

BILH Primary Care

**Vaccine Hesitancy and Deliberation:
Approaches and Resources for
Shared Decision Making in a Public
Health Crisis**

April 29, 2021



**Beth Israel Lahey Health
Primary Care**

Vaccine Hesitancy and Deliberation:

Approaches to Shared Decision Making IN a PUBLIC HEALTH CRISIS

Leonor Fernández, MD

BILH DEI Council

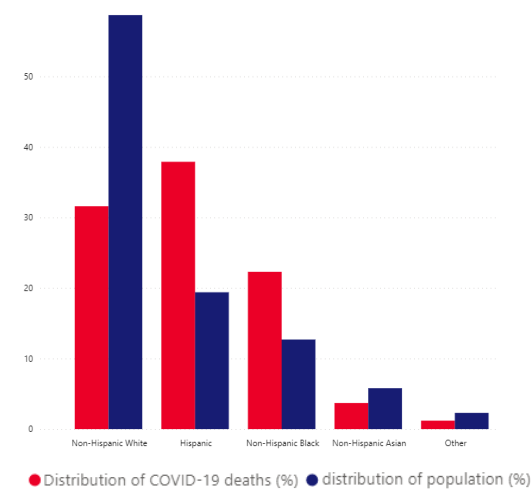
Director, Patient Engagement Healthcare Associates

CoChair BILHPC COVID Equity Advisory Council

Beth Israel Lahey Health 
Lahey Hospital & Medical Center

Far Disproportionate Impact of COVID-19...

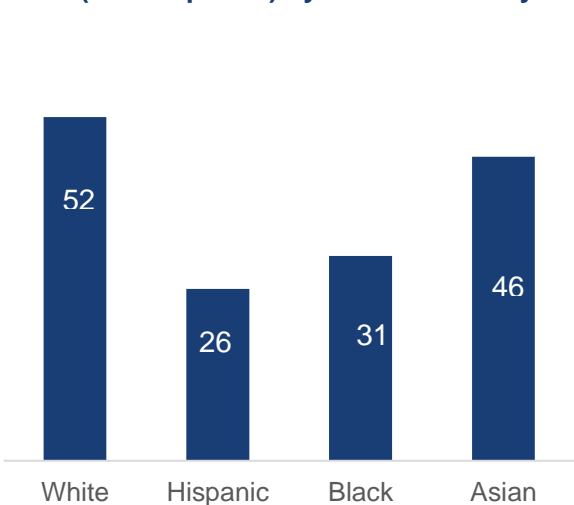
% Distribution of COVID-19 Deaths by Race / Ethnicity (Age-Adjusted) in Massachusetts



Source: National Center for Health Statistics

... And Lower Rates of Vaccination in Communities of Color

% of MA Residents with 1+ Vaccine Dose (As of April 22) by Race / Ethnicity



Source: MA Weekly COVID-19 Vaccination Dashboard

BILH Vaccine Equity – Current State [As of 4/26]

Patients Invited and Scheduling Rates By Race and Ethnicity

Race/Ethnicity Disparities Mitigated in Early Phases

Race & Ethnicity	Invites sent	Phase 2.1	Phase 2.2	Phase 2.4	Phase 2.5	Phase 3
White	815,270	19%	25%	16%	8%	3%
Asian	78,749	22%	21%	14%	10%	5%
Hispanic or Latino	75,215	23%	17%	9%	7%	2%
Black or African American	64,953	26%	19%	9%	7%	3%
American Indian or Alaska Native	1,415	26%	20%	11%	7%	3%
Native Hawaiian or Other Pacific Islander	1,696	39%	18%	5%	5%	2%
Other	58,269	23%	22%	12%	9%	4%
Unknown	129,621	14%	20%	8%	7%	2%
Total	1,225,188	19%	23%	14%	8%	3%

BILH Vaccine Equity – Current State [As of 4/27]

Patients Invited and Scheduling Rates By Language

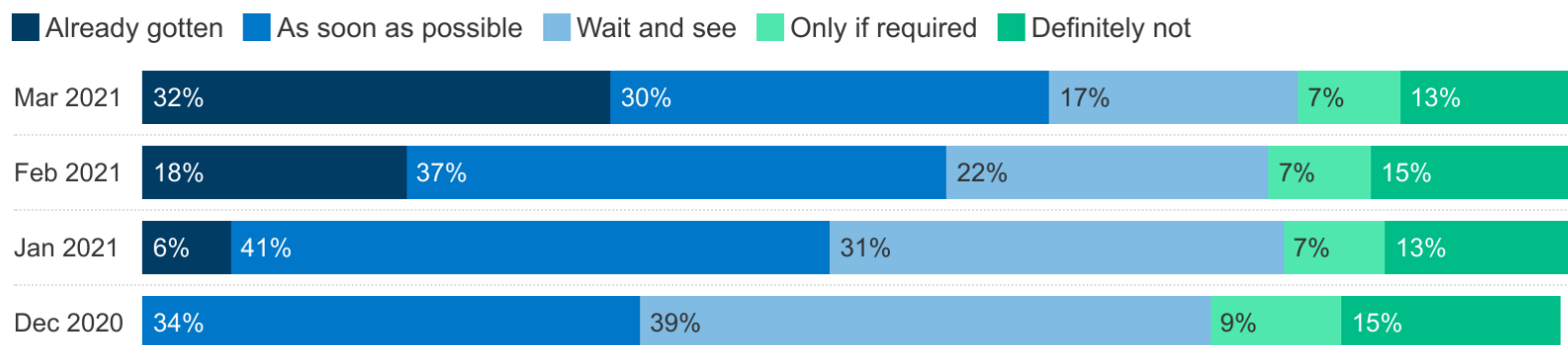
Vaccination Disparities by Language Remain Prominent

Language	Invites sent	Phase 2.1	Phase 2.2	Phase 2.4	Phase 2.5	Phase 3
English	1,035,016	20%	25%	15%	8%	3%
Spanish	28,289	15%	12%	7%	6%	2%
Chinese	28,457	15%	11%	7%	6%	4%
Russian	3,098	13%	19%	11%	5%	3%
Portuguese	5,062	23%	23%	14%	11%	5%
Cape Verdean	3,478	44%	41%	21%	12%	9%
Vietnamese	2,738	31%	27%	15%	9%	3%
Haitian	1,529	10%	9%	3%	2%	0%
Khmer/Mon-Khmer	1,004	10%	11%	12%	6%	8%
Arabic	936	22%	22%	8%	8%	6%
Korean	768	37%	29%	30%	20%	11%
Japanese	483	28%	41%	13%	19%	5%
Missing/Other	122,679	17%	17%	6%	7%	3%
Total	1,233,537	19%	23%	14%	8%	3%

1. Vaccine confidence has increased as more people have seen their friends and family members get vaccinated

- As of March, a majority the public has either already gotten vaccinated or is ready to get the vaccine as soon as they can.
- MA may soon hit a point where vaccine supply exceeds demand

Have you personally received at least one dose of the COVID-19 vaccine, or not? When an FDA authorized vaccine for COVID-19 is available to you for free, do you think you will...?

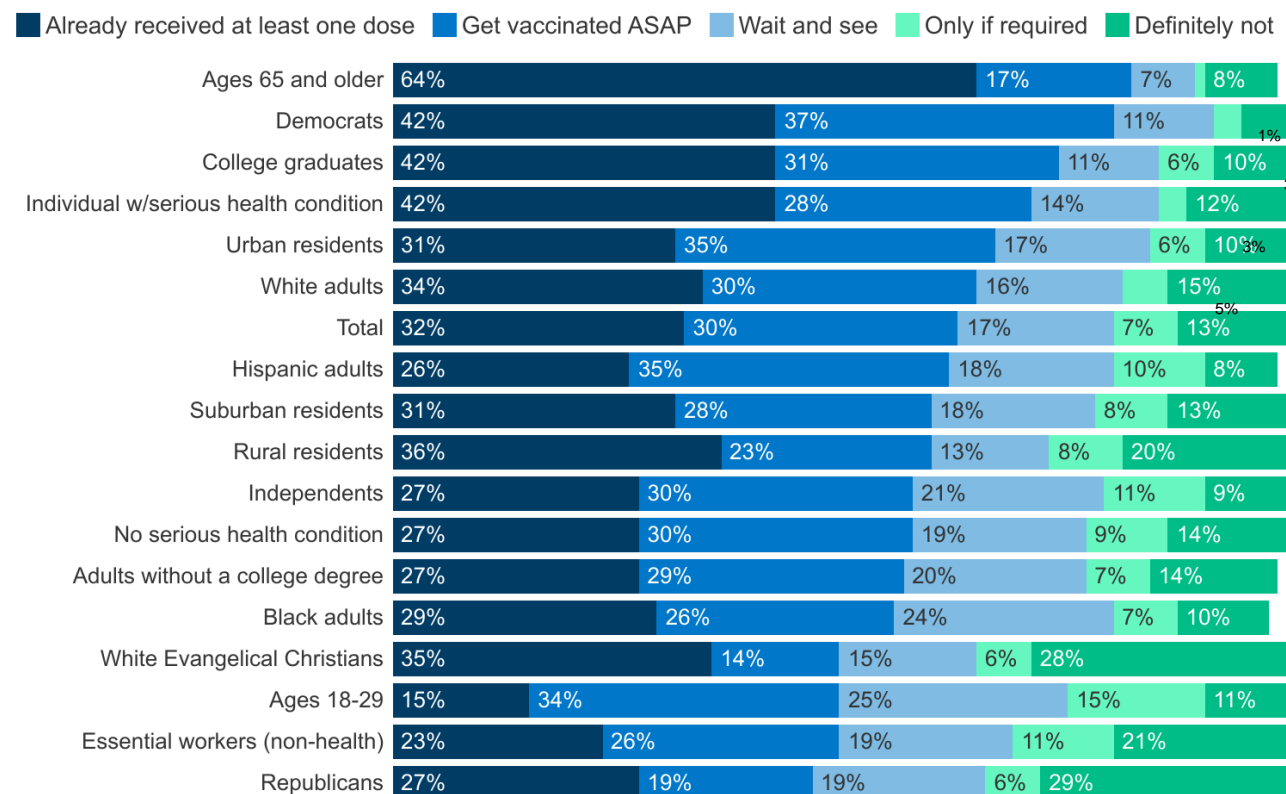


NOTE: December 2020 survey did not have an option for respondents to indicate they had already been vaccinated.

SOURCE: KFF COVID-19 Vaccine Monitor. See topline for full question wording.

2. No group is monolithic in their attitudes towards the COVID-19 vaccines

Have you personally received at least one dose of the COVID-19 vaccine, or not? When an FDA authorized vaccine for COVID-19 is available to you for free, do you think you will...?

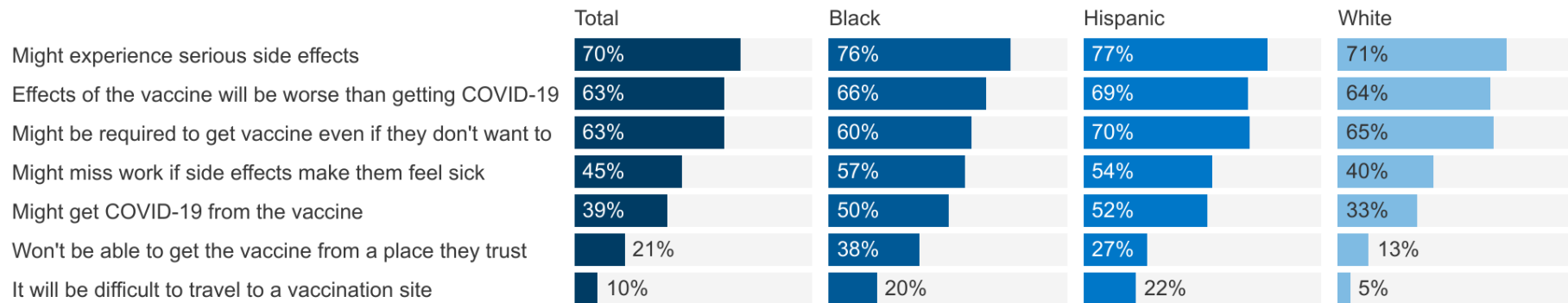


- In every demographic segment there are large shares of people who are **ready to get the vaccine**, others who are in “**wait and see**” mode, and some who are **more resistant**.

SOURCE: KFF COVID-19 Vaccine Monitor (March 15-22, 2021). See topline for full question wording.

3. People have a range of questions and concerns about the vaccine that require different strategies to address

- Some concerns reflect a lack of access to **accurate information**, including concerns about getting COVID-19 from the vaccine, cost, ID
- Other concerns reflect issues with vaccine **access**, including needing to take time off work due to vaccine side effects, transportation, or concern about not being able to get the vaccine from a trusted place



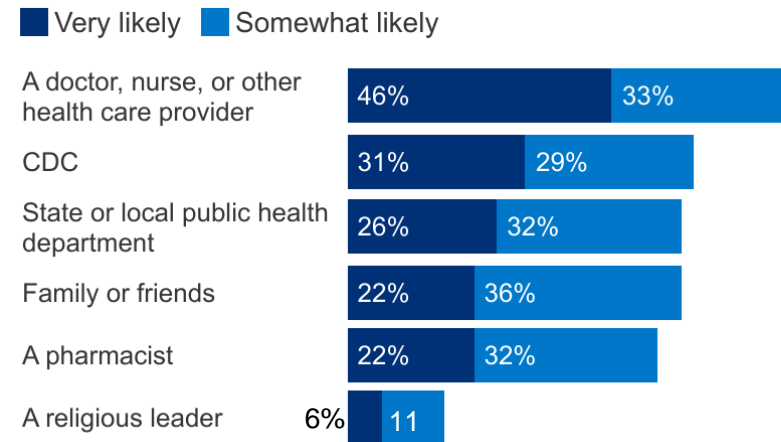
NOTE: Among those who have not been vaccinated for COVID-19 and do not want to get the vaccine as soon as possible.

SOURCE: KFF COVID-19 Vaccine Monitor (March 15-22, 2021). See topline for full question wording.

4. Individual health care providers are the most trusted messengers when it comes to information about the COVID-19 vaccines

- With trust in national public health messengers eroding and becoming increasingly partisan over the past year, local doctors, nurses, health care providers, and other **trusted community figures** have an important role to play in supplementing national campaigns to increase COVID-19 vaccine confidence and uptake.

Percent who say they are very or somewhat likely to turn to each when deciding whether to get a COVID-19 vaccine:



NOTE: Among those who have not been vaccinated against COVID-19.

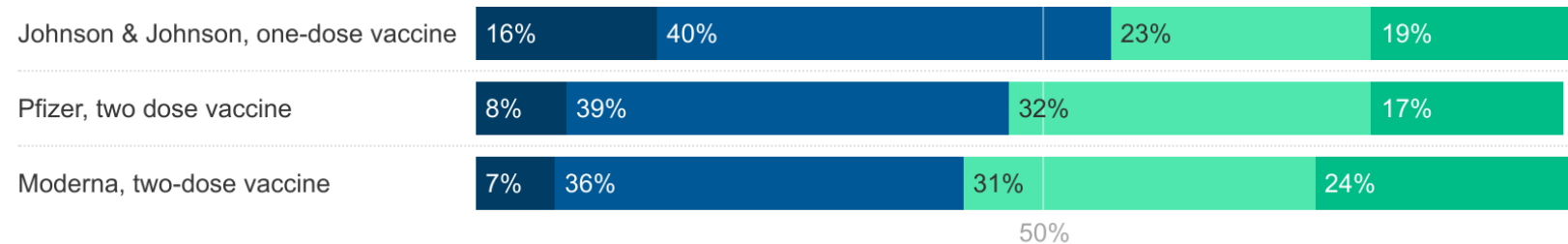
SOURCE: KFF COVID-19 Vaccine Monitor (conducted Jan. 11-18, 2021). See topline for full question wording.

5. It is too early to know what effect the pause in distribution of the Johnson & Johnson vaccine will have on vaccine confidence

- Prior to this announcement, the one-shot vaccine was an appealing option for a large share of those in the “**wait and see**” group.
- Potential vaccine side effects are a **top concern**, unclear what effect pause will have

If you were offered each of the following vaccines available in the U.S., would you...

■ Definitely get it ■ Probably get it ■ Probably not get it ■ Definitely not get it



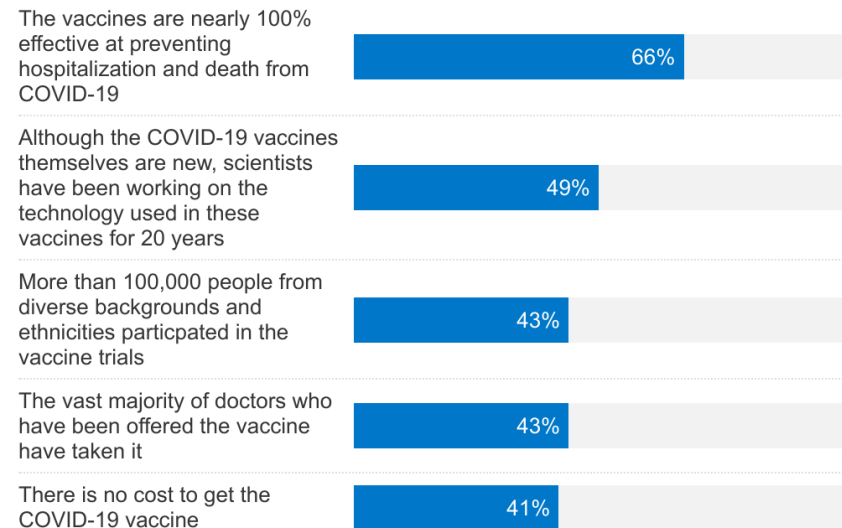
NOTE: Among those who say they want to wait and see how it is working for others before getting vaccinated for COVID-19

SOURCE: KFF COVID-19 Vaccine Monitor (March 15-22, 2021). See topline for full question wording

6. Messages about the vaccines' effectiveness work best with the “wait and see” group

- **messages about the effectiveness** of the existing vaccine options at preventing serious illness and death from COVID-19 are likely to be the **most effective** at bolstering confidence among those who are on the fence about getting the vaccine.

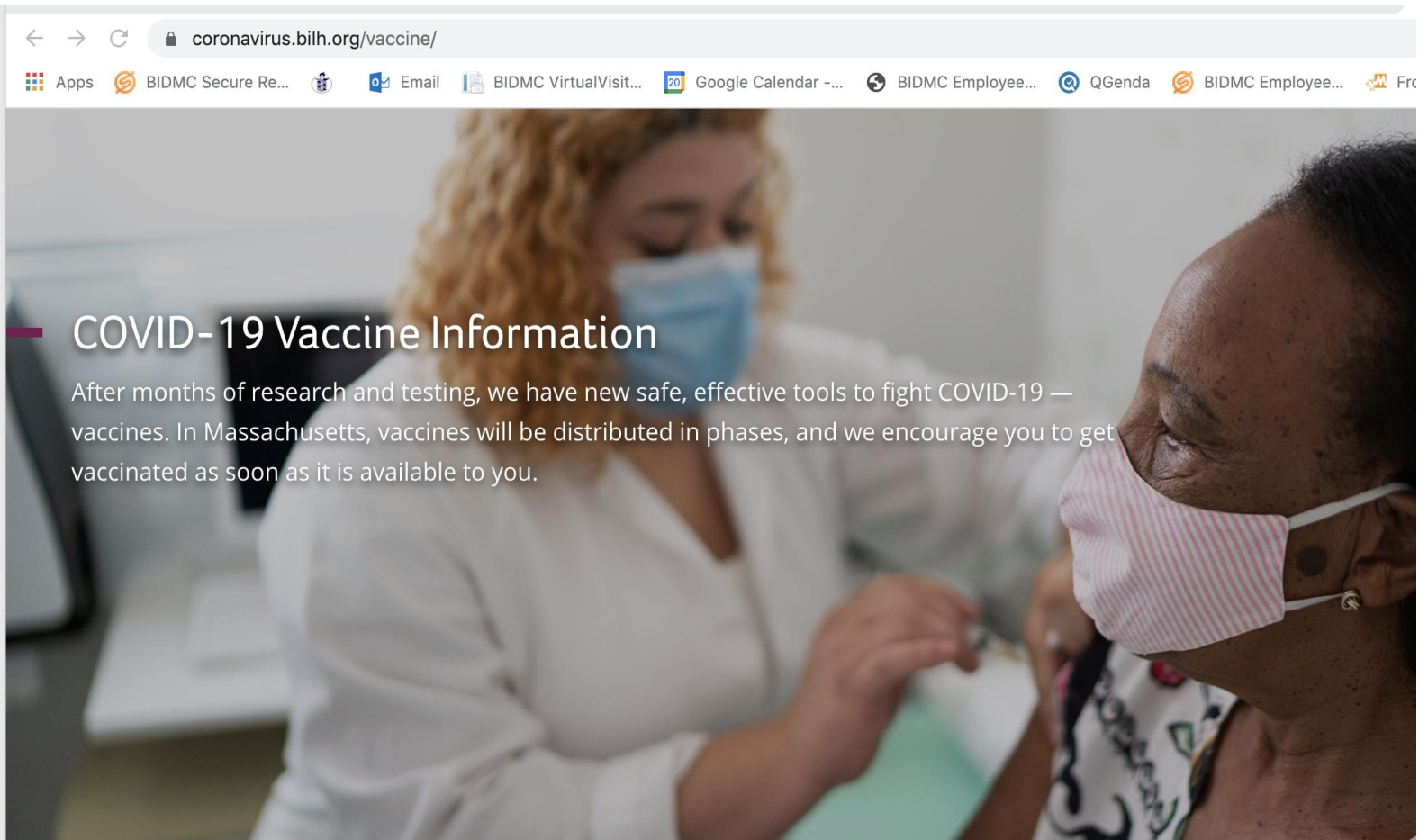
Among those who want to “wait and see,” percent who say they are more likely to get the COVID-19 vaccine if they heard each of the following:



NOTE: Based on those who want to “wait and see” before getting vaccinated for COVID-19.

SOURCE: KFF COVID-19 Vaccine Monitor (March 15-22, 2021). See topline for full question wording.

Access, Shared Decisions, Trust and Autonomy



The image is a screenshot of a web browser displaying a page from coronavirus.bihh.org/vaccine/. The browser's address bar and a row of open tabs are visible at the top. The page features a large background image of a healthcare worker in a white coat and blue mask attending to a patient wearing a pink and white striped face mask. On the left side of the page, there is a purple horizontal line followed by the section title 'COVID-19 Vaccine Information'. Below this title, a paragraph of text is displayed.

← → ↻ coronavirus.bihh.org/vaccine/

Apps BIDMC Secure Re... Email BIDMC VirtualVisit... Google Calendar -... BIDMC Employee... QGenda BIDMC Employee... Frc

COVID-19 Vaccine Information

After months of research and testing, we have new safe, effective tools to fight COVID-19 — vaccines. In Massachusetts, vaccines will be distributed in phases, and we encourage you to get vaccinated as soon as it is available to you.

Other Resources for Vaccine Deliberation

References:

Addressing Mistrust Among Patients of Color, Opel, Peek

<https://doi.org/10.7326/M21-0055>

Episode 162: Antiracism in Medicine Series - Episode 6 - Racism, Trustworthiness, and the COVID-19 Vaccine

<https://clinicalproblemsolving.com/2021/02/25/episode-162-antiracism-in-medicine-series-episode-6-racism-trustworthiness-and-the-covid-19-vaccine/> via @cpsolvers

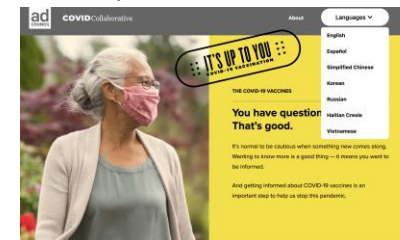


RESOURCES FOR CLINICIANS/PATIENTS

<https://www.ama-assn.org/delivering-care/public-health/covid-19-vaccine-hesitancy-10-tips-talking-patients>

<https://www.nachc.org/coronavirus/covid-vaccine-communications-toolkit/>

<https://hispaniccommunityvaccinetoolkit.org/>



<https://spanish.getvaccineanswers.org/>

https://blackfaithvaccinetoolkit.org/?_ga=2.145539828.1128787812.1619662462-1321684627.1619369865

“Move at the Speed of Trust”

-Damian Archer, MD

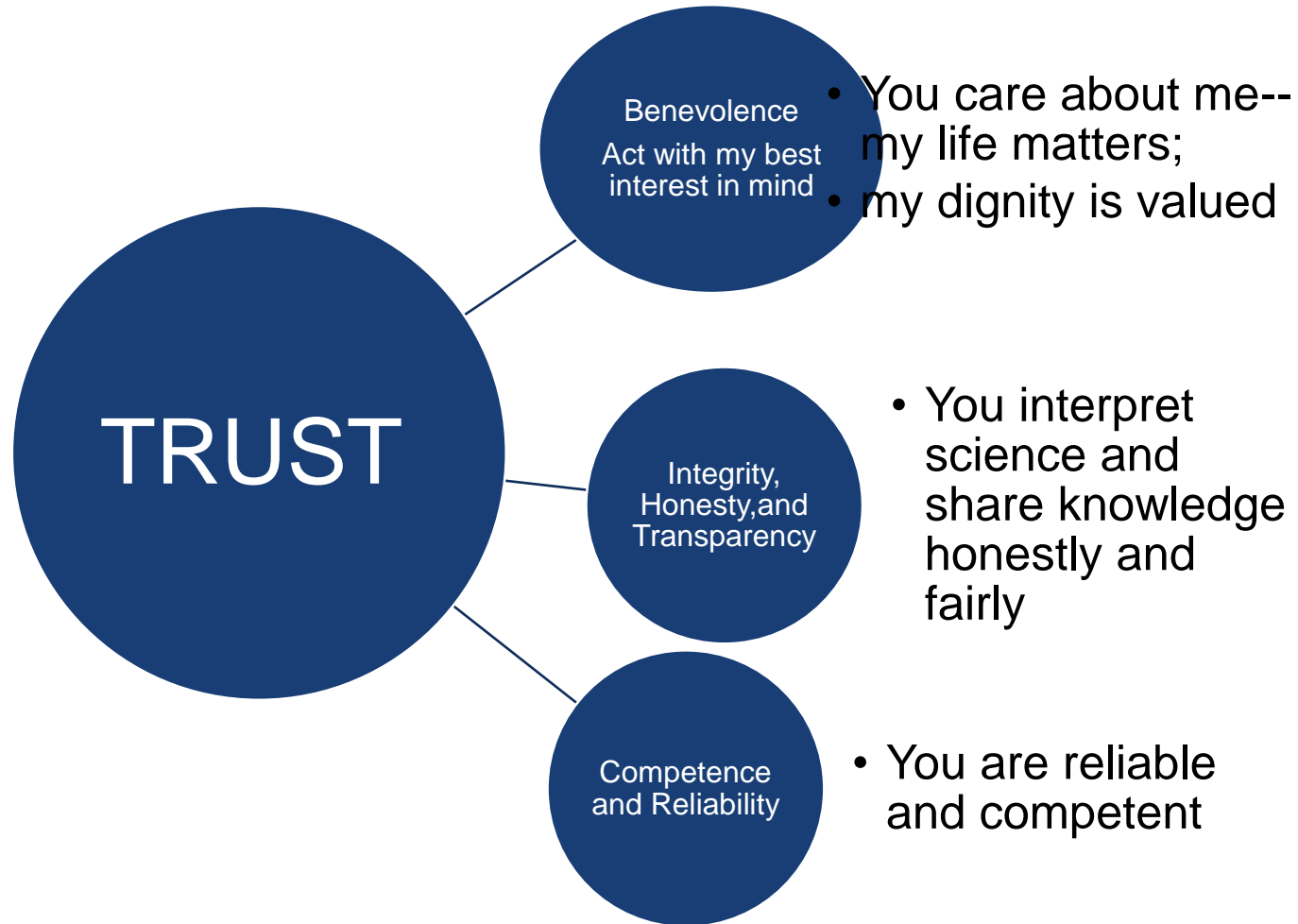


Table. COVID-19 Vaccine Communication Strategies for the Clinical Encounter to Help Address Mistrust

Motivational Interviewing Techniques		
Technique	Rationale	Example
Open-ended questions	Helps identify, explore, and understand patients' COVID-19 vaccine concerns	"Can you tell me more about what is worrying you?"
Reflection statements	Encourages partnerships, deepens rapport, and broadens understanding of patient motivations	"I hear that you want to be sure that the COVID vaccine is safe for you."
Affirmation statements	Helps patients feel supported, appreciated, and understood, which can improve their engagement in an open discussion	"You're not alone. Several of my patients have similar concerns."
Ask permission to share	Puts patients in a less defensive posture and improves receptivity to information being shared	"May I share my view with you?"
Statements that support patient autonomy	Enhances a patient's sense of control and helps them feel more at ease with the conversation	"I want you to know that this is your decision to make."
Rolling with resistance	Meeting patient resistance with curiosity (an opportunity to understand more about the patient's perspective in a nonjudgmental, respectful way) rather than confrontation encourages continued patient engagement	"I am hearing that you don't think you'll get the COVID vaccine anytime soon. Tell me more about what is concerning you."

Opel DJ, Lo B, Peek ME. Addressing Mistrust About COVID-19 Vaccines Among Patients of Color. Ann Intern Med. 2021 Feb 9:M21-0055. doi: 10.7326/M21-0055. Epub ahead of print. PMID: 33556271; PMCID: PMC7888025.

ACIP: Safety & Efficacy of the Johnson & Johnson/Janssen COVID-19 Vaccine

*Rob Duncan, MD MPH, Hospital Epidemiologist
Lahey Hospital & Medical Center*

BILH Primary Care Forum

April 29, 2021

DISCLOSURES

I will discuss vaccines for COVID-19 currently approved or pending under Emergency Use Authorizations (EUAs)

Massachusetts COVID-19 Vaccine Safety and Efficacy Evaluation Task Force

24 April 2021

VIPIT=VITT=TTS (Thrombosis with Thrombocytopenia Syndrome)

What are the clinical characteristics of TTS?

Associated with replication-defective adenoviral vector SARS-CoV-2 vaccines

Incidence: Estimated 1 case per 100,000-250,000/vaccine recipients

Age range: 21- 77 years (90% less than 60)

Gender distribution F:M 2.5 : 1

Median onset: 10 days (range 5-24 days)

Thrombotic events: Cerebral venous sinus thrombosis (N=27), DVT/PE (10), Abdominal vein clots (7), Arterial clots (6)

Heparin induced thrombocytopenia testing: Platelet factor 4 antibody immunoassay positive, Platelet activation assays (variable)

Platelet nadir: 27,000/ μ L (range 7-113,000) , Fibrinogen nadir: 125 mg/dL (range 40-568), D dimer $\uparrow\uparrow\uparrow$

Progression of thrombosis on heparin, platelet recovery with IVIG

Greinacher A, et al. N Engl J Med. 2021 Apr 9. PMID: 33835769. Schultz NH, et al. N Engl J Med. 2021 Apr 9. PMID: 33835768. Scully M, et al. N Engl J Med. 2021 Apr 16. PMID: 33861525.

Comparison of thrombotic events after Oxford-AZ and Johnson + Johnson SARS-CoV-2 vaccines

Oxford-AZ SARS-CoV-2 Vaccine Cases

- Median age 40 (range 21-77)
- Gender: F:M 2.5:1
- Onset: 5-24 days after vaccine
- Symptoms: Headache, backache, abdominal pain, visual disturbance, leg/arm weakness
- Thrombosis: Cerebral , Abdominal veins, DVT/PE, arterial thrombosis
- Platelet nadir: 7-113,000
- Heparin-Platelet factor 4 immunoassay-positive
- Platelet activation assay- positive

Johnson + Johnson SARS-CoV-2 Vaccine cases

- Age range teens to 50s
- Gender F:M 8:0
- Onset: 6-13 days
- Symptoms: Headache, lethargy, back pain, abdominal pain, neurologic symptoms
- Thrombosis: Cerebral veins, abdominal veins
- Platelet nadir: 10-127,000
- Heparin-Platelet factor 4 immunoassay-positive
- Platelet activation assay-negative 4 of 5

CVST with thrombocytopenia following COVID-19 vaccines

(conclusions from ACIP April 14, 2021)

Originally presented April 14, 2021

Summary

- CVST is rare, but clinically serious, and can result in substantial morbidity and mortality; not usually associated with thrombocytopenia
- Observed cases following Janssen COVID-19 vaccines appear to exceed expected based on background rates of CVST among women aged 20–50 years (3-fold or greater)
 - All 6 reports were in women age range 18–48 years, all with thrombocytopenia
 - No obvious patterns of risk factors detected
- CVST with thrombocytopenia has not been observed after the two authorized mRNA vaccines
 - 182 million mRNA COVID-19 doses administered with no reported cases to date
- Clinical features of Janssen cases are similar to those observed following the AstraZeneca COVID-19 vaccine in Europe
- Both Janssen and AstraZeneca vaccines contain replication-incompetent adenoviral vectors (human [Ad26.COV2.S] for Janssen and chimpanzee [ChAdOx1] for AstraZeneca) ²⁴

Reporting rates of TTS after Janssen COVID-19 vaccine

- 7.98 million vaccine doses administered* and 15 confirmed TTS cases† as of April 21, 2021
 - Some age- and sex-specific doses administered data were imputed
 - Additional potential TTS cases under review, including potential male cases

	Females			Males		
Age group	TTS cases	Doses admin	Reporting rate‡	TTS 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>; † One case was excluded from the final analysis: a female aged <50 years who had concurrent diagnosis of COVID-19 and TTS following receipt of Janssen vaccine; ‡ Reporting rate = TTS cases per 1 million Janssen

COVID-19 vaccine doses administered

Shimabukuro T ACIP Meeting 23 April 2021

Reporting rates of TTS after Janssen COVID-19 vaccine in women

- 3.99 million vaccine doses administered to women* with 15 confirmed TTS cases[†] as of April 21, 2021
 - Some age-specific doses administered data were imputed

	Females		
Age group	TTS cases	Doses admin	Reporting rate [‡]
18-29 years old	3	579,709	5.2 per million
30-39 years old	7	594,215	11.8 per million
40-49 years old	3	692,370	4.3 per million
50-64 years old	2	1,367,529	1.5 per million
65+ years old	0	757,710	0 per million

* Source of doses administered: <https://covid.cdc.gov/covid-data-tracker/#vaccinations>; [†] One case was excluded from the final analysis: a female aged <50 years who had concurrent diagnosis of COVID-19 and TTS following receipt of Janssen vaccine; [‡] Reporting rate = TTS cases per 1 million Janssen COVID-19 vaccine doses administered

Updated information on Ad26-CoV2-S trials



Pivotal Study 3001 (N=44,325)

85% vaccine efficacy against severe COVID-19 > Day 28 in the United States

- Protection starts by Day 7, indicating early onset of protection
- 100% protection against COVID-19 related hospitalizations (> Day 28) and deaths
- Consistent vaccine efficacy against severe disease across all regions

Highly protective against global variants of concern

- Equally high protection in South Africa (n > 6,500) where B.1.351 (> 95%) is highly prevalent and in Brazil (n > 4,912) where P.2 lineage (69%) is highly prevalent



Ongoing South Africa study supports strong effectiveness in presence of B.1.351

- Open-label healthcare worker study (N=288,368 vaccinated)
 - Primarily women (76%), mostly people under 50 years old (75%)
- 4 COVID-19-related deaths (0.001%) (D4, 7, 7, 20) and no deaths post-day 28
- Of 17 (0.006%) COVID-19 breakthrough cases, 3 occurred after Day 28 (D31, 31, 34)

COVID-19 VACCINE COMPARISON CHART from The Medical Letter® Updated 4.26.21

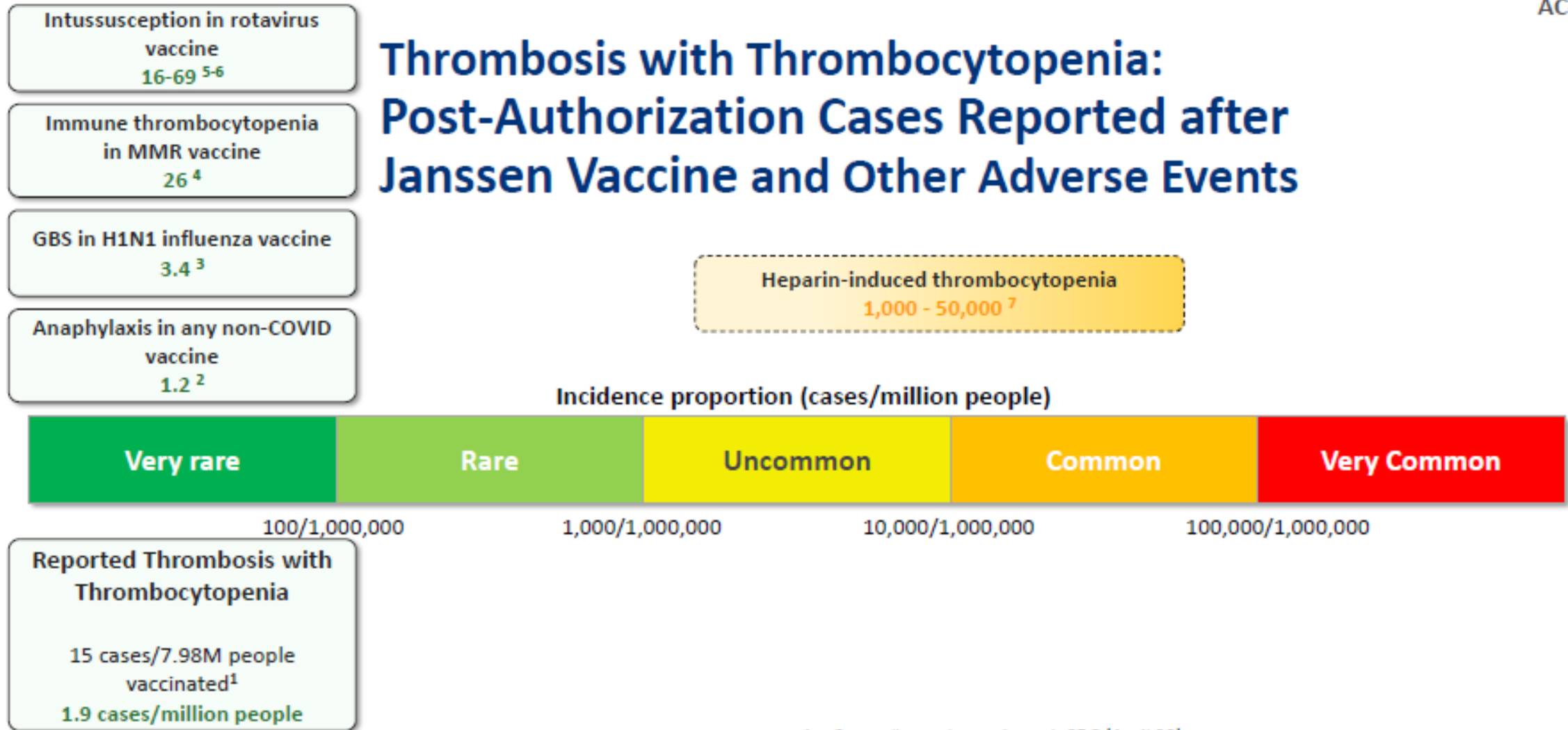
	FDA Authorized for Emergency Use in the US			Not Authorized in the US	
	Pfizer/BioNTech	Moderna	J&J (Janssen)	AstraZeneca	Novavax
Name	BNT162b2	mRNA-1273	Ad26.COV2.S	ChAdOx1 nCoV-19	NVX-CoV2373
Vaccine Type	mRNA	mRNA	Adenovirus vector	Adenovirus vector	Recombinant nanoparticle
Age	≥16 years old	≥18 years old	≥18 years old	≥18 years old	≥18 years old
Dosage	2 doses (0.3 mL) 21 days apart	2 doses (0.5 mL) 28 days apart	1 dose (0.5 mL)	2 doses 4-12 weeks apart	2 doses 21 days apart
Efficacy					
Overall	95% (7 days after 2 nd dose) ¹	94.1% (14 days after 2 nd dose) ²	66.1% (overall) ^{3,4} 72.0% (US) ^{3,4} *for moderate-severe COVID-19 from day 28	66.7% (overall; >14 days after 2 nd dose) ⁵ 82.4% (2 nd dose ≥12 wks after 1 st dose) ⁵ 54.9% (2 nd dose <6 wks after 1 st dose) ⁵ 76% (US overall; 15 days after 2 nd dose) ¹³	89.7% (overall; 7 days after 2 nd dose) ⁶
In Elderly Persons	94.7% (≥65 yrs) ¹	86.4% (≥65 yrs) ²	66.2% (≥60 yrs) ⁴	Limited data	27% of patients in the trial were >65 yrs ⁶
In Adolescents (12-15 years old)	100% ¹⁴	-	-	-	-
In Severe Disease	90% ¹	100% ²	Overall: 85.4% ⁴ US: 87.6% ⁴	100% ^{5,8}	100% ⁹
COVID-19 Death	100% ¹	100% ²	100% ⁴	100%	100% ⁹
UK Variant (B.1.1.7)	In vitro activity ¹⁰	In vitro activity ¹¹	~60-75% ⁷	74.6% ⁵ ; 70.4% ²²	86.3% ⁹
South Africa Variant (B.1.351)	In vitro lower activity ¹⁰	In vitro lower activity ¹¹	64.0% ⁴	10.4% ¹²	~48.6% ⁹
Brazil Variant (P.1)	In vitro activity ¹⁰	In vitro lower activity ¹¹	68.1% ⁴	Effective (prelim data)	Data not available
Variant-Specific Vaccine	Developing booster	Developing booster	Adapting vaccine	Adapting vaccine	Developing booster
Storage Requirements					
Transport and Storage	-60 to -80°C Alt: -25 to -15°C x 2 wks	-25 to -15°C	2-8°C	2-8°C	2-8°C
Excursions at distribution	2-8°C x 5 days 8-25°C x ≤2 hrs	2-8°C x 30 days 8-25°C x 12 hrs	9-25°C x 12 hrs	-	-
After Puncture/Dilution	2-25°C x 6 hrs	2-25°C x 6 hrs	2-8°C x 6 hrs 8-25°C x 2 hrs	2-8°C x 48 hrs 9-30°C x 6 hrs	-

	Pfizer/BioNTech	Moderna	J&J (Janssen)	AstraZeneca	Novavax
Some Post-Authorization Reports					
Efficacy	<ul style="list-style-type: none"> 90% (overall for mRNA vaccines under real-world conditions; ≥ 14 days after 2nd dose)¹⁵ <p>CDC report²¹</p> <ul style="list-style-type: none"> 5814 vaccine breakthrough infections out of >75 million vaccinated persons in the US 2622 (45%) were ≥ 60 years old 3752 (65%) in women 1695 (29%) asymptomatic 396 (7%) hospitalized; of those, 133 (34%) were asymptomatic or unrelated to COVID19 74 (1%) died; of those, 9 (12%) were asymptomatic or death was unrelated to COVID-19 	<ul style="list-style-type: none"> 90% (overall for mRNA vaccines under real-world conditions; ≥ 14 days after 2nd dose)¹⁵ <p>CDC report²¹</p> <ul style="list-style-type: none"> 5814 vaccine breakthrough infections out of >75 million vaccinated persons in the US 2622 (45%) were ≥ 60 years old 3752 (65%) in women 1695 (29%) asymptomatic 396 (7%) hospitalized; of those, 133 (34%) were asymptomatic or unrelated to COVID19 74 (1%) died; of those, 9 (12%) were asymptomatic or death was unrelated to COVID-19 	<p>CDC report²¹</p> <ul style="list-style-type: none"> 5814 vaccine breakthrough infections out of >75 million vaccinated persons in the US 2622 (45%) were ≥ 60 years old 3752 (65%) in women 1695 (29%) asymptomatic 396 (7%) hospitalized; of those, 133 (34%) were asymptomatic or unrelated to COVID19 74 (1%) died; of those, 9 (12%) were asymptomatic or death was unrelated to COVID-19 	-	-
Safety	<ul style="list-style-type: none"> Cases of herpes zoster reactivation in patients with autoimmune inflammatory rheumatic diseases¹⁶ 	<ul style="list-style-type: none"> Delayed cutaneous reactions¹⁷ 	<ul style="list-style-type: none"> CDC/FDA reviewed cases of thrombosis-thrombocytopenia syndrome (TTS) and recommend use of the vaccine resume in the US w/o age/gender restriction¹⁸ <ul style="list-style-type: none"> risk highest in women 18-49 years old onset mean of 8 days post-vaccination (range 6-15 days) vaccine labeling now contains information about the risk^{4,19} 	<ul style="list-style-type: none"> European Medicines Agency (EMA) reports possible link between vaccine and cases of CVST and splanchnic vein thrombosis with thrombocytopenia²⁰ Some countries have suspended or limited use of the vaccine 	-

Potential advantages of Ad26-CoV

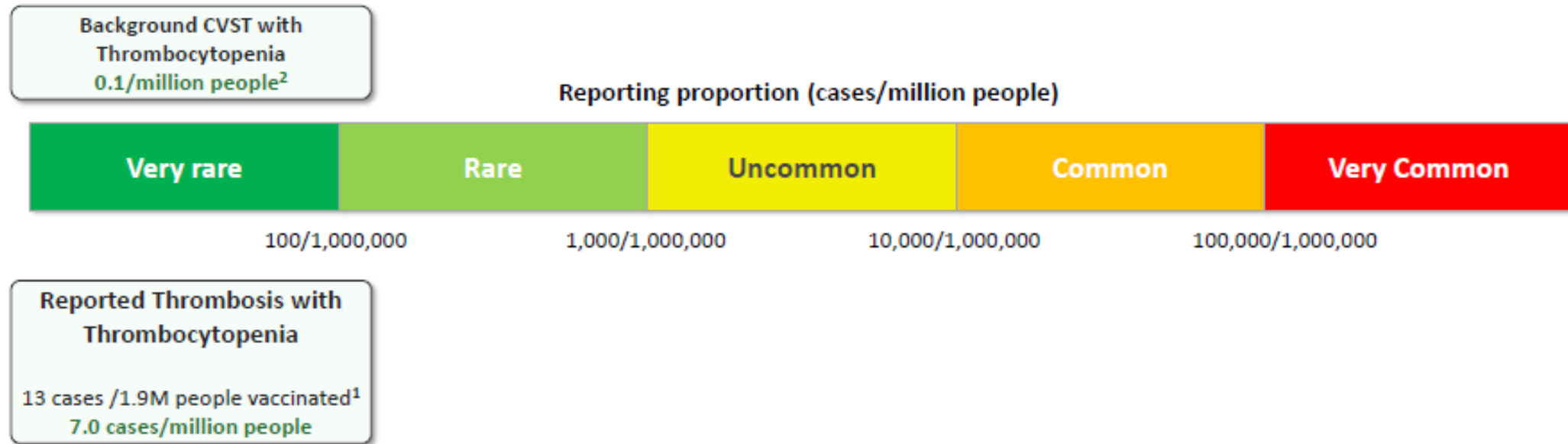
1-Dose Vaccine	<ul style="list-style-type: none">▪ Only authorized COVID-19 vaccine single-dose regimen▪ Critical option for rural and transient populations
Early Onset, Durable Response	<ul style="list-style-type: none">▪ Vaccine efficacy against severe disease seen by Day 7 in pivotal trial▪ Durable immune response based on platform, early COVID-19 data
Simple Shipping, Storage	<ul style="list-style-type: none">▪ Compatible with all existing distribution channels▪ Stored at normal refrigerator temperatures▪ Can reach remote locations

Thrombosis with Thrombocytopenia: Post-Authorization Cases Reported after Janssen Vaccine and Other Adverse Events



1. Cases, # people vaccinated: CDC (April 22)
2. McNeil, M. et al. JACI. 2016. <http://dx.doi.org/10.1016/j.jaci.2015.07.048>
3. Salmon. et al. Lancet. 2013 (IR = IRR*baseline risk = 2.5*1.2/100,000py)
4. Mantadakis, E. J Pediatr. 2010. DOI: 10.1016/j.jpeds.2009.10.015. Epub. PMID: 20097358
5. Rha, B. et al. 2014. DOI: 10.1586/14760584.2014.942223
6. Jiang, J. et al. 2013. <https://doi.org/10.1371/journal.pone.0068482>
7. Hogan, M. et al. Vasc Med. 2020. DOI: 10.1177/1358863X19898253. Epub. PMID: 32195628.

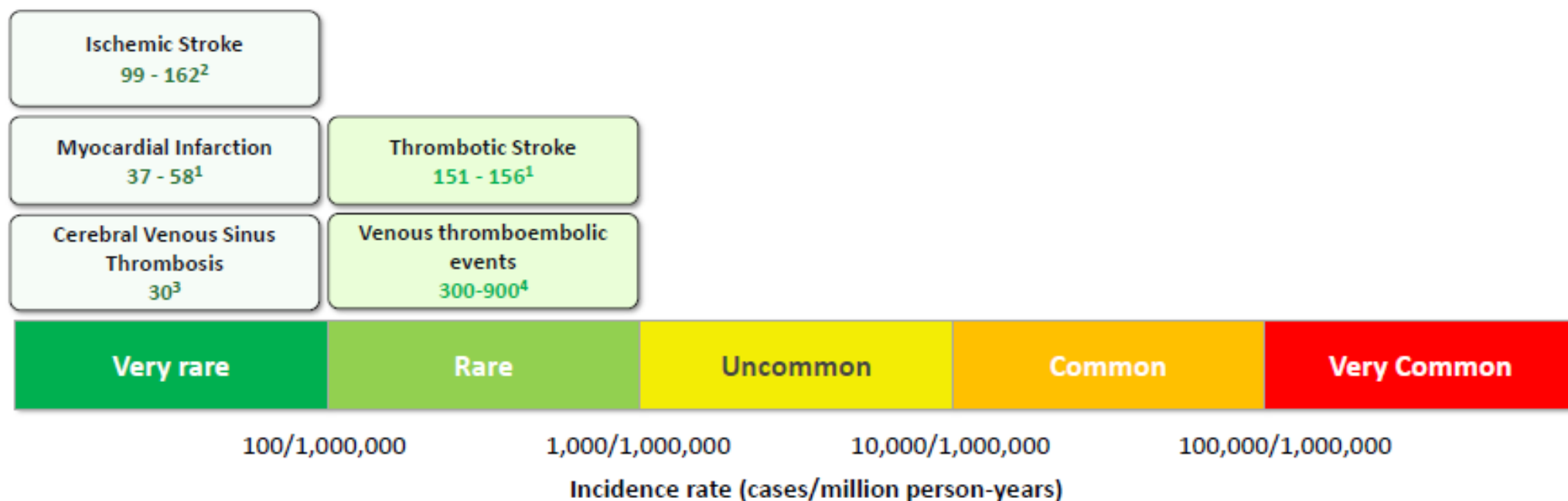
Thrombosis with Thrombocytopenia: Post-Authorization Cases Reported after Janssen Vaccine in Women Age < 50 and Background



1. Cases, # people vaccinated: CDC (April 22)

2. Background rate in 1JAN2018 from 5 US observational sources (n=63 million persons), * 28/365d (time-at-risk)

Known and Labeled Risks For Combination Oral Contraceptives in Women



All data from published literature (other than venous thromboembolic events: source is product label)

1. Lidegaard, O. et al. NEJM. 2012

2. Weill, A. et al. BMJ. 2016

3. Azoomegar. et al. Frontiers in Neurology. 2015 (IR=background rate * OR = 0.4/100,000 * 7.59)

4. Yasmin package insert: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d7ea6a60-5a56-4f81-b206-9b27b7e58875>

FDA-agreed Warning and Precaution Regarding Thrombosis with Thrombocytopenia

5.2 Thrombosis with Thrombocytopenia

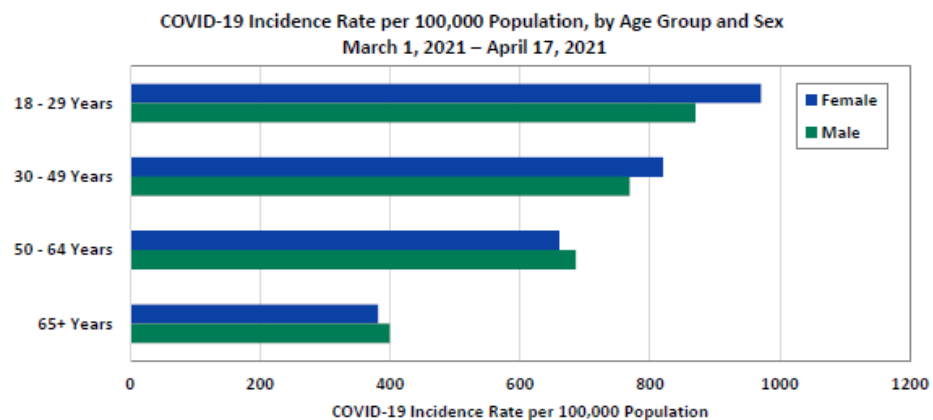
Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites (including but not limited to the large blood vessels of the abdomen and the veins of the lower extremities) combined with thrombocytopenia and with onset of symptoms approximately one to two weeks after vaccination [see *Overall Safety Summary (6.2)*]. Most cases of thrombosis with thrombocytopenia reported following the Janssen COVID-19 Vaccine have occurred in females ages 18 through 49 years; some have been fatal. Specific risk factors for thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine and the level of potential excess risk due to vaccination are under investigation. Based on currently available evidence, a causal relationship between thrombosis with thrombocytopenia and the Janssen COVID-19 Vaccine is plausible.

VaST and CVWG Meeting - April 22

- Risk for TTS following Janssen vaccine
 - 7 per million doses in females <50 years* (highest in 30-39 years)
 - <1 per million doses in female 50+ and males*
- Other potential risk factors
 - Obesity (BMI>30), OCP use, hypothyroidism, hypertension
- Outcomes
 - 3 deaths, 7 remain hospitalized (4 in ICU), 5 discharged home
- Benefit-risk assessment and Evidence-to-Recommendation framework discussed

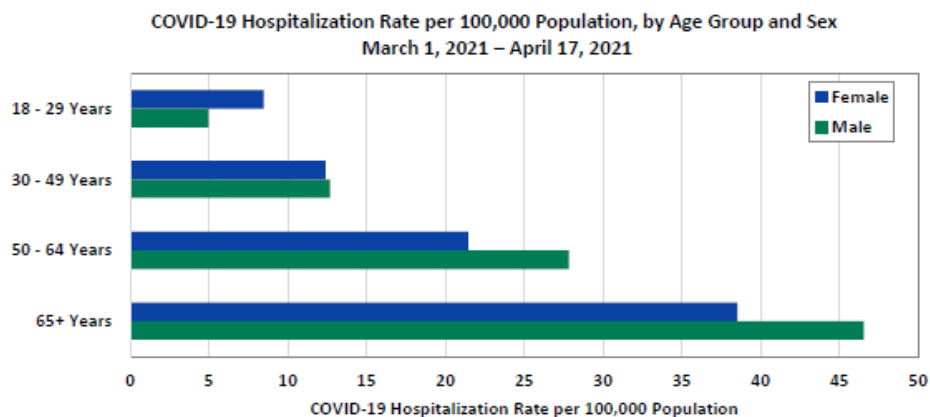
**Includes all doses (not adjusted for follow-up time)*

COVID-19 Incidence Rates, by Age Group and Sex



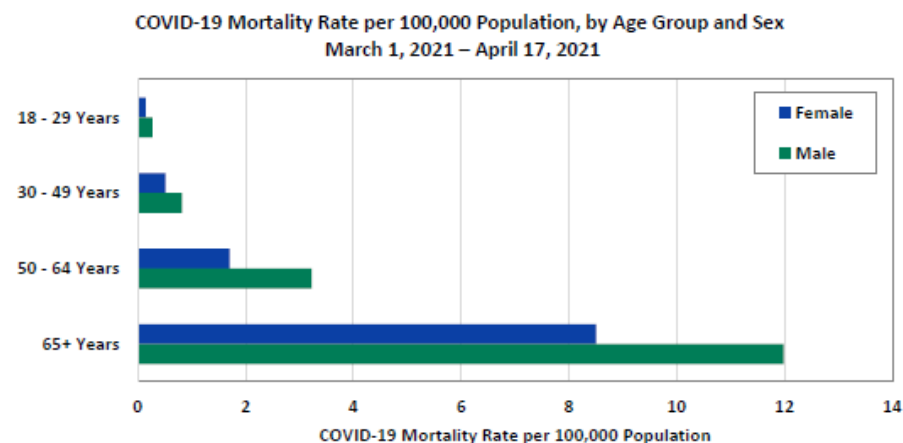
<https://covid.cdc.gov/covid-data-tracker/#demographics>

COVID-19 Hospitalization Rates, by Age Group and Sex



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

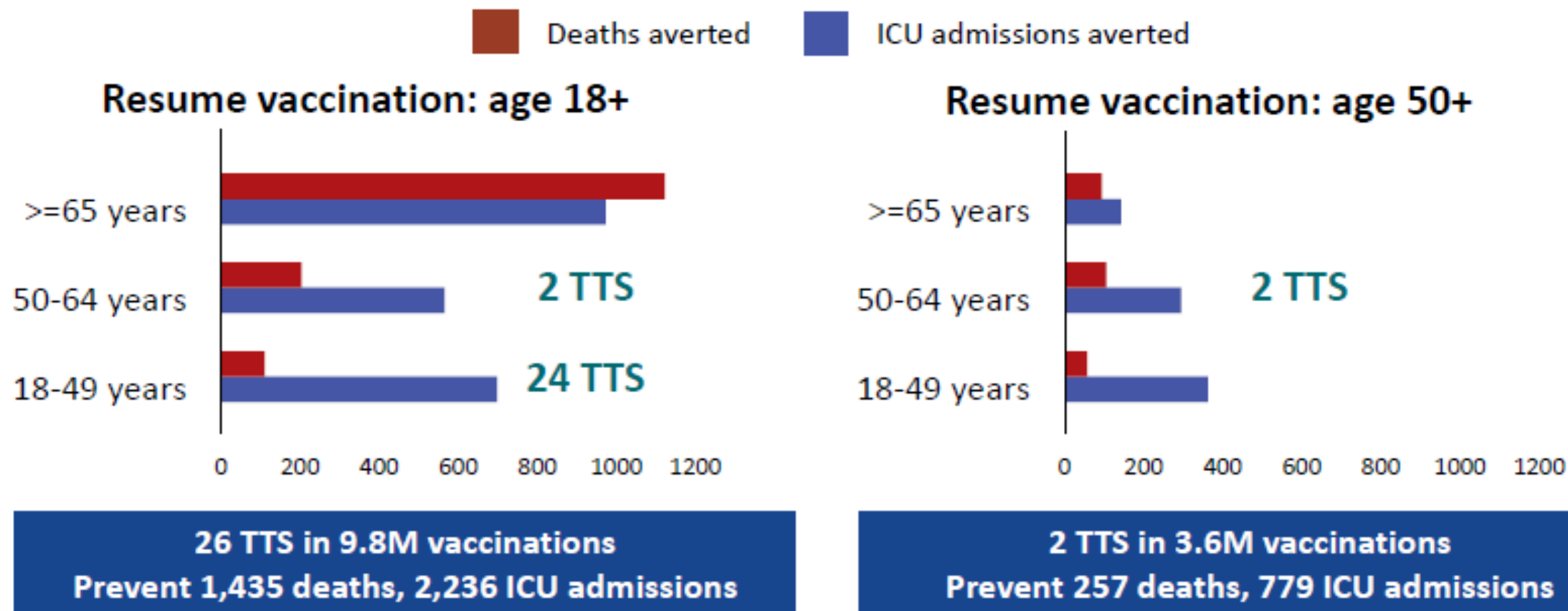
COVID-19 Mortality Rates, by Age Group and Sex



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

Benefits and harms of resuming vaccination for ages ≥ 18 years vs. ≥ 50 years over 6-month period

Moderate transmission; Vaccination resumed at 50% of rate before pause



¹ Based on observed cases adjudicated as of 4/21/2021

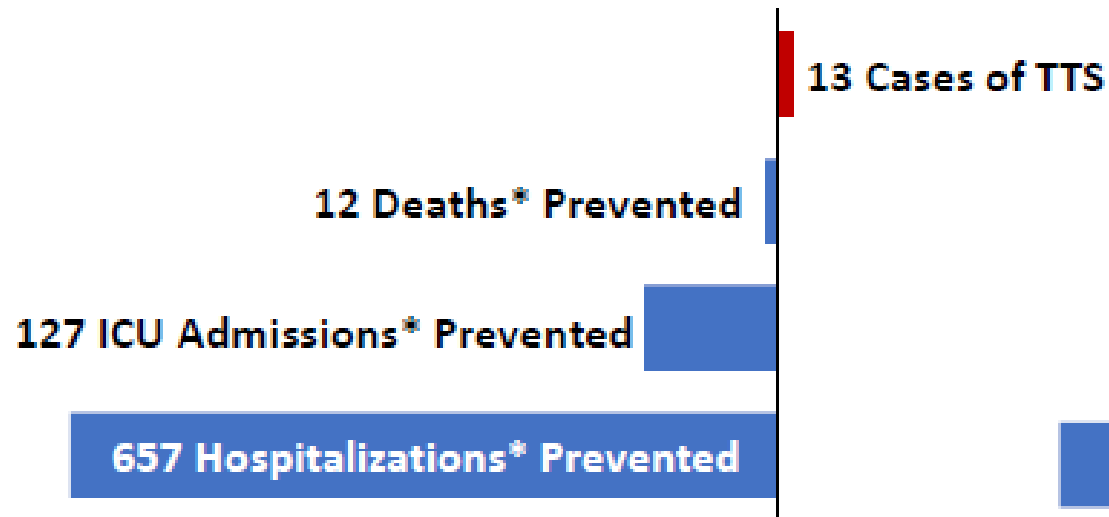
NOTE: in Phase III RCT, one male in 18-49 year age group experienced TTS; not included in this analysis

Abbreviations: Thrombosis with Thrombocytopenia Syndrome (TTS)

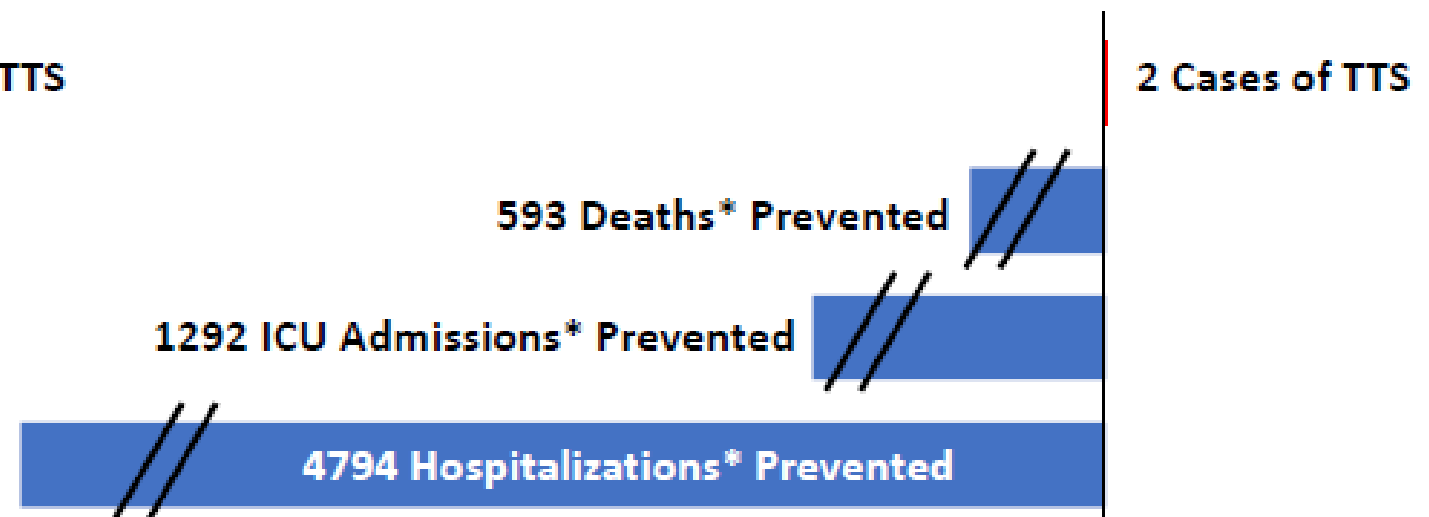
Risks and benefits females, by age group

For every 1 million doses of vaccine given with current US exposure risk¹

Females 18-49



Females 50+

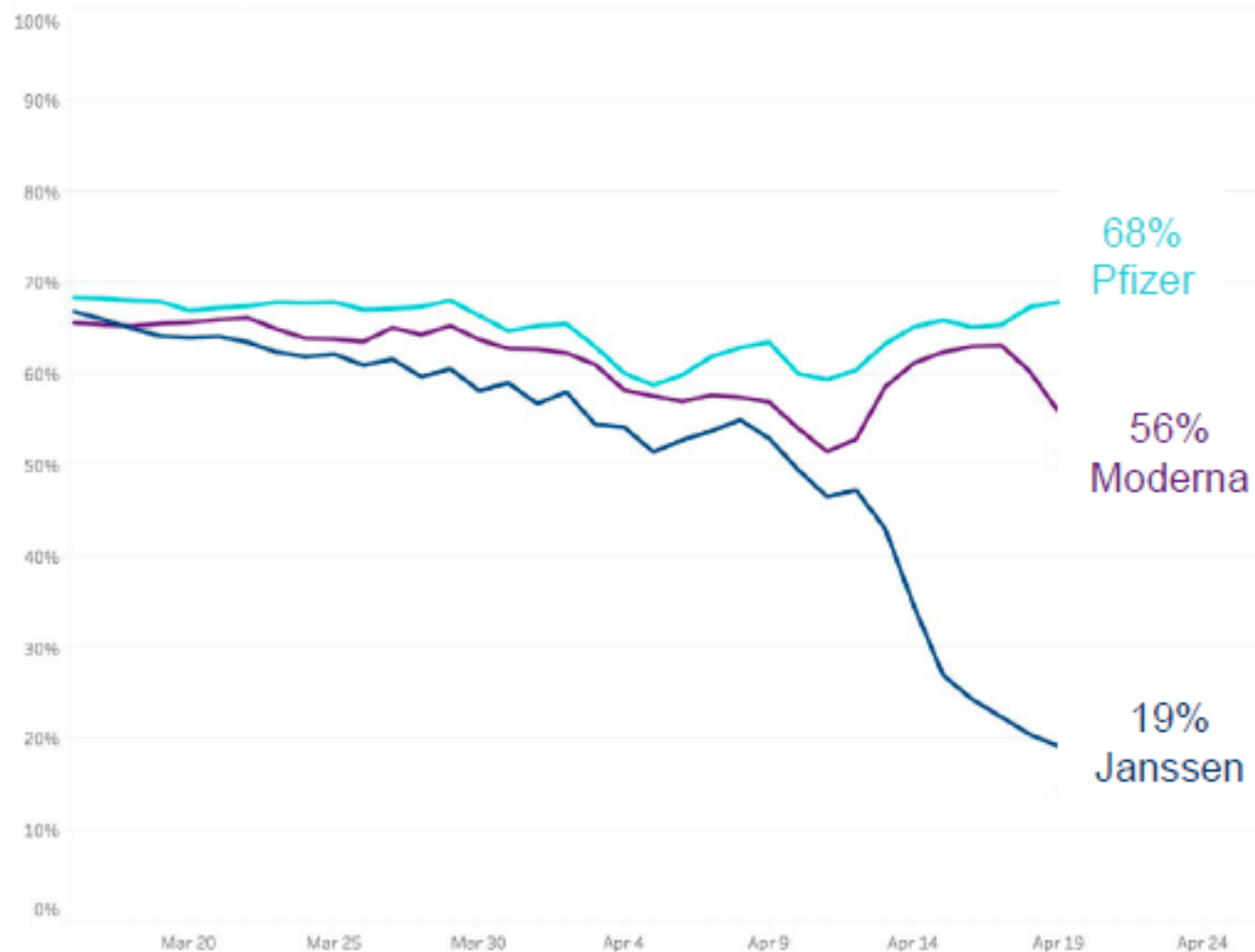


* Deaths, ICU admissions, and deaths due to COVID-19
Acronyms: Thrombosis with Thrombocytopenia Syndrome (TTS)

Willingness to receive the J&J vaccine dropped immediately as a result of the pause

(Results among those who say “yes” they plan to get vaccinated but haven’t yet)

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



Outbreaks Near Me



Boston Children's Hospital



Feasibility: Impact if Janssen recommended for specific populations

Jurisdictions may need to reconfigure some vaccination sites, update scheduling tool, and have difficulty serving disproportionately affected populations



Changes to vaccination sites and schedulers might include...

Providers may need to carry multiple vaccines, if recommendation is restricted by sex.

Challenging to set-up dedicated community PODs if Janssen recommended for specific groups.

Would require IT systems update to internal scheduling and pre-screening tools.



Health depts. expressed concern about communicating change

Concerns about difficulty of communicating rationale for specific groups to public

Potential need to revise public-facing comms materials, provider training collateral, alongside re-training staff.

Expect low uptake on Janssen vaccine given negative publicity.



Greater difficulty serving disproportionately affected populations

Likely to see drop in completed series for those "at risk of loss to follow-up" e.g., experiencing homelessness, seasonal workers.

More challenging to reduce gap in vaccine disparities for racial and ethnic minorities through mobile vaccination.

Would increase barriers to access in rural and hard-to-reach areas.

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

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)

The CDC and FDA determined:

- 1 Use of the Johnson & Johnson vaccine should resume in the U.S. in people aged 18 years or older.
- 2 The vaccine is safe and effective.
- 3 Data suggest the vaccine's potential benefits outweigh its risks.
- 4 Data show that the risk for thrombosis-thrombocytopenia syndrome is very low, but the CDC and the FDA will continue to monitor it as a risk factor.