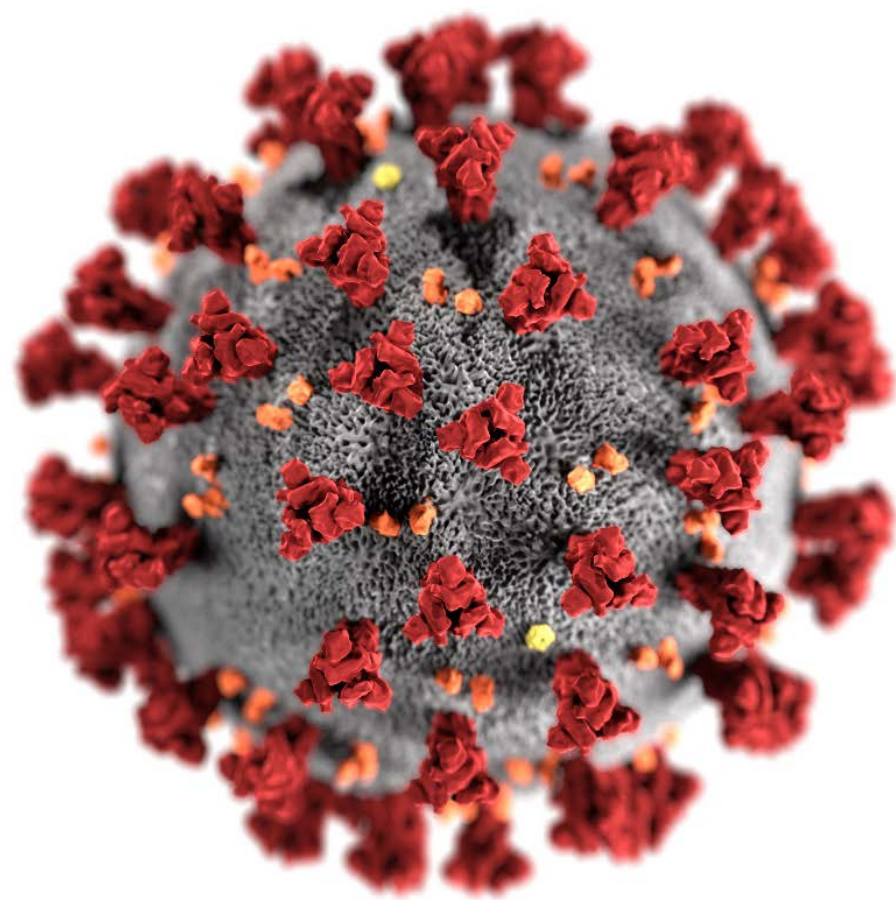


Thrombocytopenic thrombosis after Janssen vaccine: Work Group Interpretation



Sara Oliver MD, MSPH
ACIP Meeting
April 14, 2021



Discussion by the Work Group

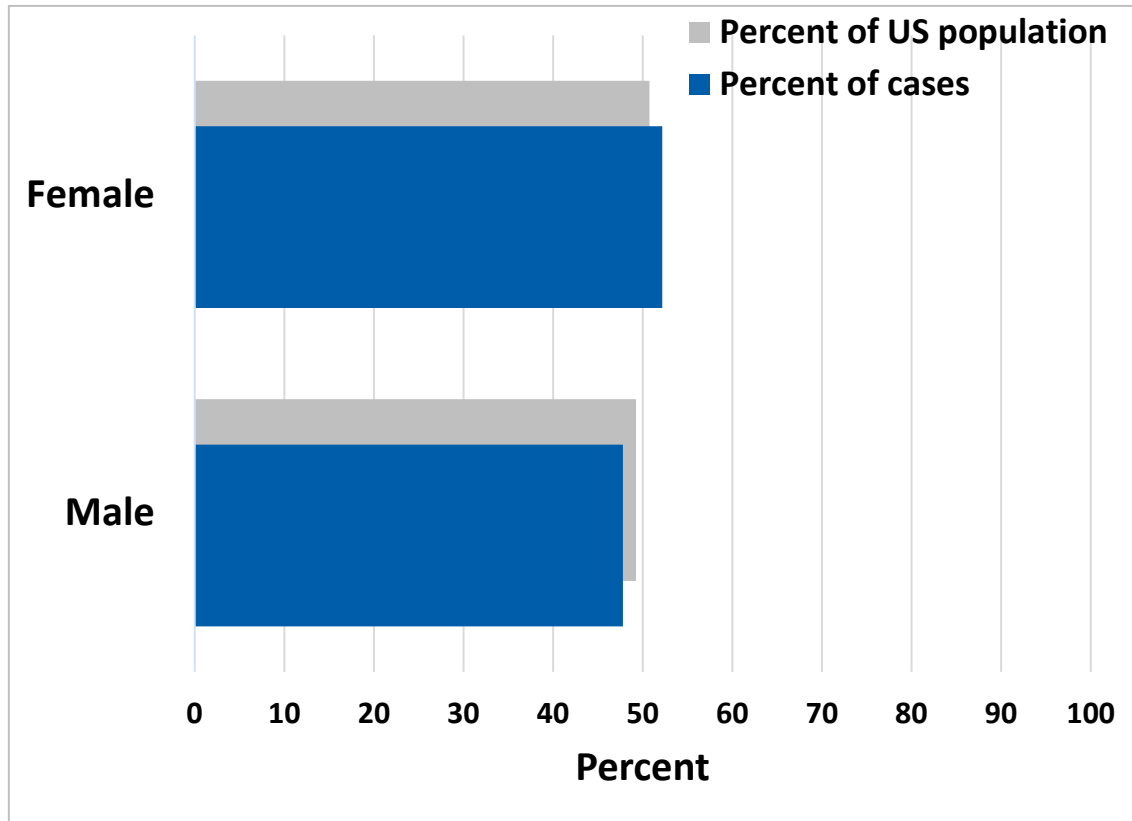
- Benefit/risk balance for use of the Janssen COVID-19 vaccine
- Review of cerebral venous sinus thrombosis (CVST) cases
- Risk of COVID-19 disease, by sex and age
- COVID-19 vaccines administered, by age
- Janssen vaccine doses administered to date
- Projected supply of COVID-19 vaccines in the US
- Policy options for updated recommendations for use for Janssen COVID-19 vaccine

CVST cases reviewed by the Work Group

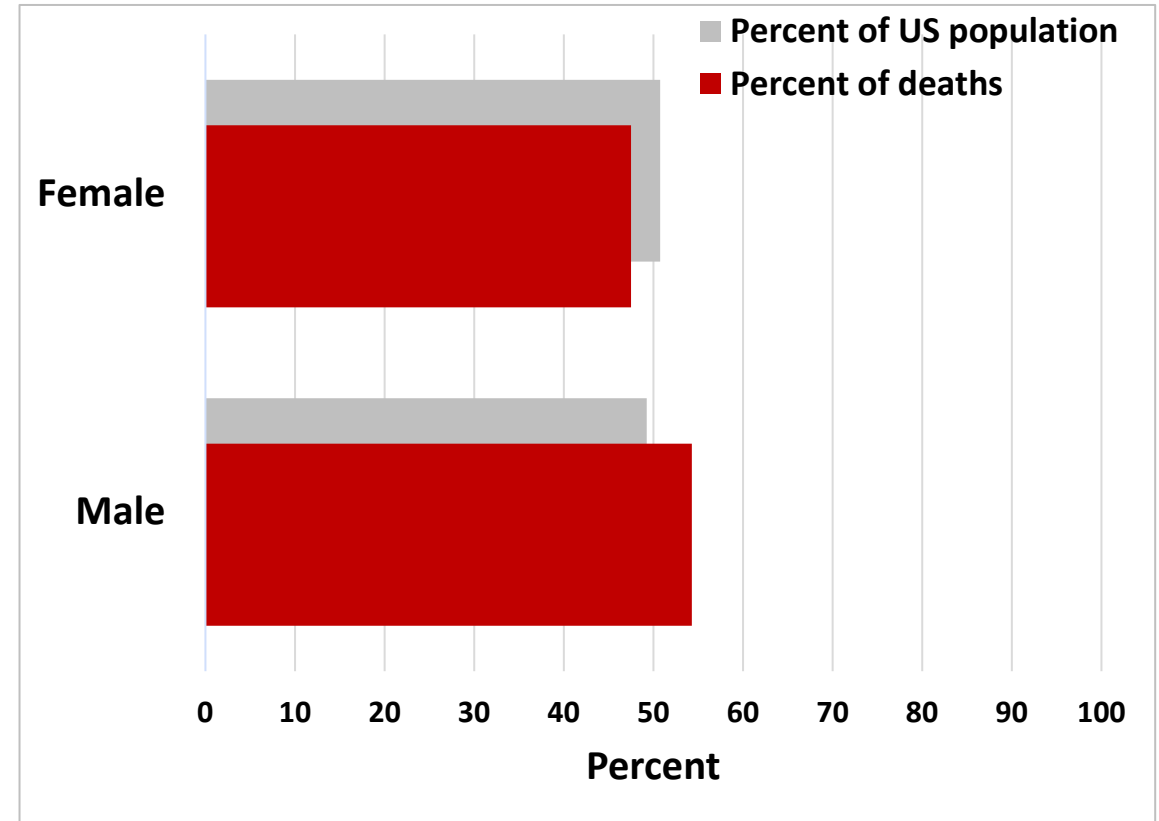
- 6 cases of CVST reported to VAERS
 - All 6 among women 18-48 years of age
 - Interval from vaccine receipt to symptom onset ranged from 6-13 days
- 1 case of CVST reported in the Phase 3 clinical trial
 - 25 year old male, no previous medical history, no medications
 - Day 9 after vaccination: fever, headache
 - Day 19 after vaccination: seizure, CT with cerebral hemorrhage
 - Day 21 after vaccination: CVST diagnosed, anti-PF4 positive

COVID-19 Cases and Deaths by Sex

COVID-19 Cases by Sex,
January 22, 2020 – April 12, 2021



COVID-19 Deaths by Sex,
January 22, 2020 – April 12, 2021

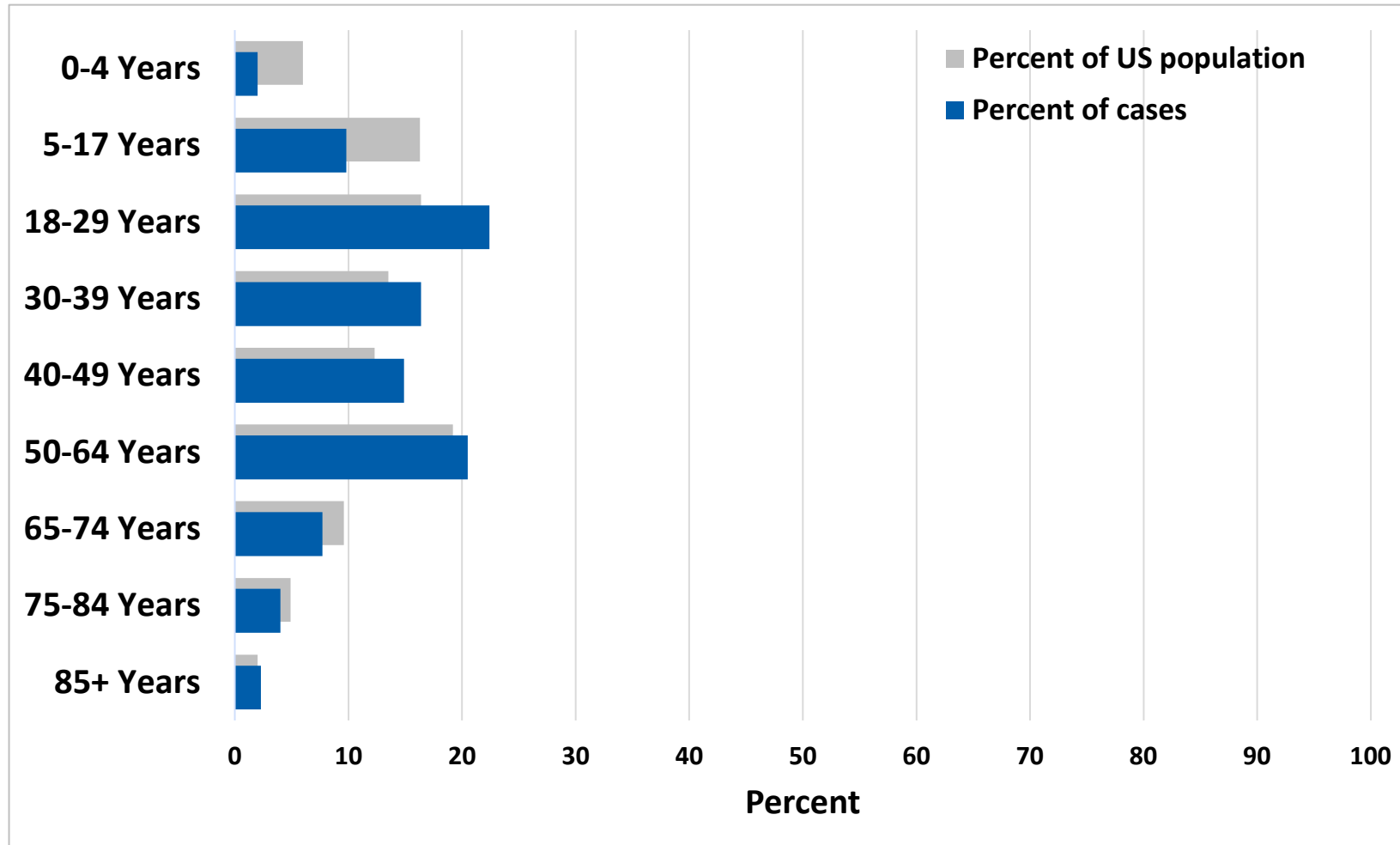


*Data from 24,349,551 cases, sex was available for 24,071,425
<https://covid.cdc.gov/covid-data-tracker/#demographics>

*Data from 433,171 deaths, sex was available for 432,059

COVID-19 Cases by Age Group

COVID-19 Cases by Age Group, January 22, 2020 – April 12, 2021

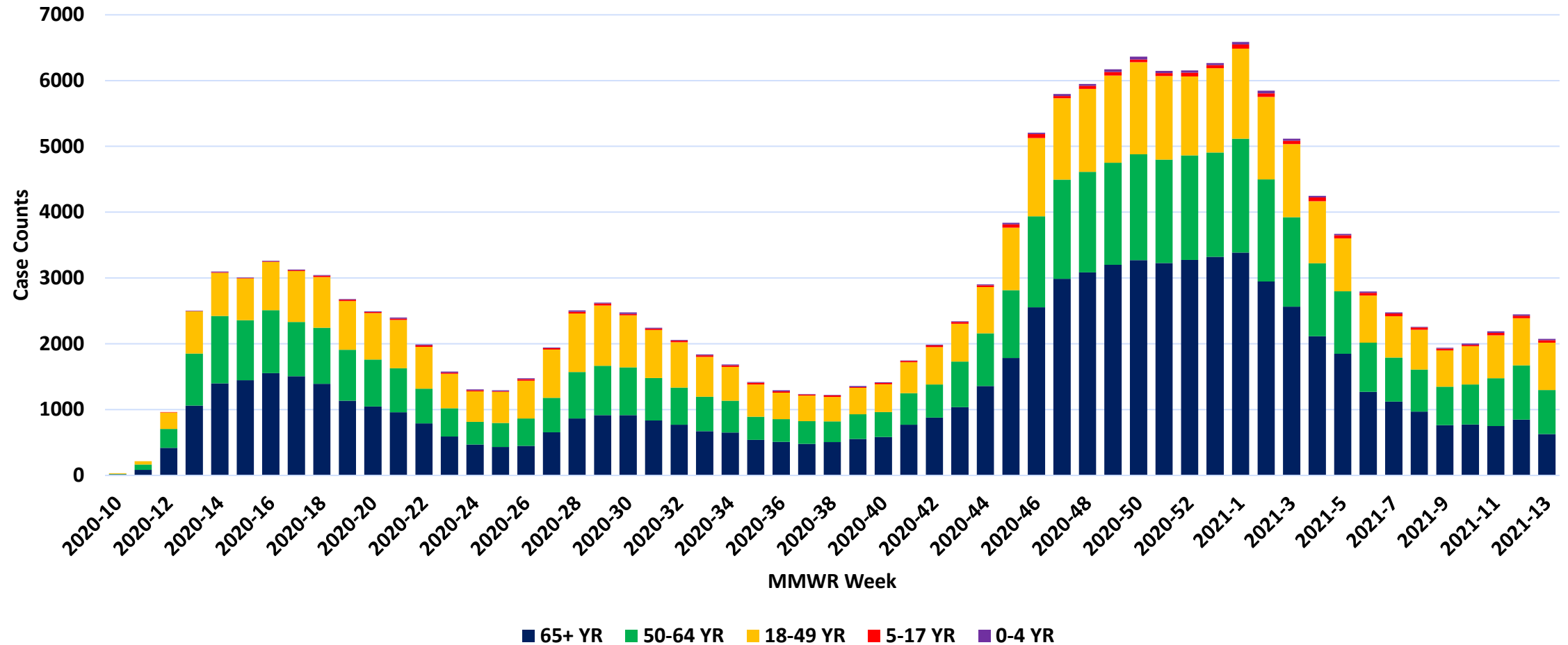


<https://covid.cdc.gov/covid-data-tracker/#demographics>

Data from 24,349,551 cases. Age group was available for 24,176,192

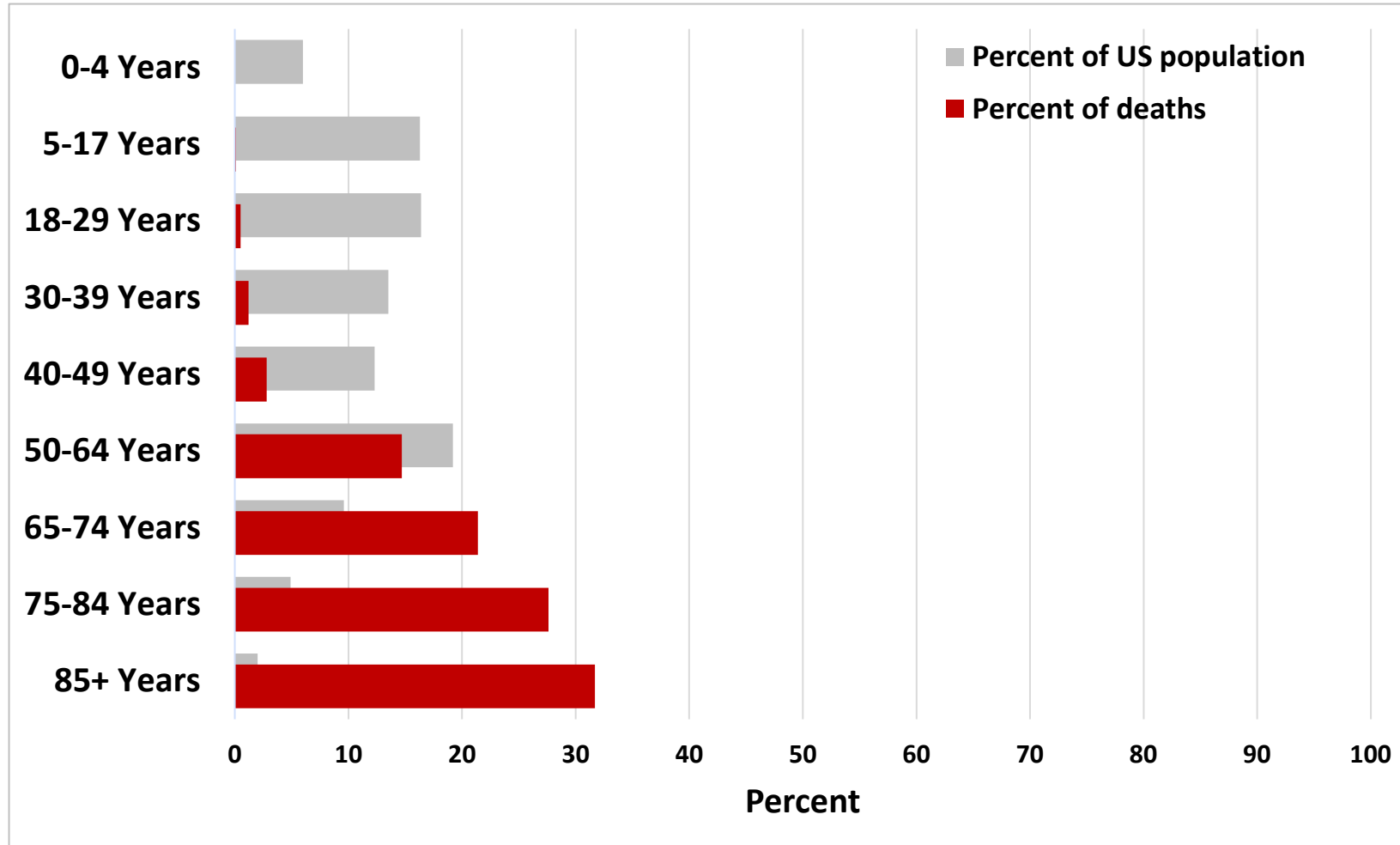
COVID-19 Associated Hospitalizations by Age Group

COVID-19-Associated Hospitalization, by Age Group
Preliminary weekly rates as of April 3, 2021



COVID-19 Deaths by Age Group

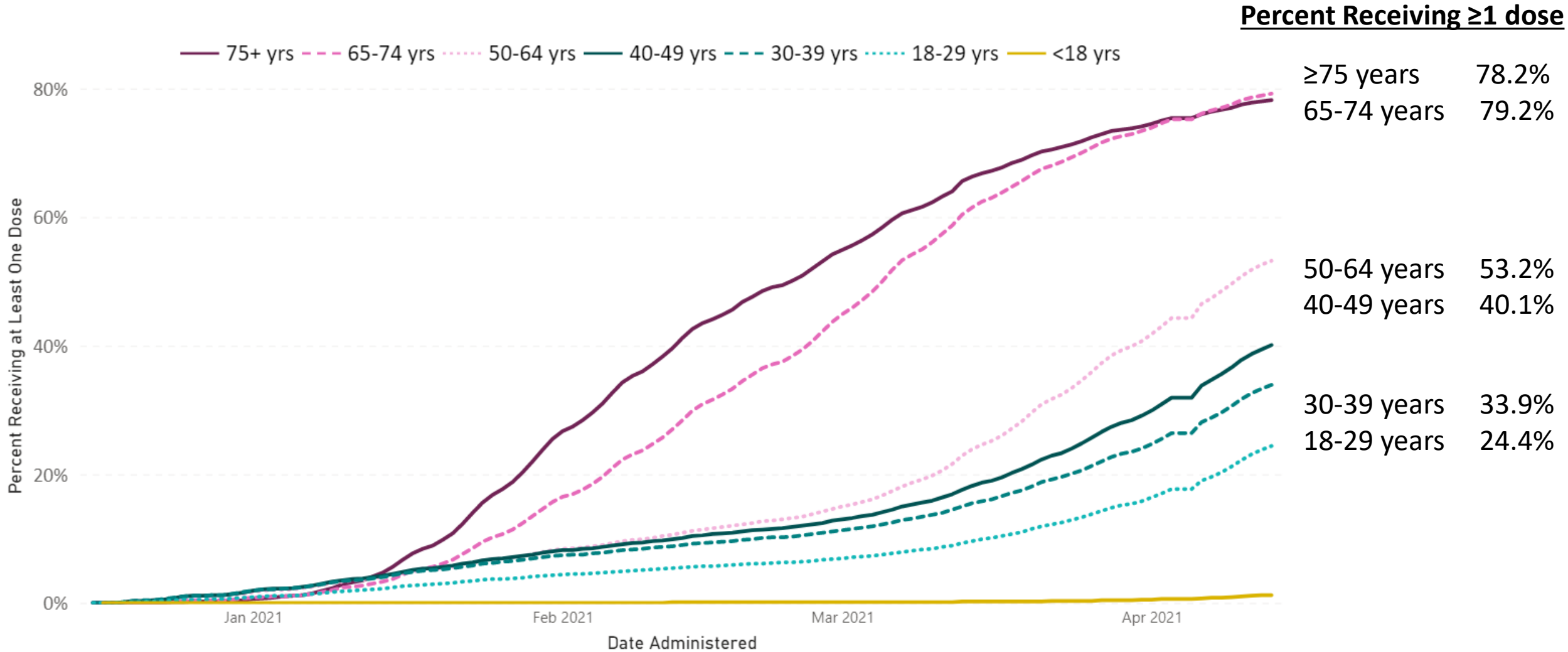
COVID-19 Deaths by Age Group, January 22, 2020 – April 12, 2021



<https://covid.cdc.gov/covid-data-tracker/#demographics>

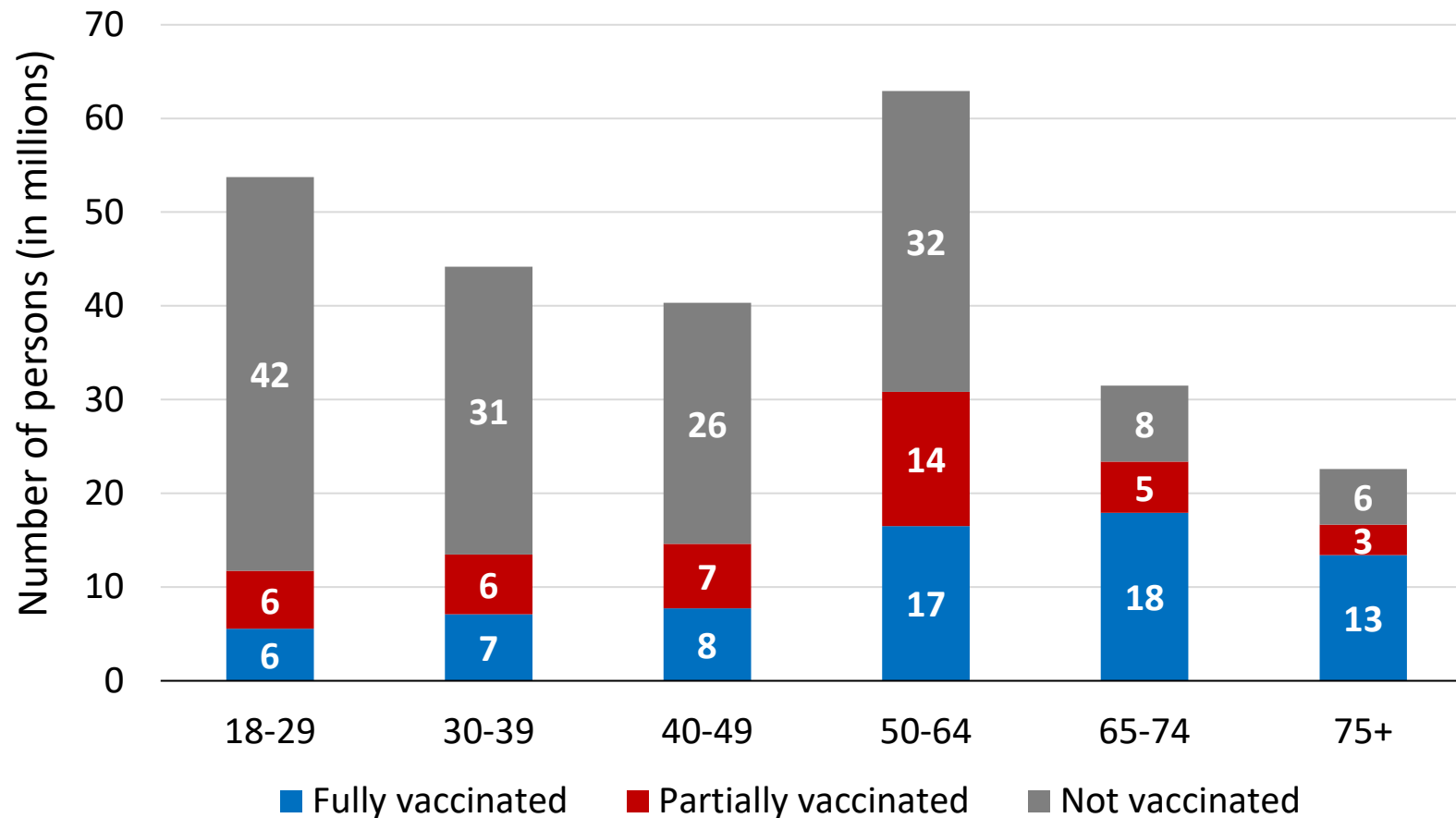
Data from 433,171 deaths. Sex was available for 433,132

COVID-19 Vaccination Coverage by Age – United States



Data as of April 13, 2021; age available for 92% of doses administered.
<https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic>

Number (in millions) of adults fully, partially, and not vaccinated, by age group



Data on vaccine doses as of April 12, 2021; age available for 92% of doses administered.

<https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic>

<https://wonder.cdc.gov>

Janssen Doses Administered to Date

- 7,233,726 Janssen doses administered to date
 - 1,495,400 Janssen doses administered to females 18-50 years of age*

Janssen Doses Administered to Date by Sex, Age Group, and Combined Race and Ethnicity – United States

Characteristic	Doses Administered	Percentage
Sex		
Male	3,539,227	49.5%
Female	3,400,989	50.5%
Age Group		
Under 18	9,299	0.1%
18-49	3,400,989	47.0%
50-64	2,508,374	34.7%
65+	1,314,359	18.2%
Combined Race and Ethnicity		
Hispanic	696,395	15.7%
NH, AI/AN	25,874	0.6%
NH, Asian	206,743	4.7%
NH, Black	429,091	9.7%
NH, Multi/Other	245,033	5.5%
NH, White	2,828,538	63.8%
Total		

NH = Non-Hispanic

AI/AN = American Indian / Alaska Native

Sex available for 99% of vaccination records; Age available for 99.9% of vaccination records; Combined race and ethnicity available for 61% of vaccination records
 Source: CDC Immunization Data Lake; Includes data reported to CDC as of 4/13/2021 at 6:00 am

Janssen Doses Administered to Date

Thrombocytopenic thrombotic events develop ~6-13 days after vaccine receipt

7,233,726 doses administered in the United States

Prior to March 30:

3,466,166 Janssen doses administered
48% of doses



Thrombocytopenic thrombotic events post-vaccine likely already occurred

March 30 to April 13

3,767,560 Janssen doses administered
52% of doses



Thrombocytopenic thrombotic events post-vaccine may still occur

COVID-19 vaccine Supply Considerations

mRNA vaccines

- Expect ~14 million first doses of Pfizer and Moderna vaccines each week

Janssen vaccines

- To date, Janssen COVID-19 vaccine comprises <5% of the vaccines administered
- Approximately 13 million doses of Janssen vaccines available
 - Estimated 3.6M doses available to order
 - Estimated 9.2M doses currently available at administration sites
- While doses for the Janssen vaccine may be less than mRNA vaccines, Janssen vaccine has been used in populations that may be difficult to reach with mRNA vaccines that require freezer temperatures or two doses

What is known so far

- Thrombocytopenic thrombotic events after the AstraZeneca vaccine have occurred
- In the US, 6 cases of CVST reported after receipt of the Janssen COVID-19 vaccine.
- No cases of CVST with thrombocytopenia reported after receipt of either Pfizer and Moderna COVID-19 vaccines
- CVST cases have occurred primarily in younger adults, females
- CVST can be clinically devastating or fatal
- In the US, alternative COVID-19 vaccines (mRNA vaccines) are available
 - Based on current projections, supply of both mRNA vaccines fairly stable for near future

What we do NOT know

- True background incidence of CVST with thrombocytopenia
- Specific risk factors for thrombocytopenic thrombotic events
- Incidence of other thrombotic (non-CVST) cases with thrombocytopenia after Janssen vaccine
- Ability to compare or generalize thrombotic cases after the AstraZeneca vaccine to Janssen vaccine
- True incidence of thrombocytopenic thrombotic events/CVST after a Janssen/J&J COVID-19 vaccine
 - More cases may be identified in the coming days/weeks

Policy options: Janssen/J&J COVID-19 vaccine



Policy options: Janssen/J&J COVID-19 vaccines

WG Discussion points

- While overall reported cases are rare, once limited to doses administered to age and sex of CVST cases seen, observed cases exceed expected cases
- Given the timing of doses administered (52% of doses administered in the previous 2 weeks), additional cases may be identified over the next 1-2 weeks
- Emphasis that robust safety surveillance is critical
 - Signal detection and evaluation of cases occurred as planned

Policy Options for Janssen Policy Recommendations



Do **not** recommend use
of Janssen vaccine

Recommend use of
Janssen/J&J COVID-19
vaccine in **all adults**
≥18 years of age

Policy Options for Janssen Policy Recommendations



Do **not** recommend use of Janssen vaccine

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

Recommend use of Janssen/J&J COVID-19 vaccine in **all adults** ≥ 18 years of age

Age or gender
specific populations?

- Adults 50 years of age and older only
- Males only

Policy options: Janssen/J&J COVID-19 vaccines

WG Discussion points

- Sex/gender-based recommendations:
 - Difficult to implement
- Age-based recommendations:
 - Concern that we may not have sufficient data at this time to inform specific age cut-off
 - Acknowledge that many countries in Europe have used age-based approach for the AstraZeneca vaccine recommendations
 - Allow for additional options (mRNA or Ad-vector) in an older, at-risk population

Policy options: Janssen/J&J COVID-19 vaccines

WG Discussion points

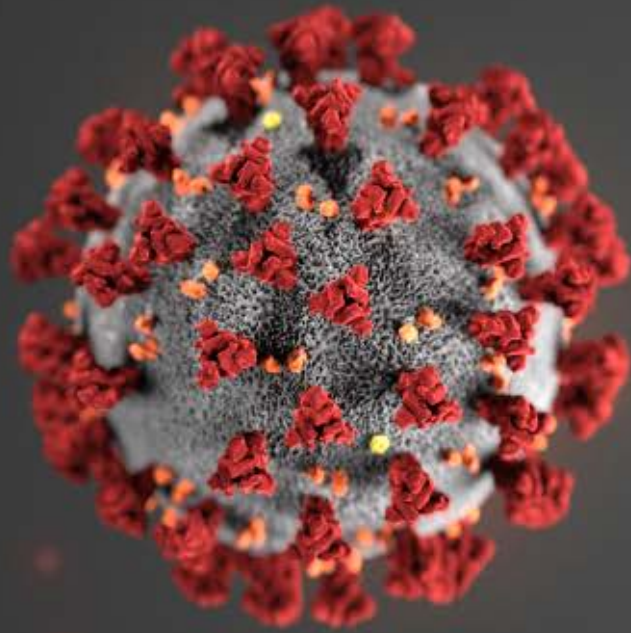
- Extending pause while awaiting additional information:
 - Potentially allow for more informed, specific recommendations for the use of the Janssen vaccine
 - Evaluate risk by age, inform possible age-based recommendation
 - Assess if thrombocytopenic thrombosis risk beyond CVST cases
 - Could have broad consequences:
 - Individuals may want to receive Janssen vaccine
 - Pause could have global implications (pausing clinical trials, availability of Janssen vaccine in other countries with more limited supply)

Previous Janssen vote:

The Janssen COVID-19 vaccine is recommended for persons 18 years of age and older in the U.S. population under the FDA's Emergency Use Authorization

Questions for ACIP to discuss:

- Does ACIP have enough information to make **interim** age or risk-factor based recommendations for use of the Janssen vaccine?
- What recommendation does ACIP feel is appropriate **today** given current available information for use of the Janssen vaccine?



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Thank you

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

