



# COVID-19 Vaccine Update

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## FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review

The two agencies have determined the following:

- Use of the Janssen COVID-19 Vaccine should be resumed in the United States.
- The FDA and CDC have confidence that this vaccine is safe and effective in preventing COVID-19.
- The FDA has determined that the available data show that the vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 years of age and older.
- At this time, the available data suggest that the chance of TTS occurring is very low, but the FDA and CDC will remain vigilant in continuing to investigate this risk.
- Health care providers administering the vaccine and vaccine recipients or caregivers should review the [Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\)](#)  and [Fact Sheet for Recipients and Caregivers](#) , which have been revised to include information about the risk of this syndrome, which has occurred in a very small number of people who have received the Janssen COVID-19 Vaccine.

# Reporting rates of TTS after Janssen COVID-19 vaccine

- 7.98 million vaccine doses administered\* and 15 confirmed TTS cases† as of April 21, 2021
  - Some age- and sex-specific doses administered data were imputed
  - Additional potential TTS cases under review, including potential male cases

Age group	Females			Males		
	TTS cases	Doses admin	Reporting rate‡	TTS cases	Doses admin	Reporting rate‡
18-49 years old	13	1,866,294	7.0 per million	0	1,977,330	0 per million
50+ years old	2	2,125,239	0.9 per million	0	2,010,144	0 per million

\* Source of doses administered: <https://covid.cdc.gov/covid-data-tracker/#vaccinations>; † One case was excluded from the final analysis: a female aged <50 years who had concurrent diagnosis of COVID-19 and TTS following receipt of Janssen vaccine; ‡ Reporting rate = TTS cases per 1 million Janssen COVID-19 vaccine doses administered

# Summary of population-level risks and benefits by recommendation, all scenarios

## Recommendation for all persons aged 18+

- **Risks:** Expect **26–45 TTS** cases, depending on uptake
- **Benefits:** Depend on uptake, amount of transmission
  - **800–3,500 fewer ICU** admissions
  - **600–1,400 fewer deaths**

## Recommendation for all persons aged 50+

- **Risks:** Expect 2–3 TTS cases, depending on uptake
- **Benefits:** Depend on uptake, amount of transmission
  - **300–1000 fewer ICU** admissions
  - **40–250 fewer deaths**

**Note: Benefits of vaccination apply to the whole population over a 6-month period, and result from direct and indirect effects**

# Addition to EUA Fact Sheet

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

Blood clots involving blood vessels in the brain, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two-weeks following vaccination. Most people who developed these blood clots and low levels of platelets were females ages 18 through 49 years. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen COVID-19 Vaccine:

- Shortness of breath,
- Chest pain,
- Leg swelling,
- Persistent abdominal pain,
- Severe or persistent headaches or blurred vision,
- Easy bruising or tiny blood spots under the skin beyond the site of the injection.

# How to report an adverse event to VAERS

- Go to [vaers.hhs.gov](https://vaers.hhs.gov)
- Submit a report online
- For help:

Call [1-800-822-7967](tel:1-800-822-7967)

Email [info@VAERS.org](mailto:info@VAERS.org)

video instructions

<https://youtu.be/sbCWhcQADFE>

- Please send records to VAERS ASAP if contacted and asked

- HIPAA permits reporting of protected health information to public health authorities including CDC and FDA



# Additional Resources

- CDPH J&J Vaccine Factsheet [Johnson & Johnson COVID-19 Vaccine Fact Sheet](#)
- [ACIP presentation slides, 4/23/21](#)
- [CDC COCA Call slides, 4/27/21](#)
- TTS after Janssen COVID-19 Vaccine, [CDC MMWR 4/27/21](#)
- Updated FDA EUA fact sheets:
  - Healthcare Providers: <https://www.fda.gov/media/146304/download>
  - Caregivers: <https://www.fda.gov/media/146305/download>
- American Society of Hematology [clinical guidance](#)