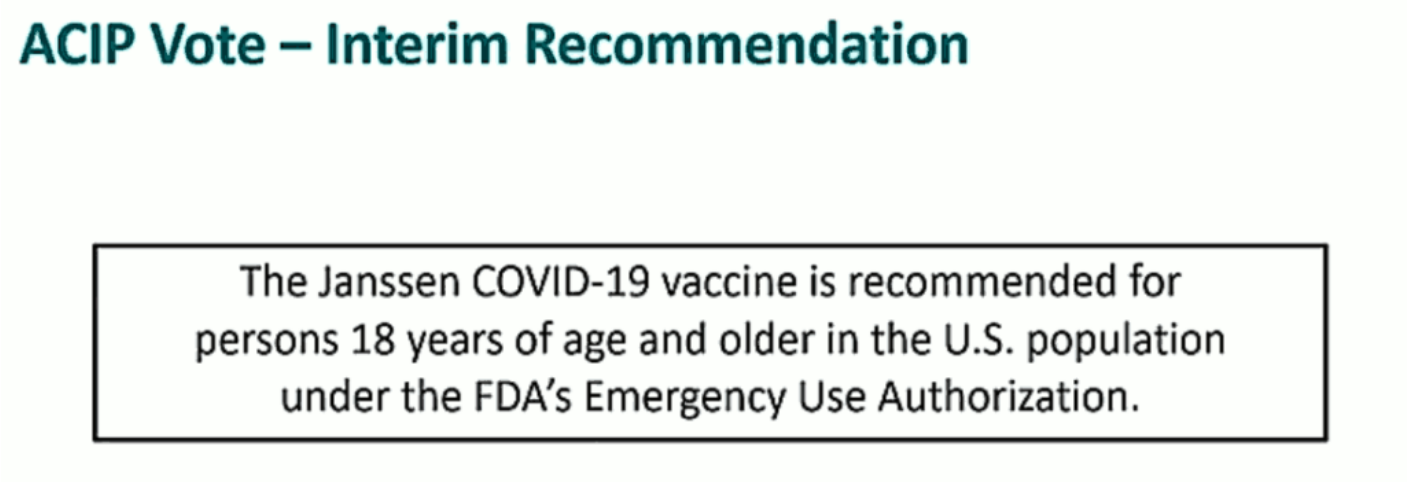
J&J vaccine use to resume next week, CDC committee recommends



Janssen vaccine policy adopted by Advisory Committee on Immunization Practices of the US CDC, April 23, 2021

Use of the Janssen (also known as Johnson & Johnson) COVID-19 vaccine should resume next week after a "pause" begun on April 13. At the end of a six-hour meeting today, the Advisory Committee on Immunization Practices (ACIP) of the US Centers for Disease Control and Prevention (CDC) voted, 10-4-1, to recommend resumption of the use of the Janssen vaccine with no specific restriction by age or sex. By Tuesday, the CDC director is expected to decide whether to accept the recommendation, ordinarily a formality, and if so it will be published by the agency as formal guidance for public health systems throughout the nation.

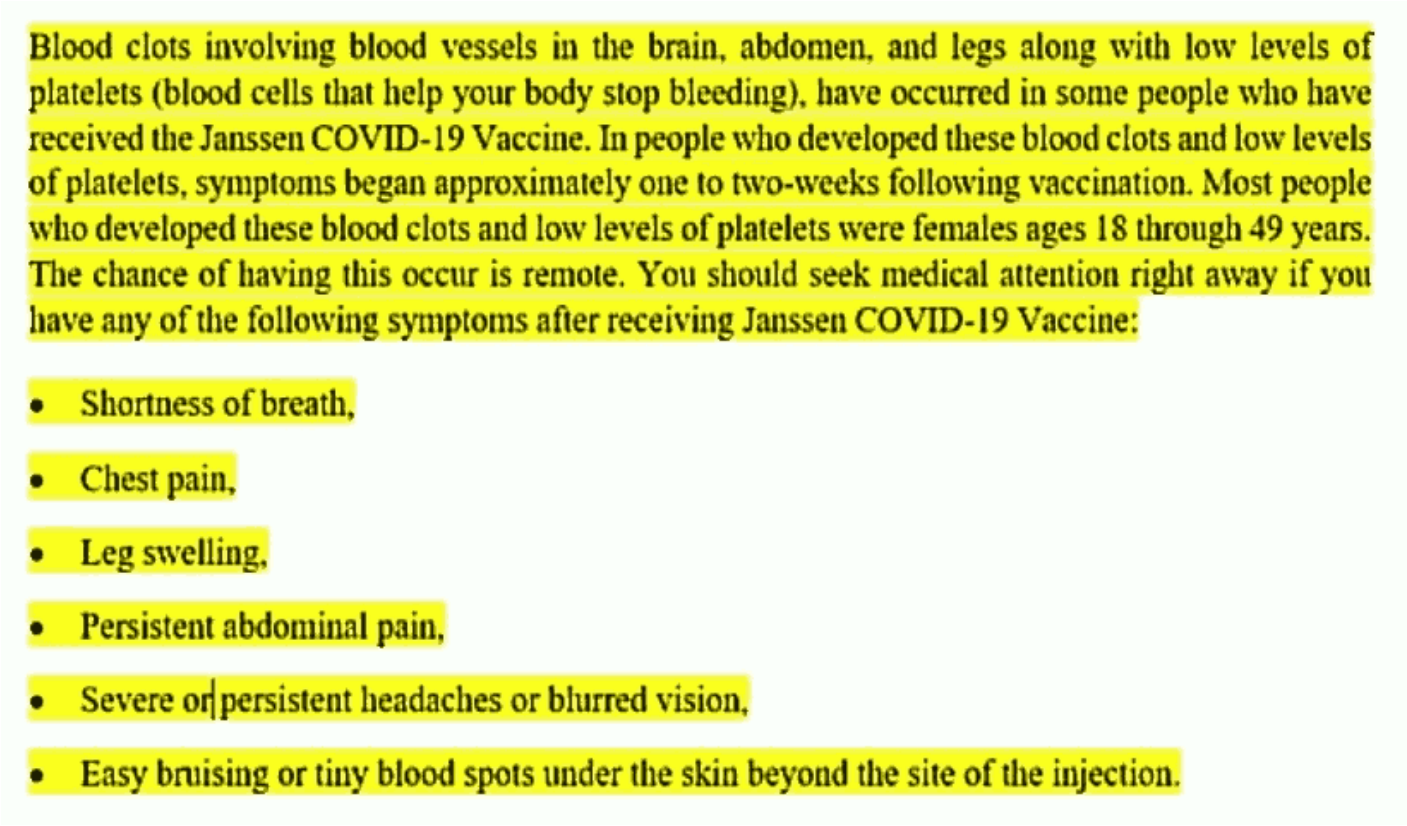
The pause was in response to six cases of an unusual blood clotting condition accompanied by a drop in blood platelet count, all in women ages 18 to 49, an incidence below one-in-a-million out of nearly seven million doses. (See "Don't panic! J&J vaccine pause and rare blood clots: One-in-a-million risk", by Michael Bilow, Apr 14, 2021.) During the pause the total of identified cases increased to 15, of which three were fatal.

Asked for comment by *Motif*, the RI Department of Health (RIDOH) responded this evening, "RIDOH is aware that the Advisory Committee on Immunization Practices (ACIP) has made a recommendation about continued use of the Johnson & Johnson (Janssen) vaccine. We will review all of the information and data and will make a decision next week. RIDOH is storing roughly 5,000 doses of Johnson & Johnson vaccine, as we were instructed to do. We would not expect to get another shipment of Johnson & Johnson vaccine for another two to three weeks. We do not expect this to have any impact on Rhode Island's COVID-19 vaccination efforts because the state's weekly allocation of Pfizer and Moderna vaccines has been increasing."

The ACIP quickly dispensed with other options on the table, including stopping use of the Janssen vaccine entirely. The ACIP concluded that restricting the vaccine to men would be unwise, both in terms of practical constraints on how to do that at points of dispensing (PODs) and because the tiny number of cases made it impossible to quantify the risk to men as opposed to women.

Eventually the ACIP reached a consensus that individuals should be given the choice whether to accept the Janssen vaccine, subject to informed consent about its known risk, in consultation with their healthcare provider, and therefore decided against restricting use to age 50 and older. In the end, members of the committee differed only as to whether their recommendation should explicitly mention that women younger than 50 may want to consider choosing an alternative vaccine, but there were concerns this would be misinterpreted and no such proviso was appended.

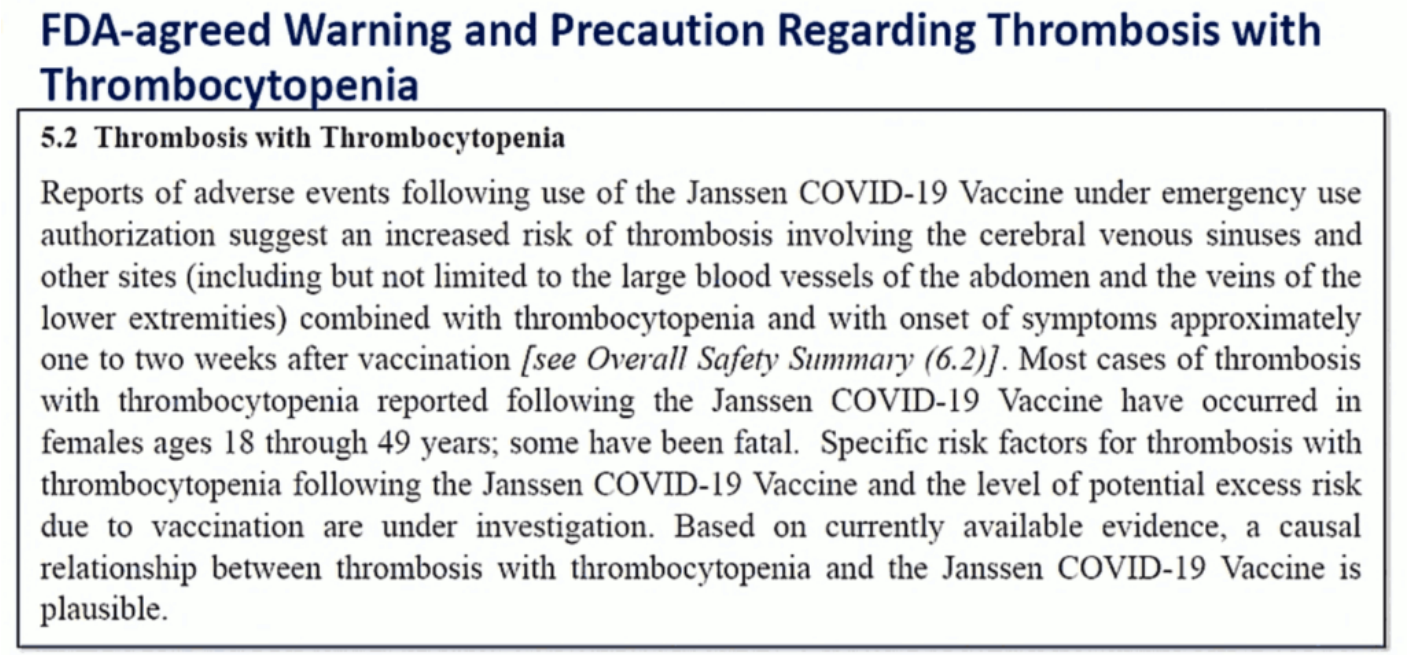
The ACIP made clear that there was an understanding patients who receive the Janssen vaccine in the future would be given explicit warning using language approved by the US Food and Drug Administration (FDA) listing the symptoms of the rare blood clot reaction, detailing what to watch for and what do.



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.

Janssen vaccine warning by FDA to patients, exhibited at CDC ACIP meeting, Apr 23, 2021.



Janssen vaccine warning by FDA to clinicians, exhibited at CDC ACIP meeting, Apr 23, 2021.

Because the Janssen vaccine is the only one authorized by the FDA for use in the US that needs a single dose and can be stored in ordinary refrigerators rather than deep freezers, it is valuable for providers dispensing small numbers of doses, especially in rural areas, and for reaching populations for whom it would be difficult to arrange a second dose, such as the home-bound, the homeless, migrants, transients and the incarcerated. As a result, the CDC internally concluded that the loss of use of the Janssen vaccine could result in more deaths due to the virus than cases of the rare blood clotting reaction, as well as tens of times more intensive care unit (ICU) unit admissions and hundreds of times more hospitalizations.

The ACIP meeting included a half-hour of public comments, limited to three minutes each, chosen by lottery from applicants in advance. A significant number of the commenters appeared to be anti-vaccine conspiracy theorists, and the members of the ACPI made no response beyond the moderator thanking them for their comments.