COVID-19 vaccine safety update

Advisory Committee on Immunization Practices (ACIP)
January 27, 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 the CDC or FDA

Topics

- V-safe update
- Vaccine Adverse Event Reporting System (VAERS) surveillance update
- Clinical Immunization Safety Assessment (CISA) Project update
- Vaccine Safety Datalink (VSD) surveillance update
- Update on anaphylaxis following COVID-19 vaccination
- Reports of deaths and mortality following COVID-19 vaccination

v-safe℠ after vaccination health checker

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

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 recipient

v-safe
after vaccination health checker

2. Clinically important event(s) reported

✓ **Received medical care**

Call center

3. A VAERS customer service representative conducts active telephone follow-up on a medically attended health impact event and takes a report if appropriate

CDC ↔ FDA

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

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

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

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

Active COVID-19 vaccine safety surveillance in v-safe

- Follow-up phone calls ongoing to v-safe participants who report medically attended health impact events
- Pregnancy registry
  - 227 pregnancies enrolled as of January 22, 2021

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

Vaccine Adverse Event Reporting System

co-managed by CDC and FDA

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

Reports to VAERS after COVID-19 vaccines*

Vaccine	N	Non-serious AEs (%)	Serious AEs† (%)	Median age in years (range)	Female (%)
Moderna	1,786	1,396 (78)	390 (22)	43 (15–102)	1,361 (76)
Pfizer-BioNTech	7,307	6,719 (92)	588 (8)	43 (17–104)	5,628 (77)
Unknown vaccine	3	2 (67)	1 (33)	58 (49–93)	3 (100)
Total	**9,096**	**8,117 (89)**	**979 (11)**	**43 (15–104)**	**6,992 (77)**

- Reporting rates: Non-serious AEs 372 reports per million doses administered
  Serious AEs 45 reports per million doses administered

* Reports received through January 18, 2021

† 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 adverse events to VAERS after COVID-19 vaccines*

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

Adverse event†	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†	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)

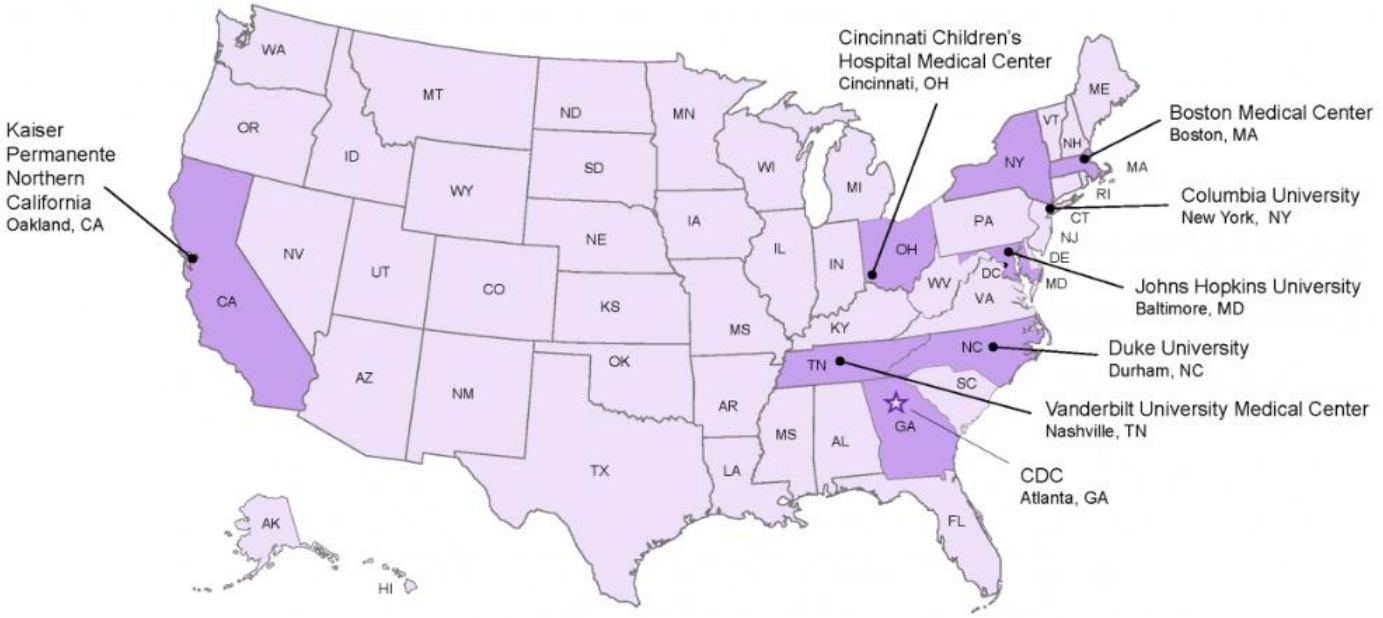
* Reports received through January 18, 2021; †Adverse events are not mutually exclusive

Empirical Bayesian data mining in VAERS

- FDA uses data mining to identify disproportional adverse event reporting for vaccines, including COVID-19 vaccines
  - Identifies, with a high degree of confidence, adverse event-vaccine pairs reported at least twice as frequently as expected for a COVID-19 vaccine compared to the VAERS database
  - i.e., lower bound of the 90% confidence interval surrounding the empirical Bayesian geometric mean (EB05 ≥2) compared to all other U.S.-licensed vaccines
- No empirical Bayesian data mining alerts (EB05 ≥2) detected for any adverse event-COVID-19 vaccine pairs (most recent [January 22, 2021] weekly results)

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

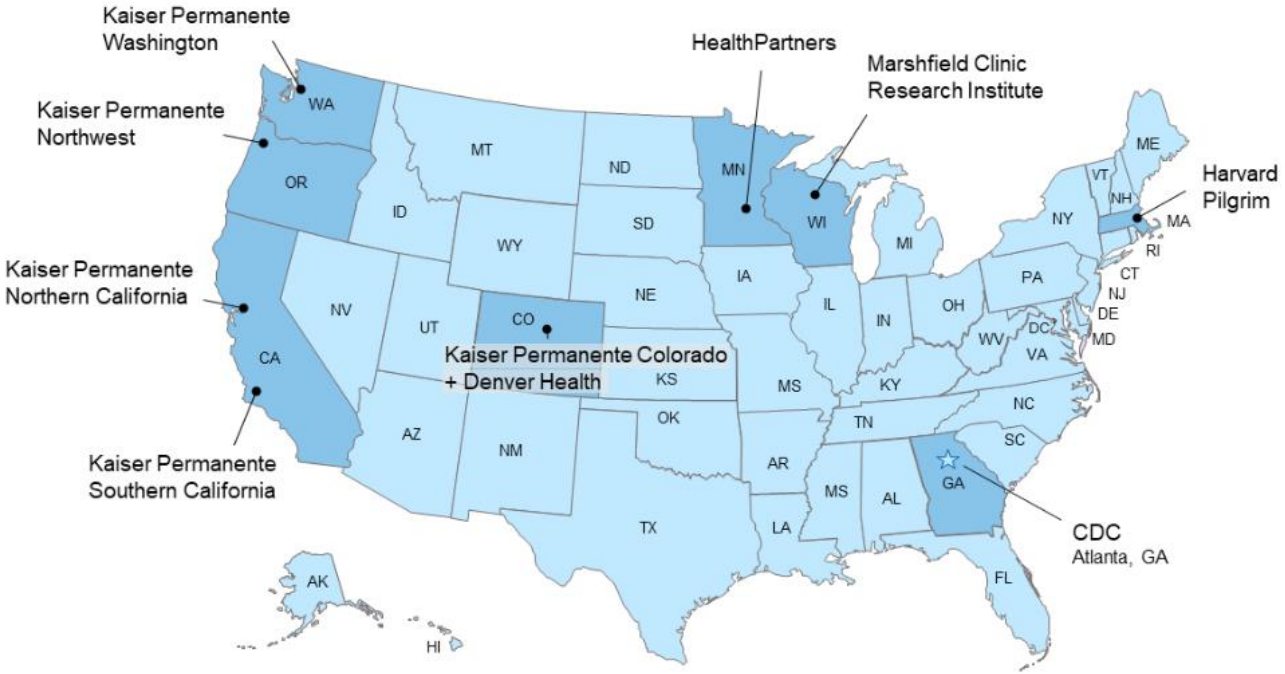
CISA Project contributions

- Responded to 143 clinical inquiries or consultation requests about COVID-19 vaccine safety*
- Assisted state health departments with evaluation of complex medical issues pertaining to COVID-19 vaccines safety
- Convened CISA Project workgroup with allergy/immunology specialists
  - Provided input for CDC's guidance on clinical considerations for use of the mRNA COVID-19 vaccines and how to prepare for managing anaphylaxis after vaccination
  - Contributed to MMWRs on anaphylaxis/allergic reactions after 1st dose of Pfizer-BioNTech and Moderna COVID-19 vaccines
  - Ongoing work to investigate possible mechanism for anaphylaxis, in collaboration with FDA, NIH and other partners

*Since December 14, 2020 – January 24, 2021

VSD

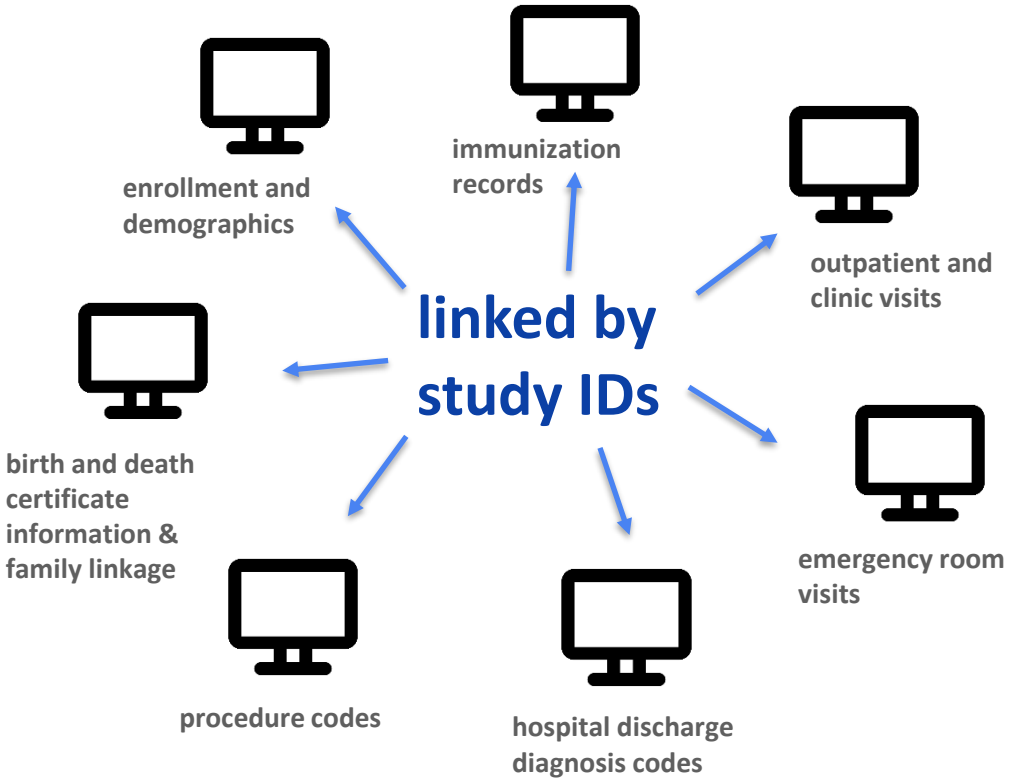
Vaccine Safety Datalink

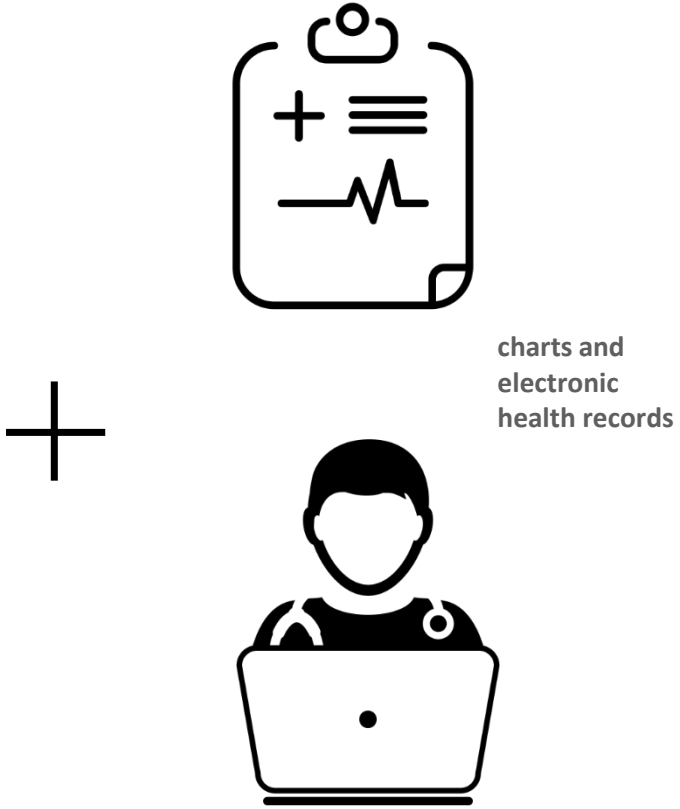


9 participating integrated healthcare organizations

data on over **12 million** persons per year

Types of information in VSD



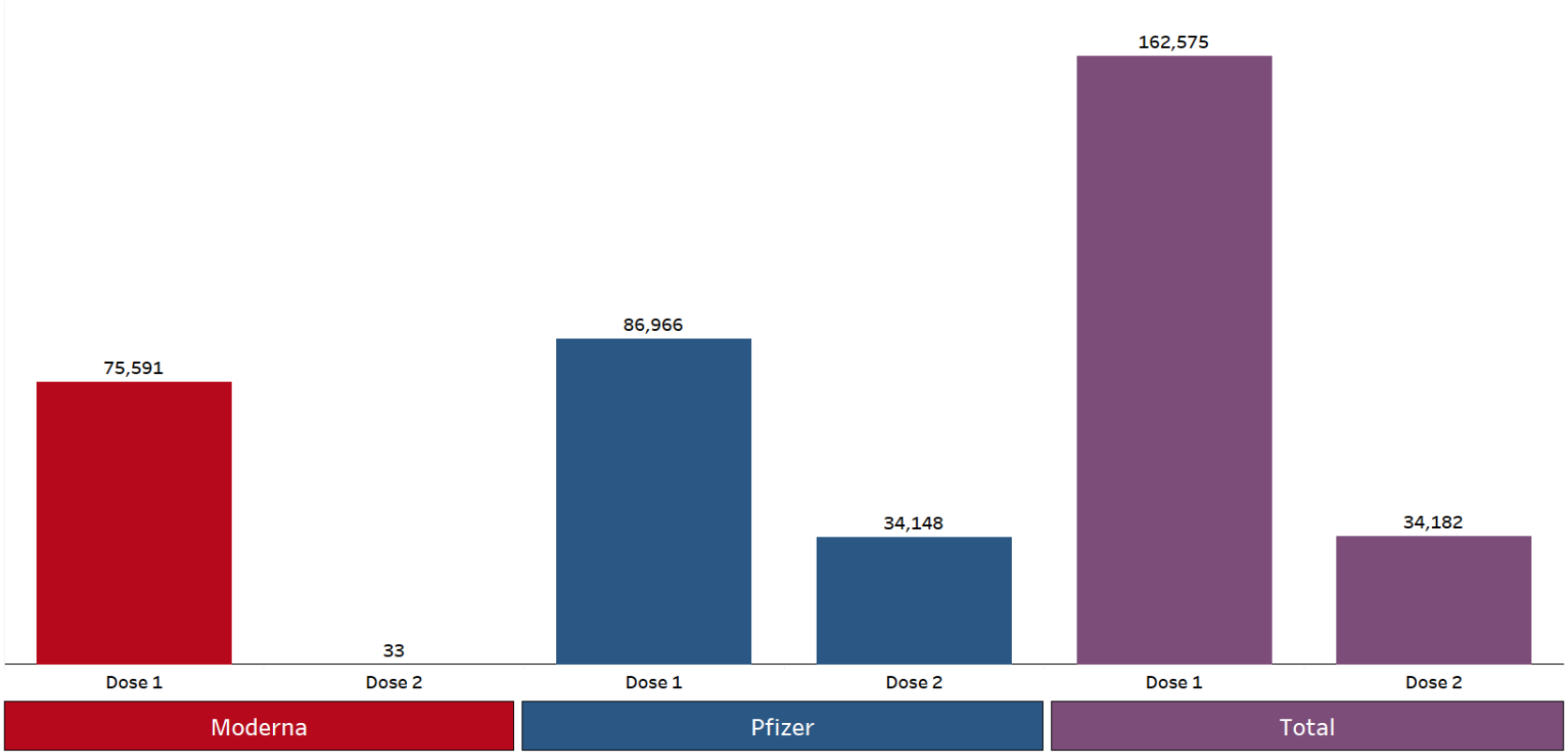


Images created by Wilson Joseph, Megan Mitchell, Ananth, and Iga from the noun project

VSD Rapid Cycle Analysis (RCA) aims

- Monitor the safety of COVID-19 vaccines weekly using pre-specified outcomes of interest among VSD members
- Assess each pre-specified outcome for a 1-21 and 1-42 day risk interval
- Describe the uptake of COVID-19 vaccines over time among eligible VSD members

VSD COVID-19 vaccine totals through Jan 16, 2021



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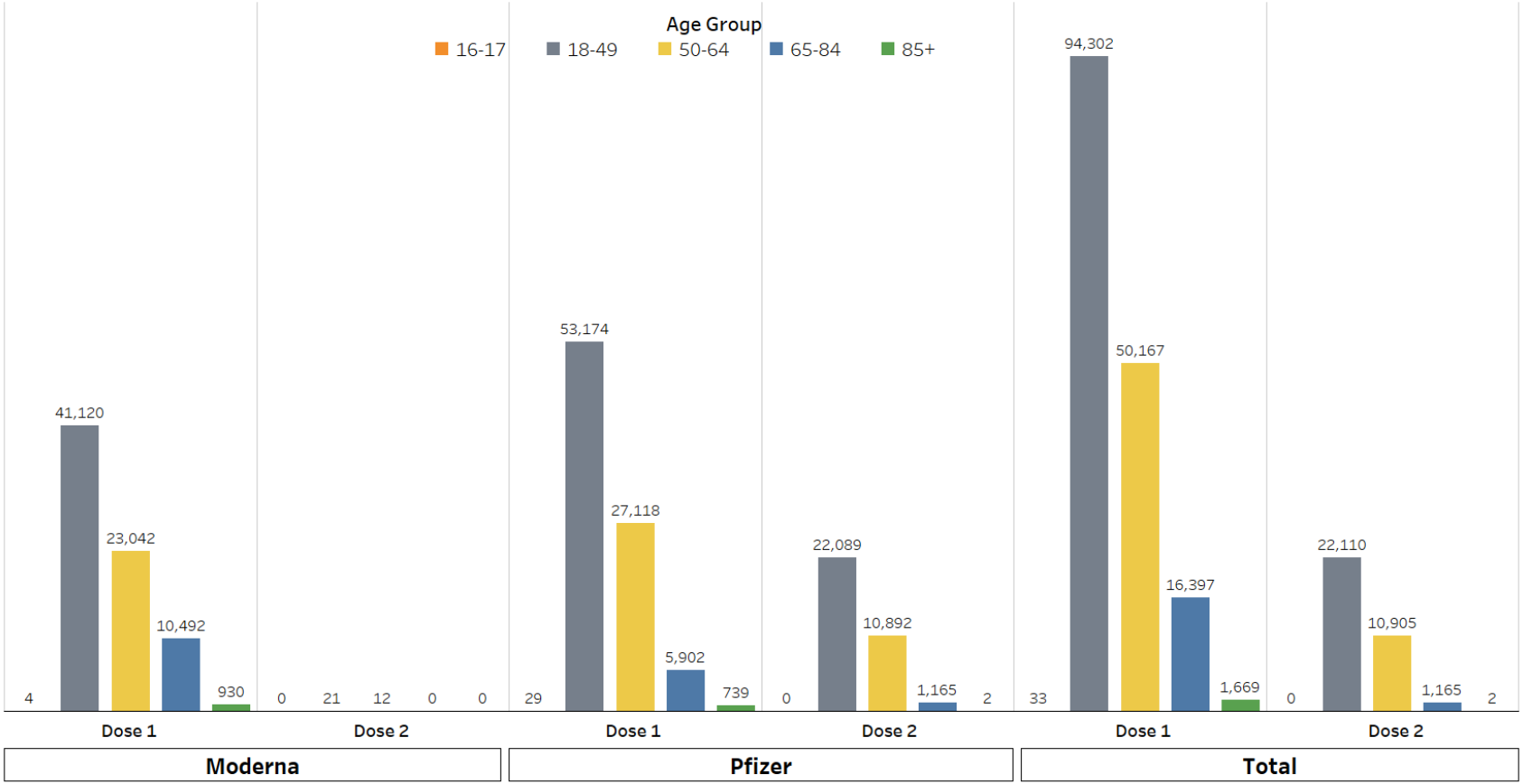


VSD RCA outcomes for COVID-19 vaccines	Concurrent comparator	Risk interval	Events in vaccinated	Events in unvaccinated	Signal (Y/N)
Acute disseminated encephalomyelitis	Unvaccinated	1-21 days	0	0	N
Acute myocardial infarction	Unvaccinated	1-21 days	1	179	N
Acute respiratory distress syndrome	Unvaccinated	1-21 days	0	4	N
Anaphylaxis	Unvaccinated	0-1 days	0	8	N
Appendicitis	Unvaccinated	1-21 days	5	267	N
Bell's palsy	Unvaccinated	1-21 days	4	358	N
Convulsions / seizures	Unvaccinated	1-21 days	0	39	N
Disseminated intravascular coagulation	Unvaccinated	1-21 days	0	14	N
Encephalitis / myelitis / encephalomyelitis	Unvaccinated	1-21 days	0	6	N
Guillain-Barré syndrome	Unvaccinated	1-21 days	0	4	N
Thrombotic thrombocytopenic purpura	Unvaccinated	1-21 days	0	4	N
Immune thrombocytopenia	Unvaccinated	1-21 days	0	21	N
Kawasaki disease	Unvaccinated	1-21 days	0	1	N
MIS-C and MIS-A	Unvaccinated	NA	0	NA	N
Myocarditis / pericarditis	Unvaccinated	1-21 days	0	12	N
Narcolepsy and cataplexy	Unvaccinated	N/A	0	8	N
Stroke, hemorrhagic	Unvaccinated	1-21 days	1	85	N
Stroke, ischemic	Unvaccinated	1-21 days	0	197	N
Transverse myelitis	Unvaccinated	1-21 days	0	0	N
Venous thromboembolism	Unvaccinated	1-21 days	3	408	N
Pulmonary embolism (subset of VTE)	Unvaccinated	1-21 days	0	132	N

- Preliminary results of VSD unvaccinated concurrent comparator analyses for COVID-19 vaccine safety
- No signals as of January 16

VSD RCA next steps – next analyses

- Vaccinated concurrent comparator analysis
  - Start when informative comparator follow-up available (expected within a week)
- Dose 1, Dose 2 analysis for each vaccine
  - Both the 1-21 and 1-42 day risk intervals
- Historical comparator analysis
  - General age comparable background rates
  - Rates following well care visits among those that received influenza vaccine in the past 18 months
  - Planning to start in mid-March

Update on anaphylaxis following COVID-19 vaccine

Anaphylaxis reports to VAERS following COVID-19 vaccines

- Suspected anaphylaxis reports to VAERS through January 18, 2021
  - Detected through early screening to identify suspected anaphylaxis reports prior to formal processing and MedDRA coding
  - Detected through a MedDRA code search strategy after formal processing and coding
- Suspected anaphylaxis reports 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)
- CDC and FDA met to discuss and further adjudicate cases if necessary

* Rüggeberg 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(31):5675-84.

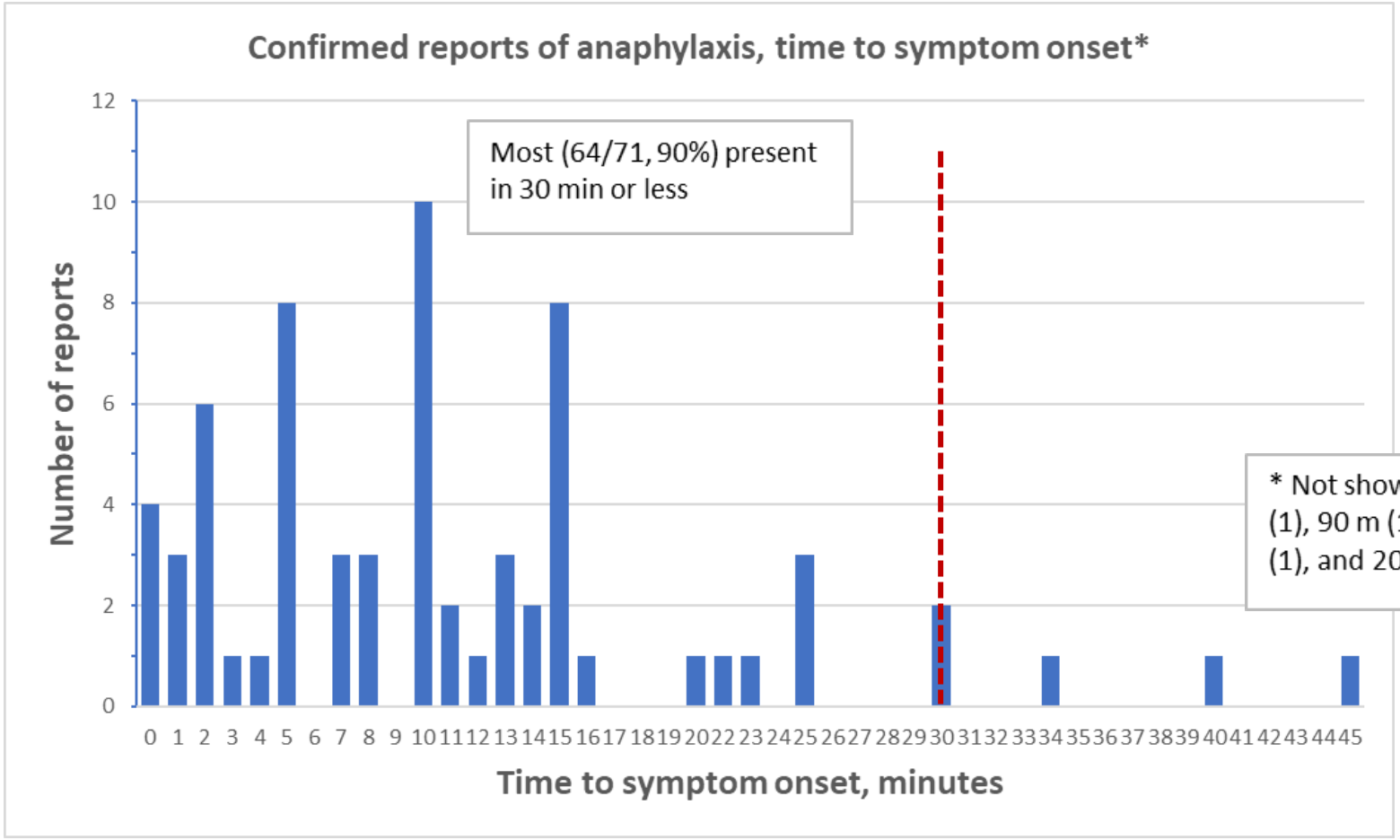
Anaphylaxis reports to VAERS following COVID-19 vaccines*

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])†	10 (<1-45)
Symptom onset ≤15 minutes (%)	37 (74)	18 (86)
Symptom onset ≤30 minutes (%)	45 (90)	19 (90)
Documented h/o of allergies or allergic rxns (%)	40 (80)	18 (86)
Documented h/o of prior anaphylaxis (%)	12 (24)	5 (24)
Dose number (1st, 2nd, 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, 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

† 20 hour onset was an outlier, the remaining onset for cases with onset >30 minutes were 34, 54, 90, and 150 minutes



Data through January 18, 2021

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/volumes/70/wr/mm7002e1.htm
- Previously reported rate for Moderna vaccine: 2.5 per million doses admin (Dec 21-Jan 10)
  https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm

* Data through January 18, 2021

Reports of deaths and mortality following COVID-19 vaccination

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.)
  - Notifies state Vaccine Safety Coordinator (VSC) of the death and provides copy of the initial report to the VSC via Epi-X
- 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

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

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

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

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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School of Public Health

Genesis

NIH National Institute on Aging

Genesis Healthcare analysis

This research was supported, in part, by a grant from the National Institute on Aging [5U54AG063546-02S5] with supplemental funding from the Centers for Disease Control and Prevention (CDC) under an inter-agency agreement.

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Vaccine Safety Monitoring among Residents of 284 Genesis Skilled Nursing Facilities

On behalf of: Barbara Bardenheier, PhD, MPH, MA
Assistant Professor of Health Services, Policy, and Practice
Assistant Professor of Epidemiology
Brown University School of Public Health

BROWN
School of Public Health

Background

- Genesis Healthcare is the largest nursing home company in the United States, spanning 24 states
  - Analysis included Skilled Nursing Facilities (284 Facilities with about 25,000 residents)
- COVID-19 vaccination began on December 18, 2021
  - By December 31, first dose of vaccine was administered in 118 facilities among 7,006 residents (61.4% in those facilities)
- Assessed 7-day mortality rates among the vaccinated and unvaccinated residents in 118 facilities as well as 17,076 residents in the 166 facilities that started vaccinating after January 1, 2021

Results

- After excluding residents with a positive SARS-CoV-2 diagnostic test within 20 days prior to their 7-day observation window
  - Mortality was lower among vaccinated versus unvaccinated residents within the same facilities and compared to residents in not-yet-vaccinated facilities, with overlapping 95% confidence intervals

Conclusions

- Findings suggest that short term mortality rates appear unrelated to vaccination for COVID-19 in skilled nursing facility residents
- This study underscores the value of having an analytic infrastructure to support near real-time monitoring of adverse events and safety during rapid vaccine deployment in this vulnerable population

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Reports of deaths following COVID-19 vaccination in LTCF residents to VAERS

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 includes attempts to collect and review death certificates and autopsy reports

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

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 and Genesis population-based surveillance 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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GACVS COVID-19 Vaccine Safety subcommittee meeting to review reports of deaths of very frail elderly individuals vaccinated with Pfizer BioNTech COVID-19 vaccine, BNT162b2

22 January 2021 | Statement | Reading time:

The GACVS COVID-19 Vaccine Safety subcommittee met virtually on Tuesday, 19 January 2021, to review available information and data on deaths reported in frail, elderly individuals who had received the Pfizer BioNTech COVID-19 mRNA vaccine, BNT162b2 (hereafter, BNT162b2). Experts invited from the European Medicines Agency (EMA) and the Uppsala Monitoring Center (UMC) provided an overview of deaths reported in Europe and in the WHO global database (VigiBase) following vaccination with BNT162b2.

Based on a careful scientific review of the information made available, the subcommittee came to the following conclusions:

The current reports do not suggest any unexpected or untoward increase in fatalities in frail, elderly individuals or any unusual characteristics of adverse events following administration of BNT162b2. Reports are in line with the expected, all-cause mortality rates and causes of death in the sub-population of frail, elderly individuals, and the available information does not confirm a contributory role for the vaccine in the reported fatal events. In view of this, the committee considers that the benefit-risk balance of BNT162b2 remains favourable in the elderly, and does not suggest any revision, at present, to the recommendations around the safety of this vaccine.

Related

COVID-19 vaccine safety surveillance manual

https://www.who.int/news/item/22-01-2021-gacvs-review-deaths-pfizer-biontech-covid-19-vaccine-bnt162b2

Reports of deaths following COVID-19 vaccination in community dwelling adults aged <65 years

Background: Sudden cardiac death in community residents

- Rate of sudden cardiac death = 29.6 per 100,000 person-years*
  - Out-of-hospital cardiac arrest in people 18–90 years of age in San Francisco County
    - Inclusion criteria: sudden unexpected death either within 1 hour of symptom onset (event witnessed), or within 24 hours of having been observed alive and symptom free (unwitnessed)
    - Excludes: (1) subjects with chronic/terminal illness in which imminent death not unexpected; (2) hospice residents; (3) subjects with identifiable noncardiac etiology of death at presentation, including drug abuse/overdose, trauma, homicide, or suicide; (4) subjects with hospital admission within prior 30 days for noncardiac illness or surgical procedure.

* Tseng et al, Circulation. 2018;137:2689–2700

Background: Sudden cardiac death in community residents

- Estimate ~13.7 million community residents vaccinated December 14–January 18, 2021 (CDC COVID Data Tracker)
- Risk period
  - Risk period = 35 days (December 14–January 18)
  - Assume each resident contributes 15 person-days (~ mid-point of risk period, adjusted downward to account for Moderna not used until December 21)
  - Total person-years contributed = 566,650 ([13.7million*15 days]/365.25)
- Expected sudden cardiac death count: 168 deaths (29.6*5.66)
- *Reported* VAERS sudden cardiac death count following COVID vaccination: 18 deaths

Reports of deaths following COVID-19 vaccination to VAERS in community dwelling adults aged <65 years* (N = 28)

Characteristics	Reports of death (N = 28)
Median age, years (range)	54 (25–63)
Female (%)	12 (43)
Median time from vaccination to death (range), days	5 (day of vax–25)
Pfizer-BioNTech	16
Moderna	12
Autopsy (completed, pending)	1, 4
Death certificate/autopsy report available	11

* Data through January 18, 2021

Reports of deaths following COVID-19 vaccination to VAERS in community dwelling adults aged <65 years with death certificate or autopsy report available* (N = 11)

Cause of death from death certificate or autopsy report
Atherosclerotic cardiovascular disease
Atherosclerotic cardiovascular heart disease, hypertension
Cardiac arrest, COVID-19
Cardiac arrest, hypertension, morbid obesity
Cardiopulmonary arrest, hypertensive heart disease, hypertension, DM type II
Hypertensive cardiovascular disease
Myocardial infarction, ventricular fibrillation
Drug overdose
Pulmonary hemorrhage from squamous cell cancer of the lung
Subarachnoid hemorrhage, intraparenchymal hemorrhage, intraventricular hemorrhage
COVID-19 stroke, COVID-19 acute respiratory failure

* Data through January 18, 2021

Closing

Closing thoughts

- 23.5 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
  - CDC's Vaccine Safety Datalink, FDA monitoring in CMS data, VA electronic health record

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V-safe Team

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Genesis

Questions