FIRST WATCH
Helping the Helpers

J&J (Janssen) COVID-19 Vaccination Restart

On the afternoon of April 23, the Advisory Committee for Immunization Practices (ACIP) recommended to the CDC & FDA, in a 10 to 4 vote, with 1 recusal, to lift the pause in administering the J&J (Janssen) COVID-19 vaccine. After the vote, those that voted 'No", said it was based on a desire to have stronger wording about the risk of TTS for women, ages 18-49. Vaccinations restarted the following day, in many places, and have rapidly expanded in the week since it was announced (the FDA/CDC Notice of the Pause Lift was published the evening of the 23rd).

In a medium-sized nutshell, the decision & subsequent guidance came down to the likelihood that Cerebral Venous Sinus Thrombosis (CVST) with Thrombocytopenia Syndrome, collectively abbreviated as TTS, is likely linked to the J&J (Janssen) vaccine, although extremely rare. TTS may also be linked to the class of vaccines known as viral-vector vaccines, since a 'similar' syndrome has been associated with the Astra-Zeneca Vaccine (not currently authorized in the US but is authorized in Canada). Note: Canada has authorized all the same vaccines as the US with the addition of the Astra-Zeneca COVID-19 vaccine.

However, it was determined by ACIP, that the benefits of restarting use of the J&J vaccine, calculated both on a population - as well as individual level - outweighed the risks. Most importantly, there was agreement it was critical that BEFORE vaccination, health care & vaccine providers must be aware and provide education to the patient & any caregiver, namely the *Fact Sheet for Recipients & Caregivers*, and must include:

1. **The risk for TTS after vaccination with the J&J (Janssen) COVID vaccine, for women in the 18 through 49-year-old age group** (the age may drop below 18 when the vaccine is relabeled for those under 18) **AND**
2. **Reminders that there are other COVID-19 vaccines available that do not appear to carry a risk of TTS,** currently Pfizer/BioNTech & Moderna.

Health care providers should counsel their patients in this age range, on their professional recommendations based on the patient's own medical history, risk factors & medications, as well as family history that might increase the risk of TTS. Furthermore, now that the syndrome has been identified, as well as how to, and how NOT to treat it, this information should also be included in education for any health care providers that may assess or treat those who may have received J&J COVID vaccine, and **are displaying the signs/symptoms (S/S) of TTS which include:**

Shortness of breath Chest Pain Leg Swelling Persistent Abdominal Pain
Severe or Persistent Headaches Blurred Vision Easy Bruising Petechiae

TTS is a newly identified syndrome, associated with viral vector COVID-19 vaccines, that occur rarely and present as acute venous or arterial thrombosis (clots) that are in large blood vessels in the brain, or in other parts of the body (i.e., lungs, legs, abdomen), and a new onset thrombocytopenia (low platelets). In order to be TTS, there cannot have been exposure to any type of heparin that might be the cause of a similar syndrome.

All post Emergency Use Authorization (EUA) TTS cases occurred in women, most (13), in the 18- 49 age range, with 2 in the > 50 age group. One case report matching the criteria was reported during the J&J Vaccine trials, in a male who was 25 years old. By April 21, 2021, about 7.98 million doses of J&J (Janssen) vaccine doses had been administered. Between March 2 & April 21, 2021, 15 cases of what is now identified as TTS, were reported to the Vaccine Adverse Event Reporting System (VAERS). **Multiple physician specialists reviewed the files and calculated the data, leading to a reported 7 cases per million doses administered to women 18-49 years old and 0.9 per million for those older than 49. No cases were reported in the 65 years plus range.** Further breakdown shows that **the greatest rate of TTS was in the 30-39 age range with 7 cases, and a calculated rate 11.8 cases per million doses administered**. The 18-29 age range had 3 cases of TTS with a calculated rate of 5.2 per million vaccine doses; 3 cases in the 40-49 age range with a calculated rate of 4.3 per million vaccine doses; and with 2 cases in the 50-64 age range, the calculated rate was 1.5 per million doses administered. (Data excerpted from ACIP Slide Presentation, *Thrombosis with Thrombocytopenia Syndrome (TTS) Following Janssen COVID-19 Vaccine*, Shimabukuro T., MD, MPH, MBA, CDC COVID-19 Vaccine Task Force, Vaccine Safety Team; 4/23/21; slides 20 & 21).

Onset of the symptoms of TTS was from 6-15 days from the date of vaccine administration. Some of the 15 had underlying health conditions or risk factors for the development of clots (hypercoagulability) including obesity, oral contraceptive use, hypertension, and hypothyroidism. Other risk factors for hypercoagulability, including pregnancy or up to 12 weeks post-partum, self or family history of previous clotting events, any self or family history of an underlying clotting disorder were not identified with any of the cases.

All 15 patients were hospitalized with a dozen admitted to ICUs. And, as of 4/21/21, 3 patients had died, 4 remained in the ICU, with 3 others hospitalized in non-ICU settings, and 5 reportedly discharged home. One female patient was excluded from the above data because she was both vaccinated by the J&J vaccine and also had acute COVID infection which carries an even greater risk of blood clots.

At this time, there have been no reports of TTS in either of the mRNA vaccines (Pfizer/BioNTech and Moderna). This is important for those that seek an alternative vaccine not associated with TTS risk, either as a personal decision or in consultation with their health care provider(s).

Since specific treatment has been identified for patients presenting with S/S of TTS who received the J&J vaccine within the previous 3 weeks, **it is imperative for all health care providers to be aware of their role including what to do and NOT give any form of heparin.** Although initial care may be in a community clinic or hospital, transfer or consult with a multi-specialty hospital with neurology and hematology is preferable. Algorithms for evaluation and treatment are available.

Just like all healthcare providers, EMS & other First Responders should be aware of the S/S of TTS, strokes, and clotting disorders such as hyper and hypocoagulability (barriers to clotting including thrombocytopenia). Also ask about recent COVID-19 vaccination, including the name/manufacturer of the vaccine and the date of the vaccination(s). If there is any chance that the patient may be at risk for TTS (S/S plus J&J vaccination within the past 3 weeks), initiate rapid transport to an appropriate emergency department, per your Policy & Protocol, in consultation with Medical Control. Alert the Receiving ED of your patient's status and possible cause, per Policy.

Note: except for the data cited specifically in the APIC slide presentation, the data and much of the information reported in this article are referenced from the CDC MMWR, *Updated Recommendations from the Advisory Committee on Immunization Practices for the Use of Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients – United States, April 2021*, Early Release Vol 70; Published April 27, 2021; pages 1-5.

Resources listed in the article, as well as others, with their URL links, are included at the end of this article for ease in accessing and reading the information for yourself. The Resources marked with * indicate those that may provide easy insight into this newly identified syndrome, including those at greatest risk, as well as how EMS and other First Responders might manage someone meeting the criteria.

Resources & Links

***MMWR – ACIP Guidance for J&J (Janssen) Vaccination Resumption (4/27/21):**
https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm?s_cid=mm7017e4_w

***MMWR – Safety Monitoring of the J&J (Janssen) Vaccine March-April 2021:**
https://www.cdc.gov/mmwr/volumes/70/wr/mm7018e2.htm?s_cid=mm7018e2_w

JAMA – Case Studies of Cerebral Venous Sinus Thrombosis with Thrombocytopenia (TTP) after J&J (Janssen) vaccination through 3/2 - 4/21 of 2021:
https://jamanetwork.com/journals/jama/fullarticle/2779731

***CDC – ACIP Slides from 4/23/21 J&J Review Meeting (note that there are slides from 4/14/21 included in one of the presentations but they are marked as such):**
https://www.cdc.gov/vaccines/acip/meetings/slides-2021-04-23.html

***FDA J&J (Janssen) Vaccine Fact Sheet for Healthcare Workers:**
https://www.fda.gov/media/146304/download

FDA J&J (Janssen) Vaccine Fact Sheet for Patients & Caregivers:
https://www.fda.gov/media/146305/download

***FDA/CDC Lift Recommended Pause of the J&J COVID Vaccine:**
https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough

CDC – COVID Vaccine Index Page – Comment at the top that the CDC will generate new educational and support materials will be published by the CDC:
https://www.cdc.gov/vaccines/covid-19/index.html

Vaccine Adverse Event Reporting System Search:
https://vaers.hhs.gov/data.html

***Stat – ACIP Recommends FDA & CDC Lift the J&J Pause:**
https://www.statnews.com/2021/04/23/cdc-advisory-panel-backs-jjs-covid-19-vaccine-clearing-way-for-pause-to-be-lifted/

CDC – J&J (Janssen) COVID Vaccine ACIP Risk & Benefit Analysis & Results:
https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/risk-benefit-analysis.html
Note: link site currently states "Content Coming Soon" with a last reviewed date on the page of 4/26/21).