites, respiratory secretions (e.g., via kissing)</td>
</tr>
<tr>
<td><strong>Diagnostic testing</strong></td>
</tr>
<tr>
<td>FDA cleared non-variola orthopoxvirus (NVO) test used by many laboratories</td>
</tr>
<tr>
<td><strong>Hospital waste management</strong></td>
</tr>
<tr>
<td>Category B*</td>
</tr>
<tr>
<td><strong>IPC for healthcare providers</strong></td>
</tr>
<tr>
<td>Gown, gloves, eye protection, N-95; in addition to standard precautions, suspected mpox infections have additional IPC precautions</td>
</tr>
<tr>
<td><strong>Patient management</strong></td>
</tr>
<tr>
<td>Dependent on severity of illness or potential for severe illness</td>
</tr>
<tr>
<td><strong>Use of JYNNEOS vaccine and therapeutics</strong></td>
</tr>
<tr>
<td>Expected to be effective regardless of clade</td>
</tr>
</tbody>
</table>


§ https://www.cdc.gov/poxvirus/mpox/clinicians/infection-control-healthcare.html
<table>
<thead>
<tr>
<th></th>
<th>Ways in which Clade I cases differ from Clade II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Populations impacted</td>
<td>Might not affect predominantly MSM; uncertain if other populations could be impacted</td>
</tr>
<tr>
<td>Clinical presentation</td>
<td>More of the severe cases <em>could</em> occur: disseminated lesions, prodromal symptoms, hospitalization</td>
</tr>
<tr>
<td>Diagnostic testing</td>
<td>Clade II specific testing available in some labs but not others</td>
</tr>
<tr>
<td>IPC for healthcare providers</td>
<td>Patients may shed more virus; adherence to IPC practices* particularly important</td>
</tr>
</tbody>
</table>

*https://www.cdc.gov/poxvirus/mpox/clinicians/infection-control-healthcare.html
Interim clinical guidance for severe MPXV infections (regardless of Clade)

- Tecovirimat (intravenous or oral)
- Brincidofovir or cidofovir
- Vaccinia immune globulin intravenous
- Trifluridine ophthalmic solution

- CDC, through health departments, available for consultations for severe mpox (i.e., involving patients with severe immunocompromise)

https://www.cdc.gov/mmwr/volumes/72/wr/mm7209a4.htm?s_cid=mm7209a4_w
CDC’s preparedness messaging*

- Remain vigilant to Clade II MPXV: it has never gone away
  - Continue to include MPXV on differential for consistent rash, particularly in the setting of epidemiologic risk factors
  - Encourage vaccinations for eligible persons during clinic appointments
- Regardless of clade, treatment is dependent on severity of infection
- At this time, no Clade I cases outside of endemic countries
- If cases identified in U.S., characterization of illnesses and additional guidance (including regarding vaccinations) will be provided

*https://emergency.cdc.gov/han/2023/han00501.asp
Additional guidance

- For patients with mpox and a history of recent travel to DRC, contact public health authorities as soon as possible so that Clade specific testing can be expedited.
- Regardless, clade specific testing is occurring for most positive specimens in the United States; CDC is collaborating with many private and public health laboratories.
Thank you
poxvirus@cdc.gov

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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CDC’s New Respiratory Virus Guidance

Brendan Jackson, MD, MPH
CDR, U.S. Public Health Service
Lead, Respiratory Viruses Response
U.S. Centers for Disease Control & Prevention
Goals of the Respiratory Virus Guidance

To provide streamlined guidance built on effective strategies so that more people take action to prevent respiratory disease.

- **Provide practical recommendations** that are clear and actionable.
- **Streamline** guidance across common respiratory virus illnesses.
- **Highlight strategies** that **effectively reduce risk**.
- **Balance** current, post-emergency risks with other health and societal needs.
The COVID-19 Threat has Changed

**DRIVERS**

Effective vaccines and treatments
Each cut the risk of severe disease in half

Broad immunity
>98% of US population now has some protective immunity from vaccination, prior infection, or both, BUT this subscription needs to be renewed with updated vaccines

Other effective tools
Masks, hygiene, steps for cleaner air, tests

**RESULTS**

Fewer hospitalizations
Weekly hospital admissions down >75% from Jan 2022 peak; now in range of flu; 95% of people hospitalized with COVID-19 not up to date on vaccine

Fewer deaths
COVID-19 went from the 3\textsuperscript{rd} leading cause of death in 2021 to 10\textsuperscript{th} in 2023

Fewer cases of other complications
Multisystem inflammatory syndrome in children (MIS-C) and Long COVID are now also less common
Vaccination Protects Against Severe Outcomes

![Bar chart showing the weighted percentage of hospitalizations by age group and vaccination status. The chart includes age groups 18-49 years, 50-64 years, ≥65 years, and all adults ≥18 years. The vaccination status categories are: No record of bivalent or updated monovalent dose, Bivalent booster, but no updated monovalent dose, and Updated monovalent dose. The chart indicates a higher percentage of hospitalizations for patients with no record of vaccination compared to those with updated monovalent doses.]
>98% of the US population now has some protective immunity
COVID-19 test positivity has remained elevated, but deaths have declined substantially.

Provisional COVID-19 Deaths and COVID-19 Nucleic Acid Amplification Test (NAAT) Percent Positivity, by Week, in The United States, Reported to CDC.

Sources: Provisional Deaths from the CDC’s National Center for Health Statistics (NCHS) National Vital Statistics System (NVSS) National Respiratory and Enteric Virus Surveillance System (NREVSS) Figure from CDC’s COVID Data Tracker.
CDC’s Respiratory Virus Guidance provides **practical recommendations and information** to help people lower health risks posed by a range of common respiratory viral illnesses.

It includes **core** and **additional prevention strategies**.
Layering prevention strategies can be especially helpful when:

- Respiratory viruses are causing a lot of illness in your community
- You or those around you have risk factors for severe illness
- You or those around you were recently exposed, are sick, or are recovering

*Stay home and away from others until, for 24 hours BOTH:

- Your symptoms are getting better
- You are fever-free (without meds)

Then take added precaution for the next 5 days
Have respiratory virus symptoms that aren’t better explained by another cause?

1. Stay home and away from others
   When, for 24 hours, both your symptoms are improving overall and you haven’t had a fever (without fever-reducing medicine), you can move to the next step.

2. Resume normal activities taking precaution for the next 5 days such as taking additional steps for cleaner air and/or hygiene, masks, physical distancing, and/or testing when you will be around other people indoors.
Test positive for a respiratory virus but you have no symptoms?

1. **Take precaution for the next 5 days** such as taking additional steps for cleaner air and/or hygiene, masks, physical distancing, and/or testing when you will be around other people indoors.
Risk Factors for Severe Illness Pages

- In addition to the general Respiratory Virus Guidance, there are several special consideration pages related to people with certain risk factors for severe illness:
  - Older Adults
  - Young Children
  - People with Weakened Immune Systems
  - Pregnant Persons
  - People with Disabilities
Thank You

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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COVID-19 Antivirals: Closing the Treatment Gap

COVID-19 Epidemiology Update
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Chief Medical Officer
Coronavirus & Other Respiratory Viruses Division
National Center for Immunization & Respiratory Diseases
U.S. Centers for Disease Control & Prevention
COVID-19 Epidemiology

Pragna Patel, MD MPH
Chief Medical Officer
March 14, 2024
Emergency Department Visits for Viral Respiratory Illness
October 1, 2022 to March 2, 2024

Total number of new hospital admissions of patients with laboratory-confirmed COVID-19 and influenza in the previous week (including both adult and pediatric patients), reported to CDC’s National Healthcare Safety Network (NHSN); data as of 3/6/24, data through 3/2/24. Respiratory Virus Data Channel Weekly Snapshot (cdc.gov)
Hospital Admissions Due to COVID-19 and Influenza
October 1, 2022 to March 2, 2024

Total number of new hospital admissions of patients with laboratory-confirmed COVID-19 and influenza in the previous week (including both adult and pediatric patients), reported to CDC’s National Healthcare Safety Network (NHSN); data as of 3/7/24, data through 3/2/24. Respiratory Virus Data Channel Weekly Snapshot (cdc.gov)
Percent of weekly COVID-19-associated hospitalization by age group, March 1, 2020 – January 27, 2024

Weekly population-based rates of COVID-19-associated hospitalization among adults ages ≥65 years, January 1, 2023 – January 27, 2024

Thin dashed lines on the far right indicate potential reporting delays and interpretation of trends should exclude these weeks.

Vaccination Status by Age Group among Adults Ages ≥18 Years Hospitalized with COVID-19, October–November 2023 (Preliminary)

Data from COVID-NET. Data are preliminary as they only include two months of hospitalization data for which the updated monovalent vaccine dose was recommended. Continued examinations of vaccine registry data are ongoing. No record of bivalent or updated monovalent dose: No recorded doses of COVID-19 bivalent or updated 2023-2024 monovalent dose. Bivalent booster, but no updated monovalent doses: Received COVID-19 bivalent booster vaccination but no record of receiving updated 2023-2024 monovalent booster dose. Updated monovalent dose: Received updated 2023-2024 monovalent dose. Persons with unknown vaccination status are excluded.
### Percent with Underlying Medical Conditions among Adults Ages ≥18 Years hospitalized with COVID-19, by Age Group, October 2022–October 2023

<table>
<thead>
<tr>
<th>Condition</th>
<th>18–49 yrs</th>
<th>50–64 yrs</th>
<th>65–74 yrs</th>
<th>≥75 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic lung disease</td>
<td>24</td>
<td>37</td>
<td>45</td>
<td>35</td>
</tr>
<tr>
<td>Asthma</td>
<td>19</td>
<td>17</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>COPD/Bronchitis</td>
<td>4</td>
<td>16</td>
<td>24</td>
<td>17</td>
</tr>
<tr>
<td><strong>Cardiovascular disease</strong></td>
<td><strong>21</strong></td>
<td><strong>47</strong></td>
<td><strong>60</strong></td>
<td><strong>67</strong></td>
</tr>
<tr>
<td>CAD/CABG/MI</td>
<td>5</td>
<td>16</td>
<td>26</td>
<td>28</td>
</tr>
<tr>
<td>CHF/Cardiomyopathy</td>
<td>6</td>
<td>19</td>
<td>24</td>
<td>25</td>
</tr>
<tr>
<td>Stroke/TIA</td>
<td>3</td>
<td>12</td>
<td>15</td>
<td>21</td>
</tr>
<tr>
<td>Diabetes</td>
<td>21</td>
<td>40</td>
<td>44</td>
<td>38</td>
</tr>
<tr>
<td>Immunocompromising condition</td>
<td>12</td>
<td>19</td>
<td>21</td>
<td>13</td>
</tr>
<tr>
<td>Neurologic condition</td>
<td>18</td>
<td>26</td>
<td>30</td>
<td>42</td>
</tr>
<tr>
<td>Dementia</td>
<td>0</td>
<td>1</td>
<td>6</td>
<td>28</td>
</tr>
<tr>
<td>Renal Disease</td>
<td>8</td>
<td>22</td>
<td>23</td>
<td>31</td>
</tr>
<tr>
<td>Obesity</td>
<td>42</td>
<td>43</td>
<td>38</td>
<td>22</td>
</tr>
</tbody>
</table>
COVID-19 Deaths and COVID-19 Nucleic Acid Amplification Test (NAAT) Percent Positivity, by Week, March 1, 2020 – March 2, 2024

Provisional Deaths from the CDC’s National Center for Health Statistics (NCHS) National Vital Statistics System (NVSS) National Respiratory and Enteric Virus Surveillance System (NREVSS) Figure from CDC’s COVID Data Tracker.
Current SARS CoV-2 Variant Proportions in the United States
November 12, 2023 to March 2, 2024

- JN.1 is the predominant variant in the United States
- JN.1 is similar to BA.2.86 but has an additional mutation in the spike protein which increased its transmissibility
- No evidence that JN.1 causes more severe illness than previous variants
- Existing vaccines, tests, and treatments work well against JN.1

Weighted and Nowcast estimates in United States for 2-week periods from November 12, 2023 to March 2, 2024. Available at: CDC COVID Data Tracker: Variant Proportions and CDC Continues to Track the Growth of JN.1 | CDC
COVID-19 Antivirals: Closing the Treatment Gap

Real-World Effectiveness of COVID-19 Antivirals: The Latest Data
Therese Tripler, PhD
Scientific Program Manager
National Center for Advancing Translational Sciences
National Institutes of Health
NCATS OpenData Portal: A curated resource on the real-world effectiveness of COVID-19 antivirals

Therese Tripler, PhD
Scientific Project Manager
Curator: Real-World Evidence Studies & Clinical Data
therese.tripler@nih.gov
The NIH-led research response to COVID-19

Investment, collaboration, and coordination have been key.

DOI: 10.1126/science.adf5167
NCATS OpenData Portal

Variants & Therapeutics

Pandemic History Explorer
Browse activity data based on variant prevalence over time.

In vitro Activity Visualization
Explore interactive graphs with variant activity data.

Data Summary
View high-level summary of variant data.

Dataset Browser
Search, view and download individual datasets.

Booster Comparisons

Heterologous Booster Activity
Explore and compare heterologous booster data.

Multivalent Booster Activity
Explore and compare multivalent booster data.

About this Data

How to Read Variant Data
Learn more about these curated in vitro datasets.

Data Glossary
View column definitions for datasets.

Therapeutic Assay Overview
Explore interactive graphs with variant activity data.
how COVID-19 antivirals are affecting real-world outcomes
Goal: collect published real-world outcomes for approved COVID-19 therapeutics and enable users to browse high-level summaries of the data

Which Real-World Evidence studies are being collected?

Preprints/publications met the following inclusion criteria:

1. Included a COVID-19 EUA or FDA approved or revoked therapeutic
2. Included a metric of analysis, such as hazard or odds ratio
3. Included a comparator or control in analysis
4. Reported a cohort size ≥ 10

Link: https://opendata.ncats.nih.gov/covid19/variant/real-world-evidence
# Real-World Evidence Studies of COVID-19 Therapeutics

Browse high-level summaries of real-world outcomes for EUA/EMA approved and revoked COVID-19 therapeutics.

**Which Real-World Evidence studies are being collected here?**

Download real-world evidence dataset here

---

## FILTER BY

### Treatment:
- Bamlatirvimab
- Bamlatirvimab/Etesevimab
- Bebtelovimab/Evusheveld
- Molnupiravir
- Paxlovid
- Remdesivir
- Sotrovimab

### Endpoint:
- Hospitalization
- Mortality
- Other

### Lineage (Variant):
- Alpha, Gamma, Delta, Beta, Eta
- Delta
- Delta, Omicron
- N/R
- Omicron
- Wild type and alpha

## 49 entries found

<table>
<thead>
<tr>
<th>Title</th>
<th>Publication Date</th>
<th>Treatment(s)</th>
<th>Study Start</th>
<th>Study End</th>
<th>Summary</th>
<th>Viral Lineage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real-World Effectiveness of Remdesivir...</td>
<td>12/18/2021</td>
<td>Remdesivir (36856); Control (36856)</td>
<td>2/23/2020</td>
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## Real-World Evidence Studies of COVID-19 Therapeutics

Browse high-level summaries of real-world outcomes for EUA/FDA approved and revoked COVID-19 therapeutics. Which Real-World Evidence studies are being collected here?

Download real-world evidence dataset here

### FILTER BY
- **Treatment:**
- **Endpoint:**
- **Lineage (Variant):**

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| Note: * = Composite outcome for this metric; ** = Composite of therapies in outcome metric; † = COVID-19 related hospitalization and/or mortality; ‡ = All-cause hospitalization and/or mortality; N/A = Not applicable; N/R = Not reported

[Download real-world evidence dataset here]
## Real-World Evidence Studies of COVID-19 Therapeutics

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### Mortality Metric

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<td>Relative risk</td>
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<td>Adjusted risk ratio</td>
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<td>Hazard ratio</td>
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### Notes

- In Paxlovid-eligible patients, treatment was associated with decreased risk of hospitalization and death.

### Additional Information

- Adequate COVID-19 vaccination: No: 0.52 (0.32–0.82); N/R | *0.43 (0.85–0.64); N/R |
- Age < 60 years: 1.06 (0.36–3.15); N/R | *Age ≥ 60 years: 0.52 (0.36–0.73); N/R |
- Malos: 0.60 (0.40–0.91); N/R | *Females: 0.46 (0.26–0.80); N/R; *Arab: 0.75 (0.52–1.17); N/R |
- Ultra-Orthodox Jewish: 0.39 (0.95–2.89); N/R | *General Jewish: 0.53 (0.37–0.70); N/R |
- Socioeconomic status: Low: 0.74 (0.42–1.29); N/R; *Mild: 0.47 (0.29–0.75); N/R; *High: 0.45 (0.21–0.97); N/R |
- Diabetes: No: 0.6 (0.40–0.93); N/R | *Yes: 0.44 (0.25–0.75); N/R |
- Cardiovascular disease: No: 0.64 (0.41–1.00); N/R | *Yes: 0.43 (0.26–0.70); N/R |
- Chronic lung disease: No: 0.45 (0.30–0.67); N/R | *Yes: 0.96 (0.63–1.31); N/R |
- Chronic kidney disease:
# Real-World Evidence Studies of COVID-19 Therapeutics

Browse high-level summaries of real-world outcomes for FDA/FDA approved and revoked COVID-19 therapeutics. Which Real-World Evidence studies are being collected here?

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</table>

**Mortality Endpoint**

- Adjusted hazard ratio, ≥65 yr
- Adjusted hazard ratio, > 65 yrs
- Adjusted hazard ratio, ≥ 60 yrs
- Adjusted hazard ratio, < 60 yrs
- Adjusted hazard ratio, Adequate COVID-19 V
- Adjusted hazard ratio, Diabetics
- Adjusted hazard ratio, Cardiovascular disease
- Adjusted hazard ratio, No Diabetes
- Adjusted hazard ratio, Diabetics
- Adjusted hazard ratio, No Cardiovascular disease
- Adjusted hazard ratio, Chronic kidney disease
- Adjusted hazard ratio, Chronic lung disease
- Adjusted hazard ratio, Malignancy in year
- Adjusted hazard ratio, Malignancy in year
- Adjusted hazard ratio, No neurological disease
- Adjusted hazard ratio, Neurological disease
- Adjusted hazard ratio, No Chronic kidney disease
- Adjusted hazard ratio, Chronic kidney disease
- Adjusted hazard ratio, Chronic lung disease
- Adjusted hazard ratio, Malignancy in year
- Adjusted hazard ratio, No Immunocompromise
- Adjusted hazard ratio, Immunocompromise
- Adjusted hazard ratio, No Immunocompromise
- Adjusted hazard ratio, Immunocompromise
- Adjusted hazard ratio, General Immune
- Adjusted hazard ratio, Ultra-Orthodox Jewish
- Adjusted hazard ratio, Arab
- Adjusted hazard ratio, Females
- Adjusted hazard ratio, Males
- Adjusted hazard ratio, 30-60 yrs
- Adjusted hazard ratio, < 60 yrs
- Adjusted hazard ratio, Inadequate COVID-19 V
- Adjusted hazard ratio, Inadequate COVID-19 V
- Adjusted hazard ratio, Inadequate COVID-19 V
- Adjusted hazard ratio, Inadequate COVID-19 V
- Adjusted hazard ratio, Inadequate COVID-19 V
- Adjusted risk ratio, Obesity (BMI ≥30.0 kg/m²)
- Adjusted risk ratio, Obesity (BMI ≥30.0 kg/m²)
- Adjusted risk ratio, mAb Screening Score 24
- Adjusted risk ratio, mAb Screening Score 23
- Adjusted risk ratio, Last V >20 wk prior
- Adjusted risk ratio, Last V >20 wk prior
- Adjusted risk ratio, V
- Adjusted risk ratio, Not fully V
- Adjusted risk ratio, 265 yrs
- Adjusted risk ratio, 50-64 yrs
- Adjusted risk ratio, 40-49 yrs
- Adjusted risk ratio, 40-49 yrs
- Adjusted risk ratio, 265 yrs
- Adjusted risk ratio, 265 yrs
- Adjusted risk ratio, 265 yrs
- Adjusted risk ratio, 265 yrs
- Adjusted risk ratio, 265 yrs

**The data may be from preliminary reports that have not been peer reviewed and thus should not be regarded as conclusive, guide clinical practice or health decisions, or be reported in news media as established information.**
## Real-World Evidence Studies

Resource currently includes RWE data from:

- **49 Publications**
- **9 COVID-19 EUA/FDA approved/revoked treatments:**
  - Paxlovid
  - Molnupiravir
  - Remdesivir
  - Sotrovimab
  - Evusheld
  - Ronapreve
  - Bamlanivimab
  - Bamlanivimab+Etesevimab
  - Bebetlovimab

### Multiple Endpoints:
- Hospitalization
- Mortality
- Other (severe disease, supplemental oxygen, etc)

### Multiple Outcomes:
- Hazard, odds, relative risk ratios and more

---

### Future directions:
A comprehensive systematic review and meta-analysis on this data is underway!
OpenData Portal Team

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Sci. Project Manager

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Contact us / Learn more!

Please reach out with any questions, feedback, or collaborative queries!

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OpenData Portal team: opendataportal@nih.gov

Other COVID resources on OpenData Portal:

**Variants & Therapeutics**
Explore and interact with >21k points of in vitro variant activity data compiled from preprints & publications

**In vivo Variants**
Browse high-level summaries of published/shared datasets with in vivo models of SARS-CoV-2 variant infection

**Heterologous & Multivalent Booster Datasets**
Explore and compare heterologous and multivalent booster data

**Therapeutic Glossary**
See data available on OpenData for each COVID-19 Therapeutic
COVID-19 Antivirals: Closing the Treatment Gap

*Closing the Treatment Gap Clinical Considerations*

Peter V. Chin-Hong, MD
Professor of Medicine and
Associate Dean for Regional Campus
Director, Transplant and Immunocompromised Host Infectious Disease Program
University of California, San Francisco
COVID-19 Antivirals
Closing the Treatment Gap
Clinical Considerations

Peter Chin-Hong MD
UCSF
March 14, 2024
Disclosures

None
Barriers

• Health system

• Patient
  • Apathy
  • Diagnostic test availability (time is money)
  • Adverse effects
  • Cost
  • Misinformation

• Clinician
  • Who to treat?
  • Fear of rebound
  • Drug-drug interactions
Barriers

• Health system

• Patient
  • Apathy
  • Diagnostic test availability (time is money)
  • Adverse effects
  • Cost
  • Misinformation

• Clinician
  • Who to treat?
  • Fear of rebound
  • Drug-drug interactions

10% Americans very concerned that they will be hospitalized

How Americans View the Coronavirus, COVID-19 Vaccines Amid Declining Levels of Concern

Continued decline in share of U.S. adults with up-to-date vaccination

Pew Research Center 3/7/24
Barriers

- Health system
- Patient
  - Apathy
  - Diagnostic test availability (time is money)
  - Adverse effects
  - Cost
  - Misinformation
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  - Fear of rebound
  - Drug-drug interactions

Free COVID tests: Why you can no longer order through government program via USPS delivery

Published 8:21 a.m. ET March 8, 2024 | Updated 8:41 a.m. ET March 11, 2024

USA Today 3/8/24
Barriers

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Pfizer to price COVID treatment Paxlovid at $1,390 per course

By Michael Eman
October 18, 2023 5:15 PM PDT - Updated 5 months ago

Reuters 10/18/24
Barriers

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  • Apathy
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• Clinician
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  • Fear of rebound
  • Drug-drug interactions

Are You an Anti-Paxxer?
As doctors drop Paxlovid because of drug interactions and research shows it causes Covid rebounds and virus shedding, Pfizer and MSM crank the PR machine to hide the facts and shame "anti-paxxers."

LINDA BONVIE
FEB 9, 2024

Rescue with Michael Capuzzo 2/9/24
Barriers

• Health system

• Patient
  • Apathy
  • Diagnostic test availability (time is money)
  • Adverse effects
  • Cost
  • Misinformation

• Clinician
  • Who to treat?
  • Fear of rebound
  • Drug-drug interactions

Why Aren't More Doctors Prescribing Paxlovid to High-Risk Patients?
— It's not all about drug-drug interactions, experts say

by Katherine Kahn, Staff Writer, MedPage Today; Cheryl Clark, Contributing Writer, MedPage Today
January 29, 2024
Last Updated February 1, 2024
COVID antiviral myths

• Population immunity is high so my patient doesn’t need Paxlovid
• My patients have a high chance of rebound if they take Paxlovid
• My patient has mild symptoms so Paxlovid or other early therapies won’t help
• Drug-drug interactions make it impossible for my patient for my patient to get early therapy
• Paxlovid is easy to get after I prescribe it

Good news: Deaths down. Not so good news: Still 576 deaths/week in US (95% no recent COVID vaccine)

https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00
COVID antiviral myths

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- Paxlovid is easy to get after I prescribe it

Small studies with mixed findings, short follow up, diff pop (Paxlovid 20-32%, no treatment 2-20%)
Difference between virologic and symptomatic rebound
When it occurs, rebound is brief and mild

Smith D et al, MMWR 72(51)
Harrington P et al, MMWR 72(51)

Smith-Jeffcoat S et al, CID, 11/14/23
Edelstein G et al, Annals Intern Med, 11/14/23
COVID antiviral myths

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Monarch PA et al, MMWR, 2024, 73(3)
COVID antiviral myths

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• Drug-drug interactions make it impossible for my patient for my patient to get early therapy
• Paxlovid is easy to get after I prescribe it

Huang C et al, 2020, Lancet 395 (10223)

Hospitalizations 7-8 days after onset symptoms
COVID antiviral myths

• Population immunity is high so my patient doesn’t need Paxlovid
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• My patient has mild symptoms so Paxlovid or other early therapies won’t help
• Drug-drug interactions make it impossible for my patient to get early therapy
• Paxlovid is easy to get after I prescribe it
Thank you!
Q&A/ Discussion
Selected Resources

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

Dr. Rao
• www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf
• https://www.cdc.gov/poxvirus/mpox/clinicians/infection-control-healthcare.html
• https://www.cdc.gov/mmwr/volumes/72/wr/mm7209a4.htm?s_cid=mm7209a4_w
• https://emergency.cdc.gov/han/2023/han00501.asp

Dr. Jackson
• https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_testpositivity_00

Dr. Patel
• https://www.cdc.gov/respiratory-viruses/data-research/dashboard/snapshot.html
• https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network
• https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_testpositivity_00
• https://covid.cdc.gov/covid-data-tracker/#variant-proportions
• https://www.cdc.gov/ncird/whats-new/JN.1-update-2023-12-22.html
Selected Resources

**Dr. Tripler**
- [https://www.science.org/doi/10.1126/science.adf5167](https://www.science.org/doi/10.1126/science.adf5167)
- [https://opendata.ncats.nih.gov/covid19/variant/real-world-evidence](https://opendata.ncats.nih.gov/covid19/variant/real-world-evidence)

**Dr. Chin-Hong**
- [https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00](https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00)
An online community bringing together information and opportunities for discussion on latest research, guidelines, tools and resources from a variety of medical subspecialties around the world.

Specialty Society Collaborators
- American Academy of Family Physicians
- American Academy of Pediatrics
- American College of Emergency Physicians
- American College of Obstetricians and Gynecologists
- American College of Physicians
- American Geriatrics Society
- American Thoracic Society
- Pediatric Infectious Diseases Society
- Society for Critical Care Medicine
- Society for Healthcare Epidemiology of America
- Society of Hospital Medicine
- Society of Infectious Diseases Pharmacists

www.COVID19LearningNetwork.org
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www.idsociety.org/cliniciancalls
-- library of all past calls available --

Contact Us:
Dana Wollins (dwollins@idsociety.org)
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