



# **What Clinicians Need to Know About COVID-19 Vaccine Safety and Effectiveness and How to Address Patient Questions and Concerns**

Clinician Outreach and Communication Activity (COCA) Webinar

Tuesday, March 9, 2021

# To Ask a Question

- All participants joining us today are in listen-only mode.
- Using the Webinar System
  - Click the “Q&A” button.
  - Type your question in the “Q&A” box.
  - Submit your question.
- The video recording of this COCA Call will be posted at [https://emergency.cdc.gov/coca/calls/2021/callinfo\\_030921.asp](https://emergency.cdc.gov/coca/calls/2021/callinfo_030921.asp) and available to view on-demand a few hours after the call ends.
- If you are a patient, please refer your questions to your healthcare provider.
- For media questions, please contact CDC Media Relations at 404-639-3286, or send an email to [media@cdc.gov](mailto:media@cdc.gov).

# Today's Presenters

- **Tom Shimabukuro, MD, MPH, MBA**  
Vaccine Safety Team Lead  
COVID-19 Response  
Centers for Disease Control and Prevention
  
- **Kathleen Dooling, MD, MPH**  
Medical Officer  
Co-lead, Advisory Committee for Immunization  
Practices COVID-19 Vaccines Work Group  
COVID-19 Response  
Centers for Disease Control and Prevention
  
- **Stephen Perez, RN, PhD**  
LT, U.S Public Health Service  
Clinical Lead, Vaccine Confidence Team  
COVID-19 Response  
Centers for Disease Control and Prevention



# **COVID-19 Vaccine Safety Update**

**CDC Clinician Outreach and Communication Activity (COCA) Call  
March 9, 2021**

**Tom Shimabukuro, MD, MPH, MBA  
CDC COVID-19 Vaccine Task Force  
Vaccine Safety Team**

# Disclaimer

- 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 (CDC) or the U.S. Food and Drug Administration (FDA).
- Mention of a product or company name is for identification purposes only and does not constitute endorsement by CDC or FDA.

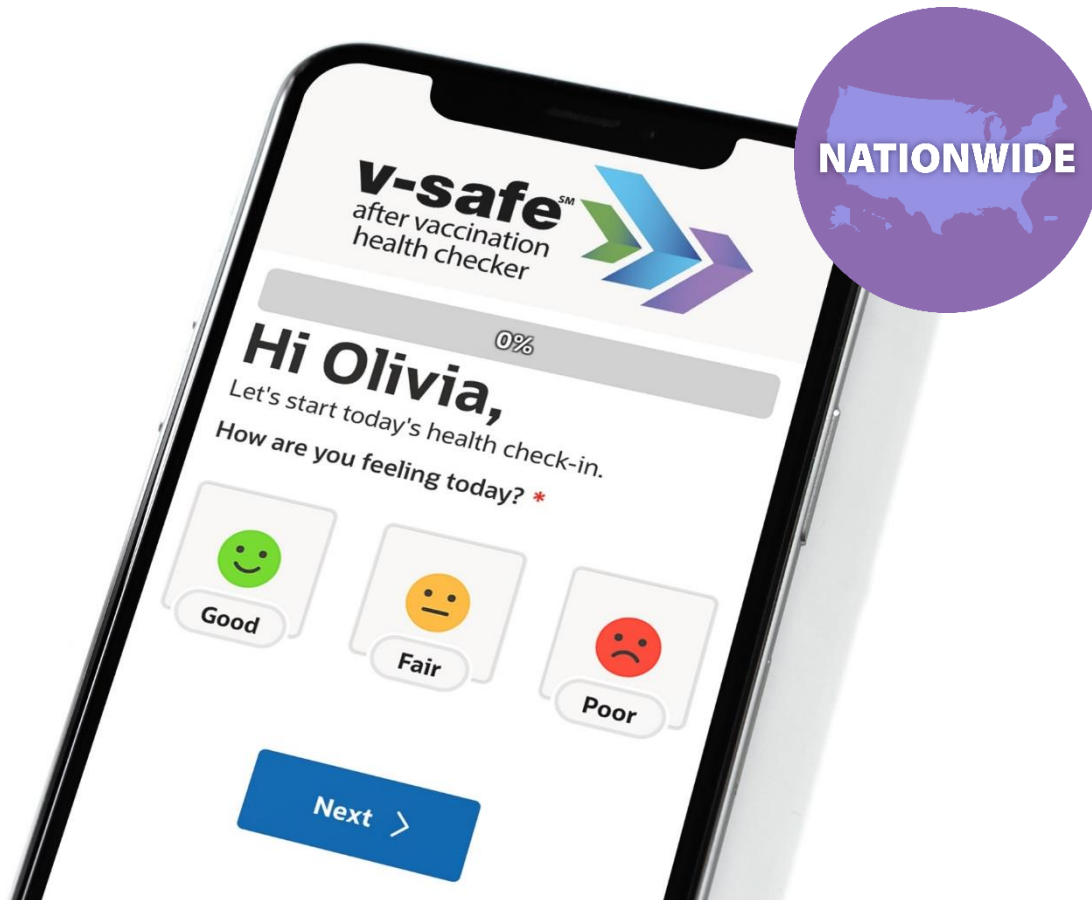
# Topics

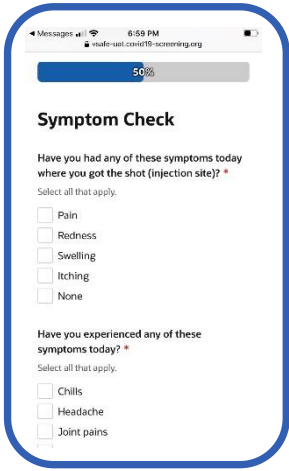
- V-safe update
- Vaccine Adverse Event Reporting System (VAERS) update
- Vaccine Safety Datalink (VSD) update
- Clinical Immunization Safety Assessment (CISA) Project update
- COVID-19 vaccine safety in pregnancy

# Smartphone-based active safety monitoring

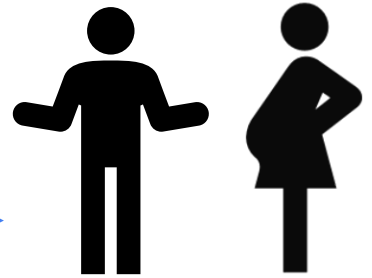


<http://cdc.gov/vsafe>





1. Text message check-ins from CDC (daily 1<sup>st</sup> week; weekly thru 6 weeks; then 3, 6, and 12 months)



vaccine recipient completes web survey\*



Vaccine recipients

2. Clinically important health impact reported

✓ received medical care

Call center



3. V-safe call center conducts active telephone follow-up on a clinically important event and takes a VAERS report if appropriate

4. Pregnancy registry team conducts outreach to assess eligibility for registry and obtain consent for enrollment and follow-up

Call center







# Summary of v-safe data as of February 16, 2021

	Pfizer-BioNTech	Moderna	Total
People receiving 1 or more doses in the United States*	28,374,410	26,738,383	55,220,364
Registrants completing at least 1 v-safe health check-in	1,776,960	2,121,022	3,897,982
Pregnancies reported to v-safe†	16,039	14,455	30,494

\* COVID Data Tracker as of Feb 16, 2021 (107,571 doses with manufacturer not identified)

† Self-reported during a v-safe health check-in

First Month of COVID-19 Vaccine Safety Monitoring — United States,  
December 14, 2020–January 13, 2021

Early Release

**TABLE 2. Percentage of v-safe enrollees who completed at least one survey (N = 1,602,065) with local and systemic reactions reported for day 0–7 and for day 1 after receiving Pfizer-BioNTech and Moderna COVID-19 vaccines — v-safe,\* United States, December 14, 2020–January 13, 2021**

Local and systemic reaction	Percentage of v-safe enrollees reporting reactions			
	Both vaccines	Pfizer-BioNTech vaccine		Moderna vaccine
	Day 0–7	Dose 1, day 1	Dose 2, day 1	Dose 1, day 1
Injection site pain	70.9	72.9	79.3	78.1
Fatigue	33.5	21.9	53.5	25.1
Headache	29.5	17.5	43.4	19.9
Myalgia	22.9	14.7	47.2	18.3
Chills	11.6	5.5	30.6	8.4
Fever	11.4	5.8	29.2	8.2
Injection site swelling	10.8	6.2	8.6	12.6
Joint pain	10.4	5.3	23.5	7.3
Nausea	8.9	4.2	14.0	5.5

**Abbreviation:** COVID-19 = coronavirus disease 2019.

\* <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>

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



## VAERS

### Vaccine Adverse Event Reporting System

<http://vaers.hhs.gov>



# VAERS

## Strengths

- National data
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

## Limitations

- Reporting bias
- Inconsistent data quality and completeness of information
- Lack of unvaccinated comparison group
- Not designed to assess causality

- VAERS accepts all reports from everyone regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event
- As a hypothesis-generating system, VAERS identifies potential vaccine safety concerns that can be studied in more robust data systems

# U.S. reports to VAERS after COVID-19 vaccination through February 16, 2021\*

Vaccine	N	Non-serious AEs (%)	Serious AEs <sup>†§</sup> (%)
Moderna	56,567	54,708 (97)	1,859 (3)
Pfizer-BioNTech	48,196	43,974 (91)	4,222 (9)
<b>Total</b>	<b>104,763</b>	<b>98,682 (94)</b>	<b>6,081 (6)</b>

\* Total pre-processed reports (reports received and classified as serious or non-serious)

† Based on the Code of Federal Regulations if one of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly or birth defect

§ Most commonly reported serious adverse events include death (456 reports of death following Moderna vaccine and 510 following Pfizer-BioNTech vaccine), dyspnoea, pyrexia, SARS-CoV-2 test negative, nausea, headache, dizziness, fatigue, asthenia, or pain

# Most commonly reported adverse events to VAERS after COVID-19 vaccination through February 16, 2021\*

## Pfizer-BioNTech

Adverse event <sup>†</sup>	N (%)
Headache	2,322 (20.0)
Fatigue	1,801 (15.5)
Dizziness	1,659 (14.3)
Pyrexia	1,551 (13.4)
Chills	1,508 (13.0)
Nausea	1,482 (12.8)
Pain	1,464 (12.6)
SARS-CoV-2 Test Positive	1,002 (8.6)
Injection Site Pain	997 (8.6)
Pain in Extremity	923 (8.0)

## Moderna

Adverse event <sup>†</sup>	N (%)
Headache	1,353 (23.4)
Pyrexia	1,093 (18.9)
Chills	1,056 (18.3)
Pain	945 (16.3)
Fatigue	888 (15.4)
Nausea	884 (15.3)
Dizziness	792 (13.7)
Injection Site Pain	671 (11.6)
Pain in Extremity	576 (10.0)
Dyspnoea	487 (8.4)

- No empirical Bayesian data mining alerts (EB05  $\geq$ 2) detected for any adverse event-COVID-19 vaccine pairs (most recent weekly results)

\* For reports received and processed (coded, redacted, and quality assurance performed)

<sup>†</sup>Adverse events are not mutually exclusive

# Anaphylaxis following mRNA COVID-19 vaccines

Clinical Review & Education

JAMA Insights

## Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021

Tom T. Shimabukuro, MD, MPH, MBA; Matthew Cole, MPH; John R. Su, MD, PhD, MPH

Shimabukuro TT, Cole M, Su JR. Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US-December 14, 2020-January 18, 2021. *JAMA*. 2021 Feb 12. doi: 10.1001/jama.2021.1967. Epub ahead of print.

	Pfizer-BioNTech	Moderna
Anaphylaxis reporting rate (cases per million doses administered)	4.7	2.5

Table. Characteristics of Reported Cases of Anaphylaxis Following Receipt of Pfizer-BioNTech (9 943 247 Doses) and Moderna (7 581 429 Doses) COVID-19 Vaccines—Vaccine Adverse Events Reporting System (VAERS), US, December 14, 2020-January 18, 2021

Characteristics	No. (%) of cases	
	Pfizer-BioNTech (n = 47)	Moderna (n = 19)
Age, median (range), y	39 (27-63) <sup>a</sup>	41 (24-63)
Female sex	44 (94)	19 (100)
Minutes to symptom onset, median (range)	10 (<1-1140 [19 h]) <sup>b</sup>	10 (1-45)
Symptom onset, min		
≤15	34 (76) <sup>b</sup>	16 (84)
≤30	40 (89) <sup>b</sup>	17 (89)
Reported history <sup>c</sup>		
Allergies or allergic reactions	36 (77)	16 (84)
Prior anaphylaxis	16 (34)	5 (26)
Vaccine dose		
First	37	17
Second	4	1
Unknown	6	1
Brighton Collaboration case definition level <sup>d</sup>		
1	21 (45)	10 (52)
2	23 (49)	8 (43)
3	3 (6)	1 (5)

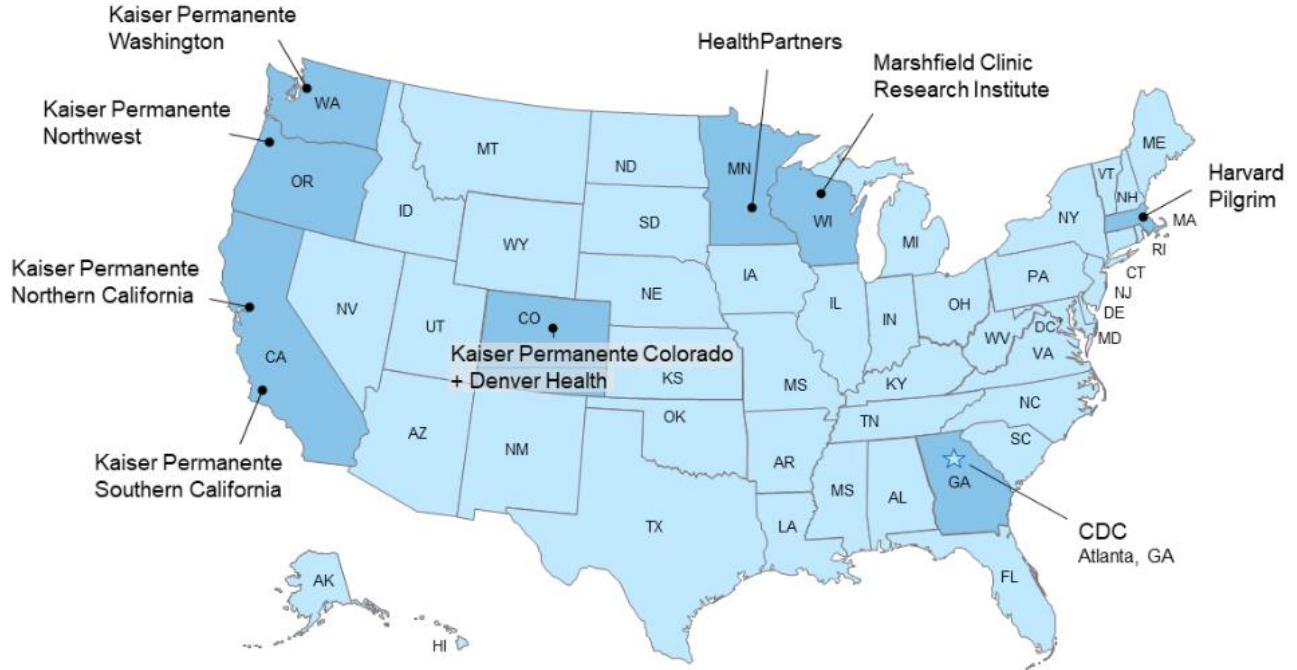
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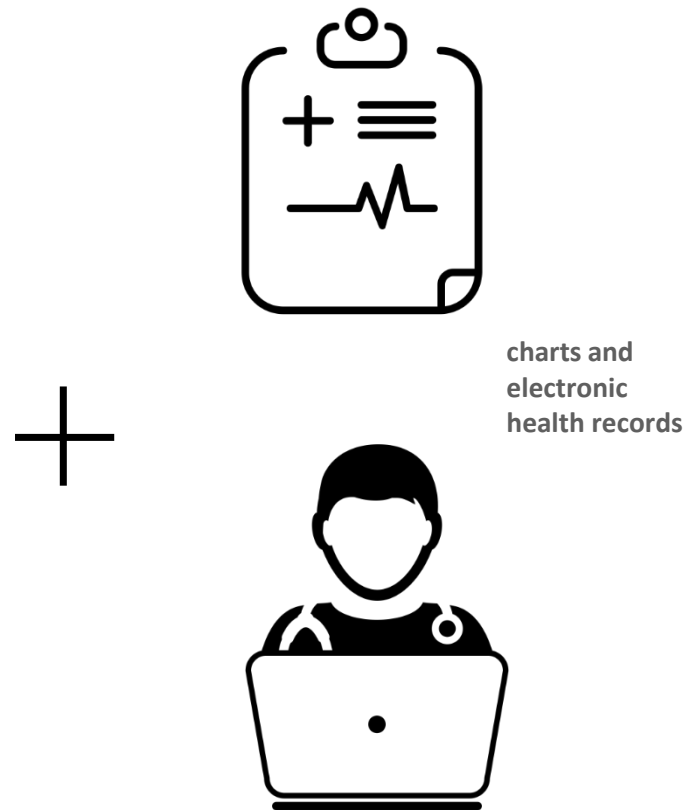
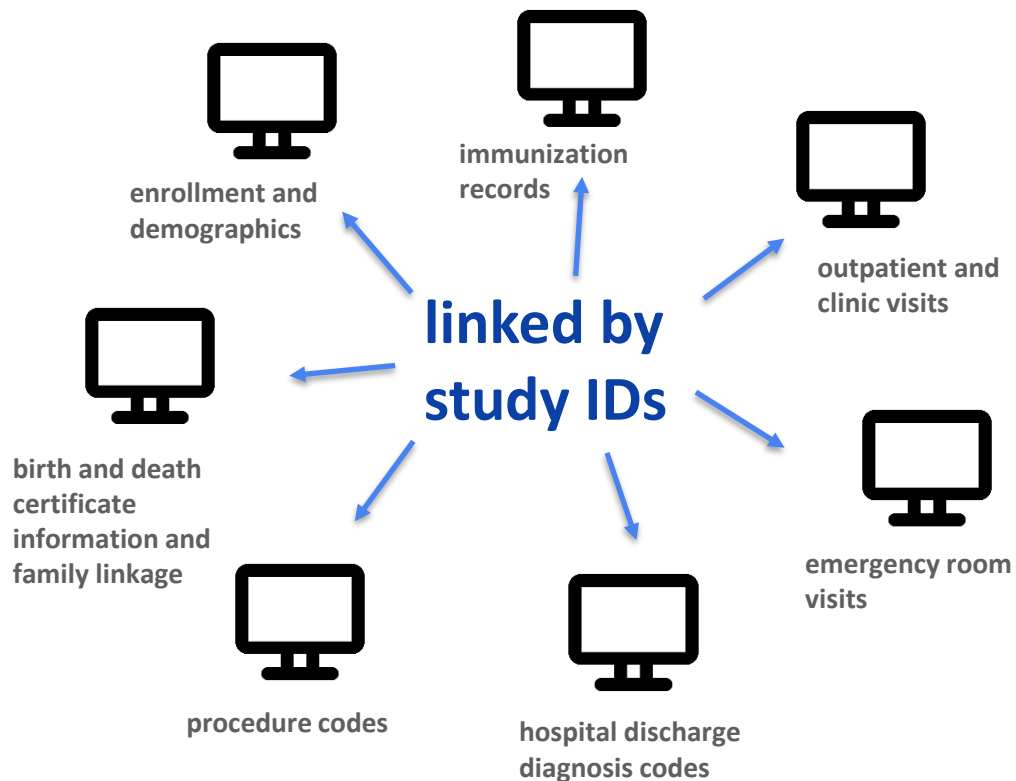
# VSD

## Vaccine Safety Datalink



- 9 participating integrated healthcare organizations
- Data on over 12 million persons per year

# Types of information in VSD



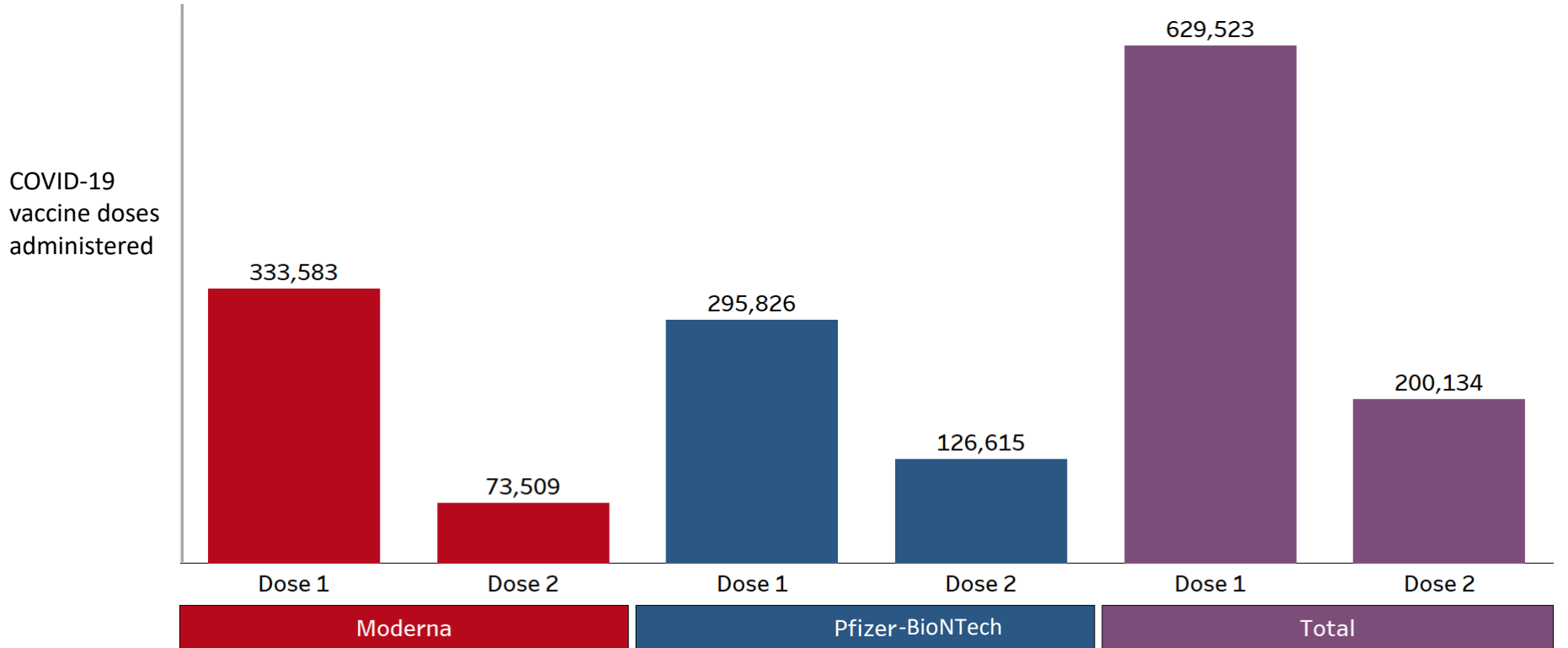
# VSD Rapid Cycle Analysis (RCA) for COVID-19 vaccines

- Data are refreshed weekly
- Outcomes monitored are prespecified (i.e., identified in advance)
- Includes methods to adjust for sequential testing
- A surveillance activity, not the same as an epidemiologic study
- Designed to detect statistically significant associations and statistical signals (values above specified statistical thresholds), which do not necessarily indicate a safety problem
- When a statistically significant association or signal occurs, assessment involves a series of checks and evaluations
- Chart-confirmation of diagnoses to confirm or exclude cases as true incident cases is a key part of statistical signal assessment

# VSD RCA for COVID-19 vaccines

- Analyses
  - Unvaccinated concurrent comparators (currently being conducted)
  - Vaccinated concurrent comparators (currently being conducted)
  - Self-controlled risk interval (planned)
  - Historical comparators (planned)

# VSD COVID-19 vaccine doses administered, by manufacturer, through February 13, 2021\*



\* Source: VSD participating integrated healthcare organizations; total includes a small number of unknown vaccine type

## VSD prespecified outcomes for COVID-19 vaccine safety monitoring

- Acute disseminated encephalomyelitis
- Acute myocardial infarction
- Acute respiratory distress syndrome
- Anaphylaxis
- Appendicitis
- Bell's palsy
- Convulsions/seizures
- Disseminated intravascular coagulation
- Encephalitis/myelitis/encephalomyelitis
- Guillain-Barré syndrome
- Thrombotic thrombocytopenic purpura
- Immune thrombocytopenia
- Kawasaki disease
- MIS-C and MIS-A
- Myocarditis/pericarditis
- Narcolepsy and cataplexy
- Stroke, hemorrhagic
- Stroke, ischemic
- Transverse myelitis
- Venous thromboembolism
- Pulmonary embolism (subset of VTE)

## Preliminary results of VSD monitoring for COVID-19 vaccine safety after either dose of any mRNA vaccine as of February 13, 2021

- Unvaccinated concurrent comparator analysis
  - No statistically significant increased risks detected for any prespecified outcomes
- Sequential vaccinated concurrent comparator analysis
  - No statistical signals detected for any prespecified outcomes

# VSD RCA next steps – next analyses

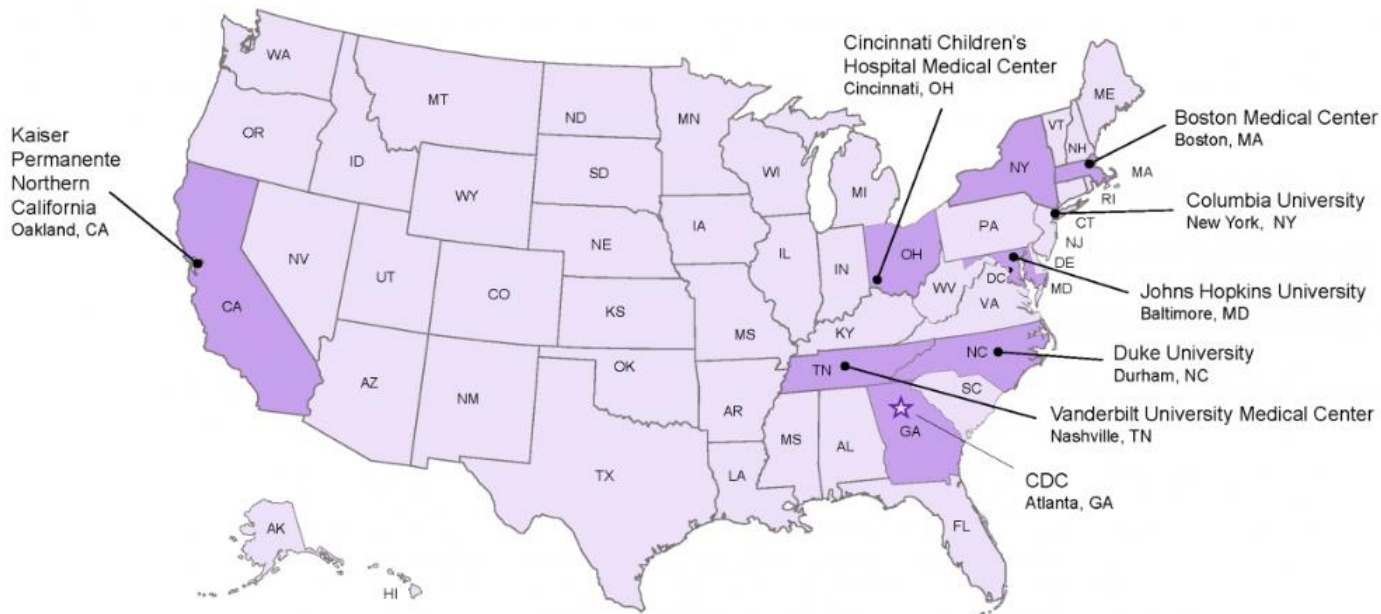
- Dose-specific analyses
- Product-specific analyses
- Analyses for two risk intervals 1-21 and 1-42 days
- Historical comparator analysis



# CISA

## Clinical Immunization Safety Assessment Project

7 participating medical research centers with vaccine safety experts



- Clinical consult services<sup>†</sup>
- Clinical research

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



# CISA Project COVIDvax

- Extension of CDC’s CISA\* Project’s clinical consultation service for U.S. healthcare providers and health departments for complex COVID-19 vaccine safety questions/issues that are†:
  - About an individual patient(s) residing in the United States
  - Not readily addressed by CDC or [ACIP](#) guidelines
- Vaccine safety subject matter expertise in multiple specialties (e.g., infectious diseases, allergy/immunology, neurology, OB/GYN, pediatrics, geriatrics)
- Requests for a CISA consult about COVID-19 vaccine safety:
  - Contact CDC-INFO: 800-CDC-INFO (800-232-4636) or [webform](#)
  - Indicate the request is for a “CDC CISA\*” consult (no patient identifiers)

\* <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>

† Advice from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management

# CISA Project contributions

- Responded to 331 clinical inquiries or consultation requests about COVID-19 vaccine safety (December 14, 2020, through February 20, 2021)
  - Received from 43 states
  - >90% from healthcare providers or health departments
  - Most common topics include anaphylaxis/allergic reactions and nervous system disorders\*
- Assisted state health departments with evaluation of complex medical issues pertaining to COVID-19 vaccine safety
- Established CISA Project workgroup with allergy/immunology specialists:
  - Provided expert input on anaphylaxis and other allergic reactions to inform clinical considerations for use of COVID-19 vaccines
  - Ongoing work to investigate possible mechanism for anaphylaxis after COVID-19 vaccine, in collaboration with FDA, NIH, and other partners

\* Includes inquiries about adverse events and for clinical guidance without adverse event

# COVID-19 Vaccine Safety in Pregnancy



# Summary of v-safe data as of February 16, 2021

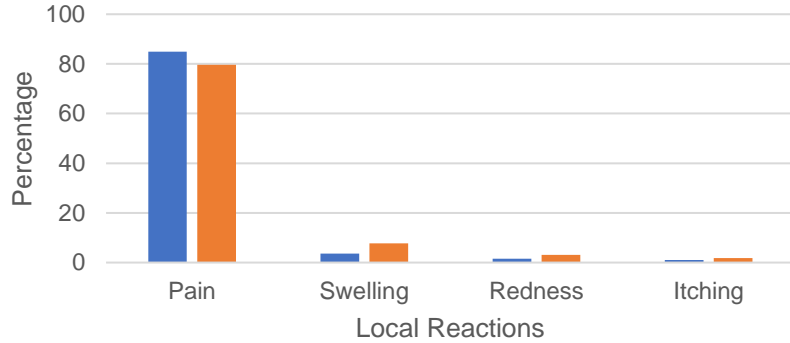
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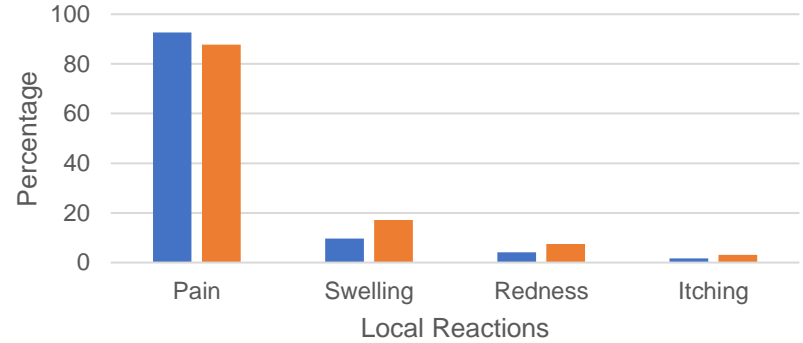
† Self-reported during a v-safe health check-in

# V-safe: Day 1 post-vaccination local reactions in pregnant and non-pregnant women aged 16-54 years\*

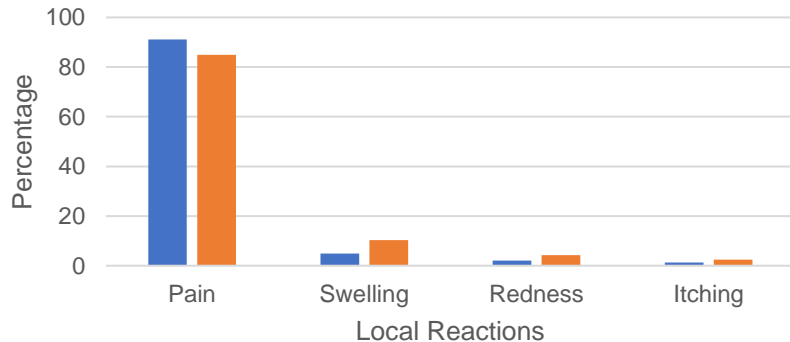
Pfizer-BioNTech Dose 1



Moderna Dose 1



Pfizer-BioNTech Dose 2



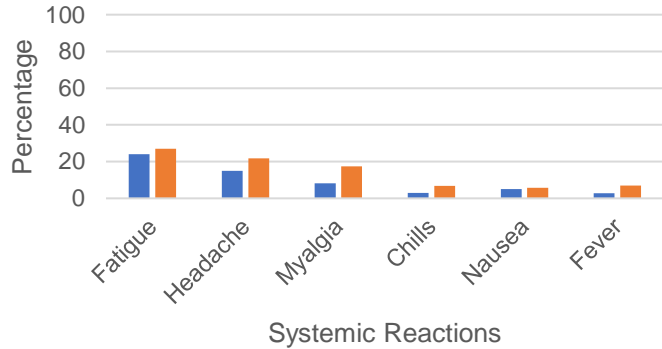
■ **Pregnant (self-report)**  
■ **Not pregnant**



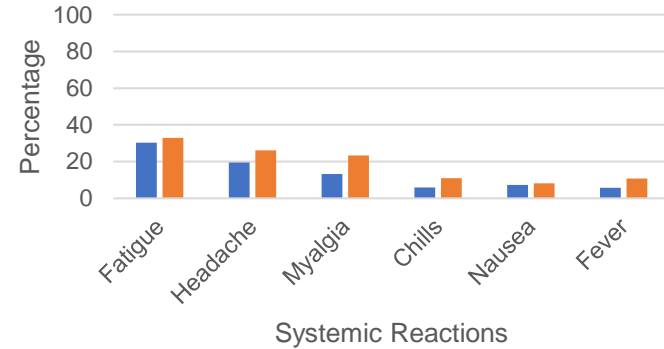
\* Source: CDC unpublished v-safe data through January 13, 2021

# V-safe: Day 1 post-vaccination systemic reactions in pregnant and non-pregnant women aged 16-54 years\*

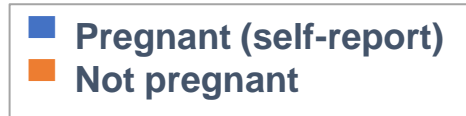
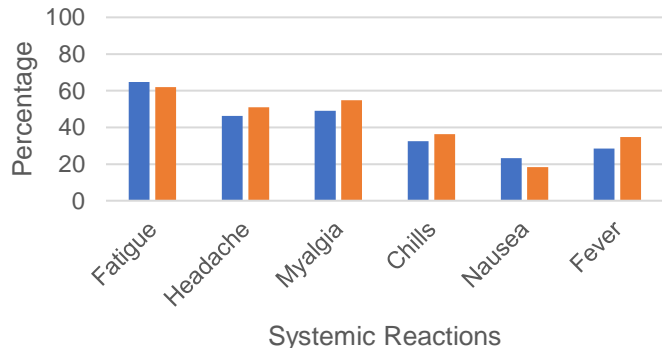
Pfizer-BioNTech Dose 1



Moderna Dose 1



Pfizer-BioNTech Dose 2



\* Source: CDC unpublished v-safe data through January 13, 2021



## V-safe pregnancy registry

- **V-safe** participants who report pregnancy following COVID-19 vaccination are actively contacted to enroll in pregnancy registry\*
- Participants are contacted once per trimester, after delivery, and when the infant is 3 months old<sup>†</sup>
- Outcomes of interest include miscarriage and stillbirth, pregnancy complications, maternal intensive care unit admission, adverse birth outcomes, neonatal death, infant hospitalizations, and birth defects

\* Must be registered in **v-safe** and have been pregnant at the time of COVID-19 vaccine receipt or within 30 days of vaccination; enrollment may discontinue when sufficient enrollment numbers are achieved

<sup>†</sup> Phone surveys are conducted along with maternal and infant medical record review



# V-safe pregnancy registry enrollment as of February 19, 2021

Registry participants to date (N = 1,949)	
Enrolled	1,815
Not eligible*	103
Refused/declined <sup>†</sup>	31

- In the enrolled population, there have been 275 completed pregnancies, including 232 live births
  - Other outcomes include miscarriage, stillbirth, ectopic/tubal, other

\* Eligibility assessment determines whether vaccination was during pregnancy or within 30 days of last menstrual period

<sup>†</sup> Refused indicates those for whom eligibility could not be fully assessed because participant chose not to engage with pregnancy registry team; declined indicates those who were eligible to participate but chose not to enroll



# V-safe pregnancy registry outcomes of interest in COVID-19 vaccinated pregnant women as of February 18, 2021\*

Outcomes	Background rates*	V-safe pregnancy registry overall
<b>Pregnancy outcome</b>		
Miscarriage (<20 weeks)	26%	15% <sup>†</sup>
Stillbirth (≥20 weeks)	0.6%	<1%
<b>Pregnancy complications</b>		
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension <sup>§</sup>	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%
<b>Neonatal</b>		
Preterm birth	10.1%	10%
Congenital anomalies <sup>‡</sup>	3%	4%
Small for gestational age <sup>^</sup>	3-7%	4%
Neonatal death	0.38%	0%

\* Sources listed on slide 33; <sup>†</sup> 93% of these were pregnancy losses <13 weeks of age; <sup>§</sup> Preeclampsia or gestational hypertension diagnosed during pregnancy and/or during delivery; <sup>‡</sup> Congenital anomalies (overall) diagnosed after delivery only; <sup>^</sup> Birth weight below the 10th percentile for gestational age and sex using INTERGROWTH-21st Century growth standards

# Sources for pregnancy outcomes and complications and neonatal outcomes background rates

- Miscarriage: <https://www.ncbi.nlm.nih.gov/books/NBK532992/>
- Stillbirth: <https://www.cdc.gov/nchs/data/nvsr/nvsr69/nvsr69-04-508.pdf>
- Gestational diabetes: <https://dmsjournal.biomedcentral.com/articles/10.1186/s13098-019-0406-1>, [https://www.cdc.gov/pcd/issues/2018/18\\_0094.htm#:~:text=An%20estimated%201%25%20to%2014,without%20gestational%20diabetes%20\(4\)](https://www.cdc.gov/pcd/issues/2018/18_0094.htm#:~:text=An%20estimated%201%25%20to%2014,without%20gestational%20diabetes%20(4))
- Preeclampsia or gestational hypertension: <https://www.frontiersin.org/articles/10.3389/fcvm.2020.00059/full>, <https://pubmed.ncbi.nlm.nih.gov/32381164/>
- Eclampsia: CDC Wonder
- Intrauterine growth restriction: <https://pubmed.ncbi.nlm.nih.gov/19404231/>
- Preterm birth: NCHS/Peristats
- Congenital anomalies: <https://www.cdc.gov/ncbddd/birthdefects/data.html>
- Small for gestational age (this has it up to 11%): <https://www.ncbi.nlm.nih.gov/books/NBK563247/>
- Neonatal death: NCHS/Peristats

# Characteristics of COVID-19 vaccine pregnancy reports to VAERS through February 16, 2021\* (N=154)



Characteristic	
Maternal age in years, median (range)	33 (16–51)
Gestational age in weeks at time of vaccination when reported, median (range)	13 (2–38)
<b>Trimester of pregnancy at time of vaccination</b>	<b>n (%)</b>
First (0-13 weeks)	60/118 (51)
Second (14-27 weeks)	36/118 (31)
Third (28+ weeks)	22/118 (19)
<b>Vaccine</b>	
Pfizer-BioNTech	97 (63)
Moderna	56 (36)
Unreported	1 (0.6)

\* Reports received and processed through February 16, 2021

# Adverse events in pregnant women following COVID-19 vaccine reported to VAERS through February 16, 2021\* (N=154)



Adverse events	N (%)
<b>Pregnancy/neonatal specific conditions</b>	<b>42 (27)</b>
Spontaneous abortion/miscarriage <sup>†</sup>	29
Premature rupture of membranes	3
Fetal hydrops	2
Neonatal death in 22-week preterm birth	1
Premature delivery	1
Gestational diabetes	1
Vaginal bleeding	1
Stillbirth	1
Shortened cervix	1
Leakage amniotic fluid	1
Calcified placenta	1
<b>Non-pregnancy specific adverse events (top 10)</b>	<b>112 (73)</b>
Headache (31), fatigue (29), chills (21), pain in extremity (17), nausea (15), dizziness (14), pain (14), pyrexia (13), injection site pain (13), injection site erythema (10)	

\* Reports received and processed through February 16, 2021

† Frequency of clinically recognized early pregnancy loss for women aged 20–30 years, 9–17%; age 30, 20%; age 40, 40%; age 45, 80%. ACOG Practice Bulletin No. 200: Early Pregnancy Loss. Obstet Gynecol. 2018;132(5):e197-e207

# Other CDC COVID-19 maternal vaccination safety activities

- VSD
  - COVID-19 vaccination coverage in pregnant women
  - Risk of miscarriage and stillbirth following COVID-19 vaccination
  - Safety in pregnancy
    - Acute adverse events in pregnancy, longer-term safety assessment of acute adverse events, pregnancy complications and birth outcomes, and infant follow-up for the first year of life
- CISA Project
  - Prospective observational cohort study
    - Adverse pregnancy and birth outcomes, serious adverse events, local and systemic reactogenicity, infant health outcomes for first 3 months of life

# Maternal vaccination safety summary

- Pregnant women were not specifically included in preauthorization clinical trials of COVID-19 vaccines
  - Post-authorization safety monitoring and research are the primary ways to obtain safety data on COVID-19 vaccination during pregnancy
- Substantial numbers of self-reported pregnant persons (>30,000) have registered in **v-safe**
- The reactogenicity profile and adverse events observed among pregnant women in **v-safe** did not indicate any safety problem
- Most (73%) reports to VAERS among pregnant women involved non-pregnancy-specific adverse events (e.g., local and systemic reactions)
- Miscarriage was the most frequently reported pregnancy-specific adverse event to VAERS; numbers are within the known background rates based on presumed COVID-19 vaccine doses administered to pregnant women

# Closing thoughts on COVID-19 vaccine safety (Feb 2021)

- 75 million COVID-19 vaccine doses have been administered in the United States through February 28
- Reactogenicity profiles of mRNA vaccines in **v-safe** monitoring are consistent with what was observed in clinical trials, and systemic and local reactions are most commonly reported to VAERS
- Anaphylaxis following both vaccines has been reported to VAERS, though rarely
- No other safety signals for serious adverse events have been detected in VAERS
- No safety concerns have been identified among VSD Rapid Cycle Analysis prespecified outcomes as of February 13
- No unexpected pregnancy or infant outcomes have been observed related to COVID-19 vaccination during pregnancy
- Safety monitoring in pregnant women is ongoing and planned in **v-safe**, VAERS, VSD, and CISA

# Acknowledgments

We wish to acknowledge the contributions of investigators from the following organizations:

## **Centers for Disease Control and Prevention**

COVID-19 Vaccine Task Force

COVID-19 Vaccine Task Force, Vaccine Safety Team

Immunization Safety Office

Division of Healthcare Quality Promotion

National Center on Birth Defects and Developmental Disabilities

Division of Reproductive Health

Vaccine Safety Datalink

Clinical Immunization Safety Assessment Project

**V-safe** Team

## **U.S. Food and Drug Administration**

Office of Biostatistics and Epidemiology



# COVID-19 Vaccines: Efficacy



# COVID-19 vaccine Phase III trial results are not directly comparable

- ACIP states no preference for any of the three authorized vaccines
  - The vaccines were not studied head-to-head
  - Results of Janssen Phase III trials not comparable with mRNA vaccines
    - Different calendar time
    - Different geography
- } Different circulating variants  
Higher background incidence

# Pfizer BioNTech COVID-19 vaccine: Phase III results

- **When:** Interim results: outcomes observed from September- November 2020
- **Who:** Persons aged  $\geq 16$  years
- **Where:** United States, Brazil, Argentina, South Africa, Turkey, Germany

<b>Outcome</b>	<b>Events/Vaccine<sup>a</sup> (n/N)</b>	<b>Events/Placebo<sup>a</sup> (n/N)</b>	<b>Vaccine efficacy (95% CI)</b>
Symptomatic Lab-confirmed <sup>b,c</sup>	8/17411	162/17511	95% (90, 98)
Hospitalization <sup>b,c</sup>	0/17399	5/17495	100% (-10, 100)
Death <sup>b,c</sup>	0/21621	0/21631	

<sup>a</sup>18,198 and 18,325 persons were randomized to vaccine and placebo, respectively; 17,411 and 17,511 in each arm had no evidence of prior infection

<sup>b</sup>Cases diagnosed  $\geq 7$  days post dose 2 vaccination among persons without evidence of prior SARS-CoV-2 infection

<sup>c</sup>COVID-19 associated

# Moderna COVID-19 vaccine Phase III results

- **When:** Interim results: outcomes observed from September- November 2020
- **Who:** Persons aged  $\geq 18$  years
- **Where:** United States

<b>Outcome</b>	<b>Events/Vaccine<sup>a</sup> (n/N)</b>	<b>Events/Placebo<sup>a</sup> (n/N)</b>	<b>Vaccine efficacy (95% CI)</b>
Symptomatic Lab-confirmed <sup>b,c</sup>	11/14134	185/14073	<b>94% (89, 97%)</b>
Hospitalization <sup>b,c</sup>	1/14134	9/14073	<b>89% (13, 99)</b>
Death <sup>b,c</sup>	0/14134	1/14073	

<sup>a</sup>18,198 and 18,325 persons were randomized to vaccine and placebo, respectively; 17,411 and 17,511 in each arm had no evidence of prior infection

<sup>b</sup>Cases diagnosed  $\geq 14$  days post dose 2 vaccination among persons without evidence of prior SARS-CoV-2 infection

<sup>c</sup>COVID-19 associated

# Janssen COVID-19 vaccine: Phase III results

- **When:** Interim results: outcomes observed from November 2020-January 2021
- **Who:** Persons aged  $\geq 18$  years
- **Where:** United States, South Africa, Brazil, Chile, Colombia, Peru, and Argentina

<b>Outcome</b>	<b>Events/Vaccine<sup>a</sup> (n/N)</b>	<b>Events/Placebo<sup>a</sup> (n/N)</b>	<b>Vaccine efficacy (95% CI)</b>
Symptomatic Lab-confirmed <sup>b,c,d</sup>	173/19,514	509/19,544	<b>66% (60, 72)</b>
Hospitalization <sup>d</sup>	2/19,514	29/19,544	<b>93% (71, 98)</b>
Death <sup>d</sup>	0/21,895	7/21,888	

<sup>a</sup>21,895 and 21,888 persons were randomized to vaccine and placebo

<sup>b</sup>Cases diagnosed  $\geq 14$  days post vaccination among persons without evidence of prior SARS-CoV-2 infection

<sup>c</sup>Primary efficacy population (per protocol); includes a total of 3113 person-years of observation in vaccine group and 3089 person-years in placebo group

<sup>d</sup>COVID-19 associated

# Summary: all authorized & recommended vaccines have demonstrated high efficacy against severe COVID-19

- **Hospitalization** efficacy  $\geq 89\%$  for all vaccines
- **No vaccinated person died due to COVID-19** during the study versus 8 COVID-19 associated deaths in placebo recipients

# Janssen COVID-19 Vaccine implementation

- During a pandemic, under EUA, offering Janssen COVID-19 vaccine to persons 18 years and older, according to established allocation and eligibility recommendations in a given jurisdiction, is an effective implementation strategy
  - Allows for jurisdictional flexibility
  - Supports rapid vaccination and increases in population immunity
  - Does not single out any group
  - Allows individuals to be vaccinated with the earliest vaccine available

# **Strategies for Addressing Patient Questions and Concerns about COVID-19 Vaccines**



# Presentation Overview

- Elements of vaccine confidence
- Strategies for building vaccine confidence
- Strategies for talking with patients about COVID-19 vaccines
- Answers to common patient questions about COVID-19 vaccines



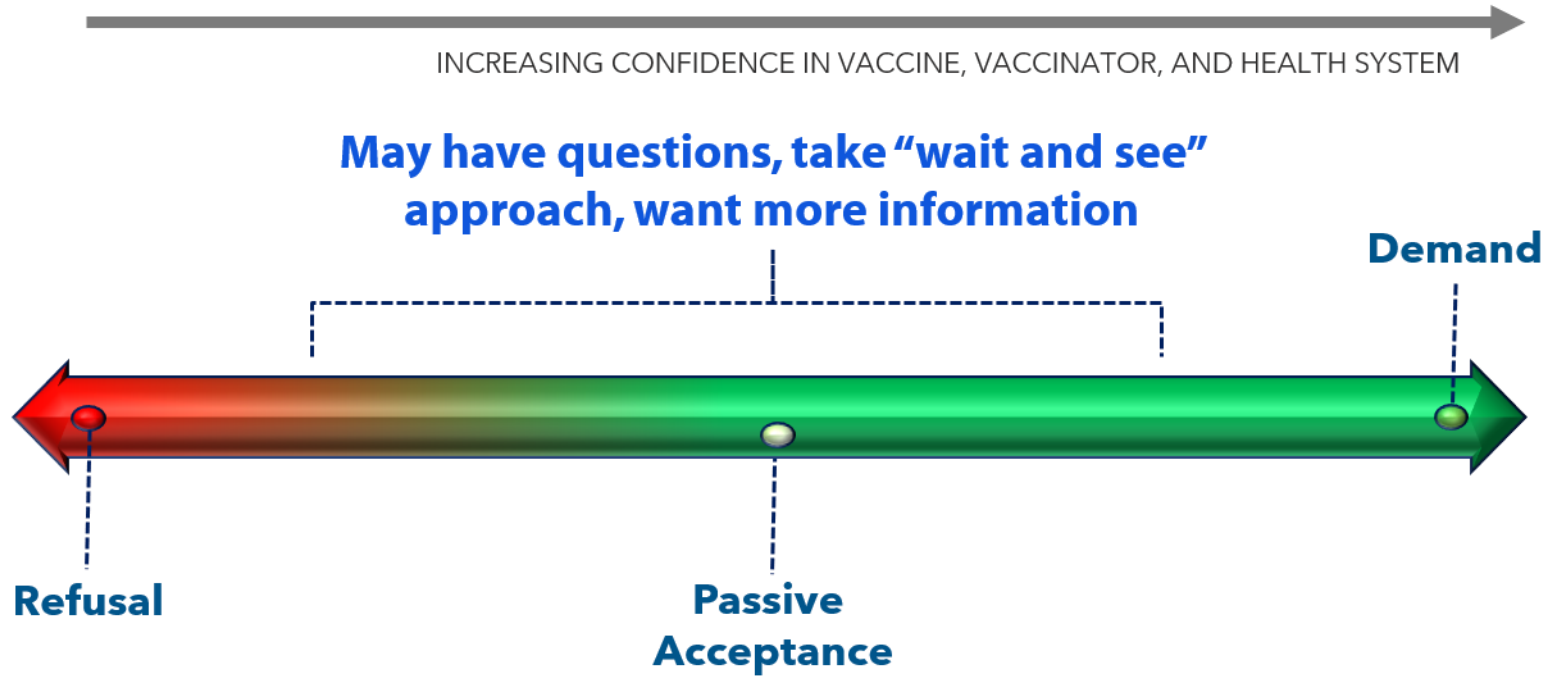
# Elements of Vaccine Confidence

# Vaccine confidence includes multiple factors

- *Vaccine confidence* is the trust that patients, parents, or providers have in:
  - recommended vaccines;
  - providers who administer vaccines; and
  - processes and policies that lead to vaccine development, licensure, manufacturing, and recommendations for use.



# Willingness to accept a vaccine falls on a continuum



# Public confidence in and acceptance of the COVID-19 vaccine is increasing

## February 2021

- **55%** (already vaccinated or will get the vaccine as soon as available)
- **22%** (adopt a wait-and-see approach)

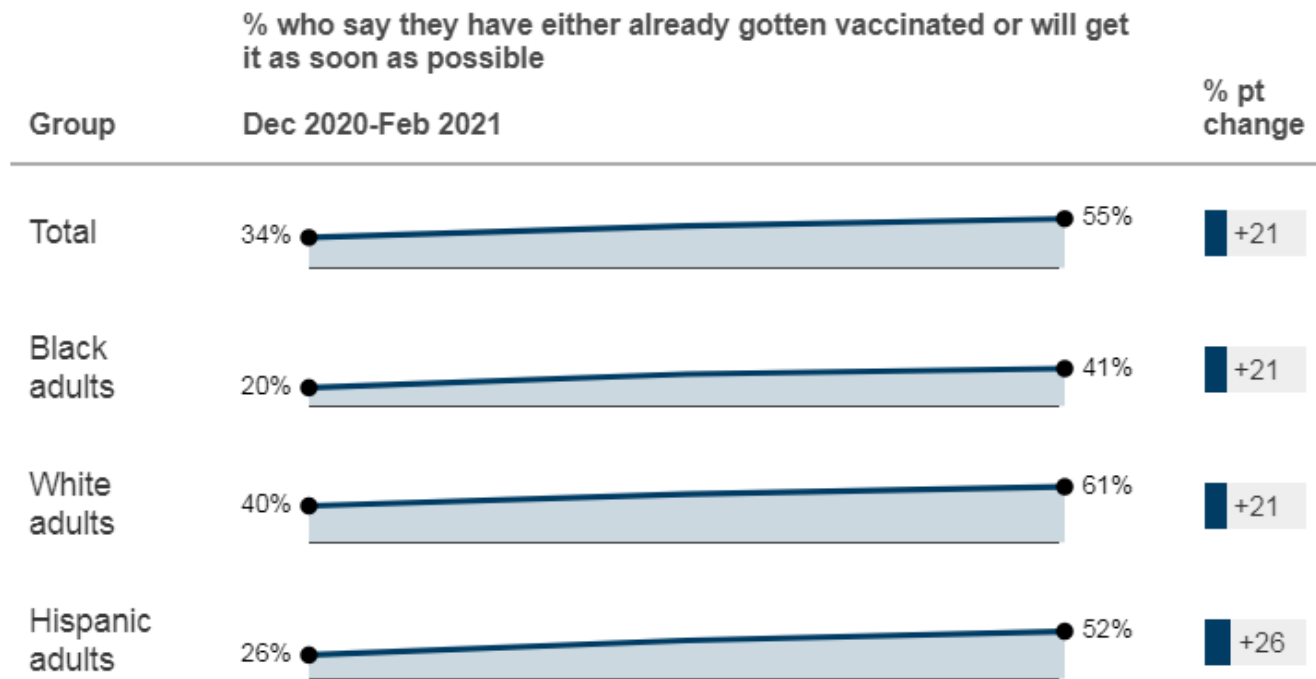
## December 2020

- **34%** (will get the vaccine as soon as available)
- **39%** (adopt a wait-and-see approach)



Source: Kaiser Family Foundation Vaccine Monitor (Nov. 30-Dec. 8, 2020, Feb. 15-Feb.23, 2021)  
[KFF COVID-19 Vaccine Monitor Dashboard](#) | [KFF](#)

# Increasing trends are seen across race/ethnicity groups

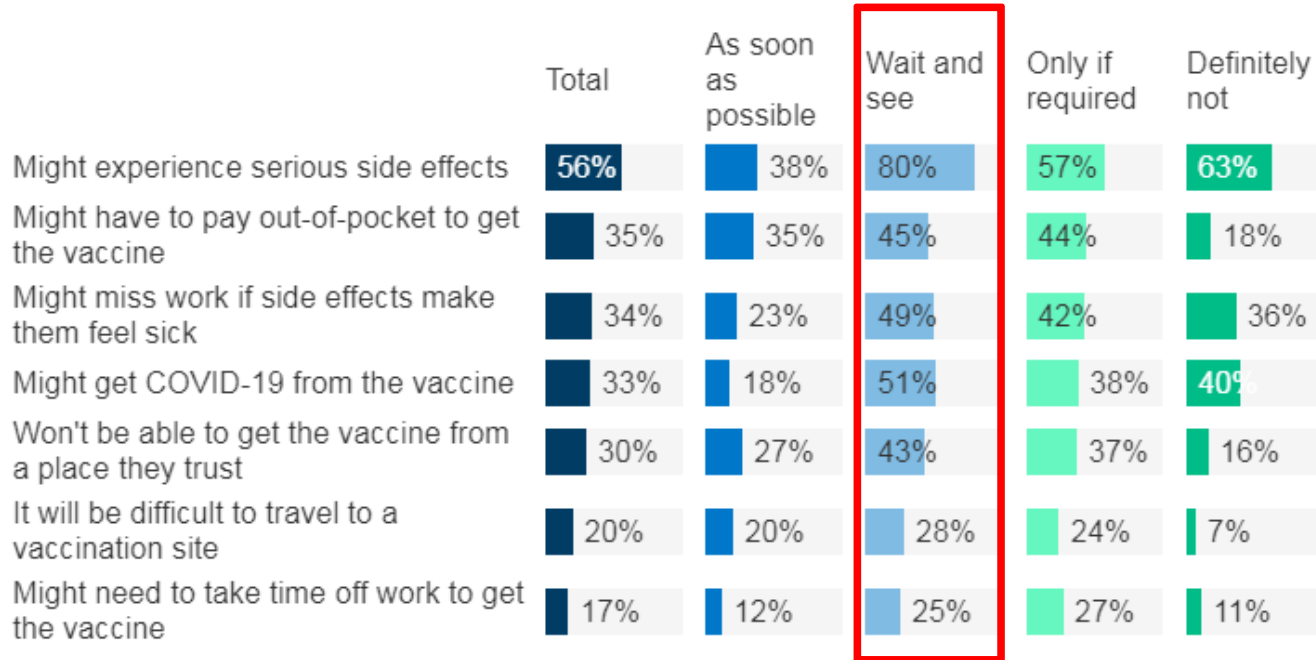


NOTE: December 2020 survey did not have options for respondents to indicate they had already been vaccinated. Data refer to Non-Hispanic Black and Non-Hispanic White adults. Source: Kaiser Family Foundation Vaccine Monitor (Nov. 30-Dec. 8, 2020, Feb. 15-Feb.23, 2021) [KFF COVID-19 Vaccine Monitor Dashboard | KFF](#)



# Of those who remain hesitant, many are concerned about side effects

Percent who say they are very or somewhat concerned about each of the following when it comes to the COVID-19 vaccine:



Source: Kaiser Family Foundation Vaccine Monitor (Feb. 15-Feb.23, 2021) [KFF COVID-19 Vaccine Monitor Dashboard](#) | KFF



# Confusion and uncertainty about the COVID-19 vaccines remain

- **COVID-19 State of Vaccine Confidence Report (released 3/1/2021)** included quantitative and qualitative analysis of >10 inputs from digital media, peer-reviewed research, polling data, social listening platforms, CDC-INFO, census inputs, and web metric data

## Major Themes



Confusion about how COVID-19 vaccines work and their benefits



People with underlying medical conditions, acute medical conditions, or allergies are unsure if vaccines are safe



Practical barriers to vaccine access remain, despite national expansion to retail pharmacy sites





# Strategies for Building Vaccine Confidence



# Vaccinate with **Confidence**

## A National Strategy to Reinforce Confidence in COVID-19 Vaccines

### **Build Trust**

**Objective:** Share clear, complete, and accurate messages about COVID-19 vaccines and take visible actions to build trust in the vaccine, the vaccinator, and the system in coordination with federal, state, and local agencies and partners.

### **Empower Healthcare Personnel**

**Objective:** Promote confidence among healthcare personnel in their decision to get vaccinated and to recommend vaccination to their patients.

### **Engage Communities & Individuals**

**Objective:** Engage communities in a sustainable, equitable, and inclusive way—using two-way communication to listen, build trust, and increase collaboration.



# Vaccinate with **Confidence**

A component of the National Strategy to Reinforce Confidence in COVID-19 Vaccines

## Empower Healthcare Personnel

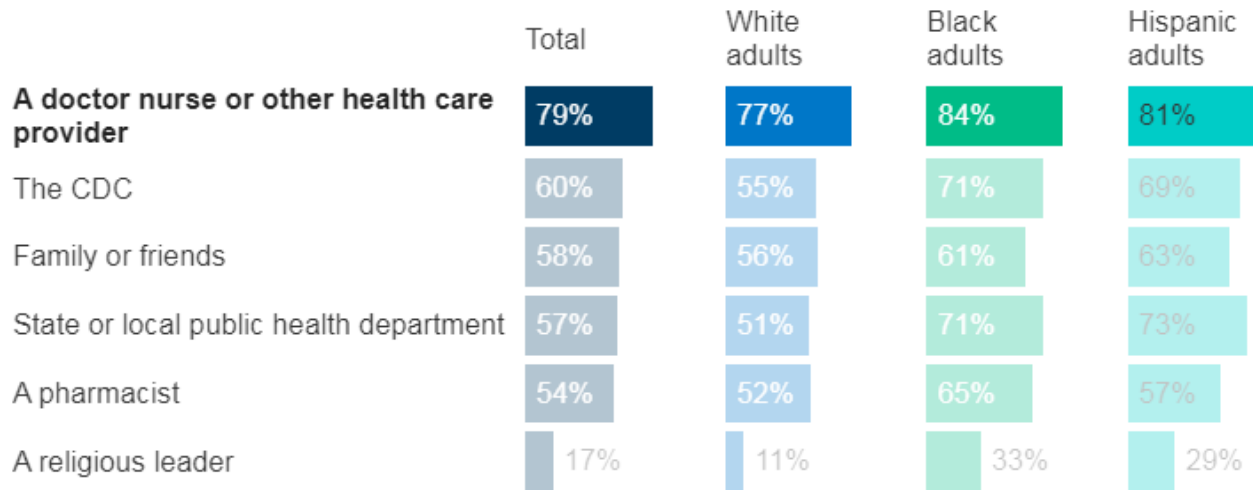
**Objective: Promote confidence among healthcare personnel in their decision to get vaccinated and to recommend vaccination to their patients.**

- Tactics**
- ✓ Engage local and national professional associations, health systems, and healthcare personnel often and early to ensure a clear understanding of the vaccine development and approval process, new vaccine technologies, and the benefits of vaccination
  - ✓ Ensure healthcare systems and medical practices are equipped to create a culture that builds confidence in COVID-19 vaccination
  - ✓ Strengthen the capacity of healthcare professionals to have empathetic vaccine conversations, address myths and common questions, provide tailored vaccine information to patients, and use motivational interviewing techniques when needed



# Healthcare providers remain a trusted source of information about COVID-19 vaccines

Percent who say they are likely to turn to each of the following when deciding whether to get a COVID-19 vaccine:



Source: Kaiser Family Foundation Vaccine Monitor (Jan. 11-18, 2021) [KFF COVID-19 Vaccine Monitor Dashboard](#) | [KFF](#)

NOTE: Among those who have not been vaccinated



# Vaccine confidence starts with you!

- As part of the healthcare team, **you** are likely included the first phase to receive a COVID-19 vaccine
- **Get a COVID-19 vaccine** when it is available to you
- **Share** your experience and your personal reasons for getting vaccinated with your patients, family, and friends
- **Visibly show** you received the vaccine by wearing a sticker, button, or lanyard and sharing on social media or other communication channels



# Strategies for Talking with Patients about COVID-19 Vaccines

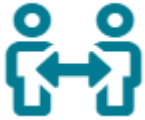
# Prepare for COVID-19 vaccine conversations



**Choose to get vaccinated**



**Start conversations early**



**Engage in effective conversations**



**Be prepared for questions**



# Key Messages

1. You can help **stop** the pandemic by getting a COVID-19 vaccine
2. Get the **information** you need to choose to get vaccinated when its available to you
3. COVID-19 vaccines are safe **and** effective
4. COVID-19 vaccine will be **free** for you
5. After COVID-19 vaccination, you **might** have some side effects. These are normal signs that your body is building protection
6. You will still need to wear a mask and socially distance after getting each shot of the vaccine **for now**.





# Know the elements of effective vaccine conversations

- Start from a place of empathy and understanding
- Assume patients will want to be vaccinated but be prepared for questions
- Give your strong recommendation
- Address misinformation by sharing key facts
- Listen to and respond to patient questions
- Proactively explain side effects

“I strongly recommend you get a COVID-19 vaccine once it is available to you”

“...This shot is especially important for you because of your [job or underlying health condition].”



# Address misinformation about COVID-19 vaccination by sharing key facts



<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html>

COVID-19 vaccines cannot give you COVID-19

People who have already gotten sick with COVID-19 may still benefit from getting vaccinated

Getting vaccinated can help prevent getting sick with COVID-19

COVID-19 vaccines will not cause you to test positive on COVID-19 **viral** tests\*



\*<https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>

# When addressing misinformation, focus on building trust and confidence

- Help patients find accurate sources of information, including patient-oriented materials from your own trusted sources of clinical and scientific information
- Focus on correcting the misinformation rather than the source, particularly if the misinformation comes from patients' families or communities
- Center on the trusted relationship between you and your patient to help build trust in your messaging around COVID-19 vaccines
- Build trust by asking your patients' permission to share information with them



# Remember to use culturally responsive messaging and messages when building vaccine confidence

- Understand that long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID-19
- Provide information through channels and in formats and languages suitable for diverse audiences
- Identify the diverse communities served by your program and partner with trusted messengers who are representative of those communities in your efforts to improve vaccine confidence
- Avoid stigmatizing language and ensure all team members are trained to identify and interrupt all forms of discrimination



# Answering Common Patient Questions about COVID-19 Vaccination

## Q: How do we know if COVID-19 vaccines are safe?

- Explain the following key facts:
  - FDA carefully reviews all safety data from clinical trials
  - FDA authorizes emergency vaccine use only when the expected benefits outweigh potential risks
  - ACIP reviews safety data before recommending any vaccine for use
  - FDA and CDC will continue to monitor the safety of COVID-19 vaccines to make sure even very rare side effects are identified

“COVID-19 vaccines are safe and effective. They were tested in large clinical trials to make sure they meet safety standards. Many people were recruited to participate in these trials to see how the vaccines offer protection to people of different ages, races, and ethnicities, as well as those with different medical conditions.”



## Q: Is it safe to get a COVID-19 vaccine if I have allergies?

- Ask what kind of allergies they are concerned about
- Explain that people should not get a vaccine if they are allergic to an ingredient in that vaccine and that you and/or a specialist can help determine a safe recommendation
- Explain that people with other types of allergies may still be vaccinated, and that you can help determine if it is safe for them

“If you have ever had a severe allergic reaction to any ingredient in a COVID-19 vaccine, you should not get that vaccine. If you have had an immediate allergic reaction of any severity to other vaccines or injectable therapies, I will help you decide if it is safe for you to get vaccinated. I can also refer you to a specialist if needed.”



## Q: Is it safe to get a COVID-19 vaccine if I am pregnant or breastfeeding?

- Explain that there are limited data about the safety of COVID-19 vaccines during pregnancy and breastfeeding, but that experts do not believe they pose a risk
- Clarify that patients may choose to get vaccinated if they are part of a recommended group
- Emphasize that vaccination is a personal decision and offer to discuss it in more depth

“There is limited information about the safety of COVID-19 vaccines during pregnancy. However, based on what we know about how these vaccines work, experts believe they are unlikely to pose a risk for pregnant people. You may choose to get vaccinated if you are part of a group that is recommended for COVID-19 vaccination. We can talk through this decision together.”





## Q: Have these vaccines been tested in all populations?

- Explain that the clinical trials recruited a diverse mix of participants
- If possible, be specific and provide the percentages of people from communities of color, people with underlying health conditions, and older adults included in the trials
- Reiterate that no serious safety concerns were identified

“The currently authorized COVID-19 vaccines were tested in a diverse group of people, including Hispanic, African American, Asian, and Native American individuals. Older adults and people with underlying medical conditions were also included. There were no significant safety concerns identified in these or any other groups.”



## Q: Is it better to get natural immunity rather than immunity from vaccines?

- Explain that while getting COVID-19 might offer some immunity, the risk of severe illness and death from COVID-19 far outweighs any benefits of natural immunity
- COVID-19 vaccination will help protect you by creating an antibody (immune system) response without having to experience sickness and the potential serious risk COVID-19 poses to them and their loved ones if they get the illness or spread it to others

“Both this disease and the vaccine are new. We don’t know how long protection lasts for those who get infected or those who are vaccinated. What we do know is that COVID-19 has caused very serious illness and death for a lot of people. If you get COVID-19, you also risk giving it to loved ones who might get sick. Getting a COVID-19 vaccine is a safer choice.”



# Q: Will the shot hurt? Will it make me sick? What about the side effects?

- Explain that they cannot get COVID-19 from the vaccine
- Explain what the most common side effects from vaccination are, how severe they might be, and that they typically go away on their own within a few days.
  - Make sure patients know that a fever is a potential side effect
- Provide a comparison if it is appropriate for the patient (for example, pain after receiving the shingles vaccine for older adults who have received it)

“These side effects are signs that your immune system is doing exactly what it is supposed to do. It is working and building up protection against disease.”

“Most people do not have serious problems after getting a vaccine. However, your arm might be sore or swollen. These symptoms usually go away on their own within a few days. Some people report getting tiredness, headache, muscle pain, chills, fever, or nausea after getting a COVID-19 vaccine. “



# Q: How do we know these vaccines are safe when they are so new? What about long-term side effects?

- Explain how FDA and CDC are continuing to monitor safety
- Let patients know that ACIP will take action to address any potential safety problems detected
- Compare the potential serious risk of COVID-19 illness with what is currently known about the safety of COVID-19 vaccines

“COVID-19 vaccines are being tested in large clinical trials to learn more about their safety and effectiveness. However, it does take time and more people getting vaccinated before we can learn about very rare or long-term side effects. That is why safety monitoring will continue. CDC has an independent group of experts that reviews all the safety data as they come in and provides regular safety updates. Any possible problems will be quickly investigated to find out if the issue is related to the COVID-19 vaccine and determine the best course of action.”



## Q: I heard that one vaccine is better than the other. Shouldn't I get the “best” vaccine?

- Clearly message that **“the best vaccine is the first vaccine that’s available to you”**
- Explain that clinical trials that found them ALL to be safe and effective in preventing severe COVID-19 illness, hospitalization, and death.
- Remind patients that, even after vaccination, patients still need to take precautions to protect themselves, their families, and their communities against COVID-19

“If you do get exposed to COVID-19, all available vaccines can prevent you from getting sick, missing work, or ending up in the hospital. It’s important to remember that even after you’re vaccinated, you will need to keep wearing a mask that covers your nose and mouth, washing your hands often, and staying at least 6 feet away from other people you do not live with. This gives you and others the best protection from catching the virus.”



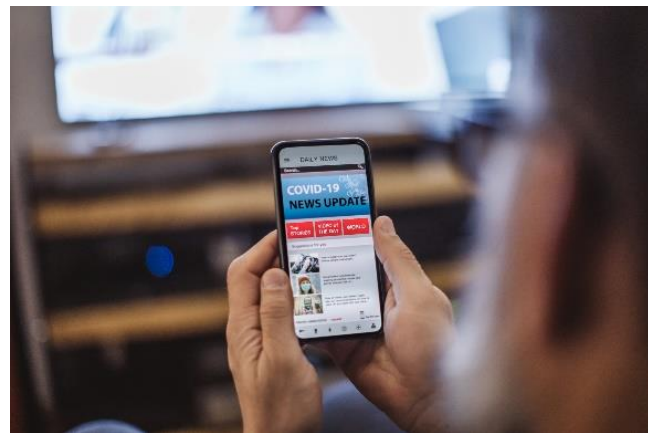
# Wrapping up the conversation

- Encourage patients to take at least one action. For example:
  - Schedule the second-dose appointment, if applicable.
  - Offer additional, easy-to-understand sources of information, if you perceive continued hesitance about vaccination.
  - Offer a follow-up phone call to continue the discussion.
- If they decline the vaccine, continue to remind them about the importance of getting a COVID-19 vaccine during future encounters.
- Wrap up the conversation by letting your patient know that you are open to continuing the discussion and answering any additional questions they may have.



# Know where to go for the latest information about COVID-19 vaccines.

- CDC and FDA websites:
  - [www.cdc.gov/covid-19/vaccines](https://www.cdc.gov/covid-19/vaccines)
  - [www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines)
- Your professional association
- Your state or local health department
- Your facility's immunization coordinator



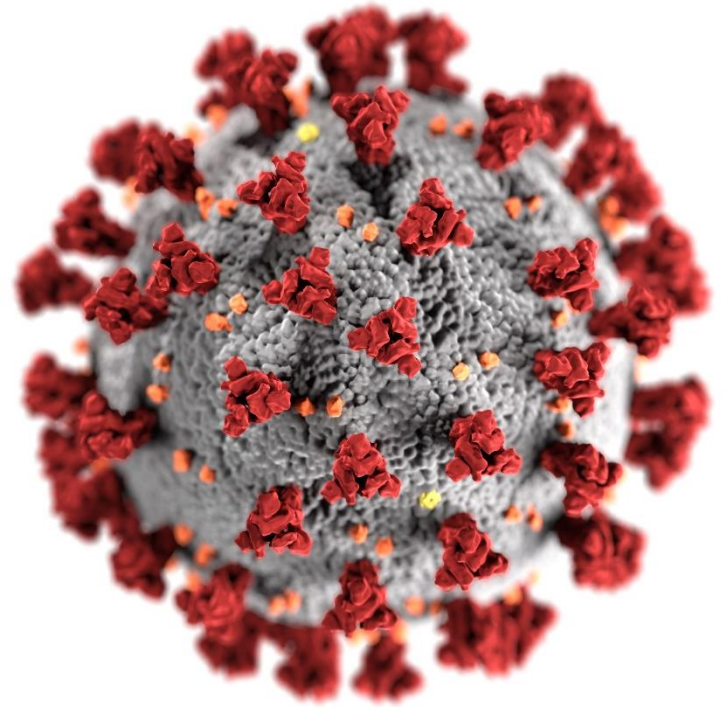
# Provider resources for COVID-19 vaccine conversations with patients

- **Preparing to Provide COVID-19 Vaccines:** <https://www.cdc.gov/vaccines/covid-19/training.html>
- **Talking to Patients about COVID-19 Vaccines:** [www.cdc.gov/vaccines/hcp/covid-conversations](https://www.cdc.gov/vaccines/hcp/covid-conversations)
- **Understanding and Explaining mRNA COVID-19 Vaccines:** <https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html>
- **Understanding and Explaining Viral Vector COVID-19 Vaccines:** <https://www.cdc.gov/vaccines/covid-19/hcp/viral-vector-vaccine-basics.html>
- **Making a Strong Recommendation for COVID-19 Vaccination:** <https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html>
- **COVID-19 FAQs for Healthcare Providers:** <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>
- **Health Equity: Promoting Fair Access to Health:** <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/index.html>





# Thank you



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

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.



# To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button.
  - Type your question in the “Q&A” box.
  - Submit your question.
- For media questions, please contact CDC Media Relations at 404-639-3286 or email [media@cdc.gov](mailto:media@cdc.gov).

# Today's COCA Call Will Be Available On-Demand

- **When:** A few hours after the live call
- **What:** Video recording
- **Where:** On the COCA Call webpage at [https://emergency.cdc.gov/coca/calls/2021/callinfo\\_030921.asp](https://emergency.cdc.gov/coca/calls/2021/callinfo_030921.asp)

# Upcoming COCA Calls

- **When:** Thursday, March 11 at 2 PM ET
- **Topic:** The Role of Telehealth in Expanding Access to Healthcare During the COVID-19 Pandemic: Considerations for Vaccine Uptake and Monitoring for Adverse Events
- **For more information:**  
[https://emergency.cdc.gov/coca/calls/2021/callinfo\\_031121.asp](https://emergency.cdc.gov/coca/calls/2021/callinfo_031121.asp)
- Subscribe to receive notifications about upcoming COCA calls or other COCA products and services at [emergency.cdc.gov/coca/subscribe.asp](https://emergency.cdc.gov/coca/subscribe.asp)
- Share call announcements with colleagues

# COCA Products & Services

The logo for COCA Call features a blue horizontal bar with the text "COCA Call" in white. To the left of the bar are four circular icons: a white eye on a blue background, a white stethoscope on a red background, a white syringe on a green background, and a white biohazard symbol on an orange background.

**COCA Call**  
CDC Clinician Outreach  
and Communication Activity

COCA Call Announcements contain all information subscribers need to participate in COCA Calls. COCA Calls are held as needed.

The logo for COCA Learn features a green horizontal bar with the text "COCA Learn" in white. To the left of the bar are four circular icons: a white eye on a blue background, a white stethoscope on a red background, a white syringe on a green background, and a white biohazard symbol on an orange background.

**COCA Learn**  
CDC Clinician Outreach  
and Communication Activity

Monthly newsletter that provides information on CDC training opportunities, conference and training resources, the COCA Partner Spotlight, and the Clinician Corner.

The logo for Clinical Action features a red horizontal bar with the text "Clinical Action" in white. To the left of the bar are four circular icons: a white eye on a blue background, a white stethoscope on a red background, a white syringe on a green background, and a white biohazard symbol on an orange background.

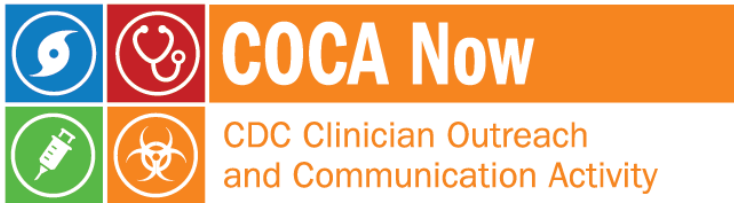
**Clinical Action**  
CDC Clinician Outreach  
and Communication Activity

As-needed messages that provide specific, immediate action clinicians should take. Contains comprehensive CDC guidance so clinicians can easily follow recommended actions.

# COCA Products & Services



Monthly newsletter providing updates on emergency preparedness and response topics, emerging public health threat literature, resources for health professionals, and additional information important during public health emergencies and disasters.



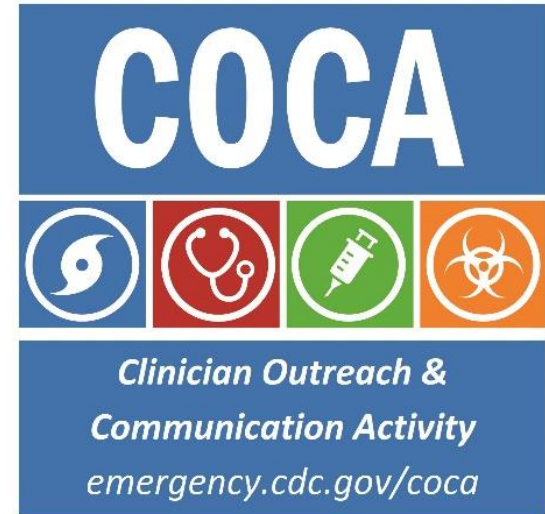
Informs clinicians of new CDC resources and guidance related to emergency preparedness and response. This email is sent as soon as possible after CDC publishes new content.



CDC's primary method of sharing information about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories.

# Join COCA's Mailing List

- **Receive information about:**
  - Upcoming COCA Calls
  - Health Alert Network (HAN) messages
  - CDC emergency response activations
  - Emerging public health threats
  - Emergency preparedness and response conferences
  - Training opportunities



[emergency.cdc.gov/coca/subscribe.asp](https://emergency.cdc.gov/coca/subscribe.asp)

# Join Us On Facebook!



The screenshot shows the Facebook profile for COCA (CDC Clinician Outreach and Communication Activity). The profile picture features a group of diverse healthcare professionals. The cover photo shows a group of six healthcare workers smiling. The page includes a navigation menu on the left with options like Home, About, Posts, Photos, Events, and Community. The main content area shows a status update from October 31, 2017, about a free CE event. The right sidebar displays location information (Atlanta, Georgia), community statistics (21,420 likes, 21,217 followers), and a map of the location.

**COCA**

CDC Clinician Outreach and Communication Activity - COCA ✓  
@CDCClinicianOutreachAndCommunicationActivity

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CDC Clinician Outreach and Communication Activity - COCA shared their event.  
October 31 at 1:18pm · 🌐

Clinicians, you can earn FREE CE with this COCA Call! Join us for this COCA Call November 7, 2017 at 2:00PM.

Government Organization in Atlanta, Georgia

Community  
21,420 people like this  
21,217 people follow this

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**Thank you for joining us today!**



[emergency.cdc.gov/coca](https://emergency.cdc.gov/coca)