

Update on Johnson&Johnson (Janssen) COVID-19 Vaccine

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SITUATION

Following a thorough safety review, from two meetings of the CDC's Advisory Committee on Immunization Practices (ACIP), 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.

BACKGROUND

On 4/13/2021, the CDC and FDA called for a pause on further administration of the Johnson & Johnson (Janssen) vaccine while they review data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the Janssen vaccine.

The ACIP met on 4/14/2021 and 4/23/2021 to discuss the recent cases and evaluate known data about the vaccine to bring forth a final recommendation to the FDA and CDC.

ASSESSMENT

Terminology

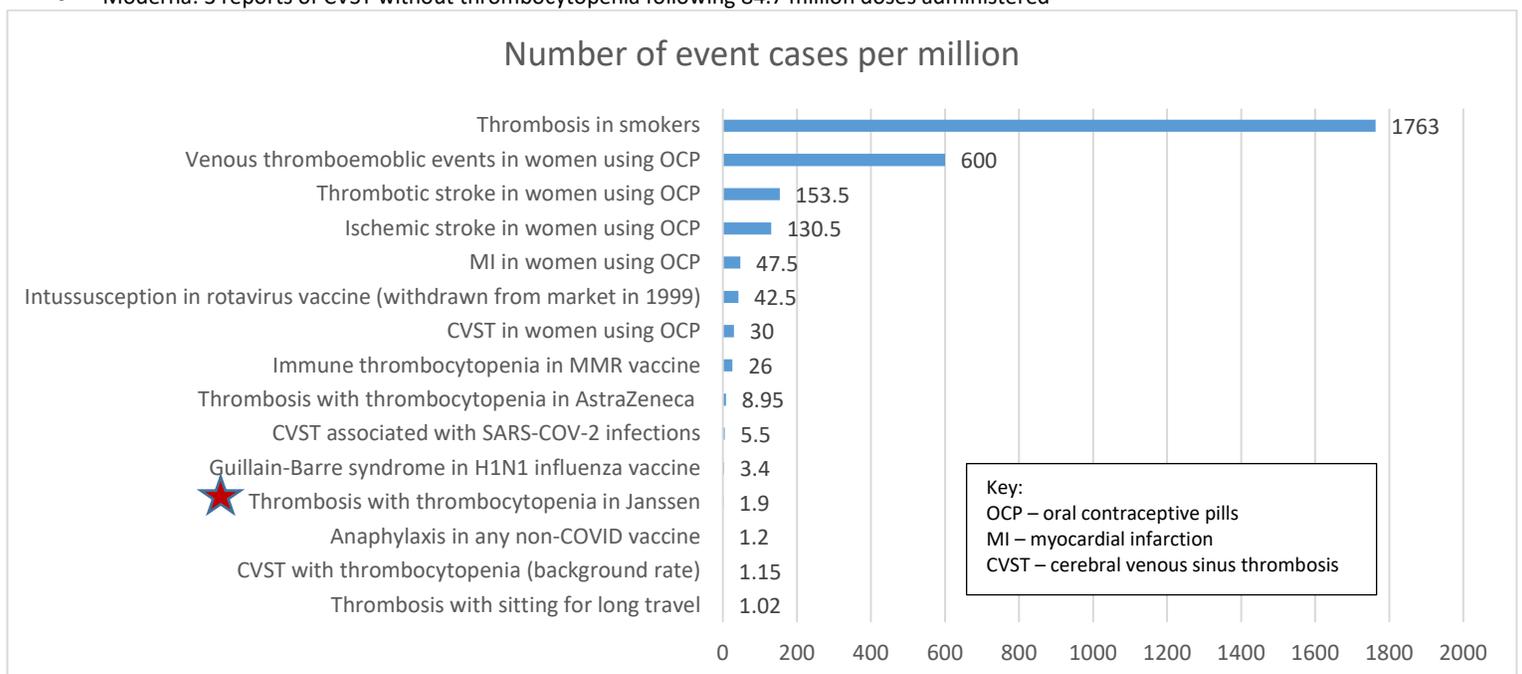
- **Thrombosis** occurs when blood clots block blood vessels. This can be caused by trauma, immobility, genetic disorders, autoimmune diseases, obesity, hormone therapy or birth control pills, pregnancy, smoking, cancer, or older age. Symptoms may include pain and swelling in the area, headache, nausea/vomiting, chest pain, numbness or weakness on one side of the body, seizure, reduced consciousness/coma.
- Platelets are blood cells that help blood to clot to stop bleeding by clumping and forming plugs in blood vessels. **Thrombocytopenia** is a condition in which you have a low blood platelet count (<150,000 per microliter). Dangerous bleeding can occur when there is a severe drop in platelet count.
- **Cerebral Venous Sinus Thrombosis (CVST)** is a clot in the veins of the brain.

RISKS

Incidence data for thrombosis following COVID-19 vaccines

As of April 21, 2021:

- Janssen: 15 reports of thrombosis with thrombocytopenia (TTS) following 7.98 million doses administered. Out of those 15 cases, 12 cases were CVST. Other locations include abdomen, arms, and legs.
 - All cases in women
 - Median age: 37 years
 - 13 in group aged 18-49 years, 2 in group aged 50+ years
 - No obvious patterns of risk factors detected
 - Median time to symptom onset 8 days
 - Risk factors for thrombosis: oral contraceptive use (n=2), obesity (n=7), hypothyroidism (n=2), hypertension (n=2)
 - Outcomes: 3 deaths, 7 remain hospitalized (4 in ICU), 5 discharged home
- Pfizer-BioNTech: 0 reports following 97.9 million doses administered
- Moderna: 3 reports of CVST without thrombocytopenia following 84.7 million doses administered



BENEFITS

SARS-COV-2 Infection Risks

- Hospitalization: 200 cases/million
- Death: 30 cases/million

Janssen Vaccine Benefits

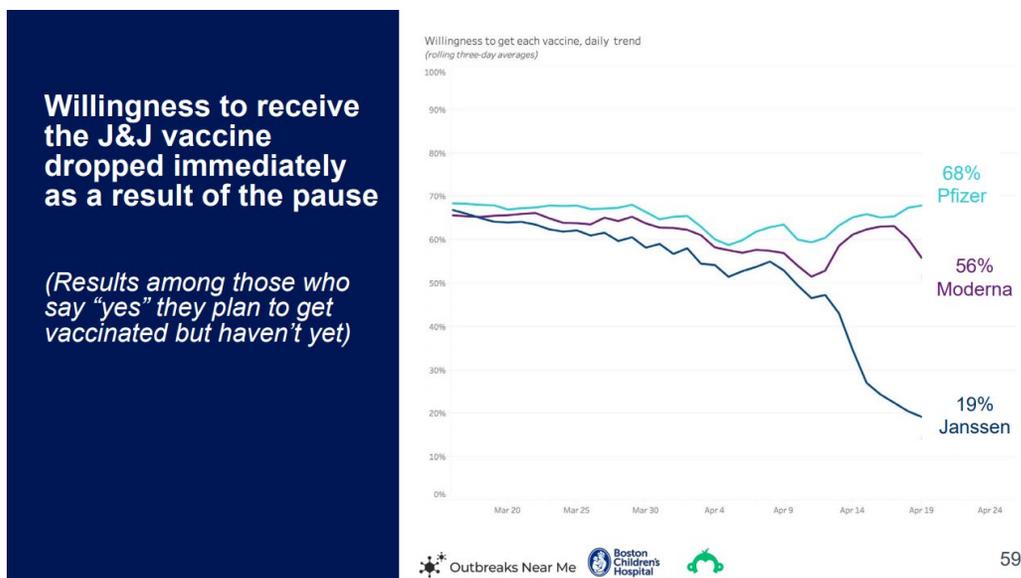
- Single dose, refrigeration storage
- 66.3% overall efficacy
- 85% vaccine efficacy against severe COVID-19
- 100% protection against COVID-19 related hospitalization and deaths
- Highly protective against global variants of concern (South Africa and Brazil) that have been identified in 36 of 50 US states

Overall COVID-19 Vaccination Benefits

Vaccinating 1 million adults 18 years and older in the US would be expected to result in:

- 2,094 fewer cases of COVID-19 related deaths
- 6,037 fewer cases of COVID-19 related hospitalization
- 1.9 additional cases of thrombosis with thrombocytopenia

Vaccine Confidence Decreased as Result of J&J Pause



RECOMMENDATION

The CDC and FDA recommend use of Johnson & Johnson (Janssen) vaccine to resume in the United States. A review of all available data at this time shows that the Janssen vaccine's known and potential benefits outweigh its known and potential risks. However, women younger than 50 years old should be aware of the rare, but increased risk of this adverse event, and that there are other COVID-19 vaccine options available for which this risk has not been seen. The CDC and FDA will continue to monitor the safety of all COVID-19 vaccines. There is a new FDA warning and precaution labeling regarding thrombosis and thrombocytopenia on Janssen vaccine packaging and fact sheet for providers and patients.

Recommended Screening

Patients presenting with symptoms of a clot (e.g. headaches, blurred vision, shortness of breath, chest pain, leg swelling, persistent abdominal pain, easy bruising or tiny blood spots under the skin beyond injection site):

- Obtain detailed history, particularly pertaining to COVID-19 vaccination within 3 weeks
- Evaluate for thrombocytopenia – platelet count
- Confirm the thrombotic event – CT, MRI, ultrasound
- Send testing for heparin-induced thrombocytopenia with platelet factor 4 immunoassay and platelet activation assay
- Consult with hematologist to confirm diagnosis

Recommended Treatment

- Treat clots with a non-heparin anticoagulant
- Treat the thrombocytopenia with intravenous immunoglobulin (IVIG)
 - Avoid platelet transfusions