

8-14-21
submitted by
Dr. James Neuenchwander



PFIZER/BIONTECH

Outcome 7: Reactogenicity^a, Severe (Grade ≥ 3) Studies with Unvaccinated Comparator (n=1)

KIDS

Study/population	Events/Vaccine (n/N)	% Vaccine	Events/Placebo (n/N)	% Placebo
Pfizer/BioNTech, unpublished	121/1131	10.7	22/1129	1.9

Outcome 7: Reactogenicity, Severe (Grade ≥ 3) Studies with Unvaccinated Comparator (n=2)

ADULTS

Study/population	Events/Vaccine (n/N)	% Vaccine	Events/Placebo (n/N)	% Placebo
Walsh, 2020 ^a	2/24	8.3	1/18	5.6
Pfizer/BioNTech, unpublished	362/4108	8.8	84/4106	2.1

REPORTS FROM VAERS

Grant Final Report

Grant ID: R18 HS 017046

**Electronic Support for Public Health–Vaccine Adverse
Event Reporting System (ESP:VAERS)**

Inclusive dates: 12/01/07 - 09/30/10

Principal Investigator:

Lazarus, Ross, MBBS, MPH, MMed, GDCCompSci

Team members:

Michael Klompas, MD, MPH

Performing Organization:

Harvard Pilgrim Health Care, Inc.

Project Officer:

Steve Bernstein

Submitted to:

The Agency for Healthcare Research and Quality (AHRQ)

U.S. Department of Health and Human Services

540 Gaither Road

Rockville, MD 20850

www.ahrq.gov

- VAERS reporting could be automated
- Fewer than 1% of all potential injuries were being reported
- Found similar problems (but not as bad) with reporting of drug adverse events as well

<https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

REPORTS FROM VAERS

Search Results

From the 7/23/2021 release of VAERS data:

Found 204 cases where Patient Died and Vaccination Date from '2019-01-01' to '2019-12-31'

Table

Age	Count	Percent
< 3 Years	61	29.9%
3-6 Years	1	0.49%
6-9 Years	1	0.49%
9-12 Years	1	0.49%
12-17 Years	2	0.98%
17-44 Years	6	2.94%
44-65 Years	9	4.41%
65-75 Years	14	6.86%
75+ Years	36	17.65%
Unknown	75	35.78%
TOTAL	204	100%

➤ All deaths reported to VAERS in 2019=204

REPORTS FROM VAERS

From the 7/23/2021 release of VAERS data:

Found 9,864 cases where Patient Died and Vaccination Date on/before '2019-12-31'

Table

↓ Age	Count	↑ ↓ Percent
< 3 Years	3,864	39.17%
3-6 Years	167	1.69%
6-9 Years	77	0.78%
9-12 Years	81	0.82%
12-17 Years	201	2.04%
17-44 Years	432	4.38%
44-65 Years	487	4.94%
65-75 Years	428	4.34%
75+ Years	815	8.26%
Unknown	3,312	33.58%
TOTAL	9,864	100%

➤ All deaths reported to VAERS in from 1991 (creation) to 2019=9864





REPORTS FROM VAERS

Search Results

From the 8/6/2021 release of VAERS data:

Found 12,791 cases where Vaccine targets COVID-19 (COVID19) and Patient Died

Table

 Age	Count	 	Percent
< 3 Years	3		0.02%
12-17 Years	13		0.1%
17-44 Years	367		2.87%
44-65 Years	1,334		10.43%
65-75 Years	1,701		13.3%
75+ Years	4,502		35.2%
Unknown	4,871		38.08%
TOTAL	12,791		100%

➤ Deaths reported to VAERS after COVID-19 vaccination = 12791 (data from 08/13/21)

PFIZER/BIONTECH

Outcome	Importance ^a	Description
Benefits		
Symptomatic lab-confirmed COVID-19	Critical	Primary outcome; current studies use PCR + specific symptoms
Hospitalization due to COVID-19	Critical	Phase 3 trials not designed to detect statistical differences between treatment groups for this outcome
All-cause death	Important	Death from all causes; phase 3 trials not designed to detect statistical differences between treatment groups for this outcome
SARS-CoV-2 seroconversion	Important	Measured using antibodies to non-spike protein to differentiate seroconversion due to natural infection from immunogenicity to vaccine; no data available
Asymptomatic SARS-CoV-2 infection	Important	Measured using serial PCR; no data available



INFECTIONS AMONG THE VACCINATED

Morbidity and Mortality Weekly Report

Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021

Catherine M. Brown, DVM¹; Johannes Venzel, MPH¹; Hillary Johnson, MD²; Megan Hutto, MPH¹; Raehela Chaturvedi, DVM³; Sumati Saha, DPH⁴; Rebecca T. Saha, MPH⁴; Naomi J. Fell, PhD⁵; Amy Forman, PhD⁵; Peter J. Schubarz, MPH⁶; Glen R. Colglough PhD⁷; Tamara Park⁸; Lawrence C. Madoff, MD⁹; Henry B. Cabral, PhD⁹; Rumona Maclean, PhD⁹; Daniel J. Paul, PhD⁹; Katherine J. Seballe, PhD⁹; Yara Heck, MS⁹; Doreen Arvidson, MSN⁹; Taylor Brock-Palmer, MS⁹; Molly Dunn, DVM⁹; Amanda Kaurin⁹; A Scott Lantry, PhD⁹

On July 30, 2021, this report was posted as an MMWR Early Release on the MMWR website (<https://www.cdc.gov/mmwr>).

During July 2021, 469 cases of COVID-19 associated with multiple summer events and large public gatherings in a town in Barnstable County, Massachusetts, were identified among Massachusetts residents; vaccination coverage among eligible Massachusetts residents was 69%. Approximately three quarters (346; 74%) of cases occurred in fully vaccinated persons (those who had completed a 2-dose course of mRNA vaccine [Pfizer-BioNTech or Moderna] or had received a single dose of Janssen [Johnson & Johnson] vaccine ≥14 days before exposure). Genomic sequencing of specimens from 133 patients identified the B.1.617.2 (Delta) variant of SARS-CoV-2, the virus that causes COVID-19, in 119 (89%) and the Delta AY.3 sublineage in one (1%). Overall, 274 (79%) vaccinated patients with breakthrough infection were asymptomatic. Among five COVID-19 patients who were hospitalized, four were fully vaccinated; no deaths were reported. Real-time reverse transcription-polymerase chain reaction (RT-PCR) cycle threshold (Ct) values in specimens from 127 vaccinated persons with breakthrough cases were similar to those from 84 persons who were unvaccinated, not fully vaccinated, or whose vaccination status was unknown (median = 22.77 and 21.54, respectively). The Delta variant of SARS-CoV-2 is highly transmissible (7); vaccination is the most important strategy to prevent severe illness and death. On July 27, CDC recommended that all persons, including those who are fully vaccinated, should wear masks in indoor public settings in areas where COVID-19 transmission is high or substantial.¹ Findings from this investigation suggest that even jurisdictions without substantial or high COVID-19 transmission might consider expanding prevention strategies, including masking in indoor public settings regardless of vaccination status, given the potential risk of infection during attendance at large public gatherings that include travelers from many areas with differing levels of transmission.

During July 3–17, 2021, multiple summer events and large public gatherings were held in a town in Barnstable County,

Massachusetts, that attracted thousands of tourists from across the United States. Beginning July 10, the Massachusetts Department of Public Health (MA DPH) received reports of an increase in COVID-19 cases among persons who reside in or recently visited Barnstable County, including in fully vaccinated persons. Persons with COVID-19 reported attending densely packed indoor and outdoor events at venues that included bars, restaurants, guest houses, and rental houses. On July 3, MA DPH had reported a 14-day average COVID-19 incidence of zero cases per 100,000 persons per day in residents of the town in Barnstable County; by July 17, the 14-day average incidence increased to 177 cases per 100,000 persons per day in residents of the town (2).

During July 10–26, using travel history data from the state COVID-19 surveillance systems, MA DPH identified a cluster of cases among Massachusetts residents. Additional cases were identified by local health jurisdictions through case investigation. COVID-19 cases were matched with the state immunization registry. A cluster-associated case was defined as receipt of a positive SARS-CoV-2 test (nucleic acid amplification or antigen) result ≤14 days after travel to or residence in the town in Barnstable County since July 3. COVID-19 vaccine breakthrough cases were those in fully vaccinated Massachusetts residents (those with documentation from the state immunization registry of completion of COVID-19 vaccination as recommended by the Advisory Committee on Immunization Practices,¹ ≥14 days before exposure). Specimens were submitted for whole genome sequencing³ to either the Massachusetts State Public Health Laboratory or the Broad Institute of the Massachusetts Institute of

¹ As of July 2021, ACP recommended that all adults aged ≥18 years receive any of the three COVID-19 vaccines available in the United States via Emergency Use Authorizations from the Food and Drug Administration, including Pfizer-BioNTech, Moderna, and Janssen patients aged ≥12 years are eligible to receive the Pfizer-BioNTech COVID-19 vaccine. Full vaccination is defined as receipt of 2 doses of the Pfizer-BioNTech or Moderna COVID-19 vaccine or 1 dose of Janssen COVID-19 vaccine ≥14 days before exposure.

² Genomic sequencing was performed using Illumina NovaSeq using the NEB Landmark RT-RTx SARS-CoV-2 kit. Small amplicons were not identified as the split points of the cluster-associated genomes compared with genomes sequenced during the same period from ongoing genomic surveillance efforts at Broad Institute. Raw and assembled genomes data are publicly available under NCBI BioProject PRJNA715749.

³ <https://www.cdc.gov/mmwr/2021/mmwr/20210730/vol44/wr4413a1.html>

- 469 cases of COVID after a few, large public gatherings in July
- 74% had received a complete series of one of the COVID vaccine
- Appeared primarily to be the delta variant

INFECTIONS AMONG THE VACCINATED

Necessity of COVID-19 vaccination in previously infected individuals

Nabin K. Shrestha,¹ Patrick C. Burke,² Amy S. Nowacki,³ Paul Terpeluk,⁴ Steven M. Gordon¹

From the Departments of ¹Infectious Diseases, ²Infection Prevention, ³Quantitative Health Sciences, and ⁴Occupational Health, Cleveland Clinic, Cleveland, Ohio.

Keywords: SARS-CoV-2, COVID-19, Incidence, Vaccines, Immunity;

Running Title: COVID-19 vaccination if already infected

Corresponding author:

Nabin K. Shrestha, MD, MPH

9500 Euclid Avenue / G-21

Cleveland, OH 44195

Phone: 216-636-1873 / Fax: 216-445-9446 / Email: shrestn@ccf.org

Summary: Cumulative incidence of COVID-19 was examined among 52238 employees in an American healthcare system. COVID-19 did not occur in anyone over the five months of the study among 2579 individuals previously infected with COVID-19, including 1359 who did not take the vaccine.

- Cleveland Clinic study of over 52K employees
- None of the 2579 employees that had COVID were re-infected
- 14 vaccinated employees developed COVID

INFECTIONS AMONG THE VACCINATED

Centers for Disease Control and Prevention
MMWR

Morbidity and Mortality Weekly Report

Early Release / Vol. 70

August 6, 2021

Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021

Alyson M. Carranagh, DPT, PhD^{1,2}; Kevin R. Spivey, MD, PhD^{2,3}; Douglas Thornthorn, PhD^{2,4}; Connor Glck, MS²; Kathleen Wintse, PhD^{2,5}

Although laboratory evidence suggests that antibody responses following COVID-19 vaccination provide better neutralization of some circulating variants than does natural infection (1,2), few real-world epidemiologic studies exist to support the benefit of vaccination for previously infected persons. This report details the findings of a case-control evaluation of the association between vaccination and SARS-CoV-2 reinfection in Kentucky during May–June 2021 among persons previously infected with SARS-CoV-2 in 2020. Kentucky residents who were not vaccinated had 2.34 times the odds of reinfection compared with those who were fully vaccinated (odds ratio [OR] = 2.34; 95% confidence interval [CI] = 1.58–3.47). These findings suggest that among persons with previous SARS-CoV-2 infection, full vaccination provides additional protection against reinfection. To reduce their risk of infection, all eligible persons should be offered vaccination, even if they have been previously infected with SARS-CoV-2.*

Kentucky residents aged ≥18 years with SARS-CoV-2 infection confirmed by positive nucleic acid amplification test (NAAT) or antigen test results¹ reported in Kentucky's National Electronic Disease Surveillance System (NEDSS) during March–December 2020 were eligible for inclusion. NEDSS data for all Kentucky COVID-19 cases were imported into a REDCap database that contains laboratory test results and case investigation data, including dates of death for deceased patients reported to public health authorities (3). The REDCap database was queried to identify previously infected persons, excluding COVID-19 cases resulting in death before May 1, 2021. A case-patient was defined as a Kentucky resident

with laboratory-confirmed SARS-CoV-2 infection in 2020 and a subsequent positive NAAT or antigen test result during May 1–June 30, 2021. May and June were selected because of vaccine supply and eligibility requirement considerations; this period was more likely to reflect resident choice to be vaccinated, rather than eligibility to receive vaccine.⁵ Control participants were Kentucky residents with laboratory-confirmed SARS-CoV-2 infection in 2020 who were not reinfected through June 30, 2021. Case-patients and controls were matched on a 1:2 ratio based on sex, age (within 3 years), and date of initial positive SARS-CoV-2 test (within 1 week). Date of initial positive test result refers to the specimen collection date, if available. The report date in NEDSS was used if specimen collection date was missing. Random matching was performed to select controls when multiple possible controls were available to match per case (4).

Vaccination status was determined using data from the Kentucky Immunization Registry (KYIR). Case-patients and controls were matched to the KYIR database using first name, last name, and date of birth. Case-patients were considered fully vaccinated if a single dose of Janssen (Johnson & Johnson) or a second dose of an mRNA vaccine (Pfizer-BioNTech or Moderna) was received ≥14 days before the reinfection date. For controls, the same definition was applied, using the reinfection date of the matched case-patient. Partial vaccination was defined as receipt of ≥1 dose of vaccine, but either the

* May and June were selected for two primary reasons. First, when vaccination begins soon after, most previously infected persons were delaying vaccination for 90 days to allow sero-neutralizing antibody response for available vaccine; however, by May 2021, demand for 90 days was no longer a concern for those infected in 2020 to receive unadjuvanted Shingles, although vaccination eligibility was initially restricted based on age, comorbidities, and occupation, by April 5, 2021, all Kentucky residents aged ≥16 years became eligible for vaccination (https://www.ky.gov/government/department/196/COVID-19/Vaccines/Updated-2021). Thus, vaccination status in May or June 2021 might more accurately reflect choice rather than eligibility to be vaccinated.

¹ <https://www.cdc.gov/vaccines/imz/downloads/pdf/196/covid-19/clinical-considerations-covid-19-vaccines-usa-16-01-2021-aa.pdf>; ² <https://www.cdc.gov/nczod/diseases/zoonotic/diseases/2019-nCoV/>; ³ <https://www.cdc.gov/nczod/diseases/zoonotic/diseases/2019-nCoV/>; ⁴ <https://www.cdc.gov/nczod/diseases/zoonotic/diseases/2019-nCoV/>; ⁵ <https://www.cdc.gov/nczod/diseases/zoonotic/diseases/2019-nCoV/>

- Study of 265K people that tested positive for SARS-CoV-2 in 2020 in Kentucky. Looked at a second positive test from May 1-June 15
- 179 people who were not vaccinated (0.067%) tested positive versus 67 people were vaccinated (0.03%)
- CDC stopped recommending that vaccinated people get tested as of May 1st

Cases by Date of Onset

Case Status ● Confirmed ● Probable

