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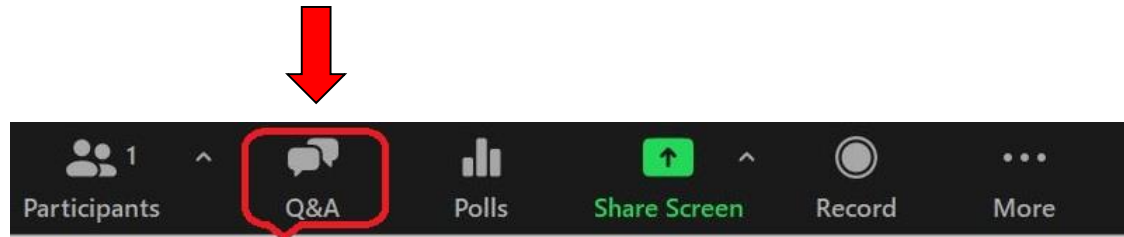
“Updates on CDC's Safety Monitoring and Communications for COVID-19 Vaccines”

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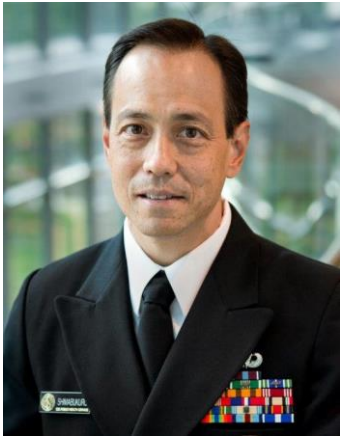
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Centers for Disease Control and Prevention Speakers



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COVID-19 vaccine safety update

Immunization Action Coalition (IAC)
March 4, 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.

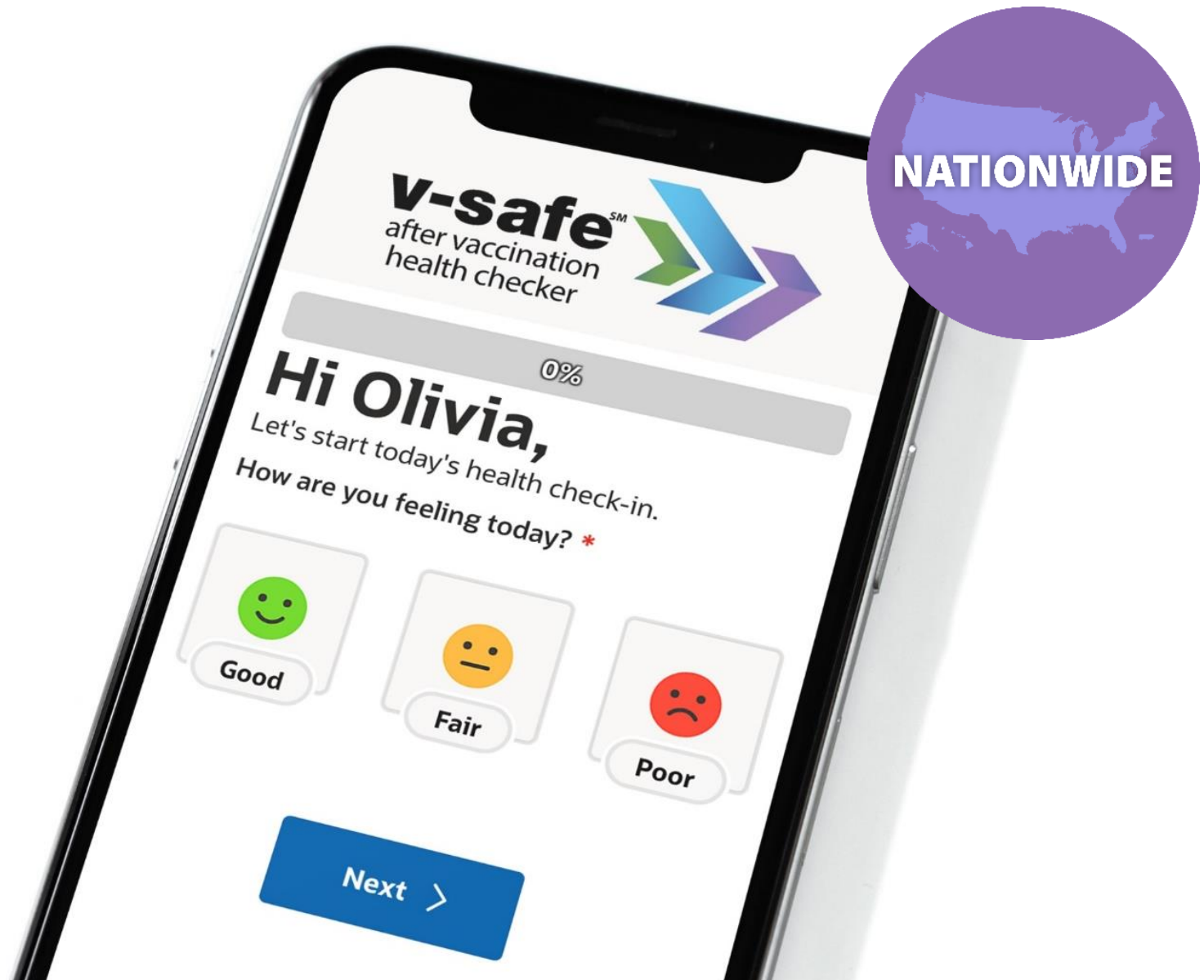
Topics

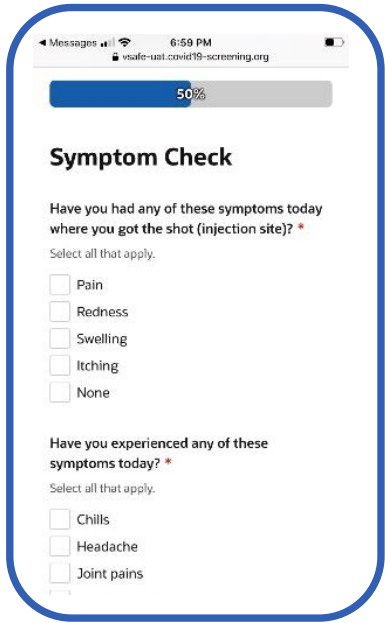
- V-safe update
- Vaccine Adverse Event Reporting System (VAERS) update
- Vaccine Safety Datalink (VSD) update
- Clinical Immunization Safety Assessment (CISA) Project update
- COVID-19 vaccine safety in pregnancy

Smartphone-based active safety monitoring



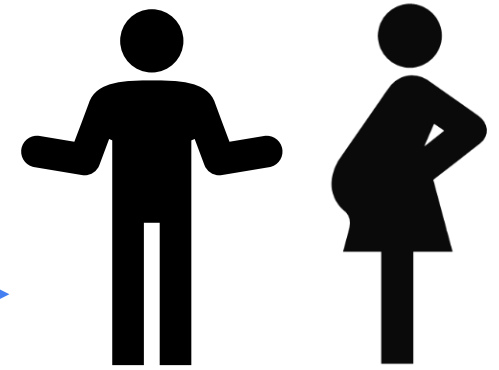
<http://cdc.gov/vsafe>





1. text message check-ins from CDC (daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 mo.)

vaccine recipient completes web survey*



Vaccine recipients

v-safeSM
after vaccination
health checker



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



* Selected web surveys capture information on pregnancy status



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>



Vaccine Adverse Event Reporting System (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 vaccines through February 16, 2021*

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

* 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, pain

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

Pfizer-BioNTech

Adverse event†	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†	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)

†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

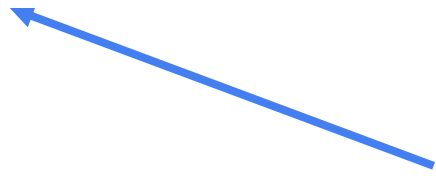
Tom T. Shimabukuro, MD, MPH, MBA; Matthew Cole, MPH; John R. Su, MD, PhD, MPH

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

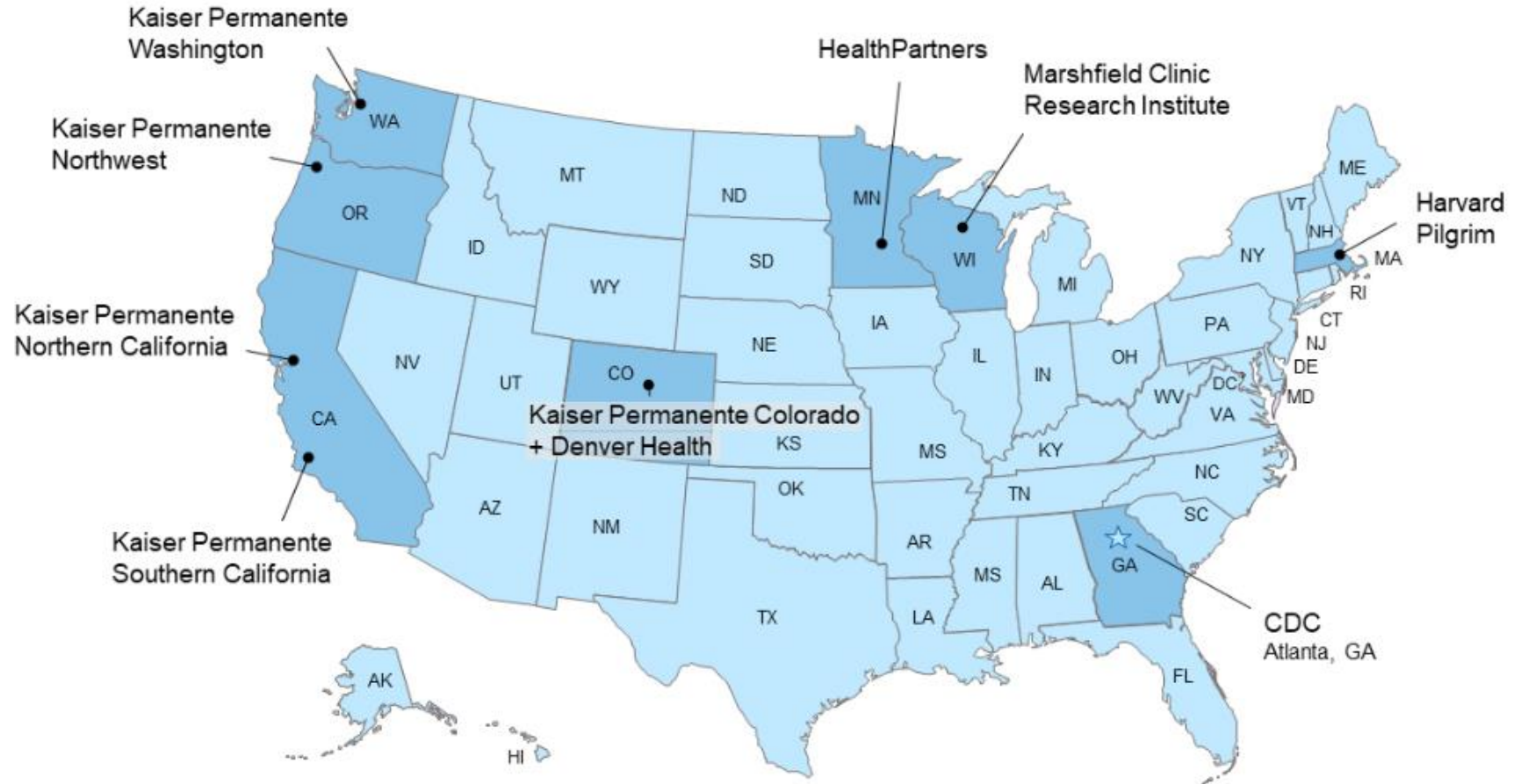
Characteristics	No. (%) of cases	
	Pfizer-BioNTech (n = 47)	Moderna (n = 19)
Age, median (range), y	39 (27-63) ^a	41 (24-63)
Female sex	44 (94)	19 (100)
Minutes to symptom onset, median (range)	10 (<1-1140 [19 h]) ^b	10 (1-45)
Symptom onset, min		
≤15	34 (76) ^b	16 (84)
≤30	40 (89) ^b	17 (89)
Reported history ^c		
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 ^d		
1	21 (45)	10 (52)
2	23 (49)	8 (43)
3	3 (6)	1 (5)
Anaphylaxis reporting rate (cases per million doses administered)	4.7	2.5





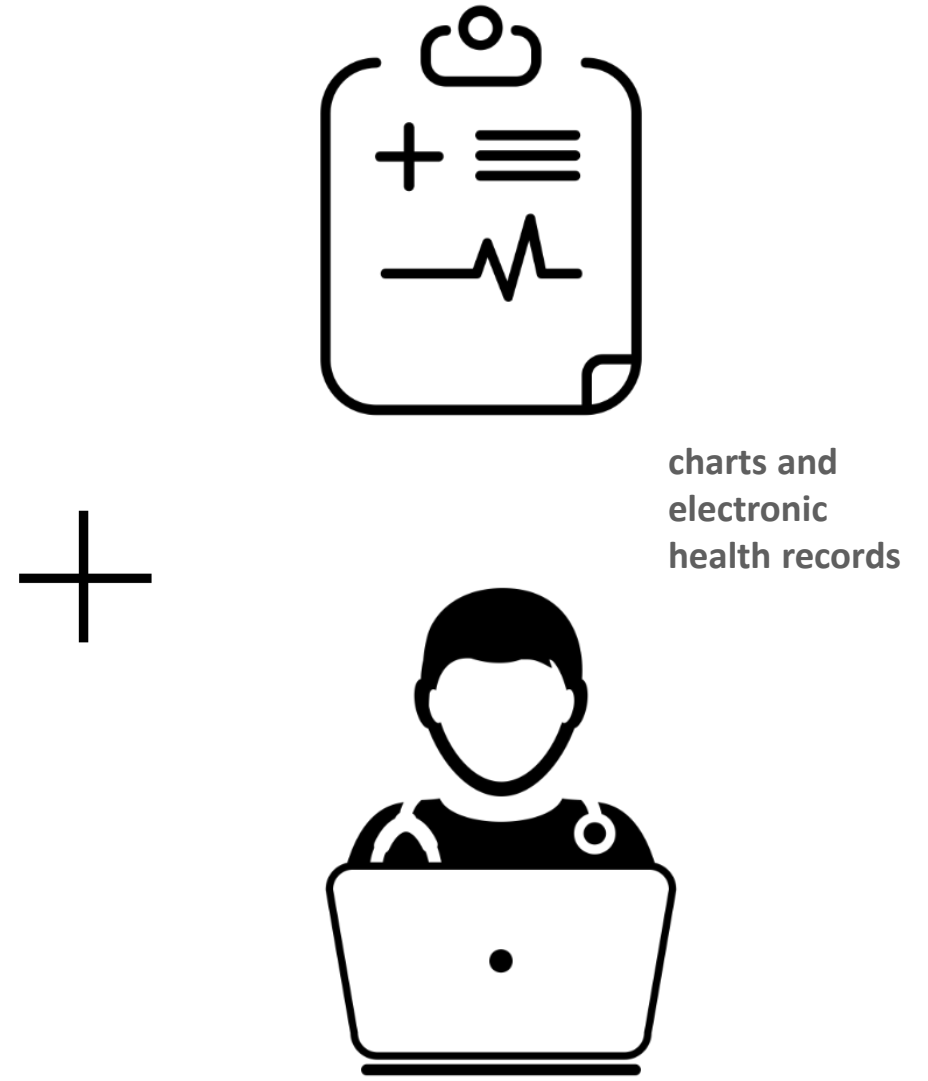
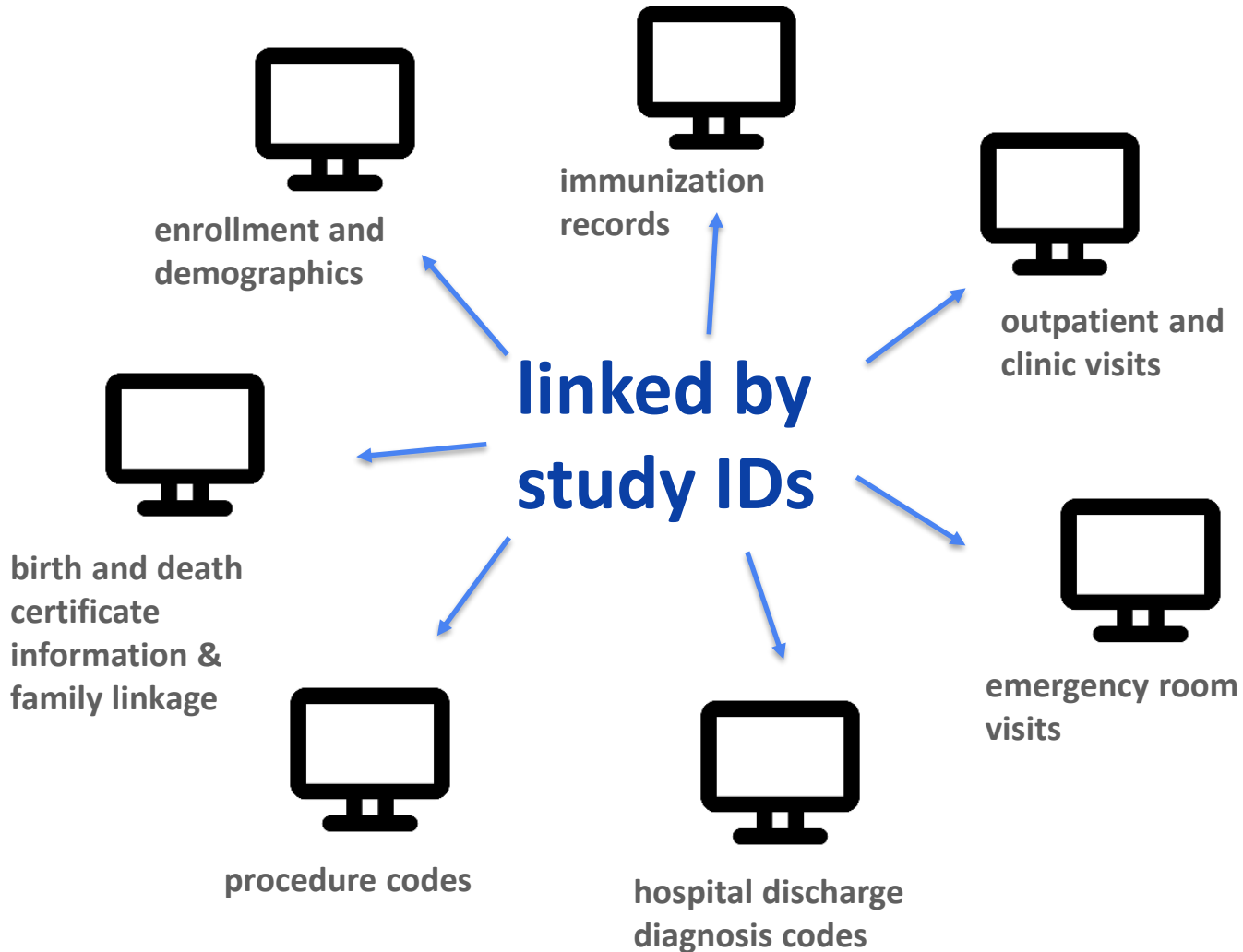
VSD

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

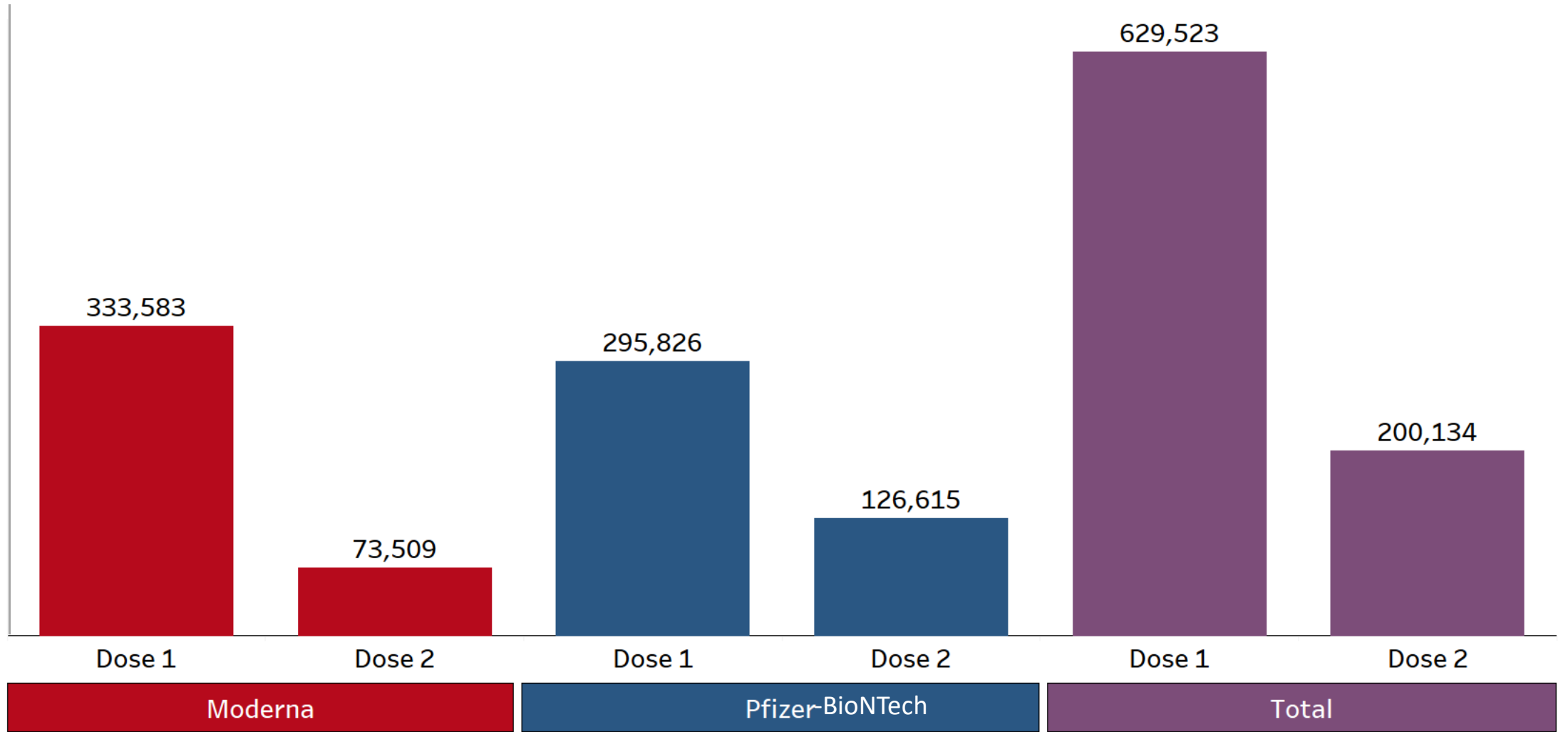
- Data are refreshed weekly
- Outcomes monitored are pre-specified (i.e., identified in advance)
- Includes methods to adjust for sequential testing
- A surveillance activity, not the same as an epidemiologic study
- Designed to detect statistically significant associations and statistical signals (values above specified statistical thresholds)
- 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*

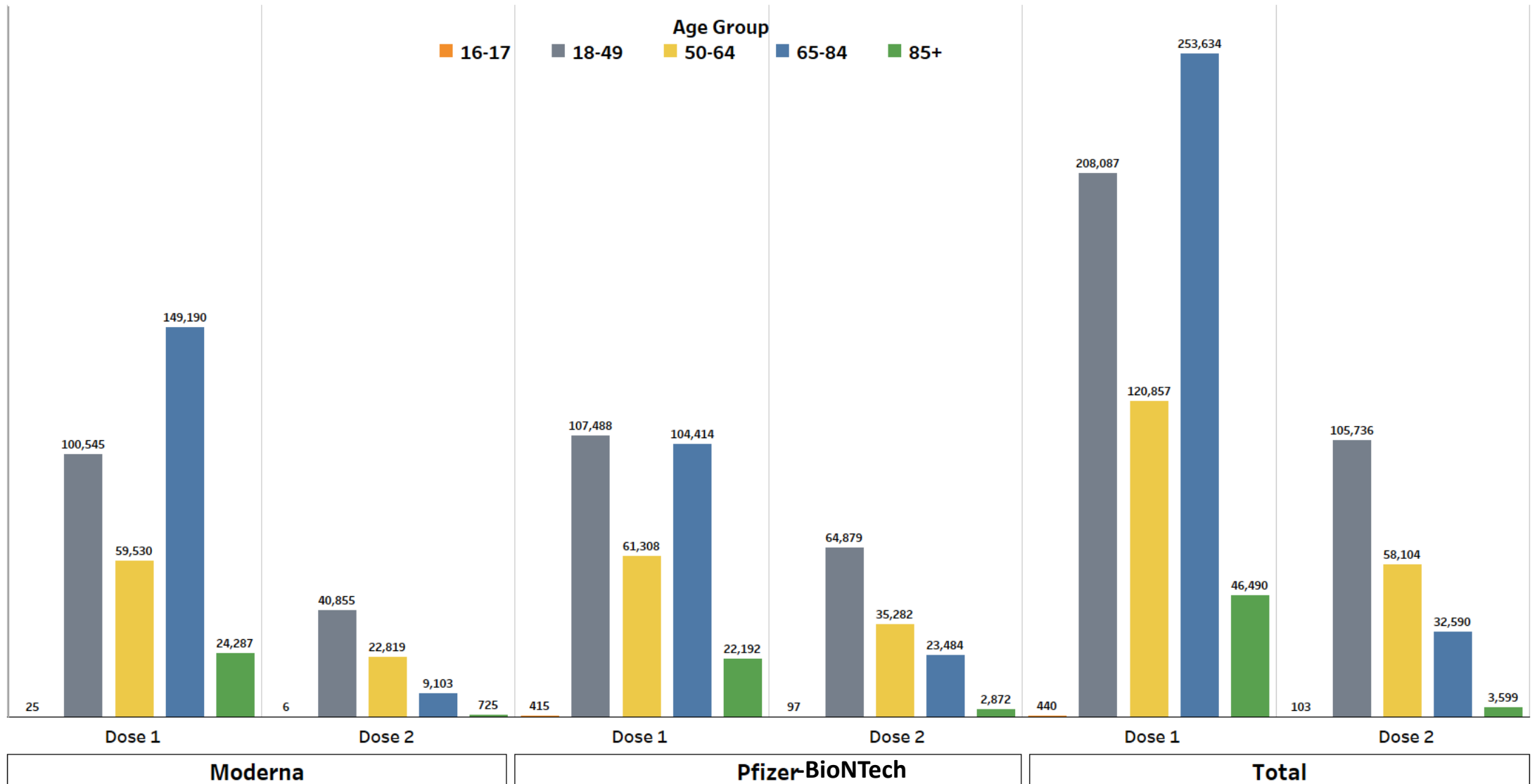
COVID-19 vaccine doses administered



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

VSD COVID-19 vaccine doses administered by manufacturer, age group, and dose number through February 13, 2021*

COVID-19
vaccine doses
administered



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

Preliminary results of the VSD **unvaccinated concurrent comparator** analysis for COVID-19 vaccine safety after either dose of any mRNA vaccine as of February 13, 2021

VSD Rapid Cycle Analysis prespecified outcomes for COVID-19 vaccines	Concurrent comparator analysis	Risk interval	Events in vaccinated	Adjusted expected events in risk interval
Acute disseminated encephalomyelitis	Unvaccinated	1-21 days	0	0
Acute myocardial infarction	Unvaccinated	1-21 days	23	26.0
Acute respiratory distress syndrome	Unvaccinated	N/A	0	N/A
Anaphylaxis	Unvaccinated	0-1 days	20	N/A
Appendicitis	Unvaccinated	1-21 days	31	23.6
Bell's palsy	Unvaccinated	1-21 days	21	20.3
Convulsions/seizures	Unvaccinated	1-21 days	10	9.6
Disseminated intravascular coagulation	Unvaccinated	1-21 days	1	1.1
Encephalitis/myelitis/encephalomyelitis	Unvaccinated	1-21 days	1	.1
Guillain-Barré syndrome	Unvaccinated	1-21 days	1	.6
Thrombotic thrombocytopenic purpura	Unvaccinated	1-21 days	0	0
Immune thrombocytopenia	Unvaccinated	1-21 days	1	1
Kawasaki disease	Unvaccinated	1-21 days	0	0
MIS-C and MIS-A	Unvaccinated	N/A	0	N/A
Myocarditis/pericarditis	Unvaccinated	1-21 days	2	2.1
Narcolepsy and cataplexy	Unvaccinated	N/A	2	N/A
Stroke, hemorrhagic	Unvaccinated	1-21 days	8	10
Stroke, ischemic	Unvaccinated	1-21 days	41	38.8
Transverse myelitis	Unvaccinated	1-21 days	0	0
Venous thromboembolism	Unvaccinated	1-21 days	26	26.3
Pulmonary embolism (subset of VTE)	Unvaccinated	1-21 days	20	21.0

- No statistically significant increased risks detected for any prespecified outcomes

Preliminary results of the VSD **sequential vaccinated concurrent comparator** analysis for COVID-19 vaccine safety after either dose of any mRNA vaccine as of February 13, 2021

- No statistical signals detected

VSD Rapid Cycle Analysis prespecified outcomes for COVID-19 vaccines*	Concurrent comparator analysis	Risk interval	Events in risk interval	Adjusted expected events in risk interval	Statistical signal (Y/N)
Acute myocardial infarction	Vaccinated	1-21 days	21	30.8	N
Appendicitis	Vaccinated	1-21 days	25	53.5	N
Bell's palsy	Vaccinated	1-21 days	17	23.1	N
Convulsions/seizures	Vaccinated	1-21 days	10	9.4	N
Disseminated intravascular coagulation	Vaccinated	1-21 days	1	0	N
Immune thrombocytopenia	Vaccinated	1-21 days	1	0	N
Myocarditis/pericarditis	Vaccinated	1-21 days	2	0	N
Stroke, hemorrhagic	Vaccinated	1-21 days	7	0	N
Stroke, ischemic	Vaccinated	1-21 days	37	43.5	N
Venous thromboembolism	Vaccinated	1-21 days	23	12.4	N
Pulmonary embolism (subset of VTE)	Vaccinated	1-21 days	19	0	N

* Only includes outcomes with events in the risk window

VSD RCA next steps – next analyses

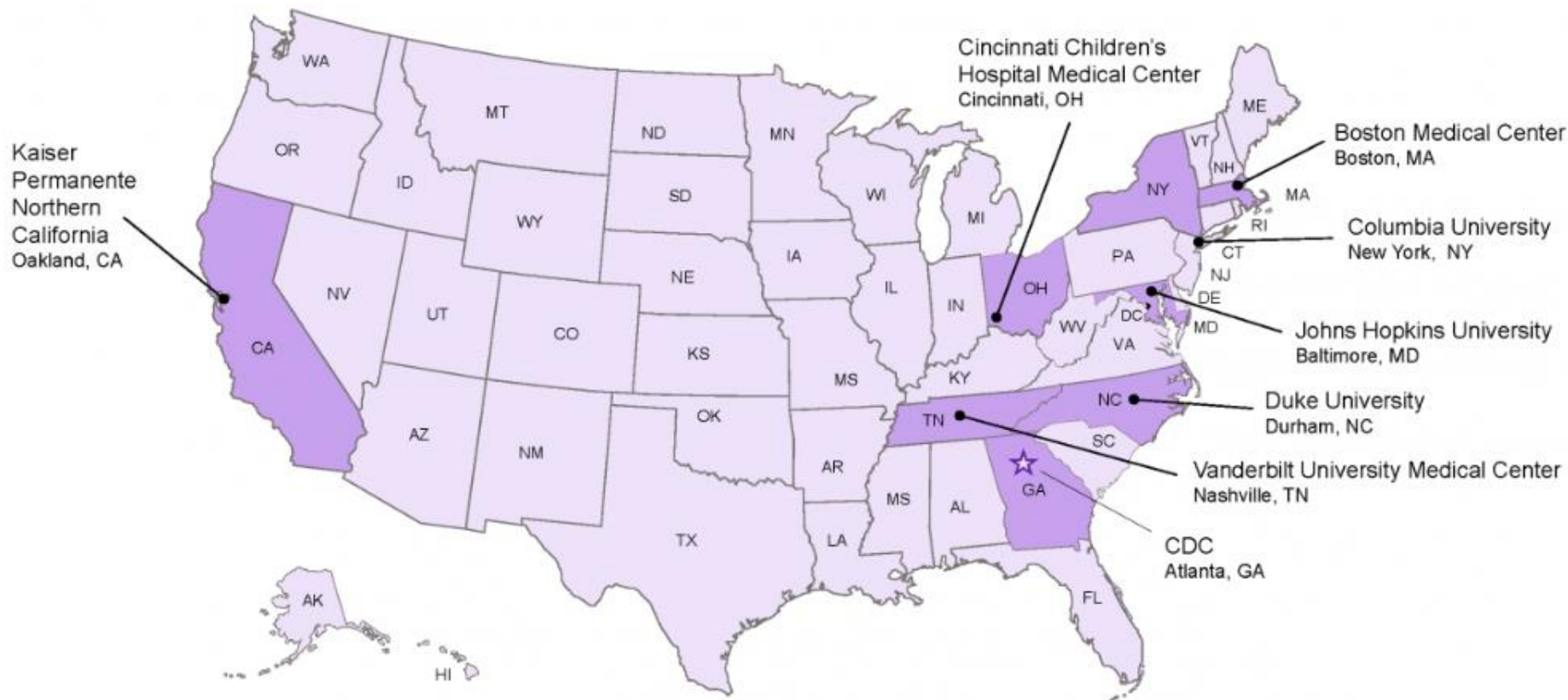
- Dose-specific analyses
- Product-specific analyses
- Analyses for two risk intervals 1-21 and 1-42 days
- Historical comparator analysis



CISA

Clinical Immunization Safety Assessment (CISA) Project

7 participating medical research centers with vaccine safety experts



- clinical consult services[†]
- clinical research

[†]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[†]
 - (1) about an individual patient(s) residing in the United States
 - (2) 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 vaccines 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



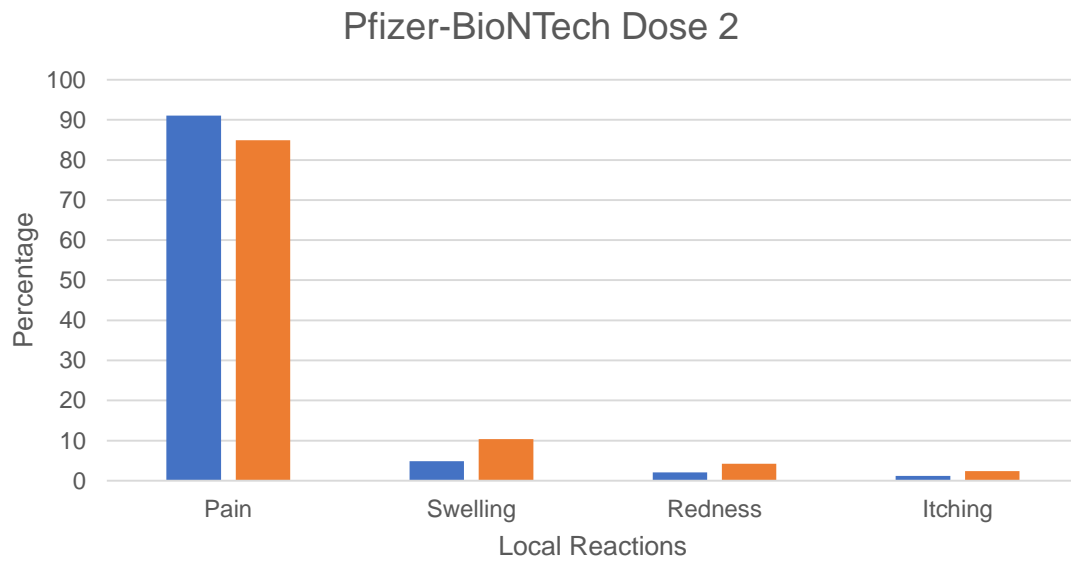
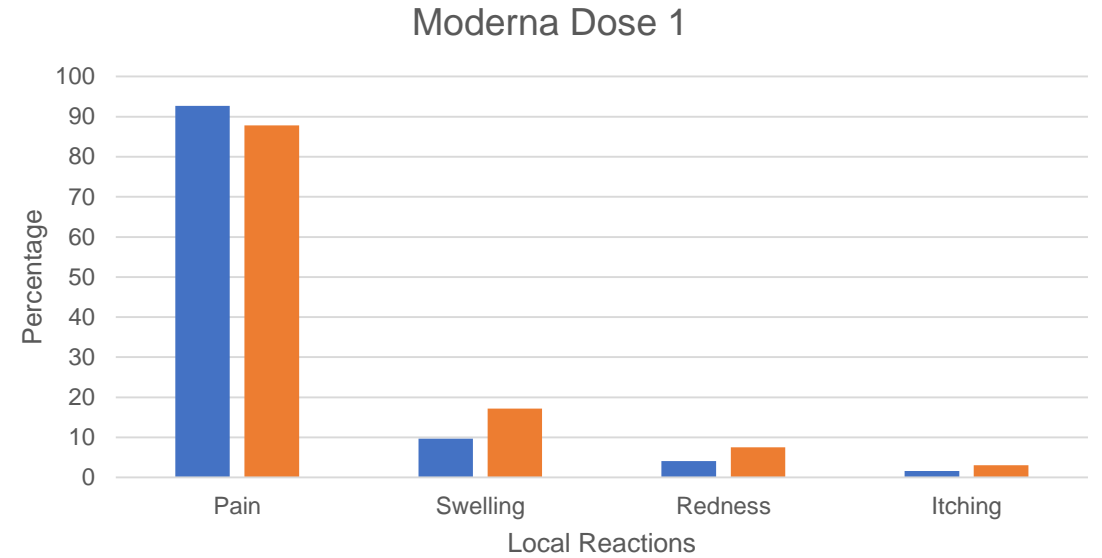
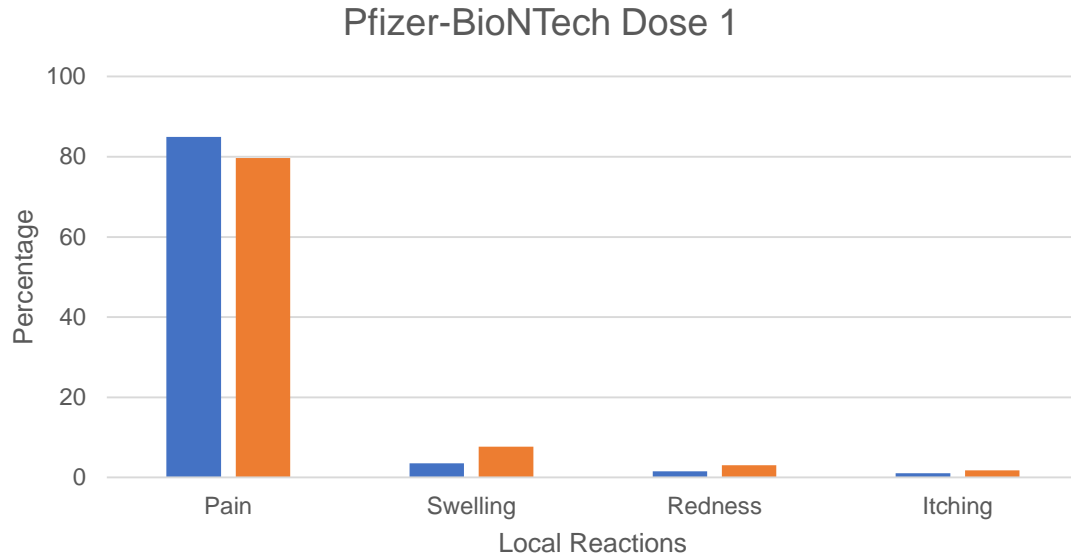
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Pregnancies reported to v-safe†	16,039	14,455	30,494

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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*

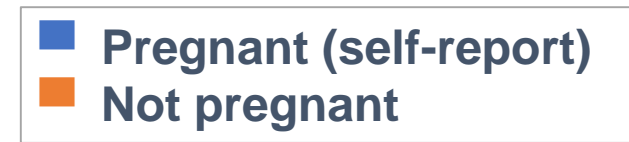
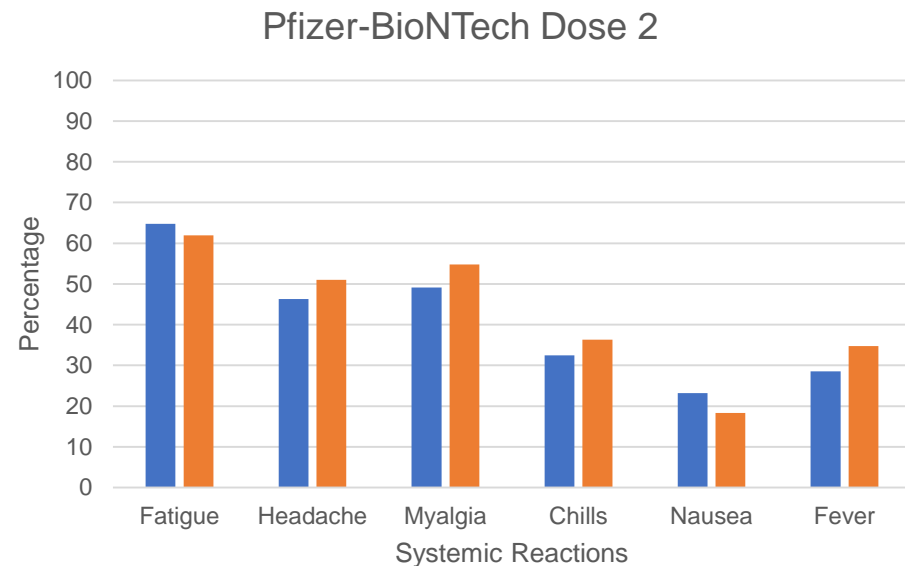
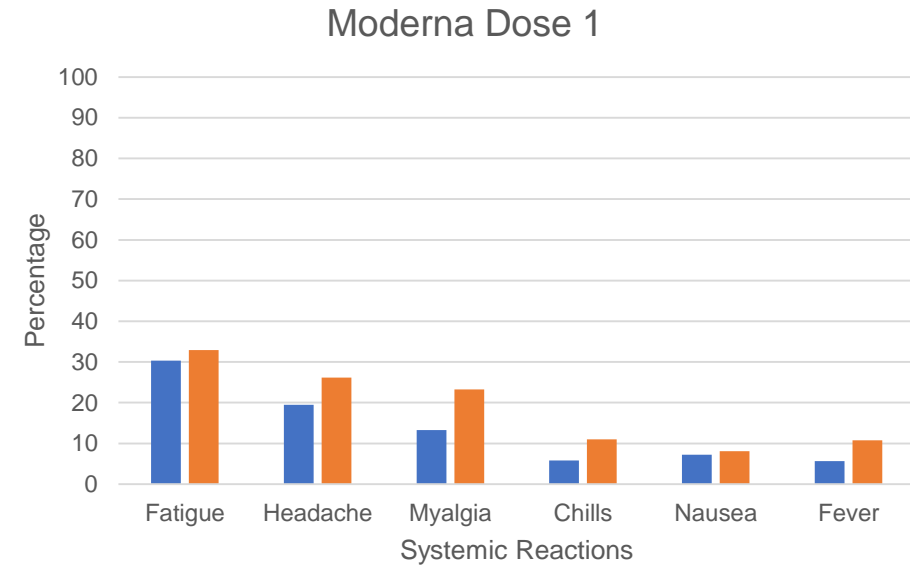
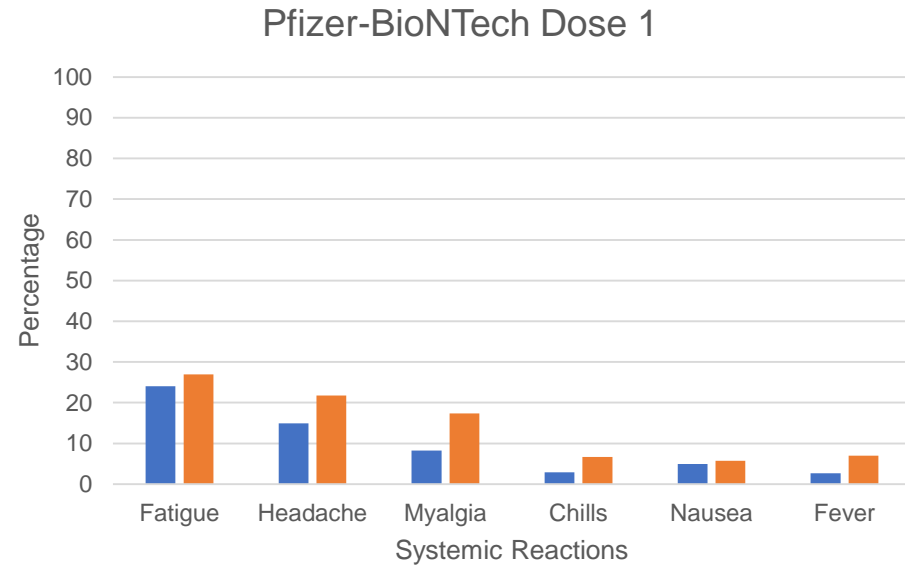


■ Pregnant (self-report)
■ Not pregnant



* 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*



* 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†
- Outcomes of interest include miscarriage and still birth, 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

† 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†	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

† 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
Pregnancy outcome		
Miscarriage (<20 weeks)	26%	15% [†]
Stillbirth (≥ 20 weeks)	0.6%	1%
Pregnancy complications		
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension [§]	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%
Neonatal		
Preterm birth	10.1%	10%
Congenital anomalies [‡]	3%	4%
Small for gestational age [^]	3-7%	4%
Neonatal death	0.38%	0%

* Sources listed on slide 33; [†] 93% of these were pregnancy losses <13 weeks of age; [§] Pre-eclampsia or gestational hypertension diagnosed during pregnancy and/or during delivery; [‡] Congenital anomalies (overall) diagnosed after delivery only; [^] Birthweight 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)
Trimester of pregnancy at time of vaccination	n (%)
First (0-13 weeks)	60/118 (51)
Second (14-27 weeks)	36/118 (31)
Third (28+ weeks)	22/118 (19)
Vaccine	
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 (%)
Pregnancy/neonatal specific conditions	42 (27)
Spontaneous abortion/miscarriage [†]	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
Non-pregnancy specific adverse events (top 10)	
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)	112 (73)

* 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

- Vaccine Safety Datalink (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
- Clinical Immunization Safety Assessment (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 pre-authorization 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

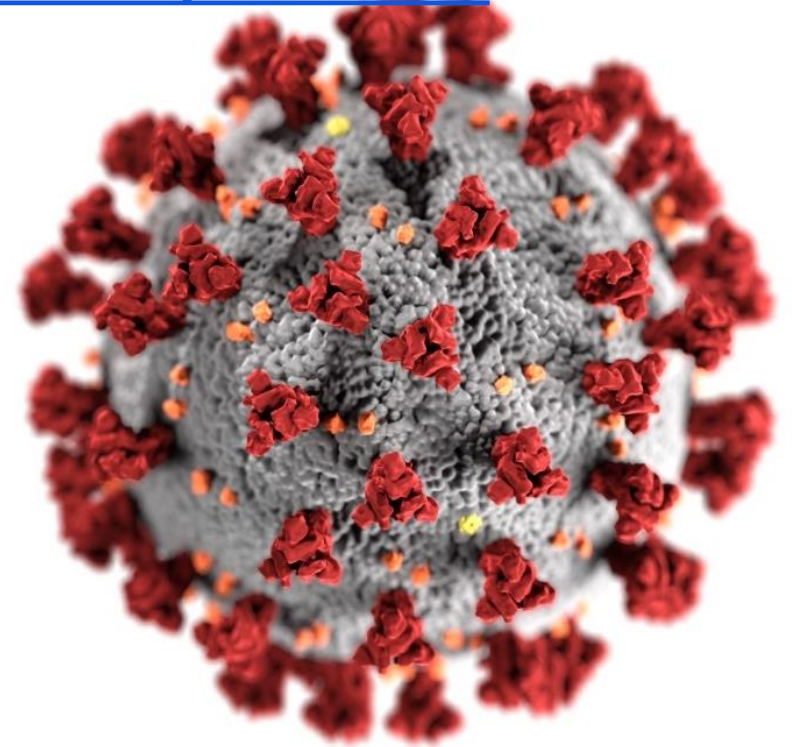
Office of Biostatistics and Epidemiology

Vaccine Task Force Communications

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

COMMUNICATION RESOURCES PAGE!

Bookmark it & check frequently for updates.



March, 2021



[cdc.gov/coronavirus](https://www.cdc.gov/coronavirus)

NEJM—March 3, 2021

An Uncertain Public — Encouraging Acceptance of Covid-19

Gillian K. SteelFisher, Ph.D., Robert J. Blendon, Sc.D., and Hannah Caporello, B.A.

We also believe that clinical physicians, rather than pharmaceutical companies, political leaders, or even medical scientists, should be at the fore of education and outreach strategies. Featuring clinicians in messaging is particularly important given that many people will not see their own physician when making vaccination decisions: current vaccine policy and cold-chain logistics mean that people will largely be attending mass-vaccination clinics.



Communication Goals and Objectives

Communication efforts established to support [the President's goal of 150M shots in 100 days](#) by:

- **Increasing acceptance, confidence, and uptake of the COVID vaccine through:**
 - Information that is timely; clear, culturally and linguistically appropriate, accurate, relevant, and actionable
- **Boosting and maintaining trust:**
 - In CDC's vaccine messaging through third party validators
 - With a special emphasis on medical providers, governmental entities and impacted communities (especially those communities that have historically had harmful experiences with providers and/or government)
- **Promoting existing CDC COVID-19 vaccine information, resources, and recommendations**



Key Components of CDC's Communication Work

- Research and evaluation
- Crisis & Emergency Risk Communication (CERC)
- Outreach to populations disproportionately affected by COVID-19
- Professional education and engagement
- Vaccine safety and effectiveness messaging
- Responding to public inquiries
- Supporting CDC vaccine programs
 - COVID Data Tracker
 - Pharmacy Partnership for Long-Term Care Program
 - Federal Retail Pharmacy Program
 - Vaccine Administration Management System (VAMS)



Why Do We Need to Reinforce Confidence in COVID-19 Vaccines?

- **71%** of the general public said they would receive a COVID-19 vaccine

(Data from December 2020 KFF poll)

Factors weighing on acceptance:

- What are the side effects?
- How well does it work?
- How safe is it?
- How much does it cost?



COVID-19 vaccine more acceptable if:

- Healthcare team said it was safe
- No costs to the individual
- Would facilitate getting back to school and work
- They could get it easily



Tyson, A, Johnson, C, & Funk, C. (2020, September 17). *U.S. Public Now Divided Over Whether to Get COVID-19 Vaccine*. Pew Research Center. <https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/>

Jackson, C., & Newall, M. (2020, September 29). *Despite COVID-19 spike, few individual behaviors are changing*. Ipsos. <https://www.ipsos.com/en-us/news-polls/axios-ipsos-coronavirus-index>

L



Vaccinate with Confidence

CDC's 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.

- ✓ Communicate transparently about the process for authorizing, approving, making recommendations for, monitoring the safety of, distributing, and administering COVID-19 vaccines, including data handling.
- ✓ Provide regular updates on benefits, safety, side effects and effectiveness; clearly communicate what is not known.
- ✓ Proactively address and mitigate the spread and harm of misinformation via social media platforms, partners, and trusted messengers.

Empower Healthcare Personnel

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

- ✓ Engage 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.

Engage Communities & Individuals

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

- ✓ Empower vaccine recipients to share their personal stories and reasons for vaccination within their circles of influence.
- ✓ Work with health departments and national partners to engage communities around vaccine confidence and service delivery strategies, including adaptation of vaccination sites to meet community needs.
- ✓ Collaborate with trusted messengers—such as faith-based and community leaders—to tailor and share culturally relevant messages and materials with diverse communities.

*Personnel = All staff working in healthcare settings, including physicians, PAs/NPs, nurses, allied health professionals, pharmacists, support staff, and community health workers

Target Audiences

Primary Audiences

- Nurses
- Long-term care facility staff
- K-12 schoolteachers and staff

Secondary Audiences

- Rural Americans
- Black Americans
- Latinx populations



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 it is **your turn**.
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**.



Using Communications to Reach At-Risk Populations

- **Culturally appropriate materials**
 - Low literacy
 - Multiple languages
 - Images that reflect audience
- **Channels of distribution**
 - Capitalize on diverse partners' channels to reach audiences
 - Federal, NGOs, and community partners

You can address information gaps and build vaccine confidence by clear, consistent communication.

Ahora está disponible una vacuna segura y eficaz contra el COVID-19.

¡Te aplicaste la vacuna? ¿Tuviste miedo?

¡No te vi para nada ayer! ¿Dónde estabas?

Trabajé tarde en la guardería infantil. Después del trabajo, me fui directo al centro médico para aplicarme la vacuna contra el COVID-19.

Como estaba un poquito nerviosa, llamé a mi hermano. Él es médico y trabaja en el centro de salud familiar.

Me dijo que podría tener el brazo dolorido, cansancio, escalofríos o una fiebre leve.

No durarán mucho, tan solo unos días, y es un signo de que la vacuna

United Way

I GOT MY COVID-19 VACCINE!

Protect From COVID-19.

Getting a COVID-19 vaccine adds one more layer of protection. www.cdc.gov

JoAnna Mendoza Retweeted
CDC @CDCgov · Feb 23
Community orgs: You play an important role in teaching your community about #COVID19 vaccines. CDC's new toolkit has the tools you need to educate community members about COVID-19 vaccines and address their questions and concerns.
See it here: bit.ly/3tSvllQ

CORONAVIRUS DISEASE 2019 (COVID-19)

cdc.gov/coronavirus

Liked by 96abrown and others
nflalumni A message from @profootballhof DB @rodwoodsonhof
Not even the @nfl best can defend COVID alone! @nflalumnihealth teamed up with @cdcgov to encourage you to #SleeveUp and get vaccinated when it's available to you. To check your vaccine eligibility visit <https://bit.ly/2gVYGz0>.
#NFLAlumni #CDC #COVID #SleeveUp #MaskUp #GetVaccinated #CaringforOurOwn



Communication Strategy In Action: Reaching Hesitant Healthcare Workers

29% of healthcare workers nationwide hesitant to receive the vaccine over concerns of potential side effects*.

Proposed outreach and research to healthcare workers includes:

- In-depth interviews and focus groups to identify reasons for declining vaccination thus far and how to overcome them
- Presenting vaccination as a public benefit to others
- Utilizing or repackaging existing materials from CDC and Ad Council
- Utilizing social media platforms such as LinkedIn
- Utilizing trusted peers and medical leaders to endorse the vaccines
- Partnering with allied health organizations, such as American College of Nurse Practitioners, American Academy of Nurses, American Academy of Physician's Assistants, National Healthcare Workers Association



*Kaiser Family Foundation COVID-19 Vaccine Monitor: December 2020

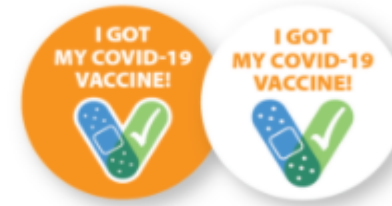
Existing Resources





COVID-19 Vaccine: Helps protect you from getting COVID-19

Get a COVID-19 vaccine, wear a mask, stay at least 6 feet apart, avoid crowds, and wash your hands to protect against COVID-19.



QUESTIONS & ANSWERS

FOR HEALTHCARE WORKERS

Getting Ready for Your COVID-19 Vaccine

Does it work?

Is it safe?

Are there side effects?

Do I need the vaccine if I've had COVID-19?

When can I stop wearing a mask and be around others again?

[WHAT YOU NEED TO KNOW >](#)

How Do I Get a Vaccine?

CDC makes recommendations for [who should get the vaccine first](#), then each state makes its own plan.

Choose your state or territory below to find your health department:

Select State / Territory ▾



COVID-19 Vaccine Communication Toolkits

- Key messages
- Frequently asked questions
- Slide deck
- Plain language fact sheet in several languages
- “I got my COVID-19 vaccine!” stickers
- Customizable newsletter content
- Customizable letters
- Posters
- Social media images and sample messages
- Fotonovela



Vaccination Communication Toolkit

For Medical Centers, Clinics, Pharmacies, and Clinicians

Build confidence about COVID-19 vaccination among your healthcare teams and other staff.



Recipient Education Toolkit

For Healthcare Professionals and Pharmacists

Educate vaccine recipients about the importance of COVID-19 vaccination.



Long-Term Care Facility (LTCF) Vaccination Toolkit

For LTCF Administrators and Leadership

Prepare staff, residents, and their families for COVID-19 vaccination in LTCFs.



Essential Worker Vaccination Toolkit

For Employers of Essential Workers

Help plan for and encourage COVID-19 vaccination in the workplace.



Community-Based Organization (CBO) Vaccination Toolkit

For Staff of Organizations Serving Communities

Educate communities about the benefits of COVID-19 vaccination, and address common questions and concerns.

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



COVID-19 Vaccine Communication Toolkit Materials



COVID-19 Vaccine Information

COVID-19 and Vaccine Basics



Key facts about COVID-19 vaccination



Getting vaccinated can help prevent getting sick with COVID-19



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



COVID-19 vaccines **cannot** give you COVID-19



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

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/about-vaccines/vaccine-myths.html>

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

Slides

Key Messages about COVID-19 Vaccines

You can help stop the pandemic by getting a COVID-19 vaccine.

To stop this pandemic, we need to use all our prevention tools. Vaccines are one of the most effective tools to protect your health and prevent disease. Vaccines work with your body's natural defenses so your body will be ready to fight the virus if you are exposed (also called "immunity").

In the coming months, doctors' offices, retail pharmacies, hospitals, and clinics will offer COVID-19 vaccine. Your doctor's office or local pharmacy may have contacted you with information about their vaccine plans. If not, you can contact your state or local health department (<https://www.cdc.gov/publichealthgateway/healthdirectories/index.html>) to find out when and where vaccines will be available in your community.



COVID-19 vaccines are safe and effective

The U.S. vaccine safety system makes sure that vaccines are as safe as possible. Learn how the federal government ensures the safety of COVID-19 vaccines (<https://www.cdc.gov/coronavirus/2019-ncov/vaccine-safety/safe.html>).

CDC has developed a new tool, v-safe (<https://www.cdc.gov/coronavirus/2019-ncov/vaccine-safety/safe.html>), to help us quickly find any safety issues with COVID-19. Download the v-safe app after you are vaccinated!

Studies show that COVID-19 vaccines are very effective at keeping you from getting sick with COVID-19. Experts also think that getting a COVID-19 vaccine may help keep you from getting sick with COVID-19, even if you do get COVID-19. These vaccines cannot give you the disease.

Key messages and FAQs

Frequently Asked Questions about the COVID-19 Vaccine

1 Why should I get vaccinated for COVID-19?

COVID-19 can cause serious illness or even death. There is no way to know how COVID-19 will affect you. And if you get sick, you could spread the disease to friends, family, and others around you. All COVID-19 vaccines currently available in the United States have been shown to be highly effective at preventing COVID-19 disease. Even if you still get infected after you get vaccinated, the vaccine may prevent serious illness.



2 Can the vaccine give me COVID-19?

No, the vaccine does not cause COVID-19. None of the approved COVID-19 vaccines contain the virus that causes COVID-19. It does take a few weeks after vaccination for your body to build up antibodies to protect you from the virus. That means it's possible you could be infected with the virus that causes COVID-19 just before or just after getting the vaccine and still get sick.

3 Will the shot hurt or make me sick?

Some people might get sore muscles, feel tired, or have mild fever after getting the vaccine. These reactions mean the vaccine is working to help teach your body how to fight COVID-19 if you are exposed. For most people, these side effects will last no longer than a few days. If you have any concerns, call your doctor or nurse.

4 Why do I need two COVID-19 shots?

Some COVID-19 vaccines need two shots. The first shot gets your body ready. If you are told you need two shots, make sure that you get your second shot at the time you are told, to make sure you have full protection.

COVID-19 Vaccine Communication Toolkit Materials

Customizable COVID-19 Vaccine Content for Community-Based Organizations

Updated Feb. 12, 2021 Languages Print

Community-Based Organizations and Leaders can use the following materials to encourage COVID-19 vaccination. You can add your own logos and customize the text to make it appropriate for your organization.

Introductory letter

This letter can be sent to branches, chapters, or affiliates to encourage review and use of the toolkit materials.

Dear Community-Based Organization Leader:

Soon the communities you serve will have access to vaccines to help protect them against COVID-19. All COVID-19 vaccines currently available in the United States have been shown to be highly effective at preventing COVID-19. Vaccination is one of our many important tools to help stop the pandemic.

Some community members may be hesitant to get the vaccine. Before they agree to be vaccinated, they will want answers to their questions about the process for developing these vaccines and information about safety and effectiveness. Your organization can help inform communities about the vaccines and help people feel confident when they decide to get vaccinated.

This COVID-19 Vaccine Communication Toolkit for Community-Based Organizations was created by the Centers for Disease Control and Prevention (CDC) to help you provide clear, consistent, and credible information about COVID-19 vaccines to your communities. We encourage you to review and customize these materials.

- **Letter to members:** Customize this letter about COVID-19 vaccination to send to your members.
- **Newsletter content:** This short newsletter-style blurb can be widely distributed to share information on COVID-19 vaccines.
- **Key messages:** Use these key messages about COVID-19 vaccine to educate your communities.
- **Frequently Asked Questions (FAQs):** Use these to help answer questions about COVID-19 vaccine in your communities.
- **Slide deck:** These basic slides about COVID-19 vaccines are for virtual town halls or other informational meetings within your communities. You can use all or part of the set or also include

On this Page

[Introductory letter](#)

[Letter to members](#)

[Newsletter content](#)



Fotonovela



Vacunarte contra el COVID-19 añade una capa más de protección.

THE COVID-19 VACCINE HELPS PROTECT YOU & YOUR FAMILY.

A safe and effective vaccine to protect against COVID-19 is now available.

www.cdc.gov



Social Media

Customizable Content

COVID-19 Vaccine Communication Toolkit Materials

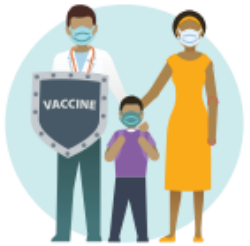
COVID-19 Vaccines

Vaccines (shots) are one of the tools we have to fight the COVID-19 pandemic.



To stop this pandemic, we need to use all of our prevention tools. Vaccines are one of the most effective tools to protect your health and prevent disease. Vaccines work with your body's natural defenses so **your body will be ready to fight the virus**, if you are exposed (also called immunity). Other steps, like wearing a mask that covers your nose and mouth and staying at least 6 feet away from other people you don't live with, also help stop the spread of COVID-19.

Studies show that COVID-19 **vaccines are very effective** at keeping you from getting COVID-19. Experts also think that getting a COVID-19 vaccine may help keep you from getting seriously ill even if you do get COVID-19. These vaccines cannot give you the disease itself.



The vaccines are safe. The U.S. vaccine safety system makes sure that all vaccines are as safe as possible. All the COVID-19 vaccines that are being used have gone through the same safety tests and meet the same standards as any other vaccines produced through the years. A system in place across the entire country that allows CDC to watch for safety issues and make sure the vaccines stay safe.



Different types of COVID-19 vaccines will be available. Most of these vaccines are given in two shots, one at a time and spaced apart. The first shot gets your body ready. The second shot is given at least three weeks later to make sure you have full protection. If you are told you need two shots, make sure that you get both of them. The vaccines may work in slightly different ways, but all types of the vaccines will help protect you.

Vacunas contra el COVID-19

Las vacunas son una de las herramientas que tenemos para luchar contra la pandemia del COVID-19.

COVID-19 疫苗

疫苗（注射）是我们抗击 COVID-19 疫情的手段之一。



为了遏制疫情蔓延，我们需要使用所有可用的预防手段。疫苗是保护健康和预防疾病的最有效手段之一。疫苗将与您的身体自然防御系统一起工作，因此，如果您暴露在病毒下，您的身体将准备好对抗病毒（也称为免疫）。其他措施，如戴口罩遮住口鼻，与其他不住在一起的人保持至少 6 英尺的距离，也有助于阻断 COVID-19 的传播。

研究表明，COVID-19 疫苗在防止您感染 COVID-19 方面非常有效。专家还认为，即使您感染了 COVID-19，接种 COVID-19 疫苗也可以帮助您避免患上严重疾病。这些疫苗本身不能给您带来疾病。

Alternative Languages: [Arabic](#) | [Spanish](#) | [Korean](#) | [Russian](#) | [Simplified Chinese](#) | [Tagalog](#) | [Traditional Chinese](#) | [Vietnamese](#)

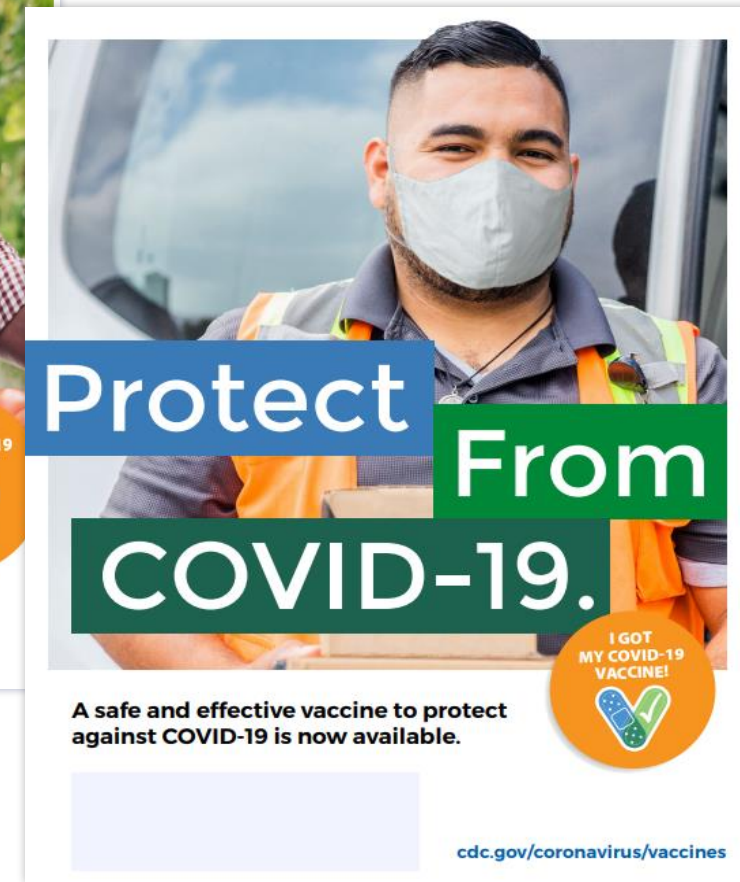
COVID-19 Vaccine Communication Toolkit Materials



Stickers

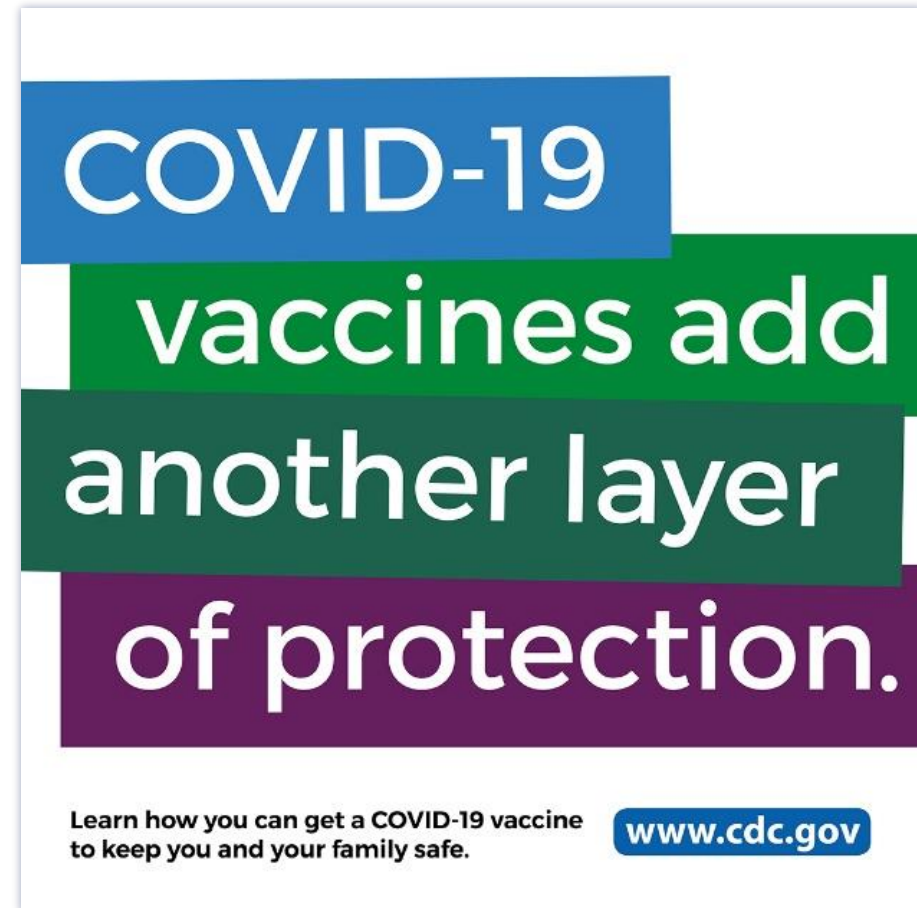


Posters



Upcoming Materials

- Health Department Toolkit
- Vaccine infographics
- Additional photos and posters
- Success story videos
- Matte articles
- How to guides



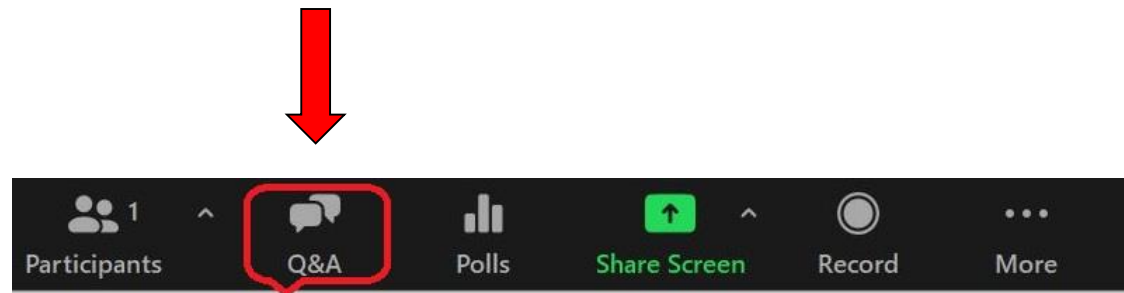
That website again....

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



Q&A

Please submit questions using the Q&A box located on the toolbar



Thank you for joining today's webinar!

Still have questions?

Email: nipinfo@cdc.gov

Visit: <https://www.cdc.gov/coronavirus/2019-nCoV/vaccines/resource-center.html>

For up-to-date information sign up for IAC's free weekly immunization newsletter, *IAC Express*

www.immunize.org/subscribe