

National Center for Immunization & Respiratory Diseases 

COVID-19 vaccine safety update

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

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Disclaimer

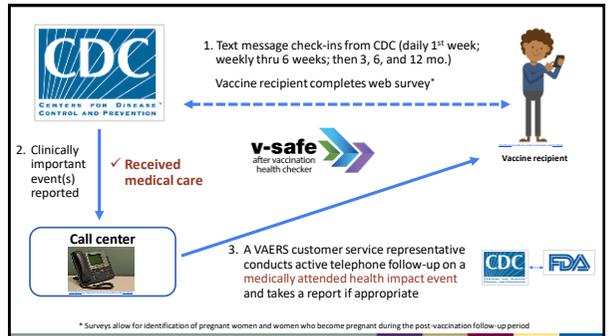
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Topics

- V-safe
- Vaccine Adverse Event Reporting System (VAERS)
- Update on anaphylaxis following COVID-19 vaccination
- Reports of deaths and mortality following COVID-19 vaccination

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Summary of v-safe data

	Pfizer-BioNTech	Moderna	All COVID-19 vaccines
People receiving 1 or more doses in the United States [†]	12,153,536	9,689,497	21,843,033
Registrants completing at least 1 v-safe health check-in [‡]	997,042	1,083,174	2,080,216
Pregnancies reported to v-safe [§]	8,633	6,498	15,131

[†] COVID Data Tracker data as of 1/24/2021
[‡] v-safe data as of 1/20/2021, 5:00 AM ET
[§] 540 pregnancies enrolled in v-safe pregnancy registry as of January 28, 2021

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Reactogenicity reported to v-safe

Local and systemic reactions, day 0-7 [†]	All vaccines %	Pfizer-BioNTech dose 1 %	Pfizer-BioNTech dose 2 %	Moderna dose 1 %
Pain	70.7	67.7	74.8	70.1
Fatigue	33.4	28.6	50.0	29.7
Headache	29.4	25.6	41.9	26.0
Myalgia	22.8	17.2	41.6	19.6
Chills	11.5	7.0	26.7	9.3
Fever	11.4	7.4	25.2	9.1
Swelling	11.0	6.8	26.7	13.4
Joint pain	10.4	7.1	21.2	8.6
Nausea	8.9	7.0	13.9	7.7

n = 765,225 n = 782,366

[†] v-safe data look point 1/24/2021, 5:00 AM ET
[‡] Reported on at least one health check-in completed on days 0-7 after receipt of vaccine

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Reactogenicity reported to v-safe

Local and systemic reactions, day 0-7 ^{1,2}	All vaccines %	Pfizer-BioNTech dose 1 %	Pfizer-BioNTech dose 2 %	Moderna dose 1 %
Pain	70.7	67.7	74.8	70.1
Fatigue	33.4	28.6	50.0	29.7
Headache	29.4	25.6	41.9	26.0
Myalgia	22.8	17.2	41.6	19.6
Chills	11.5	7.0	26.7	9.3
Fever	11.4	7.4	25.2	9.1
Swelling	11.0	6.8	26.7	13.4
Joint pain	10.4	7.1	21.2	8.6
Nausea	8.9	7.0	13.9	7.7

n = 765,225 n = 235,858

¹ v-safe data lock point 1/14/2021, 5 AM ET

² Reported on at least one health check-in completed on days 0-7 after receipt of vaccine

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



VAERS

Vaccine Adverse Event Reporting System

co-managed by
CDC and FDA

<http://vaers.hhs.gov>



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Most commonly reported adverse events to VAERS after COVID-19 vaccines*

Pfizer-BioNTech COVID-19 vaccine (N = 7,307)

Adverse event ¹	N (%)
Headache	1,550 (21.2)
Fatigue	1,192 (16.3)
Dizziness	1,113 (15.2)
Nausea	1,014 (13.9)
Chills	983 (13.5)
Pyrexia	962 (13.2)
Pain	958 (13.1)
Injection Site Pain	716 (9.8)
Pain in Extremity	610 (8.4)
Dyspnoea	536 (7.3)

Moderna COVID-19 vaccine (N = 1,786)

Adverse event ¹	N (%)
Headache	430 (24.1)
Pyrexia	333 (18.6)
Chills	315 (17.6)
Pain	290 (16.2)
Dizziness	289 (16.2)
Fatigue	287 (16.1)
Nausea	281 (15.7)
Injection Site Pain	208 (11.6)
Pain in Extremity	189 (10.6)
Dyspnoea	172 (9.6)

* Reports received through January 18, 2021; ¹Adverse events are not mutually exclusive

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Update on anaphylaxis following COVID-19 vaccine

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Anaphylaxis reports to VAERS following COVID-19 vaccines

- Suspected anaphylaxis reports to VAERS through January 18, 2021, were assessed by physicians at CDC who conducted medical record review and additional follow-up if necessary
- Cases were classified according to the Brighton Collaboration case definition criteria* (Brighton Levels 1, 2, and 3 are cases, 4 and 5 are not)

* Riegerberg et al., Brighton Collaboration Anaphylaxis Working Group. Anaphylaxis case definition and guidelines for data collection, analysis, and presentation of immunization safety data. Vaccine. 2007;25(15):1679-84.

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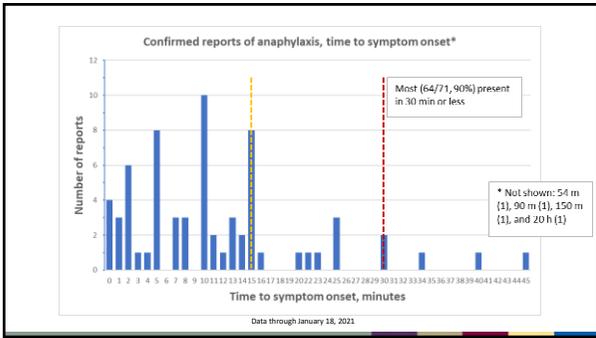
Anaphylaxis reports to VAERS following COVID-19 vaccines*

Characteristics	Pfizer-BioNTech (N = 50)	Moderna (N = 21)
Median age, years (range)	38.5 (26–63)	39 (24–63)
Female (%)	47 (94)	21 (100)
Minutes to symptom onset, median (range)	10 (<1–1200 [20 hr]) ¹	10 (<1–45)
Symptom onset ≤15 minutes (%)	37 (74)	18 (86)
Symptom onset ≤30 minutes (%)	45 (90)	19 (90)
Documented h/o allergies or allergic rxns (%)	40 (80)	18 (86)
Documented h/o prior anaphylaxis (%)	12 (24)	5 (24)
Dose number (1 st , 2 nd , unknown)	42, 3, 5	19, 1, 1

- Common allergies and allergic reactions included to drugs and foods
- Anaphylaxis cases occurred following drugs, foods, contrast media, vaccines, insect stings, and unspecified

* Reports received through January 18, 2021; Includes case reports that met Brighton Collaboration case definition criteria for anaphylaxis at Levels 1, 2, or 3 ¹20 hour onset was an outlier, the remaining onset for cases with onset >30 minutes were 34, 54, 90, and 150 minutes

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Estimated anaphylaxis reporting rates following COVID-19 vaccines based on VAERS reports and reported doses administered*

Reported vaccine doses administered	Anaphylaxis cases	Reporting rate (analytic period Dec 14-Jan 18)
Pfizer-BioNTech: 9,943,247	50	5.0 per million doses admin.
Moderna: 7,581,429	21	2.8 per million doses admin.

- Total COVID-19 vaccine doses administered thru Jan 18 by sex: Female 61%, Male 36%, Unk 3%
- Previously reported rate for Pfizer-BioNTech vaccine: 11.1 per million doses admin (Dec 14-Dec 23) <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6902a1.htm>
- Previously reported rate for Moderna vaccine: 2.5 per million doses admin (Dec 21-Jan 10) <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6904a1.htm>

* Data through January 18, 2021

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Reports of deaths and mortality following COVID-19 vaccination

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Processing and follow-up on reports of death to VAERS

- Upon receipt or notification of a reported death after COVID-19 vaccine,* the VAERS contractor:
 - Expedites processing of the report (processed the day of report)
 - Contacts the reporter for additional information (medical records, death certificate, autopsy report, etc.)
- Physicians in the CDC's Immunization Safety Office and at FDA review all reports of death following COVID-19 vaccination as soon as notified in the daily VAERS priority report and make an assessment if any immediate action is necessary
- Attempts (multiple if necessary) are made to obtain death certificates and autopsy reports, when an autopsy is conducted, to ascertain cause of death

* A similar process occurs for reports of death following influenza vaccine

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Reports of deaths (due to any cause) following COVID-19 vaccination to VAERS* (N = 196)

Characteristics	Reports of death (N = 196)
Median age, years (range)	79 (25-104)
Age <65 years (%)	43 (22)
Female (%)	91 (46)
Long-term care facility (LTCF) resident (%)	129 (66)
Pfizer-BioNTech vaccine	113
Moderna vaccine	83

- These reports of death to VAERS involve temporally associated deaths following vaccination due to any cause; adverse event reports to VAERS, including deaths, should not be assumed to be causally related to vaccination

* Data through January 18, 2021

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Background mortality in long-term care facility (LTCF) residents and reports of death following COVID-19 vaccination

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Estimated background mortality in LTCF residents

- Estimated 2 million COVID-19 vaccine doses administered in LTCFs through January 18, 2021 (CDC COVID Data Tracker)
 - Assume 65% administered to LTCF residents (1.3 million residents)
 - Assume a 22% annual mortality rate* (n = 286,000)
- Risk period
 - Assume December 21 was when vaccinations commenced in LTCFs
 - Therefore, risk period=29 days (December 21-January 18)
 - Assume each resident contributes 14.5 person-days (~ mid-point of risk period)
 - 14.5 days = 4% of a calendar year

* Thomas et al, J Gerontol A Biol Sci Med Sci, 2019, Vol. 74, 219-225

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Estimated background mortality in LTCF residents (cont.)

- Among 1.3 million LTCF residents (2M x 65%) vaccinated over the 29-day risk period (December 21-January 18)
 - Expect **11,440 deaths** among LTCF residents (= 286,000*4%) following vaccination
- By comparison, VAERS received **129 reports of deaths** following COVID-19 vaccination in LTCF residents through January 18, 2021
- Mortality in LTCF residents is high and substantial numbers of deaths in this population will occur following vaccination as temporally-associated coincidental events

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Reports of deaths in LTCF residents following COVID-19 vaccination to VAERS* (N = 129)

Characteristics	Reports of death (N = 129)
Median age, years (range)	84 (51-104)
Female (%)	65 (50)
Hospice, DNR, or DNI (%)	43 (33)
Autopsy conducted, results pending	2
Death certificate available	18
Death certificate unavailable or autopsy results pending†	112

- Initial assessment indicated that many case reports documented ill health and a history of multiple co-morbidities and common age-related diseases (e.g., heart disease, type 2 diabetes, dementia, etc.)

* Data through January 18, 2021; †Standard follow-up on reports of death include attempts to collect and review death certificates and autopsy reports

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Reports of deaths in LTCF residents following COVID-19 vaccination to VAERS with death certificates available* (N = 18)

Cause of death from death certificate
Hypertension, leading to acute myocardial infarction, leading to anoxic brain injury
Atherosclerotic cardiovascular disease, acute myocardial infarction
Arteriosclerotic Disease
Cardiac arrest, cardiopulmonary arrest
Acute congestive heart failure, non-ischemic cardiomyopathy
Congestive heart failure, non-ischemic cardiomyopathy
Congestive heart failure
Congestive heart failure
Heart failure, hypertension
End stage chronic obstructive pulmonary disease
Acute kidney failure, resulting from acute liver failure, resulting from liver masses
Hypertension, hypothyroidism, bipolar disorder, peripheral vascular disease
Pneumonia, cardiac arrest and shock
Aspiration, frontotemporal dementia
Hypertension, mixed Alzheimer's and vascular dementia
Dementia
Chronic alcohol abuse and severe malnutrition, alcohol withdrawal, electrolyte derangement, ventricular arrhythmia, cardiogenic shock
Failure to thrive

* Data through January 18, 2021

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Impression on deaths and mortality in LTCF residents following COVID-19 vaccination

- Mortality in LTCF residents is high due to the underlying health status of the LTCF resident population
- The available evidence from VAERS monitoring does not suggest a safety problem with respect to deaths in older adults residing in LTCFs
- Case reports of deaths in LTCF residents following COVID-19 vaccination to VAERS include many persons:
 - With multiple co-morbidities, including some with cognitive impairment
 - In ill health and declining states health
 - In hospice or DNR or DNI status (in one-third of reported deaths)
- Deaths in LTCF residents following COVID-19 vaccination are consistent with expected all cause mortality in this population

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Closing

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Closing thoughts

- 26 million COVID-19 vaccine doses have been administered in the United States*
- During this time, the U.S. government has implemented the most intense and comprehensive vaccine safety monitoring program in history
- Overall, the safety profiles of COVID-19 vaccines are reassuring and consistent with that observed from the pre-authorization clinical trials
- Anaphylaxis has been observed following mRNA COVID-19 vaccines, though rarely
- The data do not suggest a signal with respect to overall safety or deaths following vaccination in older adult residents of LTCFs
- Additional population-based monitoring systems will continue to gather safety data safety as vaccination increases and the immunization program broadens
 - e.g., CDC's Vaccine Safety Datalink

* As of January 28, 2021

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Acknowledgments

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