Washington State Department of Health

COVID-19 VACCINE SAFETY AND VAERS REPORTING

November 18, 2021

Before We Start…

- All participants will be muted for the presentation.
- You may ask questions using the Q&A box, and questions will be answered at the end of the presentation.
- Continuing education is available for nurses, medical assistants, pharmacists, and pharmacy technicians attending the webinar or watching the recording. If you're watching in a group setting and wish to claim CE credit, please make sure you register for the webinar and complete the evaluation as an individual.
- You can find more information on our webinar page here: www.doh.wa.gov/YouandYourFamily/Immunization/ImmunizationNews/ImmunizationTraining/COVID19VaccineSafetyVAERSReportingWebinar

Continuing Education

- The planners and speakers of this activity have no relevant financial relationships with any commercial interests pertaining to this activity.
- Information about obtaining CEs will be available at the end of this webinar.

Continuing Education

- This continuing nursing education activity was approved by the Montana Nurses Association. MNA is accredited with distinction as a provider of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation. Upon successful completion of this activity, 1.0 contact hours will be awarded.
- This program has been granted prior approval by the American Association of Medical assistants (AAMA) for 1.0 administrative continuing education unit.
- This training was approved by the Washington State Pharmacy Quality Assurance Commission (PQAC) for pharmacist education. Upon successful completion of this activity, 1.0 credit hour of continuing education will be awarded.

COVID-19 Vaccine Safety and VAERS Reporting

WA State DOH Webinar
November 18th, 2021

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Objectives

- Describe current data on COVID-19 vaccine side effects and adverse events.
- Discuss and use various vaccine safety monitoring systems used to monitor for adverse events related to COVID-19 vaccination, including VAERS system and VAERS reporting.
- Use and share COVID-19 vaccine communication and health promotion resources

Outline

- Side effects and safety data
  - Booster doses
  - 5- to 11-year-olds
  - Myocarditis
- Vaccine Safety Monitoring Systems
  - VAERS and VAERS reporting
  - Other vaccine safety monitoring systems
- Resources for answering questions about vaccine safety

COVID-19 Vaccine Safety Data: Booster Doses

COVID-19 Vaccine Booster Doses

- Pfizer booster doses for certain populations recommended by CDC on September 24th, 2021
- CDC expanded booster eligibility, approved Moderna and Janssen boosters and heterologous boosters October 21st, 2021
- Approximately 26.1 million people in the US have received booster doses to date (1)

1. U.S. Administers 434.5 Million Doses of COVID-19 Vaccines – CDC, *US News and World Report* 11/10/21. Accessed November 12th, 2021. https://www.usnews.com/news/us/articles/2021-11-10/us-administers-4345-million-doses-of-covid-19-vaccines-cdc

Booster Doses: Reports to VAERS

Age group, years	n (%)
12–17	34 (1)
18–49	1,225 (25)
50–64	1,304 (26)
≥65	2,427 (49)
Total	**4,990**

- Median age 64 years

Sex	n (%)
Male	1,823 (37)
Female	3,153 (63)
Unknown	14 (<1)
Total	**4,990**

- Majority (63%) VAERS reports among women

Adapted from 10/26/21 CDC COCA Call: What Clinicians Need to Know about the Recent Updates to CDC's Recommendations for COVID 19 Boosters. https://emergency.cdc.gov/coca/calls/2021/callinfo_102621.asp

Reports to VAERS following dose 3 mRNA or dose 2 Janssen COVID-19 vaccination

Manufacturer	Non-serious reports	Serious reports*	Total reports
Pfizer-BioNTech	3,351 (95%)	160 (5%)	3,511
Moderna	1,325 (92%)	115 (8%)	1,440
Janssen	39 (100%)	0 (0%)	39
Total	**4,715 (94%)**	**275 (6%)**	**4,990**

- Regardless of manufacturer, ≥92% of reports non-serious

Adapted from 10/26/21 CDC COCA Call: What Clinicians Need to Know about the Recent Updates to CDC's Recommendations for COVID 19 Boosters. https://emergency.cdc.gov/coca/calls/2021/callinfo_102621.asp

* Per federal law, includes reports of hospitalization, prolongation of existing hospitalization, life threatening condition, permanent disability, congenital deformity or birth defect, or death.

Most frequently reported adverse events to VAERS following dose 3 mRNA or dose 2 Janssen COVID-19 vaccination, by seriousness

Serious* (n = 275)

Rank	Adverse event**	n (%)
1	Extra dose administered	40 (23)
2	Fever	38 (14)
3	Shortness of breath	37 (14)
4	Blood test	33 (12)
5	Fatigue	32 (12)

Non-serious (n= 4,715)

Rank	Adverse event**	n (%)
1	Interchange of vaccine products	1,110 (24)
2	Extra dose administered	969 (21)
3	Fever	764 (16)
4	Headache	697 (15)
5	Fatigue	665 (14)

Adapted from 10/26/21 CDC COCA Call: What Clinicians Need to Know about the Recent Updates to CDC's Recommendations for COVID 19 Boosters. https://emergency.cdc.gov/coca/calls/2021/callinfo_102621.asp

Includes data collected during August 12–October 10, 2021 for persons aged 12 years and older.

* Per federal law, includes reports of hospitalization, prolongation of existing hospitalization, life threatening condition, permanent disability, congenital deformity or birth defect, or death.

** Not mutually exclusive.

Reports of death to VAERS following dose 3 mRNA or dose 2 Janssen COVID-19 vaccination

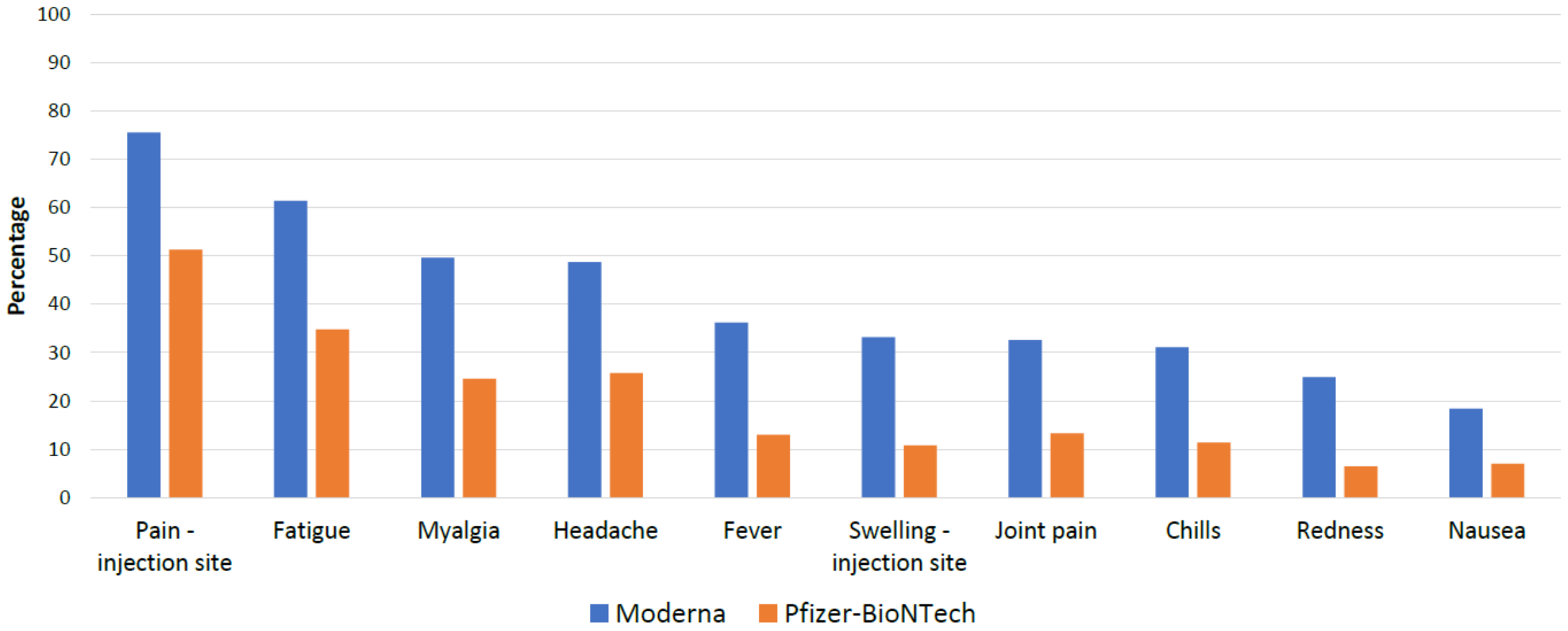
Preliminary impression of cause of death*	mRNA, dose 3
No cause specified	8
Found dead	4
Respiratory and/or cardiac arrest	3
Stroke	3
COVID-19 disease	3
Pneumonia; sepsis	2
Pulmonary embolism	2
Miscellaneous other†	5
Total	**30**

- Median age = 79 years (IQR: 69 – 88)
- Median time from third dose to death = 2 days (IQR: 0 – 9)

*Based upon physician review of initial report and available documentation, including death certificates.
†Cardiomyopathy, congestive heart failure, acute leukemia, renal failure/end stage renal disease, general decompensation/end stage disease.

Adapted from 10/26/21 CDC COCA Call: What Clinicians Need to Know about the Recent Updates to CDC's Recommendations for COVID 19 Boosters. https://emergency.cdc.gov/coca/calls/2021/callinfo_102621.asp

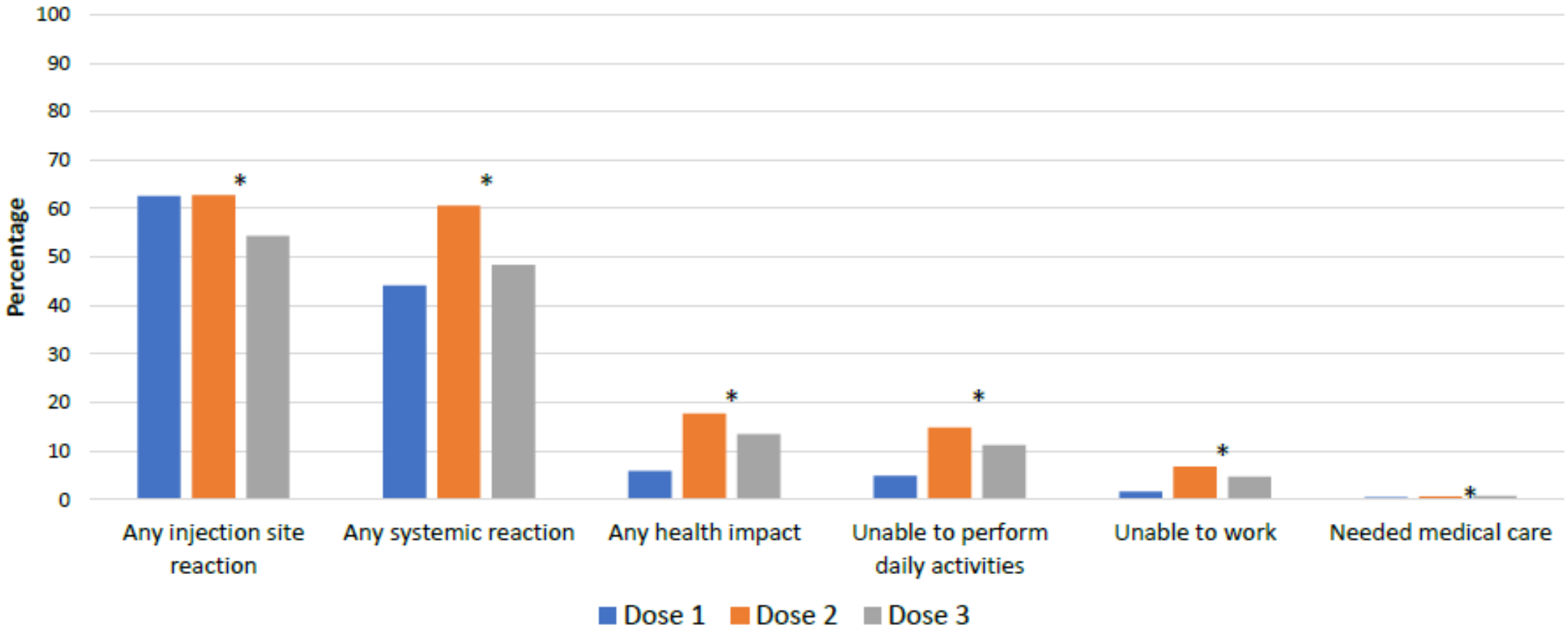
Top 10 solicited reactions reported at least once 0-7 days after dose 3 of Moderna or Pfizer-BioNTech vaccine



Includes 273,046 v-safe participants who completed at least one survey in the first week after additional dose, data collected during 8/12/21-10/10/21

Adapted from 10/26/21 CDC COCA Call: What Clinicians Need to Know about the Recent Updates to CDC's Recommendations for COVID 19 Boosters.
https://emergency.cdc.gov/coca/calls/2021/callinfo_102621.asp

Reactions and health impact events reported at least once in days 0-7 after Pfizer-BioNTech vaccination, by dose

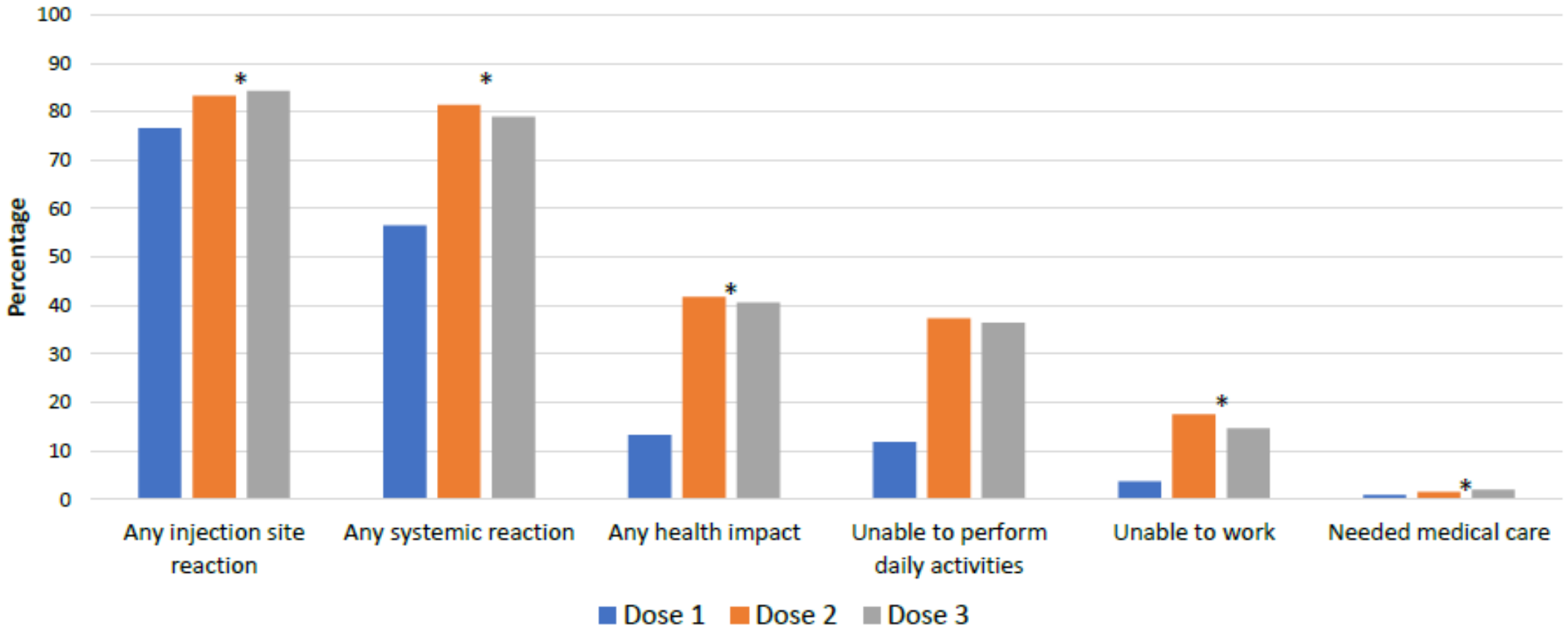


Includes 188,514 participants who completed at least one survey in the first week after each dose, data collected during August 12–October 10, 2021

* Dose 2 compared to dose 3: statistically significant difference (p-value <0.05) using multivariable generalized estimating equations model that accounted for the correlation between registrants and adjusted for demographic variables.

Adapted from 10/26/21 CDC COCA Call: What Clinicians Need to Know about the Recent Updates to CDC's Recommendations for COVID 19 Boosters. https://emergency.cdc.gov/coca/calls/2021/callinfo_102621.asp

Reactions and health impact events reported at least once in days 0-7 after Moderna vaccination, by dose



Includes 8,153 participants who completed at least one survey in the first week after each dose, data collected during August12–October 10, 2021

* Dose 2 compared to dose 3: statistically significant difference (p-value <0.05) using multivariable generalized estimating equations model that accounted for the correlation between registrants and adjusted for demographic variables.

Adapted from 10/26/21 CDC COCA Call: What Clinicians Need to Know about the Recent Updates to CDC's Recommendations for COVID 19 Boosters. https://emergency.cdc.gov/coca/calls/2021/callinfo_102621.asp

Booster Dose Safety Data: Summary

- No unexpected patterns of adverse events were identified
- ≥92% of VAERS reports following dose 3 of COVID-19 vaccination were non-serious
  - Vaccination errors and systemic symptoms were most commonly reported
- **Over 270,000 v-safe registrants reported an additional dose**
  - Most reported a primary mRNA vaccine series followed by dose 3 from the same manufacturer
  - For Pfizer-BioNTech, local and systemic reactions were reported less frequently following dose 3 than dose 2
  - For Moderna, local reactions were reported slightly more frequently and systemic reactions slightly less frequently following dose 3 than dose 2

Adapted from 10/26/21 CDC COCA Call:
What Clinicians Need to Know about the Recent Updates to CDC's Recommendations for COVID 19 Boosters.
https://emergency.cdc.gov/coca/calls/2021/callinfo_102621.asp

COVID-19 Vaccine Safety Data: 5- to 11-year-olds

Pfizer-BioNTech Pediatric COVID-19 Vaccine BNT162b2: Study Overview: 5 to <12 Years

Phase 1

48 PARTICIPANTS

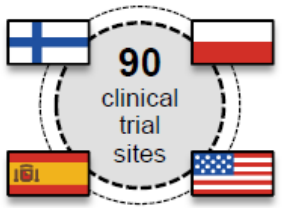
5 to <12 yrs

Identification of preferred dose level(s)

10 µg	20 µg	30 µg

Phase 2/3

2:1 randomization



~1500 BNT162b2

750 placebo

~Additional 1500 BNT162b2 and 750 placebo recipients most with ≥2 weeks post dose 2 safety data

Non-inferior immune responses have been established to infer vaccine efficacy

Children 5 to <12 years of age	Compared to	16–25-year-olds from the pivotal Phase 3 study

Although not required for EUA approval, COVID-19 surveillance was conducted permitting evaluation of vaccine efficacy

From ACIP 11/2/21 Presentation: Pfizer-BNT162b2 use in children aged 5-11 years, Dr. A Gurtman https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

Demographics for 5 to <12 Year Olds

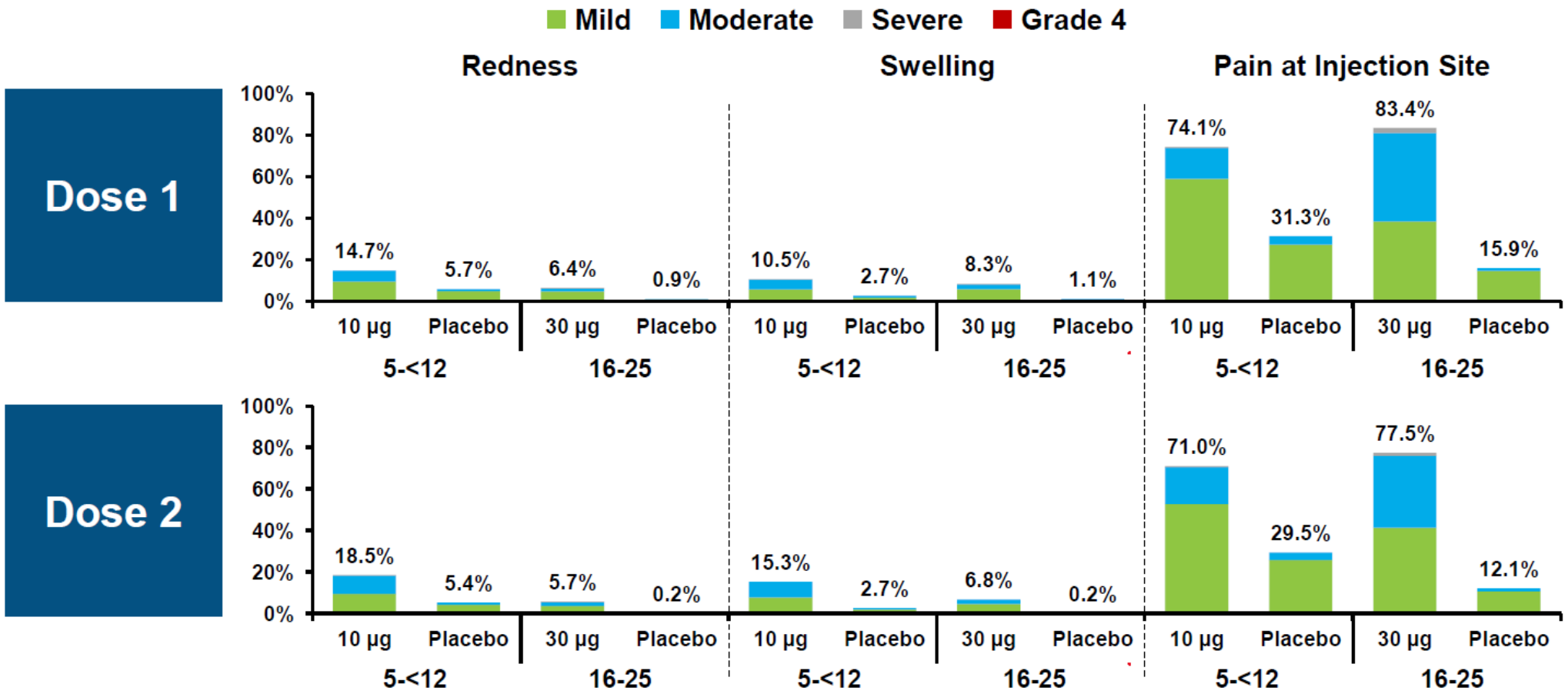
Phase 2/3 Safety Population Initial Enrollment Group (N=2268)

		BNT162b2 (10µg) N=1518	Placebo N=750
Sex, n (%)	Male	799 (52.6)	383 (51.1)
	Female	719 (47.4)	367 (48.9)
Race, n (%)	White	1204 (79.3)	586 (78.1)
	Black or African American	89 (5.9)	58 (7.7)
	American Indian or Alaska native	12 (0.8)	3 (0.4)
	Native Hawaiian or other Pacific Islander	<1%	<1%
	Asian	90 (5.9)	47 (6.3)
	Multiracial	109 (7.2)	49 (6.5)
	Not reported	<1%	<1%
Ethnicity, n (%)	Hispanic/Latino	319 (21.0)	159 (21.2)
	Non-Hispanic/non-Latino	1196 (78.8)	591 (78.8)
	Not reported	<1%	<1%
Age at vaccination	Mean (SD)	8.2 (1.93)	8.1 (1.97)
	Min, Max	(5, 11)	(5, 11)
Obese, n (%)	Yes	174 (11.5)	92 (12.3)
Comorbidities[a], n (%)	Yes	312 (20.6)	152 (20.3)

a. Participants who had at least one of the prespecified comorbidities based on MMWR 69(32);1081-1088 and/or obesity (BMI ≥ 95th percentile
b. Obese is defined as a body mass index (BMI) at or above the 95th percentile according to the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.

From ACIP 11/2/21 Presentation: Pfizer-BNT162b2 use in children aged 5-11 years, Dr. A Gurtman https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose in 5 to <12 and 16-25 Year Olds

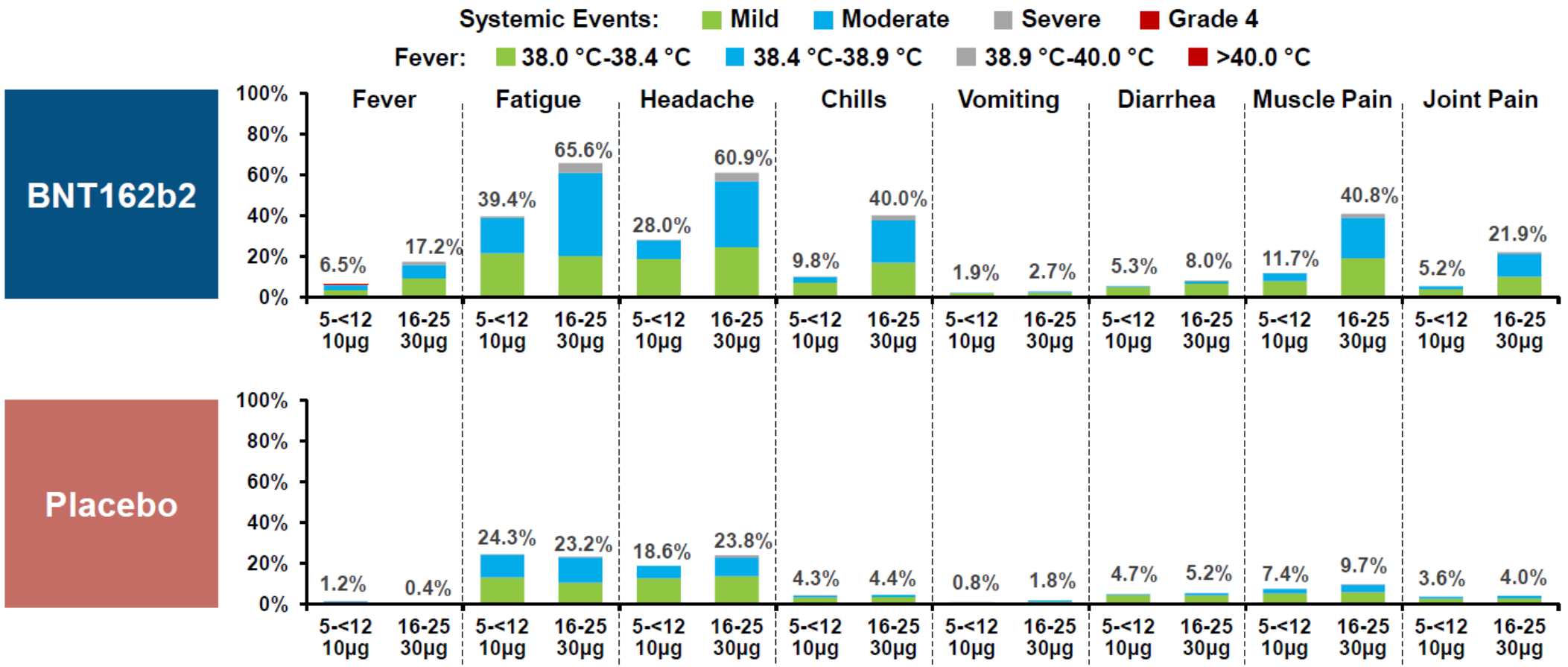


Redness and swelling severity definition: Mild= >2-5cm, Moderate= >5-10 cm; Severe= >10 cm; Grade 4= necrosis
Pain at injection site severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
Dose 1: 5-<12yrs N=2260; 16-25 yrs N=1064 Dose 2: 5-<12 yrs N=2242 16-25 yrs N=984

CC-10

From ACIP 11/2/21 Presentation: Pfizer-BNT162b2 use in children aged 5-11 years, Dr. A Gurtman https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

Systemic Events, by Maximum Severity, Within 7 Days After Dose 2 in 5 to <12 and 16-25 Year Olds

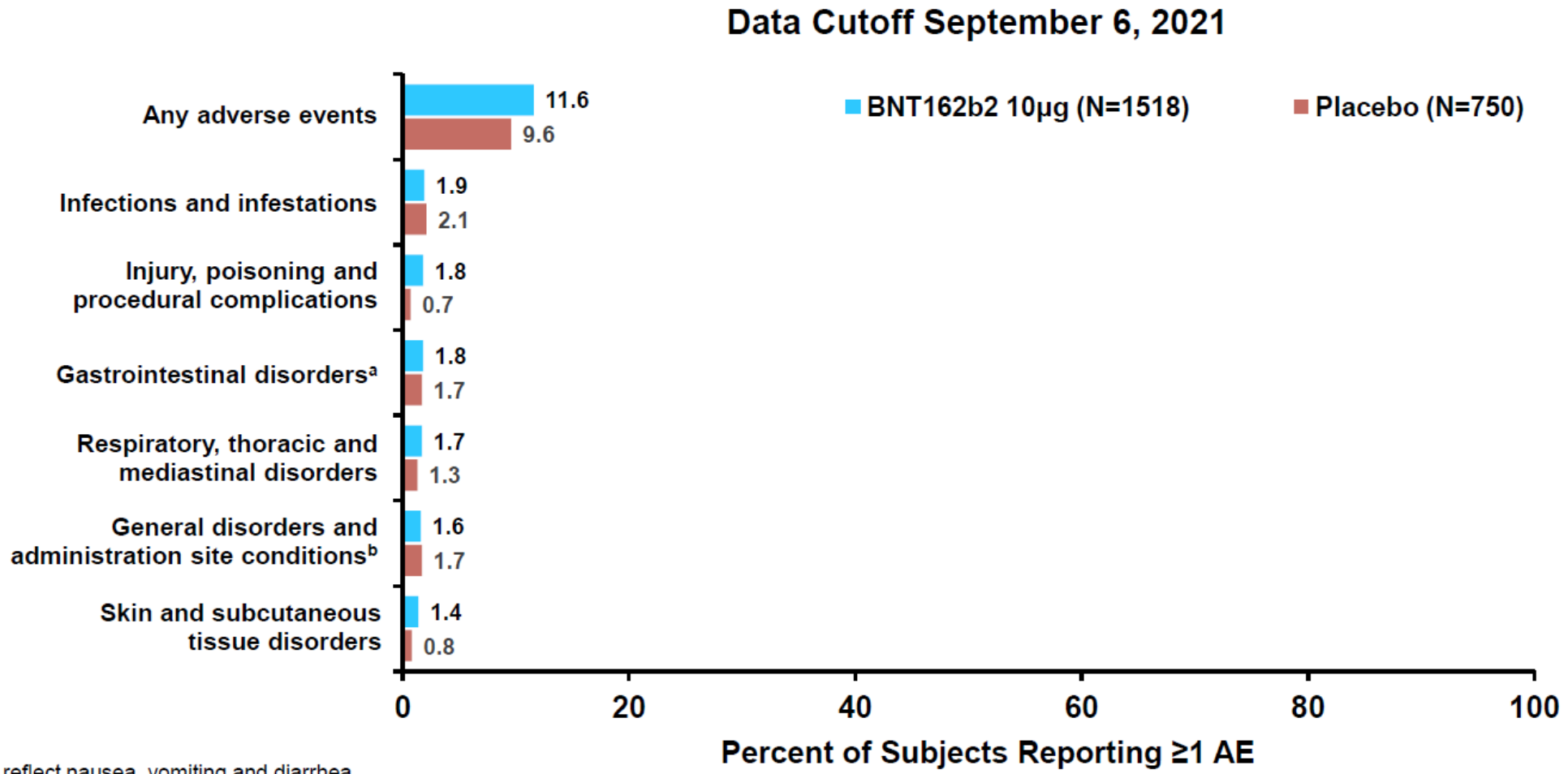


Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
Vomiting severity definition: Mild=1-2 time in 24h; Moderate=>2times in 24h; Severe=Requires IV hydration; Grade 4=ER visit or hospitalization
Diarrhea severity definition: Mild=2-3 times in 24h; Moderate=4-5 times in 24h; Severe=6 or more times in 24h; Grade 4=ER visit or hospitalization
Dose 2: 5-<12 yrs N=2242 16-25 yrs N=984

CC-11

From ACIP 11/2/21 Presentation: Pfizer-BNT162b2 use in children aged 5-11 years, Dr. A Gurtman https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

Adverse Events ≥1.0% by System Organ Class for 5 to <12 Year Olds from Dose 1 to Cutoff Date Initial Enrollment Group (N=2268)



a. Predominantly reflect nausea, vomiting and diarrhea
b. Predominantly reflect local reactions at the injection site and systemic reactions of fever and fatigue
Lymphadenopathy 0.9% in BNT162b2 group

CC-16

From ACIP 11/2/21 Presentation: Pfizer-BNT162b2 use in children aged 5-11 years, Dr. A Gurtman https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

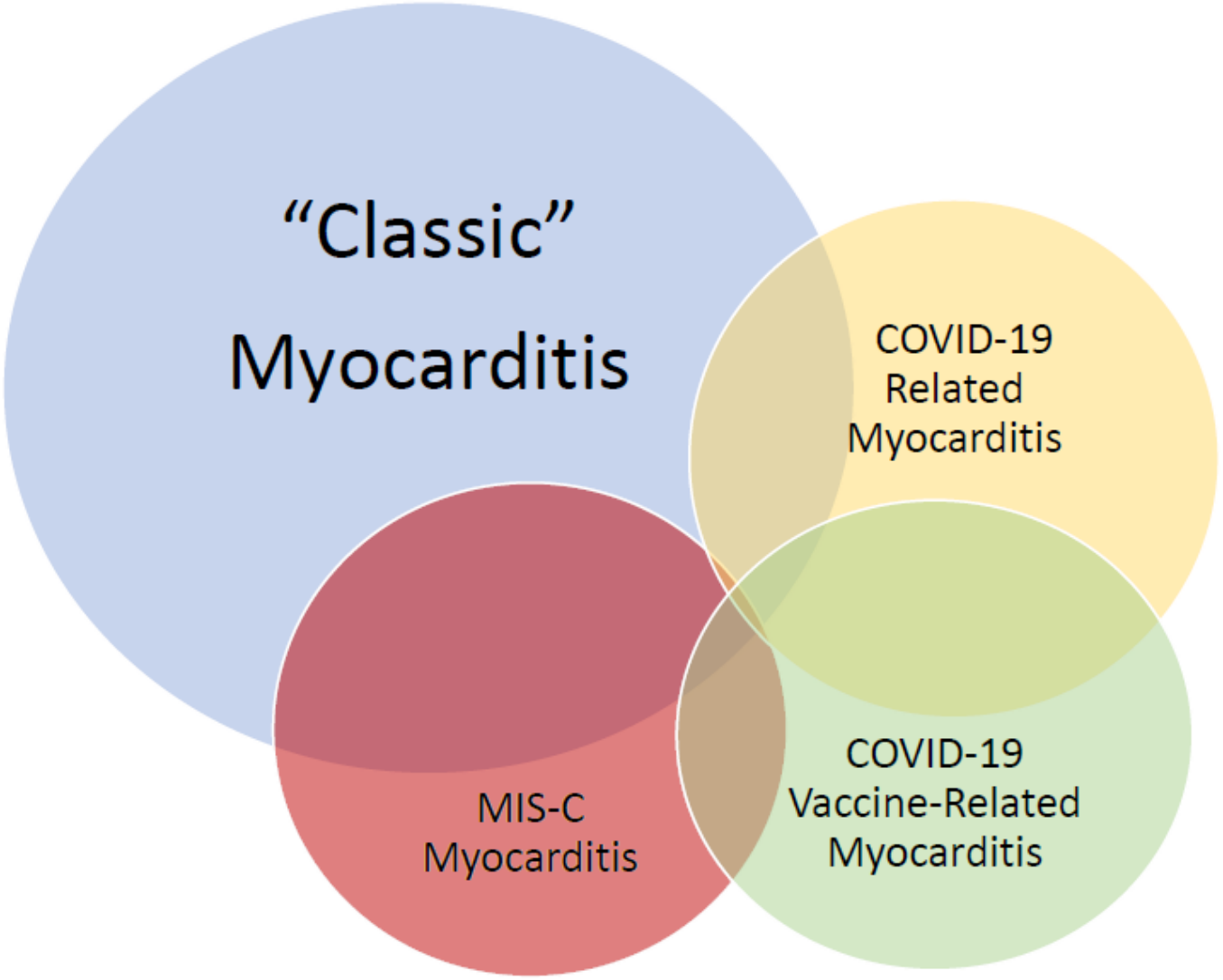
Safety Data for 5- to 11-year-olds: Summary

- Reactogenicity was mostly mild to moderate, and short lived
- Most common effect was pain at injection site
- Observed mild to moderate local reactions (redness, swelling) were more common and systemic reactions (including fever) less common than those in 16- to 25-year-olds
- The observed AE profile in this study did not suggest any safety concerns for Pfizer COVID-19 vaccination in children 5 to <12 years of age

From ACIP 11/2/21 Presentation: Pfizer-BNT162b2 use in children aged 5-11 years, Dr. A Gurtman https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

COVID-19 Vaccine-Related Myocarditis

Myocarditis Types



From ACIP 11/2/21 Presentation: mRNA COVID-19 Vaccine-Associated Myocarditis,
Dr. M Oster https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

Vaccine Adverse Event Reporting System (VAERS): Reporting rates (per 1 million doses administered) of myocarditis after mRNA COVID-19 vaccines, 7-day risk period

- Reporting rates exceed background incidence*

	Pfizer (Males)		Pfizer (Females)	
Ages	Dose 1	Dose 2	Dose 1	Dose 2
12-15	4.2	39.9	0.4	3.9
16-17	5.7	69.1	0.0	7.9
18-24	2.3	36.8	0.2	2.5
25-29	1.3	10.8	0.2	1.2
30-39	0.5	5.2	0.6	0.7
40-49	0.3	2.0	0.1	1.1
50-64	0.2	0.3	0.3	0.5
65+	0.2	0.1	0.1	0.3

From ACIP 11/2/21 Presentation: mRNA COVID-19 Vaccine-Associated Myocarditis, Dr. M Oster https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

Preliminary myocarditis cases reported to VAERS after mRNA COVID-19 vaccination in ages ≤ 30 years

- 1640 total preliminary myocarditis reports → 877 met CDC myocarditis case definition
- As of 10/6/21 (when this data was compiled):
  - 829 hospitalized
  - 789/829 discharged
  - 77% (607/789) recovered from symptoms, 33% still reporting symptoms
- 9 reports of deaths in people aged < 30 years with possible concern for myocarditis (among ~86 million doses)
  - 6 of these have undergone complete evaluation
    - 3 concluded not to be myocarditis
    - 3 with other potential infectious cause identified
    - 0 concluded to be deaths from vaccine-related myocarditis

Adapted From ACIP 11/2/21 Presentation: mRNA COVID-19 Vaccine-Associated Myocarditis, Dr. M Oster
https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

MIS-C Myocarditis

- Approximately 17% of MIS-C cases involve myocarditis (Belay et al. 2021)
  - 1 MIS-C case occurs for every 3200 SARS-CoV-2 infections, on average (Payne et al. 2021)
- 80% of MIS-C cases have any cardiovascular involvement (Feldstein et al. 2020)
- Compared to vaccine-related myocarditis, MIS-C related myocarditis and classic myocarditis are more likely to have decreased cardiac function at time of diagnosis (Patel et al. 2021)

COVID-19 Vaccine-related Myocarditis: Summary

	Myocarditis Diagnosed (%)	Myocarditis NOT Diagnosed (%)
COVID-19 (without MIS-C)	78 (0.02%)	356,721 (99.98%)
MIS-C	203 (8.10%)	2303 (91.90%)

	Myocarditis Diagnosed (%)	Myocarditis NOT Diagnosed (%)
COVID-19 (without MIS-C)	20 (0.08%)	24,144 (99.92%)
MIS-C	172 (9.04%)	1730 (90.96%)

Peak incidence of vaccine-related myocarditis (7 per 100,000 in 16-17yo males) is still much lower than incidence of COVID-19 myocarditis (around 20-80 per 100,000, per Epic and CHA data above)

Adapted From ACIP 11/2/21 Presentation: mRNA COVID-19 Vaccine-Associated Myocarditis, Dr. M Oster https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

Long-Term Effects of COVID-19 Vaccine-Related Myocarditis

Vaccine Safety Datalink Confirmed Myocarditis/pericarditis 0-21 Days after Any Dose of mRNA Vaccine by Age Group/Product: 3 month follow-up review of Cases with at least 1 follow-up visit since initial episode

3-month chart review status (not mutually exclusive)	12-17 Year-Olds (Pfizer-BioNTech) N=16	18-39 Year-Olds (Pfizer-BioNTech) N=14	18-39 Year-Olds (Moderna) N=18
Recovered, no medication, without exercise restrictions or symptoms	5 (31%)	6 (43%)	9 (50%)
Still symptomatic	4 (25%)	5 (36%)	3 (17%)
Still on medication (primarily NSAIDS, colchicine)	2 (13%)	4 (29%)	7 (39%)
Still on exercise/physical activity restrictions	7 (44%)	2 (14%)	1 (6%)

Adapted From ACIP 11/2/21 Presentation: mRNA COVID-19 Vaccine-Associated Myocarditis, Dr. M Oster https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

COVID-19 Vaccine-related Myocarditis: Summary

- Vaccine-related myocarditis is most common in teenage males, but is very rare in all groups
- There have been no confirmed deaths from vaccine-related myocarditis
- Risk of developing myocarditis and other cardiac complications with COVID-19 infection, and especially with MIS-C, is much higher than risk of vaccine-related myocarditis
- Preliminary data suggest that vaccine-related myocarditis is milder than other forms of myocarditis, although studies of long-term effects are ongoing

Vaccine Safety Monitoring Systems

- CDC
  - VAERS
  - v-safe
  - VSD
  - CISA Project
- FDA
  - BEST
  - Sentinel Initiative
  - Medicare Data
- Military
  - DOD VAERS
  - VAECS (Vaccine Adverse Events Clinical System)
  - Defense Medical Surveillance System
- Veterans
  - VA ADERS (Adverse Drug Event Reporting System)
  - VA EHR and Active Surveillance System
- Tribal Nations
  - IHS VAERS

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/reporting-systems.html

CDC Vaccine Safety Monitoring Systems

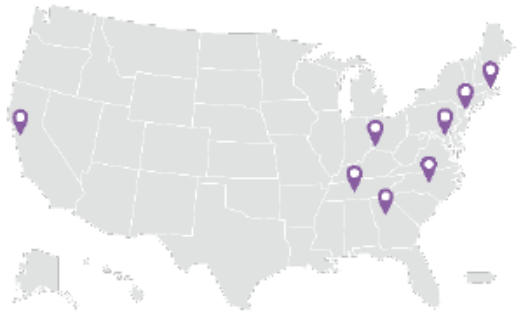
- COVID-19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history**
- Strong, complementary systems are in place—both new and established

v-safe

VAERS

VSD

CISA Project



Adapted From ACIP 11/2/21 Presentation: COVID-19 Vaccine Safety Monitoring in Children, Dr. T Shimabukuro
https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

Vaccine Adverse Event Reporting System (VAERS)

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

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

Adapted From ACIP 11/2/21 Presentation: COVID-19 Vaccine Safety Monitoring in Children, Dr. T Shimabukuro
https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

Further details on VAERS from WA DOH:
https://www.youtube.com/watch?v=Eh6xMcj0FI8

Vaccine Adverse Event Reporting System (VAERS)

- Passive reporting system
- Anyone can report an adverse event to VAERS
- Healthcare professionals are required by law to report all adverse events and administration errors
- Vaccine manufacturers are required to report all adverse events
- False report is a violation of federal law
- Reported information is coded and entered into database
- VAERS report does not mean that vaccine *caused* the health problem, only that symptoms occurred after vaccination

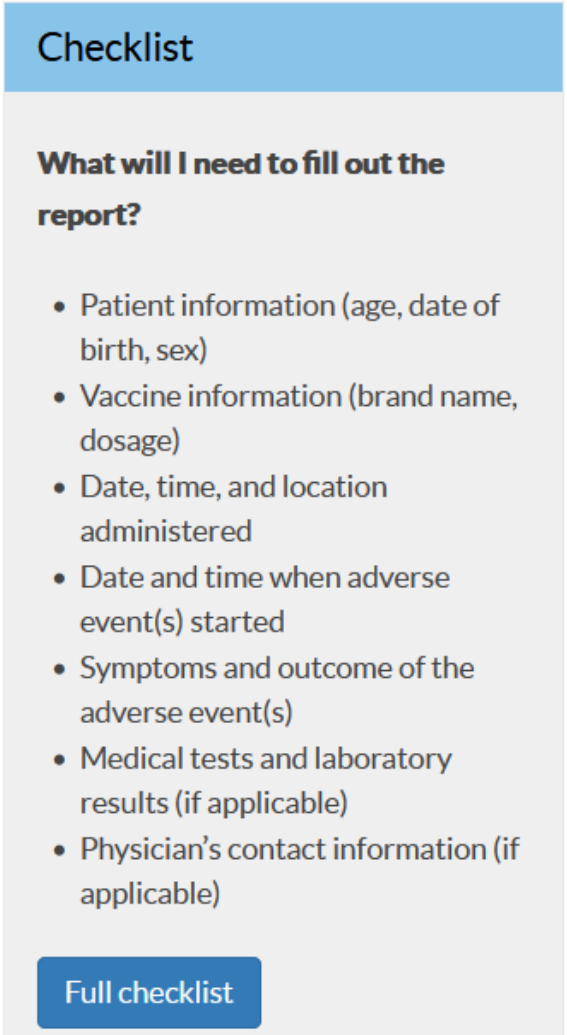
VAERS for Healthcare Providers

- Healthcare providers are **required** to report:
  - Any adverse event and/or administration error listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period (https://vaers.hhs.gov/reportevent.html)
    - For COVID-19 vaccinations specifically:
      - Vaccine administration errors, whether or not associated with an adverse event (AE)
      - Serious AEs, regardless of causality. Serious AEs per FDA are defined as: Death, life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, congenital anomaly/birth defect, an important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
      - Cases of Multisystem Inflammatory Syndrome
      - Cases of COVID-19 that result in hospitalization or death
  - Any adverse event listed by vaccine manufacturer as a contraindication to receiving further doses of the vaccine
- Healthcare providers are **strongly encouraged** to report:
  - Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event
  - Vaccine administration errors (for non COVID-19 vaccines)

Reporting to VAERS

- 2 ways to report to VAERS:
  - Submit VAERS report online (preferred)
    - Must be completed in one sitting
  - Complete writable PDF form and upload to VAERS website

- Link to VAERS reporting page: https://vaers.hhs.gov/reportevent.html
  - Also has link to full checklist of recommended information to complete VAERS report

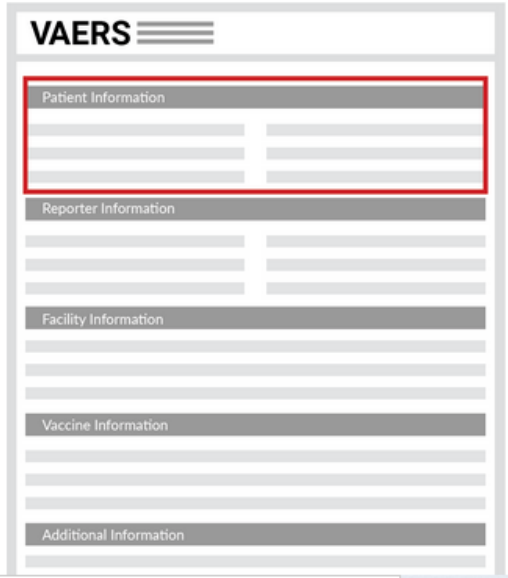


VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

About VAERS | Report an Adverse Event | VAERS Data | Resources | Submit Follow-Up Information

Completion Status

- [ ] **Patient Information**
- [ ] Reporter Information
- [ ] Facility Information
- [ ] Vaccine Information
- [ ] Additional Information



Report an Adverse Event - Patient Information

Instructions | en Español

Note: Fields marked with an * are essential and should be completed.

Item 1

Patient first name:

Patient last name:

Street address:

City:

State: Select State

County:

Zip code:

Phone:

Email:

Item 2

* Date of birth (mm/dd/yyyy or mm/yyyy)

mm/dd/yyyy

Item 3

* Sex:

Male Female Unknown

VAERS prespecified adverse events of special interest*
(as of Oct 27, 2021)

- Death
- Acute myocardial infarction
- Anaphylaxis
- Coagulopathy
  - Thrombocytopenia
  - Deep venous thrombosis or pulmonary embolism
  - Disseminated intravascular coagulopathy
- Guillain-Barré Syndrome (GBS)
- Kawasaki disease
- Multisystem inflammatory syndrome in children (MIS-C)
- Myocarditis, myopericarditis, and pericarditis
- Narcolepsy/cataplexy
- Seizure
- Stroke
- Thrombosis with thrombocytopenia syndrome (TTS)
- Transverse myelitis

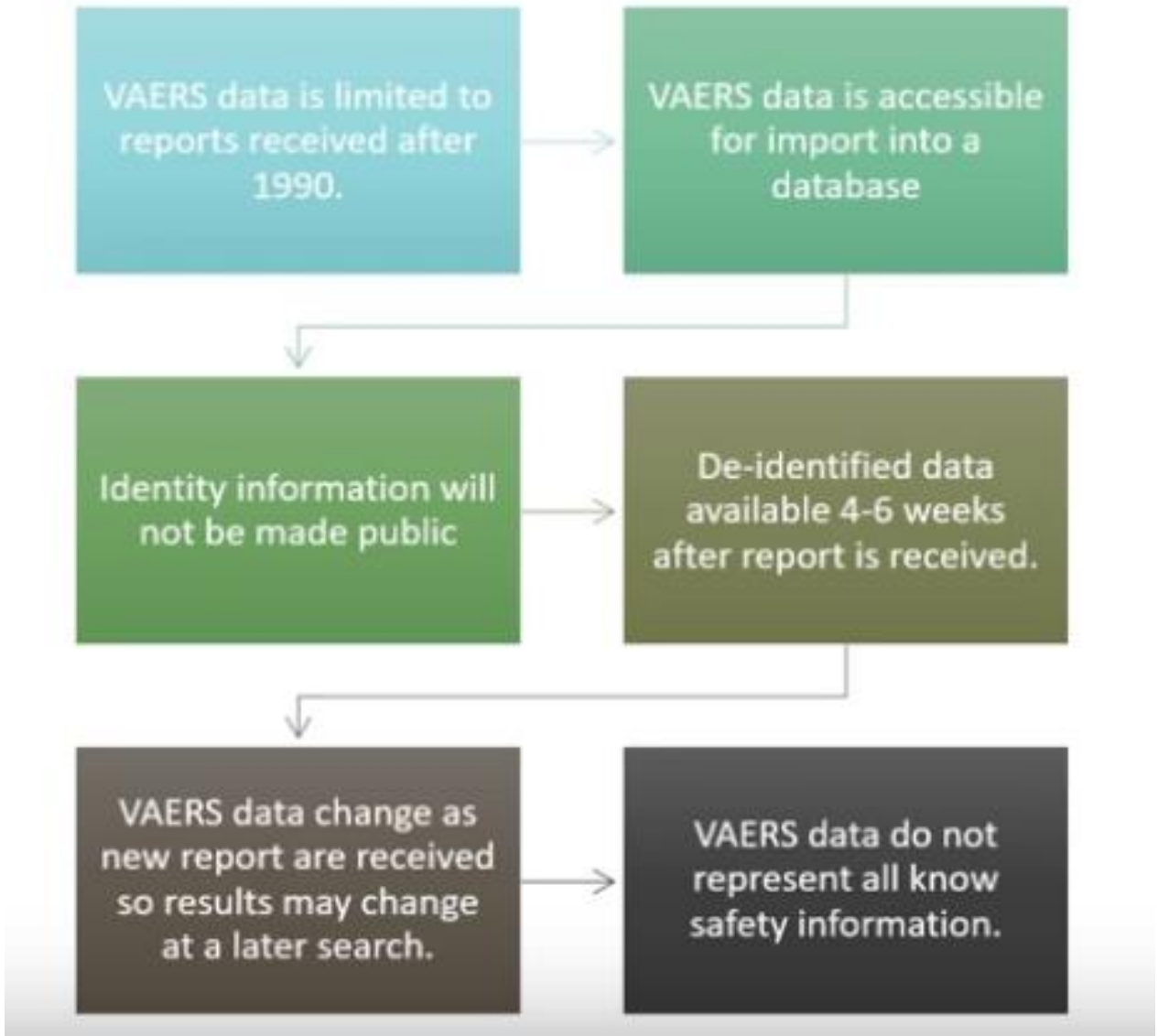
* Assessment includes: clinician review of VAERS report, follow-up to obtain and review medical records, application of case definition (where case definition exists), adjudication to classify the report with respect to case definition

Adapted From ACIP 11/2/21 Presentation: COVID-19 Vaccine Safety Monitoring in Children, Dr. T Shimabukuro
https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

Particular Focus on Myocarditis/Myopericarditis in VAERS

- Potential reports identified by Medical Dictionary for Regulatory Activities (MedDRA) standardized codes assigned to report that could indicate myocarditis or pericarditis
- Clinical abstraction
  - Review of initial report
  - Outreach to healthcare provider involved in reported patient's care
  - Request and review of medical records
  - Compare abstracted data elements against CDC case definitions for myocarditis and pericarditis
- CDC will conduct periodic analyses of case counts and reporting rates and comparison of reporting rates to background

VAERS CDC WONDER System



Resources:

CDC page on accessing VAERS data via WONDER system: https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/access-VAERS-data.html

Guide to interpreting VAERS data: https://vaers.hhs.gov/data/dataguide.html

VAERS Strengths and Limitations

Key strengths

- Rapidly detects potential safety problems
- Can detect rare adverse events

Key limitations

- Passive surveillance system
- Inconsistent quality and completeness of information
- Reporting biases
- Generally, cannot determine cause and effect

Adapted From ACIP 11/2/21 Presentation: COVID-19 Vaccine Safety Monitoring in Children, Dr. T Shimabukuro
https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

v-safe

- Developed for COVID-19
- Smartphone-based active safety monitoring system
  - Text messages and secure web surveys
- Able to enroll children and after any dose of vaccine
- Check-in schedule:
  - Once a day (days 0-7)
  - Once a week (weeks 2-6)
  - At months 3, 6, and 12
  - Schedule restarts after each dose received

v-safe℠
after vaccination
health checker

http://cdc.gov/vsafe

Smartphone-based active safety monitoring

Key strengths

- Easy and quick
- Active outreach
- Longitudinal data

Key limitations

- Voluntary enrollment
- Requires smartphone
- Generally, cannot determine cause and effect

Adapted from 10/26/21 CDC COCA Call: What Clinicians Need to Know about the Recent Updates to CDC's Recommendations for COVID 19 Boosters. https://emergency.cdc.gov/coca/calls/2021/callinfo_102621.asp

Demographic summary of 274,167 v-safe participants who reported an additional dose

Characteristic	% of participants
Sex	
Female	61.8
Male	37.3
Unknown	0.9
Age group (years)	
0-17	0.05
18-49	26.6
50-64	23.0
65-74	38.9
75-84	10.5
≥85	0.9

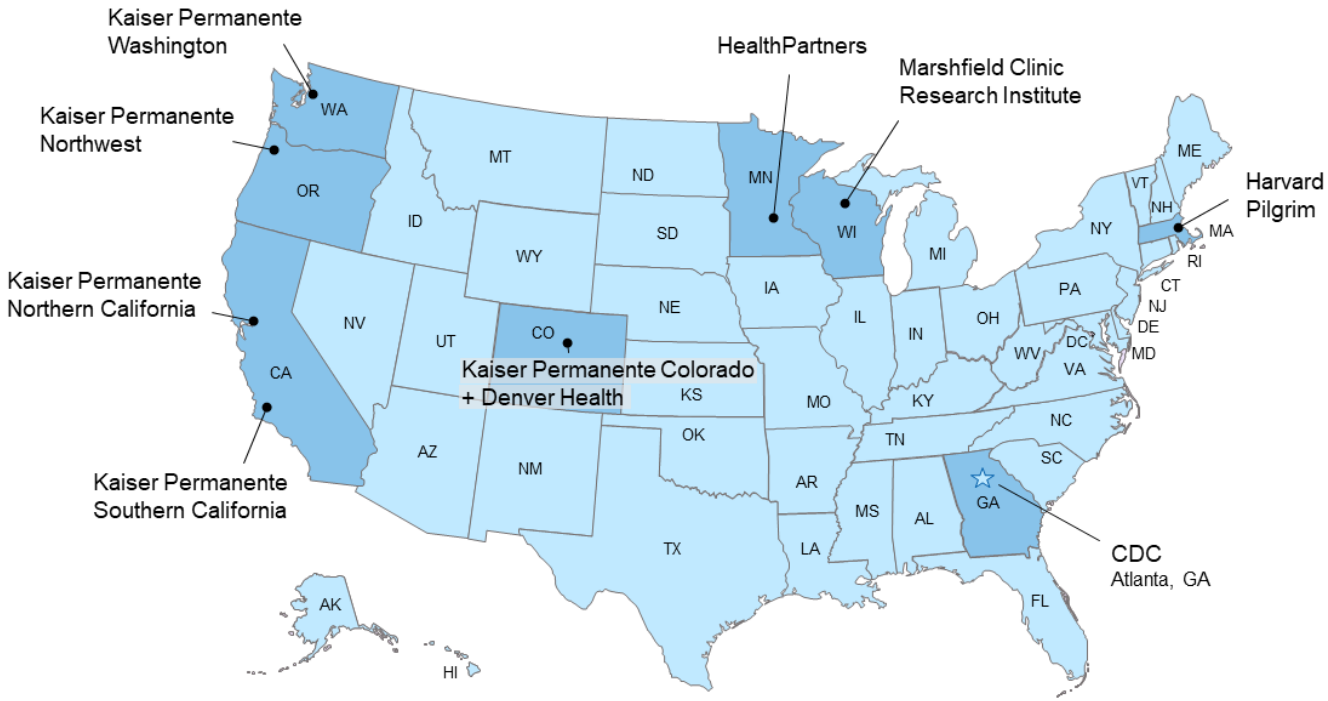
Characteristic	% of participants
Ethnicity	
Hispanic or Latino	6.3
Not Hispanic/ Latino	90.1
Unknown	3.5
Race	
AI/AN	0.4
Asian	5.6
Black or AA	5.0
NHPI	0.3
White	83.7
Multiracial	1.4
Other	1.8
Unknown	1.9

V-safe limitation: likely not representative of the vaccinated U.S. population

Includes participants who completed at least one survey in the first week after additional dose, data collected during August 12–October 10, 2021
Abbreviations: AI/AN = American Indian/Alaska Native; NHPI = Native Hawaiian or other Pacific Islander; AA=African American.

Vaccine Safety Datalink (VSD)

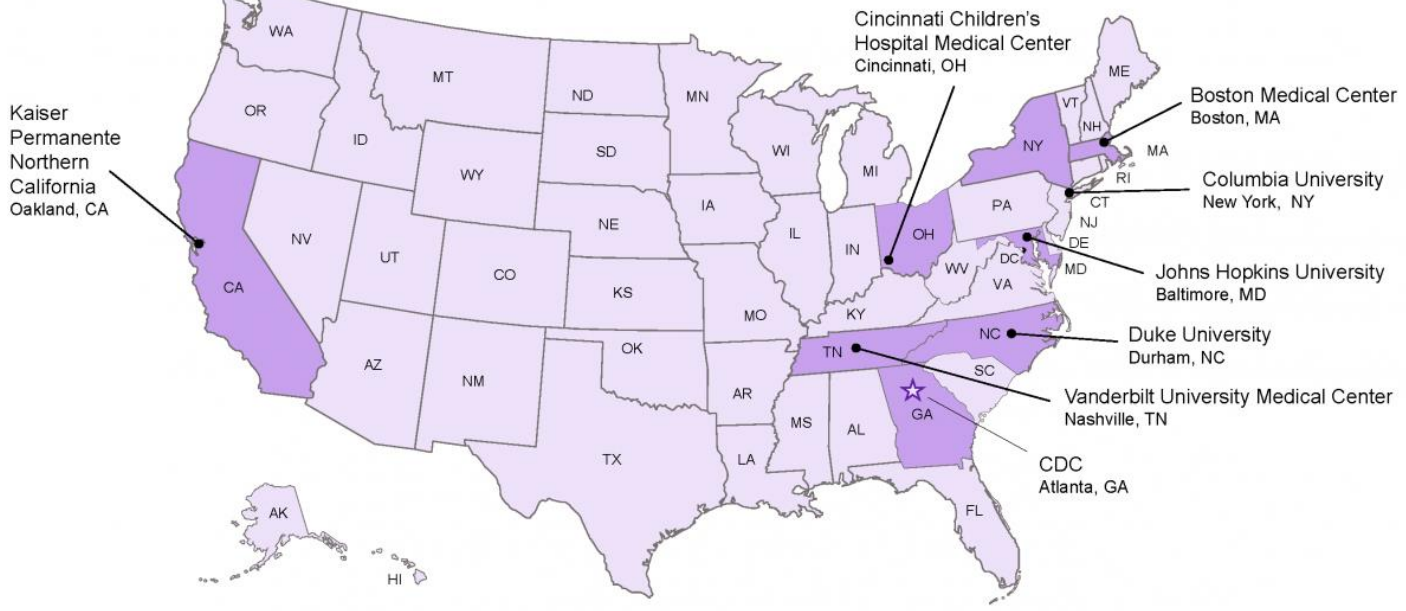
- Collaborative project between CDC's Immunization Safety Office and nine healthcare organizations
- VSD uses electronic health data from participating sites
- Monitors safety of vaccines and conducts studies about rare and serious adverse events following immunization
- Vaccine safety studies based on questions/concerns raised from the medical literature and reports to VAERS
- Data on over 12 million persons per year
- For COVID-19, uses RCA (rapid cycle analysis) to monitor safety of COVID-19 vaccines weekly using prespecified outcomes of interest



VSD's Collaborating Healthcare Organizations
https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html

Clinical Immunization Safety Assessment (CISA) Project

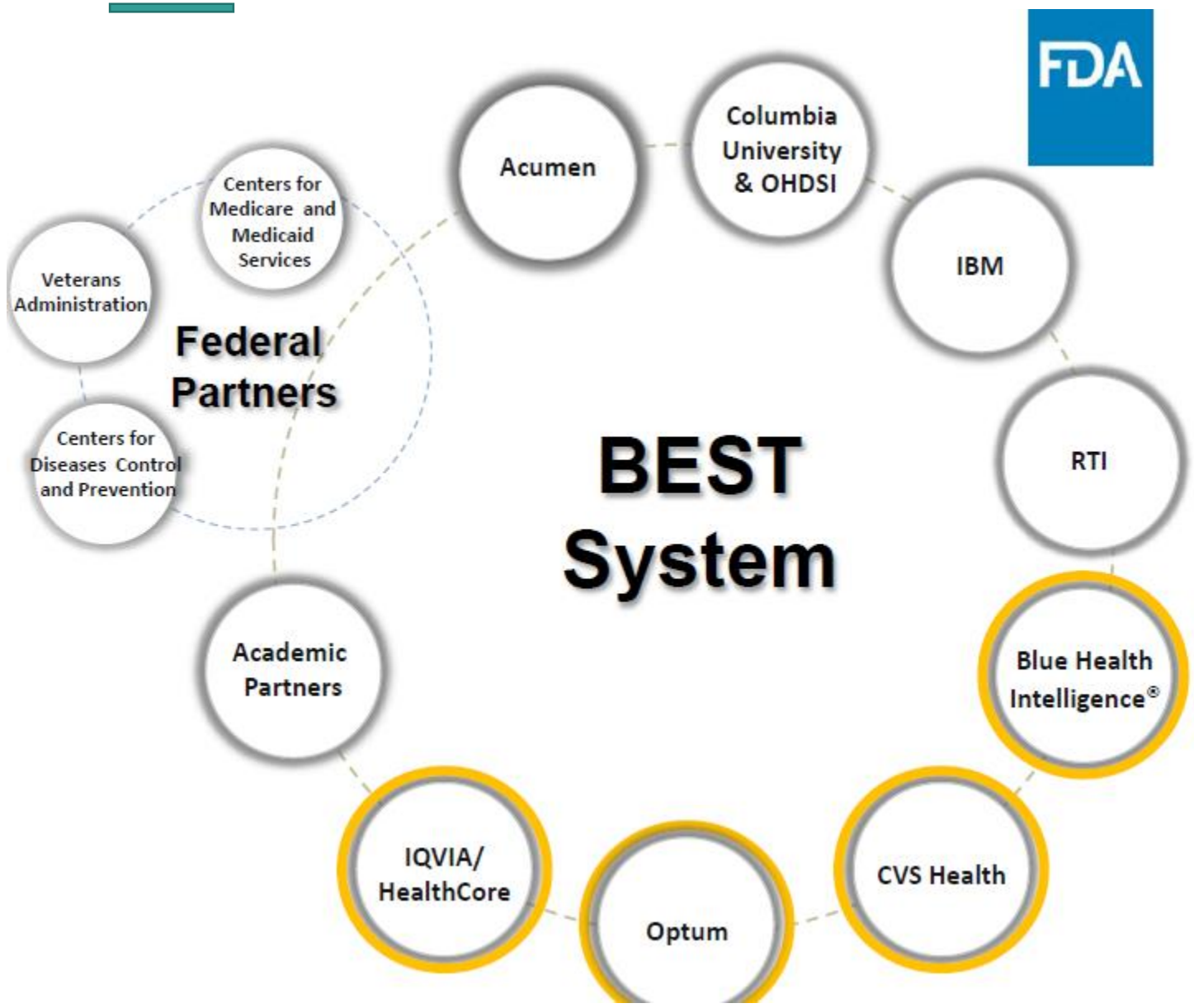
- Collaboration between CDC's Immunization Safety Office and 7 participating medical research centers with vaccine safety experts
  - Complete clinical research and offer clinical consult services
- COVID-19 vaccine core activities:
  - Clinical case reviews and clinical consults on complex cases of vaccine adverse events
  - Technical consultation on clinical guidance and clinical considerations for use of COVID-19 vaccines
  - Contributions to enhanced surveillance for adverse events
  - Clinical research, including in pediatric populations
- For more information on CISA Project and to request a consult: https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html



CISA Project's Collaborating Research Centers

FDA BEST (Biologics Effectiveness and Safety) System

- System run by FDA CBER (Center for Biologics Evaluation and Research)
- Involves multiple partner organizations
- Comprised of large-scale claims data, electronic health records (EHR), and linked claims-EHR databases
- Enables rapid queries to detect or evaluate adverse events
- The linked claims-EHR database makes it possible to study the safety of vaccines in sub-populations with pre-existing conditions or in pregnant individuals
- Learn more: https://www.bestinitiative.org/



Adapted From ACIP 11/2/21 Presentation: COVID-19 Vaccine Safety Monitoring in Children, Dr. T Shimabukuro
https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

What can you do for vaccine safety?

- Report adverse events following vaccination to VAERS even if you aren't sure if the vaccination caused the adverse event

- Enroll yourself in v-safe
- Healthcare providers, encourage your patients to enroll in v-safe
- Parents and guardians, you can enroll your children in v-safe

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

v-safe℠
after vaccination health checker

vsafe.cdc.gov/en/

CDC

Please get involved, your participation matters

Adapted from 10/26/21 CDC COCA Call: What Clinicians Need to Know about the Recent Updates to CDC's Recommendations for COVID 19 Boosters.
https://emergency.cdc.gov/coca/calls/2021/callinfo_102621.asp

Discussing Vaccine Safety with Patients and Families

- Helpful talking points on slides 17 (booster data), 24 (data for 5- to 11-year-olds), and 32 (myocarditis data)
- Other Resources
  - 11/10/21 WCAAP webinar with Dr. John Dunn: Answering Questions About Safety (recording to be posted soon: https://wcaap.org/resources/vaccines/#covid19-vaccines)
  - 9/21/21 CHOP webinar with Dr. Paul Offit: Myths and Misinformation Surrounding COVID-19 Vaccines (https://www.chop.edu/pages/current-issues-vaccines-fall-2021)
  - CDC patient FAQs about COVID-19 vaccines (https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html#serious-side-effects)
  - AAP Vaccine Campaign Toolkit (https://www.aap.org/en/news-room/campaigns-and-toolkits/covid-19-vaccine-toolkit/)
  - WA DOH COVID-19 vaccine resources in variety of languages (https://www.doh.wa.gov/Emergencies/COVID19/ResourcesandRecommendations#vaccines)
- Upcoming WCAAP webinar with Drs. Doug Opel and Yolanda Evans: COVID-19 Vaccine Communications – Ages 5-11
  - 12/1/21, 7:00-7:30 am (PST)
  - Register here: https://wcaap.org/event/covid-19-vaccine-communications-ages-5-11-2/

Obtaining Continuing Education

- Continuing education is available for nurses, medical assistants, pharmacists and pharmacy techs.
- Expiration date is 2/18/22
- Successful completion of this continuing education activity includes the following:
  - Attending the entire live webinar or watching the webinar recording
  - Completing the evaluation available after the webinar or webinar recording
  - **On the evaluation, please check Yes if you're interested in CEs and please specify which type of CE you wish to obtain**
- **Please note:** CE certificates are NOT generated after evaluation completion—CE certificates will be sent by DOH via email within a few weeks after evaluation completion.
- If you have any questions about CEs, contact Trang Kuss at trang.kuss@doh.wa.gov.

Power of Providers Initiative

Power of Providers Initiative

- Despite COVID-19 vaccination rates reaching over 70%, the state of Washington continues to experience outbreaks of COVID-19 disease.
- Given the rise of different COVID-19 variants, we want to vaccinate as many people against COVID-19 disease as possible.
- The Power of Providers Initiative asks **ALL** health care providers to help with this effort by signing up and committing to SAVE:
  - Seek
  - Ask/Educate
  - Vaccinate (or refer)
  - Empower
- Health care providers who don't vaccinate still want to help protect the community against COVID-19 disease, and they can sign up for the POP Initiative too!

Power of Providers Initiative - SAVE

- **Seek** – seek out your patient or client's vaccination status.
- **Ask/Educate** – ask them about the vaccine and offer education.
- **Vaccinate** – If the patient agrees to vaccination, vaccinate them or provide a referral for vaccination.
- **Empower** – Empower your patients to share their vaccination status with the community.

Power of Providers Initiative – Sign Up

The initiative is supported by over 20 different state health associations, Governor Inslee, and the Secretary of Health, Umair A. Shah.

We encourage all health care providers, vaccinating or not, to sign up for the initiative and help the state reduce COVID-19 disease.

To read more about the Power of Providers and to sign up, visit our web page at **www.doh.wa.gov/pop**

Providers that sign up will receive a certificate and other materials to help them with the POP Initiative.

Thank You!

Questions?

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