Prevention of SARS-CoV-2 Infection

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<table>
<thead>
<tr>
<th>Summary Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vaccines</strong></td>
</tr>
<tr>
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</tr>
<tr>
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</tr>
<tr>
<td>• The prevalence of SARS-CoV-2 Omicron subvariants that are not susceptible to the anti-SARS-CoV-2 monoclonal antibody combination tixagevimab plus cilgavimab (Evusheld) is &gt;90% in the United States. Therefore, tixagevimab plus cilgavimab is not currently authorized by the Food and Drug Administration for use as pre-exposure prophylaxis (PrEP) of COVID-19.</td>
</tr>
<tr>
<td>• The Panel <strong>recommends against</strong> the use of tixagevimab plus cilgavimab as PrEP of COVID-19 (AIII).</td>
</tr>
</tbody>
</table>

Each recommendation in the Guidelines receives a rating for the strength of the recommendation (A, B, or C) and a rating for the evidence that supports it (I, IIa, IIb, or III). See Guidelines Development for more information.

**General Prevention Measures**

Transmission of SARS-CoV-2 occurs primarily through exposure to respiratory droplets. Exposure can occur when individuals inhale droplets or particles that contain the virus (with the greatest risk of transmission occurring within 6 feet of an infectious source) or touch mucous membranes with hands that have been contaminated with the virus. Exhaled droplets or particles can also deposit the virus onto exposed mucous membranes.

Less commonly, airborne transmission of droplets and particles of SARS-CoV-2 may occur among people who are more than 6 feet apart. In rare cases, people may become infected while passing through a room that was previously occupied by a person who was infectious. In poorly ventilated, enclosed spaces, SARS-CoV-2 infection via airborne transmission of small particles can occur after prolonged exposure (i.e., >15 minutes) to a person who is infectious.

The risk of SARS-CoV-2 transmission can be reduced by covering coughs and sneezes and maintaining a distance of at least 6 feet from others. When consistent distancing is not possible, well-fitted masks may reduce the spread of infectious droplets from individuals with SARS-CoV-2 infection to others. Frequent handwashing also effectively reduces the risk of infection. Health care providers should follow the Centers for Disease Control and Prevention (CDC) recommendations for infection control and the appropriate use of personal protective equipment.

**Vaccines**

Vaccination is the most effective way to prevent COVID-19. The COVID-19 Treatment Guidelines Panel (the Panel) recommends COVID-19 vaccination as soon as possible for everyone who is eligible according to the CDC’s Advisory Committee on Immunization Practices (AI). Three COVID-19 vaccines are available in the United States: the bivalent mRNA vaccines BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) and the recombinant spike protein with matrix-M1 adjuvant vaccine NVX-CoV2373 (Novavax). The adenovirus vector vaccine Ad26.COV2.S (Johnson & Johnson/Janssen) is no longer available in the United States.
COVID-19 vaccination is recommended for everyone aged ≥6 months in the United States. The Food and Drug Administration (FDA) Emergency Use Authorization (EUA) fact sheet and the product label for each vaccine provide detailed information on the vaccination schedule and the doses that are approved or authorized for that vaccine. The type and dose of vaccine and the timing of the doses depend on the recipient’s age and underlying medical conditions. The CDC regularly updates the clinical considerations for using the COVID-19 vaccines that are currently approved by the FDA or authorized for use in the United States.5

**Adverse Events**

COVID-19 vaccines are safe and effective. Local and systemic adverse events are relatively common with these vaccines. Most of the adverse events that occurred during vaccine trials were mild or moderate in severity (i.e., they did not prevent vaccinated people from engaging in daily activities) and resolved after 1 or 2 days. There have been a few reports of severe allergic reactions following COVID-19 vaccination, including rare reports of patients who experienced anaphylaxis after receiving an mRNA vaccine.6,7

Thrombosis with thrombocytopenia syndrome is a serious condition characterized by blood clots in large blood vessels and low platelet levels. It has been reported in people who have received the Johnson & Johnson/Janssen vaccine, with a prevalence of approximately 4 people per million who receive the vaccine.8,9 The Johnson & Johnson/Janssen vaccine is no longer available in the United States. If a patient experiences thrombosis and thrombocytopenia syndrome after COVID-19 vaccination outside of the United States, a hematologist should be consulted about evaluation and management.

Myocarditis and pericarditis after COVID-19 vaccination are rare, and most of the reported cases were very mild and self-limiting.10 These conditions have occurred most often in male adolescents, young adults, and people who have received mRNA vaccines.

The results of recent studies suggest that adults aged ≥18 years who received the Johnson & Johnson/Janssen vaccine have an increased risk of Guillain-Barré syndrome. In contrast, people who received mRNA vaccines do not have an increased risk of Guillain-Barré syndrome.11,12

The CDC provides regular updates on selected adverse events of COVID-19 vaccines on its website.

**Vaccination in Pregnant or Lactating People**

Pregnant and lactating individuals were not included in the initial COVID-19 vaccine trials. However, the CDC, the American College of Obstetricians and Gynecologists (ACOG), and the Society for Maternal-Fetal Medicine recommend vaccination for pregnant and lactating people. This recommendation is based on the accumulated safety and efficacy data on the use of these vaccines in pregnant people, as well as the increased risk of severe disease in pregnant individuals with COVID-19.13-18 These organizations also recommend vaccination for people who are trying to become pregnant or who may become pregnant in the future. The ACOG publication includes a guide for clinicians on counseling pregnant patients about COVID-19 vaccination.19

**Pre-Exposure Prophylaxis**

**Anti-SARS-CoV-2 Monoclonal Antibodies**

- The Panel recommends against the use of tixagevimab plus cilgavimab (Evusheld) as pre-exposure prophylaxis (PrEP) of COVID-19 (AIII).
Due to the increased prevalence of Omicron subvariants that are not susceptible to the anti-SARS-CoV-2 monoclonal antibody combination tixagevimab plus cilgavimab in the United States, this combination is not currently authorized by the FDA for use as PrEP of COVID-19.\textsuperscript{20} Previously, the FDA authorized the use of tixagevimab plus cilgavimab as PrEP of COVID-19 in people who were not expected to mount an adequate immune response to COVID-19 vaccination and in people with COVID-19 vaccine contraindications.\textsuperscript{21}

It remains critical that these individuals:

- Keep up to date with COVID-19 vaccination and boosters, unless a contraindication exists.
- Take precautions to avoid infection. For more information, visit this webpage from the CDC.
- Be tested for SARS-CoV-2 infection if they experience signs and symptoms consistent with COVID-19 and, if infected, promptly seek medical attention.

\textbf{Other Drugs}

- The Panel \textbf{recommends against} the use of hydroxychloroquine or chloroquine as PrEP of COVID-19 (AIIa).
- There is insufficient evidence for the Panel to recommend either for or against the use of vitamin D for the prevention or treatment of COVID-19.
- The Panel \textbf{recommends against} the use of other drugs as PrEP of COVID-19, except in a clinical trial (AIII).

Different doses and durations of hydroxychloroquine have been studied in randomized controlled trials to assess whether they could prevent SARS-CoV-2 infection in people who are at risk of being exposed to individuals who are infected, such as health care workers.\textsuperscript{22,23} No study demonstrated evidence of a reduction in the rate of acquiring infection, but the studies have reported an increased frequency of mild adverse events in the treatment groups.

Several open-label or placebo-controlled trials evaluated the use of vitamin D as PrEP of COVID-19. Only 1 small trial conducted among health care workers who were largely unvaccinated has been published.\textsuperscript{24} More clinical trial data are needed before the Panel can assess the efficacy of using vitamin D as PrEP in people who are vaccinated. See Vitamin D for more information.

Other agents have been studied for use as PrEP of COVID-19. The Panel recommends against using these agents as PrEP of COVID-19, except in a clinical trial, because the available data have not demonstrated sufficient benefits for these agents.

\textbf{Post-Exposure Prophylaxis}

\textbf{Anti-SARS-CoV-2 Monoclonal Antibodies}

- The Panel \textbf{recommends against} the use of bamlanivimab plus etesevimab and casirivimab plus imdevimab for post-exposure prophylaxis (PEP), as the Omicron subvariants, which are not susceptible to these agents, are currently the dominant SARS-CoV-2 variants circulating in the United States (AIII).

Vaccination remains a highly effective way to prevent SARS-CoV-2 infection. However, despite the widespread availability of COVID-19 vaccines, some individuals are not fully vaccinated or cannot mount an adequate response to the vaccine. Some of these individuals, if infected, are at high risk of progressing to serious COVID-19. Bamlanivimab plus etesevimab and casirivimab plus imdevimab previously received FDA EUAs for PEP. However, the Omicron subvariants that are not susceptible to
these products are currently the dominant variants circulating in the United States.

Other Drugs

• The Panel recommends against the use of hydroxychloroquine or chloroquine as PEP of COVID-19 (AI).
• The Panel recommends against the use of other drugs as PEP of COVID-19, except in a clinical trial (AIII).

Several large trials have investigated whether hydroxychloroquine can reduce the risk of infection after exposure to individuals with SARS-CoV-2 infection. None of these studies demonstrated any evidence of efficacy for hydroxychloroquine, and all showed a higher risk of generally mild adverse events in those who received the drug.

Other agents have been studied for use as PEP of COVID-19. The Panel recommends against using these agents as PEP of COVID-19, except in a clinical trial, because the available data have not demonstrated sufficient benefits for these agents.

References


