Chicago Department of Public Health



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Chicago Department of Public Health Allison Arwady MD MPH, Commissioner

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URGENT: CDC and FDA pause use of Johnson & Johnson COVID-19 vaccine

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Summary and Action Items

- CDC and FDA are investigating 6 cases of a rare and severe type of blood clot that occurred in individuals receiving the Johnson and Johnson (J&J) vaccine. These 6 cases were identified out of more than 6.8 million doses of J&J that have been administered in the U.S. as of April 12.
- While CDC and FDA complete their review, all use of Johnson & Johnson vaccine should be paused.
- These events appear to be extremely rare and occurred within 2 weeks of receiving the vaccine.
- People who have received the J&J vaccine who develop severe headache, abdominal pain, leg pain, or shortness of breath within 3 weeks after vaccination should contact their health provider.

Background

- As of April 12, more than 6.8 million doses of the Johnson & Johnson (J&J) vaccine have been administered in the U.S.
- CDC and FDA are reviewing 6 cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine.
- In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia). All 6 cases occurred among women between the ages of 18 and 48, and symptoms occurred 6 to 13 days after vaccination.
- Treatment of this specific type of blood clot is different from the treatment that might typically be administered. Usually an anticoagulant drug called heparin is used to treat blood clots. In this setting, administration of heparin may be dangerous, and alternative treatments need to be given.

Review by CDC and FDA

- CDC will convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday to further review these cases and their potential significance.
- FDA will review that analysis as it also investigates these cases.
- Until that process is complete, we are recommending a pause in the use of this vaccine out of an abundance of caution.
- People who have received the J&J vaccine who develop severe headache, abdominal pain, leg pain, or shortness of breath within 3 weeks after vaccination should contact their health provider.
- Health care providers are asked to report adverse events to the Vaccine Adverse Event Reporting System at https://vaers.hhs.gov/reportevent.html.
- CDC and FDA will provide additional information and answer questions later today at a media briefing. A recording will be available on the FDA's YouTube channel.