COVID-19 Vaccine Update

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Janssen Updates

- Janssen COVID-19 vaccine is approved by the FDA under Emergency Use Authorization (EUA) in all persons aged ≥18 years
- Women <50 years can receive any FDA-authorized COVID-19 vaccine, but should be aware of the rare risk of Thrombosis with Thrombocytopenia Syndrome (TTS) after the receipt of Janssen vaccine and the availability of other FDA-authorized vaccines.
- Pt with history of an episode of immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as HIT, should be offered mRNA vaccine if within 90-180 days of resolution of illness.
- People with a history of thrombosis or risk factors for thrombosis can receive any FDAauthorized vaccine, including the Janssen COVID-19 vaccine.
- People who take aspirin or blood thinners as part of their routine medications do not need to stop these medicines prior to the receipt of the Janssen COVID-19 vaccine.

<u>Safety Monitoring of the Janssen (Johnson & Johnson) COVID-</u> <u>19 Vaccine — United States, March–April 2021 | MMWR</u> (cdc.gov)

- 97% of reported side effects were classified as non-serious
- Most commonly reported side effects: HA, fever, chills, pain, fatigue
- 17 reports consistent with TTS (thrombosis with thrombocytopenia) out of almost 8 million doses administered
- More information on reported TTS cases:
 - <u>US Case Reports of Cerebral Venous Sinus Thrombosis With</u> <u>Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021</u> <u>| Coagulation Disorders | JAMA | JAMA Network</u>

Updates: Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

People vaccinated outside US:

- Complete series with World Health Organization (WHO)-approved COVID-19 vaccine – do not need to repeat vaccine series.
- Partially vaccinated or fully vaccinated with non-WHO approved vaccine offer FDA-approved vaccine.
 - Wait at least 28 days from last dose of unauthorized vaccine.
- WHO-approved COVID-19 vaccines:
 - Pfizer-BioNTech
 - Moderna
 - Janssen
 - AstraZeneca

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Contraindications and Precautions:

- Most people with a precaution can and should be administered COVID-19 vaccine.
- Polysorbate allergy is no longer a contraindication to mRNA vaccination.
- Known polysorbate allergy is a contraindication to Janssen COVID-19 vaccine and thus, a precaution to mRNA COVID-19 vaccination.
- Consultation available from the <u>Clinical Immunization Safety Assessment</u> <u>COVIDvax</u> project for providers of patients with complex clinical vaccine safety issues not readily addressed by CDC guidance.

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	
 History of the following: Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine[†] Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine[†] 	 Among people without a contraindication, a history of: Any immediate allergic reaction* to other vaccines or injectable therapies‡ Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.# 	
 Actions: Do not vaccinate. Consider referral to allergist-immunologist. Consider other vaccine alternative.[†] 	 Actions: Risk assessment Consider referral to allergist-immunologist 30-minute observation period if vaccinated 	Interim Clinical Considera ons for Us of COVID- 19 Vaccine CDC