BRIEFING

Johnson & Johnson Adverse Events

Updated April 27, 2021

On April 23rd, after reviewing additional data and deliberating the risks and benefits of various policy options, the Advisory Committee on Immunization Practices (ACIP) voted to resume use of the Johnson & Johnson/Janssen vaccine after a 10-day pause by the US government. The pause was out of an abundance of caution due to an extremely rare blood clotting disorder, Thrombocytopenia Syndrome (TTS) occurring in a small number of recipients. The pause offered experts an opportunity to examine the data more closely, gather additional evidence on risk, and share information with clinicians to enhance diagnosis and treatment of these rare events. The FDA and CDC have accepted the recommendation, and states have resumed administration. The vaccine now includes a warning label for these rare events.

What do we know?

These are extremely rare events. Of the 7.9 million J&J doses that were administered as of April 21, 2021, there have been 15 cases of TTS. This corresponds to a 1.9 per million risk of getting a severe blood clot from the J&J vaccine; as a comparison, there is a 2 per million chance each year of being struck by lightning. Women <50 years of age have slightly higher risk. No matter your age or gender, the risk of dying of or being hospitalized with COVID-19 is far higher than the risk of getting a rare blood clot from the J&J vaccine.

Regulatory systems are working as intended. The pause gave authorities time to re-evaluate and critically analyze the available evidence, gather new data, and consider new recommendations for the use of the vaccine. Pausing also allowed the FDA and CDC to provide guidance to clinicians in the diagnosis, treatment, and reporting of TTS events.

Vaccines are a critical tool in our fight to end the pandemic. The vaccines approved under Emergency Use Authorization are all highly effective against COVID-19. As more information becomes available, there may be modifications to the recommended uses for any of the vaccines. Eligible community members should continue to get the vaccine available to them.

What can we do?

As public health and community leaders

Providing up to date information to communities on the evidence related to J&J (and other vaccines) remains important as ever. Additional engagement with those community members who receive the J&J vaccine is warranted to ensure access to health providers, to answer questions, and to address concerns.

As healthcare providers

Understand the events. The cases are Thrombocytopenia Syndrome (TTS), a type of blood clot in the brain occuring alongside low platelet counts - a combination of serious blood clotting and potential for abnormal bleeding. These are important details because TTS treatment is different than treatment for most other blood clots, and clinicians must be aware of the potential for such rare events in J&J recipients.

As community members

Stay informed, and get the vaccine that is available to you. The J&J pause was an example of a public health regulatory system that prioritizes patient safety and transparency. It reflects the ongoing commitment of the scientific community to weigh the risks and benefits of COVID-19 vaccinations.

As someone receiving the J&J vaccine

If you receive the J&J vaccine, be aware of TTS symptoms (severe headache, abdominal pain, leg pain, shortness of breath) and contact your medical providers if you are experiencing said symptoms or if you have concerns. Your risk of experiencing this adverse event is very, very small, and it decreases with time, with known cases occurring between 6 and 14 days following vaccination.

Should we use the J&J vaccine going forward?

Yes. A pause is not a stoppage, and it is a normal part of our regulatory system. Vaccines (like all medical therapeutics) have complication rates that must be understood in the context of risks and benefits: in this case, weighing the risk of complications with the risk of contracting COVID-19 and developing severe illness. Available data at this time shows that the J&J vaccine's known and potential benefits outweigh its known and potential risks. Contracting COVID-19 also raises the risk of developing blood clots, at a higher rate than is seen from vaccination.