



COVID-19 vaccine safety

DATE: May 10, 2021

PRESENTED BY: Dawn Nolt, MD MPH, Professor, Pediatric Infectious Diseases

Presentation Overview

- Monitoring the safety of COVID-19 vaccines in U.S.
- Reasons for pausing J&J vaccine administration
- Emergency ACIP meeting on 4/23/2021
- How J&J vaccine fits into the overall COVID-19 vaccine landscape
- Vaccine confidence

Monitoring the safety of COVID-19 vaccines in the U.S.

VAERS is the nation's early warning system for vaccine safety



VAERS

Vaccine Adverse Event Reporting System

co-managed by
CDC and FDA

<http://vaers.hhs.gov>

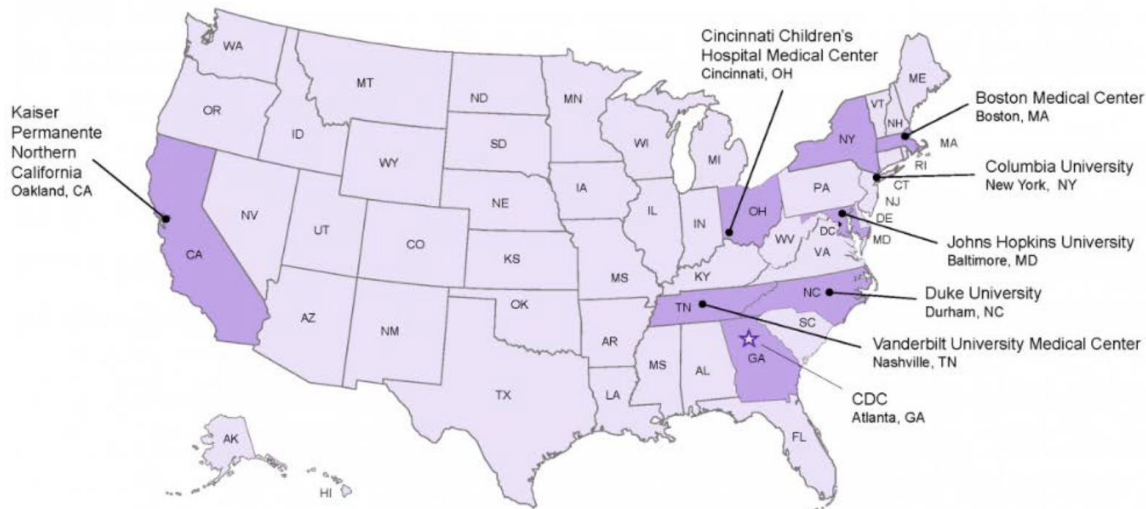
The screenshot shows the VAERS website interface. At the top, the VAERS logo is followed by the text 'Vaccine Adverse Event Reporting System' and the URL 'www.vaers.hhs.gov'. Below this is a navigation bar with links: 'About VAERS', 'Report an Adverse Event', 'VAERS Data', 'Resources', and 'Submit Follow-Up Information'. The main content area is divided into two columns. The left column contains a section titled 'Have you had a reaction following a vaccination?' with two numbered steps: '1. Contact your healthcare provider.' and '2. Report an Adverse Event using the VAERS online form or the new downloadable PDF. *New!*'. Below this is an 'Important' note: 'If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.' This is followed by a Spanish version of the same section. The right column features a large image of a family (father, mother, and two children) looking at a laptop, with the text 'What is VAERS?' below it. At the bottom, there are four smaller images with corresponding text boxes: 'REPORT AN ADVERSE EVENT' (Report significant adverse events after vaccination), 'SEARCH VAERS DATA' (Download VAERS Data and search the CDC WONDER database), 'REVIEW RESOURCES' (Find materials, publications, learning tools, and other resources), and 'SUBMIT FOLLOW-UP INFORMATION' (Upload additional information related to VAERS reports).



CISA

Clinical Immunization Safety Assessment (CISA) Project

7 participating medical
research centers with
vaccine safety experts



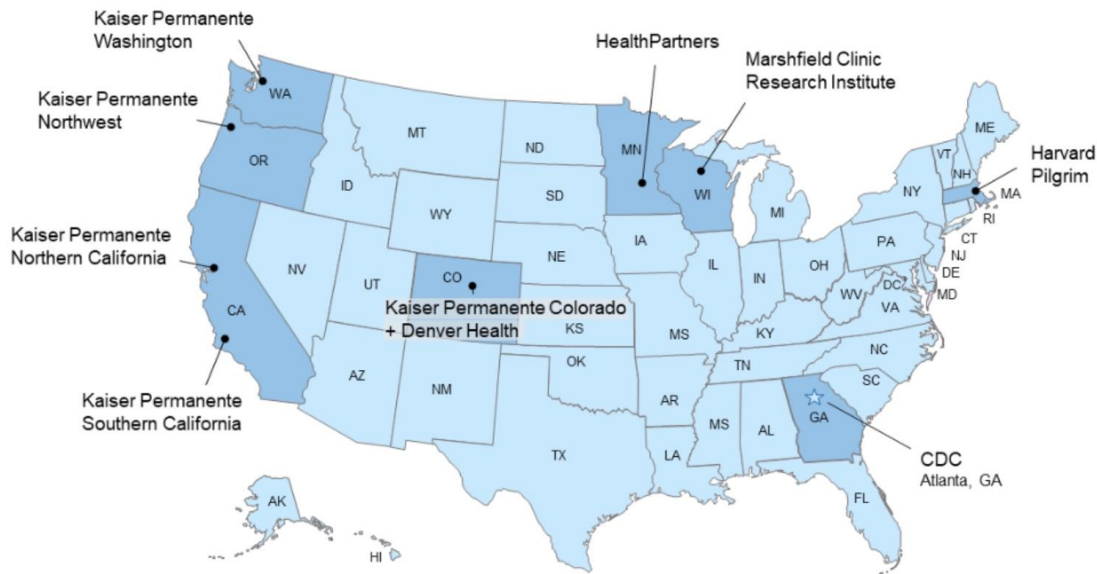
- clinical consult services[†]
- clinical research

[†]More information about clinical consults available at
<http://www.cdc.gov/vaccinesafety/Activities/CISA.html>



VSD

Vaccine
Safety
Datalink



9 participating integrated healthcare organizations

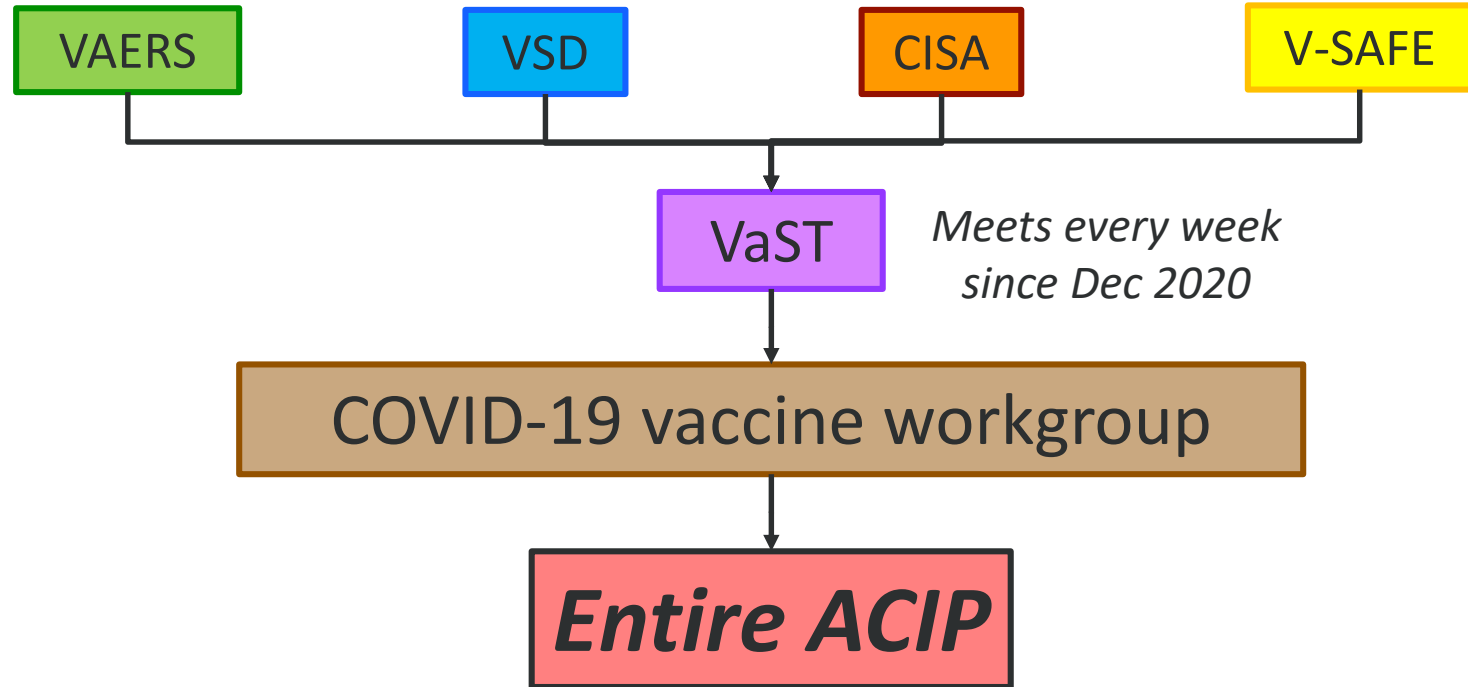
data on over **12 million** persons per year



Use your smartphone
to tell CDC about
any side effects after
getting the COVID-19
vaccine. You'll also get
reminders if you need a
second vaccine dose.



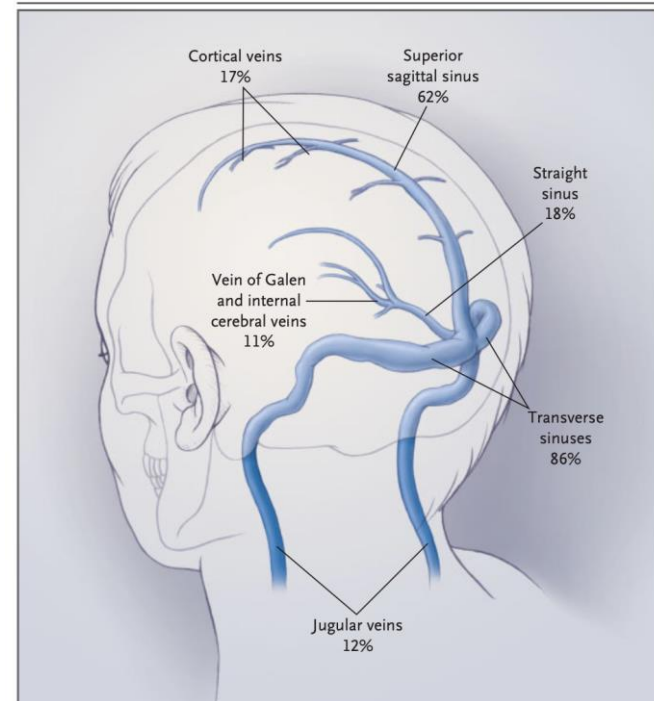
COVID-19 Vaccine Safety Technical Subgroup (VaST)



3 reasons for pausing J&J vaccine

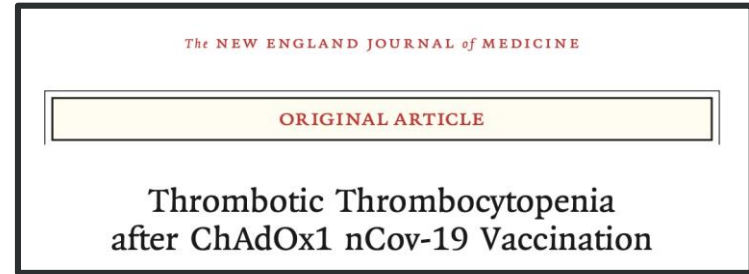
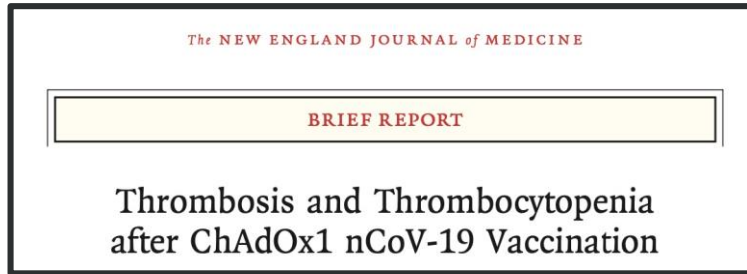
Reason #1 for pause of J&J vaccine

- **Safety signal in VAERS**
 - Six (6) cases in U.S. reported of rare and severe blood clot
 - Cerebral venous sinus thrombosis (CVST)
 - Recipients: female, 18-48 years of age
 - Onset: 6-13 days following J&J vaccine



Reason #2 for pause of J&J vaccine

- **Probable causal link** that adenovirus vectored vaccines were causing rare clotting in Europe (publications 4/9/2021)

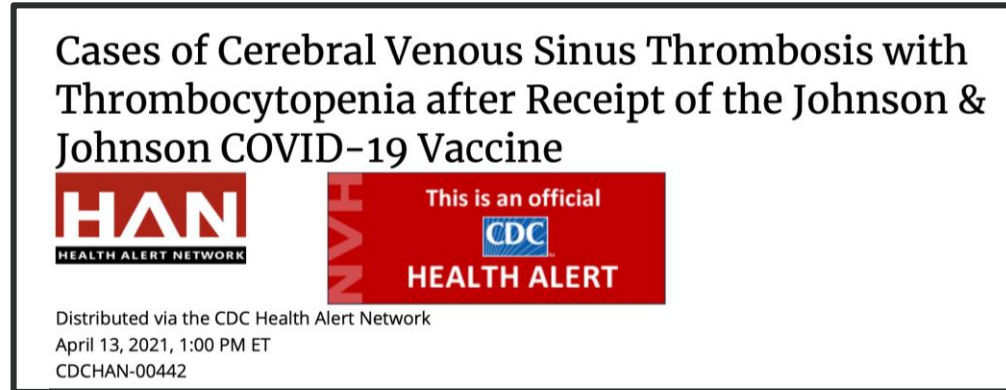


Adenovirus Vector

J&J (United States)
AstraZeneca (Europe)

Reason #3 for pause of J&J vaccine

- **Increase awareness of this unusual syndrome of clots**
 - What should providers, public health, and general public look out for...



ACIP emergency meeting: 4/23/2021

Potential Harms of the Janssen COVID-19 vaccine

- 7.98 million vaccine doses administered* and 15 confirmed TTS cases as of April 21, 2021
 - Additional potential TTS cases under review, including potential male cases

	Females			Males		
Age group	Cases	Doses admin	Reporting rate [†]	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>; Some age- and sex-specific doses administered data were imputed

[†] Reporting rate = TTS cases per 1 million Janssen COVID-19 vaccine doses administered

* One TTS case occurred in the Phase 3 trial in a male aged 18-49 years.

Acronyms: Thrombosis with Thrombocytopenia Syndrome (TTS)

ACIP meeting, April 23, 2021



What happens if we restrict J&J vaccination?

- Restricting from adults 18-50 years of age
 - In 6 months:
 - 1300-3500 excess hospitalizations
 - 50-250 excess deaths
 - 2 cases of clotting

mRNA vaccines (Pfizer, Moderna)

“Currently, there is a lack of evidence of an association between mRNA COVID-19 vaccines and CVST with thrombocytopenia”

*Tom Shimabukuro, MD, MPH, MBA
CDC COVID-19 Vaccine Task Force
ACIP meeting, 4/23/2021*

Policy Options for Janssen Policy Recommendations



Do **not** recommend use
of Janssen vaccine

Recommend use of Janssen
vaccine in **all adults**
≥18 years of age

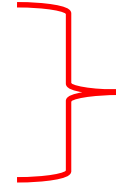
Recommend use of
Janssen/J&J COVID-19
vaccine in **some**
populations

Policy Options for Janssen Policy Recommendations

- Recommend **against** use for all persons
- Reaffirm recommendations for **all** age and sex
 - FDA to include warning statement with EUA
- Recommend vaccination only for adults **≥50 years of age**
- Reaffirm recommendations for use; women aged <50 years should **be aware** of the increased risk of TTS, and **may choose** another COVID-19 vaccine (i.e. mRNA vaccines)

Policy Options for Janssen Policy Recommendations

- Reaffirm recommendations for **all** age and sex
 - FDA to include warning statement with EUA



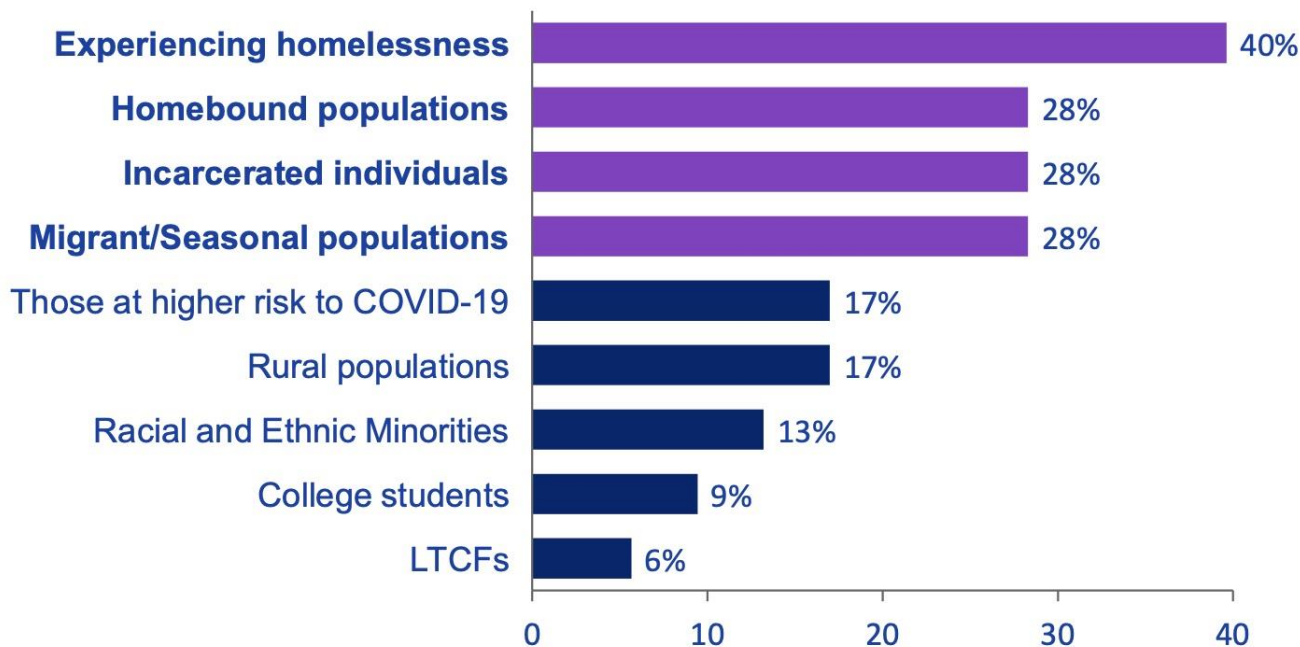
10	Yes
4	No
1	Abstain

How J&J fits in the COVID-19 vaccine landscape

Benefits of J&J vaccine

- Single-dose
- Stable in refrigerator temperatures
- Easier to reach populations
 - COVID-19 disease has disproportionate impact *-and/or-*
 - Difficult to return for 2nd dose

Q: Which, if any, populations would be disproportionately impacted if Janssen vaccine was no longer recommended or recommended for only a subset of the population?



ACIP meeting, April 23, 2021

Share of jurisdictions surveyed

Jurisdictional survey on impacts of Janssen pause, April 18th- 21st, 2021 (n=53)

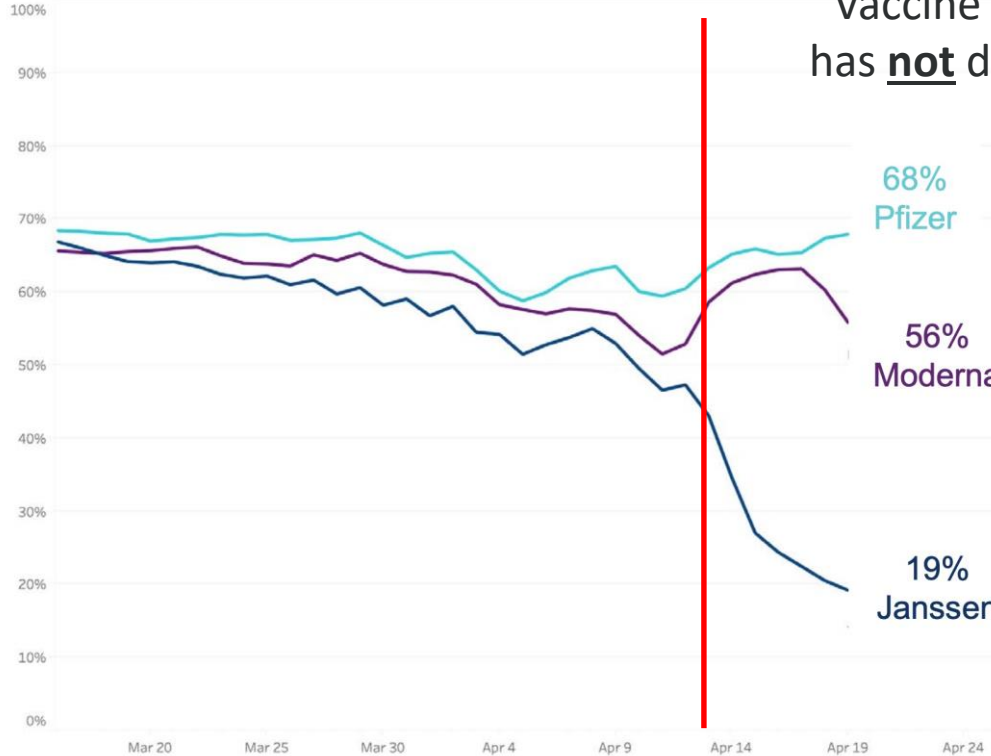
Vaccine confidence

Decision-making around vaccinations

CDC, April 5, 2021

“Many factors influence vaccine decision-making, including cultural, social, and political factors; individual and group factors; and vaccine-specific factors.”

Willingness to get each vaccine, daily trend
(rolling three-day averages)



Of persons who are willing to be vaccinated:
Vaccine confidence in mRNA vaccines
has not declined with J&J vaccine pause



Building trust in 3 areas

- The vaccine itself
- The providers who give the vaccines
- The process that leads to vaccine development, review, manufacturing, and recommendations



Building confidence

- Vaccines are tested thoroughly
- Vaccine safety is actively monitored
- Concerns around vaccines are varied
- The most important resource for vaccine decision-making is an informed, caring, and concerned provider

Edwards KM, Hackell JM, et al. Countering Vaccine Hesitancy. Clinical Report, American Academy of Pediatrics, 2016.

Summation

Take-home points

- Monitoring for vaccine safety in U.S. is working
 - Detection of 6 cases in >7 million doses of J&J vaccine
 - Transparent discussion of risk/benefit from ACIP
- J&J vaccine has clear benefits and belongs in the COVID-19 vaccine landscape
- COVID-19 vaccinations is a safe and effective intervention in an ongoing pandemic



Extra slides

VAERS – more data is needed for causality

Vaccinated with side effect	Vaccinated without side effects
Not vaccinated with side effect	Not vaccinated without side effect

VAERS – more data is needed for causality

Vaccinated with hair dye problem	Vaccinated without hair dye problem
Not vaccinated with hair dye problem	Not vaccinated without hair dye problem