

Montana Health Alert Network

DPHHS HAN

UPDATE

Cover Sheet

DATE

April 29, 2021

SUBJECT

Johnson & Johnson (Janssen) Vaccine Pause Lifted and
Updated Healthcare Infection Prevention and Control Recommendations

INSTRUCTIONS

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For LOCAL HEALTH DEPARTMENT reference only
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1-406-444-0273

Immunization Section
1-406-444-5580

For technical issues related to the HAN message contact the Emergency Preparedness Section at 1-406-444-0919

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Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

Information Service: passes along low level priority messages that do not fit other HAN categories and are for informational purposes only.

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Information Sheet



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BACKGROUND

Following a thorough safety review, including two meetings of the CDC's Advisory Committee on Immunization Practices, the U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC) have determined that the recommended pause regarding the use of the Johnson & Johnson (Janssen) COVID-19 Vaccine in the U.S. should be lifted and use of the vaccine should resume.

The pause was recommended after reports of six cases of a rare and severe type of blood clot in individuals following administration of the Janssen COVID-19 Vaccine. During the pause, medical and scientific teams at the FDA and CDC examined available data to assess the risk of thrombosis involving the cerebral venous sinuses, or CVST (large blood vessels in the brain), and other sites in the body (including but not limited to the large blood vessels of the abdomen and the veins of the legs) along with thrombocytopenia, or low blood platelet counts. The teams at FDA and CDC also conducted extensive outreach to providers and clinicians to ensure they were made aware of the potential for these adverse events and could properly manage and recognize these events due to the unique treatment required for these blood clots and low platelets, also known as thrombosis-thrombocytopenia syndrome (TTS).

CDC updated the healthcare infection prevention and control recommendations in response to COVID-19 vaccination on April 27th, 2021.

INFORMATION

On April 23, the Advisory Committee on Immunization Practices concluded that the benefits of resuming Janssen COVID-19 vaccination among persons aged ≥ 18 years outweighed the risks and reaffirmed its interim recommendation under FDA's Emergency Use Authorization (EUA), which includes a new warning for rare clotting events among women aged 18–49 years.

On April 27th, 2021, CDC revised the "Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination"¹ for healthcare facilities.

¹ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html>

RECOMMENDATIONS

Healthcare Providers

Healthcare providers should resume the use of the Johnson & Johnson (Janssen) COVID-19 vaccine following the review of the updated safety and recommendation information. These activities include:

- Review of the updated *Clinical Considerations for use of JOHNSON & JOHNSON in certain populations*² prior to resuming vaccination with Johnson & Johnson.
- Review of the *Fact Sheet for Recipients and Caregivers*³ prior to resuming vaccination with Johnson & Johnson.
- Provide all patients receiving the Johnson & Johnson vaccine the *Fact Sheet for Recipients and Caregivers*³ prior to the administration.
- Maintain a supply of alternative COVID-19 vaccine in case a patient opts out of JOHNSON & JOHNSON at the time of vaccination.

2 <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#janssen-vaccine-certain-populations>

3 <https://www.fda.gov/media/146305/download>

Updated SARS-CoV-2 Testing Recommendations for Healthcare Settings

Anyone with symptoms of COVID-19, regardless of vaccination status, should receive a viral test immediately

Asymptomatic healthcare personnel (HCP) with a *higher-risk exposure*⁴ and patients or residents with prolonged close contact with someone with SARS-CoV-2 infection, regardless of vaccination status, should have a series of two viral tests for SARS-CoV-2 infection. In these situations, testing is recommended immediately and 5–7 days after exposure. People with SARS-CoV-2 *infection in the last 90 days*⁵ do not need to be tested if they remain asymptomatic, including those with a known contact.

In healthcare facilities with an outbreak of SARS-CoV-2, recommendations for viral testing HCP, residents, and patients (regardless of vaccination status) remain unchanged.

Expanded screening testing of asymptomatic HCP

- Fully vaccinated HCP may be exempt from expanded screening testing. However, per recommendations above, vaccinated HCP should have a viral test if the HCP is symptomatic, has a higher-risk exposure or is working in a facility experiencing an outbreak.
- In nursing homes, unvaccinated HCP should continue expanded screening testing as *previously recommended*⁶.
- For other healthcare facilities that are performing expanded screening testing for asymptomatic HCP who do not have a known exposure, vaccinated HCP can be excluded from such a testing program.

Updated visitation guidance to include recommendations for acute care facilities and to describe circumstances when source control and physical distancing are not required during visitation

4 <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html>

5 <https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Testing.-Isolation.-and-Quarantine-for-Persons-Who-Have-Recovered-from-Previous-SARS-CoV-2-Infection>

6 <https://www.cms.gov/files/document/qso-20-38-nh.pdf>

Added guidance for communal activities and dining in healthcare settings

Patients/Residents Group activities

- If all patients/residents participating in the activity are fully vaccinated, then they may choose to have close contact and to not wear source control during the activity.
- If unvaccinated patients/residents are present, then all participants in the group activity should wear source control and unvaccinated patients/residents should physically distance from others.

Patients/Residents Communal dining

- Fully vaccinated patients/residents can participate in communal dining without use of source control or physical distancing.
- If unvaccinated patients/residents are dining in a communal area (e.g., dining room) all patients/residents should use source control when not eating and unvaccinated patients/residents should continue to remain at least 6 feet from others.

Local Health Jurisdictions

Continue to work with vaccine providers in the community to update messaging around the safety and efficacy of the Johnson & Johnson COVID-19 vaccine.

Maintain a supply of alternative vaccine at COVID-19 vaccine clinics to provide an alternative vaccine choice for those who opt out of the Johnson & Johnson vaccine.

Additional Resources

Updated Recommendation from the ACIP for Johnson and Johnson MMWR

https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm?s_cid=mm7017e4_e&ACSTrackingID=USCDC_921-DM55766&ACSTrackingLabel=MMWR%20Early%20Release%20-%20Vol.%2070%2C%20April%2027%2C%202021&deliveryName=USCDC_921-DM55766

FDA Press Release Regarding JOHNSON & JOHNSON

<https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough>