

COVID Vaccine Update

VAC

March 4, 2021

# COVID Vaccine Program Updates

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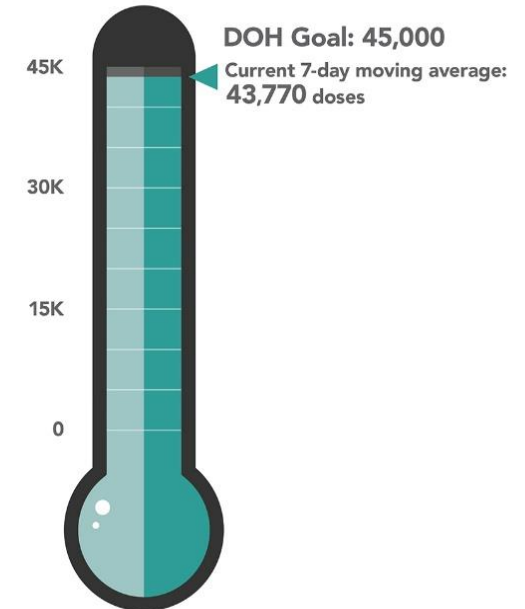
SHEANNE ALLEN

# Getting to 45K doses a day



Photo credit: Seattle Times 1/14/2021: Randall Thomas, 71, took this photo as he waited in line for a coronavirus vaccination on Thursday in Sequim, only to be turned away just 10 cars from... (Courtesy of Randall Thomas)

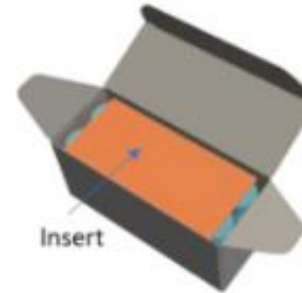
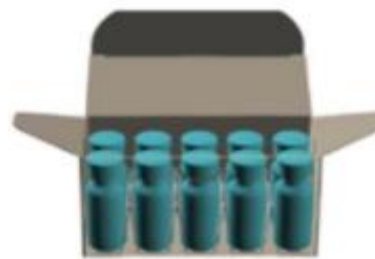
## COVID-19 Vaccine Doses Administered Daily



70% of eligible population – 4.3 million  
population over 7 months / desire for faster



# Janssen Investigational COVID-19 Vaccine Anticipated Pandemic Supply Configuration & Storage Conditions



## Primary packaging

### 2R glass vial

- No preservative and no reconstitution required
- Blue matte finish button with silver crimp combination
- High volume 5-dose vial for EUA
- 0.5 ml per dose ( $5 \times 10^{10}$  vp)

## Secondary packaging

- 10 vials per carton
- 1 product insert per carton

## Tertiary packaging

- 48 cartons per shipper case
- Carton material: solid bleached sulfate (SBS)

## Anticipated storage conditions (under EUA)



### Long-term storage<sup>1</sup>:

**-20°C**  
For 2 years

Of which

### End-user storage:

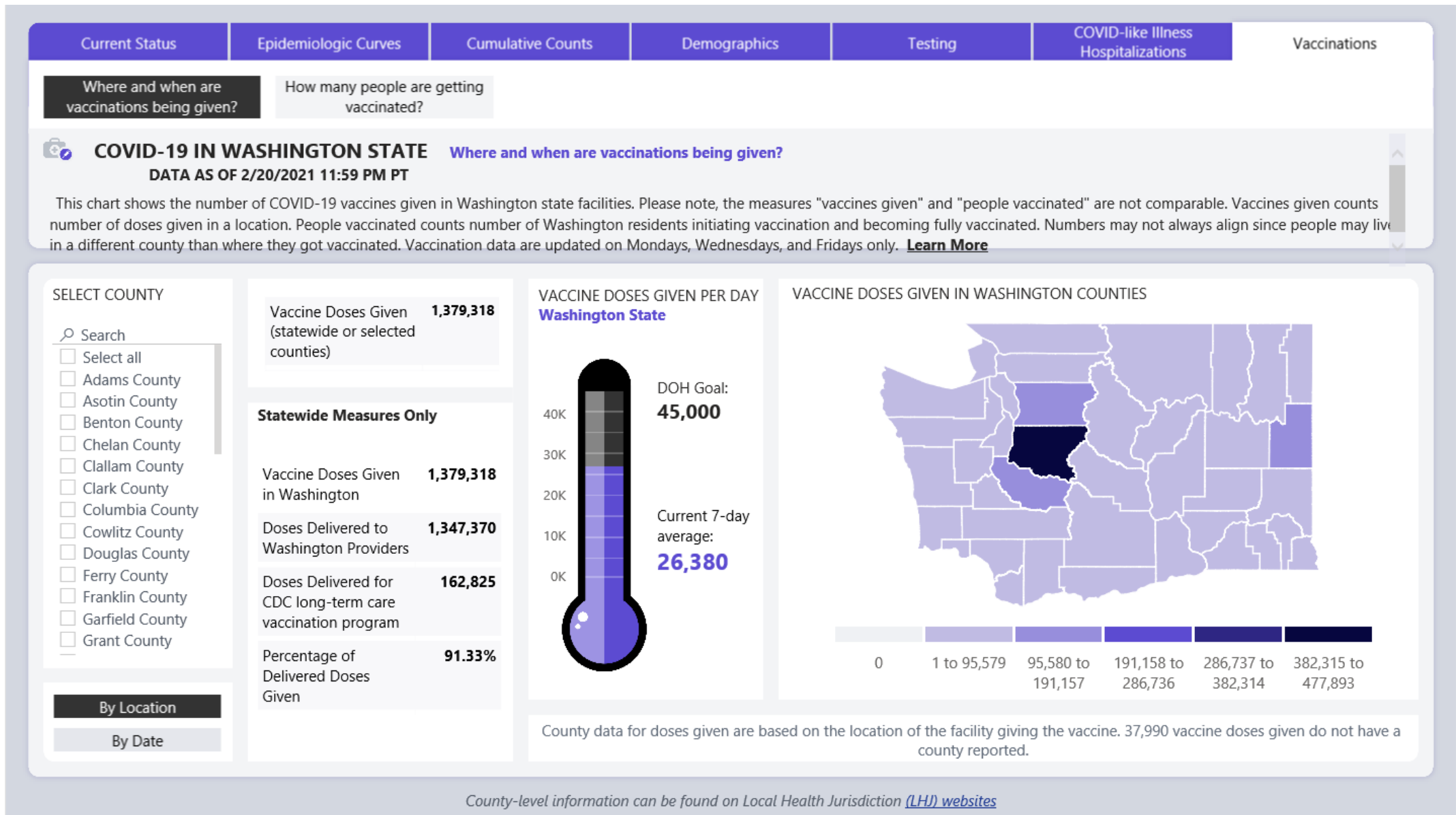
**2-8°C**  
Up to 3 months

### After first use<sup>\*</sup>:

**2-8°C**  
Up to 6 hours

<sup>1</sup>Long term storage by manufacturer or distributor ONLY – not to be refrozen by end-user

<sup>\*</sup>The vaccine can be held for a limited time within vial or syringe at either 2°C to 8°C (36°F to 46°F) or room temperature (maximally 25°C or 77°F) after the first puncturing of the vial. The vaccine should be discarded if not used within this time.

County-level information can be found on Local Health Jurisdiction [\(LHJ\) websites](#)

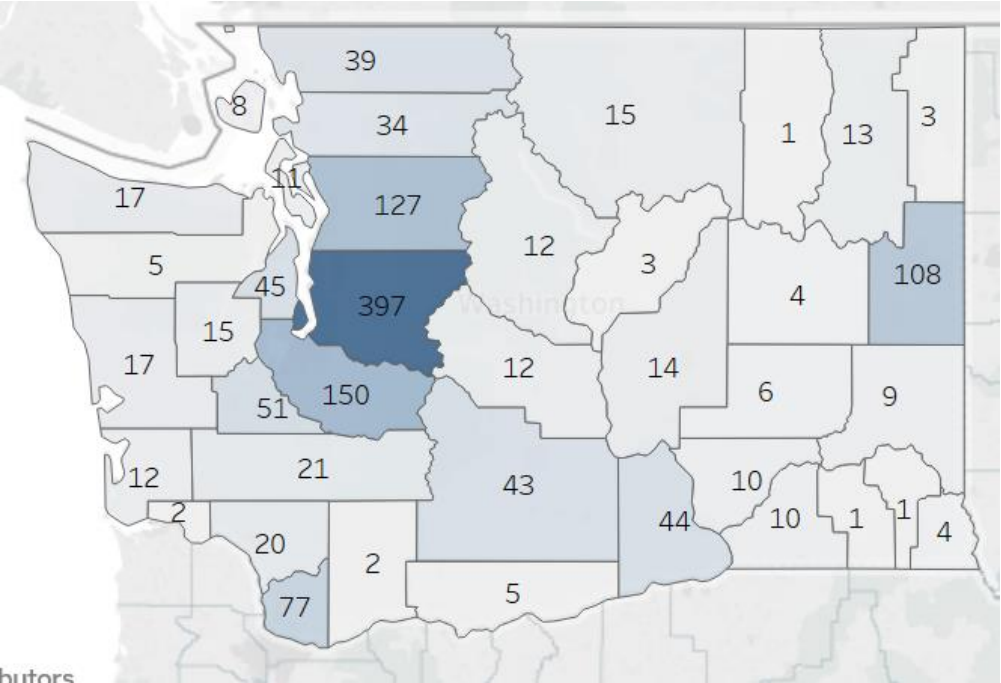
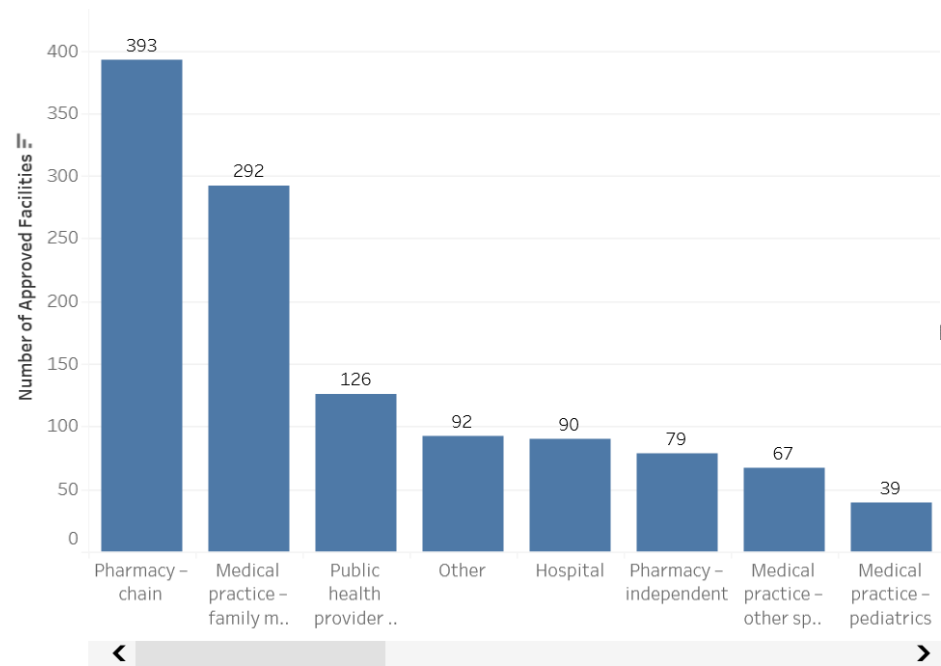
<https://www.doh.wa.gov/Emergencies/COVID19/DataDashboard#dashboard>

# Provider Enrollment Snapshot

Total Facilities Approved

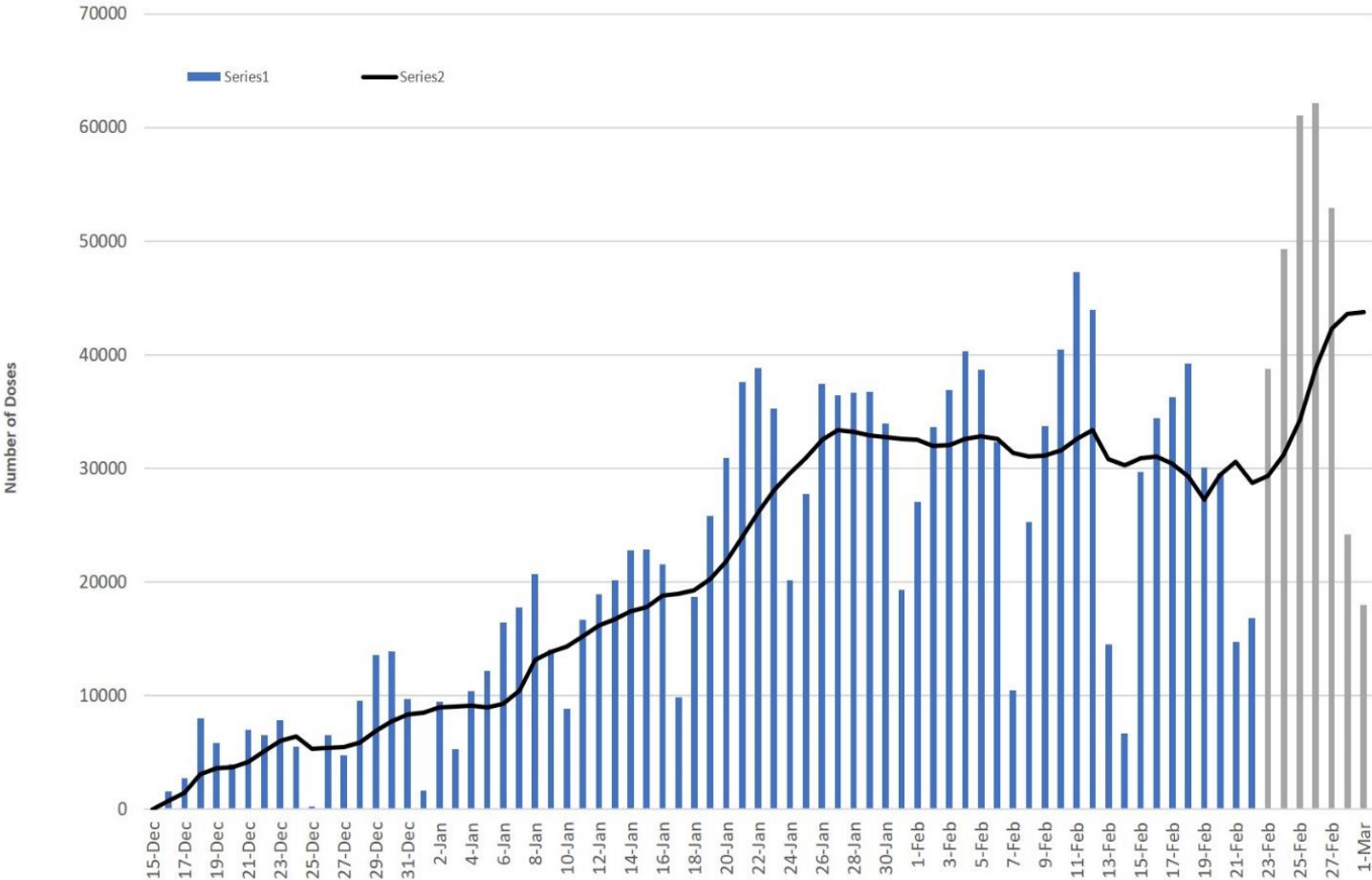
1,367

Approved Facilities by Facility Type



# COVID-19 Vaccine Doses Administered by Date

COVID-19 Vaccine Doses Administered in Washington State by Date



Data source: Washington State Immunization System, reported as of 11:59pm 3/1/2021  
Light grey bars represent incomplete data due to reporting lag  
**Note:** Dose administration data reported as of date lags by 2 days to allow for data processing and quality assurance checks.

# Complex and evolving landscape for COVID-19 vaccine

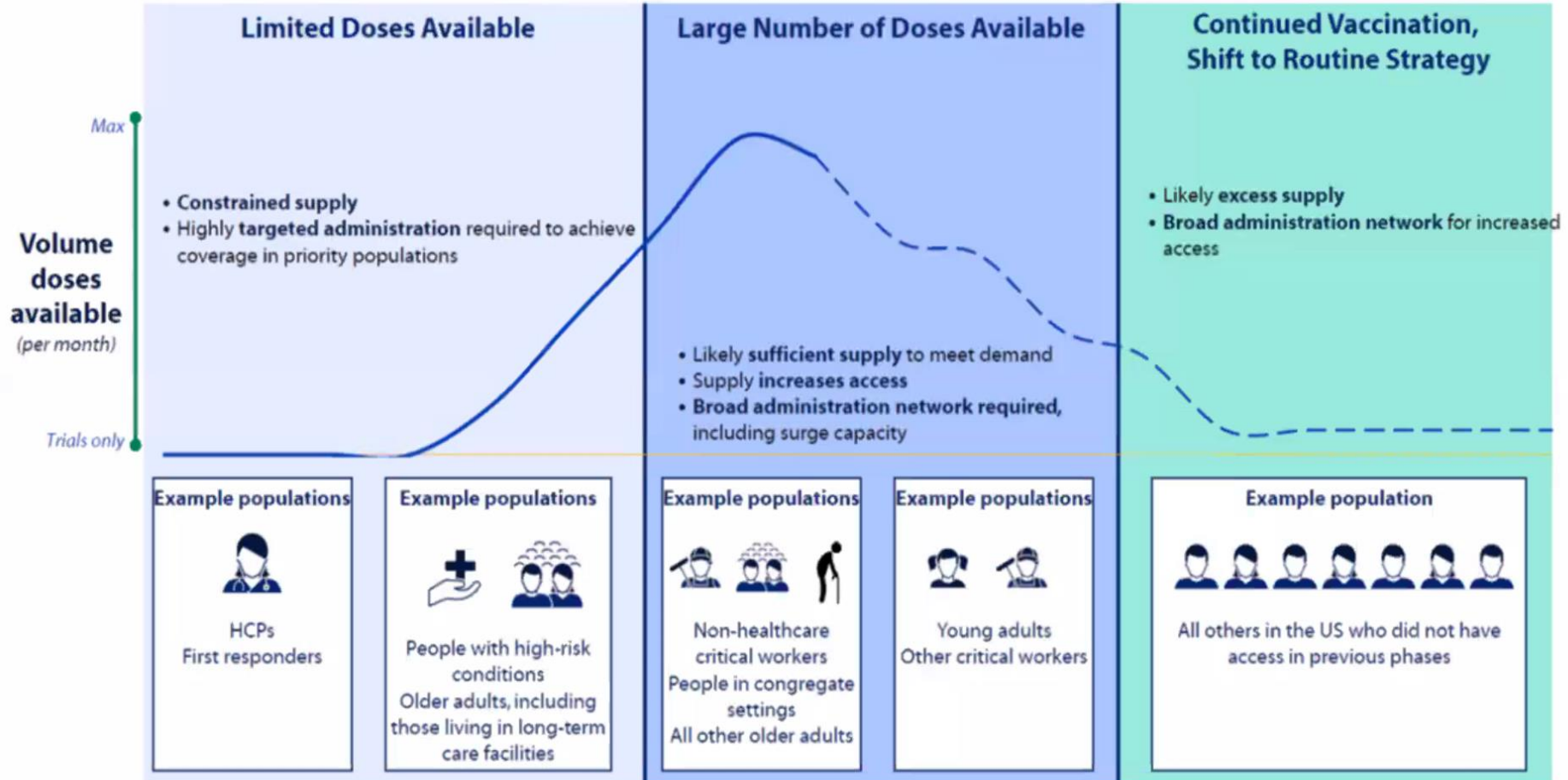
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- One vs. two doses series, products not interchangeable
- Varying presentations
- Vaccine efficacy and adverse event profile in different populations
- Varying cold chain requirements
- Need for socially distanced vaccination practices
- Communication and education
- Some high-risk groups for COVID-19 may distrust public health



# Vaccine Supply

Distribution will adjust as volume of vaccine doses increases



# 3 Week Forecast

	March 07, 2021 Forecast For Week Ending	March 14, 2021 Forecast For Week Ending	March 21, 2021 Forecast For Week Ending
All Vaccines	309,770 Total Doses - All Vaccine Types	320,300 Total Doses - All Vaccine Types	327,320 Total Doses - All Vaccine Types
Pfizer	91,260 1st Doses - Pfizer	91,260 1st Doses - Pfizer	91,260 1st Doses - Pfizer
	73,710 2nd Doses - Pfizer	84,240 2nd Doses - Pfizer	91,260 2nd Doses - Pfizer
Moderna	72,400 1st Doses - Moderna	72,400 1st Doses - Moderna	72,400 1st Doses - Moderna
	72,400 2nd Doses - Moderna	72,400 2nd Doses - Moderna	72,400 2nd Doses - Moderna
Janssen	0 1st Doses - Janssen	0 1st Doses - Janssen	0 1st Doses - Janssen

# Federal Retail Pharmacy Partnership (FRPP)

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## Highlights of the Program

- Enroll and allocate vaccine to retail pharmacies that can reach those at risk and identified on the Social Vulnerability Index (SVI)
- Currently program is allocating 2 million weekly doses nationally, but will work up to 4 million doses by the end of March

## In Washington:

- Currently 6 retail pharmacies are activated: Albertsons, Kroger, Costco, Rite Aid, Walmart, and HealthMart
- Week 1 allocation – 22,500 (Moderna)
- Week 2 allocation – 62,060 (Moderna and Pfizer)
- Week 3 allocation\* – 65,670 (Moderna, Pfizer, and Janssen)

# Federally Qualified Health Center (FQHC) Federal Program

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## Highlights of the Program

- To ensure underserved communities and those disproportionately affected by COVID-19 are equitably vaccinated against COVID-19 HRSA and CDC launched a program to directly allocate a limited supply of COVID-19 vaccine to select HRSA-funded health centers
  - Goal is to supplement state awarded doses, not replace state allocation
  - Program is temporary, but currently undefined timeline

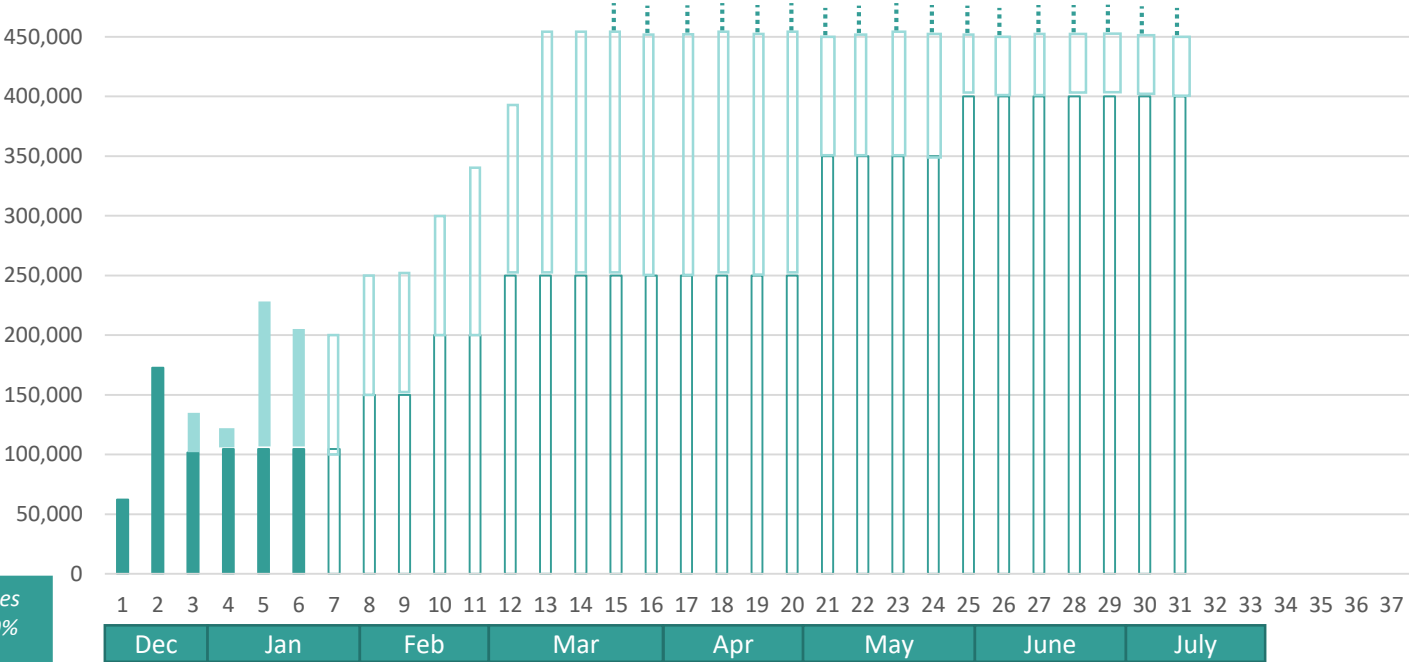
## In Washington:

- Cohort 1 - Week 1 allocation – 18,300 doses across 21 facilities
- Cohort 1&2 - Week 2 allocation – 11,800 doses across 43 facilities
- Cohort 1, 2, & 3 – Week 3 allocation – Unknown

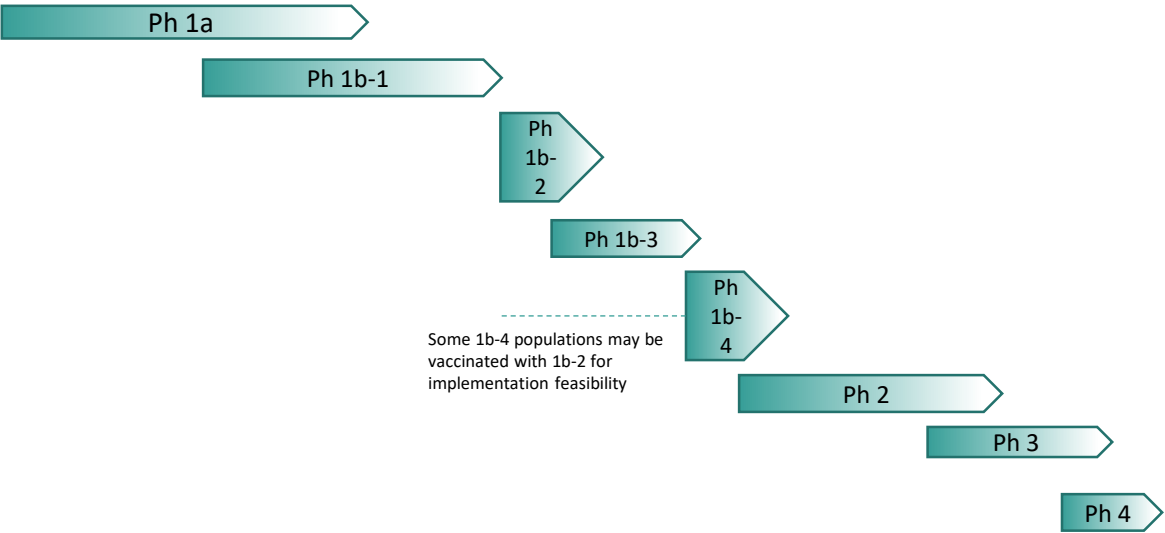
# WA State COVID-19 Best Guess Supply & Phase Projections

Updated 1/18/21

45k/day target inclusive  
first and second doses



Phase	Size estimate <i>(sizes not overlapping and assumes 100% vaccine adoption)</i>
1a	850,000
1b-1	1,484,000
1b-2	95,000
1b-3	1,100,000
1b-4	370,000
2	1,620,000
3	2,000,000
4	200,000





# Washington Plan for Increased Vaccinations

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***Note: Vaccine Supply Constraints Remain***

- **Traditional** Delivery Systems

1. Healthcare system (hospitals and clinics)
2. Pharmacies
3. Workplace clinics

- **Enhanced** Delivery Systems:

1. Local jurisdiction operation high volume community vaccination sites
2. Mobile vaccination teams
3. Community-based pop-up clinics

- **Mass Vaccination** Delivery Systems (state-supported):

- High through-put mass vaccination sites
- Mobile vaccination teams

# Mass Vaccination Sites

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- Four DOH Sites
  - Benton County Fairgrounds- Kennewick, Clark County Fairgrounds- Ridgefield, Town Toyota Center- Wenatchee, Spokane Arena- Spokane
- 3 drive through sites administering Pfizer
  - Currently in the last week of booster doses
- 1 walk through site administering Moderna
  - In week 2 of booster doses
- Averaging 895 vaccinations a day
- Spokane will begin partnership with Safeway as provider starting March 9

# Mass Vaccination Sites

As of: 3/3/2021	4:00 PM
POD/V	Total
<u>Benton County Fairground</u>	23,768
<u>Spokane Arena</u>	18,299
<u>Chelan County Toyota Town Center</u>	20,114
<u>Clark County Fairground</u>	21,444
<u>Mobile Team 5</u>	3,482
<u>Mobile Nurse team</u>	206
<b>Total Residents Vaccinated:</b>	<b>87,313</b>

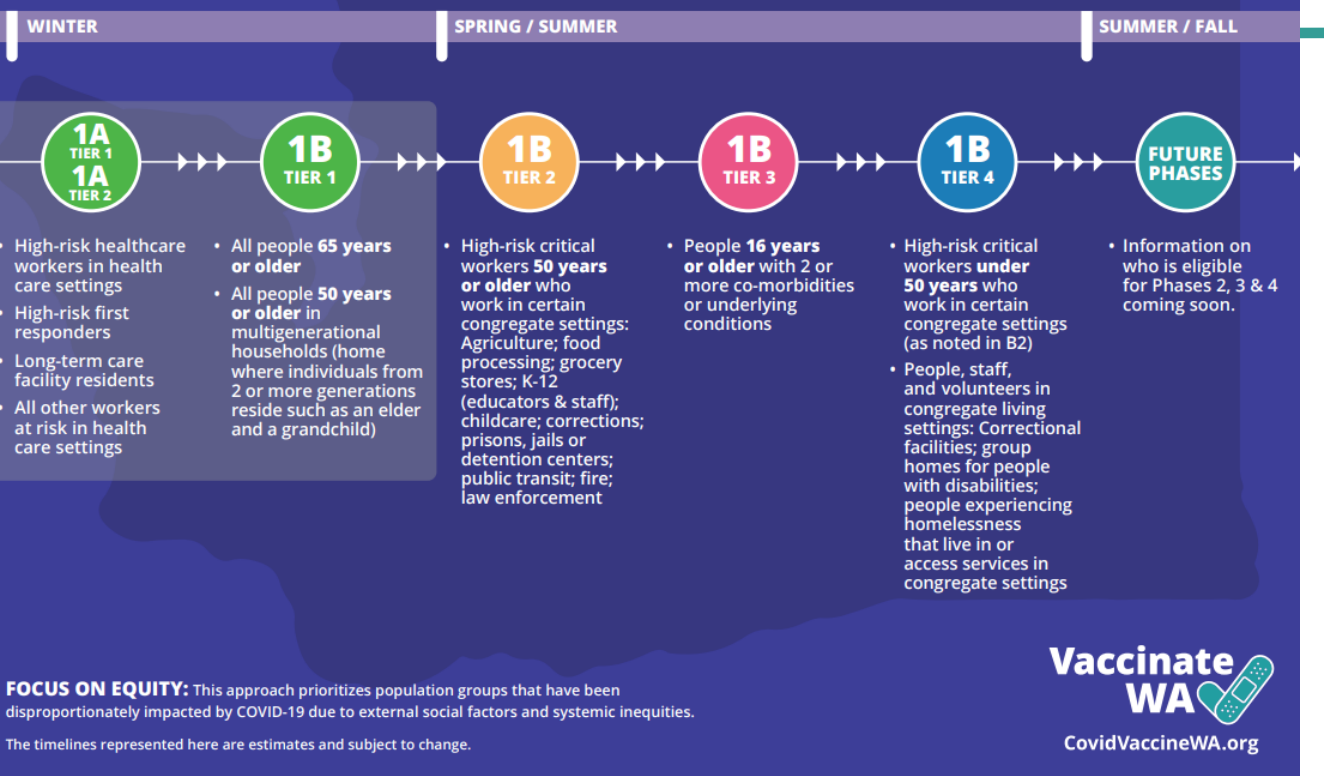






# WASHINGTON'S COVID-19 VACCINE PHASES

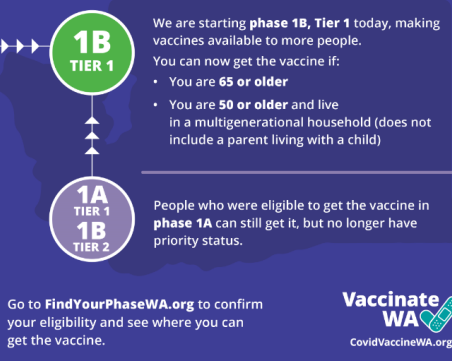
Phase 1 Estimated Start Dates (Tiers A and B)  
Find out if it's your turn at [FindYourPhaseWA.org](https://www.findyourphasewa.org)



<https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/AllocationandPrioritization>

## PHASE 1B OF COVID-19 VACCINATIONS STARTS TODAY

What that means:



## WHAT DOES MULTIGENERATIONAL HOUSEHOLD MEAN?

A household where individuals from 2 or more generations live such as an elder and a grandchild.

### ELIGIBLE WITHIN THE DEFINITION OF MULTIGENERATIONAL HOUSEHOLD:

- A person over 50 who:
- Cannot live independently and receives long-term care from a caregiver
- Lives with someone who works outside the home
- Lives with a young child like grandparent/grandchild or aunt/nephew

### NOT ELIGIBLE IN THIS PHASE:

- Someone younger than 50
- Someone over 50 who cares for a partner or friend
- Any parent or guardian caring for their small child or teen

[CovidVaccineWA.org](https://www.covidvaccinewa.org)

## GLOSSARY OF TERMS

### CO-MORBIDITIES

Morbidity is a medical term that means illness or disease. Co-morbidities means more than one illness or disease occurring in one person at the same time. Phase 1 – Tier 3 includes people with 2 more comorbidities or underlying conditions that put them at increased risk for severe illness if infected with COVID. This list of these conditions can be found on the CDC website: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>.

### CONGREGATE SETTING

An environment where individuals work and/or reside in an enclosed space and where they are interacting with a high volume of people over an extended period of time and not able to consistently maintain physical distance.

### CRITICAL WORKERS

Individuals working in an industry that maintains critical infrastructure for social and economic systems in our state. (See reverse side for detailed list.)

### HIGH-RISK WORKERS IN A HEALTHCARE SETTING

Workers who are at higher risk of COVID-19 infection because they meet one or more of the following criteria:

- Administer COVID-19 testing or handle COVID-19 specimens
- Administer COVID-19 vaccine or have patient contact in a COVID-19 vaccination site.
- Work at a community-based, congregate living facility (for example, long-term care facility, adult family home or residential care community) where people over 65 years old receive care, supervision or assistance.
- A professional care provider to someone who is at higher risk of severe outcomes if infected with COVID-19 (for example, home health aide, dialysis provider, or cancer treatment provider).

### HIGH-RISK WORKERS IN A HEALTHCARE SETTING (CON'T)

- Worker (for example, healthcare provider, security, environmental management) in a setting that provides direct care for suspected or confirmed COVID-19 patients.
- First responder (for example, EMS, police or firefighter) in settings where direct care is provided to suspected or confirmed COVID-19 patients.
- Worker at high risk of infection and transmission of COVID-19 because of exposure to the general public.

### LONG-TERM CARE FACILITY

For the purposes of the vaccine allocation guidance, long-term care facilities are defined as community-based, congregate living settings where most individuals over 65 years of age are receiving care, supervision, or assistance and are unable to reside independently in the community.

### MULTIGENERATIONAL HOUSEHOLD

Household where individuals from 2 or more generations reside such as an elder and a grandchild. Does **not** include a parent or guardian caring for a child or teen.

### WORKERS IN HEALTHCARE SETTINGS

Includes the full spectrum of workers at health agencies including all types of staff (e.g., contracted, part-time, unpaid/volunteer) and the spectrum of staff who provide services (e.g., ambulatory, direct patient care, support services).

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email [civil.rights@doh.wa.gov](mailto:civil.rights@doh.wa.gov).



# Recommendation: Equity as a cross-cutting factor

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**People with access barriers to health care:** People with limited transportation, people with limited English proficiency, individuals with disabilities, people without health insurance, undocumented people

**People at higher risk for exposure:** Farm and factory workers, essential workers, people who live in congregate housing, people experiencing homelessness, people who are incarcerated or detained, people in workplaces with outbreaks

**People essential to health and wellbeing of populations at higher risk:** Doula, caregivers (both formal and informal), home care aides, health care interpreters, community and mutual aid volunteers, community health workers

**People who live in areas with greater spread:** Geographic hotspots and outbreaks, congregate housing with outbreaks

**People who have been disproportionately impacted by COVID-19 because of systemic inequities:** Communities of color, people with limited English proficiency, individuals with disabilities, low-income people

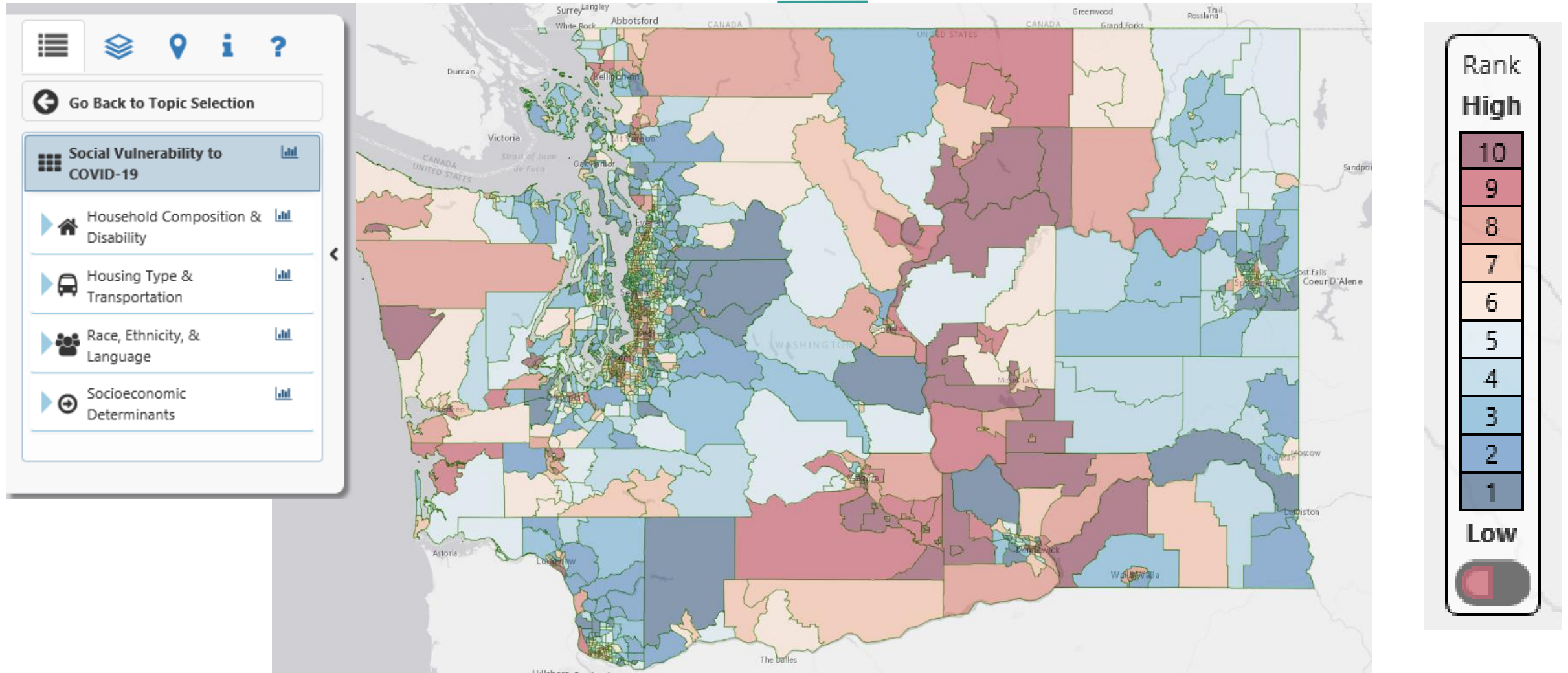
**People at risk for severe illness:** Older adults and elders, pregnant people, people with underlying medical conditions that put them at a higher risk for severe morbidity or mortality if infected with COVID-19

**People who are at higher risk for spreading COVID-19 to high risk populations:** Caregivers, people living in multi-generational households, children and youth, essential workers, people who must travel for work

# Strategies to Ensure Equitable Access

1. **Prioritize communities with higher social vulnerability** to COVID-19 by using [Washington Tracking Network, Information by Location Mapping Tool: COVID-19 Social Vulnerability Index](#).
2. **Address work schedule barriers** through:
  1. Evening & weekend appointments
  2. Onsite, employment based vaccine clinics
  3. Encouraging employers to provide paid time for getting a vaccine
3. **Address language barriers** through:
  1. Translation of materials
  2. Culturally & linguistically appropriate outreach
  3. Interpretation services
4. **Promote vaccine trust and confidence** by partnering with trusted community leaders and members.
5. **Focus on the hard to reach groups** – put more effort into reaching the people who will be missed by traditional channels.

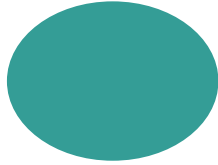
# COVID-19 Social Vulnerability Index



<https://fortress.wa.gov/doh/wtn/WTNIBL/>

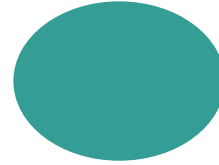
# Compliance Process

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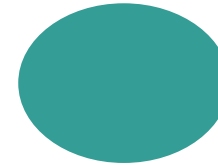
## Investigation

- Following up with the complainant
- Reaching out to the provider to investigate



## Education

- Discuss current process
- Provide education if not in compliance with DOH guidance



## Action

- If non-compliance continues to be an issue formal notice of action will be given to provider
- AAG office involvement

# Top Compliance Concerns

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1

## **Vaccinating Ineligible Patients**

- VaccineFinder
- Federal Pharmacy Partnership Program and Federally Qualified Health Centers
- Avoiding wastage

2

## **Charging Patients Directly**

- Providing education on billing best practices
- Connecting providers to billing resources

3

## **Requiring SSNs**

- All people living and/or working in Washington should get vaccinated
- Health equity



# Vaccine Locator



## Changes to Vaccine Locator

- Easier-to-navigate map
- Easier to see where vaccine is in stock\*
- Multiple languages
- Updated daily
- *More coming soon!*

\* Current data are only as reliable as providers reporting in WA Health

**COVID-19 Vaccination Locations**  
Map as of 02/22/2021 08:30:09 PM

County: All City: All Postal code: All Appointment: All Vaccine type: All [RESET](#)

Here is a list of places where you can get a COVID-19 vaccination in Washington State.

**ACTS PHARMACY AND HEALTHCARE SERVICES**  
1901 S Union Ave, Bldg B Suite 2011, Tacoma, WA 98405  
Vaccines are provided by appointment. Visit our COVID-19 vaccine link to check availability.  
Last updated by provider 3 hours ago  
[Check appointment](#)

**ALBERTSON'S PHARMACY #3106**  
11012 canyon Rd E, Puyallup, WA 98373  
Appointments are required. If there are no spots left on the scheduling link, all appointment times have been filled. We will add more appointments when we receive more vaccine.

As reported by providers  
Appointment: Available (blue dot) Not available (grey dot)

Select the LIST button to view vaccination locations in a list. [MAP](#) [LIST](#)

# Phase Finder

## Changes to Online Phase Finder

- Now available in 10 languages
- *Coming soon: 20 more languages*

## New: Paper Version!

- Providers: Please print to help anyone who has struggled with the online version
- Found in partner toolkit:  
<https://coronavirus.wa.gov/partner-toolkit/covid-19-vaccine-phase-finder>

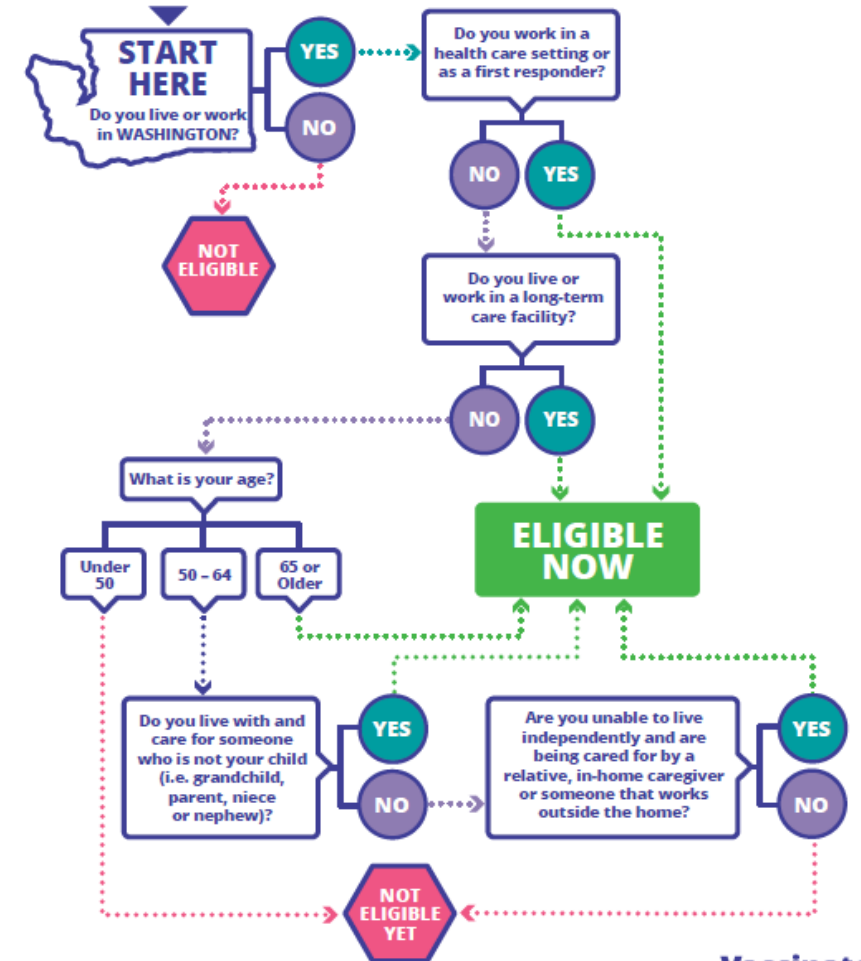


Vaccine Phase Finder

Washington State Department of

## ARE YOU CURRENTLY ELIGIBLE FOR THE COVID-19 VACCINE?

This chart will be updated as we move into future eligibility phases.



As we get more vaccine in the state, more people will be able to get vaccinated. Thank you for your patience!

**Vaccinate WA**  
CovidVaccineWA.org

CovidVaccineWA.org

# Detailed Guidance

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- Detailed documents on Phase 1B [posted](#)
  - [Summary guidance for Phases 1A and 1B \(PDF\)](#) Updated January 7, 2021
  - [Washington state's interim vaccine allocation and prioritization guidance \(PDF\)](#) Updated January 7, 2021
- More details and answers to frequently asked questions regarding vaccine distribution, planning, safety, efficacy, administration and tracking can be found on our website at:
  - <https://www.doh.wa.gov/Emergencies/COVID19/Vaccine>
- Questions from the public can be sent to our COVID-19 Vaccine Inbox:
  - [COVID.Vaccine@doh.wa.gov](mailto:COVID.Vaccine@doh.wa.gov)

# COVID-19 Vaccination Coverage by Race and Ethnicity and Age in Washington State (PDF)

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## COVID-19 Data Dashboard

[Dashboard](#) | [Data Tables](#) | [Data Downloads](#) | [Reports](#) | [Technical Notes](#) | [View other WA State COVID-19 dashboards](#)

The Department of Health and Microsoft's AI for Health team have partnered to create the interactive data dashboard below.

<https://www.doh.wa.gov/Emergencies/COVID19/DataDashboard#reports>



## REPORTING

System	Action	Frequency	Timing
VaccineFinder	<input type="checkbox"/> Vaccine inventory	Daily	Daily
WA HEALTH	<input type="checkbox"/> Number of vaccine doses on-hand <input type="checkbox"/> Number of vaccine doses administered yesterday	Daily	Daily
	<input type="checkbox"/> Number of doses you plan to administer in the next week	Weekly	Mondays
Washington State Immunization Information System	<input type="checkbox"/> Patient demographics <input type="checkbox"/> Vaccination Information See <a href="#">required data elements</a> list.	As needed	Within 24 hours of vaccine administration



## ALLOCATION

System	Action	Frequency	Timing
REDCap Survey	<input type="checkbox"/> Complete survey questions. DOH uses this to decide how to allocate vaccine.	Weekly	Saturday 7:30 AM to Tuesday 10 AM



## ORDERING

System	Action	Frequency	Timing
Washington State Immunization Information System	<input type="checkbox"/> Order prime (first) doses	Weekly	Friday 5 PM to Monday 5 PM
	<input type="checkbox"/> Order booster (second) doses <input type="checkbox"/> Pfizer-BioNTech booster doses <b>three weeks</b> after prime doses <input type="checkbox"/> Moderna booster doses <b>four weeks</b> after prime doses	Weekly, based on timing of prime dose	Friday 5 PM to Monday 5 PM
	<input type="checkbox"/> Receive prime and booster doses ( <b>one week after ordering</b> )	Weekly	Monday to Tuesday



- [Getting Vaccinated \(PDF\)](#)  [Additional languages](#)

[Amharic](#)

[Hmong](#)

[Portuguese \(Brazil\)](#)

[Tamil](#)

[Arabic](#)

[Japanese](#)

[Punjabi](#)

[Telugu](#)

[Burmese](#)

[Karen](#)

[Romanian](#)

[Thai](#)

[Chinese \(Simplified\)](#)

[Khmer \(Cambodian\)](#)

[Russian](#)

[Tigrinya](#)

[Chinese \(Traditional\)](#)

[Korean](#)

[Samoan](#)

[Ukrainian](#)

[Farsi](#)

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[Vietnames](#)

[German](#)

[Nepali](#)

[Swahili](#)

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[Oromo](#)

[Tagalog](#)

# COVID-19 Vaccine Newsletter

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- The COVID-19 Vaccine Newsletter is a topic people can subscribe to on GovDelivery.
- People can manage their subscriptions by going to the following [link](#).
  - From there, click on 'add subscriptions' at the bottom of the page.

## Add Subscriptions

- On the next page, expand the 'Immunizations' tab and check the box for "COVID-19 Vaccine Partner Newsletter."

☐ Immunization ⓘ

☒ School Nurses and Immunizations ⓘ

☒ Childcare and Preschool Staff and Immunizations List ⓘ

☒ COVID-19 Vaccine Partner Newsletter ⓘ

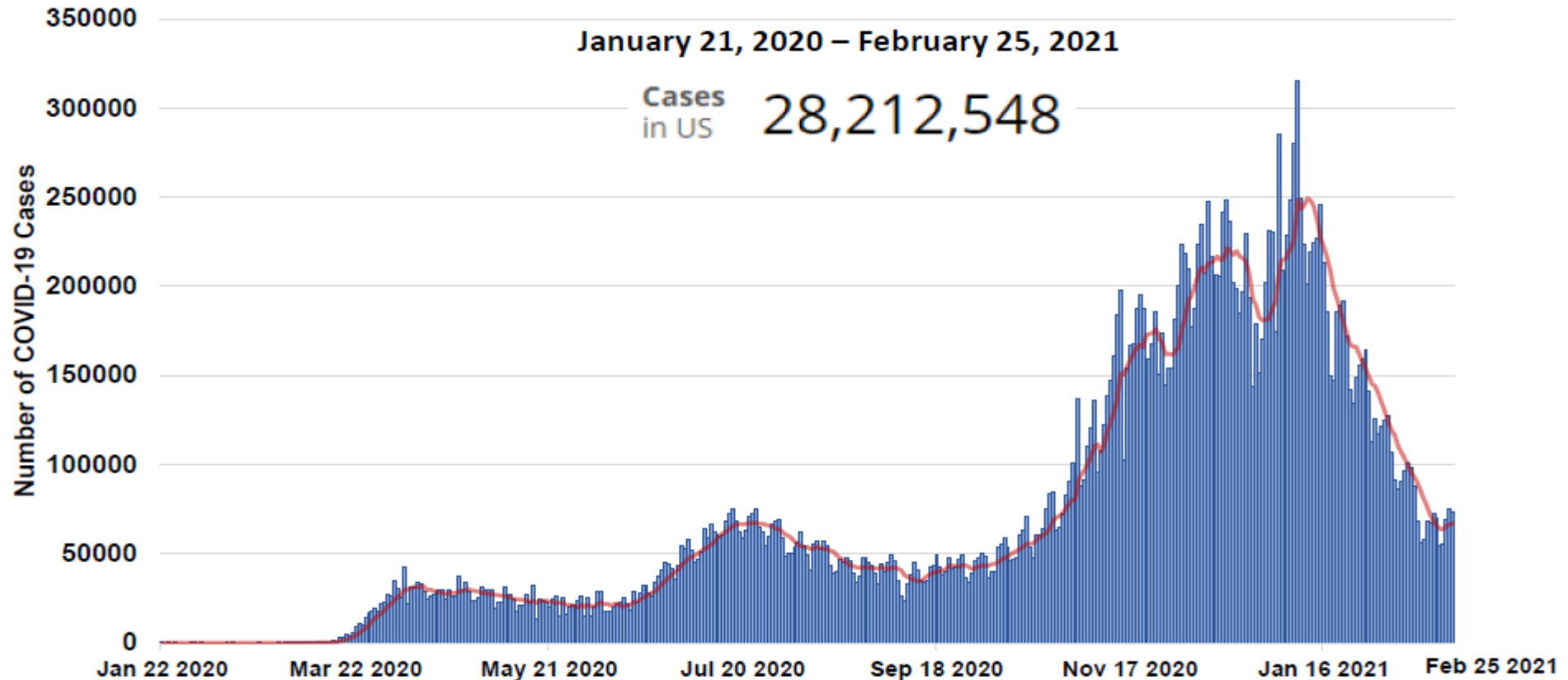
Janssen (Johnson & Johnson) Vaccine

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KATHY BAY DNP, RN, CENP

# Public Health Problem:

## Review of the Available Evidence

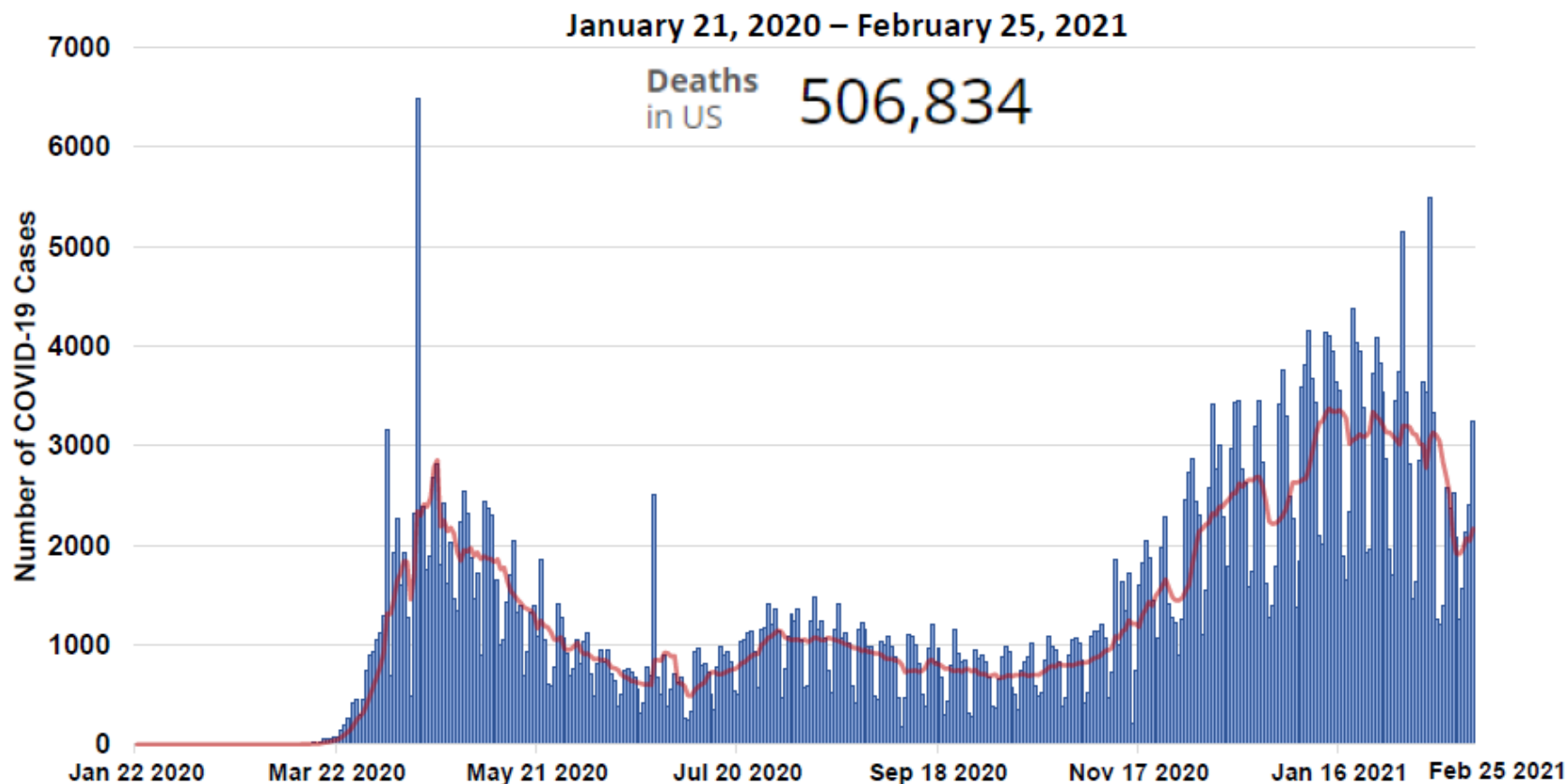


Source: ACIP meeting 03-01-2021. Available  
<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf>; accessed 03-03-2021.

[https://covid.cdc.gov/covid-data-tracker/#trends\\_dailytrendscases](https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases)

# Public Health Problem:

## Review of the Available Evidence



[https://covid.cdc.gov/covid-data-tracker/#trends\\_dailytrendscases](https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases)

Source: ACIP meeting 03-01-2021. Available <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf>; accessed 03-03-2021.



## Key Efficacy Findings from Ad26.COV2.S Single-Dose Study Demonstrate Protection Against Symptomatic COVID-19



### 85% vaccine efficacy\* against severe COVID-19 globally, including the United States

- Consistent vaccine efficacy against severe disease across all regions
- Equally high protection in South Africa (n > 6,500) where B.1.351 is highly prevalent (> 95%)
- Complete protection against COVID-19 related hospitalizations as of day 28 and no COVID-19 related deaths in the Ad26 group compared to 5 in the placebo group



### 72% vaccine efficacy\* against moderate to severe/critical COVID-19 in the United States

- Participants reflected diversity of US population (n > 19,000)



### 66% vaccine efficacy\* against moderate to severe/critical COVID-19 across all countries

- Protection as of 2 weeks after vaccination





Similar vaccine efficacy demonstrated by age, comorbidities status, sex, race, and ethnicity

\* > Day 28

Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.

# Vaccine Efficacy (VE) Results Support Protection Against Emerging Variants

 COV3001 site locations  
 Countries with emerging variants

Trial conducted in areas where COVID-19 incidence was highest and where variants were emerging

86% VE  
severe/  
critical

**United States**

% variant  
96% D614G  
3% CAL.20C

88% VE  
severe/  
critical

**Brazil**

% variant  
69% P.2 lineage  
31% D614G

**South Africa**  
% variant  
95% B.1.351 lineage  
3% D614G

82% VE  
severe/  
critical

VE based on total dataset, including non-centrally PCR confirmed cases

Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.

# Substantial Experience with Adenovirus 26-based Vaccines

## Substantial clinical experience with Ad26-based vaccines (N > 193,000)

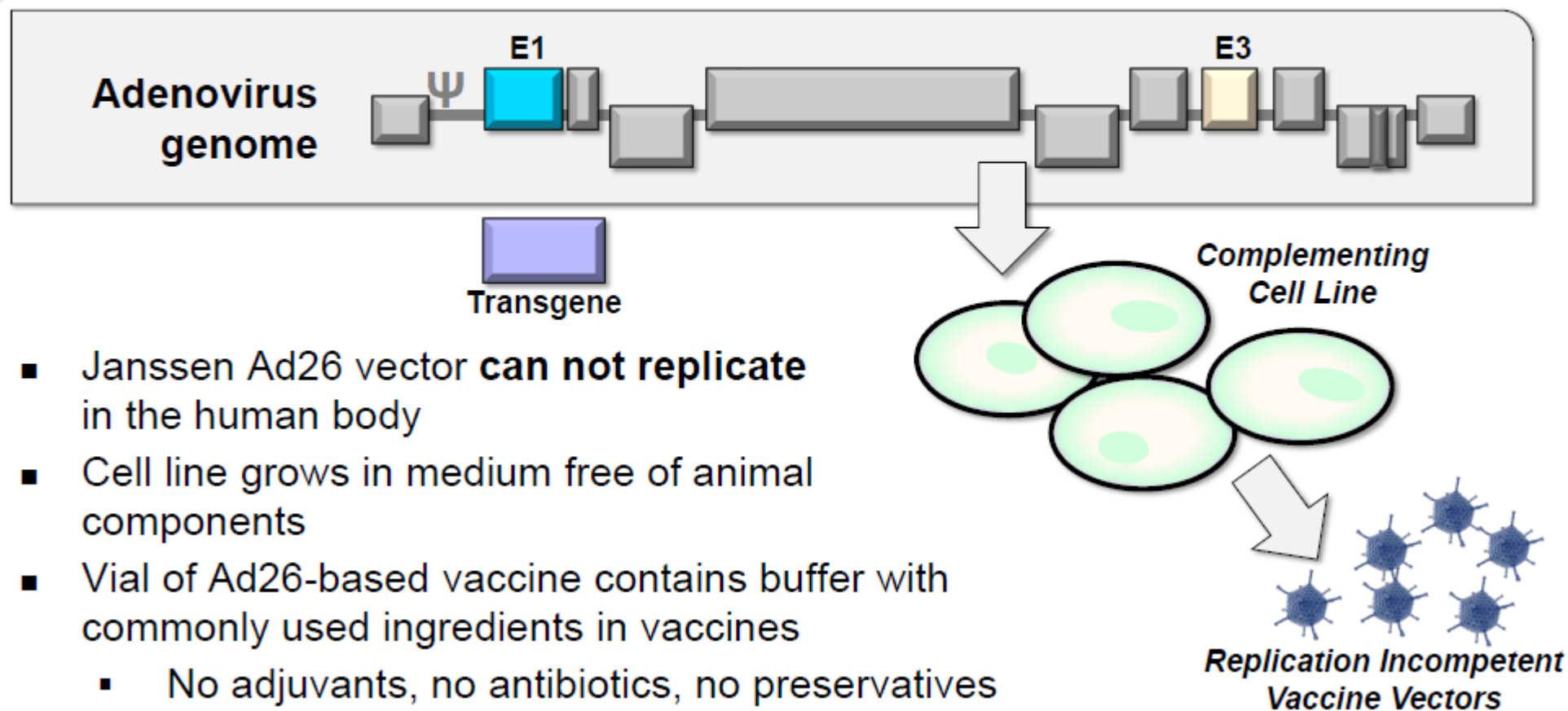
- Across continents
- Healthy adults
- Elderly > 65 years
- Breastfeeding, pregnant women within Ebola program
- Various races, ethnicities
- Infants  $\geq 4$  months
- People with HIV

## Regular database reviews show good tolerability, safety

- Local, systemic reactogenicity in line with other licensed vaccines
- Database searches for AESIs revealed no safety signals

AESIs: Adverse Events of Special Interest

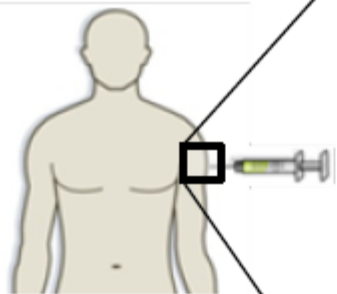
## Ad26 Vector is Replication Incompetent



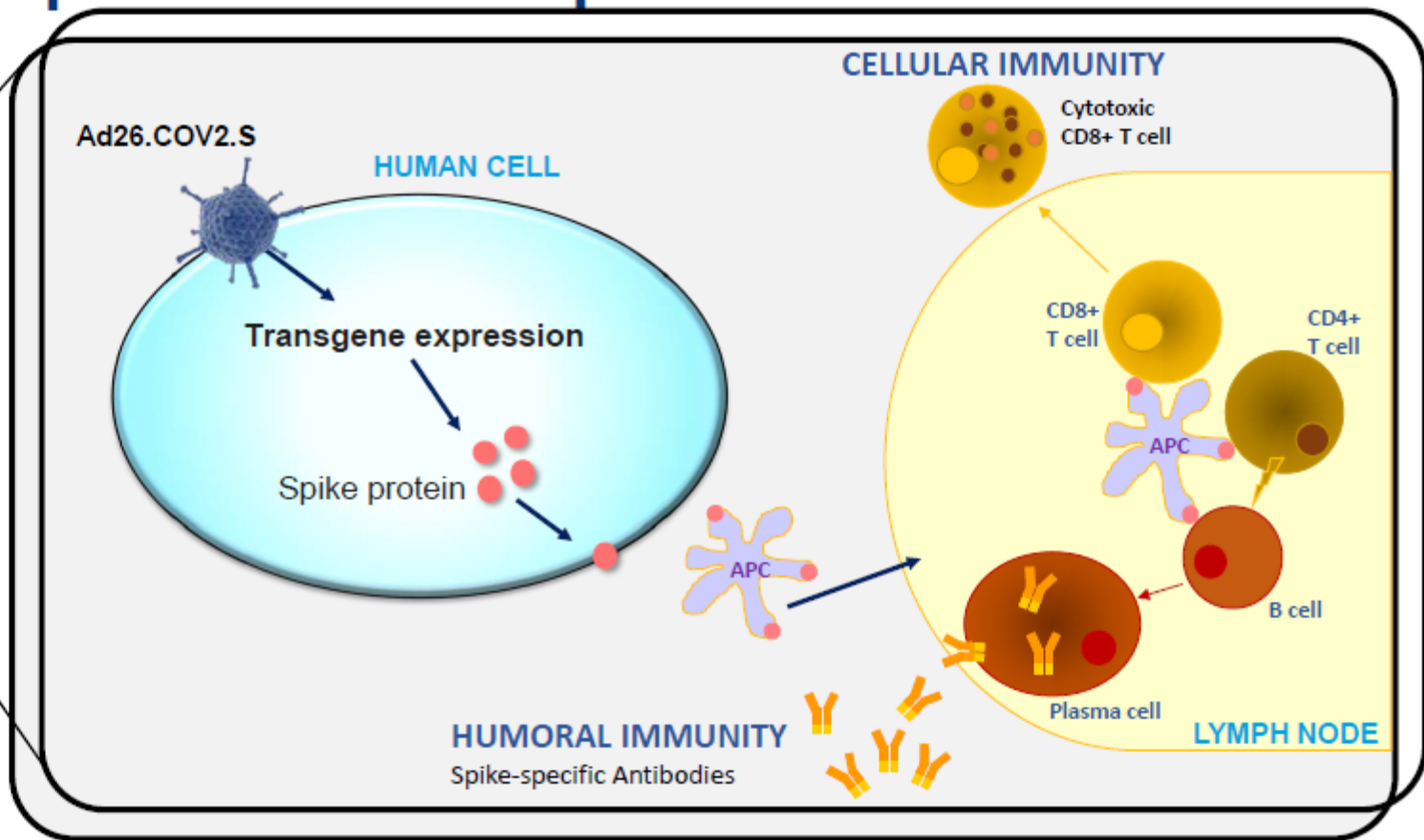
Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.

# Ad26.COVS.S Expresses SARS-CoV-2 Spike Protein, Eliciting Multiple Immune Responses

I.M.  
injection of  
Ad26.COVS.S



Adenoviral  
vectors  
classified as  
non-integrating\*

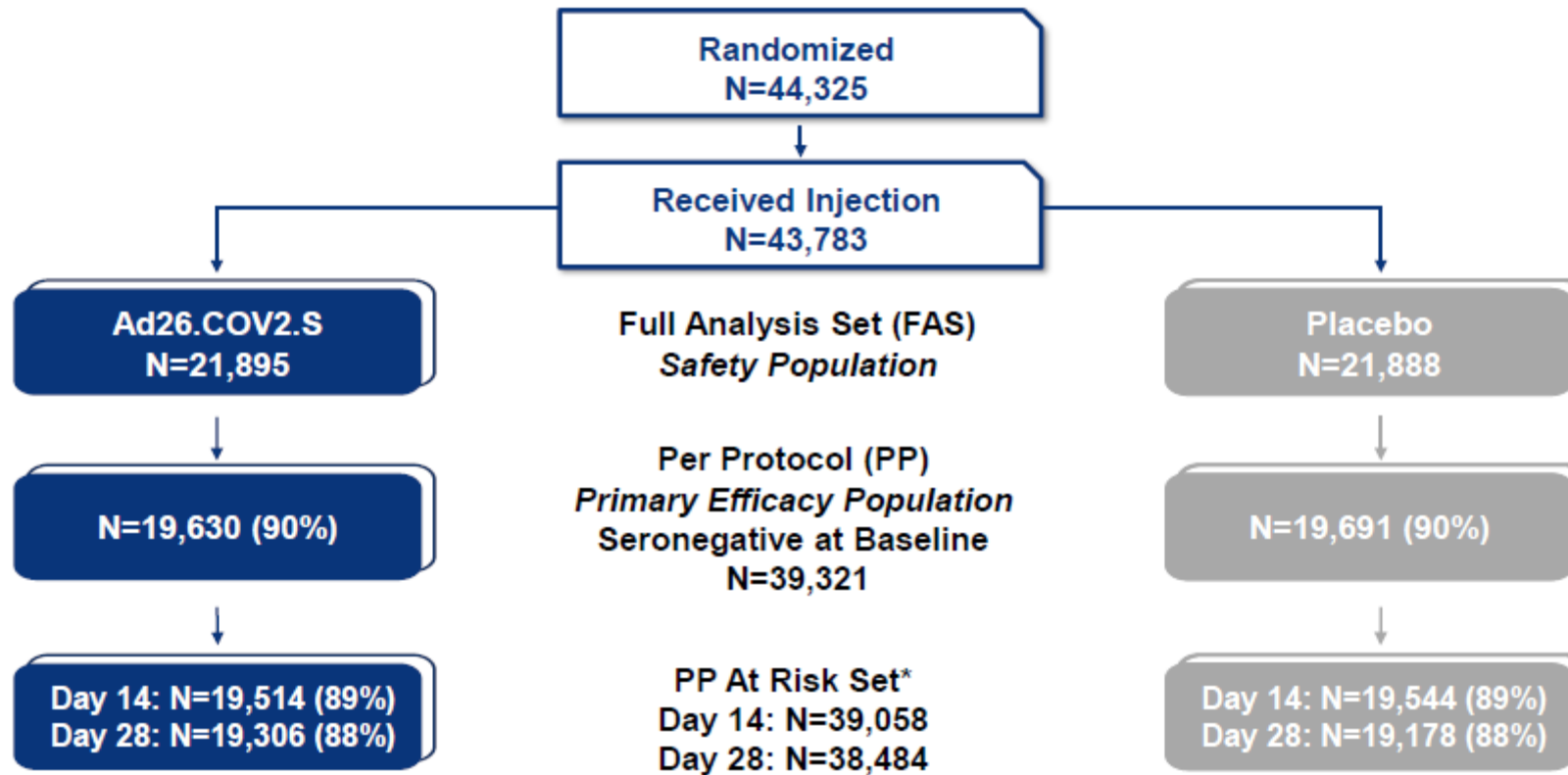


\*FDA Guidance, 2020

Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.



# COV3001 Disposition of Participants



\*PP At Risk set: excluded participants with positive polymerase chain reaction (PCR) test for SARS-CoV-2 between vaccination and day of efficacy assessment

Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.

# COV3001: Case Definition for Moderate COVID-19

RT-PCR or molecular test confirmation of SARS-CoV-2 infection

**AND**

At any time during observation period:

## ≥ 1 new or worsening sign or symptom

- Respiratory rate ≥ 20 bpm
- Abnormal oxygen saturation (> 93% on room air)
- Evidence of pneumonia
- Deep vein thrombosis (DVT)
- Shortness of breath

OR

## ≥ 2 new or worsening sign or symptoms

- Fever
- Heart rate ≥ 90 bpm
- Shaking chills
- Muscle pain
- Changes to olfaction or taste
- Gastrointestinal symptoms
- Red or bruised feet or toes
- Malaise
- Headache
- Cough
- Sore throat

Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.

# COV3001: Case Definition for Severe/Critical COVID-19

RT-PCR or molecular test confirmation of SARS-CoV-2 infection

**AND**

At any time during observation period:

## ≥ 1 of these signs or symptoms

- **Clinical signs indicative of severe systemic illness:** Respiratory rate  $\geq 30$  bpm, heart rate  $\geq 125$  bpm,  $\text{SpO}_2 \leq 93\%$  on room air at sea level or  $\text{PaO}_2/\text{FiO}_2 < 300$  mmHg
- **Respiratory failure:** Needing high-flow oxygen, non-invasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation [ECMO]
- **Evidence of shock:** Systolic blood pressure  $< 90$  mmHg, diastolic blood pressure  $< 60$  mmHg, or requiring vasopressors
- **Significant acute renal, hepatic, or neurologic dysfunction**
- **Admission to ICU**
- **Death**

Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.

# COV3001: No Relevant Differences at Baseline Between Vaccine and Placebo Groups Globally

Full Analysis Set	Ad26.COV2.S N = 21,895		Placebo N = 21,888	
	n	%	n	%
Sex, female	9,820	45%	9,902	45%
Mean Age (SD), years	50.7 (15.0)		50.7 (15.0)	
Age group				
18-59	14,564	67%	14,547	66%
≥ 60	7,331	33%	7,341	34%
≥ 65	4,259	19%	4,302	20%
≥ 75	809	4%	732	3%
Race				
American Indian or Alaska Native	2,083	10%	2,060	9%
Asian	743	3%	687	3%
Black or African American	4,251	19%	4,264	20%
Native Hawaiian or other Pacific Islander	58	0.3%	48	0.2%
White	12,858	59%	12,838	59%
Multiple, unknown, not reported	1,901	9%	1,989	9%
Ethnicity				
Hispanic or Latino	9,874	45%	9,963	46%

Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.

## COV3001: US Participants with Comorbidities Similar Between Vaccine and Placebo Groups

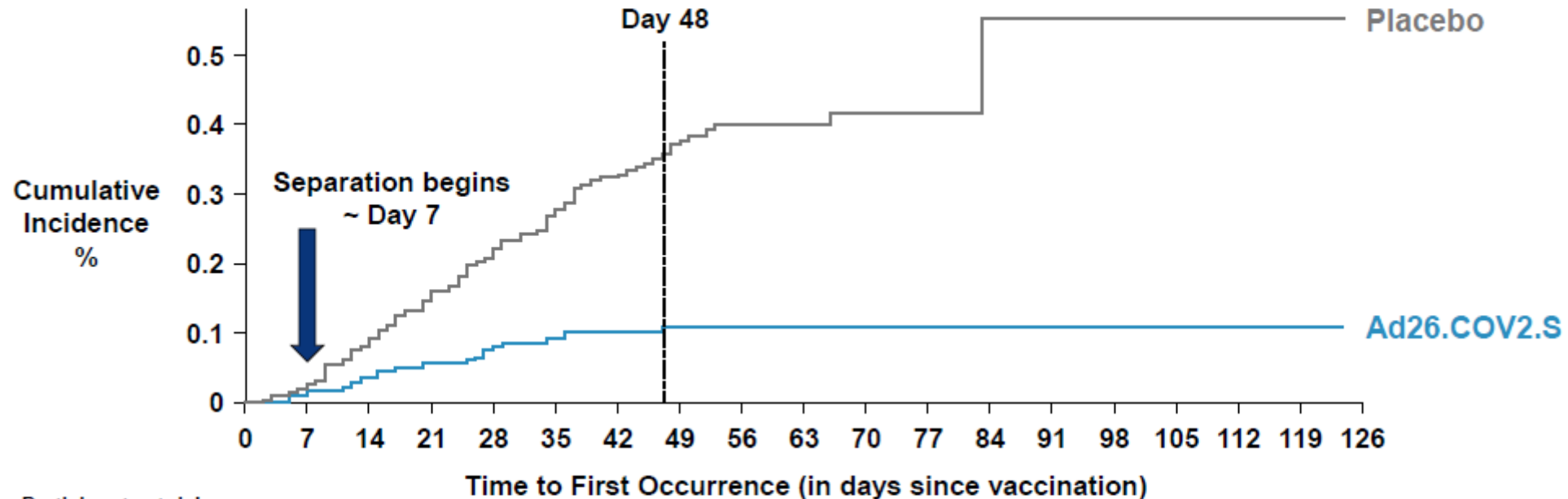
<i>Full Analysis Set</i> Baseline Comorbidity* Category, ≥ 2%	Ad26.COVS.2.S N = 9,655		Placebo N = 9,647	
	n	%	n	%
≥ 1 risk factor	4,227	43.8%	4,247	44.0%
Obesity ≥ 30 kg/m <sup>2</sup>	3,085	32.0%	3,054	31.7%
Hypertension	1,139	11.8%	1,166	12.1%
Type 2 Diabetes Mellitus	743	7.7%	729	7.6%
Serious heart conditions	291	3.0%	304	3.2%
Asthma	160	1.7%	203	2.1%

\*Pre-existing medical risk factor for developing severe COVID-19

Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.



# Time to First Occurrence of Severe/Critical COVID-19 Demonstrates Early Onset of Protection



Participants at risk

Ad26.COV2.S	19744	19741	19734	19725	19718	19705	18685	15043	11046	7919	4039	1481	720	490	490	489	146	31	0
Placebo	19822	19817	19799	19779	19760	19725	18682	15088	11069	7939	3995	1485	732	500	497	495	137	29	0

Number of cases

Ad26.COV2.S	0	3	7	11	16	18	20	21	21	21	21	21	21	21	21	21	21	21	21
Placebo	0	5	18	32	44	55	65	73	76	76	77	77	78	78	78	78	78	78	78

OV3001; Full Analysis Set; baseline seronegative; confirmed: positive PCR centrally confirmed COVID-19 cases

Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.

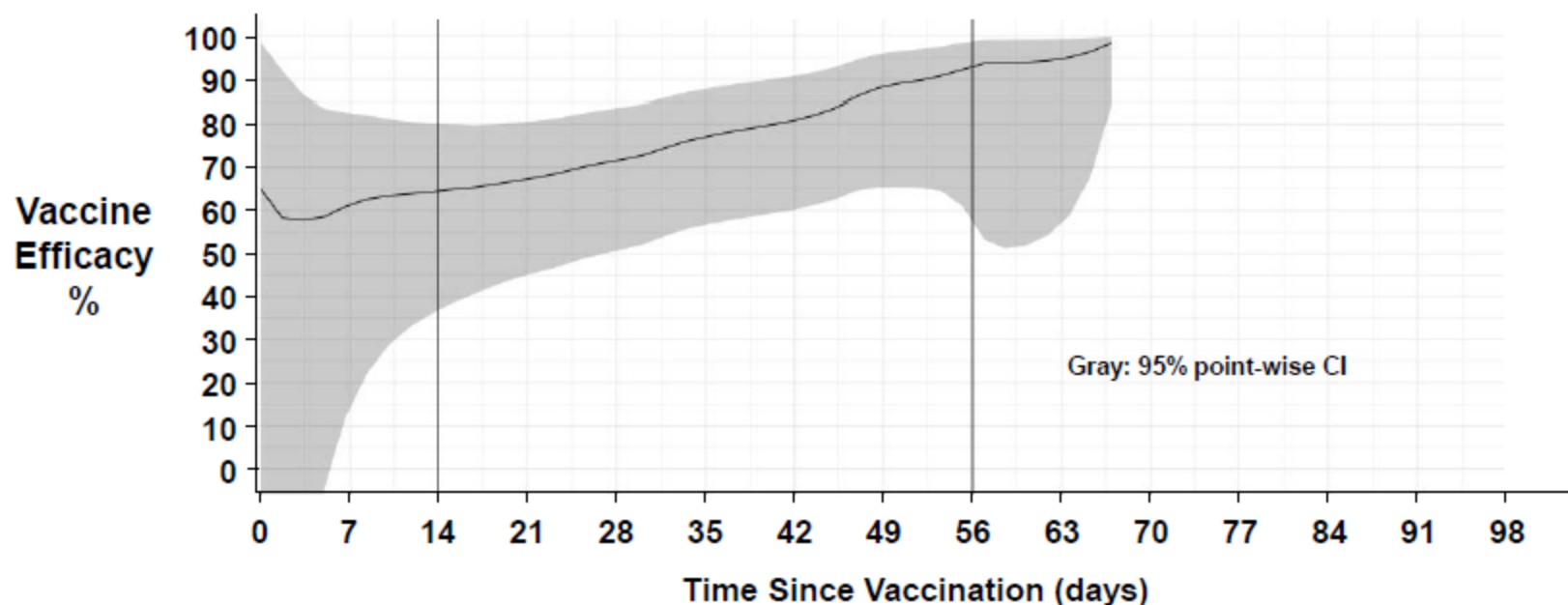
## Ad26.COV2.S Protects Against Moderate to Severe/Critical COVID-19 in US Population

<i>PP At Risk Set</i>	> Day 14		> Day 28	
	Ad26.COV2.S N = 9,119	Placebo N = 9,086	Ad26.COV2.S N = 8,958	Placebo N = 8,835
Number of cases, n	51	196	32	112
Person-years	1,414	1,391	1,403	1,376
Vaccine efficacy (95% CI)	74.4% (65.0, 81.6)		72.0% (58.2, 81.7)	

COV3001; non-confirmed: all COVID-19 cases with a positive PCR from any source, regardless of central confirmation

Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.

# Vaccine Efficacy Against Severe/Critical COVID-19 Increased Over Time Through Day 56

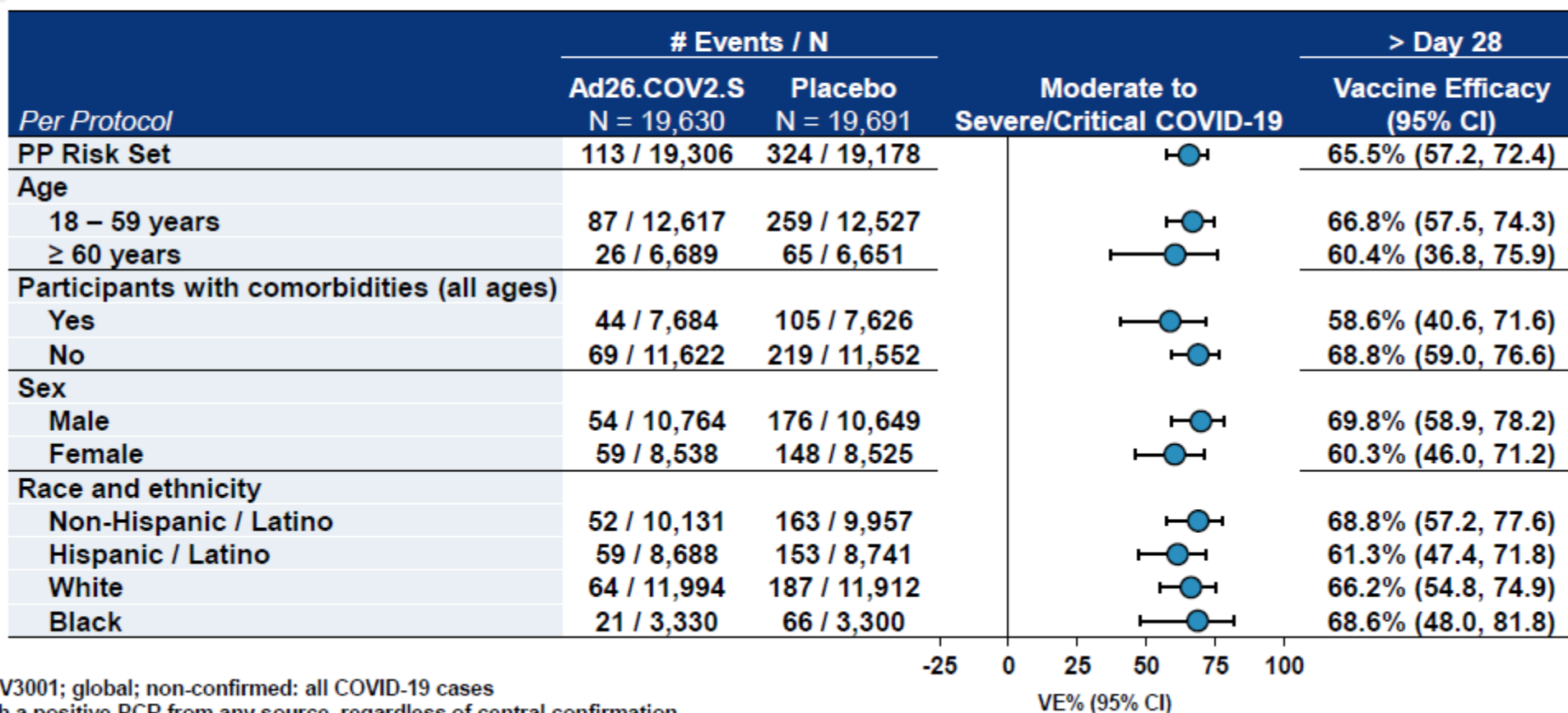


Days of follow-up	7	14	28	42	56	70	84	98
% of participants with follow-up	~100%	~100%	99%	93%	55%	20%	4%	2%

COV3001; Full Analysis Set; baseline seronegative; confirmed: positive PCR centrally confirmed COVID-19 cases

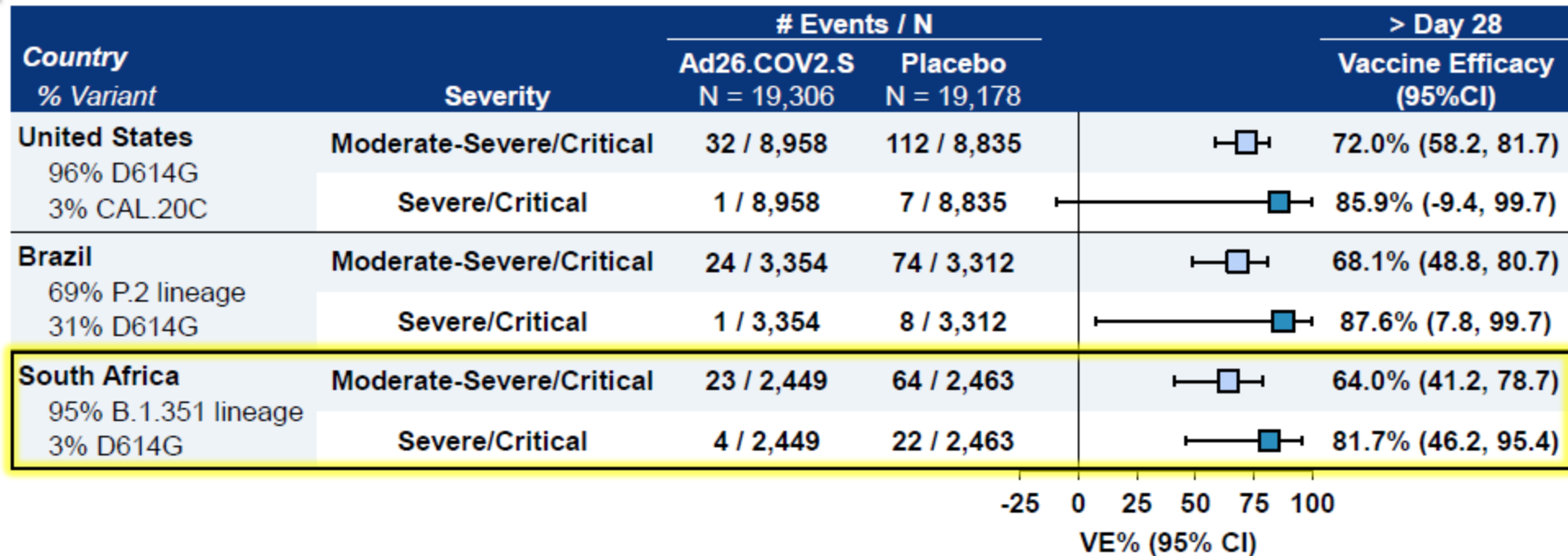
Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.

# Overall VE Against Moderate to Severe/Critical COVID-19 Consistent Across Prespecified Subgroups



Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.

# Vaccine Efficacy Consistently High Across Key Countries > Day 28



South Africa    PP At Risk Set (N = 4,912)    Hospitalizations > Day 28\*: 0 vs 6 (Ad26.COVS.2.S vs placebo)  
    Full Analysis Set (N = 6,576)    COVID-related deaths: 0 vs 5\*\* (Ad26.COVS.2.S vs placebo)

COV3001; non-confirmed: all COVID-19 cases with a positive PCR from any source, regardless of central confirmation

\*Sources: MRU (Medical Resource Utilization), SAE, and MA-COV (medical attendance-COV); \*\*6th case excluded due to PCR+ test at baseline

Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.



## Summary of the Available Evidence: Vaccine Efficacy

- The clinical trial demonstrated efficacy against symptomatic, laboratory-confirmed COVID-19. The overall efficacy was **66.3%** (95% CI: 59.9%, 71.8%).
- For COVID-19 associated hospitalization, 31 events occurred, 29 in the placebo group, 2 in the vaccine group. Vaccine efficacy against hospitalization was **93%** (95% CI: 71%, 98%).
- For all-cause deaths, 5 occurred in the vaccine group and 20 in the placebo group. Vaccine efficacy against all-cause death was **75%** (95% CI: 33%, 91%).

Source: Clinician Outreach and Communication Activity (COCA) Webinar 03-02-2021. Available at: [https://emergency.cdc.gov/coca/ppt/2021/030221\\_slide.pdf](https://emergency.cdc.gov/coca/ppt/2021/030221_slide.pdf); accessed 03-04-2021.

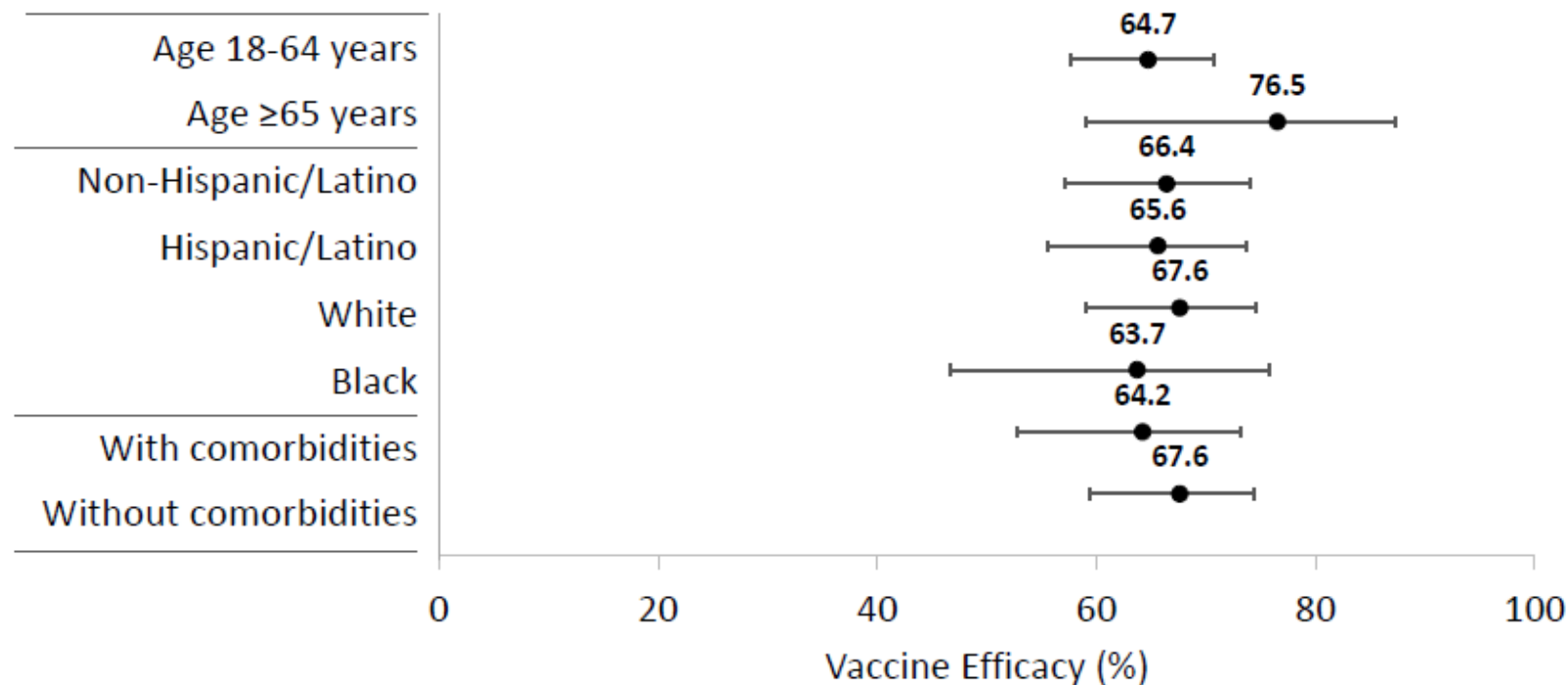
## Summary of the Available Evidence: Vaccine Efficacy

- Preliminary data were available to assess vaccine efficacy against seroconversion between days 29 and 71, based on the first 7% of specimens tested.
- Analysis was based on detection of N-binding antibody among persons who remained asymptomatic and did not have a positive SARS-CoV-2 PCR at any time in the study.
- Between four and ten weeks after vaccination with the Janssen COVID-19 vaccine, 10/1346 participants (**0.7%**) seroconverted, compared to 37/1304 (**2.8%**) of those receiving placebo. Vaccine efficacy against seroconversion was **74%** (95% CI: 48%, 87%).

Source: Clinician Outreach and Communication Activity (COCA) Webinar 03-02-2021. Available at: [https://emergency.cdc.gov/coca/ppt/2021/030221\\_slide.pdf](https://emergency.cdc.gov/coca/ppt/2021/030221_slide.pdf); accessed 03-04-2021.

## Summary of the Available Evidence: Vaccine Efficacy

- **Similar** efficacy for across age, sex, race, and ethnicity categories, and those with underlying medical conditions at  $\geq 14$  days post-vaccination



Source: Clinician Outreach and Communication Activity (COCA) Webinar 03-02-2021. Available at: [https://emergency.cdc.gov/coca/ppt/2021/030221\\_slide.pdf](https://emergency.cdc.gov/coca/ppt/2021/030221_slide.pdf); accessed 03-04-2021.

## Summary of the Available Evidence: Vaccine Efficacy

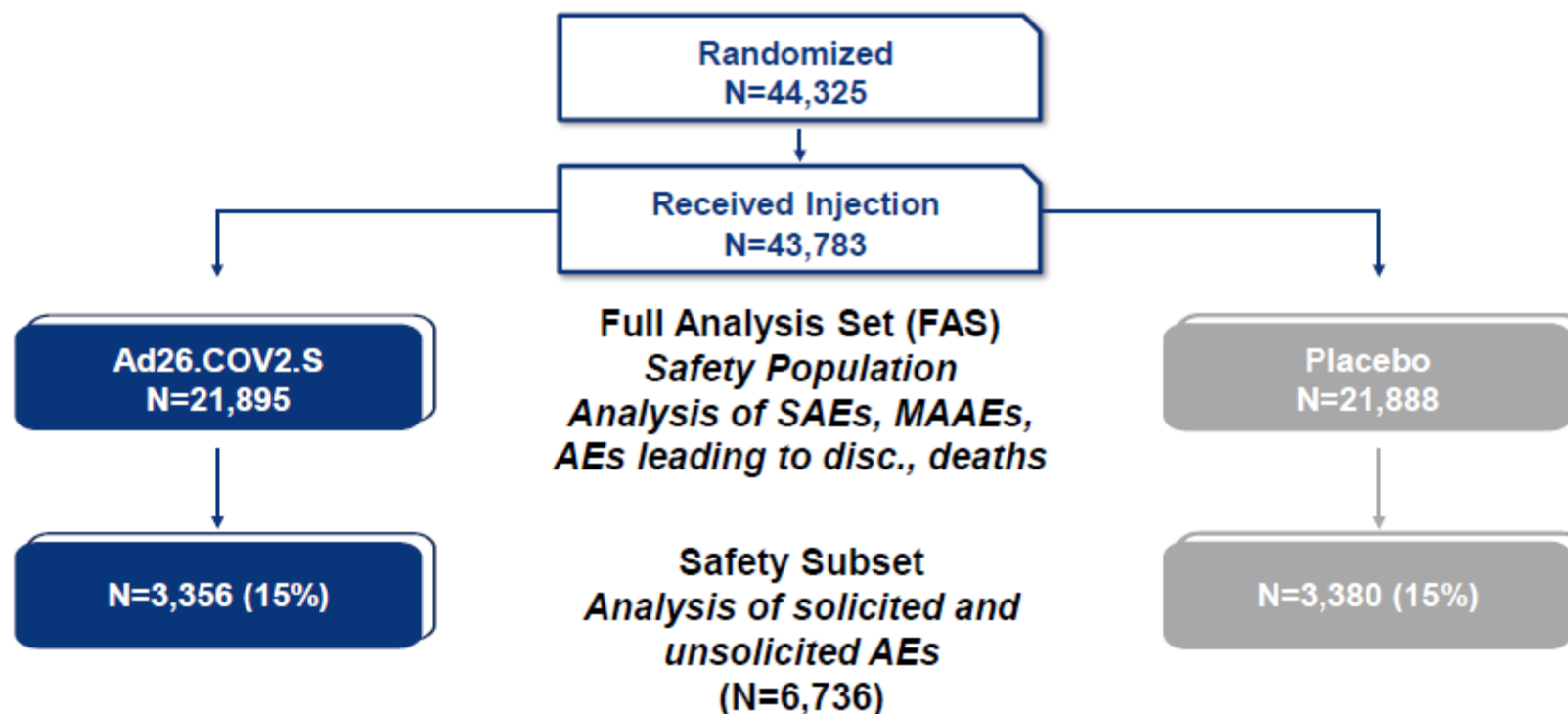
- **Higher** efficacy against **severe** outcomes than for any symptomatic COVID-19\*
  - VE against **deaths** due to COVID-19: **100%**
- Efficacy estimates for severe outcomes **assessed  $\geq 28$  days** post vaccination were **higher: 83.5%** for severe disease<sup>†</sup>, **100%** for hospitalization
- Efficacy against severe disease<sup>†</sup> remained high across world regions (**73-82%\***), suggesting protection against severe illness with variant strains

<sup>†</sup>**Definition:** Respiratory Rate  $\geq 30$ , Heart Rate  $\geq 125$ , SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level or PaO<sub>2</sub>/FIO<sub>2</sub>  $< 300$  mm Hg; OR respiratory failure or Acute Respiratory Distress Syndrome (ARDS), defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO; OR evidence of shock (systolic blood pressure  $< 90$  mmHg, diastolic BP  $< 60$  mmHg or requiring vasopressors); OR significant acute renal, hepatic or neurologic dysfunction; OR admission to an intensive care unit or death

\*Assessed  $\geq 14$  days post vaccination

Source: Clinician Outreach and Communication Activity (COCA) Webinar 03-02-2021. Available at: [https://emergency.cdc.gov/coca/ppt/2021/030221\\_slide.pdf](https://emergency.cdc.gov/coca/ppt/2021/030221_slide.pdf); accessed 03-04-2021.

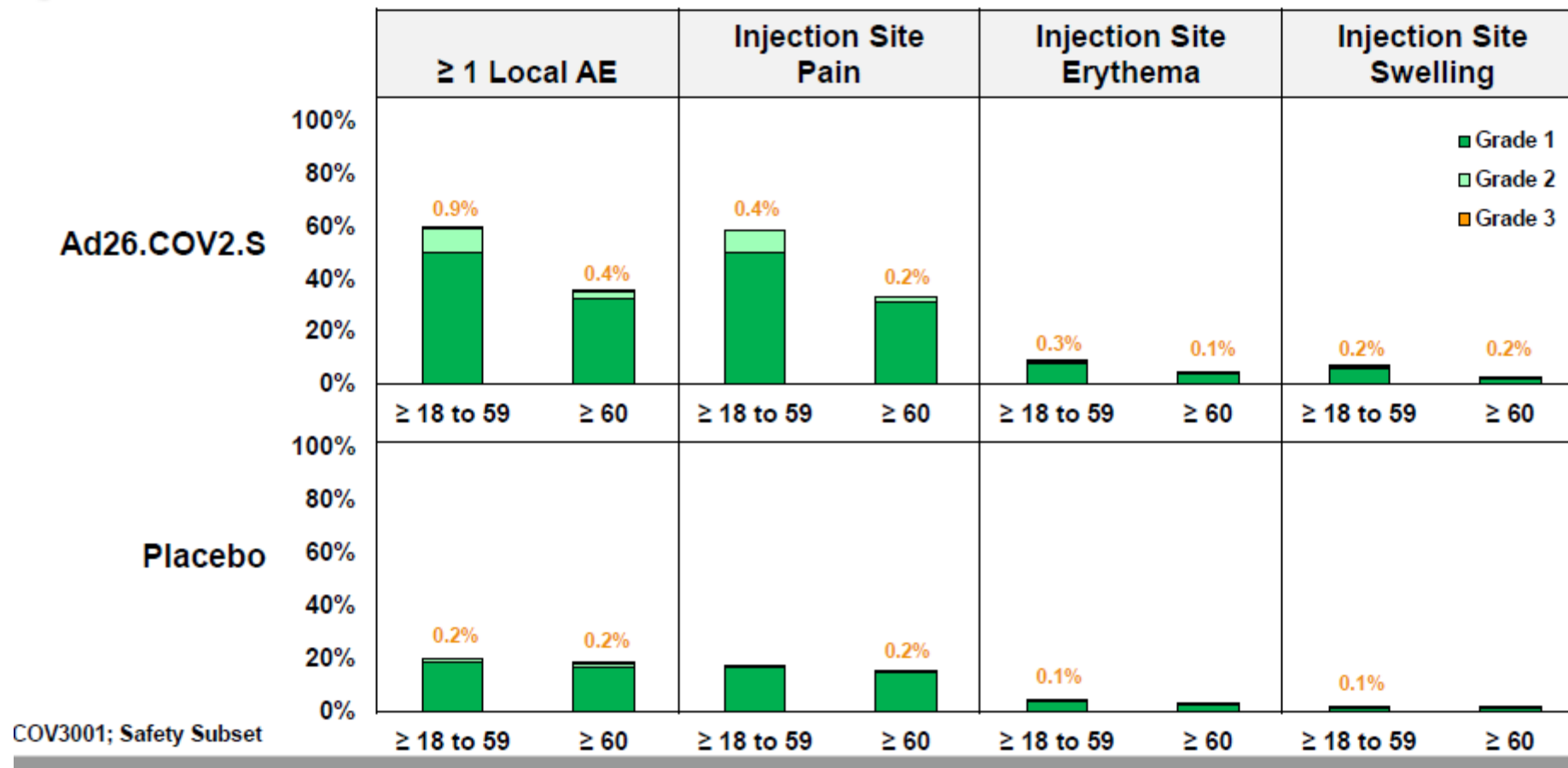
# COV3001 Safety Subset Includes Data on Solicited and Unsolicited Adverse Events



Safety analysis cut off date: January 22, 2021

Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.

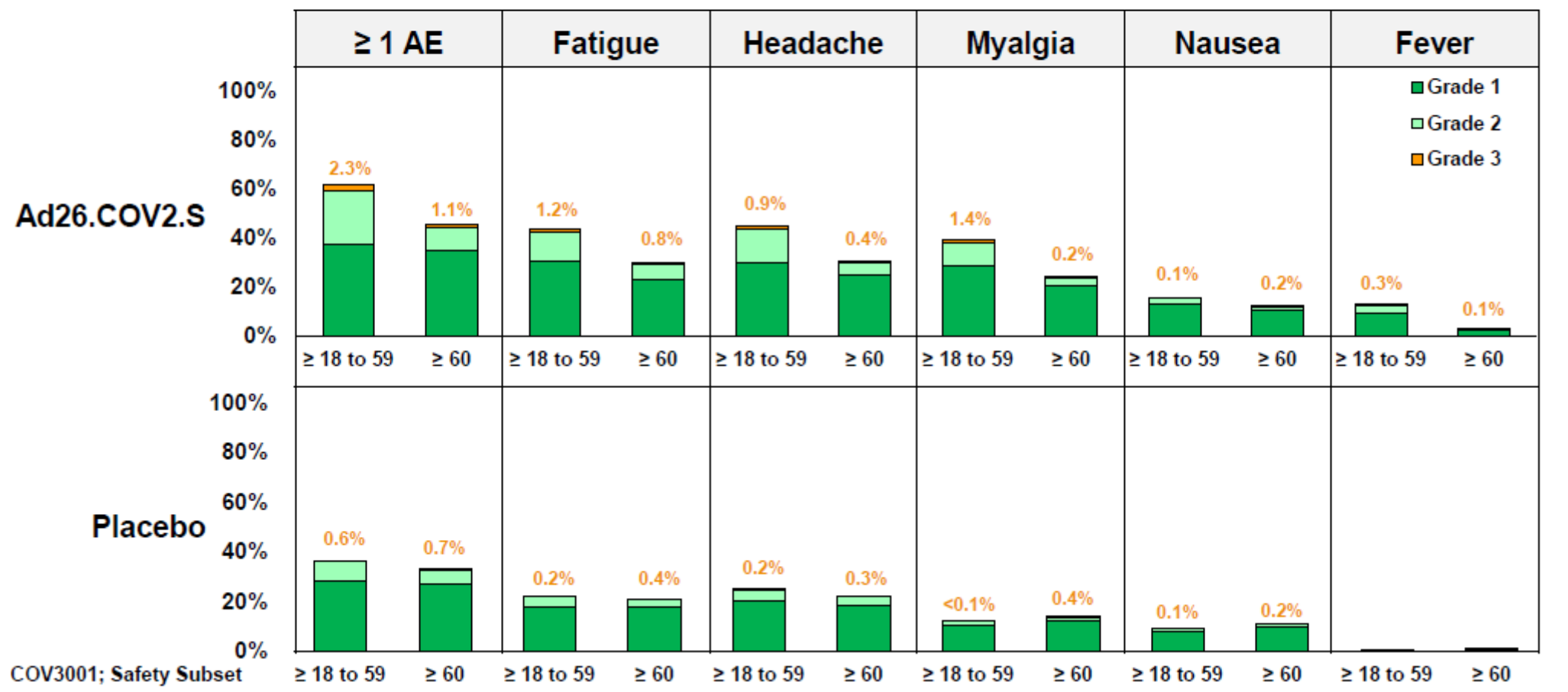
# Local Adverse Events, Nearly All Grade 1 and 2 in Severity, All Events Resolved 2-3 Days After Injection



Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.



# Systemic Adverse Events Transient with Median Duration of 1-2 Days



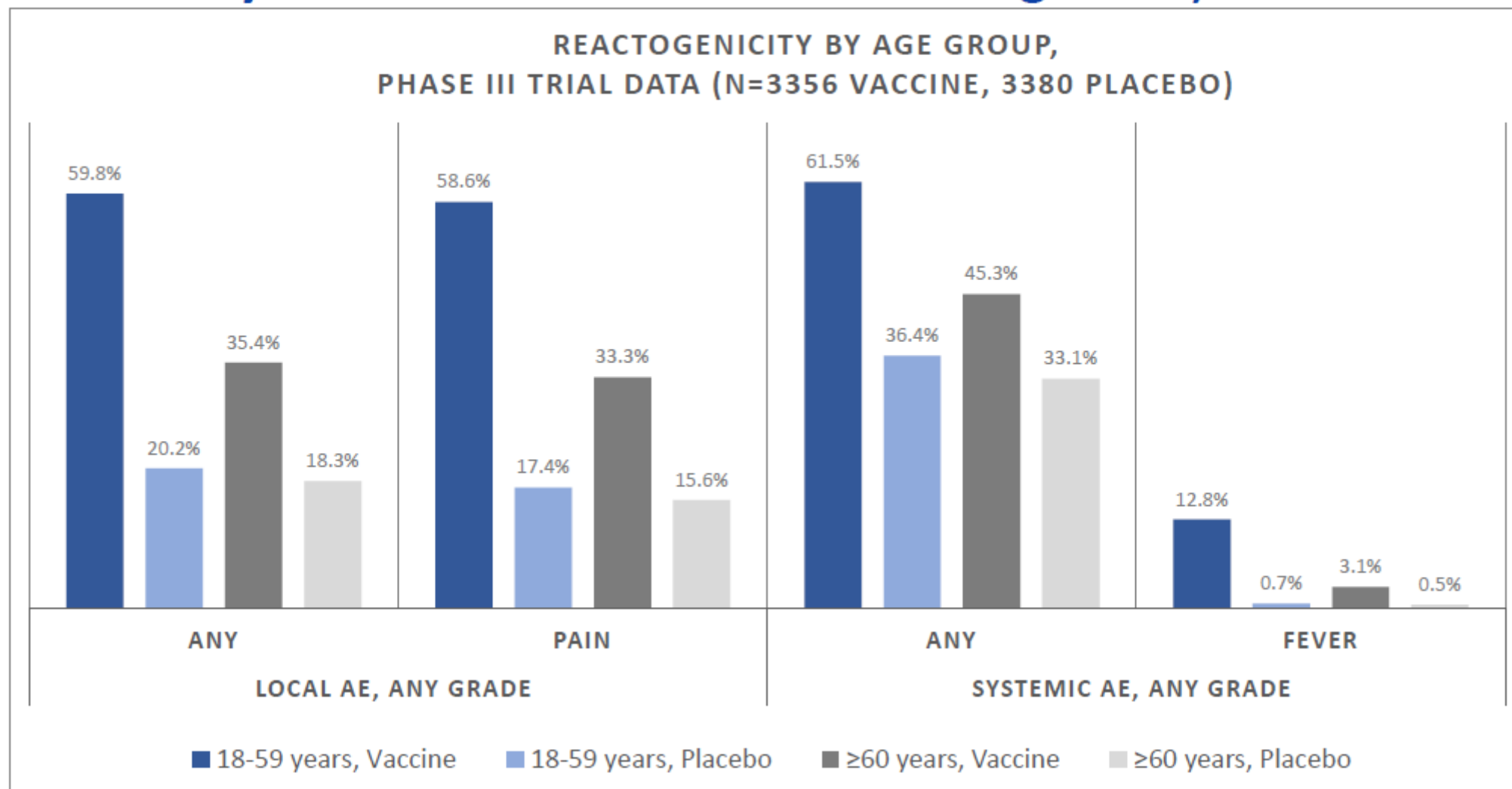
Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.

## Summary of the Available Evidence: Safety and Reactogenicity

- **Local** reactions within 7 days occurred in ~50% vaccine recipients
  - Pain at the injection site most common
- **Systemic** reactions within 7 days occurred in ~55% vaccine recipients
  - Headache, fatigue, and myalgia most common
- Most symptoms resolved after 1-2 days

Source: Clinician Outreach and Communication Activity (COCA) Webinar 03-02-2021. Available at: [https://emergency.cdc.gov/coca/ppt/2021/030221\\_slide.pdf](https://emergency.cdc.gov/coca/ppt/2021/030221_slide.pdf); accessed 03-04-2021.

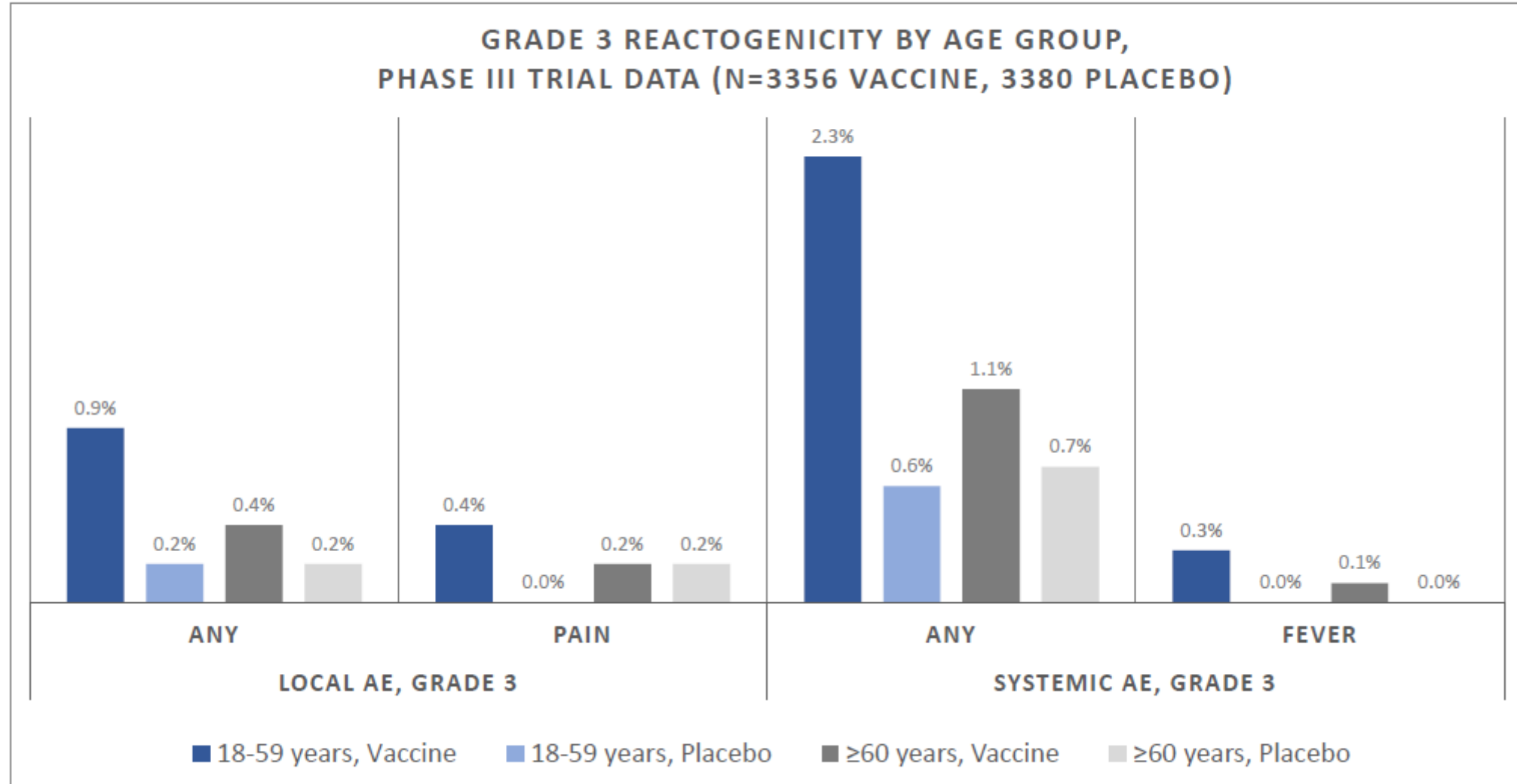
# Summary of Available Evidence: Reactogenicity



Abbreviations, AE= Adverse Events

Source: Clinician Outreach and Communication Activity (COCA) Webinar 03-02-2021. Available at: [https://emergency.cdc.gov/coca/ppt/2021/030221\\_slide.pdf](https://emergency.cdc.gov/coca/ppt/2021/030221_slide.pdf); accessed 03-04-2021.

# Summary of Available Evidence: Reactogenicity



Abbreviations, AE= Adverse Events

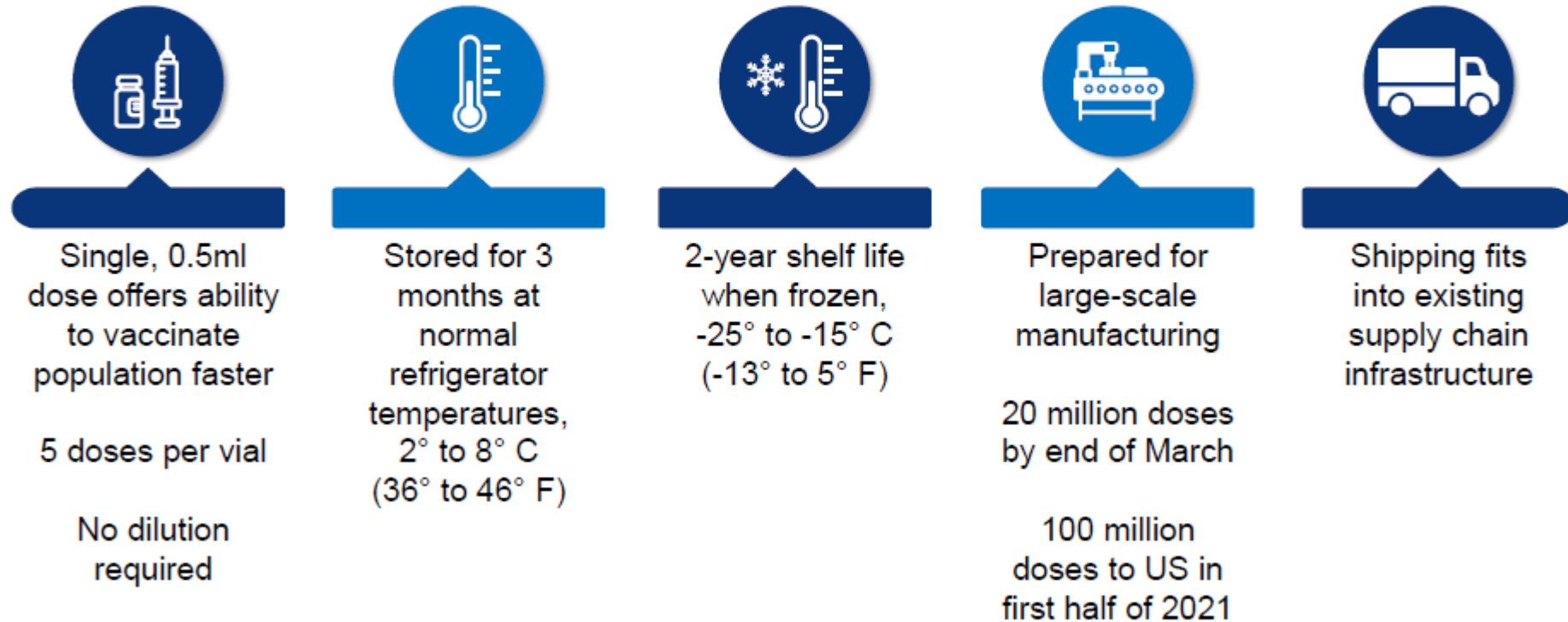
Source: Clinician Outreach and Communication Activity (COCA) Webinar 03-02-2021. Available at: [https://emergency.cdc.gov/coca/ppt/2021/030221\\_slide.pdf](https://emergency.cdc.gov/coca/ppt/2021/030221_slide.pdf); accessed 03-04-2021.

## Benefits of Ad26.COV2.S Outweigh Known and Potential Risks

- Demonstrated acceptable safety and reactogenicity profile
- Overall, reactogenicity mild and transient
  - Grade 3 reactogenicity rare
- Most AEs mild or moderate
  - Generally resolved 1 to 2 days post vaccination
- Safety further supported by > 193,000 individuals exposed to Janssen Ad26-based vaccines

Source: ACIP meeting 03-01-2021; available <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/02-COVID-Douoguih.pdf>. Accessed 03-01-2021.

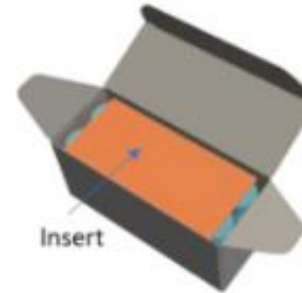
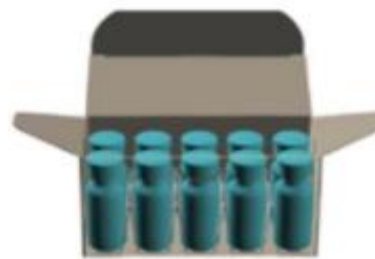
## Logistical, Practical Advantages to Help Simplify Distribution and Expand Vaccine Access of Single Dose Ad26.COV2.S



Source: Janssen Pharmaceuticals presentation, ACIP 02-28-2021; available <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html>. Accessed 02-28-2021.



# Janssen Investigational COVID-19 Vaccine Anticipated Pandemic Supply Configuration & Storage Conditions



## Primary packaging

### 2R glass vial

- No preservative and no reconstitution required
- Blue matte finish button with silver crimp combination
- High volume 5-dose vial for EUA
- 0.5 ml per dose ( $5 \times 10^{10}$  vp)

## Secondary packaging

- 10 vials per carton
- 1 product insert per carton

## Tertiary packaging

- 48 cartons per shipper case
- Carton material: solid bleached sulfate (SBS)

## Anticipated storage conditions (under EUA)



### Long-term storage<sup>1</sup>:

**-20°C**  
For 2 years

Of which

### End-user storage:

**2-8°C**  
Up to 3 months

### After first use<sup>\*</sup>:

**2-8°C**  
Up to 6 hours

<sup>1</sup>Long term storage by manufacturer or distributor ONLY – not to be refrozen by end-user

<sup>\*</sup>The vaccine can be held for a limited time within vial or syringe at either 2°C to 8°C (36°F to 46°F) or room temperature (maximally 25°C or 77°F) after the first puncturing of the vial. The vaccine should be discarded if not used within this time.

# COVID Vaccines

Vaccine	Authorized age group	Dose	Dose volume	Number doses/series	Interval between doses
Pfizer-BioNTech	≥16 years	30 µg	0.3 ml	2	3 weeks (21 days)
Moderna	≥18 years	100 µg	0.5 ml	2	1 month (28 days)
Janssen	≥18 years	5×10 <sup>10</sup> virus particles	0.5 ml	1	N/A

# Summary of the Evidence:

## All authorized COVID-19 vaccines

- No trials compared efficacy between vaccines in the **same** study at the **same** time
  - All Phase 3 trials differed by calendar time and geography
  - Vaccines were tested against different circulating variants and in settings with different background incidence
- All authorized COVID-19 vaccines demonstrated efficacy (range 65 to 95%) against symptomatic lab-confirmed COVID-19
- All authorized COVID-19 vaccines demonstrated **high** efficacy ( $\geq 89\%$ ) against COVID-19 severe enough to require **hospitalization**
- In the vaccine trials, **no** participants who received a COVID-19 vaccine **died** from COVID-19
  - The Moderna and Janssen trials each had COVID-19 deaths in the placebo arm

Source: Clinician Outreach and Communication Activity (COCA) Webinar 03-02-2021. Available at: [https://emergency.cdc.gov/coca/ppt/2021/030221\\_slide.pdf](https://emergency.cdc.gov/coca/ppt/2021/030221_slide.pdf); accessed 03-04-2021.

# Clinical considerations for use of mRNA COVID-19 vaccines

- CDC clinical considerations for mRNA COVID-19 vaccines published previously:
  - <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>
- Clinical considerations are being updated to include Janssen COVID-19 vaccine
  - Viral vector COVID-19 vaccine

## Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States



Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

### Summary of recent changes (last updated February 10, 2021):

- New recommendations for preventing, reporting, and managing mRNA COVID-19 vaccine administration errors (Appendix A).
- Clarification on contraindications and precautions. Persons with a known (diagnosed) allergy to PEG, another mRNA vaccine component, or polysorbate, have a contraindication to vaccination. Persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is PEG, another mRNA vaccine component or polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction have a precaution to vaccination.
- Updated information on delayed, local injection-site reactions after the first mRNA vaccine dose. These reactions are neither a contraindication or precaution to the second dose.
- Updated quarantine recommendations for vaccinated persons. Fully vaccinated persons who meet criteria will no longer be required to quarantine following an exposure to someone with COVID-19. Additional considerations for patients and residents in healthcare settings are provided.
- Additional information and updated recommendations for testing for TB infection. TB testing can be done before or at the same time as mRNA COVID-19 vaccination, or otherwise delayed for ≥4 weeks after the completion of mRNA COVID-19 vaccination.

### On This Page

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[Administration](#)

[Interchangeability with other COVID-19 vaccine products](#)

[Coadministration with other vaccines](#)

[Booster doses](#)

[Vaccination of persons with a SARS-CoV-2 infection or exposure](#)

[Vaccination of persons with underlying medical conditions](#)

[Vaccination of pregnant or lactating people](#)

[Vaccination of children and adolescents](#)

[Patient counseling](#)

Sign up to receive email updates when clinical considerations are updated: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

Source: Clinician Outreach and Communication Activity (COCA) Webinar 03-02-2021. Available at: [https://emergency.cdc.gov/coca/ppt/2021/030221\\_slide.pdf](https://emergency.cdc.gov/coca/ppt/2021/030221_slide.pdf); accessed 03-04-2021.



# Interchangeability of COVID-19 vaccine products

- Any COVID-19 vaccine can be used when indicated; no product preference
- COVID-19 vaccines are **not** interchangeable
  - Safety and efficacy of a mixed series has not been evaluated
- If first dose of mRNA COVID-19 vaccine was received but patient unable to complete series with same or different mRNA vaccine
  - Single dose of Janssen COVID-19 vaccine may be administered at minimum interval of 28 days from mRNA dose\*
  - Considered to have received valid, single-dose Janssen vaccination, not mixed vaccination series (mRNA/viral vector)

\*Persons with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine. In these patients, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

Source: Clinician Outreach and Communication Activity (COCA) Webinar 03-02-2021. Available at: [https://emergency.cdc.gov/coca/ppt/2021/030221\\_slide.pdf](https://emergency.cdc.gov/coca/ppt/2021/030221_slide.pdf); accessed 03-04-2021.

# Contraindications and precautions for COVID-19 vaccines

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
<p>History of the following:</p> <ul style="list-style-type: none"> <li>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine<sup>†</sup></li> <li>Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine<sup>†</sup></li> </ul> <p>Actions:</p> <ul style="list-style-type: none"> <li>Do not vaccinate.</li> <li>Consider referral to allergist-immunologist.</li> <li>Consider other vaccine alternative.<sup>†</sup></li> </ul>	<p>Among persons without a contraindication, a history of:</p> <ul style="list-style-type: none"> <li>Any immediate allergic reaction* to other vaccines or injectable therapies<sup>†</sup></li> </ul> <p>Note: persons with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa<sup>#</sup></p> <p>Actions:</p> <ul style="list-style-type: none"> <li>Risk assessment</li> <li>Consider referral to allergist-immunologist</li> <li>30-minute observation period if vaccinated</li> </ul>	<p>Among persons without a contraindication or precaution, a history of:</p> <ul style="list-style-type: none"> <li>Allergy to oral medications (including the oral equivalent of an injectable medication)</li> <li>History of food, pet, insect, venom, environmental, latex, etc., allergies</li> <li>Family history of allergies</li> </ul> <p>Actions:</p> <ul style="list-style-type: none"> <li>30-minute observation period: persons with history of anaphylaxis (due to any cause)</li> <li>15-minute observation period: all other persons</li> </ul>

\* See [Appendix C](#) for a list of ingredients. Persons with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

<sup>†</sup> Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

<sup>\*</sup>Includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction.

<sup>#</sup>Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known [diagnosed] allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among persons who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). Persons with a contraindication to Janssen COVID-19 vaccine (including due to a known [diagnosed] allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. In patients with these precautions, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

Source: ACIP meeting 03-01-2021. Available at: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/03-COVID-MacNeil.pdf>; accessed 03-03-2021.





## Resources

[cdc.gov/vsafe](https://cdc.gov/vsafe)

[cdc.gov/coronavirus/2019-ncov/vaccines/safety/troubleshooting](https://cdc.gov/coronavirus/2019-ncov/vaccines/safety/troubleshooting)

[cdc.gov/coronavirus/2019-ncov/vaccines/safety/faq](https://cdc.gov/coronavirus/2019-ncov/vaccines/safety/faq)

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



## VAERS

Vaccine Adverse Event  
Reporting System

co-managed by  
CDC and FDA

[vaers.hhs.gov](https://vaers.hhs.gov)

The screenshot shows the VAERS website homepage. 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 features a large 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 text. To the right of this text is a large image of a family (father, mother, and two children) looking at a laptop. Below the image is the text "What is VAERS?". At the bottom of the page, there are four smaller sections, each with an image and a title: "REPORT AN ADVERSE EVENT" (with a photo of a doctor and patient), "SEARCH VAERS DATA" (with a photo of hands pointing at a tablet), "REVIEW RESOURCES" (with a photo of a woman reading), and "SUBMIT FOLLOW-UP INFORMATION" (with a photo of a woman at a computer). Each section has a brief description of its function.

## Communication & Updates

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- Washington State Department of Health:  
<https://www.doh.wa.gov/>.
- COVID Vaccine Email
  - [COVID.Vaccine@doh.wa.gov](mailto:COVID.Vaccine@doh.wa.gov)



To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email [civil.rights@doh.wa.gov](mailto:civil.rights@doh.wa.gov).