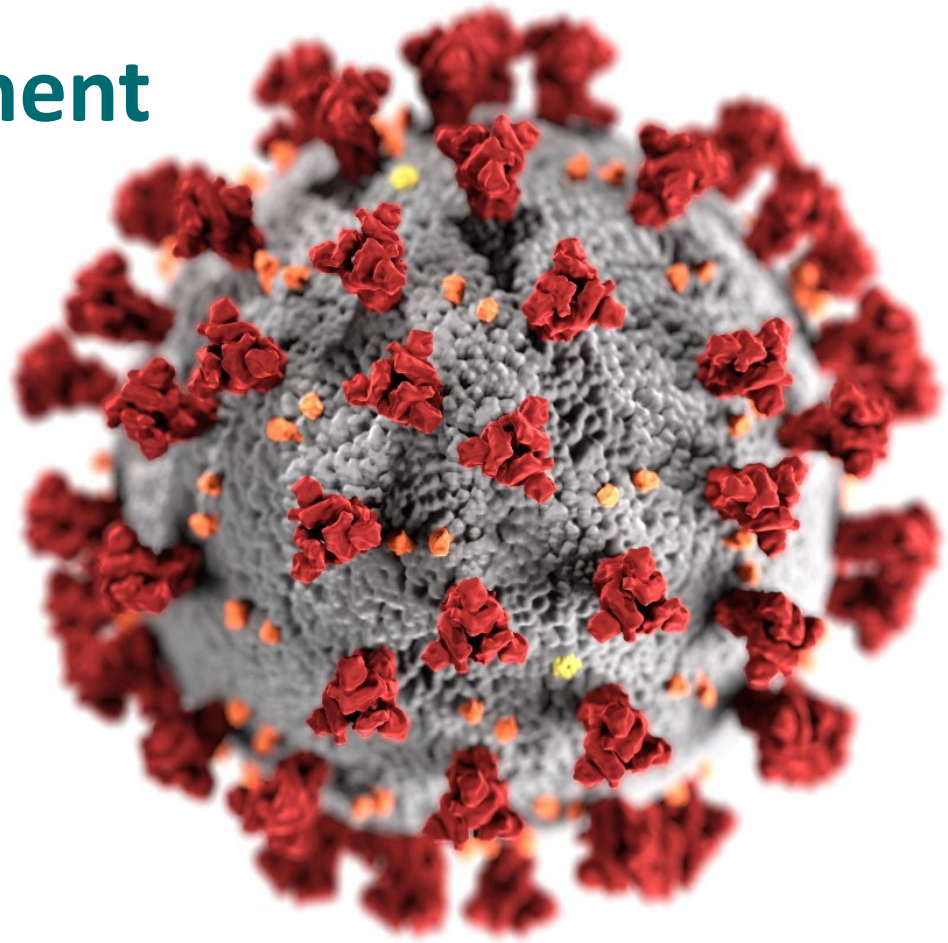
Updates to the benefit/risk assessment for Janssen COVID-19 vaccines:

Applying the Evidence to Recommendation Framework



Sara Oliver, MD MSPH
ACIP Meeting
December 16, 2021

cdc.gov/coronavirus

Evidence to Recommendations (EtR) Framework

Policy Question

- Should vaccination with the Janssen COVID-19 vaccine (1 dose) be recommended for persons 18 years of age and older under an Emergency Use Authorization?

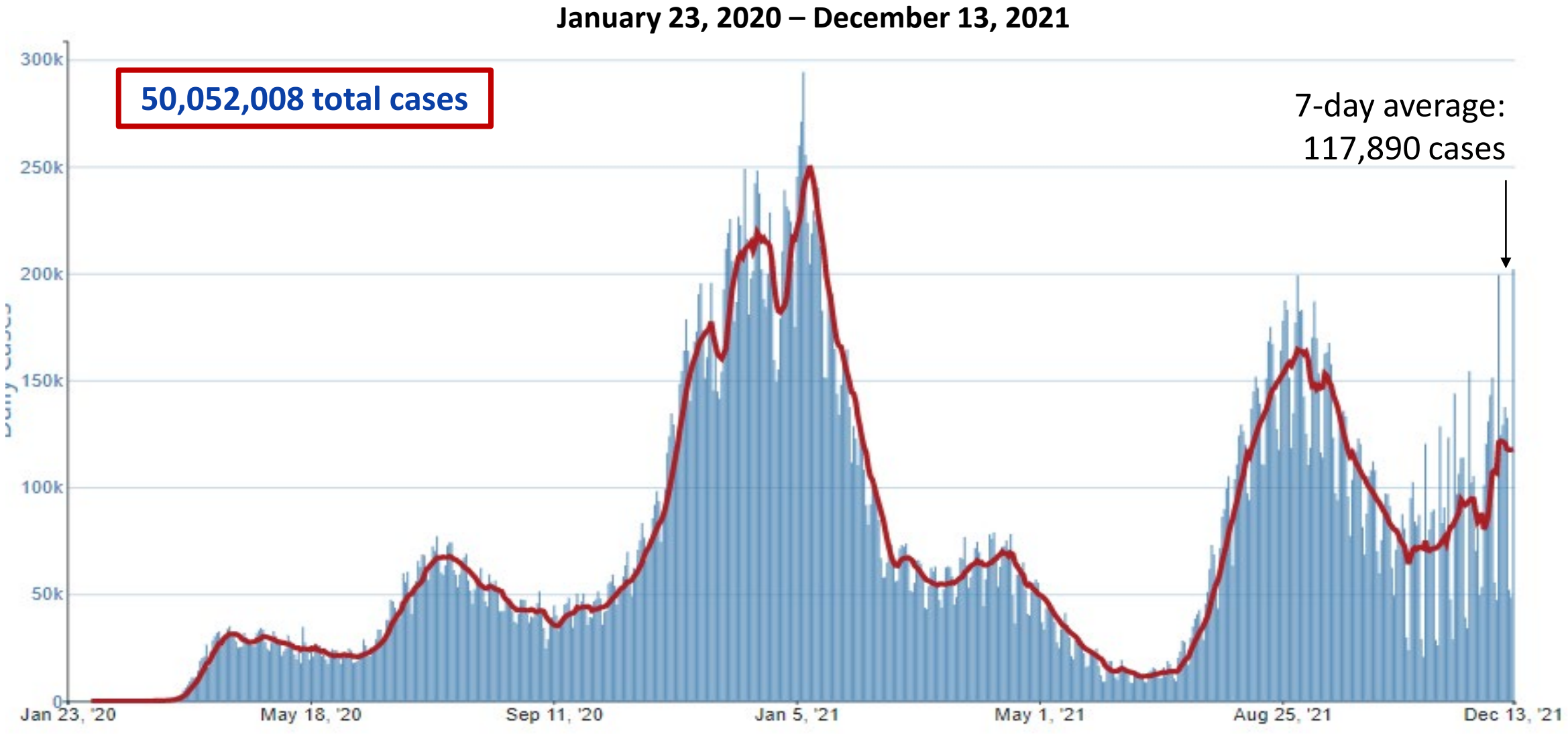
Evidence to Recommendations (EtR) Framework:

Adaptation to Benefit/Risk assessment for Janssen COVID-19 vaccine recommendations

EtR Domain	Question
Public Health Problem	• Recent COVID-19 Epidemiology • Summary of TTS after Janssen COVID-19 vaccine in the United States • Thrombosis after AstraZeneca COVID-19 vaccines: Global data
Benefits and Harms	• Benefit/Risk Assessment of COVID-19 vaccines
Values **Acceptability** **Feasibility**	• Intent to receive Janssen COVID-19 vaccine over time • Use of Janssen COVID-19 vaccine in the United States • Jurisdictional use of Janssen COVID-19 vaccine
Equity	• Considerations around use of the Janssen COVID-19 vaccine in disproportionately affected populations
Resource Use	• No information available

Public Health Problem

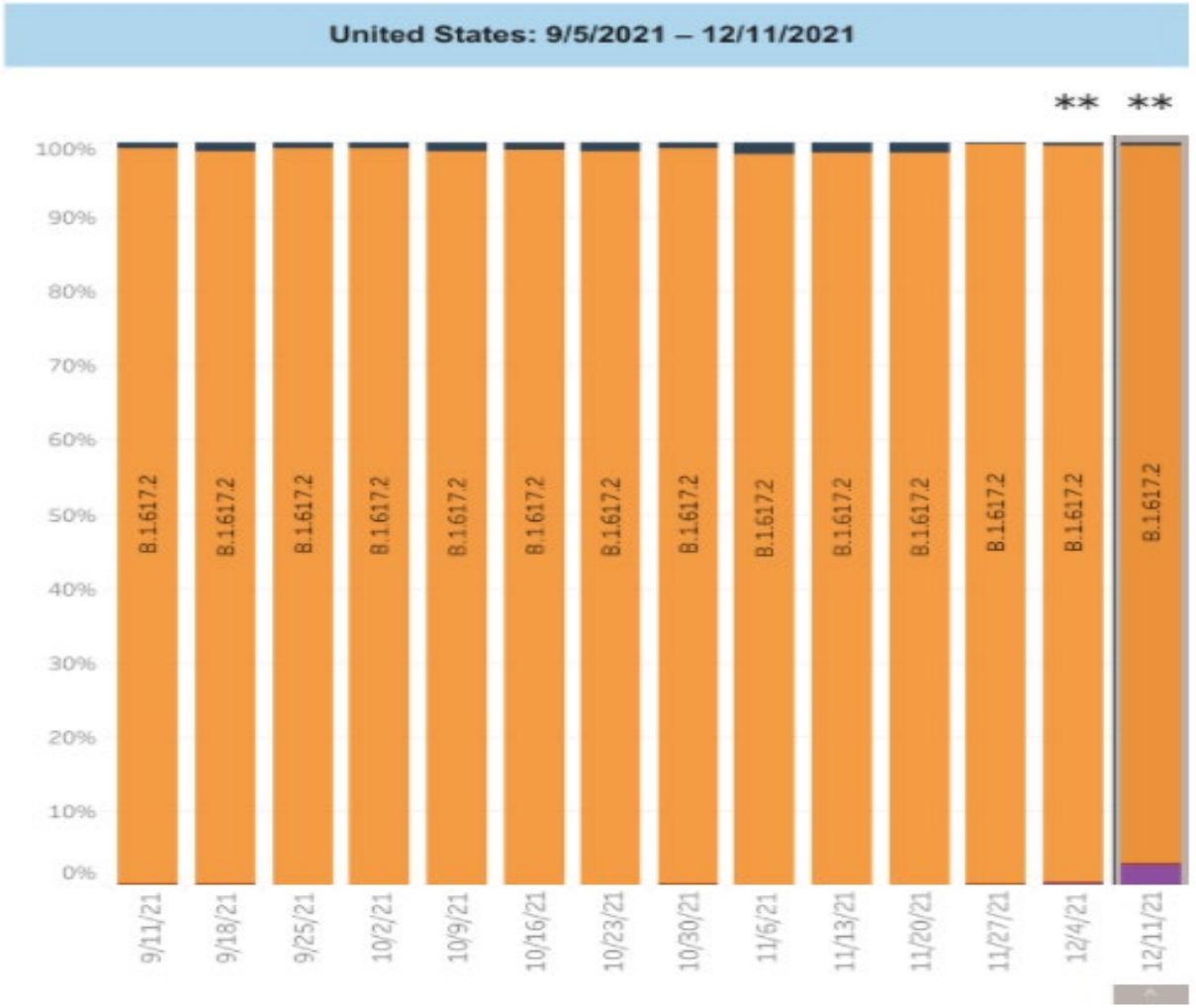
Trends in COVID-19 cases in the United States



CDC. https://covid.cdc.gov/covid-data-tracker/#trends_dailycases. Accessed December 14, 2021

SARS-CoV-2 Variants Circulating in the United States

Variant Proportions, August 29 - December 11, 2021



WHO label	Lineage #	US Class	%Total	95%PI
Delta	B.1.617.2	VOC	96.7%	85.9-99.6%
	AY.1	VOC	0.1%	0.0-0.1%
	AY.2	VOC	0.0%	0.0-0.0%
Omicron	B.1.1.529	VOC	2.9%	0.2-14.7%
Other	Other*		0.3%	0.2-0.6%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# AY.3-AY.125 and their sublineages are aggregated with B.1.617.2. BA.1 and BA.2 are aggregated with B.1.1.529.

https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Thrombosis with Thrombocytopenia Syndrome (TTS) after Janssen COVID-19 vaccine in the United States

- Through August 31, 2021: **54** cases of TTS identified after Janssen COVID-19 vaccine, for an overall reporting rate of **3.83 per million** Janssen doses
  - TTS rates highest among females 30–39 years of age (10.6 per million doses) and 40–49 years of age (9.0 per million doses)

- Through December 2, 2021: **9** TTS deaths following Janssen COVID-19 vaccine, for an overall reporting rate of **0.57 per million** Janssen doses
  - TTS death rates highest among females 30–39 years of age (1.93 per million doses) and 40–49 years of age (1.8 per million doses)

Thrombosis with Thrombocytopenia Syndrome (TTS) after AstraZeneca COVID-19 vaccine in Europe

- April 2021: EU reporting ~**10 cases per million** vaccinated adults
  - Most cases in women aged <60 years within 2 weeks of receiving 1st vaccine dose
- September 2021: EMA's PRAC updated the product information by removing the previous statement reporting TTS cases occurred mostly in women <60 years of age
  - **43%** of cases in males and **37%** in vaccinated person >60 years
  - 1503 cases of TTS reported, 592 million doses administered worldwide as of 25 July 2021
- December 2021: UK reported **428 cases** of blood clotting with low platelets
  Rate: **15.3 per million** doses (49 million doses given)
  - 50% of cases in women. Age range: 18–93 years. 74 deaths (17%); 6 deaths after second dose
  - Most cases occurred after **first vaccine dose**; 47 cases occurred after second dose

EU: European Union EMA: European Medicines Agency PRAC: Pharmacoviligiance Risk Assessment Committee

https://www.who.int/news/item/16-04-2021-global-advisory-committee-on-vaccine-safety-(gacvs)-review-of-latest-evidence-of-rare-adverse-blood-coagulation-events-with-astrazeneca-covid-19-vaccine-(vaxzevria-and-covishield)
https://www.ema.europa.eu/en/documents/prac-recommendation/signal-assessment-report-embolic-thrombotic-events-smq-covid-19-vaccine-chadox1-s-recombinant_en.pdf
https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-vaxzevria-previously-covid-19-vaccine-astrazeneca-8-september-2021_en.pdf
https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting#yellow-card-reports

Vaccine policy for adenovirus vector vaccines

- Vaccine policy evaluated from 16 countries*
  - Primarily higher income countries with broad access to mRNA and adenovirus vector vaccines, not globally representative of all adenovirus vector vaccine policy
- All 16 had recommendations for use of the AstraZeneca COVID-19 vaccine:
  - 5 (31%) halted use of the vaccine
  - 7 (44%) use the vaccine, but have a **preferential recommendation** for other COVID-19 vaccines
  - 2 (12%) don't have a preferential recommendation, but recommend use only in older ages
  - 2 (12%) recommend use of the vaccine in all ages/populations
- 12 had recommendations for use of the Janssen COVID-19 vaccine:
  - 3 (25%) halted use of the vaccine
  - 4 (33%) use the vaccine, but have a **preferential recommendation** for other COVID-19 vaccines
  - 1 (8%) doesn't have a preferential recommendation, but recommend use only in older ages
  - 4 (33%) recommend use of the vaccine in all ages/populations

*Australia, Canada, Denmark, Finland, France, Germany, Israel, Japan, Mexico, Netherlands, Norway, Philippines, South Africa, Spain, Sweden, United Kingdom

National Advisory Committee on Immunization (NACI)

Canada

- A complete series with an **mRNA COVID-19 vaccine** should be **preferentially offered** to individuals in the authorized age group without contraindications to the vaccine.
- A viral vector COVID-19 vaccine **may be offered** to individuals in the authorized age group without contraindications to the vaccine to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, as well as the need to see immediate medical care should symptoms develop.
- A booster dose of an authorized viral vector vaccine should only be considered when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, as well as the need to seek immediate medical care should symptoms develop.

https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html

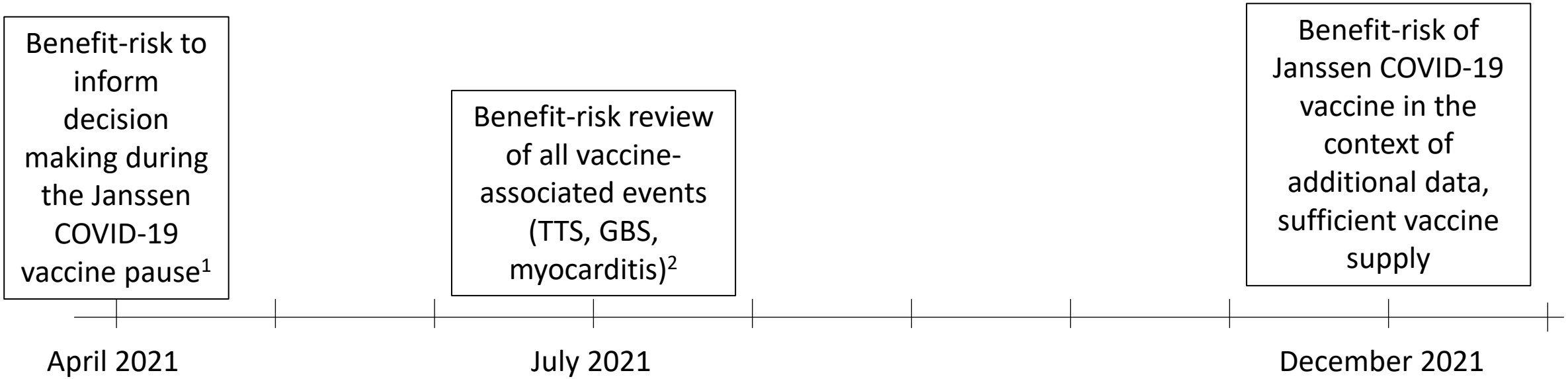
Summary

- Recent increases in reported COVID-19 cases
- US is reporting cases of Omicron variant
- Globally, TTS cases have been reported after adenovirus vector vaccines (both Janssen COVID-19 vaccine and AstraZeneca COVID-19 vaccines)
  - Resulted in changes to vaccine policy for adenoviral vector vaccines in many higher-income countries with access to alternative vaccines

recommendations-use-covid-19-vaccines-en.pdf (canada.ca)

Benefit-Risk Analysis for Janssen COVID-19 vaccine

Timeline of Janssen COVID-19 benefit-risk review



TTS= Thrombosis with thrombocytopenia syndrome; GBS= Guillain-Barré syndrome

1. MacNeil et al. http://dx.doi.org/10.15585/mmwr.mm7017e4
2. Rosenblum et al. http://dx.doi.org/10.15585/mmwr.mm7032e4

Benefits and risks of Janssen COVID-19 vaccine

Benefits of Janssen COVID-19 vaccine

Risks after Janssen COVID-19 vaccine

Benefits and risks of Janssen COVID-19 vaccine

Benefits of Janssen COVID-19 vaccine

Risks after Janssen COVID-19 vaccine

In the setting of widely available mRNA COVID-19 vaccines

Methods for assessment of benefit-risk balance

Benefits — Calculated per 1 million fully vaccinated people

- Age groups: 18 – 49 years, 50 – 64 years, ≥65 years
- Age/sex specific hospitalization rates: COVID-NET (week ending Nov 13, 2021)[2]
- Age/vaccine specific VE estimates from IVY Network[3]
- Time Horizon: 180-day period

Harms — Calculated per 1 million fully vaccinated people

- TTS rates from cases reported to VAERS and reviewed with clinicians from CDC's Clinical Immunization Safety Assessment (CISA) Project
- Previously presented GBS[4] and myocarditis[5] rates from VAERS

VE: Vaccine Effectiveness
[1]https://covid.cdc.gov/covid-data-tracker/#trends_dailycases
[2]https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html
[3]Self et al. MMWR 2021
[4]https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-07/02-COVID-Alimchandani-508.pdf
[5]https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/04-COVID-Oster-508.pdf

Vaccine-specific estimates of effectiveness against COVID-19 hospitalization

VE against COVID-19 hospitalization		
	IVY Network, March–August 2021[1,2]	
Age group	Janssen, % (95% CI)	mRNA, % (95%)
18-49 years	73 (37-88)	92 (88-95)
50-64 years	69 (38-84)	92 (88-94)
65+ years	76 (48-89)	88 (84-91)

VE= vaccine effectiveness; VE reported for 1 dose of Janssen COVID-19 vaccine, and 2 doses of mRNA COVID-19 vaccines

1. https://www.cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm
2. For age strata specific estimates, adjusted for continuous age in years, calendar date (biweekly), HHS region, sex, and race/ethnicity

Changes to methods from original benefit-risk assessment

Original benefit-risk (April 2021)	Current benefit-risk
Assumed that all COVID-19 hospitalizations were occurring among unvaccinated	Model accounts for COVID-19 hospitalizations occurring among vaccinated
Assumed equal sex-specific risk of COVID-19 associated hospitalization, ICU admission, and death	Use age and sex specific COVID-19 associated hospitalization, ICU admission, and death rates
Assumed 90% VE against hospitalization for Janssen COVID-19 vaccine based on RCT	Assume 69-76% VE against hospitalization for Janssen COVID-19 vaccine based on observational data
Hospitalization rates from week ending March 27, 2021, overall weekly rate of 8/100,000 population[1]	Hospitalization rates from week ending Nov 13, 2021, overall weekly rate of 11/100,000 population[1]
Time horizon of 30 days (expected delay in vaccination if Janssen not available)	Time horizon of 180 days (known duration of protection)

1. Hospitalization rates for persons aged ≥18

Reporting rates of TTS following Janssen COVID-19 vaccination (per million doses administered)

	Females		Males	
Age group	**TTS case rate**	**TTS death rate**	**TTS case rate**	**TTS death rate**
18-49 years old	8.7	1.2	2.8	0.5
50-64 years old	4.5	1.0	2.1	0
≥65 years old	1.8	0.0	0.0	0

Data as of August 31, 2021.

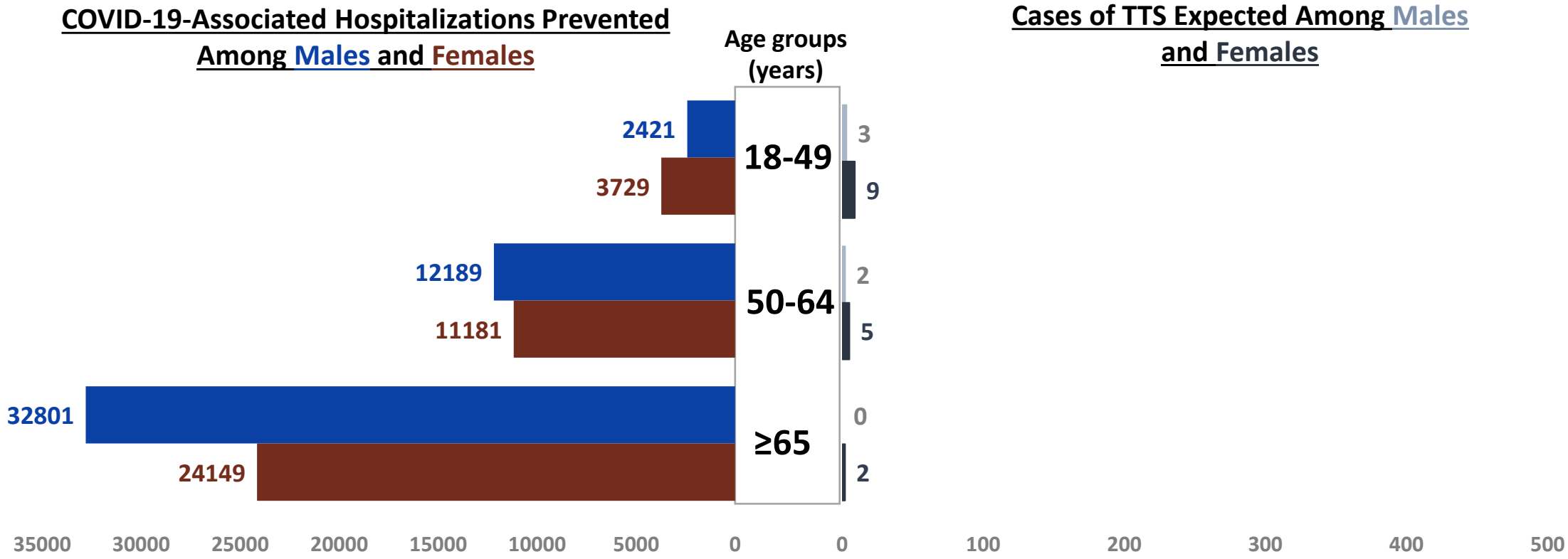
Framework for benefit-risk analysis

- Benefits vs risks of Janssen COVID-19 vaccine compared with no vaccine, by age and sex
  - Differential benefits and risks of Janssen COVID-19 vaccine compared with mRNA COVID-19 vaccines, including risks of GBS and myocarditis

Benefits and risks after Janssen COVID-19 vaccine

per million fully vaccinated people

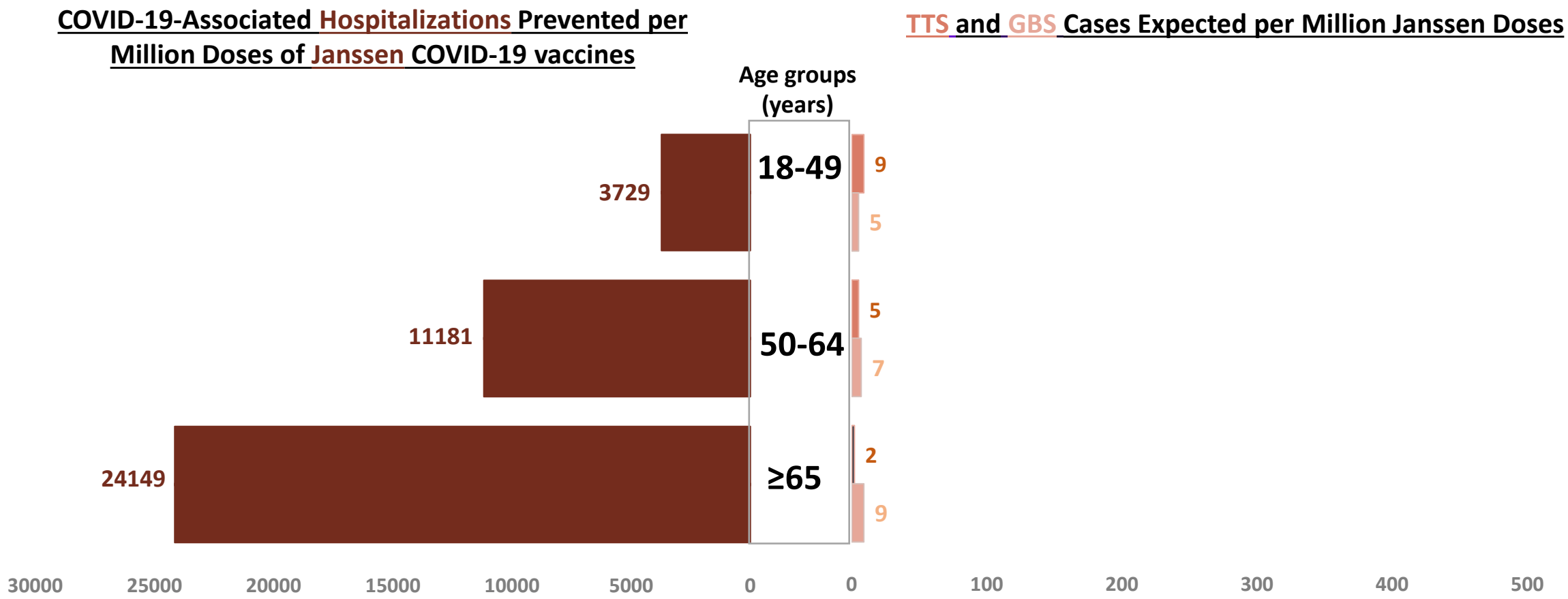
- COVID-19-associated hospitalizations prevented by Janssen COVID-19 vaccine compared with TTS cases expected
- Presented by age groups and sex



Benefits and risks after Janssen COVID-19 vaccine, Females

per million fully vaccinated people

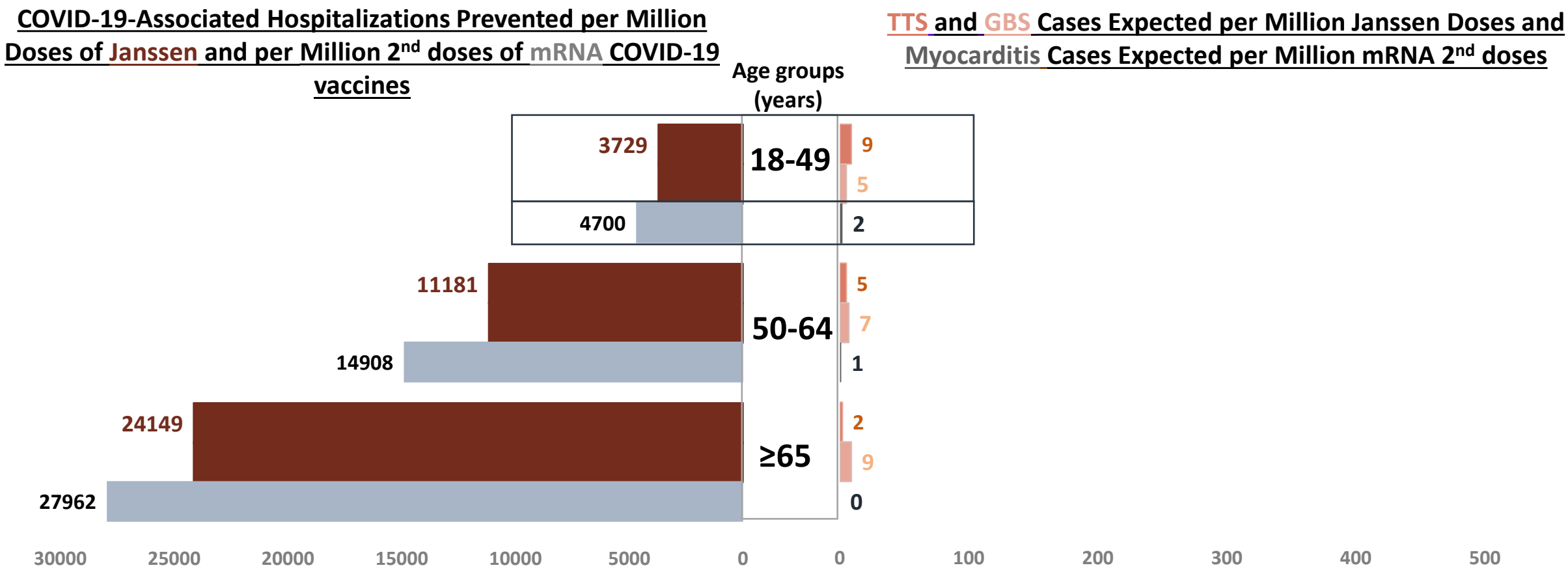
- COVID-19 associated **hospitalizations** prevented by Janssen COVID-19 vaccine compared with **TTS and GBS cases** expected
- Presented by age groups for females



Benefits and risks after Janssen and mRNA COVID-19 vaccine, Females

*per **million** fully vaccinated people*

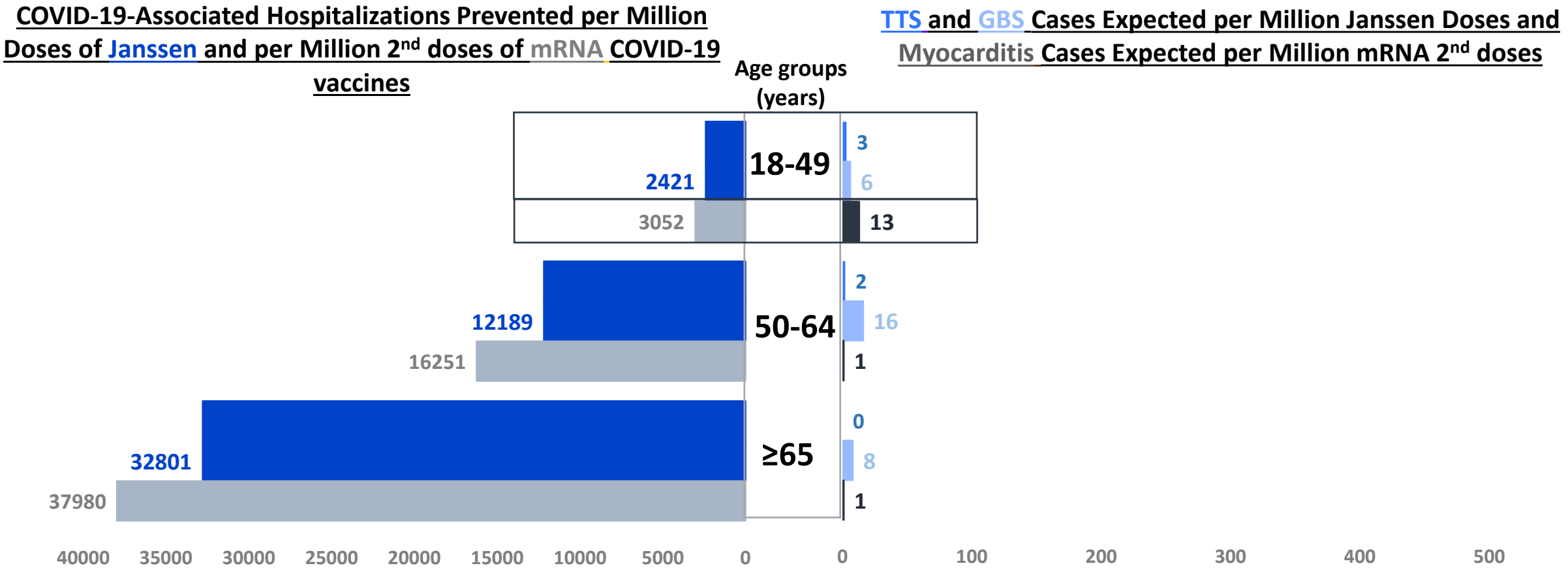
- COVID-19 associated hospitalizations prevented by Janssen COVID-19 vaccine (1 dose) compared with TTS and GBS cases expected
- **COVID-19 associated hospitalizations prevented by mRNA COVID-19 vaccines (2 dose) compared with myocarditis cases expected**
- Presented by age groups for females



Benefits and risks after Janssen and mRNA COVID-19 vaccine, Males

For every million doses of vaccine given

- COVID-19 associated hospitalizations prevented by Janssen COVID-19 vaccine (1 dose) compared with TTS and GBS cases expected
- COVID-19 associated hospitalizations prevented by mRNA COVID-19 vaccines (2 dose) compared with myocarditis cases expected
- Presented by age groups for **males**



Severity of vaccine associated events

Myocarditis after mRNA COVID-19 vaccines[1]

- At 3 month follow-up, over half report no symptoms and over 90% are ‘fully recovered’ by cardiologist or healthcare provider
- No confirmed deaths

TTS after Janssen COVID-19 vaccines[2]

- ~15% mortality rate
- 17% required discharge to post-acute care/rehabilitation facility

GBS after Janssen COVID-19 vaccines[3]

- ~1% mortality rate
- 10% required mechanical ventilation

[1]ACIP Presentation, Dr. Oster: November 2, 2021 https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/04-COVID-Oster-508.pdf
[2]Presentation, Dr. See:
[3]ACIP Presentation, Dr. Alimchandani: July 22, 2021 https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-07/02-COVID-Alimchandani-508.pdf

Limitations

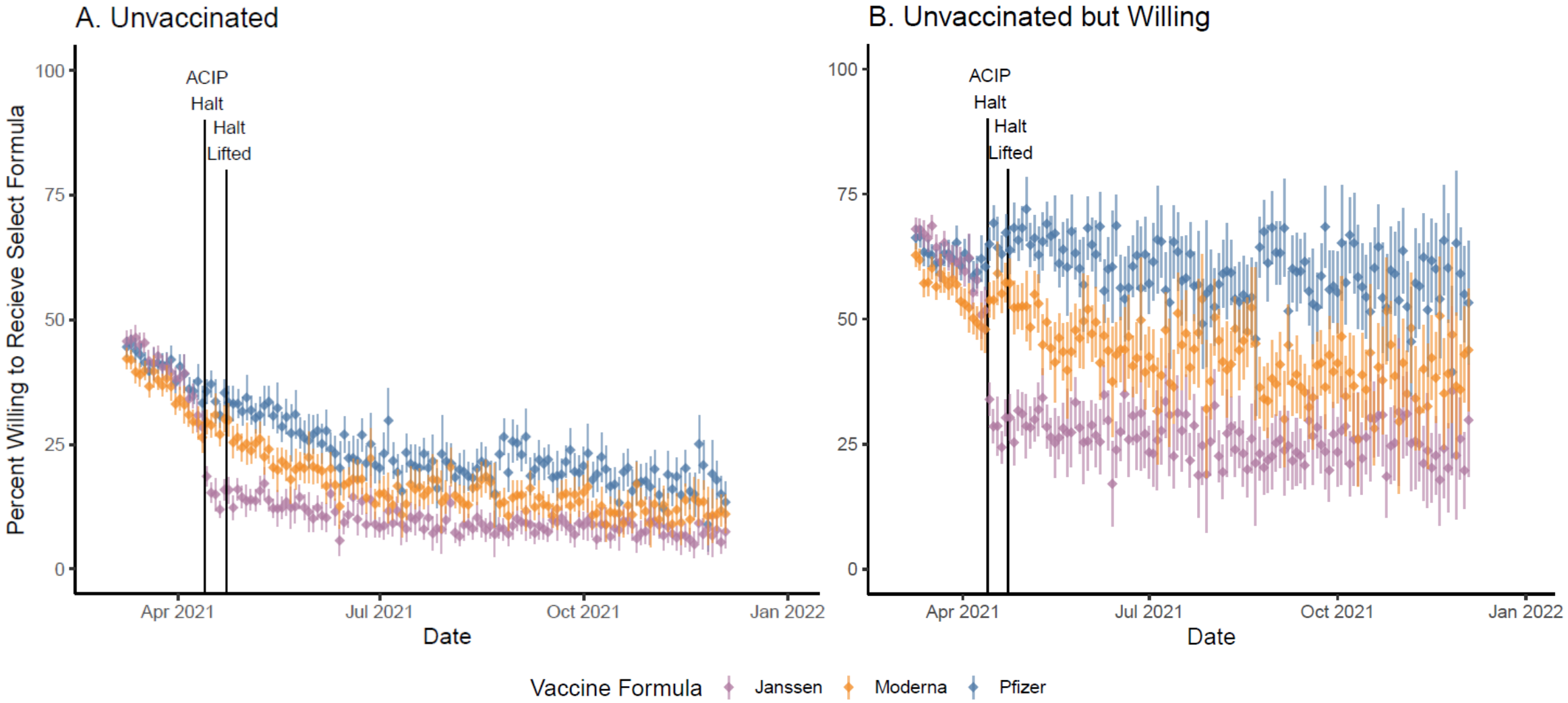
- Benefit-risk analysis considers direct benefits and risk over a 180-day period **comparing vaccine** vs. **no vaccine**
- Model compares single dose Janssen series with 2-dose mRNA series
- Model assumes static hospitalization rate and VE over a 6-month period
- Model does not account for booster doses or prior infection

Summary of benefit-risk balance for Janssen COVID-19 vaccine

- Direct benefit-risk assessment for Janssen COVID-19 vaccine & TTS
  - Considers individual benefits of vaccination vs. individual risks
- Using current VE estimates, benefit/risk balance of Janssen COVID-19 vaccine is still favorable for all age and sex groups **compared with no vaccine**
- When compared to benefit-risk balance for mRNA COVID-19 vaccines, the Janssen vaccine prevents **fewer** COVID-19 hospitalizations, ICU admissions, and deaths
- **More severe** health impacts from TTS and GBS after Janssen COVID-19 vaccine, compared to impacts from myocarditis after mRNA COVID-19 vaccines
- In a setting where mRNA and Janssen COVID-19 vaccines are both available, **benefit/risk balance** for mRNA COVID-19 vaccines likely **more favorable** across all age and sex groups

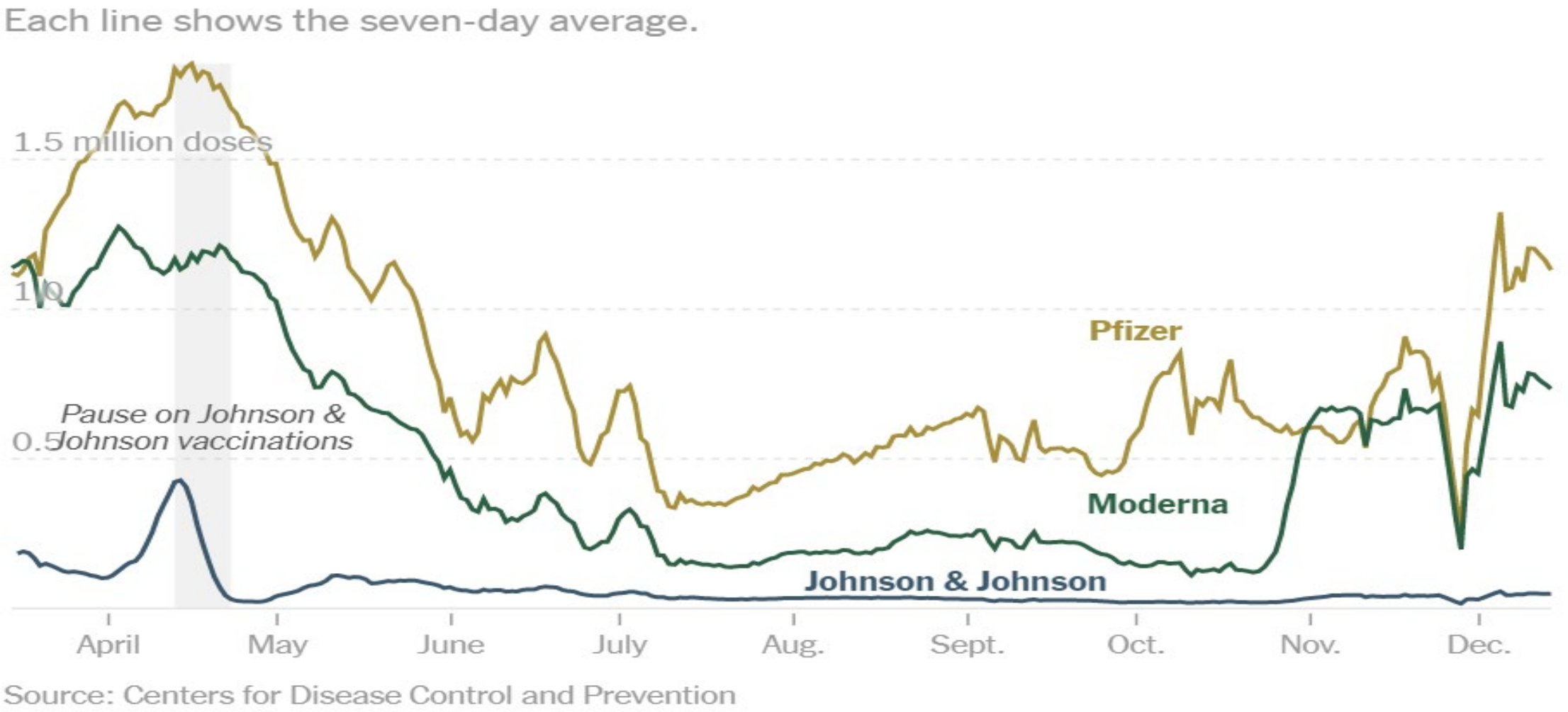
Values
Acceptability
Feasibility

Willingness to receive COVID-19 vaccine over time



Rader, et al. Persistent drop in confidence following US recommended pause of Ad26.COV2.S vaccine administration. Data updates as of December 2021.

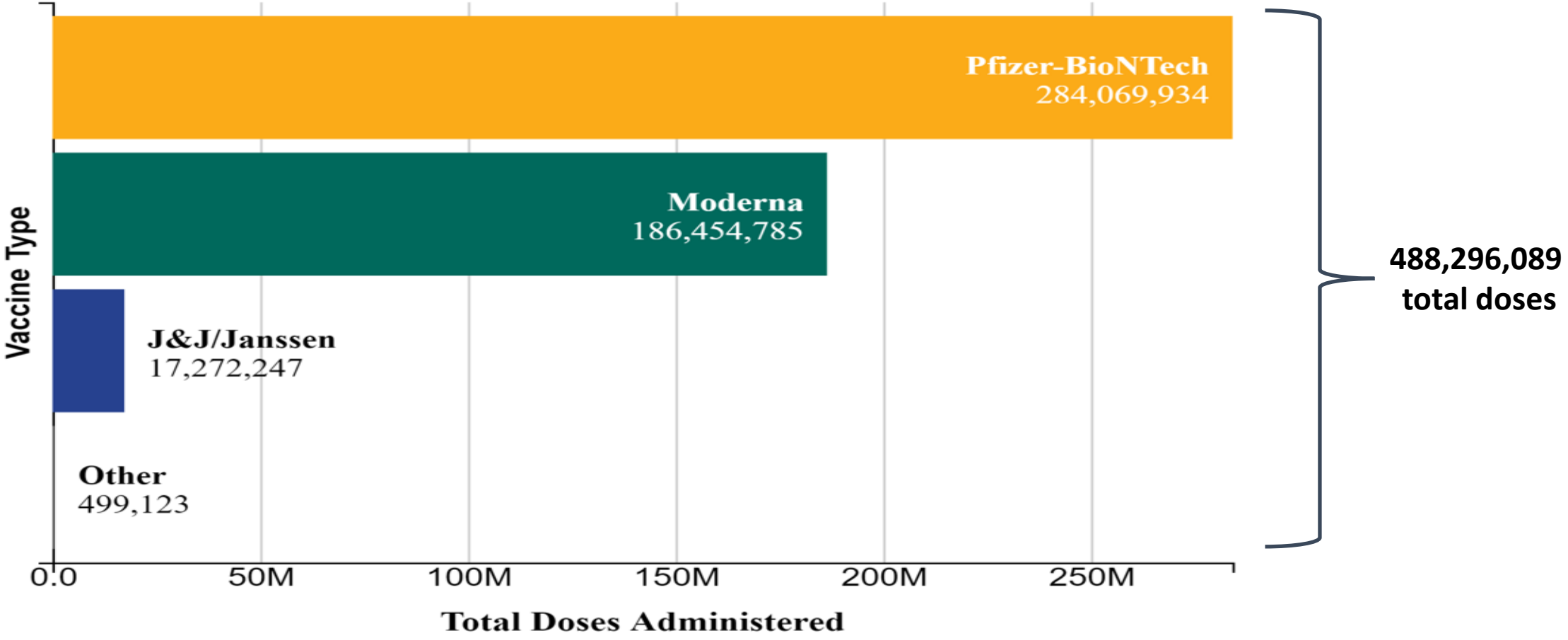
Daily reported doses given by manufacturer



The New York Times. Covid-19 Vaccinations: County and State Tracker. https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html. Accessed December 15, 2021.

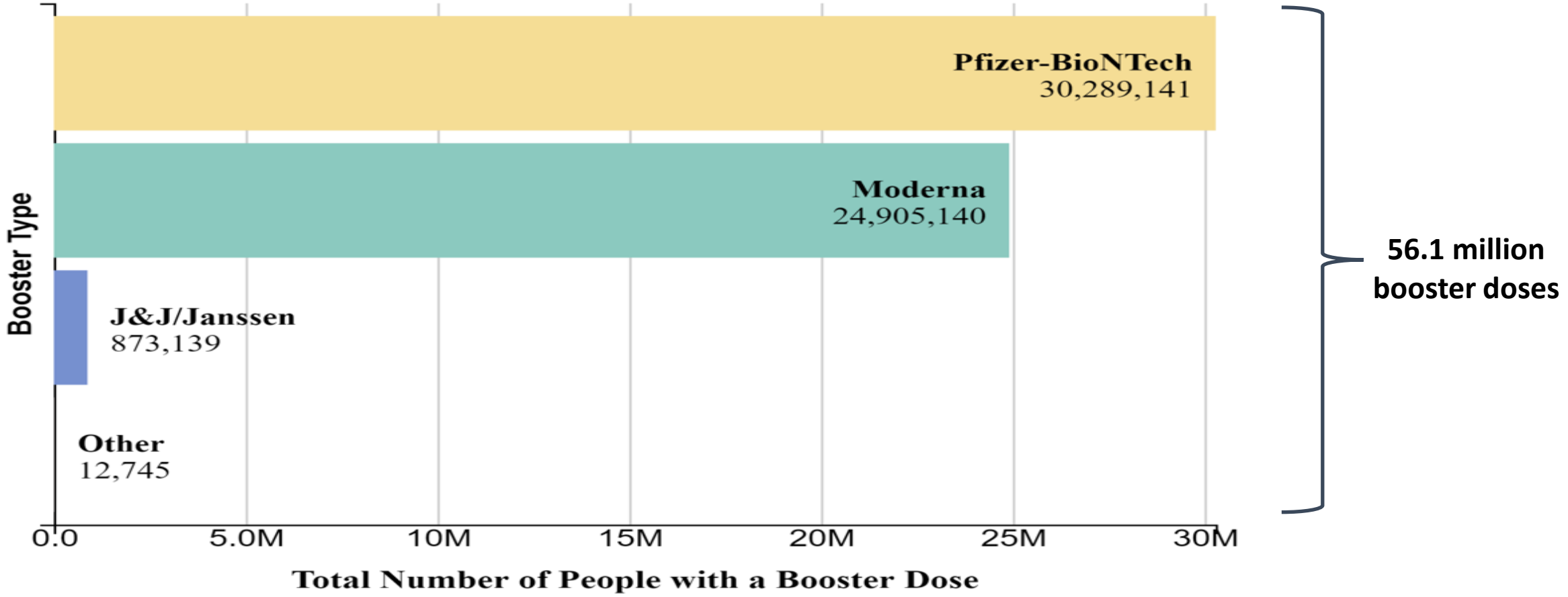
U.S. COVID-19 vaccine administration by vaccine type

As of December 15, 2021



CDC. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total. Accessed December 15, 2021

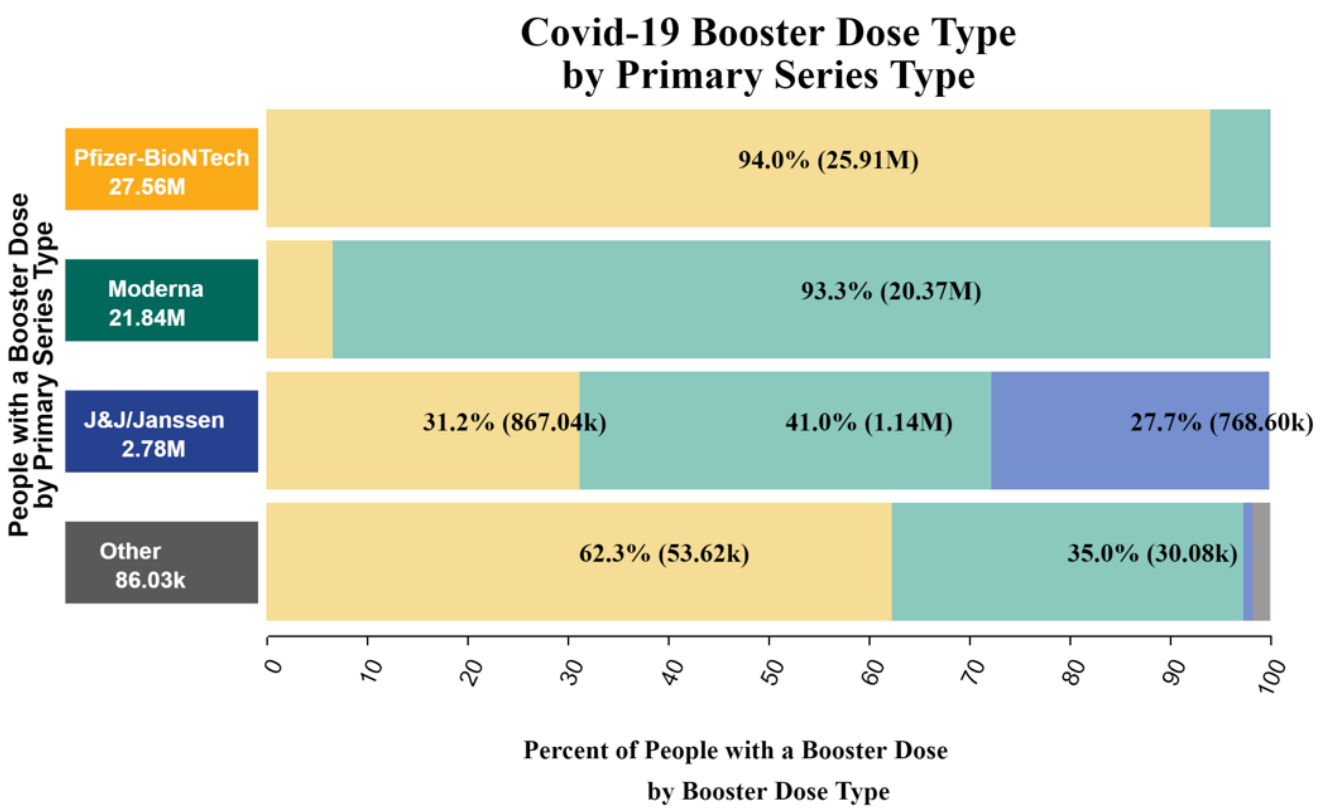
Number of people with a booster dose in the U.S. by COVID-19 vaccine type As of December 15, 2021

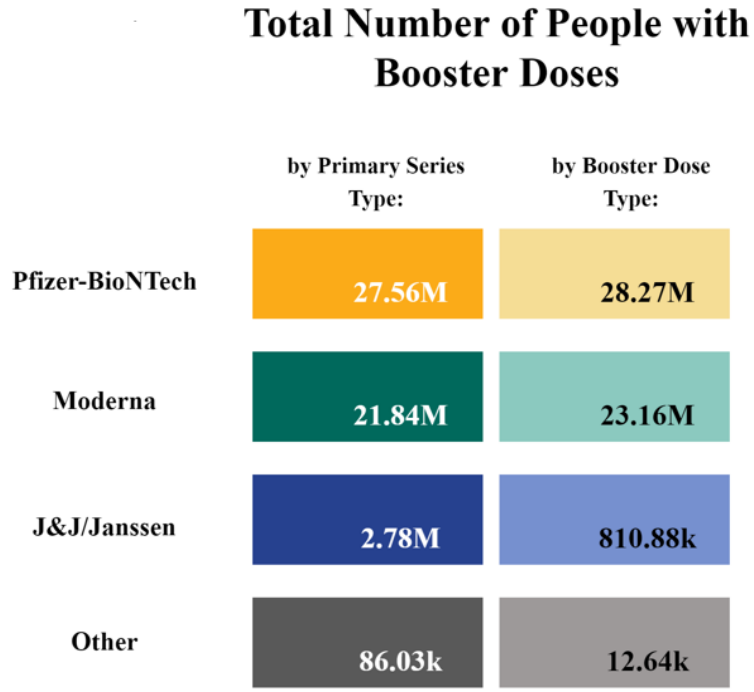


CDC. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total. Accessed December 15, 2021

COVID-19 booster dose type by primary series type

United States, as of December 15, 2021

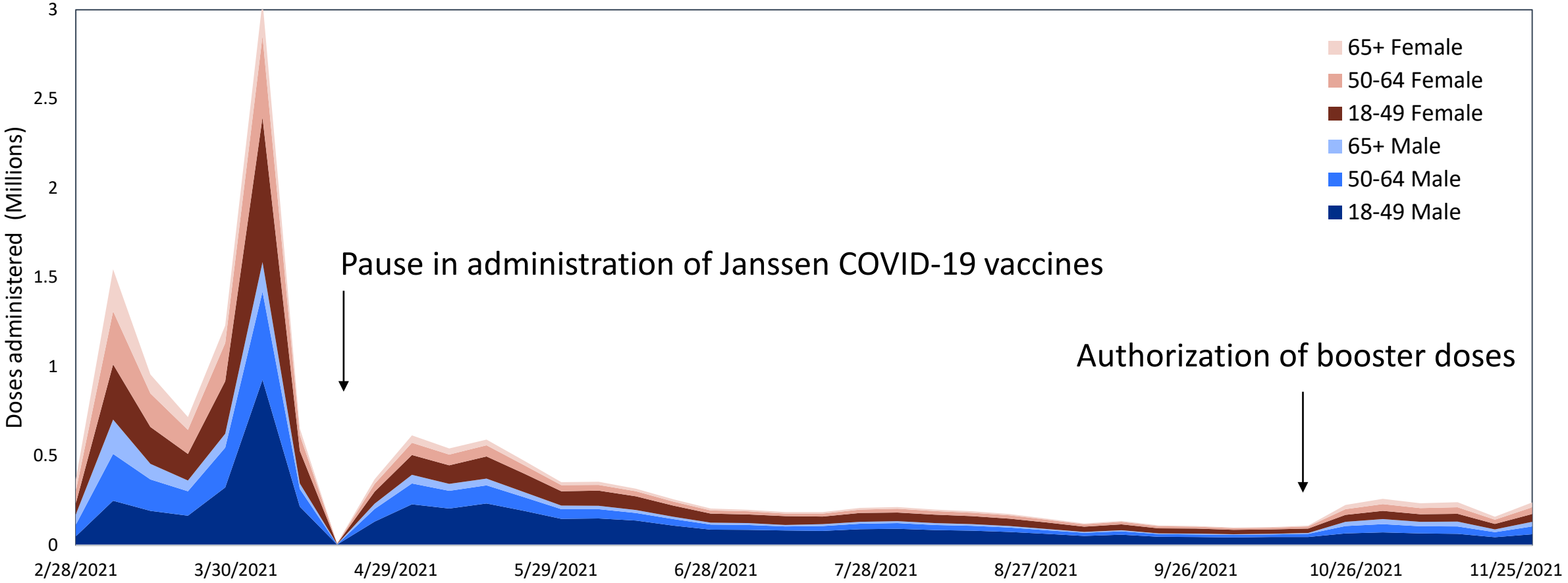




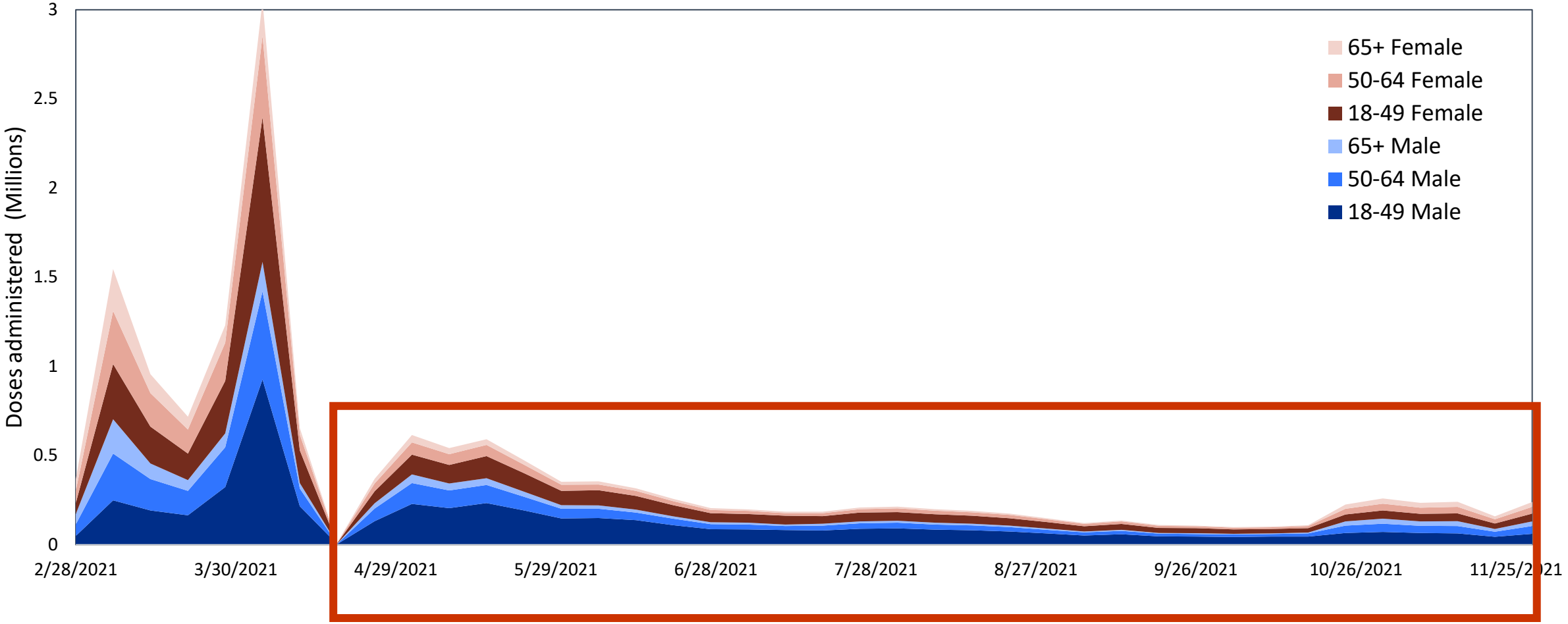
Data on booster dose type by primary series type for Texas are unavailable. As such, these metrics do not include people who received doses of vaccine in Texas.

CDC. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total. Accessed December 15, 2021

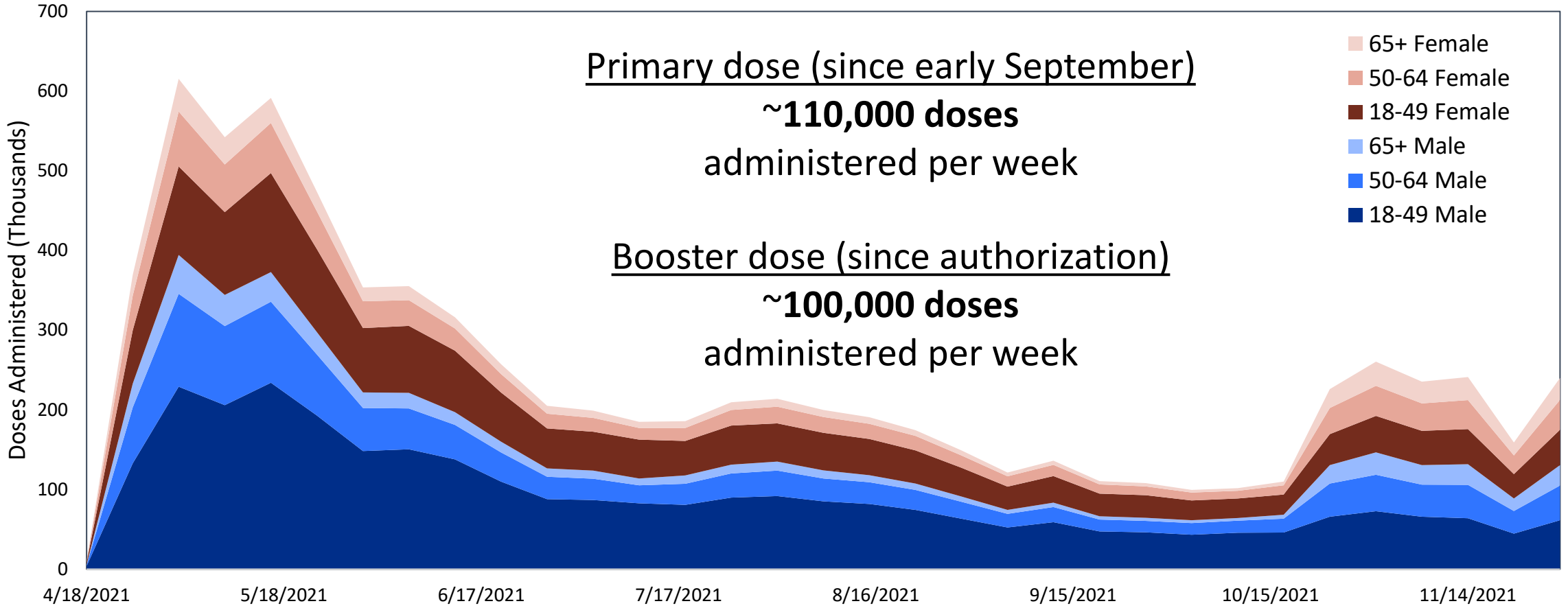
Administration of Janssen COVID-19 vaccines in the U.S. since authorization by age and sex, primary series and booster doses



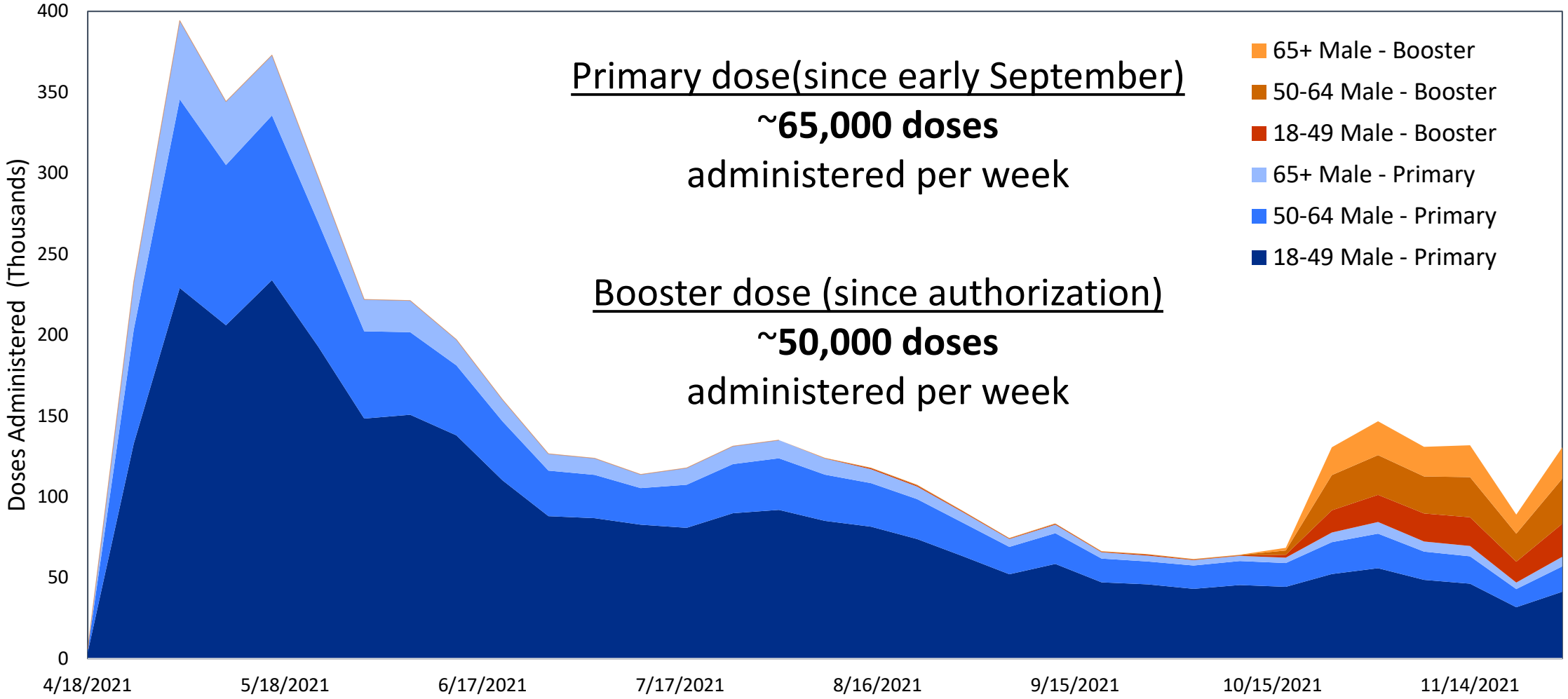
Administration of Janssen COVID-19 vaccines in the U.S. since authorization by age and sex, primary series and booster doses



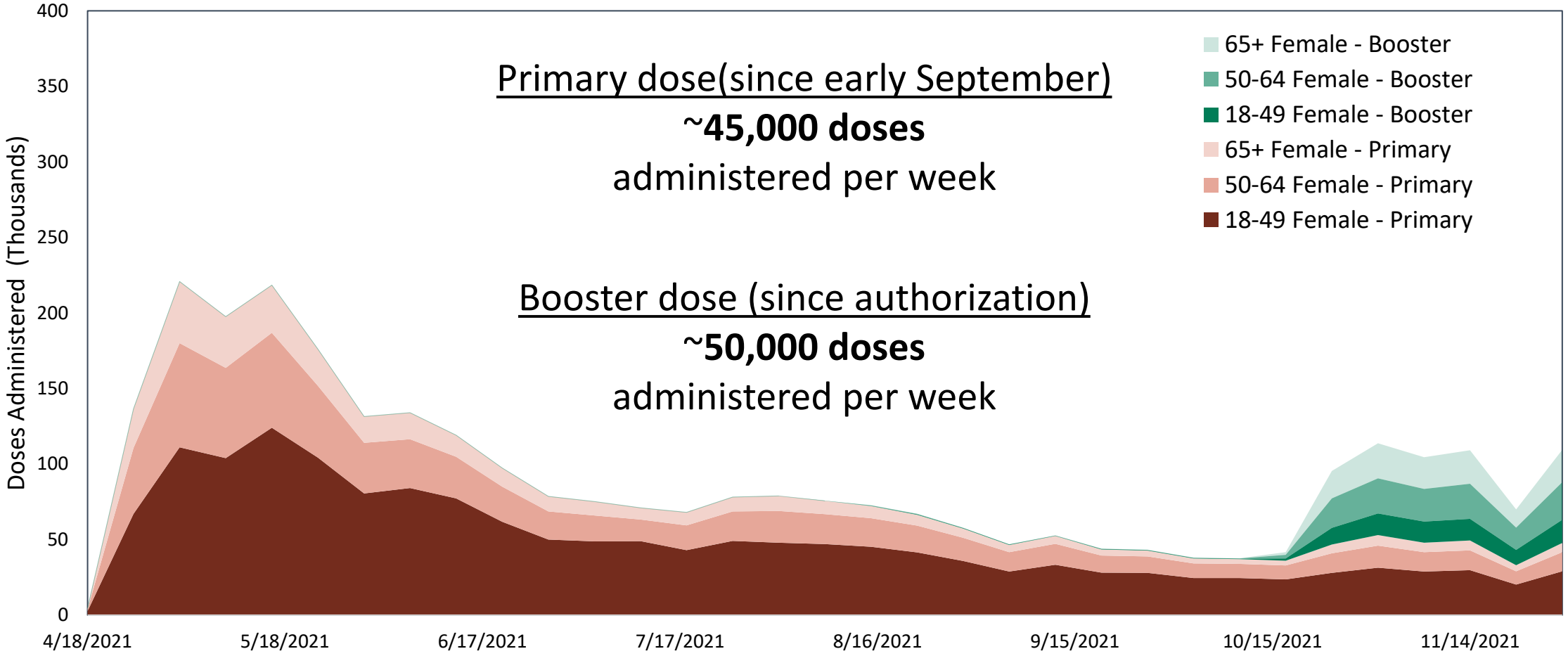
Administration of Janssen COVID-19 vaccines in the U.S. since pause by age and sex, primary dose and booster dose



Administration of Janssen COVID-19 vaccines in the U.S. among males since pause, primary series and booster doses



Administration of Janssen COVID-19 vaccines in the U.S. among females since pause, primary series and booster doses

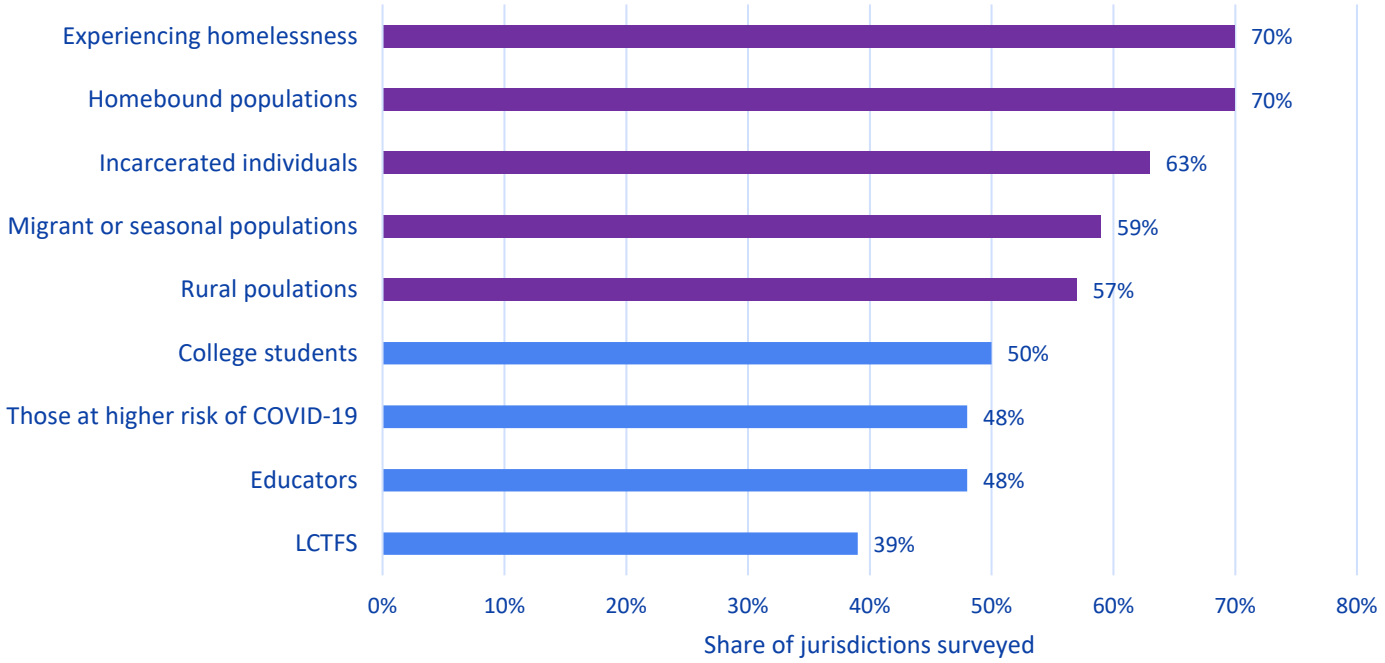


Most populations can receive the Janssen vaccine

Jurisdictional survey, December 2021

Jurisdictions reported that the Janssen vaccine was available to **nearly all** populations

Q: Which populations are offered the Janssen vaccine?



Jurisdictions also conveyed **easier, more widespread** access to all populations

"Any individual may receive Janssen if they go to a provider that offers it."

“All providers are given the option to order and administer J+J.”

"Pretty much anyone who wants the Janssen vaccine can have it as long as they go to a provider who carries it.”

"It is offered specifically if requested by the person setting up the clinic, but it is also offered as a choice at all community clinics and mass vaccination sites.”

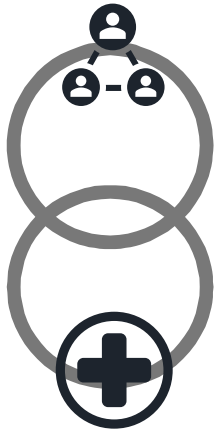
Jurisdictional survey on Janssen vaccine, December 12-15, 2021 (n=46)

Janssen is offered widely, but is the preferred option in more transient/transitional settings

Jurisdictional survey, December 2021

Janssen is offered at….

LOCAL SETTINGS



Community Events

Pharmacies

… while it may be the ONLY option at…

TRANSITIONAL SETTINGS

Correctional Facilities

Homeless Shelters

Airports

Jurisdictional survey on Janssen vaccine, December 12-15, 2021 (n=46)

Impact if Janssen COVID-19 vaccine was no longer recommended

Jurisdictional survey, December 2021

Jurisdictions are particularly concerned about recipient preference, vaccine confidence/hesitancy, logistics, and equity

1

Issues with Access and Demand

- Individuals who prefer a single dose will no longer have access
- Some providers with lower volumes of patients have preference for single dose vaccine
- Some individuals hesitant about receiving an mRNA vaccine
- Increased challenge to reach homebound, transient, and rural populations because of need to administer second dose

2

Decreased Confidence in COVID-19 Vaccines

- Diminished access could undermine confidence in the COVID-19 vaccine program
- Lack of vaccine choices could contribute to mistrust and misinformation about COVID-19 vaccines available
- Could reinforce the idea that an inferior vaccine was given to at-risk communities
- Could over all hinder vaccination rates

3

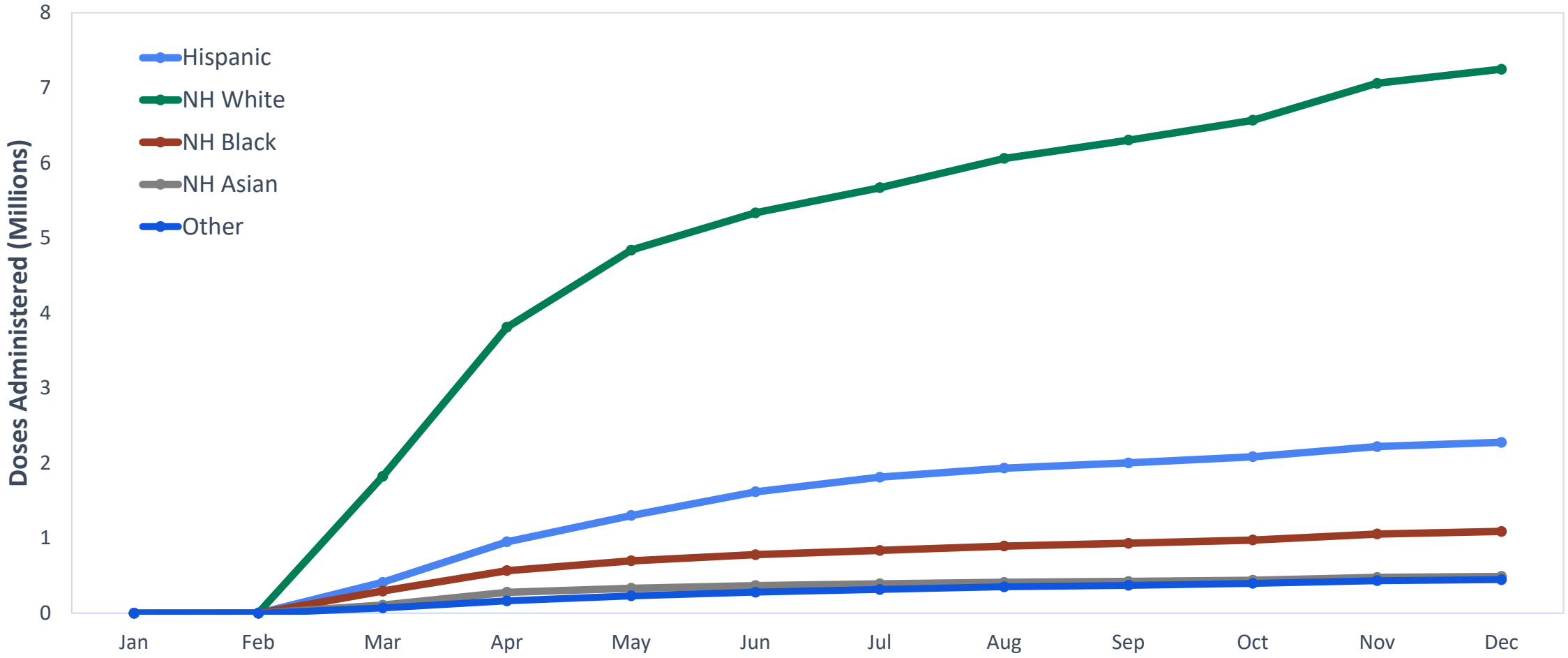
Disruptions to Logistics Flow

- Major supply changes could pose challenges to current workflows
- Shift in recommendations could add confusion to already resource-constrained providers and vaccine distributors

Jurisdictional survey on Janssen vaccine, December 12-15, 2021 (n=46)

Equity

Administration of Janssen COVID-19 vaccines in the U.S. since pause, by race and ethnicity

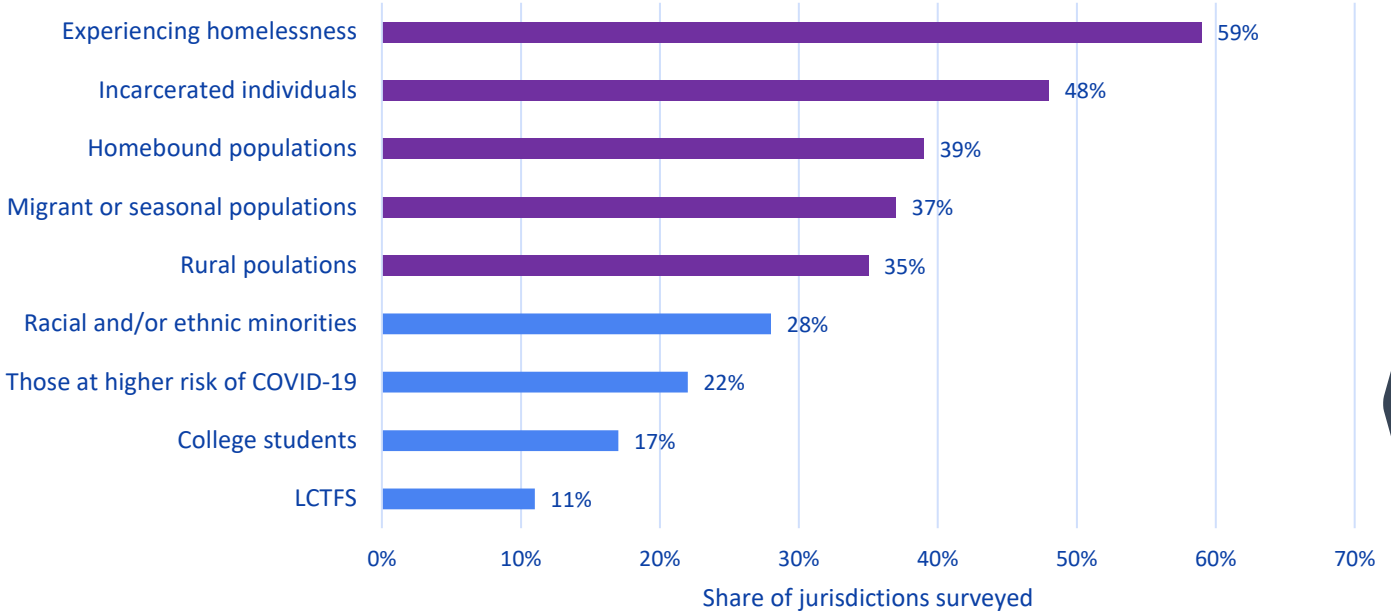


CDC. Vaccine Task Force. Vaccine Data Section/Data, Analytics & Visualization Task Force. Data updates as of December 15, 2021

Jurisdictions concerned revised recommendations would disproportionately affect several populations

Jurisdictions fear **more populations at greater risk of disproportionate impact** now than when previously surveyed in April 2021

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



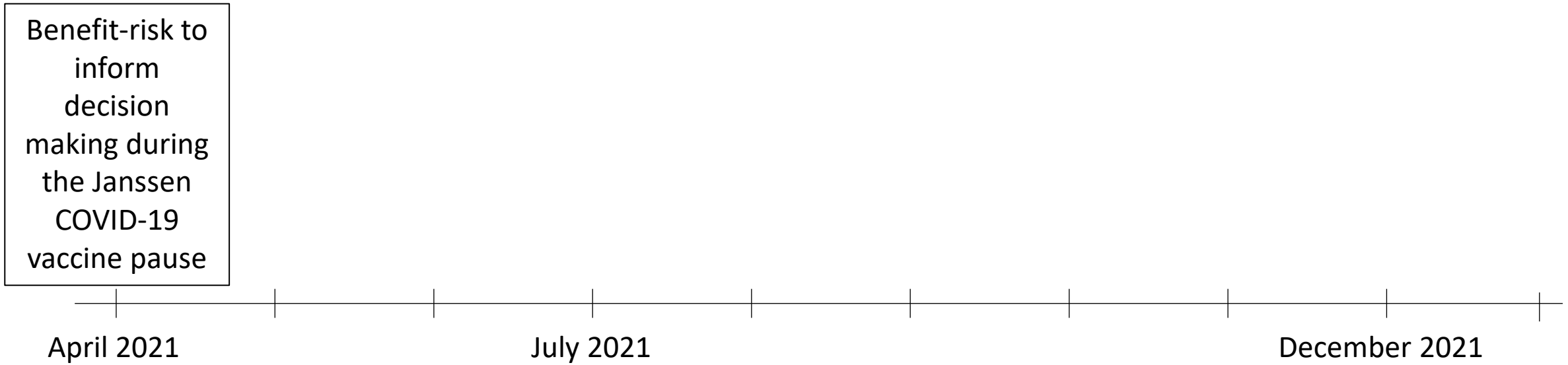
Jurisdictional survey on Janssen vaccine, December 12-15, 2021 (n=46)

Jurisdictions described other populations that may be **disproportionately impacted**, including:

1. Transient individuals or those who travel frequently
2. Lower-income individuals
3. Socially-isolated individuals
4. Individuals who receive vaccines at consulates
5. Temporary agricultural workers
6. Individuals who prefer a single dose of vaccine rather than a multi-dose series
7. Inpatient and ED patients
8. Younger populations in general

Summary

Timeline of Janssen COVID-19 vaccine benefit-risk review

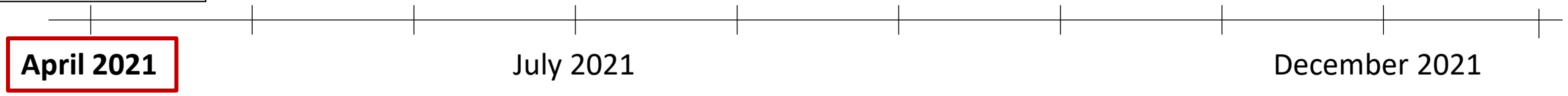


Timeline of Janssen COVID-19 vaccine benefit-risk review

Benefit-risk to inform decision making during the Janssen COVID-19 vaccine pause

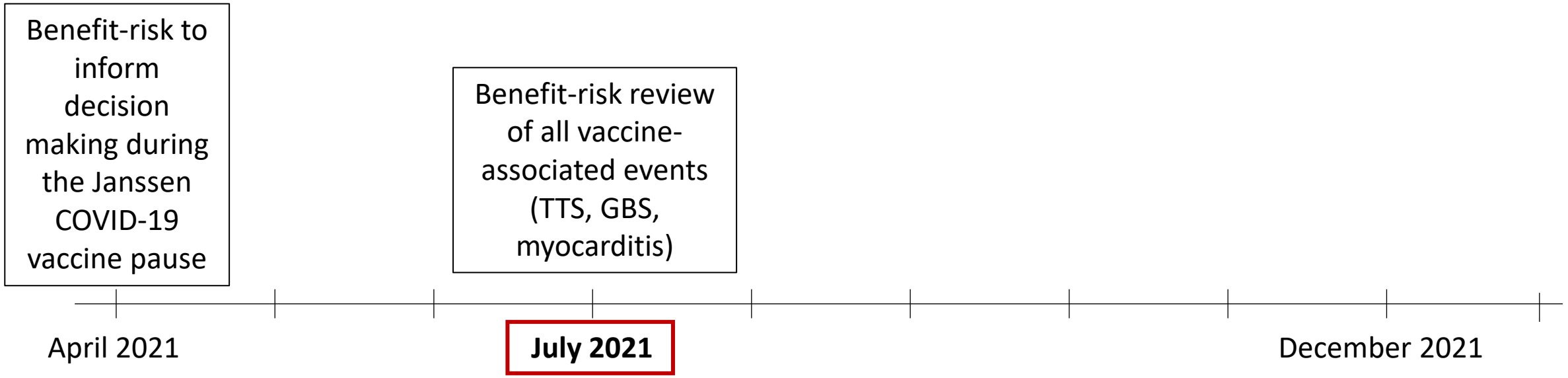
Limited supply of mRNA COVID-19 vaccines

- Estimated that if Janssen COVID-19 vaccine not resumed, could take nearly **3 months** for all vaccine-intending adults to complete a COVID-19 vaccine series, based on supply at that time



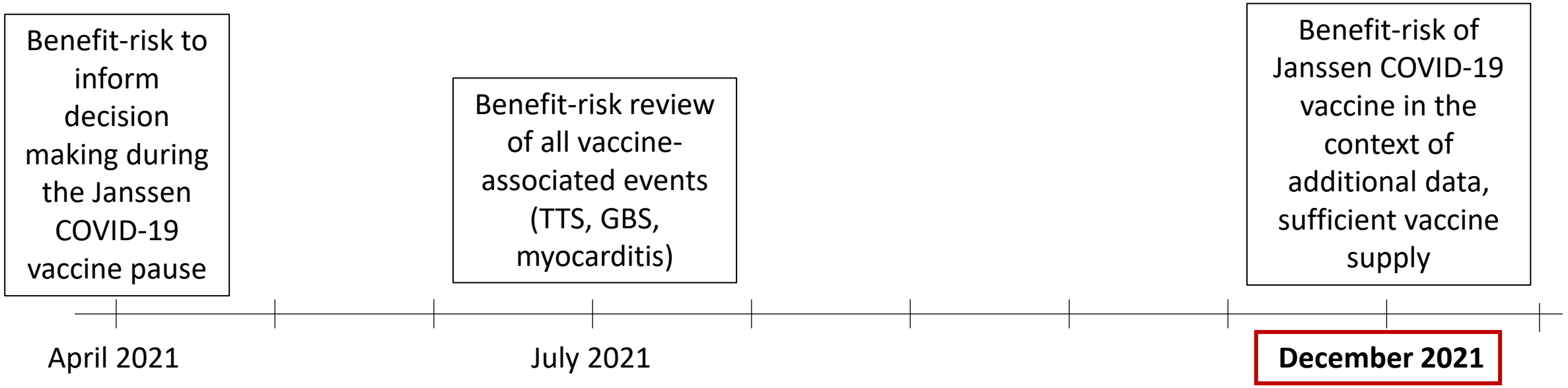
- ACIP reaffirmed its interim recommendation for use of the Janssen COVID-19 vaccine in all persons aged ≥18 years under FDA's EUA, including a warning that rare clotting events might occur after vaccination, primarily among women aged 18-49 years
  - Education around the **risk for TTS** with Janssen COVID-19 vaccine, as well as the **availability of alternative COVID-19 vaccines**, is required to guide vaccine decision-making

Timeline of Janssen COVID-19 vaccine benefit-risk review



- GBS after Janssen vaccine identified and benefit/risk balance reassessed
- ACIP determined that overall, the benefits of COVID-19 vaccination in preventing COVID-19 morbidity and mortality outweigh the risks for these rare serious adverse events
  - Balance of benefits and risks varies by sex

Timeline of Janssen COVID-19 vaccine benefit-risk review



- Additional case review and ongoing safety surveillance identified cases (previous and newly occurring) of TTS, including deaths
- No longer in the setting of limited mRNA COVID-19 vaccine supply in the US

Proposed policy options for Janssen COVID-19 recommendations discussed with the Work Group

- Reaffirm recommendations for **all** age and sex
  - In setting of FDA warning on EUA, guidance in clinical considerations
- Recommend vaccination only for **older adults** (≥50 or ≥65 years of age)
- Recommend **against** use for all persons
- **Preferential recommendations** for mRNA COVID-19 vaccines over the Janssen COVID-19 vaccines

Policy Option #1

Reaffirm recommendations for the Janssen COVID-19 vaccine for all age and sex*

PROS	CONS
• Allow for flexibility/choice • Allow for use of the vaccine in harder to reach populations	• May lead to more cases of TTS and GBS • Burden on individual to make decision for type of vaccine received; health dept/providers to convey risk • At-risk populations for COVID-19 may have limited opportunity for discussion of risk associated with vaccine • At-risk populations for COVID-19 may be at risk for barriers to rapid TTS identification and treatment

*in setting of FDA warning on EUA, guidance in clinical considerations

Policy Option #2

Recommend the Janssen COVID-19 vaccine only for older adults (≥50 years or ≥65 years of age)

PROS	CONS
• Would remove vaccine from most at-risk population (reduce TTS cases) • Age-based recommendations easier to communicate/ implement	• VE lower for Janssen COVID-19 vaccine, compared to mRNA COVID-19 vaccines: May provide less protection in a population at risk for severe disease • In US, most older adults already initiated COVID-19 vaccine primary vaccine series • Removes the option of a Janssen COVID-19 vaccine for younger men, who are at higher risk of myocarditis • Risk of GBS higher in older adults • If ≥50 years of age cut-off: still cases and deaths from TTS reported in those 50-64 years of age*

*2 deaths in 50-64 year old females; TTS rates in those 50-64 years: 4.5/million in females, 2/million in males

Policy Option #3

Recommend against use of the Janssen COVID-19 vaccine for all persons

PROS	CONS
• No further cases of TTS or GBS after Janssen COVID-19 vaccine • No further deaths due to TTS or GBS after Janssen COVID-19 vaccine	• Would remove choice from individuals for primary series and booster • Would limit options for those with contraindications to mRNA vaccines • May have global implications around confidence in Janssen COVID-19 vaccine, which could impact global vaccine supply

Policy Option #4

Preferential recommendation for mRNA COVID-19 vaccines over the Janssen COVID-19 vaccine

PROS	CONS
• Acknowledges the benefit/risk balance more favorable for mRNA vaccines in all ages/sexes: Higher VE, less severe adverse events • Allows for flexibility and choice • Allows vaccine option for someone with contraindication to mRNA vaccines	• Burden on individual to make decision for type of vaccine received; health dept/providers to convey risk • At-risk populations for COVID-19 may have limited opportunity for discussion of risk associated with vaccine • May be confusion around how to implement a preferential recommendation

Work Group Summary

- In the setting where there are **no alternative** COVID-19 vaccines, the benefits of Janssen COVID-19 vaccines outweigh the risks
  - Important for global situations where there may not be other COVID-19 vaccines available
- Due to both higher vaccine effectiveness of mRNA vaccines and severity of safety issues with the Janssen vaccine, in the setting of widely available mRNA COVID-19 vaccines in the US, the benefit/risk balance of **mRNA COVID-19 vaccines** is **more favorable** than for Janssen COVID-19 vaccines

Work Group Summary

- Based on reviewing the totality of the data, the Work Group supported a **preferential recommendation** for mRNA COVID-19 vaccines
  - Similar to other countries with mRNA and adenovirus-vector vaccines available
- Will continue to review available data on vaccine effectiveness and safety; updates to recommendations can be made as needed
- **Education** around the risks associated with adenovirus-vector vaccines will be critical for those who may choose to receive Janssen vaccine
- Ensuring **access** to mRNA COVID-19 vaccines in all individuals is critical
  - If Janssen COVID-19 vaccine is only vaccine offered to some harder-to-reach populations, could result in inequitable distribution of risk for TTS and GBS

Possible language for a preferential recommendation

- mRNA COVID-19 vaccines are **preferred** over the Janssen COVID-19 vaccine for the prevention of COVID-19 for those ≥18 years of age
- Janssen COVID-19 vaccines may be offered when other authorized COVID-19 vaccines are contraindicated or inaccessible
- This includes vaccines administered as a part of the primary series and booster doses

Possible guidance for a preferential recommendation

- Education about the risk for adverse events, including TTS or GBS after the Janssen COVID-19 vaccine, is required to guide vaccine decision-making
- Janssen COVID-19 vaccines may be offered to the following populations:
  - Persons with a contraindication to mRNA COVID-19 vaccines (e.g. severe allergic reaction after a previous dose or to a component of an mRNA COVID-19 vaccine)
  - Persons who would otherwise remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines
  - Persons who would prefer the Janssen COVID-19 vaccine despite safety concerns identified
- Vaccine providers should start the two-dose mRNA COVID-19 vaccine series, even if there is uncertainty about how the patient will receive their second dose. Two-dose mRNA COVID-19 vaccines can be used in any population or setting.

Questions for ACIP to discuss

- Given the review of the benefits and risks, what recommendation does ACIP feel is appropriate for use of the Janssen COVID-19 vaccine?

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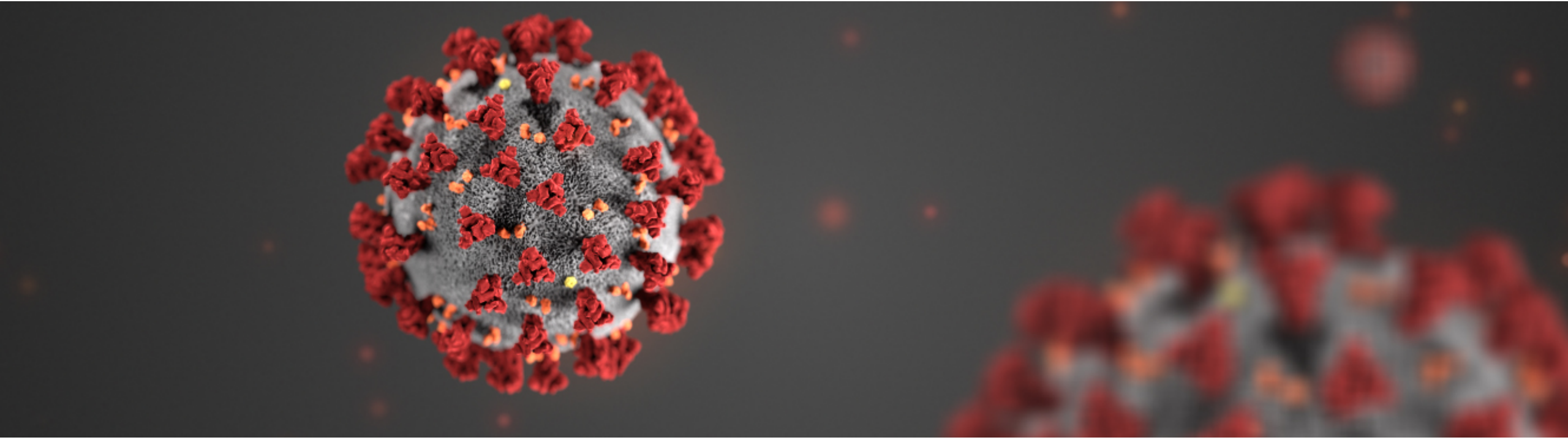
- Christopher Taylor
- Ruth Link-Gelles
- Mark Tenforde
- COVID-NET Team
- DAV Vaccine Team
- Vaccine Safety Team
- Epidemiology and Surveillance Task Force
- Vaccine Task Force



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.