

Update on Janssen (J & J) Vaccine

What is known:

On April 13, 2021, FDA/ CDC recommended pausing use of the Janssen COVID-19 vaccine after 6 reports of rare thrombosis with thrombocytopenia syndrome (TTS) among vaccine recipients. Incidence was extremely rare, but safety being a top priority, it warranted further investigation.

What is new information:

On April 23, the Advisory Committee on Immunization Practices concluded that the overall safety, efficacy, and need for the Janssen vaccine was thought to far outweigh the very low risk of TTS. Recommendation was to resume Janssen COVID-19 vaccination among persons aged ≥ 18 years. The FDA's Emergency Use Authorization added a new warning for rare clotting events among women aged 18–49 years.

The data:

The updated incidence of findings was extremely rare at two per million for the Janssen vaccine, based on a total of 15 cases reported following 7.98 million doses administered. The rate was seven per million in the highest risk group of women younger than 50 years; however, even in this group, the risk/benefit strongly favored vaccination, based on a predicted 116 deaths from COVID-19 disease per million at current infection and mortality rates.

What are the implications:

Resuming use of the highly efficacious Janssen COVID-19 vaccine will ensure flexibility, choice, and improved access. The single dose of this vaccine remains an attractive option for long-term care residents and staff.

Recommendations

- Resume use. Consonus has the Janssen vaccine available in OR, NV and AZ.
- Monitor for rare symptoms of TTS that include severe, recurrent, or persistent symptoms 4-30 days following vaccination, including intense headache, abdominal/back pain, nausea/vomiting, vision changes, change in mental status, SOB, leg pain/swelling, and/or bleeding/petechiae. The peak time for initial symptoms is days 6 to 14 days. If noted, urgently report to medical provider.
- Report serious or life-threatening adverse events following any vaccine to Vaccine Adverse Event Reporting System ([VAERS](#)).
- Address vaccine hesitancy related to the vaccine pause. The vaccine is safe, efficacious and a very important tool in ending the pandemic. Reach out to your consultants for educational resources if needed.