From: "Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)" <[redacted]>
To: "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: RE: data refresh -- bivalent booster dose
Date: Wed, 25 Jan 2023 17:32:20 +0000
Importance: Normal
Attachments: VAERS_COVID_BIVALENT_Descriptive_Stats_5_yrs_and_older_08.31.2022_to_01.08.2023.doc

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Ok. So I ran multiple bivalent requests with varying criteria. I assumed you were using the criteria for the document attached. Those 7 ids are not in the search performed among the 17,841 (attached output) since they do not fit the criteria. Your total would be greater if I expanded it to include people that got Pfizer or Moderna with dose >2 by 08/31/2022.--- I will send line list shortly.

Based on data as of 01/09/2023 with vaccination date between 08/31/2022 to 01/08/2023 and on the report indicated it was bivalent there were 115 deaths. Among those 115, 7 of them are ischemic strokes. The attached output shows the 115 deaths.

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Wednesday, January 25, 2023 12:00 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: data refresh -- bivalent booster dose

Hi Paige,

The total of 40 reports (all of which are chart-confirmed reports of ischemic stroke/TIA) came from searches you performed, as well as text searches I performed. In many cases, the vaccine was not specified as "bivalent", but was administered after bivalent vaccine was authorized – the implication being that the vaccine was bivalent, as monovalent was no longer authorized. Please provide a detailed line list of all 40 reports (Tom wants to know how many were deaths).

So, to be clear – we've had 115 deaths reported after bivalent vaccine – of them, 7 were deaths after ischemic stroke?

Thanks!

- John

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Wednesday, January 25, 2023 11:37 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: data refresh -- bivalent booster dose

Hey John,
I have 115 deaths in my bivalent dataset for vaccinated 08/31/2022 to 01/08/2023, not 110. Of the 115 deaths, 7 are ischemic strokes (attached line list).

In regards to the 40 ids you listed, were did you get them. I only have 33 of them in my data. The other 7 are not listed as bivalent. Should I just give you the 33 ids?

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Wednesday, January 25, 2023 9:47 AM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: data refresh -- bivalent booster dose
Importance: High

Hi Paige,

Two asks:

1. For deaths reported after bivalent vaccine (n=110), how many were of ischemic stroke? (ie, would you please run the same search we did for ischemic stroke, but applied to these 110 reports)
2. Please send me the detailed line list for the below list of VAERS IDs

Tom needs these data for VRBPAC, so as soon as possible would be greatly appreciated. Thanks!

- John

2440868
2454631
2459749
2462038
2470311
2472938
2474245
2475449
2475627
2477910
2480512
2484385
2487101
2487324
2488430
2488686
2488712
2489819
2493564
2496859
2499563
2500002
2500533
2508589
2510921
2511821
2512797
2513747
2516891
2519874
2521980
2523180
2524255
2524382
2529696

2535384
2536545
2536857
2548970
2549516

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, January 10, 2023 11:21 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: data refresh -- bivalent booster dose

Hey John- Did you find out what ages to include in the bivalent analysis? I went ahead and refreshed it for 5+ Pfizer and 6+ Moderna, just in case. Here is the descriptive stats

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From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Monday, January 9, 2023 3:48 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: data refresh -- bivalent booster dose
Importance: High

Hi Paige,

Also, Tom was wanting a refresh of reports after bivalent mRNA COVID-19 booster dose. Please rerun the same usual query, with the same output (e.g., descriptive data and line list), current as of Jan 8, 2023. Please get to me ASAP – I need to get slides to him by Friday. Thanks!

- John

John R. Su, M.D., Ph.D., M.P.H.
CAPT, U.S. Public Health Service
Acting Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Road, MS H17-3
Atlanta, GA 30333
[redacted]

VAERS Initial Domestic Reports- PFIZER/Moderna Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years and Moderna Bivalent 6+ years
VAERS archive data 01/09/2023

	Manufacturer					
	MODERNA BIVALENT		PFIZER-BIONTECH BIVALENT		ALL	
	N	%	N	%	N	%
Severity						
SERIOUS-DEATH	43	0.56	72	0.71	115	0.64
SERIOUS-NONDEATH	328	4.27	591	5.81	919	5.15
NON-SERIOUS	7308	95.17	9501	93.48	16807	94.20
All	7679	100.00	10164	100.00	17841	100.00
Sex						
F	4652	60.58	6238	61.37	10888	61.03
M	2928	38.13	3756	36.95	6684	37.46
U	99	1.29	170	1.67	269	1.51
All	7679	100.00	10164	100.00	17841	100.00
age_group						
05-11 yrs	78	1.02	927	9.12	1005	5.63
12-17 yrs	82	1.07	507	4.99	589	3.30
18+ yrs	7519	97.92	8730	85.89	16247	91.07
All	7679	100.00	10164	100.00	17841	100.00
vax_alone						
No	1046	13.62	1893	18.62	2937	16.46
Yes	6633	86.38	8271	81.38	14904	83.54
All	7679	100.00	10164	100.00	17841	100.00

[a] Serious Non-Death: hospitalization, extended hospital stay, life threatening illness, disability illness, and/or birth defect/congenital anomaly [Code of Federal Regulations, Title 21 (21 CFR 314.80)]
[b] 2 reportes received Moderna and Pfizer Bivalent

VAERS Initial Domestic Reports- PFIZER/Moderna Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years and Moderna Bivalent 6+ years
VAERS archive data 01/09/2023

	Manufacturer					
	MODERNA BIVALENT		PFIZER-BIONTECH BIVALENT		ALL	
	N	%	N	%	N	%
race_ethnicity						
HISPANIC/LATINO ANY RACE INCLUDING UNKNOWN	342	4.45	576	5.67	918	5.15
AMERICAN INDIAN/ALASKA NATIVE NON-HISPANIC	18	0.23	44	0.43	62	0.35
ASIAN NON-HISPANIC	140	1.82	263	2.59	403	2.26
BLACK NON-HISPANIC	203	2.64	355	3.49	557	3.12
NATIVE HAWAIIAN/OTHER PACIFIC ISLANDER NON-HISPANIC	8	0.10	5	0.05	13	0.07
WHITE NON-HISPANIC	2963	38.59	4618	45.43	7581	42.49
MULTIPLE NON-HISPANIC	55	0.72	94	0.92	149	0.84
OTHER NON-HISPANIC	33	0.43	44	0.43	77	0.43
UNKNOWN RACE OR ETHNICITY(EXCLUDES HISPANIC UNK RACE)	3917	51.01	4165	40.98	8081	45.29
All	7679	100.00	10164	100.00	17841	100.00

[a] Serious Non-Death: hospitalization, extended hospital stay, life threatening illness, disability illness, and/or birth defect/congenital anomaly [Code of Federal Regulations, Title 21 (21 CFR 314.80)]
[b] 2 reportes received Moderna and Pfizer Bivalent

VAERS Initial Domestic Reports- PFIZER/Moderna Bivalent 5+ years- Race and Ethnicity
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years and Moderna Bivalent 6+ years
VAERS archive data 01/09/2023

	Manufacturer					
	MODERNA BIVALENT		PFIZER-BIONTECH BIVALENT		ALL	
	N	%	N	%	N	%
RACE						
AIAN	35	0.46	78	0.77	113	0.63
ASIAN	166	2.16	327	3.22	493	2.76
BLACK	256	3.33	494	4.86	749	4.20
MULTIRACIAL	69	0.90	118	1.16	187	1.05
N/A	5	0.07	8	0.08	13	0.07
NHOPI	10	0.13	12	0.12	22	0.12
OTHER	560	7.29	1191	11.72	1751	9.81
UNK	3109	40.49	2370	23.32	5478	30.70
WHITE	3469	45.18	5566	54.76	9035	50.64
All	7679	100.00	10164	100.00	17841	100.00
ETHNICITY						
MIS	1761	22.93	1766	17.38	3526	19.76
N	3464	45.11	5502	54.13	8965	50.25
N/A	5	0.07	8	0.08	13	0.07
U	2107	27.44	2312	22.75	4419	24.77
Y	342	4.45	576	5.67	918	5.15
All	7679	100.00	10164	100.00	17841	100.00

[a] Serious Non-Death: hospitalization, extended hospital stay, life threatening illness, disability illness, and/or birth defect/congenital anomaly [Code of Federal Regulations, Title 21 (21 CFR 314.80)]
[b] 2 reportes received Moderna and Pfizer Bivalent

VAERS Initial Domestic Reports- PFIZER/Moderna Bivalent 5+ years- Outcomes
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years and Moderna Bivalent 6+ years
VAERS archive data 01/09/2023

	Manufacturer					
	MODERNA BIVALENT		PFIZER-BIONTECH BIVALENT		ALL	
	N	%	N	%	N	%
DEATH						
N	7635	99.43	10092	99.29	17731	99.38
Y	44	0.57	72	0.71	110	0.62
All	7679	100.00	10164	100.00	17841	100.00
ANAPHYLAXIS						
N	7668	99.86	10144	99.80	17812	99.84
Y	11	0.14	20	0.20	29	0.16
All	7679	100.00	10164	100.00	17841	100.00
MYOPERICARDITIS						
N	7651	99.64	10137	99.73	17786	99.69
Y	28	0.36	27	0.27	55	0.31
All	7679	100.00	10164	100.00	17841	100.00
SEIZURE						
N	7648	99.60	10084	99.21	17722	99.33
Y	31	0.40	80	0.79	119	0.67
All	7679	100.00	10164	100.00	17841	100.00

[a] Serious Non-Death: hospitalization, extended hospital stay, life threatening illness, disability illness, and/or birth defect/congenital anomaly [Code of Federal Regulations, Title 21, 21 CFR 314.80]

AGE STATS following VAERS Initial Domestic Reports- PFIZER/Moderna Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years and Moderna Bivalent 6+ years
VAERS archive data 01/09/2023
(N=17841)

Obs	VAX_NAME	total	max_age	Q3_age	median_age	Q1_age	min_age
1	COVID19 (COVID19 (MODERNA BIVALENT))	7679	101	71	61	44	6
2	COVID19 (COVID19 (PFIZER-BIONTECH BIVALENT))	10164	103	69	56	33	5
3	ALL	17843	103	70	58	38	5

Top 25 Pts following ALL VAERS Initial Domestic Reports- PFIZER/Moderna Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years and Moderna Bivalent 6+ years
VAERS archive data 01/09/2023
(N=17841)

Obs	PT_NAME	count	percent
1	NO ADVERSE EVENT	2702	15.1%
2	COVID-19	2230	12.5%
3	FATIGUE	1695	9.50%
4	HEADACHE	1693	9.49%
5	PYREXIA	1688	9.46%
6	SARS-COV-2 TEST POSITIVE	1563	8.76%
7	PAIN	1529	8.57%
8	PRODUCT STORAGE ERROR	1306	7.32%
9	INCORRECT PRODUCT FORMULATION ADMINISTERED	1248	7.00%
10	COUGH	1135	6.36%
11	CHILLS	1119	6.27%
12	UNDERDOSE	1075	6.03%
13	INCORRECT DOSE ADMINISTERED	1052	5.90%
14	PAIN IN EXTREMITY	917	5.14%
15	DIZZINESS	913	5.12%
16	NAUSEA	859	4.81%
17	OROPHARYNGEAL PAIN	743	4.16%
18	EXPIRED PRODUCT ADMINISTERED	728	4.08%
19	MALAISE	615	3.45%
20	SARS-COV-2 TEST	613	3.44%
21	DYSPNOEA	606	3.40%

Top 25 Pts following ALL VAERS Initial Domestic Reports- PFIZER/Moderna Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years and Moderna Bivalent 6+ years
VAERS archive data 01/09/2023
(N=17841)

Obs	PT_NAME	count	percent
22	INJECTION SITE PAIN	596	3.34%
23	ARTHRALGIA	588	3.30%
24	WRONG PRODUCT ADMINISTERED	550	3.08%
25	RASH	546	3.06%

Top 25 Pts following SERIOUS VAERS Initial Domestic Reports- PFIZER/Moderna Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years and Moderna Bivalent 6+ years
VAERS archive data 01/09/2023
(N=1034)

Obs	PT_NAME	count	percent
1	COVID-19	280	27.1%
2	SARS-COV-2 TEST POSITIVE	243	23.5%
3	DYSPNOEA	168	16.2%
4	ASTHENIA	107	10.3%
5	CONDITION AGGRAVATED	99	9.57%
6	PYREXIA	99	9.57%
7	BLOOD TEST	97	9.38%
8	DEATH	93	8.99%
9	COUGH	80	7.74%
10	FATIGUE	76	7.35%
11	ANTICOAGULANT THERAPY	75	7.25%
12	VACCINE BREAKTHROUGH INFECTION	72	6.96%
13	CHEST PAIN	71	6.87%
14	LABORATORY TEST	67	6.48%
15	ELECTROCARDIOGRAM	66	6.38%
16	NAUSEA	66	6.38%
17	DIZZINESS	65	6.29%
18	PAIN	64	6.19%
19	CHEST X-RAY ABNORMAL	61	5.90%
20	ATRIAL FIBRILLATION	58	5.61%
21	HEADACHE	58	5.61%

Top 25 Pts following SERIOUS VAERS Initial Domestic Reports- PFIZER/Moderna Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years and Moderna Bivalent 6+ years
VAERS archive data 01/09/2023
(N=1034)

Obs	PT_NAME	count	percent
22	ACUTE RESPIRATORY FAILURE	57	5.51%
23	MALAISE	56	5.42%
24	VOMITING	55	5.32%
25	COMPUTERISED TOMOGRAM	53	5.13%

Top 25 Pts following NONSERIOUS VAERS Initial Domestic Reports- PFIZER/Moderna Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years and Moderna Bivalent 6+ years
VAERS archive data 01/09/2023
(N=16807)

Obs	PT_NAME	count	percent
1	NO ADVERSE EVENT	2700	16.1%
2	COVID-19	1950	11.6%
3	HEADACHE	1635	9.73%
4	FATIGUE	1619	9.63%
5	PYREXIA	1589	9.45%
6	PAIN	1465	8.72%
7	SARS-COV-2 TEST POSITIVE	1320	7.85%
8	PRODUCT STORAGE ERROR	1306	7.77%
9	INCORRECT PRODUCT FORMULATION ADMINISTERED	1247	7.42%
10	UNDERDOSE	1074	6.39%
11	CHILLS	1071	6.37%
12	COUGH	1055	6.28%
13	INCORRECT DOSE ADMINISTERED	1052	6.26%
14	PAIN IN EXTREMITY	883	5.25%
15	DIZZINESS	848	5.05%
16	NAUSEA	793	4.72%
17	EXPIRED PRODUCT ADMINISTERED	727	4.33%
18	OROPHARYNGEAL PAIN	727	4.33%
19	SARS-COV-2 TEST	588	3.50%
20	INJECTION SITE PAIN	583	3.47%
21	ARTHRALGIA	561	3.34%

Top 25 Pts following NONSERIOUS VAERS Initial Domestic Reports- PFIZER/Moderna Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years and Moderna Bivalent 6+ years
VAERS archive data 01/09/2023
(N=16807)

Obs	PT_NAME	count	percent
22	MALAISE	559	3.33%
23	WRONG PRODUCT ADMINISTERED	547	3.25%
24	RASH	541	3.22%
25	RESPIRATORY TRACT CONGESTION	531	3.16%

Top 25 Pts following ALL MODERNA BIVALENT VAERS Initial Domestic Reports- Moderna Bivalent 6+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Moderna Bivalent 6+ years
VAERS archive data 01/09/2023
(N=7679)

Obs	PT_NAME	count	percent
1	NO ADVERSE EVENT	1734	22.6%
2	UNDERDOSE	980	12.8%
3	PYREXIA	757	9.86%
4	HEADACHE	756	9.85%
5	COVID-19	733	9.55%
6	FATIGUE	720	9.38%
7	SARS-COV-2 TEST POSITIVE	656	8.54%
8	PAIN	639	8.32%
9	INCORRECT DOSE ADMINISTERED	548	7.14%
10	CHILLS	499	6.50%
11	COUGH	475	6.19%
12	EXPIRED PRODUCT ADMINISTERED	458	5.96%
13	PAIN IN EXTREMITY	405	5.27%
14	DIZZINESS	367	4.78%
15	NAUSEA	358	4.66%
16	PRODUCT TEMPERATURE EXCURSION ISSUE	357	4.65%
17	POOR QUALITY PRODUCT ADMINISTERED	354	4.61%
18	OROPHARYNGEAL PAIN	313	4.08%
19	ARTHRALGIA	294	3.83%
20	INCORRECT PRODUCT FORMULATION ADMINISTERED	291	3.79%
21	INJECTION SITE PAIN	272	3.54%

Top 25 Pts following ALL MODERNA BIVALENT VAERS Initial Domestic Reports- Moderna Bivalent 6+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Moderna Bivalent 6+ years
VAERS archive data 01/09/2023
(N=7679)

Obs	PT_NAME	count	percent
22	PRODUCT STORAGE ERROR	265	3.45%
23	DYSPNOEA	258	3.36%
24	RASH	255	3.32%
25	MALAISE	251	3.27%

Top 25 Pts following SERIOUS MODERNA BIVALENT VAERS Initial Domestic Reports- Moderna Bivalent 6+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Moderna Bivalent 6+ years
VAERS archive data 01/09/2023
(N=371)

Obs	PT_NAME	count	percent
1	COVID-19	99	26.7%
2	SARS-COV-2 TEST POSITIVE	85	22.9%
3	DYSPNOEA	68	18.3%
4	BLOOD TEST	40	10.8%
5	CONDITION AGGRAVATED	37	9.97%
6	ASTHENIA	36	9.70%
7	COUGH	35	9.43%
8	ANTICOAGULANT THERAPY	34	9.16%
9	DEATH	34	9.16%
10	PYREXIA	32	8.63%
11	DIZZINESS	31	8.36%
12	FATIGUE	28	7.55%
13	CHEST PAIN	27	7.28%
14	HEADACHE	26	7.01%
15	MALAISE	25	6.74%
16	NAUSEA	25	6.74%
17	CHEST X-RAY ABNORMAL	23	6.20%
18	CHILLS	22	5.93%
19	ECHOCARDIOGRAM	22	5.93%
20	ACUTE RESPIRATORY FAILURE	21	5.66%
21	ATRIAL FIBRILLATION	21	5.66%

Top 25 Pts following SERIOUS MODERNA BIVALENT VAERS Initial Domestic Reports- Moderna Bivalent 6+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Moderna Bivalent 6+ years
VAERS archive data 01/09/2023
(N=371)

Obs	PT_NAME	count	percent
22	VACCINE BREAKTHROUGH INFECTION	21	5.66%
23	LABORATORY TEST	20	5.39%
24	ELECTROCARDIOGRAM	19	5.12%
25	ELECTROCARDIOGRAM ABNORMAL	19	5.12%

Top 25 Pts following NONSERIOUS MODERNA BIVALENT VAERS Initial Domestic Reports- Moderna Bivalent 6+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Moderna Bivalent 6+ years
VAERS archive data 01/09/2023
(N=7308)

Obs	PT_NAME	count	percent
1	NO ADVERSE EVENT	1733	23.7%
2	UNDERDOSE	980	13.4%
3	HEADACHE	730	9.99%
4	PYREXIA	725	9.92%
5	FATIGUE	692	9.47%
6	COVID-19	634	8.68%
7	PAIN	625	8.55%
8	SARS-COV-2 TEST POSITIVE	571	7.81%
9	INCORRECT DOSE ADMINISTERED	548	7.50%
10	CHILLS	477	6.53%
11	EXPIRED PRODUCT ADMINISTERED	458	6.27%
12	COUGH	440	6.02%
13	PAIN IN EXTREMITY	386	5.28%
14	PRODUCT TEMPERATURE EXCURSION ISSUE	357	4.89%
15	POOR QUALITY PRODUCT ADMINISTERED	354	4.84%
16	DIZZINESS	336	4.60%
17	NAUSEA	333	4.56%
18	OROPHARYNGEAL PAIN	308	4.21%
19	INCORRECT PRODUCT FORMULATION ADMINISTERED	290	3.97%
20	ARTHRALGIA	286	3.91%
21	INJECTION SITE PAIN	270	3.69%

Top 25 Pts following NONSERIOUS MODERNA BIVALENT VAERS Initial Domestic Reports- Moderna Bivalent 6+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Moderna Bivalent 6+ years
VAERS archive data 01/09/2023
(N=7308)

Obs	PT_NAME	count	percent
22	PRODUCT STORAGE ERROR	265	3.63%
23	RASH	252	3.45%
24	PRURITUS	240	3.28%
25	RESPIRATORY TRACT CONGESTION	232	3.17%

Top 25 Pts following ALL Pfizer VAERS Initial Domestic Reports- Pfizer Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years
VAERS archive data 01/09/2023
(N=10164)

Obs	PT_NAME	count	percent
1	COVID-19	1497	14.7%
2	PRODUCT STORAGE ERROR	1041	10.2%
3	FATIGUE	975	9.59%
4	NO ADVERSE EVENT	969	9.53%
5	INCORRECT PRODUCT FORMULATION ADMINISTERED	957	9.42%
6	HEADACHE	937	9.22%
7	PYREXIA	931	9.16%
8	SARS-COV-2 TEST POSITIVE	907	8.92%
9	PAIN	890	8.76%
10	COUGH	660	6.49%
11	CHILLS	620	6.10%
12	DIZZINESS	546	5.37%
13	SARS-COV-2 TEST	518	5.10%
14	PAIN IN EXTREMITY	512	5.04%
15	INCORRECT DOSE ADMINISTERED	504	4.96%
16	NAUSEA	501	4.93%
17	OROPHARYNGEAL PAIN	430	4.23%
18	DRUG INEFFECTIVE	416	4.09%
19	MALAISE	364	3.58%
20	DYSPNOEA	348	3.42%
21	WRONG PRODUCT ADMINISTERED	342	3.36%

Top 25 Pts following ALL Pfizer VAERS Initial Domestic Reports- Pfizer Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years
VAERS archive data 01/09/2023
(N=10164)

Obs	PT_NAME	count	percent
22	INJECTION SITE PAIN	324	3.19%
23	ASTHENIA	315	3.10%
24	RESPIRATORY TRACT CONGESTION	308	3.03%
25	ARTHRALGIA	294	2.89%

Top 25 Pts following SERIOUS Pfizer VAERS Initial Domestic Reports- Pfizer Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years
VAERS archive data 01/09/2023

(N=663)

Obs	PT_NAME	count	percent
1	COVID-19	181	27.3%
2	SARS-COV-2 TEST POSITIVE	158	23.8%
3	DYSPNOEA	100	15.1%
4	ASTHENIA	71	10.7%
5	PYREXIA	67	10.1%
6	CONDITION AGGRAVATED	62	9.35%
7	DEATH	59	8.90%
8	BLOOD TEST	57	8.60%
9	VACCINE BREAKTHROUGH INFECTION	51	7.69%
10	PAIN	50	7.54%
11	FATIGUE	48	7.24%
12	ELECTROCARDIOGRAM	47	7.09%
13	LABORATORY TEST	47	7.09%
14	COUGH	45	6.79%
15	CHEST PAIN	44	6.64%
16	ANTICOAGULANT THERAPY	41	6.18%
17	NAUSEA	41	6.18%
18	VOMITING	39	5.88%
19	CHEST X-RAY ABNORMAL	38	5.73%
20	ATRIAL FIBRILLATION	37	5.58%
21	ACUTE RESPIRATORY FAILURE	36	5.43%

Top 25 Pts following SERIOUS Pfizer VAERS Initial Domestic Reports- Pfizer Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years
VAERS archive data 01/09/2023

(N=663)

Obs	PT_NAME	count	percent
22	COMPUTERISED TOMOGRAM	35	5.28%
23	CONFUSIONAL STATE	34	5.13%
24	DIZZINESS	34	5.13%
25	CHEST X-RAY NORMAL	33	4.98%

Top 25 Pts following NONSERIOUS Pfizer VAERS Initial Domestic Reports- Pfizer Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years
VAERS archive data 01/09/2023

(N=9501)

Obs	PT_NAME	count	percent
1	COVID-19	1316	13.9%
2	PRODUCT STORAGE ERROR	1041	11.0%
3	NO ADVERSE EVENT	968	10.2%
4	INCORRECT PRODUCT FORMULATION ADMINISTERED	957	10.1%
5	FATIGUE	927	9.76%
6	HEADACHE	905	9.53%
7	PYREXIA	864	9.09%
8	PAIN	840	8.84%
9	SARS-COV-2 TEST POSITIVE	749	7.88%
10	COUGH	615	6.47%
11	CHILLS	594	6.25%
12	DIZZINESS	512	5.39%
13	INCORRECT DOSE ADMINISTERED	504	5.30%
14	SARS-COV-2 TEST	499	5.25%
15	PAIN IN EXTREMITY	497	5.23%
16	NAUSEA	460	4.84%
17	OROPHARYNGEAL PAIN	419	4.41%
18	DRUG INEFFECTIVE	412	4.34%
19	WRONG PRODUCT ADMINISTERED	339	3.57%
20	MALAISE	333	3.50%
21	INJECTION SITE PAIN	313	3.29%

Top 25 Pts following NONSERIOUS Pfizer VAERS Initial Domestic Reports- Pfizer Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years
VAERS archive data 01/09/2023

(N=9501)

Obs	PT_NAME	count	percent
22	RESPIRATORY TRACT CONGESTION	299	3.15%
23	RASH	289	3.04%
24	ARTHRALGIA	275	2.89%
25	RHINORRHOEA	274	2.88%

Top 25 Vaccine Types for ALL VAERS Initial Domestic Reports- PFIZER/Moderna Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years and Moderna Bivalent 6+ years
VAERS archive data 01/09/2023

(N=2937)

Obs	VAX_TYPE	count	percent
1	COVID19-2	2937	100%
2	FLU4	1457	49.6%
3	FLUX	447	15.2%
4	FLUC4	361	12.3%
5	FLUA4	263	8.95%
6	COVID19	123	4.19%
7	VARZOS	97	3.30%
8	FLUR4	81	2.76%
9	TDAP	66	2.25%
10	PNC20	46	1.57%
11	UNK	34	1.16%
12	PPV	33	1.12%
13	HPV9	31	1.06%
14	MNQ	25	0.85%
15	HEP	16	0.54%
16	HEPA	16	0.54%
17	MMR	13	0.44%
18	VARCEL	13	0.44%
19	IPV	10	0.34%
20	HEPAB	9	0.31%
21	PNC13	9	0.31%

Top 25 Vaccine Types for ALL VAERS Initial Domestic Reports- PFIZER/Moderna Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years and Moderna Bivalent 6+ years
VAERS archive data 01/09/2023

(N=2937)

Obs	VAX_TYPE	count	percent
22	SMALLMNK	7	0.24%
23	FLU3	6	0.20%
24	FLUN4	5	0.17%
25	MENB	4	0.14%

Top 25 Vaccine Types for MODERNA BIVALENT Initial Domestic Reports- Moderna Bivalent 6+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Moderna Bivalent 6+ years
VAERS archive data 01/09/2023

(N=1046)

Obs	VAX_TYPE	count	percent
1	COVID19-2	1046	100%
2	FLU4	529	50.6%
3	FLUX	165	15.8%
4	FLUC4	137	13.1%
5	FLUA4	100	9.56%
6	VARZOS	34	3.25%
7	FLUR4	26	2.49%
8	TDAP	22	2.10%
9	COVID19	18	1.72%
10	PNC20	15	1.43%
11	UNK	14	1.34%
12	HPV9	11	1.05%
13	MNQ	8	0.76%
14	PPV	8	0.76%
15	VARCEL	8	0.76%
16	HEPA	7	0.67%
17	MMR	7	0.67%
18	HEP	6	0.57%
19	IPV	5	0.48%
20	HEPAB	4	0.38%
21	PNC13	3	0.29%

Top 25 Vaccine Types for MODERNA BIVALENT Initial Domestic Reports- Moderna Bivalent 6+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Moderna Bivalent 6+ years
VAERS archive data 01/09/2023

(N=1046)

Obs	VAX_TYPE	count	percent
22	FLU3	2	0.19%
23	DTAP	1	0.10%
24	FLUA3	1	0.10%
25	FLUN4	1	0.10%

Top 25 Vaccine Types for Pfizer Initial Domestic Reports- Pfizer Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years
VAERS archive data 01/09/2023

(N=1893)

Obs	VAX_TYPE	count	percent
1	COVID19-2	1893	100%
2	FLU4	929	49.1%
3	FLUX	282	14.9%
4	FLUC4	224	11.8%
5	FLUA4	164	8.66%
6	COVID19	105	5.55%
7	VARZOS	63	3.33%
8	FLUR4	55	2.91%
9	TDAP	44	2.32%
10	PNC20	31	1.64%
11	PPV	25	1.32%
12	HPV9	20	1.06%
13	UNK	20	1.06%
14	MNQ	17	0.90%
15	HEP	10	0.53%
16	HEPA	9	0.48%
17	SMALLMNK	7	0.37%
18	MMR	6	0.32%
19	PNC13	6	0.32%
20	HEPAB	5	0.26%
21	IPV	5	0.26%

Top 25 Vaccine Types for Pfizer Initial Domestic Reports- Pfizer Bivalent 5+ years
Processed and Vaccinated 08/31/2022 - 01/08/2023
Includes Pfizer Bivalent 5+ years
VAERS archive data 01/09/2023

(N=1893)

Obs	VAX_TYPE	count	percent
22	VARCEL	5	0.26%
23	FLU3	4	0.21%
24	FLUN4	4	0.21%
25	MENB	4	0.21%

From: "Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)" <[redacted]>
To: "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Cc: "Gee, Julianne (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief
Date: Sun, 12 Feb 2023 19:13:47 +0000
Importance: Normal
Attachments: For_Review_COVID-19_Selected_AE_CLEANv2_12_Feb_2023_alt_tts.docx
Inline-Images: image001.png

I had a couple comments. I suggest deleting the myocarditis rates and deleting the ischemic stroke content. We can always be overruled.

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Sunday, February 12, 2023 1:05 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Hi folks,

Please see revised versions, based upon Tom's feedback. I've left the reporting rates for myocarditis from VSD present – we can delete if desired, but there will be push back, as (based upon experience) the public wants quantitative information about how often we observe myocarditis after mRNA COVID-19 vaccination. If you want me to remove this section before submitting back to Alanna, please let me know.

Also, I've moved the bit about ischemic stroke to the end, and provided some context. The "alt" version of the document contains an abbreviated section on this topic (which seems somewhat long to me). I've also tried to paraphrase the initial language into more plain language; hopefully, the language is still accurate – please correct if not. Please let me know which version you prefer.

Thanks!

- John

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Sunday, February 12, 2023 12:05 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

My main comment is that they shouldn't lead with the ischemic stroke content right at the beginning with no context at all. It's out of place and unnecessarily alarming.

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Friday, February 10, 2023 6:04 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Hi Tom,

Please see enclosed, which incorporate some suggestions Julianne made. Please take a look, and revise as you see fit. I can then send a clean copy back to Alanna to move forward.

Have a great weekend. Thanks!

- John

From: Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 4:50 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Good afternoon all,

Related to Lyn's update earlier, I've attached the following for your review:

- Clean and tracked changes versions of the Selected Adverse Events page with highlights of the proposed changes
- Rollout plan explaining these changes (I revised the previous version of the rollout we used for the earlier revision related to children and adolescents)

Please review and let me know if additional edits/updates are required. Once Tom/John approve, we can continue routing through DHQP Comms clearance, then submit to JIC for final clearance. After JIC clears, the documents will be ready to share with HHS to get approval for the update (discontinuing the weekly case counts on the public-facing page).

Please let me know if you have any questions.

Alanna S. Moorer, MPS
Lead, Immunization Safety Communications Team
Immunization Safety Office (ISO)
Division of Healthcare Quality Promotion (DHQP)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention (CDC)

Phone: [redacted]
Email: [redacted]

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:36 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Yes

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:30 PM

To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

I'll defer to Tom, but offhand, I think he and I are sufficient.

- John

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:29 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Correct! Also, please let us know if there is anyone else in ISO that should review/clear the drafts when Comms sends them out.

-Lyn

Lyn Thi Nguyen, MPH *(she/her/hers)*

Public Health Analyst

Division of Healthcare Quality Promotion (DHQP)

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

U.S. Centers for Disease Control and Prevention

1600 Clifton Road NE, MS H16- 2

Atlanta, GA 30329

[redacted]

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:26 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Hi Lyn,

Do I understand correctly: finishing touches are being put on these documents, and once those touches are complete, you'll forward to Tom and me to give the okay for those documents to go forward?

- John

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:22 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Tom and John,

Wanted to give a quick update are where things are on behalf of the DHQP Policy and Comms Teams. **The next steps will be for you both to review and sign off on the appropriate documents reflecting the proposed changes and messages.** Please let us know if there is anyone else who should be part of the review/clear process for ISO. DHQP Comms will be sending updated drafts and the rollout plan for your review later today. Once you have signed off, we can move forward on the other required clearances before sending this back to Deb Lubar to continue her conversation on discontinuing our updates of case counts for the Director's Weekly brief.

Comms docs:

- **Updates to the CDC Selected Adverse Events page:** Comms sent clean and tracked changes of the page for SME review earlier today (2/9), but, per John's email, will need to add publications to the reports of death section so we can stop all case count reporting for that page. Alanna will make the update today and will share the updated versions of those attachments so you can review the proposed changes.
- **Rollout plan:** Comms will complete a rollout plan explaining the rationale for the change to the SAE page later today for review and clear.
    - Alanna- feel free to use the initial BLUF/ messages from the previous document I sent to help fill out the components of the roll out plan: Changes to CDC's website on Select AEs myocarditis section_Feb 2023.docx

Once these communication documents route through DHQP comms, both will need to go through JIC clearance, then HHS for approval. DHQP Policy will in parallel handle getting the cleared proposed web update draft and TPs back to Deb.

Please let us know if you have additional questions on where we are with this process.

Thanks.
-Lyn

Lyn Thi Nguyen, MPH *(she/her/hers)*

Public Health Analyst

Division of Healthcare Quality Promotion (DHQP)

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

U.S. Centers for Disease Control and Prevention

1600 Clifton Road NE, MS H16- 2

Atlanta, GA 30329

[redacted]

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 1:28 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Yes, what John said.

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 1:18 PM
To: Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) [redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Hi Alanna,

Historically, the preliminary counts of deaths reported to VAERS after COVID-19 vaccination have come from the daily priority reports, and are updated weekly on the Selected Adverse Events page. We would like to stop updating those counts and refer to published literature, as we would for anaphylaxis, myocarditis, and other adverse events on that page.

Related to this effort (ie, the consolidated vaccine safety page), we would like to stop providing updated case counts for the Weekly Director's Update. Any word on where we are on that effort?

Thanks!

- John

From: Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 12:00 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Good morning all,

I'm following up on Lyn's email below and have attached clean and tracked changes versions of the entire Selected Adverse Events page and highlighted proposed changes to the myocarditis/pericarditis section of the page (for clearance purposes, comms needs to submit web updates this way). Please review and let me know if additional updates are required.

Our team also updates the Reports of death section with the content from Pedro's report. Would that reporting continue on a weekly basis? Or should we also point to published manuscripts for that section as well?

Thanks so much!

Alanna S. Moorer, MPS
Lead, Immunization Safety Communications Team
Immunization Safety Office (ISO)
Division of Healthcare Quality Promotion (DHQP)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention (CDC)

Phone: [redacted]
Email: [redacted]

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Friday, February 3, 2023 12:08 PM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Hi everyone,

Adding our Comms folks to this email thread so they are on the same page with the latest discussions. Per Deb's request, attached is a draft summary of what we are proposing to do. Let me know if you have additional edits/ comments.

Given the Select Adverse Events page will also need to be updated to no longer reflect weekly case counts for myocarditis/pericarditis for children and adolescents, I wanted to confirm whether ISO leadership would like the updates to include additional published papers (similar to what we did on TTS and anaphylaxis sections last year). If so, did you want us to use all of the relevant ISO published papers that is listed on our publications website or are there certain ones you would prefer us to call out specifically. Currently, we only have this JAMA paper (https://jamanetwork.com/journals/jama/fullarticle/2788346) on the Select AE website. In regards to GBS section and given how the website is currently laid out, I do not think there is anything more we need to do on GBS unless there are other published links you would want us to reference in this section.

Below are the list of other myocarditis/ pericarditis papers on our ISO publications page for COVID-19. I highlighted the ones that seemed most relevant to include given the removal of weekly reporting on the children and adolescent cases for this section. However, let us know if you prefer we add any of these to the website or add others that may not be on here. We plan to discuss some of this at today's monthly policy/comms/partnerships touch base meeting.

1. Goddard K, Hanson KE, Lewis N, Weintraub E, Fireman B, Klein NP. Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States.. *Annals of Internal Medicine.* 2022 Oct 4. doi.org/10.7326/M22-2274.
2. Kracalik I, Oster ME, Broder KR, Cortese MM, Glover M, Shields K, Creech CB, Romanson B, Novosad S, Soslow J, Walter EB, Marquez P, Dendy JM, Woo J, Valderrama AL, Ramirez-Cardenas A, Assefa A, Campbell MJ, Su JR, Magill SS, Shay DK, Shimabukuro TT, Basavaraju SV. Outcomes at least 90 days onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study. *Lancet Child Adolesc Health*. 2022 Nov 6;6(11):788-798. Epub 2022 Sept 22.
3. Goddard K, Lewis N, Fireman B, Weintraub E, Shimabukuro T, Zerbo O, Boyce TG, Oster ME, Hanson KE, Donahue JG, Ross P, Naleway A, Nelson JC, Lewin B, Glanz JM, Williams JTB, Kharbanda EO, Yih WK, Klein NP. Risk of myocarditis and pericarditis following BNT162b2 and mRNA-1273 COVID-19 vaccination. *Vaccine* 2022 Aug 19; 40(35):5153-5159. Epub 2022 Jul 12.

4. Weintraub ES, Oster ME, Klein NP. Myocarditis or Pericarditis Following mRNA COVID-19 Vaccination. *JAMA* 2022 Jun 24; 5(6):e2218512. doi:10.1001/jamanetworkopen.2022.18512
5. Paddock CD, Reagan-Steiner S, Su JR, Oster ME, Martines RB, Bhatnagar J, Shimabukuro TT. Autopsy Histopathologic Cardiac Findings in Two Adolescents Following the Second COVID-19 Vaccine Dose. *Arch Pathol Lab Med* 2022 Apr 11. Doi: 10.5858/arpa.2022-0084-LE. Online ahead of print.
6. Block JP, Boehmer TK, Forrest CB, Carton TW, Lee GM, Ajani UA, Christakis DA, Cowell LG, Draper C, Ghildayal N, Harris AM, Kappelman MD, Ko JY, Mayer KH, Nagavedu K, Oster ME, Paranjape A, Puro J, Ritchey MD, Shay DK, Thacker D, Gundlapalli AV. Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination – PCORnet, United States, January 2021-January 2022. *MMWR Morb Mortal Wkly Rep*. 2022 Apr 8;71.
7. Oster ME, Shay DK, Su JR, Gee J, Creech B, Broder KR, Edwards K, Soslow JH, Dendy JM, Schlaudecker E, Lang SM, Barnett ED, Ruberg FL, Smith MJ, Campbell MJ, Lopes RD, Sperling LS, Baumblatt JA, Thompson DL, Marquez PL, Strid P, Woo J, Puglsey R, Reagan-Steiner S, DeStefano F, Shimabukuro TT. Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US from December 2020 to August 2021 *JAMA.* 2022 Jan 18;327(4):331-340. Online ahead of print.
8. Gargano JW, Wallace M, Hadler SC, Langley G, Su JR, Oster ME, Broder KR, Gee J, Weintraub E, Shimabukuro T, Scobie HM, Moulia D, Markowitz LE, Wharton M, McNally VV, Romero JR, Keipp Talbot H, Lee GM, Daley MF, Oliver SE. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021 *MMWR Morb Mortal Wkly Rep.* 2021 Jul 9;70:977-982.
9. Shay DK, Shimabukuro, TT, DeStefano F. Myocarditis After Immunization with mRNA-Based COVID-19 Vaccines: Editorial. *JAMA Cardiol.* Published online June 29, 2021. doi:10.1001/jamacardio.2021.2821.

Thanks.
-Lyn

Lyn Thi Nguyen, MPH *(she/her/hers)*

Public Health Analyst

Division of Healthcare Quality Promotion (DHQP)

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

U.S. Centers for Disease Control and Prevention

1600 Clifton Road NE, MS H16- 2

Atlanta, GA 30329

[redacted]

From: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 2, 2023 10:30 AM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Without Deb and with Lyn.

I've asked Lyn to help put together a synthesis of what would change on the website. I know there are previous email strings, but a synthesized doc would help with side by side of what would change on the public website.

From: Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]>
Sent: Thursday, February 2, 2023 10:26 AM
To: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP)

<[redacted]>; Oliver, Angela (CDC/OD/OCS) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Thanks, Seth. Can you send an email proposing the changes you want, and if there are changes to websites, please show those. If it's just stopping the email, I have what I need.

From: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 2, 2023 10:23 AM
To: Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Oliver, Angela (CDC/OD/OCS) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

And it would have some downstream effects on public websites too, which HHS previously had to approve when we changed.

From: Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]>
Sent: Thursday, February 2, 2023 10:22 AM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Oliver, Angela (CDC/OD/OCS) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Just EZID, please do not set up a big meeting about this. I will put it on my list for discussion with Brendan next week and see if we can stop the weekly reporting. For now, let's just answer his question about deaths from anaphylaxis.

From: Goldstein, Robert (CDC/OD/OCS) <[redacted]>
Sent: Thursday, February 2, 2023 10:16 AM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED) <[redacted]>; Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]>
Cc: Morrison, Melissa (CDC/DDPHSIS/CPR/DSLR) <[redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Re: Updated case counts for Director's Weekly Brief

Julianne,

Thanks for sharing this. I don't think we need a formal query for anaphylaxis, but the Director was wondering if we have historically seen any deaths associated with anaphylaxis. Do you know the answer to that question?

-Robbie

From: "Gee, Julianne (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Date: Thursday, February 2, 2023 at 10:10 AM
To: "Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED)" <[redacted]>, "Goldstein, Robert (CDC/OD/OCS)" <[redacted]>, "Lubar, Debra (CDC/DDID/NCEZID/OD)" <[redacted]>
Cc: "Morrison, Melissa (CDC/DDPHSIS/CPR/DSLR)" <[redacted]>, "Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Kroop, Seth (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: Re: Updated case counts for Director's Weekly Brief

Hi Brendan,

We are seeing increased case counts of myocarditis in VAERS. For anaphylaxis, we are no longer conducting enhanced monitoring for this outcome and can conduct a formal search in the VAERS database to provide you this information.

We seek additional information (medical records, etc) for myocarditis cases and they reviewed by VAERS medical officers. If death is reported, further review is conducted. To date none of the myocarditis cases have been associated with COVID vaccine.

Related to my inquiry on Monday of ending our weekly reporting of myocarditis and GBS for the Director's brief, I spoke to Nicole Coffin yesterday for background and suggestions on how to move forward. I understand that Seth Kroop has also been involved in this issue. I think it will be best if I send a meeting invite to everyone on this email to decide if these weekly updates are still needed. And if so, who should be receiving the email as the distribution list is quite outdated.

Thanks.
Julianne

From: Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED) <[redacted]
Sent: Thursday, February 2, 2023 9:02 AM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Goldstein, Robert (CDC/OD/OCS) <[redacted]>; Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]
Cc: Morrison, Melissa (CDC/DDPHSIS/CPR/DSLR) <[redacted]
Subject: Re: Updated case counts for Director's Weekly Brief

Hi Julianne,

Could you please answer the questions below from OD/OD re: myocarditis?

Thanks,
Brendan

You mentioned earlier this week that we continue to get reports of myocarditis and anaphylaxis post-vaccination weekly. Do you know if those reports also include deaths associated with either condition and, if so, if there are associated deaths?

From: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Monday, January 30, 2023 10:00 AM
To: Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED) <[redacted]>; Mahon, Barbara (CDC/DDID/NCIRD/OD) <[redacted]
Subject: FW: Updated case counts for Director's Weekly Brief

Hi Brendon and Barb,

This is the email that I was referring to on the policy call. In addition to you two, who else do you recommend be involved in these discussions to retire these weekly emails?

Thanks so much!
Julianne

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Friday, January 27, 2023 7:09 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Sives, Katelyn (CDC/DDPHSIS/CSTLTS/OD) <[redacted]>; Wiley, Sarah D. (CDC/DDID/NCEZID/DFWED) <[redacted]>; CDC IMS 2019 NCOV Response VCU Policy <[redacted]>; Ward Gokhale, Lindsay (CDC/OCOO/OFR/OA) <[redacted]>; Banister, Christina (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Hicks, Lauri (CDC/DDID/NCEZID/DHQP) <[redacted]>; Leach, Caitlin (CDC/DDID/NCHHSTP/DSTDP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Langley, Gayle E. (CDC/OD/OADPS) <[redacted]>; Layden, Jennifer (CDC/DDPHSS/OD) <[redacted] Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[redacted]>; DHQP_Policy (CDC) <[redacted]>; See, Isaac (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>; Taylor, Allan W. (CDC/DDPHSIS/CGH/OD) <[redacted]>; Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <[redacted]>; Al-Shawaf, Maeh (CDC/DDNID/NCCDPHP/OSH) <[redacted]>; Rodriguez, Rockie (CDC/DDPHSIS/CPR/DSLR) <[redacted]>; NCIRD Congressional (CDC) <[redacted]>; Beauvais, Denise (CDC/DDID/NCIRD/OD) <[redacted]>; Frederick, Charles (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; Frederick, Charles (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; CDC IMS SA Public Health Scientist (CDC) <[redacted]>
Subject: Updated case counts for Director's Weekly Brief

Good afternoon,

Please see updated case counts for myocarditis, and GBS. All counts are current **as of January 26, 2023:**

- Status of myocarditis investigation: there were 1060 reports among persons known to be <18 years of age under review for potential myocarditis. Of them,
  - 247 remain under review
  - 813 had symptoms and diagnostics confirmed by provider interview or review of medical records
    - **710** met the CDC working definition for myocarditis:
      - 5-11 years: 23 verified reports of myocarditis after 23,178,311 doses administered
      - 12-15 years: 371 verified reports of myocarditis after 25,791,756 doses administered
      - 16-17 years: 316 verified reports of myocarditis after 14,117,149 doses administered

- There were 337 preliminary reports of Guillain Barre syndrome following J&J/Janssen vaccination
  - **Note:** these reports were identified by automated computer search; the count might include reports that would not meet a standardized case definition for GBS.

Please let me know if you have any questions. Have a great weekend!

Pedro

Pedro L. Moro, M.D., M.P.H.
Acting Team Lead

VAERS Project and Response Team
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Road, MS V18-4
Atlanta, GA 30329-4027
[redacted]

Selected Adverse Events Reported after COVID-19 Vaccination

Updated Feb. 6, 2023
Español | Other Languages
Print

~~CDC's Vaccine Safety Datalink (VSD) met the statistical criteria to prompt additional investigation into whether there was a safety concern for ischemic stroke in people ages 65 and older who received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. To date, no other safety systems have not shown a similar signal and other factors besides vaccination may be contributing to the finding. multiple subsequent analyses have not validated this signal. No change is recommended in COVID-19 vaccination practice.~~
~~Read More~~

Safety of COVID-19 Vaccines
Some people have no side effects. Many people have reported side effects, such as headache, fatigue, and soreness at the injection site, that are generally mild to moderate and go away within a few days.
Are the Vaccines Safe?

What You Need to Know

- COVID-19 vaccines are **safe and effective and severe reactions after vaccination are rare.**
- CDC recommends everyone ages 6 months and older get vaccinated ~~as soon as possible~~ to protect against COVID-19 and its potentially severe complications.
- ~~Although mRNA vaccines (Pfizer-BioNTech or Moderna COVID-19 vaccines) are preferred, Johnson & Johnson's Janssen COVID-19 vaccine may be considered in some situations.~~
- Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring program in U.S. history.
- CDC, the U.S. Food and Drug Administration (FDA), and other federal agencies continue to monitor the safety of COVID-19 vaccines.
- ~~Adverse events described on this page have been reported to the Vaccine Adverse Event Reporting System (VAERS).~~
- ~~VAERS accepts reports of any adverse event following vaccination.~~

The benefits of COVID-19 vaccination continue to outweigh any potential risks.

~~CDC is providing timely updates on the following adverse events of interest:~~

Commented [ayv61]: This statement is not accurate, or at least it's misleading.
Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
2023-02-11 23:35:00

Commented [ayv62]: Why not shift this content to later in the page and provide some context first. It doesn't make sense to lead with it. It's out of place right here at the top and it's overly alarming and unnecessary. The data are weak.

Just pull some content off of the ACIP briefing document:

•Following availability and use of updated bivalent mRNA COVID-19 booster vaccines, CDC conducted vaccine safety monitoring for

Commented [SJ(3]: Do we need to mention that Janssen's vaccine will soon no longer be available in the United States?
Su, John (CDC/DDID/NCEZID/DHQP)
2023-02-09 23:07:00

Commented [ayv64R3]: Check with NCIRD first but I recommend getting rid of Janssen content or treating the vaccine as a historical topic. This statement is dated.
Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

Commented [SJ(5R3]: I think omitting Janssen content will be challenging while discussing GBS and TTS. However, we state in those sections that Janssen is no longer available in the United States, and we also mention ACIP's preferential recommendation in those

Commented [ayv66]: But it's not just VAERS data on this page. It's VSD data too.
Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
2023-02-11 23:44:00

Commented [SJ(7R6]: These statements are likely vestigial; we can omit them.
Su, John (CDC/DDID/NCEZID/DHQP)
2023-02-12 12:54:00

Commented [ayv68]: Aren't we going to stop doing this?
Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
2023-02-11 23:45:00

Commented [SJ(9R8]: Indeed. This language has been deleted.
Su, John (CDC/DDID/NCEZID/DHQP)
2023-02-12 11:38:00

- **Anaphylaxis after COVID-19 vaccination is rare** and has occurred at a rate of approximately 5 cases per one million vaccine doses administered. Anaphylaxis, a severe type of allergic reaction, can occur after any kind of vaccination. If it happens, healthcare providers can effectively and immediately treat the reaction. Learn more about COVID-19 vaccines and allergic reactions, including anaphylaxis.

  - CDC scientists have conducted detailed reviews of cases of anaphylaxis and made the information available to healthcare providers and the public:
    - Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine
    - Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021
    - Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine— United States, December 21, 2020-January 10, 2021

- **Reports of death after COVID-19 vaccination are rare.** Multiple factors contribute to reports of death after COVID-19 vaccination, including heightened public ~~attention~~awareness of ~~to~~ COVID-19 vaccines, ~~FDA~~ requirements under FDA authorization for COVID-19 vaccines that~~s~~ healthcare providers ~~to~~ report any death after COVID-19 vaccination to VAERS (~~,~~ even if it's unclear whether the vaccine was the cause), and reporting requirement in CDC vaccine provider agreements. People receiving COVID-19 vaccines are less likely to die from COVID-19 and its complications~~,~~ **and are at no greater risk of death** from non-COVID causes, than unvaccinated people. CDC scientists and ~~colleagues~~partners have ~~conducted~~performed detailed ~~reviews~~assessments ~~of cases of reports of deaths~~ after COVID-19 vaccination and made the information available to healthcare providers and the public:
  - A Safety Study Evaluating non-COVID-19 Mortality Risk Following COVID-19 Vaccination
  - COVID-19 Vaccination and Non-COVID-19 Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020-July 31, 2021
  - Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021
  - Safety of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme

- **Guillain-Barré Syndrome** (GBS) ~~(GBS) in people who have received the J&J/Janssen COVID-19 vaccine is rare~~. GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. GBS has largely been observed among men ages 50 years and older.

  Based on an ~~recent~~ analysis of data from the Vaccine Safety Datalink, the rate of GBS within the first 21 days following J&J/Janssen COVID-19 vaccination was found to be 21 times

Commented [SJ(10)]: Tom, is this correct?
Su, John (CDC/DDID/NCEZID/DHQP)
2023-02-10 14:17:00

Commented [ayv611R10]: Yes.
Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
2023-02-11 23:47:00

Commented [SJ(12)]: I'm guessing VSD are colleagues, but not necessarily "CDC scientists"…
Su, John (CDC/DDID/NCEZID/DHQP)
2023-02-10 14:21:00

Commented [ayv613R12]: partners
Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
2023-02-11 23:48:00

Commented [MA(14)]: Note for developers: Link to - https://www.sciencedirect.com/science/article/pii/S0264410X22015614?dgcid=raven_sd_aip_email
Moorer, Alanna (CDC/DDID/NCEZID/DHQP)
2023-02-09 14:21:00

Commented [MA(15)]: Note to developers: Link to - https://www.cdc.gov/mmwr/volumes/70/wr/mm7043e2.htm
Moorer, Alanna (CDC/DDID/NCEZID/DHQP)
2023-02-09 14:23:00

Commented [SJ(16)]: Note to developers: Link to – Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021 | medRxiv
Su, John (CDC/DDID/NCEZID/DHQP)
2023-02-10 13:17:00

Commented [SJ(17)]: Note to developers: Link to – Safety of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to the Vaccine Adverse Event Reporting System and v-safe - ScienceDirect
Su, John (CDC/DDID/NCEZID/DHQP)
2023-02-10 14:06:00

Commented [ayv618]: I'm not sure you want to say this. Relatively speaking, it's high.
Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
2023-02-11 23:54:00

higher than after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). After the first 42 days, the rate of GBS was 11 times higher following J&J/Janssen COVID-19 vaccination. The analysis found no increased risk of GBS after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). ~~CDC and FDA will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.~~ Similarly, CDC found higher than expected rates of GBS reported to the Vaccine Adverse Event Reporting System (VAERS) after J&J/Janssen COVID-19 vaccination but not after mRNA COVID-19 vaccination. These observations contributed to the preferential recommendation by ACIP to use mRNA COVID-19 vaccines over J&J/Janssen COVID-19 vaccine, which is no longer available in the United States.

CDC and FDA will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination ~~and will share more information as it becomes available.~~

- **Myocarditis and pericarditis after COVID-19 vaccination are rare.** Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the outer lining of the heart. Most patients with myocarditis or pericarditis after COVID-19 vaccination responded well to medicine and rest and felt better quickly. Most cases have been reported after receiving ~~Pfizer-BioNTech or Moderna (~~mRNA~~)~~ COVID-19 vaccines.

Data from the Vaccine Safety Datalink and from VAERS indicate that rates of myocarditis are highest among males in their late teens and early 20s, usually following the second dose of the primary series. After the second dose of the primary series of Pfizer-BioNTech COVID-19 vaccine, the following rates of myocarditis have been observed:

- Males ages 5–11 years: approximately 14 cases per million doses administered
- Males ages 12–17 years: approximately 137–151 cases per million doses administered
- Males ages 18–29 years: approximately 81 cases per million doses administered

~~No cases of myocarditis after mRNA COVID-19 vaccination have been observed in the United States among people ages <5 years.~~

CDC scientists have conducted detailed reviews of cases of myocarditis and pericarditis and made the information available to healthcare providers and the public:

- Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States
- Outcomes at least 90 days onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study
- Risk of myocarditis and pericarditis following BNT162b2 and mRNA-1273 COVID-19 vaccination
- Myocarditis or Pericarditis Following mRNA COVID-19 Vaccination
- Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021

Commented [SJ(19]: Perhaps "which is (or will soon be) no longer available in the United States", depending upon if any remaining stocks are still before their expiration date.

Commented [ayv620]: You need to add this caveat to the other Janssen-related content in the document. Treat Janssen vaccination like a historical event.

Commented [SJ(21R20]: Please see revised language.
Su, John (CDC/DDID/NCEZID/DHQP)

Commented [ayv622]: Consider adding something about the preferential recommendation for mRNA vaccines over Janssen at the end of this section (and

Commented [SJ(23R22]: Please see revised language.
Su, John (CDC/DDID/NCEZID/DHQP)

Commented [SJ(24]: There's a strong public want for quantitative data on myocarditis after mRNA COVID-19 vaccination. The VSD data are more recent

Commented [ayv625]: Suggest deleting.
Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

Commented [SJ(26R25]: Per previous comment, the public wants this information (so I understand). We can delete it, but we should expect some

Commented [ayv627R25]: My recommendation is to delete. These aren't even true rates, they are linked to risk window.

Commented [ayv628]: Not that we are aware of but I don't think we know this for sure.
Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

Commented [MA(29]: Note for developer: Link to - https://www.acpjournals.org/doi/10.7326/M22-2274
Moorer, Alanna (CDC/DDID/NCEZID/DHQP)

Commented [MA(30]: Note for developer: Link to - https://pubmed.ncbi.nlm.nih.gov/36152650/
Moorer, Alanna (CDC/DDID/NCEZID/DHQP)

Commented [MA(31]: Note for developer: Link to - https://pubmed.ncbi.nlm.nih.gov/35902278/
Moorer, Alanna (CDC/DDID/NCEZID/DHQP)

Commented [MA(32]: Note for developer: Link to - https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2793555

Commented [SJ(33]: Note for developer: Link to - https://jamanetwork.com/journals/jama/fullarticle/2788346

To date, evidence indicates that **the benefits of mRNA COVID-19 vaccination outweigh the risk of myocarditis**. CDC and FDA will continue to monitor for and evaluate reports of myocarditis and pericarditis after COVID-19 vaccination ~~and will share more information as it becomes available~~. Learn more about myocarditis and pericarditis, including clinical considerations, after mRNA COVID-19 vaccination.

- ~~Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14-23, 2020~~

- **Thrombosis with thrombocytopenia syndrome (TTS)** has been rarely observed **after J&J/Janssen COVID-19 vaccination** ~~is rare~~ and has occurred in approximately 4 cases per one million doses administered. TTS is a rare but serious adverse event that causes blood clots in large blood vessels and low platelets (blood cells that help form clots).
  A review of reports indicates a causal relationship between the J&J/Janssen COVID-19 vaccine and TTS. This observation contributed to the preferential recommendation by ACIP to use mRNA COVID-19 vaccines over J&J/Janssen COVID-19 vaccine, which is no longer available in the United States. CDC scientists have conducted detailed reviews of TTS cases and made the information available to healthcare providers and the public:
  - US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021
  - Case Series of Thrombosis with Thrombocytopenia Syndrome following COVID-19 vaccination—United States, December 2020–August 2021
  - Updates on Thrombosis with Thrombocytopenia Syndrome (TTS) [1.3 MB, 39 Pages]
  - Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices - United States, December 2021 - PubMed (nih.gov)

- ~~**Guillain-Barré Syndrome (GBS) in people who have received the J&J/Janssen COVID-19 vaccine is rare.** GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. GBS has largely been reported in men ages 50 years and older.~~
  ~~Based on a recent analysis of data from the Vaccine Safety Datalink, the rate of GBS within the first 21 days following J&J/Janssen COVID-19 vaccination was found to be 21 times higher than after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). After the first 42 days, the rate of GBS was 11 times higher following J&J/Janssen COVID-19 vaccination. The analysis found no increased risk of GBS after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). CDC and FDA will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.~~

  ~~Similarly, CDC found higher than expected rates of GBS reported to the Vaccine Adverse Event Reporting System (VAERS) after J&J/Janssen COVID-19 vaccination but not after mRNA COVID-19 vaccination. CDC and FDA will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.~~

Commented [SJ(34]: Note for developer: Link to – https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html
Su, John (CDC/DDID/NCEZID/DHQP)
2023-02-10 00:06:00

Commented [SJ(35]: The JAMA article cited above is essentially the same article as this one. I suggest deleting this reference (JAMA gets higher visibility ☺).
Su, John (CDC/DDID/NCEZID/DHQP)
2023-02-09 23:10:00

Commented [SJ(36]: Perhaps "which is (or will soon be) no longer available in the United States", depending upon if any remaining stocks are still before their expiration date.
Su, John (CDC/DDID/NCEZID/DHQP)
2023-02-10 14:10:00

Commented [ayv637]: You need to add this caveat to the other Janssen-related content in the document. Treat Janssen vaccination like a historical event.
Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
2023-02-11 23:58:00

- **Myocarditis and pericarditis after COVID-19 vaccination are rare.** Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the outer lining of the heart. Most patients with myocarditis or pericarditis after COVID-19 vaccination responded well to medicine and rest and felt better quickly. Most cases have been reported after receiving Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines), particularly in male adolescents and young adults.

A review of vaccine safety data in VAERS from December 2020–August 2021 found a small but increased risk of myocarditis after mRNA COVID-19 vaccines. Over 350 million mRNA vaccines were given during the study period and CDC scientists found that rates of myocarditis were highest following the second dose of an mRNA vaccine among males in the following age groups:

- 12–15 years (70.7 cases per one million doses of Pfizer-BioNTech)
- 16–17 years (105.9 cases per one million doses of Pfizer-BioNTech)
- 18–24 years (52.4 cases and 56.3 cases per million doses of Pfizer-BioNTech and Moderna, respectively)

Multiple studies and reviews of data from vaccine safety monitoring systems continue to show that vaccines are safe. CDC scientists have conducted detailed reviews of cases of myocarditis and pericarditis and made the information available to healthcare providers and the public:

- Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States
- Outcomes at least 90 days onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study
- Risk of myocarditis and pericarditis following BNT162b2 and mRNA-1273 COVID-19 vaccination
- Myocarditis or Pericarditis Following mRNA COVID-19 Vaccination

As the COVID-19 vaccines are authorized for younger children, CDC and FDA will continue to monitor for and evaluate reports of myocarditis and pericarditis after COVID-19 vaccination and will share more information as it becomes available. Learn more about myocarditis and pericarditis, including clinical considerations, after mRNA COVID-19 vaccination.

- **Reports of death after COVID-19 vaccination are rare.** FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. CDC scientists have conducted detailed reviews of cases of reports of death after COVID-19 vaccination and made the information available to healthcare providers and the public:
  - A Safety Study Evaluating non-COVID-19 Mortality Risk Following COVID-19 Vaccination
  - COVID-19 Vaccination and Non-COVID-19 Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020–July 31, 2021

Information about a potential association between bivalent Pfizer-BioNTech mRNA COVID-19 vaccination and ischemic stroke in people aged ≥65 years:

Commented [MA(38)]: Note for developer: Link to - https://www.acpjournals.org/doi/10.7326/M22-2274
Moorer, Alanna (CDC/DDID/NCEZID/DHQP)
2023-02-09 11:31:00

Commented [MA(39)]: Note for developer: Link to - https://pubmed.ncbi.nlm.nih.gov/36152650/
Moorer, Alanna (CDC/DDID/NCEZID/DHQP)
2023-02-09 11:33:00

Commented [MA(40)]: Note for developer: Link to - https://pubmed.ncbi.nlm.nih.gov/35902278/
Moorer, Alanna (CDC/DDID/NCEZID/DHQP)
2023-02-09 11:34:00

Commented [MA(41)]: Note for developer: Link to - https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2793555
Moorer, Alanna (CDC/DDID/NCEZID/DHQP)
2023-02-09 11:36:00

Commented [MA(42)]: Note for developers: Link to - https://www.sciencedirect.com/science/article/pii/S0264410X22015614?dgcid=raven_sd_aip_email
Moorer, Alanna (CDC/DDID/NCEZID/DHQP)
2023-02-09 14:21:00

Commented [MA(43)]: Note to developers: Link to - https://www.cdc.gov/mmwr/volumes/70/wr/mm7043e2.htm
Moorer, Alanna (CDC/DDID/NCEZID/DHQP)
2023-02-09 14:23:00

Commented [ayv644]: Put the ischemic stroke content here, at the end. It's the weakest of all the evidence.
Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
2023-02-11 23:59:00

Commented [SJ(45R44]: Relocated. Please also see some suggested language.
Su, John (CDC/DDID/NCEZID/DHQP)
2023-02-12 12:59:00

Commented [ayv646R44]: In retrospect, I would just delete this altogether. This is a statistical signal in one monitoring system, in one age group, for one vaccine, and the finding is being driven by simultaneous vaccination with HD flu. It should not be given the same credence as anaphylaxis, myocarditis, TTS, and GBS. If it's covered on another website then we are being transparent, but I would not include it on this webpage.

- CDC has been monitoring the safety of bivalent mRNA COVID-19 vaccines using three vaccine safety systems: the Vaccine Adverse Event Reporting System (VAERS) (co-managed by CDC and FDA), v-safe, and VSD.
- Analysis of data from v-safe and VAERS showed that adverse events observed after bivalent booster COVID-19 vaccines were consistent with those after monovalent booster.
- In VSD's primary analysis, the risk of selected outcomes among people 1–21 days (the "risk interval") after receiving bivalent COVID-19 vaccination was compared to the risk of the same selected outcomes among people 22–42 days (the "comparison interval") after receiving bivalent COVID-19 vaccination.
    - A statistical association with ischemic stroke after Pfizer-BioNTech bivalent vaccine was identified among people aged ≥65 years.
        - Further analysis suggests this statistical association is driven by people receiving high-dose influenza vaccine and Pfizer-BioNTech bivalent vaccine at the same clinic visit. However, this analysis was limited by small case counts, and other factors could have contributed to this finding.
    - VSD performed a secondary analysis that compared the risk for ischemic stroke during the risk and comparison intervals among people who received Pfizer-BioNTech bivalent vaccine, to the risk during the same intervals among people who did not receive the vaccine. **These comparisons showed no statistical association with ischemic stroke.**
- To date, other safety systems have not shown a similar statistical association with ischemic stroke. **No change is recommended in COVID-19 vaccination practice.**

Read More

Related Pages

- Safety of COVID-19 Vaccines
- Vaccine Adverse Event Reporting System (VAERS): What Reports Mean and How VAERS Works
- COVID-19 Vaccine Safety Publications

Last Updated Oct. 24, 2022

Source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases

Commented [ayv647]: Why not shift this content to later in the page and provide some context first. It doesn't make sense to lead with it. It's out of place right here at the top and it's overly alarming and unnecessary. The data are weak.

Just pull some content off of the ACIP briefing document:

•Following availability and use of updated bivalent mRNA COVID-19 booster vaccines, CDC conducted vaccine safety monitoring for these vaccines in three systems: the Vaccine Adverse Event Reporting System (VAERS) (co-managed by CDC and FDA), v-safe, and VSD.
•CDC published two studies assessing the safety of bivalent COVID-19 vaccines, using data from v-safe and VAERS.
○Adverse events reported after a bivalent COVID-19 booster dose in persons aged ≥12 years appeared consistent with those reported after a monovalent booster and were less common and less serious than health impacts associated with COVID-19 illness .
•Early safety findings for bivalent booster vaccination in children aged 5–11 years were similar to those described for monovalent booster vaccination. Most VAERS reports represented vaccine errors rather than adverse events. Neither myocarditis nor death were reported after bivalent booster vaccination in this age group.VSD assessed pre-specified health outcomes after bivalent COVID-19 vaccine during weekly sequential monitoring. In the primary analysis risks of pre-specified outcomes 1–21 days following a bivalent vaccination (risk interval) were compared with bivalent vaccinated individuals who were 22–42 days (comparison interval) following the bivalent dose.
○VSD did not identify signals for any pre-specified outcome after Moderna bivalent vaccine in any age group and did not identify any signals after Pfizer-BioNTech bivalent vaccine in persons aged <65 years.
○In November 2022, VSD detected a statistical signal for ischemic stroke after Pfizer-BioNTech bivalent COVID-19 vaccine in persons aged ≥65 years. Through January 7, 2023 approximately 550,000 persons aged ≥65 had received the Pfizer-BioNTech bivalent vaccine in VSD (approximately 290,000 had received Moderna

From: "Moorer, Alanna (CDC/DDID/NCEZID/DHQP)" <[redacted]>
To: "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief
Date: Mon, 27 Feb 2023 15:16:53 +0000
Importance: Normal
Inline-Images: image001.png

Hi John,

In clearance DHQP Comms requested an intro summary for all the publications listed on the page so I'm working those in now. I hope to send a draft back to you/Tom for review today for review before re-submitting it to clearance.

Alanna S. Moorer, MPS
Lead, Immunization Safety Communications Team
Immunization Safety Office (ISO)
Division of Healthcare Quality Promotion (DHQP)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention (CDC)

Phone: [redacted]
Email: [redacted]

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Monday, February 27, 2023 9:59 AM
To: Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Hi Alanna,

I hope yours was a good weekend! Just following up on this email to see where we are with things re: updating the language on the consolidated vaccine safety page/selected adverse events page, and discontinuing providing counts for the Director's weekly update. Thanks!

- John

From: Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Monday, February 13, 2023 1:21 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Hi John,

Thanks so much for your review. Everything looks straightforward; I don't have any additional questions. I asked Martha to weigh in on the reactive media statement in the rollout plan. Once I hear back from her, I'll continue both documents through DHQP Comms clearance, then on to the JIC. If anything comes up in the clearance process, I'll loop back with you.

Thanks so much!

Alanna S. Moorer, MPS
Lead, Immunization Safety Communications Team
Immunization Safety Office (ISO)
Division of Healthcare Quality Promotion (DHQP)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention (CDC)

Phone: [redacted]
Email: [redacted]

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Monday, February 13, 2023 9:38 AM
To: Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Hi Alanna,

Thanks for these documents. Please see enclosed revisions from ISO. Given that the statistical association between Pfizer-BioNTech bivalent mRNA COVID-19 vaccine and ischemic stroke among people ages 65 years and older is still being assessed, we recommend omitting that discussion from the selected adverse events page.

Please let us know if you have any questions or comments, or need further information. Thanks!

- John

From: Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 4:50 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Good afternoon all,

Related to Lyn's update earlier, I've attached the following for your review:

- Clean and tracked changes versions of the Selected Adverse Events page with highlights of the proposed changes
- Rollout plan explaining these changes (I revised the previous version of the rollout we used for the earlier revision related to children and adolescents)

Please review and let me know if additional edits/updates are required. Once Tom/John approve, we can continue routing through DHQP Comms clearance, then submit to JIC for final clearance. After JIC clears, the documents will be ready to share with HHS to get approval for the update (discontinuing the weekly case counts on the public-facing page).

Please let me know if you have any questions.

Alanna S. Moorer, MPS

Lead, Immunization Safety Communications Team
Immunization Safety Office (ISO)
Division of Healthcare Quality Promotion (DHQP)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention (CDC)

Phone: [redacted]
Email: [redacted]

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:36 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Yes

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:30 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

I'll defer to Tom, but offhand, I think he and I are sufficient.

- John

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:29 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Correct! Also, please let us know if there is anyone else in ISO that should review/clear the drafts when Comms sends them out.

-Lyn

Lyn Thi Nguyen, MPH *(she/her/hers)*

Public Health Analyst

Division of Healthcare Quality Promotion (DHQP)

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

U.S. Centers for Disease Control and Prevention

1600 Clifton Road NE, MS H16- 2

Atlanta, GA 30329

[redacted]

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:26 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Hi Lyn,

Do I understand correctly: finishing touches are being put on these documents, and once those touches are complete, you'll forward to Tom and me to give the okay for those documents to go forward?

- John

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:22 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Tom and John,

Wanted to give a quick update are where things are on behalf of the DHQP Policy and Comms Teams. **The next steps will be for you both to review and sign off on the appropriate documents reflecting the proposed changes and messages.** Please let us know if there is anyone else who should be part of the review/clear process for ISO. DHQP Comms will be sending updated drafts and the rollout plan for your review later today. Once you have signed off, we can move forward on the other required clearances before sending this back to Deb Lubar to continue her conversation on discontinuing our updates of case counts for the Director's Weekly brief.

Comms docs:

- **Updates to the CDC Selected Adverse Events page:** Comms sent clean and tracked changes of the page for SME review earlier today (2/9), but, per John's email, will need to add publications to the reports of death section so we can stop all case count reporting for that page. Alanna will make the update today and will share the updated versions of those attachments so you can review the proposed changes.
- **Rollout plan:** Comms will complete a rollout plan explaining the rationale for the change to the SAE page later today for review and clear.
  - Alanna- feel free to use the initial BLUF/ messages from the previous document I sent to help fill out the components of the roll out plan: Changes to CDC's website on Select AEs myocarditis section_Feb 2023.docx

Once these communication documents route through DHQP comms, both will need to go through JIC clearance, then HHS for approval. DHQP Policy will in parallel handle getting the cleared proposed web update draft and TPs back to Deb.

Please let us know if you have additional questions on where we are with this process.

Thanks.
-Lyn

Lyn Thi Nguyen, MPH *(she/her/hers)*

Public Health Analyst

Division of Healthcare Quality Promotion (DHQP)

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

U.S. Centers for Disease Control and Prevention

1600 Clifton Road NE, MS H16- 2

Atlanta, GA 30329

[redacted]

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Thursday, February 9, 2023 1:28 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Yes, what John said.

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Thursday, February 9, 2023 1:18 PM
To: Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Hi Alanna,

Historically, the preliminary counts of deaths reported to VAERS after COVID-19 vaccination have come from the daily priority reports, and are updated weekly on the Selected Adverse Events page. We would like to stop updating those counts and refer to published literature, as we would for anaphylaxis, myocarditis, and other adverse events on that page.

Related to this effort (ie, the consolidated vaccine safety page), we would like to stop providing updated case counts for the Weekly Director's Update. Any word on where we are on that effort?

Thanks!

- John

From: Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 12:00 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Good morning all,

I'm following up on Lyn's email below and have attached clean and tracked changes versions of the entire Selected Adverse Events page and highlighted proposed changes to the myocarditis/pericarditis section of the page (for clearance purposes, comms needs to submit web updates this way). Please review and let me know if additional updates are required.

Our team also updates the Reports of death section with the content from Pedro's report. Would that reporting continue on a weekly basis? Or should we also point to published manuscripts for that section as well?

Thanks so much!

Alanna S. Moorer, MPS
Lead, Immunization Safety Communications Team
Immunization Safety Office (ISO)
Division of Healthcare Quality Promotion (DHQP)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention (CDC)

Phone: [redacted]
Email: [redacted]

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Friday, February 3, 2023 12:08 PM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]> Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Hi everyone,

Adding our Comms folks to this email thread so they are on the same page with the latest discussions. Per Deb's request, attached is a draft summary of what we are proposing to do. Let me know if you have additional edits/ comments.

Given the Select Adverse Events page will also need to be updated to no longer reflect weekly case counts for myocarditis/pericarditis for children and adolescents, I wanted to confirm whether ISO leadership would like the updates to include additional published papers (similar to what we did on TTS and anaphylaxis sections last year). If so, did you want us to use all of the relevant ISO published papers that is listed on our publications website or are there certain ones you would prefer us to call out specifically. Currently, we only have this JAMA paper (https://jamanetwork.com/journals/jama/fullarticle/2788346) on the Select AE website. In regards to GBS section and

given how the website is currently laid out, I do not think there is anything more we need to do on GBS unless there are other published links you would want us to reference in this section.

Below are the list of other myocarditis/ pericarditis papers on our ISO publications page for COVID-19. I highlighted the ones that seemed most relevant to include given the removal of weekly reporting on the children and adolescent cases for this section. However, let us know if you prefer we add any of these to the website or add others that may not be on here. We plan to discuss some of this at today's monthly policy/comms/partnerships touch base meeting.

1. Goddard K, Hanson KE, Lewis N, Weintraub E, Fireman B, Klein NP. Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States.. *Annals of Internal Medicine.* 2022 Oct 4. doi.org/10.7326/M22-2274.
2. Kracalik I, Oster ME, Broder KR, Cortese MM, Glover M, Shields K, Creech CB, Romanson B, Novosad S, Soslow J, Walter EB, Marquez P, Dendy JM, Woo J, Valderrama AL, Ramirez-Cardenas A, Assefa A, Campbell MJ, Su JR, Magill SS, Shay DK, Shimabukuro TT, Basavaraju SV. Outcomes at least 90 days onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study. *Lancet Child Adolesc Health*. 2022 Nov 6;6(11):788-798. Epub 2022 Sept 22.
3. Goddard K, Lewis N, Fireman B, Weintraub E, Shimabukuro T, Zerbo O, Boyce TG, Oster ME, Hanson KE, Donahue JG, Ross P, Naleway A, Nelson JC, Lewin B, Glanz JM, Williams JTB, Kharbanda EO, Yih WK, Klein NP. Risk of myocarditis and pericarditis following BNT162b2 and mRNA-1273 COVID-19 vaccination. *Vaccine* 2022 Aug 19; 40(35):5153-5159. Epub 2022 Jul 12.
4. Weintraub ES, Oster ME, Klein NP. Myocarditis or Pericarditis Following mRNA COVID-19 Vaccination. *JAMA* 2022 Jun 24; 5(6):e2218512. doi:10.1001/jamanetworkopen.2022.18512
5. Paddock CD, Reagan-Steiner S, Su JR, Oster ME, Martines RB, Bhatnagar J, Shimabukuro TT. Autopsy Histopathologic Cardiac Findings in Two Adolescents Following the Second COVID-19 Vaccine Dose. *Arch Pathol Lab Med* 2022 Apr 11. Doi: 10.5858/arpa.2022-0084-LE. Online ahead of print.
6. Block JP, Boehmer TK, Forrest CB, Carton TW, Lee GM, Ajani UA, Christakis DA, Cowell LG, Draper C, Ghildayal N, Harris AM, Kappelman MD, Ko JY, Mayer KH, Nagavedu K, Oster ME, Paranjape A, Puro J, Ritchey MD, Shay DK, Thacker D, Gundlapalli AV. Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination – PCORnet, United States, January 2021-January 2022. *MMWR Morb Mortal Wkly Rep*. 2022 Apr 8;71.
7. Oster ME, Shay DK, Su JR, Gee J, Creech B, Broder KR, Edwards K, Soslow JH, Dendy JM, Schlaudecker E, Lang SM, Barnett ED, Ruberg FL, Smith MJ, Campbell MJ, Lopes RD, Sperling LS, Baumblatt JA, Thompson DL, Marquez PL, Strid P, Woo J, Puglsey R, Reagan-Steiner S, DeStefano F, Shimabukuro TT. Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US from December 2020 to August 2021 *JAMA.* 2022 Jan 18;327(4):331-340. Online ahead of print.
8. Gargano JW, Wallace M, Hadler SC, Langley G, Su JR, Oster ME, Broder KR, Gee J, Weintraub E, Shimabukuro T, Scobie HM, Moulia D, Markowitz LE, Wharton M, McNally VV, Romero JR, Keipp Talbot H, Lee GM, Daley MF, Oliver SE. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021 *MMWR Morb Mortal Wkly Rep.* 2021 Jul 9;70:977-982.
9. Shay DK, Shimabukuro, TT, DeStefano F. Myocarditis After Immunization with mRNA-Based COVID-19 Vaccines: Editorial. *JAMA Cardiol.* Published online June 29, 2021. doi:10.1001/jamacardio.2021.2821.

Thanks.
-Lyn

Lyn Thi Nguyen, MPH *(she/her/hers)*

Public Health Analyst

Division of Healthcare Quality Promotion (DHQP)

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

U.S. Centers for Disease Control and Prevention

1600 Clifton Road NE, MS H16- 2

Atlanta, GA 30329

[redacted]

From: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 2, 2023 10:30 AM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Without Deb and with Lyn.

I've asked Lyn to help put together a synthesis of what would change on the website. I know there are previous email strings, but a synthesized doc would help with side by side of what would change on the public website.

From: Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]>
Sent: Thursday, February 2, 2023 10:26 AM
To: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Oliver, Angela (CDC/OD/OCS) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Thanks, Seth. Can you send an email proposing the changes you want, and if there are changes to websites, please show those. If it's just stopping the email, I have what I need.

From: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 2, 2023 10:23 AM
To: Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Oliver, Angela (CDC/OD/OCS) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

And it would have some downstream effects on public websites too, which HHS previously had to approve when we changed.

From: Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]>
Sent: Thursday, February 2, 2023 10:22 AM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Oliver, Angela (CDC/OD/OCS) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Just EZID, please do not set up a big meeting about this. I will put it on my list for discussion with Brendan next week and see if we can stop the weekly reporting. For now, let's just answer his question about deaths from anaphylaxis.

From: Goldstein, Robert (CDC/OD/OCS) <[redacted]>
Sent: Thursday, February 2, 2023 10:16 AM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED) <[redacted]>; Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]>
Cc: Morrison, Melissa (CDC/DDPHSIS/CPR/DSLR) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP)

<[redacted]>
Subject: Re: Updated case counts for Director's Weekly Brief

Julianne,

Thanks for sharing this. I don't think we need a formal query for anaphylaxis, but the Director was wondering if we have historically seen any deaths associated with anaphylaxis. Do you know the answer to that question?

-Robbie

From: "Gee, Julianne (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Date: Thursday, February 2, 2023 at 10:10 AM
To: "Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED)" <[redacted]>, "Goldstein, Robert (CDC/OD/OCS)" <[redacted]>, "Lubar, Debra (CDC/DDID/NCEZID/OD)" <[redacted]>
Cc: "Morrison, Melissa (CDC/DDPHSIS/CPR/DSLR)" <[redacted]>, "Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Kroop, Seth (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: Re: Updated case counts for Director's Weekly Brief

Hi Brendan,

We are seeing increased case counts of myocarditis in VAERS. For anaphylaxis, we are no longer conducting enhanced monitoring for this outcome and can conduct a formal search in the VAERS database to provide you this information.

We seek additional information (medical records, etc) for myocarditis cases and they reviewed by VAERS medical officers. If death is reported, further review is conducted. To date none of the myocarditis cases have been associated with COVID vaccine.

Related to my inquiry on Monday of ending our weekly reporting of myocarditis and GBS for the Director's brief, I spoke to Nicole Coffin yesterday for background and suggestions on how to move forward. I understand that Seth Kroop has also been involved in this issue. I think it will be best if I send a meeting invite to everyone on this email to decide if these weekly updates are still needed. And if so, who should be receiving the email as the distribution list is quite outdated.

Thanks.
Julianne

From: Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED) <[redacted]>
Sent: Thursday, February 2, 2023 9:02 AM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Goldstein, Robert (CDC/OD/OCS) <[redacted]>; Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]>
Cc: Morrison, Melissa (CDC/DDPHSIS/CPR/DSLR) <[redacted]>
Subject: Re: Updated case counts for Director's Weekly Brief

Hi Julianne,

Could you please answer the questions below from OD/OD re: myocarditis?

Thanks,

Brendan

You mentioned earlier this week that we continue to get reports of myocarditis and anaphylaxis post-vaccination weekly. Do you know if those reports also include deaths associated with either condition and, if so, if there are associated deaths?

From: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Monday, January 30, 2023 10:00 AM
To: Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED) <[redacted]>; Mahon, Barbara (CDC/DDID/NCIRD/OD) <[redacted]
Subject: FW: Updated case counts for Director's Weekly Brief

Hi Brendon and Barb,

This is the email that I was referring to on the policy call. In addition to you two, who else do you recommend be involved in these discussions to retire these weekly emails?

Thanks so much!
Julianne

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Friday, January 27, 2023 7:09 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Sives, Katelyn (CDC/DDPHSIS/CSTLTS/OD) <[redacted]>; Wiley, Sarah D. (CDC/DDID/NCEZID/DFWED) <[redacted]>; CDC IMS 2019 NCOV Response VCU Policy <[redacted]>; Ward Gokhale, Lindsay (CDC/OCOO/OFR/OA) <[redacted]>; Banister, Christina (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]
Cc: Hicks, Lauri (CDC/DDID/NCEZID/DHQP) <[redacted]>; Leach, Caitlin (CDC/DDID/NCHHSTP/DSTDP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Langley, Gayle E. (CDC/OD/OADPS) <[redacted]>; Layden, Jennifer (CDC/DDPHSS/OD) <[redacted]>; Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[redacted]>; DHQP_Policy (CDC) <[redacted]>; See, Isaac (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>; Taylor, Allan W. (CDC/DDPHSIS/CGH/OD) <[redacted]>; Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <[redacted]>; Al-Shawaf, Maeh (CDC/DDNID/NCCDPHP/OSH) <[redacted]>; Rodriguez, Rockie (CDC/DDPHSIS/CPR/DSLR) <[redacted]>; NCIRD Congressional (CDC) <[redacted]>; Beauvais, Denise (CDC/DDID/NCIRD/OD) <[redacted]>; Frederick, Charles (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; Frederick, Charles (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; CDC IMS SA Public Health Scientist (CDC) <[redacted]
Subject: Updated case counts for Director's Weekly Brief

Good afternoon,

Please see updated case counts for myocarditis, and GBS. All counts are current **as of January 26, 2023:**

- Status of myocarditis investigation: there were 1060 reports among persons known to be <18 years of age under review for potential myocarditis. Of them,
  - 247 remain under review
  - 813 had symptoms and diagnostics confirmed by provider interview or review of medical records
    - **710** met the CDC working definition for myocarditis:

- 5-11 years: 23 verified reports of myocarditis after 23,178,311 doses administered
- 12-15 years: 371 verified reports of myocarditis after 25,791,756 doses administered
- 16-17 years: 316 verified reports of myocarditis after 14,117,149 doses administered

- There were 337 preliminary reports of Guillain Barre syndrome following J&J/Janssen vaccination
  - **Note:** these reports were identified by automated computer search; the count might include reports that would not meet a standardized case definition for GBS.

Please let me know if you have any questions. Have a great weekend!

Pedro

Pedro L. Moro, M.D., M.P.H.
Acting Team Lead
VAERS Project and Response Team
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Road, MS V18-4
Atlanta, GA 30329-4027
[redacted]

From: "Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR)" <[redacted]>
To: "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Cc: "Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: FW: 23-00523-FOIA: Request for Documents
Date: Wed, 22 Feb 2023 22:19:38 +0000
Importance: Normal
Attachments: PAL_Request_Form.pdf; Article_-_CDC_&_FDA_Identify_Preliminary_COVID-19_Vaccine.pdf

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Good afternoon Dr. Su,

We received the attached FOIA requesting all communications between CDC officials, and between the CDC and FDA, concerning this statement "CDC & FDA Identify Preliminary COVID-19 Vaccine Safety Signal for Persons Aged 65 Years and Older" from the link https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/bivalent-boosters.html. See attached FOIA request and article for details.

I'm wondering who I should work with in ISO for responsive documents. I saw "Vaccine Safety Signals" mentioned in the title of the article and wanted to know if it may be VAERS related, VSD related, and/or both VAERS and VSD. The due date is March 8, 2023 and the FOIA office also stated **PLEASE PROVIDE CDC and FDA custodians to gauge requester interest**.

Any and all guidance you provide is appreciated. Thanks so much.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email:[redacted]
Phone: [redacted]

Centers for Disease Control and Prevention

COVID-19

CDC & FDA Identify Preliminary COVID-19 Vaccine Safety Signal for Persons Aged 65 Years and Older

Updated Jan. 13, 2023

Transparency and vaccine safety are top priorities for the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). U.S. government agencies use multiple, complementary safety monitoring systems to help detect possible safety signals for vaccines and other medical countermeasures as early as possible and to facilitate further investigation, as appropriate. Often these safety systems detect signals that could be due to factors other than the vaccine itself.

All signals require further investigation and confirmation from formal epidemiologic studies. When one system detects a signal, the other safety monitoring systems are checked to validate whether the signal represents an actual concern with the vaccine or if it can be determined to be of no clinical relevance.

Following the availability and use of the updated (bivalent) COVID-19 vaccines, CDC's Vaccine Safety Datalink (VSD), a near real-time surveillance system, met the statistical criteria to prompt additional investigation into whether there was a safety concern for ischemic stroke in people ages 65 and older who received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Rapid-response investigation of the signal in the VSD raised a question of whether people 65 and older who have received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent were more likely to have an ischemic stroke in the 21 days following vaccination compared with days 22-42 following vaccination.

This preliminary signal has not been identified with the Moderna COVID-19 Vaccine, Bivalent. There also may be other confounding factors contributing to the signal identified in the VSD that merit further investigation. Furthermore, it is important to note that, to date, no other safety systems have shown a similar signal and multiple subsequent analyses have not validated this signal:

- A large study of updated (bivalent) vaccines (from Pfizer-BioNTech and Moderna) using the Centers for Medicare and Medicaid Services database revealed no increased risk of ischemic stroke
- A preliminary study using the Veterans Affairs database did not indicate an increased risk of ischemic stroke following an updated (bivalent) vaccine
- The Vaccine Adverse Event Reporting System (VAERS) managed by CDC and FDA has not seen an increase in reporting of ischemic strokes following the updated (bivalent) vaccine
- Pfizer-BioNTech's global safety database has not indicated a signal for ischemic stroke with the updated (bivalent) vaccine
- Other countries have not observed an increased risk for ischemic stroke with updated (bivalent) vaccines

Although the totality of the data currently suggests that it is very unlikely that the signal in VSD represents a true clinical risk, we believe it is important to share this information with the public, as we have in the past, when one of our safety monitoring systems detects a signal. CDC and FDA will continue to evaluate additional data from these and other vaccine safety systems. These data and additional analyses will be discussed at the upcoming January 26 meeting of the FDA's Vaccines and Related Biological Products Advisory Committee.

No change in vaccination practice is recommended. CDC continues to recommend that everyone ages 6 months of age and older stay up-to-date with COVID-19 vaccination; this includes individuals who are currently eligible to receive an updated (bivalent) vaccine. Staying up-to-date with vaccines is the most effective tool we have for reducing death, hospitalization, and severe disease from COVID-19, as has now been demonstrated in multiple studies conducted in the United States and other countries:

- Data have shown an updated COVID-19 vaccine reduces the risk of hospitalization from COVID-19 by nearly 3-fold compared to those who were previously vaccinated but have not yet received the updated vaccine.
- Data have shown that the updated COVID-19 vaccine also reduces the risk of death from COVID-19 by nearly 19-fold compared to those who are unvaccinated.
- Other preliminary data from outside the U.S. have demonstrated more than 80% protection against severe disease and death from the bivalent vaccine compared to those who have not received the bivalent vaccine.

Overall safety data for the bivalent COVID-19 vaccines are available here.

Once again, **no change is recommended in COVID-19 vaccination practice**, which can be found here.

Last Updated Jan. 13, 2023

From: "Gallego, Ruth (CDC/DDID/NCEZID/DHQP)" <[redacted]>
To: "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Moro, Pedro (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Cc: "Woo, Jared (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: RE: abstraction of ischemic stroke -- chart confirmed reports?
Date: Wed, 11 Jan 2023 20:48:13 +0000
Importance: Normal

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hopefully this is the last...

- 36 Yes
- 19 No
- 2 blank (emailed abstractor to complete field)

From: Gallego, Ruth (CDC/DDID/NCEZID/DHQP)
Sent: Wednesday, January 11, 2023 3:41 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Woo, Jared (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: RE: abstraction of ischemic stroke -- chart confirmed reports?

see attachment

From: Gallego, Ruth (CDC/DDID/NCEZID/DHQP)
Sent: Wednesday, January 11, 2023 3:40 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]
Cc: Woo, Jared (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: RE: abstraction of ischemic stroke -- chart confirmed reports?

Hi john,

i realized i pulled the wrong variable (coag instead of stroke)

57/110 cases have medical record,

to the question, *Did a physician diagnose the patient's as having experienced a stroke? (i.e., was the VAERS report filed by a physician, or do available medical records state, "Doctor diagnosed...stroke?")*

- 36 Yes
- 16 No
- 2 blank (emailed abstractor to complete field)

Question, we are not pulling all stroke cases but just the recent 110 cases (which i assume are after bivalent), correct?

Ruth

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Wednesday, January 11, 2023 2:47 PM
To: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[redacted]; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Woo, Jared (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: RE: abstraction of ischemic stroke -- chart confirmed reports?

Okay, thanks.

- John

From: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Wednesday, January 11, 2023 2:32 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Woo, Jared (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: abstraction of ischemic stroke -- chart confirmed reports?

1. How many reports have medical records associated with them
   in this attachment, you will the list of redcap records with medical records. there is no current field that corresponds to this

2. Of them, how many indicate the diagnosis of ischemic stroke or transient ischemic attack (TIA)
   my sense is that you are referring to the variable coag_phys_diag, Did a physician diagnose the patient's as having experienced a stroke? (i.e., was the VAERS report filed by a physician, or do available medical records state, "Doctor diagnosed...stroke?")
   at the moment, responses to this field is not populating.

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Wednesday, January 11, 2023 12:49 PM
To: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Woo, Jared (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: abstraction of ischemic stroke -- chart confirmed reports?

Hi folks,

I just pulled the data from REDCap, and am having some difficulty with the below:

1. How many reports have medical records associated with them
2. Of them, how many indicate the diagnosis of ischemic stroke or transient ischemic attack (TIA)

Would you be able to take a look and let me know? Thanks!

- John

John R. Su, M.D., Ph.D., M.P.H.
CAPT, U.S. Public Health Service
Acting Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Road, MS H17-3
Atlanta, GA 30333
[redacted]

From: "Moorer, Alanna (CDC/DDID/NCEZID/DHQP)" <[redacted]>
To: "Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Moro, Pedro (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Cc: "Kroop, Seth (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "DHQP_Policy (CDC)" <[redacted]>, "Nguyen, Lyn (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Hamburger, Tanya (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Gee, Julianne (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief
Date: Thu, 9 Feb 2023 21:49:46 +0000
Importance: Normal
Attachments: For_Review_Rollout_Plan_COVID-19_Selected_AE.docx; For_Review_COVID-19_Selected_AE_TRACKED_CHANGES.docx; For_Review_COVID-19_Selected_AE_CLEANv2.docx
Inline-Images: image001.png

Good afternoon all,

Related to Lyn's update earlier, I've attached the following for your review:

- Clean and tracked changes versions of the Selected Adverse Events page with highlights of the proposed changes
- Rollout plan explaining these changes (I revised the previous version of the rollout we used for the earlier revision related to children and adolescents)

Please review and let me know if additional edits/updates are required. Once Tom/John approve, we can continue routing through DHQP Comms clearance, then submit to JIC for final clearance. After JIC clears, the documents will be ready to share with HHS to get approval for the update (discontinuing the weekly case counts on the public-facing page).

Please let me know if you have any questions.

Alanna S. Moorer, MPS
Lead, Immunization Safety Communications Team
Immunization Safety Office (ISO)
Division of Healthcare Quality Promotion (DHQP)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention (CDC)

Phone: [redacted]
Email: [redacted]

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:36 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Yes

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:30 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

I'll defer to Tom, but offhand, I think he and I are sufficient.

- John

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:29 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Correct! Also, please let us know if there is anyone else in ISO that should review/clear the drafts when Comms sends them out.

-Lyn

Lyn Thi Nguyen, MPH *(she/her/hers)*

Public Health Analyst

Division of Healthcare Quality Promotion (DHQP)

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

U.S. Centers for Disease Control and Prevention

1600 Clifton Road NE, MS H16- 2

Atlanta, GA 30329

[redacted]

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:26 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Hi Lyn,

Do I understand correctly: finishing touches are being put on these documents, and once those touches are complete, you'll forward to Tom and me to give the okay for those documents to go forward?

- John

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 2:22 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Tom and John,

Wanted to give a quick update are where things are on behalf of the DHQP Policy and Comms Teams. **The next steps will be for you both to review and sign off on the appropriate documents reflecting the proposed changes and messages.** Please let us know if there is anyone else who should be part of the review/clear process for ISO. DHQP Comms will be sending updated drafts and the rollout plan for your review later today. Once you have signed off, we can move forward on the other required clearances before sending this back to Deb Lubar to continue her conversation on discontinuing our updates of case counts for the Director's Weekly brief.

Comms docs:

- **Updates to the CDC Selected Adverse Events page:** Comms sent clean and tracked changes of the page for SME review earlier today (2/9), but, per John's email, will need to add publications to the reports of death section so we can stop all case count reporting for that page. Alanna will make the update today and will share the updated versions of those attachments so you can review the proposed changes.
- **Rollout plan:** Comms will complete a rollout plan explaining the rationale for the change to the SAE page later today for review and clear.
  - Alanna- feel free to use the initial BLUF/ messages from the previous document I sent to help fill out the components of the roll out plan: Changes to CDC's website on Select AEs myocarditis section_Feb 2023.docx

Once these communication documents route through DHQP comms, both will need to go through JIC clearance, then HHS for approval. DHQP Policy will in parallel handle getting the cleared proposed web update draft and TPs back to Deb.

Please let us know if you have additional questions on where we are with this process.

Thanks.
-Lyn

Lyn Thi Nguyen, MPH *(she/her/hers)*

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U.S. Centers for Disease Control and Prevention

1600 Clifton Road NE, MS H16- 2

Atlanta, GA 30329

[redacted]

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Thursday, February 9, 2023 1:28 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Yes, what John said.

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 1:18 PM
To: Moorer, Alanna (CDC/DDID/NCEZID/DHQP) [redacted]; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Hi Alanna,

Historically, the preliminary counts of deaths reported to VAERS after COVID-19 vaccination have come from the daily priority reports, and are updated weekly on the Selected Adverse Events page. We would like to stop updating those counts and refer to published literature, as we would for anaphylaxis, myocarditis, and other adverse events on that page.

Related to this effort (ie, the consolidated vaccine safety page), we would like to stop providing updated case counts for the Weekly Director's Update. Any word on where we are on that effort?

Thanks!

- John

From: Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 9, 2023 12:00 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) [redacted]; Gee, Julianne (CDC/DDID/NCEZID/DHQP) [redacted]; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Good morning all,

I'm following up on Lyn's email below and have attached clean and tracked changes versions of the entire Selected Adverse Events page and highlighted proposed changes to the myocarditis/pericarditis section of the page (for clearance purposes, comms needs to submit web updates this way). Please review and let me know if additional updates are required.

Our team also updates the Reports of death section with the content from Pedro's report. Would that reporting continue on a weekly basis? Or should we also point to published manuscripts for that section as well?

Thanks so much!

Alanna S. Moorer, MPS
Lead, Immunization Safety Communications Team
Immunization Safety Office (ISO)
Division of Healthcare Quality Promotion (DHQP)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention (CDC)

Phone: [redacted]
Email: [redacted]

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Friday, February 3, 2023 12:08 PM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hamburger, Tanya (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; DHQP_Policy (CDC) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Hi everyone,

Adding our Comms folks to this email thread so they are on the same page with the latest discussions. Per Deb's request, attached is a draft summary of what we are proposing to do. Let me know if you have additional edits/ comments.

Given the Select Adverse Events page will also need to be updated to no longer reflect weekly case counts for myocarditis/pericarditis for children and adolescents, I wanted to confirm whether ISO leadership would like the updates to include additional published papers (similar to what we did on TTS and anaphylaxis sections last year). If so, did you want us to use all of the relevant ISO published papers that is listed on our publications website or are there certain ones you would prefer us to call out specifically. Currently, we only have this JAMA paper (https://jamanetwork.com/journals/jama/fullarticle/2788346) on the Select AE website. In regards to GBS section and given how the website is currently laid out, I do not think there is anything more we need to do on GBS unless there are other published links you would want us to reference in this section.

Below are the list of other myocarditis/ pericarditis papers on our ISO publications page for COVID-19. I highlighted the ones that seemed most relevant to include given the removal of weekly reporting on the children and adolescent cases for this section. However, let us know if you prefer we add any of these to the website or add others that may not be on here. We plan to discuss some of this at today's monthly policy/comms/partnerships touch base meeting.

1. Goddard K, Hanson KE, Lewis N, Weintraub E, Fireman B, Klein NP. Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States.. *Annals of Internal Medicine.* 2022 Oct 4. doi.org/10.7326/M22-2274.
2. Kracalik I, Oster ME, Broder KR, Cortese MM, Glover M, Shields K, Creech CB, Romanson B, Novosad S, Soslow J, Walter EB, Marquez P, Dendy JM, Woo J, Valderrama AL, Ramirez-Cardenas A, Assefa A, Campbell MJ, Su JR, Magill SS, Shay DK, Shimabukuro TT, Basavaraju SV. Outcomes at least 90 days onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study. *Lancet Child Adolesc Health*. 2022 Nov 6;6(11):788-798. Epub 2022 Sept 22.
3. Goddard K, Lewis N, Fireman B, Weintraub E, Shimabukuro T, Zerbo O, Boyce TG, Oster ME, Hanson KE, Donahue JG, Ross P, Naleway A, Nelson JC, Lewin B, Glanz JM, Williams JTB, Kharbanda EO, Yih WK, Klein NP. Risk of

myocarditis and pericarditis following BNT162b2 and mRNA-1273 COVID-19 vaccination. *Vaccine* 2022 Aug 19; 40(35):5153-5159. Epub 2022 Jul 12.

4. Weintraub ES, Oster ME, Klein NP. Myocarditis or Pericarditis Following mRNA COVID-19 Vaccination. *JAMA* 2022 Jun 24; 5(6):e2218512. doi:10.1001/jamanetworkopen.2022.18512
5. Paddock CD, Reagan-Steiner S, Su JR, Oster ME, Martines RB, Bhatnagar J, Shimabukuro TT. Autopsy Histopathologic Cardiac Findings in Two Adolescents Following the Second COVID-19 Vaccine Dose. *Arch Pathol Lab Med* 2022 Apr 11. Doi: 10.5858/arpa.2022-0084-LE. Online ahead of print.
6. Block JP, Boehmer TK, Forrest CB, Carton TW, Lee GM, Ajani UA, Christakis DA, Cowell LG, Draper C, Ghildayal N, Harris AM, Kappelman MD, Ko JY, Mayer KH, Nagavedu K, Oster ME, Paranjape A, Puro J, Ritchey MD, Shay DK, Thacker D, Gundlapalli AV. Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination – PCORnet, United States, January 2021-January 2022. *MMWR Morb Mortal Wkly Rep*. 2022 Apr 8;71.
7. Oster ME, Shay DK, Su JR, Gee J, Creech B, Broder KR, Edwards K, Soslow JH, Dendy JM, Schlaudecker E, Lang SM, Barnett ED, Ruberg FL, Smith MJ, Campbell MJ, Lopes RD, Sperling LS, Baumblatt JA, Thompson DL, Marquez PL, Strid P, Woo J, Puglsey R, Reagan-Steiner S, DeStefano F, Shimabukuro TT. Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US from December 2020 to August 2021 *JAMA.* 2022 Jan 18;327(4):331-340. Online ahead of print.
8. Gargano JW, Wallace M, Hadler SC, Langley G, Su JR, Oster ME, Broder KR, Gee J, Weintraub E, Shimabukuro T, Scobie HM, Moulia D, Markowitz LE, Wharton M, McNally VV, Romero JR, Keipp Talbot H, Lee GM, Daley MF, Oliver SE. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021 *MMWR Morb Mortal Wkly Rep.* 2021 Jul 9;70:977-982.
9. Shay DK, Shimabukuro, TT, DeStefano F. Myocarditis After Immunization with mRNA-Based COVID-19 Vaccines: Editorial. *JAMA Cardiol.* Published online June 29, 2021. doi:10.1001/jamacardio.2021.2821.

Thanks.
-Lyn

Lyn Thi Nguyen, MPH *(she/her/hers)*

Public Health Analyst

Division of Healthcare Quality Promotion (DHQP)

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

U.S. Centers for Disease Control and Prevention

1600 Clifton Road NE, MS H16- 2

Atlanta, GA 30329

[redacted]

From: Kroop, Seth (CDC/DDID/NCEZID/DHQP) [redacted]
Sent: Thursday, February 2, 2023 10:30 AM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) [redacted] Gee, Julianne (CDC/DDID/NCEZID/DHQP) [redacted]
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [redacted]; Su, John (CDC/DDID/NCEZID/DHQP) [redacted]
Subject: RE: Updated case counts for Director's Weekly Brief

Without Deb and with Lyn.

I've asked Lyn to help put together a synthesis of what would change on the website. I know there are previous email strings, but a synthesized doc would help with side by side of what would change on the public website.

From: Lubar, Debra (CDC/DDID/NCEZID/OD) [redacted]
Sent: Thursday, February 2, 2023 10:26 AM

To: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Oliver, Angela (CDC/OD/OCS) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Thanks, Seth. Can you send an email proposing the changes you want, and if there are changes to websites, please show those. If it's just stopping the email, I have what I need.

From: Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 2, 2023 10:23 AM
To: Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Oliver, Angela (CDC/OD/OCS) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

And it would have some downstream effects on public websites too, which HHS previously had to approve when we changed.

From: Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]>
Sent: Thursday, February 2, 2023 10:22 AM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Oliver, Angela (CDC/OD/OCS) <[redacted]>
Subject: RE: Updated case counts for Director's Weekly Brief

Just EZID, please do not set up a big meeting about this. I will put it on my list for discussion with Brendan next week and see if we can stop the weekly reporting. For now, let's just answer his question about deaths from anaphylaxis.

From: Goldstein, Robert (CDC/OD/OCS) <[redacted]>
Sent: Thursday, February 2, 2023 10:16 AM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED) <[redacted]>; Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]>
Cc: Morrison, Melissa (CDC/DDPHSIS/CPR/DSLR) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Re: Updated case counts for Director's Weekly Brief

Julianne,

Thanks for sharing this. I don't think we need a formal query for anaphylaxis, but the Director was wondering if we have historically seen any deaths associated with anaphylaxis. Do you know the answer to that question?

-Robbie

From: "Gee, Julianne (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Date: Thursday, February 2, 2023 at 10:10 AM
To: "Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED)" <[redacted]>, "Goldstein, Robert (CDC/OD/OCS)" <[redacted]>, "Lubar, Debra (CDC/DDID/NCEZID/OD)" <[redacted]>
Cc: "Morrison, Melissa (CDC/DDPHSIS/CPR/DSLR)" <[redacted]>, "Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Kroop, Seth (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: Re: Updated case counts for Director's Weekly Brief

Hi Brendan,

We are seeing increased case counts of myocarditis in VAERS. For anaphylaxis, we are no longer conducting enhanced monitoring for this outcome and can conduct a formal search in the VAERS database to provide you this information.

We seek additional information (medical records, etc) for myocarditis cases and they reviewed by VAERS medical officers. If death is reported, further review is conducted. To date none of the myocarditis cases have been associated with COVID vaccine.

Related to my inquiry on Monday of ending our weekly reporting of myocarditis and GBS for the Director's brief, I spoke to Nicole Coffin yesterday for background and suggestions on how to move forward. I understand that Seth Kroop has also been involved in this issue. I think it will be best if I send a meeting invite to everyone on this email to decide if these weekly updates are still needed. And if so, who should be receiving the email as the distribution list is quite outdated.

Thanks.
Julianne

From: Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED) <[redacted]
Sent: Thursday, February 2, 2023 9:02 AM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]; Goldstein, Robert (CDC/OD/OCS) <[redacted]; Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]
Cc: Morrison, Melissa (CDC/DDPHSIS/CPR/DSLR) <[redacted]
Subject: Re: Updated case counts for Director's Weekly Brief

Hi Julianne,

Could you please answer the questions below from OD/OD re: myocarditis?

Thanks,
Brendan

You mentioned earlier this week that we continue to get reports of myocarditis and anaphylaxis post-vaccination weekly. Do you know if those reports also include deaths associated with either condition and, if so, if there are associated deaths?

From: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Monday, January 30, 2023 10:00 AM
To: Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED) <[redacted]; Mahon, Barbara (CDC/DDID/NCIRD/OD) <[redacted]
Subject: FW: Updated case counts for Director's Weekly Brief

Hi Brendon and Barb,

This is the email that I was referring to on the policy call. In addition to you two, who else do you recommend be involved in these discussions to retire these weekly emails?

Thanks so much!

Julianne

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Friday, January 27, 2023 7:09 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Sives, Katelyn (CDC/DDPHSIS/CSTLTS/OD) <[redacted]; Wiley, Sarah D. (CDC/DDID/NCEZID/DFWED) <[redacted]; CDC IMS 2019 NCOV Response VCU Policy <[redacted]; Ward Gokhale, Lindsay (CDC/OCOO/OFR/OA) <[redacted]; Banister, Christina (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]; Moorer, Alanna (CDC/DDID/NCEZID/DHQP) <[redacted]; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]
Cc: Hicks, Lauri (CDC/DDID/NCEZID/DHQP) <[redacted]; Leach, Caitlin (CDC/DDID/NCHHSTP/DSTDP) <[redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]; Langley, Gayle E. (CDC/OD/OADPS) <[redacted]; Layden, Jennifer (CDC/DDPHSS/OD) <[redacted]; Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[redacted]; DHQP_Policy (CDC) <[redacted]; See, Isaac (CDC/DDID/NCEZID/DHQP) <[redacted]; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <[redacted]; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[redacted]; Nair, Narayan (FDA/CBER) <[redacted]; Alimchandani, Meghna (FDA/CBER) <[redacted]; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]; Taylor, Allan W. (CDC/DDPHSIS/CGH/OD) <[redacted]; Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <[redacted]; Al-Shawaf, Maeh (CDC/DDNID/NCCDPHP/OSH) [redacted]; Rodriguez, Rockie (CDC/DDPHSIS/CPR/DSLR) <[redacted]; NCIRD Congressional (CDC) <[redacted]; Beauvais, Denise (CDC/DDID/NCIRD/OD) <[redacted]; Frederick, Charles (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]; Frederick, Charles (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]; CDC IMS SA Public Health Scientist (CDC) <[redacted]
Subject: Updated case counts for Director's Weekly Brief

Good afternoon,

Please see updated case counts for myocarditis, and GBS. All counts are current **as of January 26, 2023:**

- Status of myocarditis investigation: there were 1060 reports among persons known to be <18 years of age under review for potential myocarditis. Of them,
  - 247 remain under review
  - 813 had symptoms and diagnostics confirmed by provider interview or review of medical records
    - **710** met the CDC working definition for myocarditis:
      - 5-11 years: 23 verified reports of myocarditis after 23,178,311 doses administered
      - 12-15 years: 371 verified reports of myocarditis after 25,791,756 doses administered
      - 16-17 years: 316 verified reports of myocarditis after 14,117,149 doses administered

- There were 337 preliminary reports of Guillain Barre syndrome following J&J/Janssen vaccination
  - **Note:** these reports were identified by automated computer search; the count might include reports that would not meet a standardized case definition for GBS.

Please let me know if you have any questions. Have a great weekend!

Pedro

Pedro L. Moro, M.D., M.P.H.
Acting Team Lead
VAERS Project and Response Team
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Road, MS V18-4
Atlanta, GA 30329-4027
[redacted]

Selected Adverse Events Reported after COVID-19 Vaccination

Updated Feb. 6, 2023
Español | Other Languages
Print

CDC's Vaccine Safety Datalink (VSD) met the statistical criteria to prompt additional investigation into whether there was a safety concern for ischemic stroke in people ages 65 and older who received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. To date, no other safety systems have shown a similar signal and multiple subsequent analyses have not validated this signal. **No change is recommended in COVID-19 vaccination practice.**
Read More

Safety of COVID-19 Vaccines
Some people have no side effects. Many people have reported side effects, such as headache, fatigue, and soreness at the injection site, that are generally mild to moderate and go away within a few days.
Are the Vaccines Safe?

What You Need to Know

- COVID-19 vaccines are **safe and effective and severe reactions after vaccination are rare.**
- CDC recommends everyone ages 6 months and older get vaccinated as soon as possible to protect against COVID-19 and its potentially severe complications.
- Although mRNA vaccines (Pfizer-BioNTech or Moderna COVID-19 vaccines) are preferred, Johnson & Johnson's Janssen COVID-19 vaccine may be considered in some situations.
- Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring program in U.S. history.
- CDC, the U.S. Food and Drug Administration (FDA), and other federal agencies continue to monitor the safety of COVID-19 vaccines.
- Adverse events described on this page have been reported to the Vaccine Adverse Event Reporting System (VAERS).
- VAERS accepts reports of any adverse event following vaccination.

The benefits of COVID-19 vaccination continue to outweigh any potential risks.

CDC is providing timely updates on the following adverse events of interest:

- **Anaphylaxis after COVID-19 vaccination is rare** and has occurred at a rate of approximately 5 cases per one million vaccine doses administered. Anaphylaxis, a severe

type of allergic reaction, can occur after any kind of vaccination. If it happens, healthcare providers can effectively and immediately treat the reaction. Learn more about COVID-19 vaccines and allergic reactions, including anaphylaxis.
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- Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine
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- Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14-23, 2020

- **Thrombosis with thrombocytopenia syndrome (TTS) after J&J/Janssen COVID-19 vaccination is rare** and has occurred in approximately 4 cases per one million doses administered. TTS is a rare but serious adverse event that causes blood clots in large blood vessels and low platelets (blood cells that help form clots).
A review of reports indicates a causal relationship between the J&J/Janssen COVID-19 vaccine and TTS. CDC scientists have conducted detailed reviews of TTS cases and made the information available to healthcare providers and the public:
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  - Updates on Thrombosis with Thrombocytopenia Syndrome (TTS) [1.3 MB, 39 Pages]
- **Guillain-Barré Syndrome (GBS) in people who have received the J&J/Janssen COVID-19 vaccine is rare.** GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. GBS has largely been reported in men ages 50 years and older.
Based on a recent analysis of data from the Vaccine Safety Datalink, the rate of GBS within the first 21 days following J&J/Janssen COVID-19 vaccination was found to be 21 times higher than after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). After the first 42 days, the rate of GBS was 11 times higher following J&J/Janssen COVID-19 vaccination. The analysis found no increased risk of GBS after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). CDC and FDA will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.

  Similarly, CDC found higher than expected rates of GBS reported to the Vaccine Adverse Event Reporting System (VAERS) after J&J/Janssen COVID-19 vaccination but not after mRNA COVID-19 vaccination. CDC and FDA will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.

- **Myocarditis and pericarditis after COVID-19 vaccination are rare.** Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the outer lining of the heart. Most patients with myocarditis or pericarditis after COVID-19 vaccination responded well to medicine and rest and felt better quickly. Most cases have been reported after receiving Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines), particularly in male adolescents and young adults.
  A review of vaccine safety data in VAERS from December 2020–August 2021 found a small but increased risk of myocarditis after mRNA COVID-19 vaccines. Over 350 million mRNA vaccines were given during the study period and CDC scientists found that rates of myocarditis were highest following the second dose of an mRNA vaccine among males in the following age groups:
  - 12–15 years (70.7 cases per one million doses of Pfizer-BioNTech)
  - 16–17 years (105.9 cases per one million doses of Pfizer-BioNTech)
  - 18–24 years (52.4 cases and 56.3 cases per million doses of Pfizer-BioNTech and Moderna, respectively)

  Multiple studies and reviews of data from vaccine safety monitoring systems continue to show that vaccines are safe. CDC scientists have conducted detailed reviews of cases of myocarditis and pericarditis and made the information available to healthcare providers and the public: ~~As a result, the agency will refocus enhanced surveillance and safety monitoring efforts toward children and adolescents.~~
  - Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States
  - Outcomes at least 90 days onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study
  - Risk of myocarditis and pericarditis following BNT162b2 and mRNA-1273 COVID-19 vaccination
  - Myocarditis or Pericarditis Following mRNA COVID-19 Vaccination

  ~~As of February 2, 2023, there have been 1,062 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 247 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 711 reports have been verified to meet CDC's working case definition for myocarditis. See below for counts of verified reports of myocarditis by age group.~~

  ~~5-11 years: 23 verified reports of myocarditis after 23,224,881 doses administered~~
  ~~12-15 years: 372 verified reports of myocarditis after 25,825,265 doses administered~~
  ~~16-17 years: 316 verified reports of myocarditis after 14,131,776 doses administered~~

  As the COVID-19 vaccines are authorized for younger children, CDC and FDA will continue to monitor for and evaluate reports of myocarditis and pericarditis after COVID-19 vaccination and will share more information as it becomes available. Learn more about myocarditis and pericarditis, including clinical considerations, after mRNA COVID-19 vaccination.

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Moorer, Alanna (CDC/DDID/NCEZID/DHQP)
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Moorer, Alanna (CDC/DDID/NCEZID/DHQP)
2023-02-09 11:33:00

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2023-02-09 11:34:00

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Moorer, Alanna (CDC/DDID/NCEZID/DHQP)
2023-02-09 11:36:00

Commented [MA(5]: Note for reviewers: The dates, # reports, and # doses administered are updated weekly. The numbers listed here are current as of Feb 9, 2023
Moorer, Alanna (CDC/DDID/NCEZID/DHQP)
2023-02-09 11:21:00

- **Reports of death after COVID-19 vaccination are rare**. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. **Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem.** CDC scientists have conducted detailed reviews of cases of reports of death after COVID-19 vaccination and made the information available to healthcare providers and the public:
  - A Safety Study Evaluating non-COVID-19 Mortality Risk Following COVID-19 Vaccination
  - COVID-19 Vaccination and Non-COVID-19 Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020-July 31, 2021
- ~~More than 669 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through February 1, 2023. During this time, VAERS received 19,115 preliminary reports of death (0.0029%) among people who received a COVID-19 vaccine. CDC and FDA clinicians review reports of death to VAERS including death certificates, autopsy, and medical records. Continued monitoring has identified nine deaths causally associated with J&J/Janssen COVID-19 vaccination. CDC and FDA continue to review reports of death following COVID-19 vaccination and update information as it becomes available.~~

Commented [MA(6]: Note for reviewers: The dates, # reports, and # doses administered are updated weekly. The numbers listed here are current as of Feb 9, 2023

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Moorer, Alanna (CDC/DDID/NCEZID/DHQP)
2023-02-09 14:21:00

Commented [MA(8]: Note to developers: Link to - https://www.cdc.gov/mmwr/volumes/70/wr/mm7043e2.htm
Moorer, Alanna (CDC/DDID/NCEZID/DHQP)
2023-02-09 14:23:00

Related Pages

- Safety of COVID-19 Vaccines
- Vaccine Adverse Event Reporting System (VAERS): What Reports Mean and How VAERS Works
- COVID-19 Vaccine Safety Publications

Last Updated Oct. 24, 2022
Source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases

Selected Adverse Events Reported after COVID-19 Vaccination

Updated Feb. 6, 2023

Español | Other Languages

Print

CDC's Vaccine Safety Datalink (VSD) met the statistical criteria to prompt additional investigation into whether there was a safety concern for ischemic stroke in people ages 65 and older who received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. To date, no other safety systems have shown a similar signal and multiple subsequent analyses have not validated this signal. **No change is recommended in COVID-19 vaccination practice.**

Read More

Safety of COVID-19 Vaccines

Some people have no side effects. Many people have reported side effects, such as headache, fatigue, and soreness at the injection site, that are generally mild to moderate and go away within a few days.

Are the Vaccines Safe?

What You Need to Know

- COVID-19 vaccines are **safe and effective and severe reactions after vaccination are rare.**
- CDC recommends everyone ages 6 months and older get vaccinated as soon as possible to protect against COVID-19 and its potentially severe complications.
- Although mRNA vaccines (Pfizer-BioNTech or Moderna COVID-19 vaccines) are preferred, Johnson & Johnson's Janssen COVID-19 vaccine may be considered in some situations.
- Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring program in U.S. history.
- CDC, the U.S. Food and Drug Administration (FDA), and other federal agencies continue to monitor the safety of COVID-19 vaccines.
- Adverse events described on this page have been reported to the Vaccine Adverse Event Reporting System (VAERS).
- VAERS accepts reports of any adverse event following vaccination.

The benefits of COVID-19 vaccination continue to outweigh any potential risks.

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Related Pages

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Last Updated Oct. 24, 2022

Source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases

From: "Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)" <[redacted]>
To: "Moro, Pedro (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: RE: VAERS Stroke Cases as of 02.06.2023
Date: Tue, 4 Apr 2023 23:09:26 +0000
Importance: Normal
Attachments: COVID_Stroke_NEW_Cases_04022023_.xlsx

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59 new ischemic stroke cases

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, April 4, 2023 9:56 AM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: VAERS Stroke Cases as of 02.06.2023
Importance: High

Hi Paige,

I hope you are well. At the morning meeting we were informed there may be an ACIP meeting on April 20 where safety data will be presented. The safety data will include the ischemic stroke data in VAERS. Tom is asking for data up to April 2. Could you do a search for ischemic stroke, as you've done before, but just provide any new reports that may have come in? also if you could let me know which ones have records and which ones haven't

Thanks

Pedro

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, February 7, 2023 9:42 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: VAERS Stroke Cases as of 02.06.2023

Hey John and Pedro,
I have identified 226 STROKE cases, 118 are NEW cases. I used EUA dates for Bivalent and looked at COVID19 (dose>2) or COVID19-2.
There were 110 OLD STROKE cases, but 2 of them have now been linked (see below) so now there are 108 OLD cases.
Please find the attached line list that provides the id, case status, and medical records status.

Linked VAERS ID	Target VAERS ID	Date Linked
2547029	2545614	01/12/2023 12:56 PM
2549670	2544877	01/13/2023 3:45 PM

Medical Records	NEW CASE	OLD CASE	Total
N	108	21	129
	47.79	9.29	57.08

Medical Records	NEW CASE	OLD CASE	Total
Y	10	87	97
	4.42	38.50	42.92
Total	118	108	226
	52.21	47.79	100.00

Paige Marquez
Statistician |Immunization Safety Office
CDC | Division of Healthcare Quality Promotion
Office [redacted]

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From: "Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)" <[redacted]>
To: "Moro, Pedro (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: RE: VAERS Stroke Cases as of 02.06.2023
Date: Wed, 8 Feb 2023 14:27:03 +0000
Importance: Normal

Oh ok… that makes sense

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Wednesday, February 8, 2023 9:02 AM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: VAERS Stroke Cases as of 02.06.2023

Yes, I know. I was expecting maybe a few more from January 2023

Pedro

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Wednesday, February 8, 2023 7:49 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) [redacted]
Subject: RE: VAERS Stroke Cases as of 02.06.2023

These are bivalent covid19 stroke cases so they have to be vaccinated in 2022 (08.31.2022 -present).

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) [redacted]
Sent: Tuesday, February 7, 2023 9:59 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) [redacted]; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: VAERS Stroke Cases as of 02.06.2023

Paige,

I see the majority were vaccinated in 2022. I wonder how these numbers for ischemic stroke compare to those after the monovalent from a year ago

Thanks

Pedro

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, February 7, 2023 9:42 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) [redacted]; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: VAERS Stroke Cases as of 02.06.2023

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Paige Marquez
Statistician |Immunization Safety Office
CDC | Division of Healthcare Quality Promotion
Office [redacted]

From: "Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR)" <[redacted]>
To: "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Cc: "Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: RE: VAERS Stroke Cases as of 02.06.2023
Date: Tue, 14 Feb 2023 18:12:59 +0000
Importance: Normal
Attachments: COVID_Stroke_Cases_updated_02062023_with_Vax_Manuf.xlsx

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I have attached the line list with vaccine manufacturer included as the last column.

Thanks,

Bicheng (Tony) Zhang

Data Analyst III
Chenega Enterprise Systems and Solutions (CHESS)
Division of Healthcare Quality Promotion (DHQP)/Immunization Safety Office (ISO)
Centers for Disease Control and Prevention
[redacted]

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, February 14, 2023 12:30 PM
To: Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: VAERS Stroke Cases as of 02.06.2023

Thanks, Tony – much appreciated!

- John

From: Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>
Sent: Tuesday, February 14, 2023 12:30 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) [redacted]
Subject: Re: VAERS Stroke Cases as of 02.06.2023

Hi John,

No problem I will get started on this ASAP.

Tony

Sent from my Verizon, Samsung Galaxy smartphone
Get Outlook for Android

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, February 14, 2023 12:00:55 PM
To: Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: VAERS Stroke Cases as of 02.06.2023

Hi Tony,

Sorry for the late minute ask. I just realized this line list doesn't contain vaccine (Moderna or Pfizer). For the listed VAERS IDs, would you please include manufacturer? I need them to update a slide set for Tom, and need these data ASAP. Thanks!

- John

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, February 7, 2023 9:42 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
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Paige Marquez
Statistician |Immunization Safety Office
CDC | Division of Healthcare Quality Promotion
Office [redacted]

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From: "Gallego, Ruth (CDC/DDID/NCEZID/DHQP)" <[redacted]>
To: "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Cc: "Ennulat, Carol (CDC/DDID/NCEZID/DHQP) (CTR)" <[redacted]>, "Moro, Pedro (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: RE: medical records for reports of ischemic stroke after bivalent mRNA COVID-19 vaccine
Date: Fri, 30 Dec 2022 18:22:32 +0000
Importance: Normal

As of today, out of 53 stroke cases

- 13 cases received medical records
- 14 cases medical records already available
- 21 cases MR needed or additional MR needed. MR request faxed successfully (MR team will focus on follow-up next week)
- 5 cases incomplete MR request information (missing pii or facility info)

From: Gallego, Ruth (CDC/DDID/NCEZID/DHQP)
Sent: Thursday, December 29, 2022 9:22 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Ennulat, Carol (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>; Starling, Doneshia (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>
Subject: RE: medical records for reports of ischemic stroke after bivalent mRNA COVID-19 vaccine

all 37 cases with missing medical records have been assigned to current staff

---

From: Gallego, Ruth (CDC/DDID/NCEZID/DHQP)
Sent: Thursday, December 29, 2022 9:04 AM
To: Starling, Doneshia (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Ennulat, Carol (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: medical records for reports of ischemic stroke after bivalent mRNA COVID-19 vaccine

Good morning,

Out of 53 cases,

- 16 medical records and/or death certificate
- 37 has no medical records
- 3 deaths: 2 with only death certificates and 1 with medical records and death certificates
- none of the cases has duplicates in the AESI database

VAERS ID	medical records
2450799	n
2451140	y
2454631	y
2459749	y
2462038	y
2463444	y

2463762	n
2469780	n
2470311	y
2470896	n
2471349	n
2472485	n
2472938	n
2474245	y
2475627	n
2476163	n
2477910	n
2480512	y
2483194	n
2484385	n
2485509	n
2486548	n
2486638	y
2487101	n
2487324	y
2488279	n

From: Starling, Doneshia (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]
Sent: Wednesday, December 28, 2022 3:24 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]
Cc: Ennulat, Carol (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[redacted]; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: RE: medical records for reports of ischemic stroke after bivalent mRNA COVID-19 vaccine

Sounds good 😊

Doneshia Starling
Program Coordinator
Eagle Health Analytics, LLC
Center for Disease Control and Prevention
Ph: [redacted]
Email: [redacted]

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Wednesday, December 28, 2022 3:24 PM
To: Starling, Doneshia (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]
Cc: Ennulat, Carol (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[redacted]; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: RE: medical records for reports of ischemic stroke after bivalent mRNA COVID-19 vaccine

Thanks, Doneshia. In truth, I won't be sending requests – but if you receive any from the abstraction team(s) noting that the report is of ischemic stroke after bivalent vaccine, you'll know to prioritize it. 😉 Thanks again!

- John

From: Starling, Doneshia (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>
Sent: Wednesday, December 28, 2022 3:05 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Ennulat, Carol (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: medical records for reports of ischemic stroke after bivalent mRNA COVID-19 vaccine

Hi John,

I have received your email. Yes, please send any priority request to us and our team will be sure to process them immediately.

Thank you,

Doneshia Starling
Program Coordinator
Eagle Health Analytics, LLC
Center for Disease Control and Prevention
Ph: [redacted]
Email [redacted]

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Wednesday, December 28, 2022 2:56 PM
To: Starling, Doneshia (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>
Cc: Ennulat, Carol (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: medical records for reports of ischemic stroke after bivalent mRNA COVID-19 vaccine

Hi Doneshia,

I hope the holiday season has been treating you well!

I understand you're the coordinator for medical record acquisition. We've received a high priority request from leadership to assess reports in VAERS of ischemic stroke – specifically, to confirm such reports by medical documentation (e.g., hospital records). I understand that for routine work, there's a bit of a delay or backlog? I just wanted to clarify that any requests for medical records pertaining to abstraction of ischemic stroke after bivalent vaccine should take top priority, ahead of all other requests. There aren't many such reports, and we plan to complete such efforts in the next couple of weeks – then it's back to business as usual. 😉

Please let me know if you have any questions. Thanks in advance!

- John

John R. Su, M.D., Ph.D., M.P.H.
CAPT, U.S. Public Health Service
Acting Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Road, MS H17-3
Atlanta, GA 30333
[redacted]

From: "Gallego, Ruth (CDC/DDID/NCEZID/DHQP)" <[redacted]>
To: "Starling, Doneshia (CDC/DDID/NCEZID/DHQP) (CTR)" <[redacted]>, "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Cc: "Ennulat, Carol (CDC/DDID/NCEZID/DHQP) (CTR)" <[redacted]>, "Moro, Pedro (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: RE: medical records for reports of ischemic stroke after bivalent mRNA COVID-19 vaccine
Date: Thu, 29 Dec 2022 14:04:12 +0000
Importance: Normal

Good morning,

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2484385	n
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From: Starling, Doneshia (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>
Sent: Wednesday, December 28, 2022 3:24 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Ennulat, Carol (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: medical records for reports of ischemic stroke after bivalent mRNA COVID-19 vaccine

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Doneshia Starling
Program Coordinator
Eagle Health Analytics, LLC
Center for Disease Control and Prevention
Ph:[redacted]
Email:[redacted]

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Wednesday, December 28, 2022 3:24 PM
To: Starling, Doneshia (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>
Cc: Ennulat, Carol (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
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Sent: Wednesday, December 28, 2022 3:05 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Ennulat, Carol (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: medical records for reports of ischemic stroke after bivalent mRNA COVID-19 vaccine

Hi John,

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Thank you,

Doneshia Starling
Program Coordinator
Eagle Health Analytics, LLC
Center for Disease Control and Prevention
Ph:[redacted]
Email:[redacted]

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Wednesday, December 28, 2022 2:56 PM

To: Starling, Doneshia (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]
Cc: Ennulat, Carol (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: medical records for reports of ischemic stroke after bivalent mRNA COVID-19 vaccine

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Please let me know if you have any questions. Thanks in advance!

- John

John R. Su, M.D., Ph.D., M.P.H.
CAPT, U.S. Public Health Service
Acting Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Road, MS H17-3
Atlanta, GA 30333
[redacted]

From: "Baer, Bethany" <[redacted]>
To: "Mcneil, Michael M (CDC)" <[redacted]>, "Strid, Penelope (CDC)" <[redacted]>, "Menschik, David" <[redacted]>, "Markowitz, Lauri (CDC)" <[redacted]>, "Myers, Tanya R (CDC)" <[redacted]>, "Rosenblum, Hannah (CDC)" <[redacted]>, "Gee, Julianne M (CDC)" <[redacted]>, "Liu, Ruiling (CDC)" <[redacted]>, "Marquez, Paige L (CDC)" <[redacted]>, "Zhang, Bi C (CDC)" <[redacted]>, "Abara, Winston E (CDC)" <[redacted]>, "Hause, Anne M (CDC)" <[redacted]>, "Su, John (CDC)" <[redacted]>, "Shimabukuro, Tom (CDC)" <[redacted]>, "Shay, David K (CDC)" <[redacted]>
Subject: RE: [EXTERNAL] RE: 6 month safety review for journal submission- please fill out author contribution by noon 10/26
Date: Mon, 25 Oct 2021 21:34:06 +0000
Importance: Normal
Attachments: tlid-author-signatures_6_month_trm_LM_PS2_MM_BB.pdf

---

Added my signature as well.
Thanks,
Bethany

From: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Monday, October 25, 2021 12:54 PM
To: Strid, Penelope (CDC) <[redacted]>; Menschik, David <[redacted]>; Markowitz, Lauri (CDC) <[redacted]>; Myers, Tanya R (CDC) <[redacted]>; Rosenblum, Hannah (CDC) <[redacted]>; Gee, Julianne M (CDC) <[redacted]>; Liu, Ruiling (CDC) <[redacted]>; Marquez, Paige L (CDC) <[redacted]>; Zhang, Bi C (CDC) <[redacted]>; Abara, Winston E (CDC) <[redacted]>; Hause, Anne M (CDC) <[redacted]>; Baer, Bethany <Bethany.Baer[redacted]>; Su, John (CDC) <[redacted]>; Shimabukuro, Tom (CDC) <[redacted]>; Shay, David K (CDC) <[redacted]>
Subject: RE: [EXTERNAL] RE: 6 month safety review for journal submission- please fill out author contribution by noon 10/26

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Added my signature, thanks
Mike

From: Strid, Penelope (CDC/DDNID/NCCDPHP/DRH) <[redacted]>
Sent: Monday, October 25, 2021 11:21 AM
To: Menschik, David (FDA/CBER) <[redacted]>; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Liu, Ruiling (CDC/NIOSH/WTCHP) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>; Abara, Winston E. (CDC/DDID/NCHHSTP/DSTDP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hause, Anne M. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Baer, Bethany (FDA/CBER) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shay, David (CDC/DDID/NCIRD/ID) <[redacted]>
Subject: RE: [EXTERNAL] RE: 6 month safety review for journal submission- please fill out author contribution by noon 10/26

David and I sent at the same time, so I updated to be included with his and others.

-Penelope

From: Menschik, David <[redacted]
Sent: Monday, October 25, 2021 11:17 AM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <[redacted]; Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]; Gee, Julianne (CDC/DDID/NCEZID/DHQP) [redacted]; Liu, Ruiling (CDC/NIOSH/WTCHP) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]; Strid, Penelope (CDC/DDNID/NCCDPHP/DRH) <[redacted]; Abara, Winston E. (CDC/DDID/NCHHSTP/DSTDP) <[redacted]; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]; Hause, Anne M. (CDC/DDID/NCEZID/DHQP) [redacted] Baer, Bethany (FDA/CBER) <[redacted]; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]; Shay, David (CDC/DDID/NCIRD/ID) <[redacted]
Subject: RE: [EXTERNAL] RE: 6 month safety review for journal submission- please fill out author contribution by noon 10/26

I added my signature as well per attached
Thanks,
David

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Monday, October 25, 2021 11:00 AM
To: Myers, Tanya R (CDC) <[redacted]; Rosenblum, Hannah (CDC) <[redacted]; Gee, Julianne M (CDC) <[redacted]; Liu, Ruiling (CDC) <[redacted] Marquez, Paige L (CDC) <[redacted]; Zhang, Bi C (CDC) <[redacted] Strid, Penelope (CDC) <[redacted]; Abara, Winston E (CDC) <[redacted]; Mcneil, Michael M (CDC) <[redacted]; Hause, Anne M (CDC) [redacted]; Menschik, David <[redacted]; Baer, Bethany <[redacted]; Su, John (CDC) [redacted]; Shimabukuro, Tom (CDC) <[redacted]; Shay, David K (CDC) <[redacted]
Subject: [EXTERNAL] RE: 6 month safety review for journal submission- please fill out author contribution by noon 10/26

I added my signature to this form.

From: Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Monday, October 25, 2021 10:41 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]; Liu, Ruiling (CDC/NIOSH/WTCHP) <[redacted]; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]; Strid, Penelope (CDC/DDNID/NCCDPHP/DRH) <[redacted]; Abara, Winston E. (CDC/DDID/NCHHSTP/DSTDP) <[redacted]; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]; Hause, Anne M. (CDC/DDID/NCEZID/DHQP) <[redacted]; Menschik, David (FDA/CBER) <[redacted]; Baer, Bethany (FDA/CBER) <[redacted]; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted] Shay, David (CDC/DDID/NCIRD/ID) <[redacted]; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]
Subject: RE: 6 month safety review for journal submission- please fill out author contribution by noon 10/26

Good morning, Hannah,

Attached is the tlid form, signed. I believe I've already returned the COI form, but if I'm mistaken, please let me know.

Kind regards,
Tanya

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]>
Sent: Monday, October 25, 2021 10:26 AM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]; Liu, Ruiling (CDC/NIOSH/WTCHP) <[redacted]; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) [redacted]; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]; Strid, Penelope (CDC/DDNID/NCCDPHP/DRH) <[redacted] Abara, Winston E. (CDC/DDID/NCHHSTP/DSTDP) <[redacted] McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <[redacted]; Hause, Anne M. (CDC/DDID/NCEZID/DHQP) <[redacted]; Menschik, David (FDA/CBER) <[redacted]; Baer, Bethany (FDA/CBER) <[redacted]; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]; Shay, David (CDC/DDID/NCIRD/ID) <[redacted]; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]
Subject: 6 month safety review for journal submission- please fill out author contribution by noon 10/26
Importance: High

Good morning co-authors:

The manuscript reviewing six months of mRNA safety data is ready for submission to Lancet ID. Before submission could you please:

1) Review your affiliation, name, and degree on the attached version's title page. Lancet ID only allows use of one degree, so if you have multiple, I had to choose one. Please correct me if I did not choose your intended degree.

2) Complete the attached Author contribution form. I selected roles for each of you- if you agree with this designation please sign the form and send back to me. If you wish to edit your roles, that's fine- just let me know.

3) Only if you have not filled out the ICMJE COI form already, please send me back a copy.

If you can complete these tasks ASAP or by **noon tomorrow, 10/26**, I'd be very grateful!

Thanks everyone and thank you so much for all of your work on this.

All the best,
Hannah

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)
Sent: Friday, October 22, 2021 9:52 AM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]; Liu, Ruiling (CDC/NIOSH/WTCHP) <[redacted]; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR) [redacted]; Strid, Penelope (CDC/DDNID/NCCDPHP/DRH) [redacted]; Abara, Winston E. (CDC/DDID/NCHHSTP/DSTDP) [redacted] McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <[redacted]; Hause, Anne M. (CDC/DDID/NCEZID/DHQP) <[redacted]; Menschik, David (FDA/CBER) <[redacted]; Baer, Bethany (FDA/CBER) <[redacted]; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]; Shay, David (CDC/DDID/NCIRD/ID) <[redacted]; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]
Subject: RE: 6 month safety review-COI form- please fill out and send back by COB 10/21

Good morning all,
Attached is a copy of the clean version that is being submitted for posting to medRxiv.

Thanks to all of you for your hard work on this.

Hannah

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)
Sent: Wednesday, October 20, 2021 6:16 PM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Liu, Ruiling (CDC/NIOSH/WTCHP) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR) [redacted]; Strid, Penelope (CDC/DDNID/NCCDPHP/DRH) <[redacted]>; Abara, Winston E. (CDC/DDID/NCHHSTP/DSTDP) <[redacted]; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Hause, Anne M. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Menschik, David (FDA/CBER) <[redacted]; Baer, Bethany (FDA/CBER) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]; Shay, David (CDC/DDID/NCIRD/ID) <[redacted]>; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]>
Subject: 6 month safety review-COI form- please fill out and send back by COB 10/21

Dear co-authors,

Thanks so so much for all of your hard work and feedback on the 6 month safety review manuscript. The paper has been through CDC and FDA clearance, and is in final revision stages. Our plan is to submit to the medRxiv pre-print server, to be followed by journal submission shortly therefore.

I will send a revised draft for all of you to review in the next day or two- **in the meantime, could you please complete and return the attached COI form with your name, the date and any disclosures by COB tomorrow, 10/21/21?**

Thanks so very much,
Hannah

Hannah G. Rosenblum, MD
Epidemic Intelligence Service Officer

HPV Team, Viral Vaccine-Preventable Diseases Branch
Division of Viral Diseases, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: "Markowitz, Lauri (CDC/DDID/NCIRD/DVD)" <[redacted]>
To: "Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)" <[redacted]>, "Shay, David (CDC/DDID/NCIRD/ID)" <[redacted]>, "Gee, Julianne (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Su, John (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: RE: observed/expected
Date: Sat, 18 Sep 2021 13:13:29 +0000
Importance: Normal
Inline-Images: image001.png

Hannah,
I just took a quick look and will review again after Tom and others from ISO have a chance to weight in. I like the reorganization of the text in results section on deaths (and the new info) and the split into two paragraphs, as we discussed. I also think this the discussion on deaths is much improved. As you noted in the comments, I feel the paragraph on EB data mining should be shortened considerably as most is not relevant to this paper.
Lauri

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]>
Sent: Wednesday, September 15, 2021 8:10 PM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]>; Shay, David (CDC/DDID/NCIRD/ID) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: observed/expected

Lauri-Thanks so much for these comments and talking through the paper today. Here is the updated link.

In addition to an overall review:

1. Could we revisit the EB data mining results paragraph? Lauri suggests really paring it down since those alerts aren't very meaningful – see the modification in track changes. Can go out to FDA too but wanted everyone's opinion first before suggesting-
2. Re: reports of death – Table 4 is new, and really tried to frame the deaths clearly in the discussion. John, thanks for running the time interval data and for your edits to the sentence about challenge of death report records overall.

Looking forward to your review of the manuscript.

Hannah

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]>
Sent: Wednesday, September 15, 2021 1:12 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]>; Shay, David (CDC/DDID/NCIRD/ID) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) [redacted]; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [redacted]
Subject: RE: observed/expected

Hi Hannah and all,
I started going through this and am sending some initial comments and edits. I'll schedule a time to speak with you (Hannah) later this afternoon.
Lauri

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]>
Sent: Wednesday, September 15, 2021 12:41 PM
To: Shay, David (CDC/DDID/NCIRD/ID) <[redacted]>; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]> Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) [redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: observed/expected

Thanks David-
To clarify do you mean, explicitly add something about the use of Winston's expected rates paper? Or it's OK as it is?

Hannah

From: Shay, David (CDC/DDID/NCIRD/ID) <[redacted]>
Sent: Wednesday, September 15, 2021 8:48 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]>; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted] Su, John (CDC/DDID/NCEZID/DHQP) [redacted] Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: RE: observed/expected

Agree – all methods used to produce the data presented in text/tables/figures need to be described in the methods main text or methods suppl material.

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Wednesday, September 15, 2021 8:09 AM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Cc: Shay, David (CDC/DDID/NCIRD/ID) <[redacted]
Subject: RE: observed/expected

Thanks Lauri!
The calculation of the rates of death per persons should be accounted for in methods, but I didn't include anything about the expected and just footnoted the paper in that table.
Certainly can add something there if you think needed on your review.

Hannah

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Tuesday, September 14, 2021 11:09 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted] Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Cc: Shay, David (CDC/DDID/NCIRD/ID) <[redacted]
Subject: RE: observed/expected

Hi Hannah,

I have started going over this and will send some comments tomorrow. Do you (and others) think anything is needed about the methods for table 4?

Lauri

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Monday, September 13, 2021 9:34 PM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Cc: Shay, David (CDC/DDID/NCIRD/ID) <[redacted]
Subject: RE: observed/expected

Hi all,
Thanks for speaking last week about the framing of the death reports following mRNA vaccination in the last 6 months.

Please see this link for an updated manuscript draft.

I've modified to work in our new Table 4, and the framing we discussed in the discussion about reports of death, and certainly welcome any and all feedback to get this back into clearance as soon as we can.

Thank you so much,
Hannah

From: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Thursday, September 9, 2021 10:33 PM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Cc: Shay, David (CDC/DDID/NCIRD/ID) [redacted]
Subject: RE: observed/expected

Just sent an invite for tomorrow to discuss.
-Julianne

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, September 9, 2021 10:09 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Cc: Shay, David (CDC/DDID/NCIRD/ID) <[redacted]; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: RE: observed/expected

It would be good to get all together to discuss how this type of calculation can be used for the deaths – if we think it can be.

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Thursday, September 9, 2021 6:13 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Cc: Shay, David (CDC/DDID/NCIRD/ID) <[redacted]; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]
Subject: RE: observed/expected

Hi Hannah,

The below text comes from a response I provided for an inquiry, and explains how we calculate expected counts of a given condition as background incidence. Please let me know if you have any questions.

- John

To estimate background expected cases of myocarditis, the following data were used:

- Doses administered data for the given age group as of a specified date
- The background estimated incidence of myocarditis (1 to 10 per 100,000 person years) ← from Gubernot et al (2021)

A risk period from day of vaccination through Day 6 after vaccination (a 7-day risk period), during which myocarditis could occur, was assumed.

Estimation of background expected cases of myocarditis were calculated in the following fashion:

{[(7 day risk period)/(365 days per year)] * doses administered } / annual incidence = estimated expected background cases

This method adjusts the annual incidence to match the risk period, so that for the number of doses administered during the risk period, an estimate of expected background cases can be calculated.

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Thursday, September 9, 2021 2:30 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [redacted]
Cc: Shay, David (CDC/DDID/NCIRD/ID) [redacted] Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) [redacted]
Subject: observed/expected

Hi John and Tom,

Hope you're well. For the 6 month mRNA safety review paper, we're reworking the reported deaths analysis and some of the tables/figures to try and better compare deaths reported to VAERS to expected deaths by age.

When you've presented data about myocarditis (or other safety events) in the past from VAERS (screenshot below), what do you use to determine the number of cases of myocarditis expected? If I'm understanding correctly, the cases observed are crude rates from VAERS in the risk period, but are the expected cases from the literature and are they per any certain population denominator?

Using Winston's recent pre-print paper, I've drafted a new table (new Table 5 in this manuscript draft) and am awaiting some dose data by age to use as the denominator for comparison to the expected death rates, but just wanted to see how you have been doing this for myocarditis so can use similar methods.

Let me know if setting up a short call would be easier than talking about this by email.
Thanks so much
Hannah

Expected vs. Observed reports after mRNA vaccination dose 2, 7-day risk period (N=765)*

Age group, years	Females		Males	
	Cases of myopericarditis, expected	Cases of myopericarditis, observed	Cases of myopericarditis, expected	Cases of myopericarditis, observed
12–15*	0–3	12	1–5	117
16–17*	0–2	15	0–3	121
18–24*	1–8	24	1–11	213
25–29*	1–6	16	1–9	56
30–39	2–21	10	2–19	72
40–49	2–22	22	2–19	45
50–64	4–40	15	4–35	13
65+	4–44	6	4–36	8

* As of Aug 18, 2021; assumes a 7-day observation window, with 765 of 897 reports after mRNA vaccines occurring during Days 0–6 after vaccination; counts among 12–29 years from reports meeting case definition for myopericarditis; expected estimates for females 12–29 years adjusted to reflect reduced incidence in this age group

7

Hannah G. Rosenblum, MD
Epidemic Intelligence Service Officer

HPV Team, Viral Vaccine-Preventable Diseases Branch
Division of Viral Diseases, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: "Moro, Pedro (CDC/DDID/NCEZID/DHQP)" <[redacted]>
To: "Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)" [redacted]
Cc: "Vaccine Safety (CDC)" <[redacted]>
Subject: RE: RESPONSE REQUIRED;; Topic [Data Collection for Strokes in Elderly People After Pfizer COVID Vaccination] [CDC-2814760-Y2W2T8] CRM:09452932
Date: Tue, 14 Mar 2023 16:22:12 +0000
Importance: Normal

Elaine,

I think this looks good but we are not really answering his question if persons<60 or 65 years will participate in any stroke study which we don't really know

Thanks

Pedro

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, March 14, 2023 11:58 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Vaccine Safety (CDC) <vaccinesafety([redacted]>
Subject: FW: RESPONSE REQUIRED;; Topic [Data Collection for Strokes in Elderly People After Pfizer COVID Vaccination] [CDC-2814760-Y2W2T8] CRM:09452932

Hi Pedro,
Please send edits.
Thanks,
Elaine

Dear Dr. Estensen,

Thank you for contacting the CDC.

At this time, CDC systems do not indicate a causal association between the Moderna or Pfizer COVID-19 vaccines and strokes.

In January of 2023, CDC posted information about a **preliminary** safety signal for ischemic stroke in persons aged 65 and older after the **Pfizer** BioNTech bivalent COVID-19 vaccine (see CDC & FDA Identify Preliminary COVID-19 Vaccine Safety Signal for Persons Aged 65 Years and Older | CDC). That preliminary signal was NOT found after the Moderna COVID-19 vaccine and also was not found for the Pfizer vaccines in other safety monitoring systems.

In a recent meeting for the Advisory Committee on Immunization Practices (ACIP) on February 24th 2023, updated analysis showed no signal of strokes after receiving mRNA vaccines (Pfizer or Moderna). Slide 33 states there has been no safety signal detected for ischemic stroke with either COVID-19 mRNA (Pfizer and Moderna) primary series, monovalent boosters, or bivalent boosters. No safety concern for strokes with mRNA vaccination were observed in the Vaccine Adverse Event Reporting System (VAERS), the FDA monitoring the CMS data, and in the Department of Veterans Affairs monitoring the VA system. Furthermore, surveillance conducted by international regulatory and public health partners has not detected a safety concern for ischemic stroke following bivalent COVID-19 mRNA vaccination.

The data presented at the Advisory Committee on Immunizations Practices meeting last month are attached.

We continue to closely monitor the safety of COVID-19 vaccines, including the risk for stroke after COVID-19 vaccination.

Sincerely,
Staff of the CDC Immunization Safety Office
Atlanta, GA

From: Vaccine Safety (CDC) <[redacted]
Sent: Tuesday, March 14, 2023 11:05 AM
To: NIPINFO (CDC) <[redacted]>
Cc: Vaccine Safety (CDC) <[redacted]
Subject: RE: RESPONSE REQUIRED;; Topic [Data Collection for Strokes in Elderly People After Pfizer COVID Vaccination] [CDC-2814760-Y2W2T8] CRM:09452932

Hi Suzanne,
We will respond.

Thanks,

Elaine

From: NIPINFO (CDC) <[redacted]
Sent: Tuesday, March 14, 2023 10:46 AM
To: Vaccine Safety (CDC) <[redacted]>
Subject: FW: RESPONSE REQUIRED;; Topic [Data Collection for Strokes in Elderly People After Pfizer COVID Vaccination] [CDC-2814760-Y2W2T8] CRM:09452932

Hi Shaeyla,

Can Vaccine Safety please help with this inquiry, far below?

THANK YOU in advance!
Suzanne for NIPINFO

From: CDC IMS 2019 NCOV Response Data Analytics Visualization TF OD <[redacted]>
Sent: Tuesday, March 14, 2023 10:38 AM
To: CDCInfoResponse <[redacted]>; NIPINFO (CDC) <[redacted]>; CDC IMS 2019 NCOV Response Data Analytics Visualization TF OD <[redacted]
Subject: RE: RESPONSE REQUIRED;; Topic [Data Collection for Strokes in Elderly People After Pfizer COVID Vaccination] [CDC-2814760-Y2W2T8] CRM:09452932

Defer to ISD

From: CDCInfoResponse <[redacted]
Sent: Tuesday, March 14, 2023 7:14 AM
To: CDC IMS 2019 NCOV Response Data Analytics Visualization TF OD <[redacted]>
Subject: RESPONSE REQUIRED;; Topic [Data Collection for Strokes in Elderly People After Pfizer COVID Vaccination] [CDC-2814760-Y2W2T8] CRM:09452932

---------- Call Description ----------
Name: Dr. Bonnie Estensen
E-mail: [redacted]

Phone: [redacted]
Date, Time ET: 3/13/2023, 11:20 AM EST
General Public: Are they currently collecting data on strokes for people under 65 or 60 years and under after COVID-19 vaccination with the Pfizer COVID-19 vaccine?

From: "Barry, Brooke (CDC/DDID/NCIRD/OD)" <[redacted]>
To: "Eiring, Hilary (CDC/DDID/NCIRD/OD)" <[redacted], "Pearson, Kate L. (CDC/DDID/NCIRD/OD)" <[redacted], "Beauvais, Denise (CDC/DDID/NCIRD/OD)" <[redacted], "Hill, Jonathan (CDC/DDID/NCIRD/OD)" <[redacted], "Sharpe, Sonya Robinson (CDC/DDID/NCIRD/OD)" <[redacted]>
Subject: FW: Reactive statement
Date: Thu, 26 Jan 2023 14:02:25 +0000
Importance: Normal
Attachments: 012523_Draft_VRBPAC_Statement_v2.docx

FYA

From: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, January 26, 2023 8:49 AM
To: Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED) <[redacted]>; Mahon, Barbara (CDC/DDID/NCIRD/OD) <[redacted]>; Wharton, Melinda (CDC/DDID/NCIRD/OD) <[redacted]>; Downs, Alycia E. (CDC/DDID/NCIRD/OD) <[redacted]>; Jorgensen, Cynthia (CDC/DDID/NCIRD/OD) <[redacted]>; Williams, Paula O. (CDC/DDPHSS/CSELS/OD) <[redacted]>; Hansen, Donda L. (CDC/DDPHSIS/CPR/DEO) <[redacted]>; Barry, Brooke (CDC/DDID/NCIRD/OD) <[redacted]>; Weakland, Aliki P. (CDC/DDID/NCIRD/OD) <[redacted]>; Burns, Erin (CDC/DDID/NCIRD/ID) <[redacted]>; Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) <[redacted]>; Das, Mansi S. (CDC/OD/OADC) <[redacted] Haynes, Benjamin (CDC/OD/OADC) <[redacted] Crawford, Carol Y. (CDC/OD/OADC) <[redacted]>; Mitchell, Betsy (CDC/OD/OADC) [redacted]; Schindelar, Jessica (CDC/OD/OADC) <[redacted]>; Dempsey, Jay H. (CDC/OD/OADC) <[redacted]>; Robertson, Alaina B. (CDC/OD/OADC) <[redacted]>
Cc: Nordlund, Kristen (CDC/OD/OADC) <[redacted]>
Subject: Reactive statement

As folks know, there is a safety presentation at today's VRBAC meeting to provide more details around the analysis of VSD related to the CDC and FDA statement a few weeks ago. The reactive statement that CDC and FDA will be using is attached.
Thanks,
~Nicole

Nicole Coffin, MA
Deputy Associate Director for Communications (Acting), CDC

REACTIVE STATEMENT

CDC & FDA Provide Further Evidence of Safety of COVID-19 Vaccines for Persons Aged 65 and Older

In presentations to the Vaccines and Related Biological Products Advisory Committee (VRBPAC), the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) provided reassuring data on a signal first identified in the Vaccine Safety Datalink (VSD).

Ongoing analyses of the VSD data demonstrate the safety of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent when given alone and may even suggest a reduced rate of ischemic stroke following vaccine administration. The agencies continue to review data from multiple additional databases, which to date have not identified any risk of stroke following vaccination with the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. While subgroup analyses may suggest that co-administration of Pfizer-BioNTech COVID-19 Vaccine, Bivalent with high-dose or adjuvanted influenza vaccine may have contributed to or biased the safety signal seen in VSD, a similar finding was not identified in FDA's analysis of Medicare data where nearly 40% of those 65 and older had co-administration of COVID and influenza vaccines. Both agencies will review future analyses of vaccine co-administration.

To be attributed to FDA Commissioner Robert Califf, MD:
"The system worked as expected. A signal was detected, and further analysis of independent data sets has found no evidence of a safety risk. The work of safety surveillance continues, including detailed analysis of existing data sets and a formal epidemiological study. The substantial reduction in serious illness and death conferred by up-to-date vaccination also discussed at the VRPBAC meeting leads us to hope that all eligible people will get an updated vaccine."

To be attributed to CDC Director Rochelle P. Walensky, MD, MPH:
"I encourage everyone who is eligible to get an updated COVID-19 vaccine. Getting an updated vaccine substantially decreases the risk of hospitalization and death from COVID-19 and is especially important for those who are 65 and older and at greater risk for severe complications. Our ongoing analyses continue to reassure us that COVID-19 vaccines are both safe and effective."

Tough QA

Q1: Are you still recommending that people get the updated vaccine?
A: Yes. We continue to strongly recommend that people who are eligible get the updated COVID-19 vaccine.

Q2: For doctors out there who see that you are going to be doing additional analysis of the safety of coadministration of the updated COVID and flu vaccines and are wondering whether they should recommend that their elderly patients get both shots, what should they do?
A: First, it is important to remember that very few people receive flu shots this late in the season. Historically, >90% of flu vaccination has occurred by mid-January of each season. We continue to recommend co-administration of COVID-19 and influenza vaccines, most especially for those who may not otherwise receive both. The benefits in terms of protection against serious illness and death are clear and indisputable for both vaccines.

Q3: Are patients who received the high-dose flu vaccine and the bivalent vaccine at the same time at ongoing increased risk for developing a stroke?

A: More than 90% of folks received these vaccines three months ago and are well outside the potential window of risk. For those who received their vaccines more than 3 weeks ago, there is no evidence of an increased risk. In addition, an analysis of CMS's database over more than 5 million vaccinated seniors and people with disabilities shows no link between the Pfizer bivalent vaccine and stroke. FDA is launching a long-term formal study.

Q4: Why did CDC recommend co-administration of COVID and influenza vaccines for this season?
A: A CDC study published in 2022 did not find any safety concerns when giving both vaccines at the same time. This study was done prior to a recommendation for those 65 and older to preferentially receive a high dose flu vaccine.

From: "Jernigan, Daniel B. (CDC/DDPHSS/OD)" <[redacted]>
To: "Houry, Debra E. (CDC/DDNID/NCIPC/OD)" <[redacted]>, "Berger, Sherri (CDC/OD/OCS)" <[redacted]>, "Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Goldstein, Robert (CDC/OD/OCS)" <[redacted]>
Cc: "Lubar, Debra (CDC/DDID/NCEZID/OD)" <[redacted]>, "Bell, Michael MD (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Wharton, Melinda (CDC/DDID/NCIRD/OD)" <[redacted]>, "Jordan, Franshay (CDC/DDPHSS/OD) (CTR)" <[redacted]>
Subject: RE: FYSA - VSD/bivalent booster
Date: Mon, 19 Dec 2022 13:37:20 +0000
Importance: Low

Will work with Mike, Tom, and Melinda to get a meeting on the calendar.
Thanks
Dan.

From: Houry, Debra E. (CDC/DDNID/NCIPC/OD) <[redacted]>
Sent: Monday, December 19, 2022 8:17 AM
To: Berger, Sherri (CDC/OD/OCS) <[redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]> Jernigan, Daniel B. (CDC/DDPHSS/OD) [redacted] Goldstein, Robert (CDC/OD/OCS) <[redacted]>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) [redacted] Bell, Michael MD (CDC/DDID/NCEZID/DHQP) <[redacted]>; Wharton, Melinda (CDC/DDID/NCIRD/OD) <[redacted]>
Subject: Re: FYSA - VSD/bivalent booster

Happy to join as well

Get Outlook for iOS

From: Berger, Sherri (CDC/OD/OCS) [redacted]
Sent: Monday, December 19, 2022 8:04:57 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [redacted] Jernigan, Daniel B. (CDC/DDPHSS/OD) <[redacted]; Houry, Debra E. (CDC/DDNID/NCIPC/OD) [redacted] Goldstein, Robert (CDC/OD/OCS) <[redacted]>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) [redacted] Bell, Michael MD (CDC/DDID/NCEZID/DHQP) [redacted]; Wharton, Melinda (CDC/DDID/NCIRD/OD) [redacted]
Subject: RE: FYSA - VSD/bivalent booster

I'm happy to listen in, if helpful. Thanks

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Sunday, December 18, 2022 4:17 PM
To: Jernigan, Daniel B. (CDC/DDPHSS/OD) <[redacted]; Berger, Sherri (CDC/OD/OCS) <[redacted]> Houry, Debra E. (CDC/DDNID/NCIPC/OD) <[redacted]; Goldstein, Robert (CDC/OD/OCS) [redacted]
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]>; Bell, Michael MD (CDC/DDID/NCEZID/DHQP) <[redacted]>; Wharton, Melinda (CDC/DDID/NCIRD/OD) <[redacted]>
Subject: RE: FYSA - VSD/bivalent booster

I would propose having a call to discuss and including the CDC ACIP COVID-19 WG folks (Sara Oliver et al.) and other relevant NCIRD leadership.

From: Jernigan, Daniel B. (CDC/DDPHSS/OD) <[redacted]>
Sent: Sunday, December 18, 2022 2:02 PM
To: Berger, Sherri (CDC/OD/OCS) <[redacted]; Houry, Debra E. (CDC/DDNID/NCIPC/OD) [redacted]; Goldstein, Robert (CDC/OD/OCS) <[redacted]
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [redacted]; Bell, Michael MD (CDC/DDID/NCEZID/DHQP) <[redacted]; Wharton, Melinda (CDC/DDID/NCIRD/OD) <[redacted]
Subject: RE: FYSA - VSD/bivalent booster

Sherri
Sorry for delay. Getting information from the Tom and the team on estimates of time relative to ACIP WG discussion on the topic.
Dan

From: Berger, Sherri (CDC/OD/OCS) [redacted]
Sent: Friday, December 16, 2022 8:42 AM
To: Jernigan, Daniel B. (CDC/DDPHSS/OD) <[redacted] Houry, Debra E. (CDC/DDNID/NCIPC/OD) <[redacted]; Goldstein, Robert (CDC/OD/OCS) <[redacted]
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) [redacted] Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [redacted]; Bell, Michael MD (CDC/DDID/NCEZID/DHQP) <[redacted] Wharton, Melinda (CDC/DDID/NCIRD/OD)[redacted]
Subject: RE: FYSA - VSD/bivalent booster

Hi Dan,

Thanks for the update.

Do we have an approx. ETA on the additional CDC analyses, would it be before the ACIP WG meeting refenced below (exact date TBD)? Regarding the separate CMS/FDA data collection and analyses, is the goal to try to present those to the ACIP WG as well?

I added Melinda here.

Thank you,
Sherri

From: Jernigan, Daniel B. (CDC/DDPHSS/OD) <[redacted]>
Sent: Thursday, December 15, 2022 7:38 PM
To: Houry, Debra E. (CDC/DDNID/NCIPC/OD) <[redacted] Berger, Sherri (CDC/OD/OCS) <[redacted]; Goldstein, Robert (CDC/OD/OCS) <[redacted]>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]; Bell, Michael MD (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: FW: FYSA - VSD/bivalent booster

Deb, Sherri, Robbie:

BLUF: Early signal from Vaccine Safety Datalink (VSD) associating bivalent Pfizer COVID-19 booster vaccination and ischemic stroke in 65yo and older recipients. Additional analyses are underway and will take a few weeks. See note below from Mike and team in DHQP below. Let me know if you would like a brief discussion with ISO on the issue.
Thanks
Dan.

From: Bell, Michael MD (CDC/DDID/NCEZID/DHQP) [redacted]
Sent: Thursday, December 15, 2022 6:01 PM
To: Jernigan, Daniel B. (CDC/DDPHSS/OD) <[redacted] Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [redacted] Srinivasan, Arjun (CDC/DDID/NCEZID/DHQP) [redacted]; Craig, Michael R. (CDC/DDID/NCEZID/DHQP) [redacted]; McDonald, Clifford (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: FYSA - VSD/bivalent booster

Dan, Deb;
For awareness only at this point, but sharing an early heads up.

Monitoring in the Vaccine Safety Datalink (VSD) has detected a statistical signal for bivalent Pfizer COVID-19 booster vaccination and ischemic stroke in 65yo and older recipients. The rate ratio (similar to relative risk) is around 1.9 with 95% CIs that do not include 1. It is important to note that the finding of a statistical signal does not necessarily indicate an increased risk. You'll recall that VSD does ongoing analyses of EHR data from several integrated healthcare organizations to detect associations for pre-specified clinical outcomes. The VSD team is working with site investigators to conduct additional analyses to further assess the finding and confirm the signal. It will require confirmation over the coming weeks, especially since the parallel CMS data monitored at FDA are not showing a signal for Pfizer COVID-19 bivalent boosters and ischemic stroke, although the CMS data are limited at this point. FDA analyses are ongoing and more data are expected in the coming weeks. Signal assessment analyses can further evaluate for a causal association.

Wanting you to be aware given the WH and HHS intense push to increase uptake of the booster in that age group. Based on the current data, excess cases of ischemic stroke are estimated to be ~10/100,000. Given the co-administration of high dose flu vaccine (~40% of Bivalent recipients are getting both), that is being assessed as a potential factor as well. VSD monitoring is also detecting an elevated rate ratio for bivalent Pfizer COVID-19 booster vaccination and ischemic stroke in 18-64 yo but it has not yet reached the threshold for a statistical signal. No similar signal has been seen for Moderna, though uptake in VSD is less and later. FDA is aware per above, and an ACIP COVID-19 Vaccine Safety Technical WG call is scheduled in January to present the VSD and FDA CMS findings.

Including Tom for any technical clarifications, and Michael, Arjun, and Cliff for awareness over the next couple weeks. We'll keep you closely updated.
-Mike

From: "Kroop, Seth (CDC/DDID/NCEZID/DHQP)" <[redacted]>
To: "Lubar, Debra (CDC/DDID/NCEZID/OD)" <[redacted]>
Cc: "OConnor, John (CDC/DDID/NCEZID/OD)" <[redacted]>
Subject: RE: FYSA - VSD/bivalent booster
Date: Thu, 22 Dec 2022 14:24:31 +0000
Importance: Normal

I think you ended up receiving the info from Katy, right?

From: Lubar, Debra (CDC/DDID/NCEZID/OD) [redacted]
Sent: Tuesday, December 20, 2022 11:12 AM
To: Kroop, Seth (CDC/DDID/NCEZID/DHQP) [redacted]
Cc: OConnor, John (CDC/DDID/NCEZID/OD) [redacted]
Subject: FW: FYSA - VSD/bivalent booster
Importance: Low

Seth, are there processes in place for how and when we share information about signals?

From: Berger, Sherri (CDC/OD/OCS) [redacted]
Sent: Friday, December 16, 2022 8:42 AM
To: Jernigan, Daniel B. (CDC/DDPHSS/OD) [redacted]; Houry, Debra E. (CDC/DDNID/NCIPC/OD) [redacted]; Goldstein, Robert (CDC/OD/OCS) [redacted]
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) [redacted] Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [redacted]; Bell, Michael MD (CDC/DDID/NCEZID/DHQP) [redacted]; Wharton, Melinda (CDC/DDID/NCIRD/OD) [redacted]
Subject: RE: FYSA - VSD/bivalent booster
Importance: Low

Hi Dan,

Thanks for the update.

Do we have an approx. ETA on the additional CDC analyses, would it be before the ACIP WG meeting refenced below (exact date TBD)? Regarding the separate CMS/FDA data collection and analyses, is the goal to try to present those to the ACIP WG as well?

I added Melinda here.

Thank you,
Sherri

From: Jernigan, Daniel B. (CDC/DDPHSS/OD) [redacted]
Sent: Thursday, December 15, 2022 7:38 PM
To: Houry, Debra E. (CDC/DDNID/NCIPC/OD) [redacted] Berger, Sherri (CDC/OD/OCS) [redacted] Goldstein, Robert (CDC/OD/OCS) [redacted]
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) [redacted] Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [redacted]; Bell, Michael MD (CDC/DDID/NCEZID/DHQP) [redacted]
Subject: FW: FYSA - VSD/bivalent booster

Deb, Sherri, Robbie:

BLUF: Early signal from Vaccine Safety Datalink (VSD) associating bivalent Pfizer COVID-19 booster vaccination and ischemic stroke in 65yo and older recipients. Additional analyses are underway and will take a few weeks. See note below from Mike and team in DHQP below. Let me know if you would like a brief discussion with ISO on the issue.
Thanks
Dan.

From: Bell, Michael MD (CDC/DDID/NCEZID/DHQP) [redacted]
Sent: Thursday, December 15, 2022 6:01 PM
To: Jernigan, Daniel B. (CDC/DDPHSS/OD) <[redacted]; Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [redacted]; Srinivasan, Arjun (CDC/DDID/NCEZID/DHQP) [redacted]; Craig, Michael R. (CDC/DDID/NCEZID/DHQP) [redacted] McDonald, Clifford (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: FYSA - VSD/bivalent booster

Dan, Deb;
For awareness only at this point, but sharing an early heads up.

Monitoring in the Vaccine Safety Datalink (VSD) has detected a statistical signal for bivalent Pfizer COVID-19 booster vaccination and ischemic stroke in 65yo and older recipients. The rate ratio (similar to relative risk) is around 1.9 with 95% CIs that do not include 1. It is important to note that the finding of a statistical signal does not necessarily indicate an increased risk. You'll recall that VSD does ongoing analyses of EHR data from several integrated healthcare organizations to detect associations for pre-specified clinical outcomes. The VSD team is working with site investigators to conduct additional analyses to further assess the finding and confirm the signal. It will require confirmation over the coming weeks, especially since the parallel CMS data monitored at FDA are not showing a signal for Pfizer COVID-19 bivalent boosters and ischemic stroke, although the CMS data are limited at this point. FDA analyses are ongoing and more data are expected in the coming weeks. Signal assessment analyses can further evaluate for a causal association.

Wanting you to be aware given the WH and HHS intense push to increase uptake of the booster in that age group. Based on the current data, excess cases of ischemic stroke are estimated to be ~10/100,000. Given the co-administration of high dose flu vaccine (~40% of Bivalent recipients are getting both), that is being assessed as a potential factor as well. VSD monitoring is also detecting an elevated rate ratio for bivalent Pfizer COVID-19 booster vaccination and ischemic stroke in 18-64 yo but it has not yet reached the threshold for a statistical signal. No similar signal has been seen for Moderna, though uptake in VSD is less and later. FDA is aware per above, and an ACIP COVID-19 Vaccine Safety Technical WG call is scheduled in January to present the VSD and FDA CMS findings.

Including Tom for any technical clarifications, and Michael, Arjun, and Cliff for awareness over the next couple weeks. We'll keep you closely updated.
-Mike

From: "Menschik, David" <[redacted]
To: "Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)" <[redacted]
Subject: RE: [EXTERNAL] FW: Weekly data mining
Date: Wed, 23 Jun 2021 16:07:49 -0000
Importance: Normal

Sure Tom – the age brackets are: 0-1, 2-8, 9-18, 19-44, 45-64, and ≥65 years (corresponding to columns F through K respectively in the weekly excel spreadsheet per below)

Best,
David

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [redacted]
Sent: Wednesday, June 23, 2021 11:37 AM
To: Menschik, David <[redacted]
Subject: [EXTERNAL] FW: Weekly data mining

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi David – Would you be able to address Frank's question/issue? Thanks.
Tom

From: Destefano, Frank (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Wednesday, June 23, 2021 9:31 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: RE: Weekly data mining

It would be informative to know how they define the age groups. What I see is an "Adult" and "Teen" group. Maybe it's not showing up because they are not specifying the right age group of 12-29 or 12-39?

Frank DeStefano, MD, MPH

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [redacted]
Sent: Tuesday, June 22, 2021 12:08 PM
To: Destefano, Frank (CDC/DDID/NCEZID/DHQP) [redacted]
Subject: FW: Weekly data mining

I'm perplexed that myocarditis isn't alerting for either of the mRNA vaccines. I'm wondering if it's getting washout out in the half million reports.

From: Menschik, David <[redacted]
Sent: Tuesday, June 22, 2021 6:51 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]; Nair, Narayan (FDA/CBER) <[redacted]; Alimchandani, Meghna (FDA/CBER) <[redacted]; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) [redacted]
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 6/18/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

From: "Menschik, David" <[redacted]
To: "Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)" <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond
Date: Mon, 13 Sep 2021 23:52:12 -0000
Importance: Normal

Thanks!

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Monday, September 13, 2021 3:59 PM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Ok thanks- I'll plan edit a bit on our end and send you back a copy to review as it moves along.

Hannah

From: Menschik, David <[redacted]
Sent: Friday, September 10, 2021 3:08 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hmm… you should have seen the earlier iterations of this! ☺ Yes, it should say "disproportionality" -autocorrect strikes again! Thanks for correcting that…
Our goal was to simplify as much as possible while not losing key concepts and this is where we landed after working the sentence over…
I think you've got the main point that if the comparison group is enriched with so many mRNA COVID-vaccine reports, that it becomes very difficult to exceed the EB05>2 alert threshold even for an adverse event that may be associated with mRNA vaccines – thus data mining has blind spots and this is why it's so good to have so many complimentary vaccine safety surveillance systems (e.g., VSD) that can cover different blind spots of other systems…
Happy to have a phone call if helpful to explain the importance of including specific words or anything else…

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Friday, September 10, 2021 2:51 PM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi David,

Certainly will pass along the draft when ready for clearance at FDA!

In looking the additional sentence over in more detail, it seems pretty technical. If I'm understanding correctly, you're saying that the sheer volume of COVID-19 vaccine reports basically washes out the possibility of finding disproportionality (I think it should say disproportionality instead of disproportionately right?)

Do you think you can simplify the sentence so it would be understandable for the average clinician reader?

Hannah

From: Menschik, David <[redacted]
Sent: Friday, September 10, 2021 10:46 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thank you Hannah for all your efforts. Once you advise that paper is ready to clear at FDA, will be very helpful, if possible, to have a version with indication of where specific changes were made from prior cleared version, so that we can do our best to optimize time to re-clear here…

Wishing you an enjoyable weekend,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Friday, September 10, 2021 9:21 AM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thank you David and Bethany!

Hannah

From: Menschik, David <[redacted]
Sent: Friday, September 10, 2021 7:53 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Bethany and I have edits for the data mining limitations section on page 13 of the attached draft manuscript. Please see attached and glad to discuss if any questions.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Thursday, September 09, 2021 3:44 PM

To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Sounds like a plan!

Hannah

From: Menschik, David <[redacted]
Sent: Thursday, September 9, 2021 3:41 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks – working with Bethany now on new data mining limitation language and will share with you in near future. I'll wait to run changes by my leadership for clearance until you advise me that no further substantive edits are forthcoming prior to submission.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Thursday, September 09, 2021 3:33 PM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Definitely
Here's the latest version – the discussion has gotten a little messy so if you can excuse some of the part that is clearly still in revision.

Hannah

From: Menschik, David <[redacted]
Sent: Thursday, September 9, 2021 3:01 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks Hannah!
Given the current stage of the manuscript, would we be able to add an additional data mining limitation to the manuscript?
Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Thursday, September 09, 2021 2:20 PM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Dear David,
Thanks so much for writing. The manuscript has moved through CDC clearance rather quickly but we've decided to revise some of the analysis about reported deaths to make it more meaningful/interpretable.
Will definitely send you an updated version of the manuscript as this evolves.

Thanks so very much for your continued engagement on this,
Hannah

From: Menschik, David <[redacted]
Sent: Thursday, September 9, 2021 1:32 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Hope all well on your end. Wondering if there is any status update for this manuscript?

Best,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Thursday, August 05, 2021 2:48 PM
To: Baer, Bethany <[redacted]
Cc: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Excellent!! I hope you had a nice leave. On my end, we're ***almost*** through the CDC clearance process – will keep you posted!

Hannah

From: Baer, Bethany <[redacted]
Sent: Thursday, August 5, 2021 2:44 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Menschik, David (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,
I was on leave for several weeks, so I realize my response is a little delayed. I have caught up on the email exchanges between you and David. I have reviewed the manuscript you sent on July 21st and the minor changes you mentioned in the email below. I, Bethany Baer, approve submission of the manuscript titled 'Reactogenicity and Adverse Events during the First Six Months of mRNA COVID-19 Vaccination in the United States: A Prospective Observational Study of Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe ' to clearance and to journal publication."

Thank you for all of your hard work on this!
Bethany

From: Menschik, David <[redacted]
Sent: Thursday, July 29, 2021 3:37 PM
To: Rosenblum, Hannah (CDC) <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

I agree that these are not substantive changes and will send you the authorship agreement statement shortly.
Thanks so much to you and other teammates for all the amazing work on this very impressive paper!

Congratulations on this key milestone!
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, July 29, 2021 3:33 PM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi David,
Thanks for asking and sorry I didn't write to you about this earlier.
Several small changes were made since you saw the draft (and I'm not sure what you consider substantive so I'll just list them all here):

1. A previously supplemental table about impressions of deaths was moved to a main table (Table 4)
2. The previous table 9 had duplicate data as Figure 2 so that table was moved to supplemental
3. We split 'serious reports' and 'non serious reports' by meddra PT code in Table 2 to more accurately reflect the breakdown.
4. A sentence was added in the discussion stating that the serious /nonserious report distribution is similar to other adult vaccines (since there was concern that we didn't include enough about adverse events in the discussion).

Thank you so so much for all of your responses, feedback and work on this.
Warm regards,
Hannah

From: Menschik, David <[redacted]
Sent: Thursday, July 29, 2021 3:26 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks Hannah! Can you please confirm that there were no substantive edits since the version cleared at FDA (or else share these edits)?

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Thursday, July 29, 2021 3:22 PM
To: Gee, Julianne M (CDC) [redacted] Liu, Ruiling (CDC) <[redacted] Marquez, Paige L (CDC) [redacted]
Zhang, Bi C (CDC) [redacted] Strid, Penelope (CDC) [redacted] Abara, Winston E (CDC) [redacted];

Mcneil, Michael M (CDC) [redacted]; Myers, Tanya R (CDC) <[redacted]; Hause, Anne M (CDC) [redacted] Menschik, David <[redacted]; Baer, Bethany <[redacted]; Su, John (CDC) [redacted]; Shimabukuro, Tom (CDC) <[redacted]; Shay, David K (CDC) [redacted]
Subject: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond
Importance: High

Dear co-authors,

Thank you so much for all of your hard work and feedback on the 6 month safety review manuscript. The manuscript has been revised based on all of your feedback, and we're in a good position to submit to CDC clearance.

Please double check your names/degrees to make sure I haven't made any mistakes and that you are listed appropriately.

If you agree with submission of the draft in its current form, please reply with "I, **NAME**, approve submission of the manuscript titled 'Reactogenicity and Adverse Events during the First Six Months of mRNA COVID-19 Vaccination in the United States: A Prospective Observational Study of Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe ' to clearance and to journal publication."

We are planning to submit to the journal *Lancet ID* and the formatting of the draft matches their requirements.

All the very best,
Hannah

Hannah G. Rosenblum, MD
Epidemic Intelligence Service Officer

HPV Team, Viral Vaccine-Preventable Diseases Branch
Division of Viral Diseases, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: "Menschik, David" <[redacted]>
To: "Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)" <[redacted]>, "Baer, Bethany" <[redacted]>
Cc: "Shay, David K (CDC)" <[redacted]>
Bcc: "Menschik, David" <[redacted]>
Subject: RE: [EXTERNAL] [WARNING : MESSAGE ENCRYPTED] FW: Your Submission THELANCETID-D-21-02703
Date: Fri, 03 Dec 2021 14:29:01 -0000
Importance: Normal

Hi Hannah,

Bethany and I have reviewed the comments from the Lancet ID Reviewers, and we agree with Reviewer #5's comment that disproportionality analysis is extremely limited when the background database has such a high proportion of reports involving the vaccine of interest. We acknowledged this in the limitations and understand that there is a considerable bias toward the null when using our data mining methods in this current, unprecedented situation. Therefore, we agree with the Lancet ID editor's comments on page 1 that it would be best to remove the disproportionality analysis from this paper. As the disproportionality analysis was the only aspect of this paper that Bethany and I were involved in, it would be most appropriate to remove Bethany and me from authorship on the paper.

Best,
David and Bethany

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Wednesday, December 01, 2021 4:24 PM
To: Menschik, David <[redacted]> Baer, Bethany <[redacted]>
Cc: Shay, David K (CDC) [redacted]
Subject: [EXTERNAL] [WARNING : MESSAGE ENCRYPTED] FW: Your Submission THELANCETID-D-21-02703
Importance: High

Dear David and Bethany
I hope you are both well. I'm writing with news that we've received an invitation to **revise** the 6 month mRNA safety manuscript from The Lancet ID.

I'm attaching a document of their comments with our team's draft responses in red and **some specific flags in tracked changes for you re: data mining and questions about death 'causality'.**

Also attached is a tracked changes updated copy of the version that was submitted to them (and also revised to remove one duplicate myocarditis death report since submission), that I will clean for submission to them for your reference.

They have asked for comments by December 7- I apologize for the tight deadline, but if you're able to **send your feedback by COB Friday, 12/3**, that would be excellent- if you need more time, of course, let me know.

All the very best,
Hannah

From: [redacted] **On Behalf Of** Phoebe Hall
Sent: Tuesday, November 23, 2021 11:03 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: Your Submission THELANCETID-D-21-02703

Manuscript: THELANCETID-D-21-02703, Safety Monitoring of mRNA Vaccines Administered During the Initial 6 Months of the U.S. COVID-19 Vaccination Program: Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe

Dear Dr. Rosenblum,

Thank you for submitting your manuscript to *The Lancet Infectious Diseases*.

Your submission has now been assessed by external advisers and discussed by the Editorial team. We would like to invite you to REVISE your paper in light of the editorial and reviewers' comments below.

Please be aware that an invitation to revise does not imply acceptance. Our target revision time is 10 working days for normal track.

Comments to the Author:
We wonder whether the paper would be better if the inferential analyses were removed from the paper given concerns from the reviewers about the comparison of expected with observed mortality (which we note is based on a preprint and not adequately described in the Methods) and the disproportionality analysis. Please justify their inclusion if you wish to keep them in the paper.

Editorial points - IMPORTANT:

- The following points list items that **must be included before considered** further. Addressing them at this stage reduces the risk of errors and delays later.
- Please read the requirements below carefully and consult me or https://www.thelancet.com/preparing-your-manuscript, for further details or clarification if needed.
- Please note that not every point below will be relevant to your manuscript.

Authorship and reporting guidelines:

1. Please check that all author name spellings and affiliations are correct.
2. Please indicate any authors who are full professors.
3. Please list the highest degree for each author (one degree only, please).
4. Please follow the appropriate EQUATOR network reporting guidelines and include the corresponding checklist(s). These include: CONSORT reporting guidelines for randomised trials (http://www.consort-statement.org), STROBE for observational studies, PRISMA for systematic reviews, STARD for diagnostic studies, CHEERS for economic evaluations and RECORD for routinely collected health data. *Lancet* specific guidelines for reporting RCT and systematic reviews and meta analyses are available here:
http://www.thelancet.com/pb/assets/raw/Lancet/authors/Rctguidelines.pdf
https://thelancet.com/pb/assets/raw/Lancet/authors/metaguidelines.pdf

Title/summary:

5. Please ensure that the title of the paper is non-declamatory (i.e, it describes the aim of the study rather than the findings) and that it includes a description of the study type (e.g. a randomised controlled trial).
6. Please limit the summary to pre-defined primary endpoints and safety endpoints.
7. For RCTs, please state the trial registration number.

Methods:

8. At the end of the methods section please state the role of the funder in: data collection, analysis, interpretation, writing of the manuscript and the decision to submit.
9. Please explain any deviations from the protocol.
10. Please ensure that all outcomes specified in the protocol (including all secondary outcomes) are reported in the manuscript. If there are any secondary endpoints that cannot be included please mention these explicitly and explain why and where they will be made available.
11. If any exploratory outcomes are reported that were not pre-specified, please make it clear that these analyses were post-hoc.
12. Please use rINNs for drug names. For genes and proteins, authors can use their preferred terminology so long as it is in current use by the community, but should provide the preferred name from Uniprot (http://www.uniprot.org/uniprot/) for proteins and HUGO (http://www.genenames.org) for genes at first use to assist non-specialists.
13. For drug studies, please ensure that details of doses, route of delivery, and schedule are included.

Results:

14. For the main outcome measures, please include a result for each group, plus a point estimate (eg, RR, HR) with a measure of precision (e.g, 95% CI) for the absolute difference between groups, in both the Summary and the main Results section of the paper.
15. p-values should be given to two significant figures, but no longer than 4 decimal places (e.g. $p<0.0001$).
16. Please provide absolute numbers to accompany all percentages. Percentages should be rounded to whole numbers unless the study population is very large (>1000 individuals).
17. Please give 95% confidence intervals for hazard ratios/odds ratios.
18. For means, please provide standard deviation (or error, as appropriate).
19. Please provide interquartile ranges for medians.
20. Please provide numbers at risk for Kaplan-Meier plots and ensure that plots include a measure of effect (e.g, log-rank p); estimates should be reported with 95% CIs.

Discussion:

21. Please ensure that the Discussion contains a section on limitations of the study.

Additional requirements:

22. Please provide the text, tables, and figures in an editable format (eg, EPS files, PowerPoint files, depending on software used to produce them. If figures are composed of photographs or other images, high resolution files (300dpi or greater) should be provided. More information can be found here: https://www.thelancet.com/for-authors/forms?section=artwork.
23. References should be in Vancouver style. For references with six authors or fewer, all authors should be listed. For those with seven or more authors, only the first three authors and 'et al' should be listed. Please ensure that reference numbering throughout the manuscript is not inserted with electronic referencing software, such as Endnote, as this is incompatible with our production system (if used, please convert to normal text before resubmission). If the references “move” from the body text into tables or figures, please maintain the sequence of citation. Please ensure tables and figures are cited correctly in the body text to prevent the need for renumbering of references should the table and figure citations subsequently move. All web references should have the exact date they were last accessed. With your revised submission please enclose copies of any papers cited as being 'in-press', along with a copy of the acceptance letter from the journal. References that are "submitted" should be removed and citations in the text replaced with "(unpublished data; authors)".

24. If accepted, only 5-6 non-text items (figures, tables, or panels) can be accommodated in the main paper; additional material can be provided in a web appendix. Please indicate which items can go in a web appendix.
25. Please provide a research in context panel with 3 parts: Evidence before this study (which includes a description of how you searched for evidence and how you assessed the quality of that evidence); Added value of the study; and Implications of all the available evidence.
26. At the end of the manuscript, please provide a Contributors statement that summarises the contribution of each author to the work. *The Lancet's* journals require that more than one author has verified the underlying data in all research articles. Please state which author(s) have accessed and verified the data, and which author(s) were responsible for the decision to submit the manuscript.
27. At the end of the manuscript please summarise the declaration of interests for each author.
28. In the Contributors section list at least two authors who accessed and verified all the data.
29. If your author line has more than 20 authors, we very strongly encourage the use of a study group name. Collaborators' names and affiliations may be listed at the end of the paper or in the appendix. Additionally, if you wish the names of collaborators within a study group to appear on PubMed, please upload with your revision a list of names of all study group members presented as a two-column table in Word. First and middle names or initials should be placed in the first column, and surnames in the second column. Names should be ordered as you wish them to appear on PubMed. The table will not be included in the paper itself - it's simply used to make sure that PubMed adds the names correctly.
30. Please note our guideline length for research articles is 3500 words and 30 references. For RCTs, the text can be expanded to 4500 words.
31. All research articles must contain a data sharing statement, to be included at the end of the manuscript. For more information on these required statements see the Data sharing section of the Information for Authors (https://thelancet.com/pb-assets/Lancet/authors/tlid-info-for-authors.pdf) and (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)31282-5/fulltext)
32. Please ensure that the funding source is stated in the Acknowledgement section.

Reviewers' Comments:

Note that reviewer numbers are allocated by the system at invitation and not at completion of reviews, so some numbers might be missing.

- In your point-by-point reply to the reviewers', please indicate the text changes which have been made (if any) and the line number on the tracked changes manuscript at which your change can be found. [Line numbers can be added to your word document using the 'page layout' tab. Please select continuous numbers.]
- Please do not use boxes for responses as this slows assessment.
- When interpreting editorial points made by reviewers, please remember that we will edit the final manuscript if accepted.

Reviewer #2: Thank you very much for the opportunity to review this manuscript. The authors reviewed and summarised adverse events reported after COVID-19 vaccination with two mRNA vaccines based on reports from two vaccine-specific pharmacovigilance systems in the US, the Vaccine Adverse Events Reporting System and the active surveillance system v-safe.

The manuscript is very well written and provides important insight to spontaneously reported adverse events following mRNA vaccination, which should be available to a wide audience. With the broad rollout of mRNA COVID-vaccines in the US and worldwide, these results are reassuring and provide important information for the risk-benefit assessment of these vaccines.

Major comments:
* The reviewers missed some important information on selection bias in v-safe. Is it possible to compare the included participants to non-respondents? This would give important insight into the representativeness of the resulting data
* The authors present disproportionality measures for mortality from VAERS. It feels like a missed opportunity not to report these also for the other pre-specified AESI. Is this possible?
* The analyses of v-safe are purely descriptive. Is there any disproportionality or further analysis planned from

this database?

Minor comments:
-Methods, p. 7 paragraph 1, line 5. What are the pre-specified AESI? Please provide a reference or refer to table 2 where the results for the AESI are presented.
-Discussion, p. 11 paragraph 2, line 1: "more health impact was reported […] received mRNA-1273 versus BNT162b2". While this is an interesting and relevant finding to report, there may have been differences (e.g. in terms of underlying comorbidities) between the patient collectives receiving the different vaccines. It might be worth considering adding a sentence in the discussion/limitations to highlight that this finding from spontaneous reports should not be interpreted in that one mRNA vaccine is "safer" than the other.
Table 1, Table 5: Race and Ethnicity are reported. The term "Unknown ethnicity", which is further split into subgroups entitled "White", "Black", "Asian" etc. is confusing for the reader as "unknown" should not have subgroups. Consider to rename or merge with "Non-Hispanic" if this refers to the same ethnic subgroups.

Reviewer #3: This is a very important report of the first 6 months of mRNA vaccine rollout as capture through the passive and active surveillance system.
The major limitations of this approach is not knowing the denominator and not knowing what portion of the population is being missed or not included because of the nature of how the data is being collected.
This is underscored by the demographics which show that both for passive surveillance and the active reports through V-safe the populations represented are largely White women between the ages of 18-60.
Realizing that many of the reactions both reactogenic and other are occurring in this demographic there is also the very real affect that this is reporting artifact and that we do need to understand to a much better extent what types of events are occurring in the populations not represented well is Vsafe in particular. This might be an opportunity on how to develop Vsafe into a program that is more inclusively represents age, sex and race. This is captured in VSafe and VAERS does not capture race information. Perhaps trying to give some representative demographics (e.g. 6% of respondents are Blacks although they represent 12% of the US population). It would also be interesting to see if there are any geographic differences in where reports come from across the United States - by State, level of education and insured versus uninsured)
Otherwise I think the findings are important but somewhat expected in terms of the reactogenic symptoms higher in age <65 and women
Supplemental tables 2,3 and 4 are important but has vaccination disproportionately reduced death in COVID related morbidities in educated Whites.
The report is important and should be published and I guess I am thinking about this more in terms of the next steps for both VSafe and VAERS but particularly VSafe to be representative of the US population and more inclusive across age, race, sex, level of education and socioeconomic status. For the targeted reports of interest (myopericarditis, anaphylaxis) it would be helpful to see the data broken down by age and sex.
Although not the goal of Vsafe clearly important if socioeconomically disadvantage and uninsured individuals are vaccine hesitant because of fear of reactogenic events that would cause them to have unpaid time off work or visits to the ER.

There is a lot of data represented in this report but also of interest to know what happened with reporting of events as the vaccine rollout matured. Is it possible to show data from the first 3 months versus second 3 months. Women were more likely to be over-represented during the initial three months in view of healthcare rollout. It would be of interest if the reporting of any of the events including reactogenic events changed as time went on and there was more societal familiarity with these.

Reviewer #4: These are important data to publish as full transparency around AEs is necessary for public trust in vaccination and ending the pandemic. My questions and clarifications are as follows:
MAJOR COMMENTS
1. P5: Cause of death had ICD codes, covid related, or unknown but what about causality assessment to the vaccines? Is no standardized causality assessment performed? If not, wht not? The only mention of "vaccine related" is in supplemental table 3 and denotes only 4 deaths related to the vaccine, but what is the precedent for this very narrow definition? All AEs reported to FDA at minimum are marked unrelated, related, or possibly related. Causality assessments used in safety research can further refine.

2. P5/P7/Table 4: It is not at all clear to me that this is a fair or valid comparison to make. Deaths reported to VAERS are considered potentially related to the vaccine by reporters and not all deaths in vaccinated individuals are reported to VAERS. The comparison to all-cause mortality in vaccinated individuals appears flawed. Death within days of vaccination has a high suspicion of causality and deaths from other causes would not be expected to be spontaneously reported to VAERS. Background mortality rates from all causes are not surprisingly higher —the reporting of deaths to VAERS are only for deaths suspected potentially from the vaccine. I don't think this comparison is valid and to me, it undermines the message of transparency. It assumes when we as clinicians are reporting deaths, we do so indiscriminately but we don't. I considered the method of EB data mining with e EB05>2 a stronger way to assess any safety outliers in this paper and perhaps more focus should be placed on those methods and findings.
3. Regarding the death reports, it is critically important to specifically address whether any deaths were from the two known related serious AEs: anaphylaxis or myocarditis. This requires specific data and mention in the manuscript. Deaths from these within a reasonable time frame post vaccination would be causal. Really all of the special interest AEs in Table 2 would be useful to indicate deaths for transparency.

MINOR COMMENTS
4. P5: Is there a basis for the definition of serious used? Is this standard from prior vaccines?
5. P6: Time from vaccination to reported death is referred to as "onset interval" but is perhaps better described as latency?
6. VSD studies should also be mentioned in the discussion (Nicola Klein et al JAMA) as these provide more valid comparator groups for severe outcomes.
7. The increased reactogenicity symptoms are interesting in the younger/female. Did pregnancy impact this at all? higher or lower in the pregnant female compared to similar age non pregnant female?
8. The healthcare utilization and out of work time is impressive—were there any demographic predictors associated with needing healthcare resource use or out of work?
9. Supp Table 2- Other is such a large category—what comprised other? Can anaphylaxis and myocarditis be added here?
10. Can any modelling of associated factors for severe outcomes or high reactogenicity be performed?

Reviewer #5: This article provides a picture of reports of AEFI in the first six months of utilization of mRNA COVID-19 vaccines in the United States. I think that similar reports are highly desirable to reassure the population about vaccine safety and therefore priority is high. However, in the attempt of providing more information, the study goes beyond the simple description of reports from VAERS and providing a survey of data collected by v-safe. Unfortunately, the authors made this step without providing important information to the readers. With the current information I cannot establish whether and to what extent the results deserve to be discussed with more caution.
Specific comments
Introduction (page 3) "We reviewed VAERS and v-safe […] vaccines were administered". Instead of providing a simple descriptive report of the data collected in these two databases the authors 1) calculated a rate of report of death and compared that with that expected in an unspecified vaccinated population and 2) performed a disproportionality analysis. These are objectives to be declared in the and text and in the abstract.
For the above mentioned analysis the authors did not included in the methods important information.
For the disproportionality analysis we have no information on the dataset. What were the vaccines included in the dataset? What was the proportion of COVID-19 vaccines? For the latter question, the authors reported in the limitation that in the analyzed period (we know only that they included reports up to June 14th, 2021 but we have not the initial date) the great majority of reports was for the vaccines of interest. If this proportion is over 90% the possibility of identifying a signal was likely close to zero. So, why performing such an analysis?
For the comparison of mortality rates we have not information about the comparator: does it refers to mortality following immunization with any vaccine? From the reference number 20 it seems that this rate was calculated (how?) only for COVID-19 vaccines? So what is the rationale for this comparison? Estimating the under-reporting of fatal cases? Estimating the number of reports over a mortality for any cause that was attributed to vaccines (not accidental) by reporters? What was the period in which mortality was calculated in the reference? 14 days after vaccination or longer? In summary, I think that these two rates cannot be compared or should be interpreted in a different way, at least with the details of information provided by the authors.

Page 7: "there were 4,496 reports of death…." Were all these reports from US? Did the VAERS include reports from other countries? I suppose these fatal cases have been occurred all in the US since the authors used this number to estimate the reporting rate for fatal cases using the number of doses of vaccines administered in the US. If this is the case, it should be clearly stated.
Page 8: "During the analytic period, 7,914,583 mRNA COVID-19 vaccine recipients […]". How many patients dropped out after the initial enrolment? In case the drop-out is quite high (as I suppose) the authors should compare the population included in the analysis with the population dropped out to check for a possible selection that could have had an impact on the results.
Page 10 "Analysis of deaths reported to VAERS demonstrated lower than expected reported mortality rates compared to background mortality rates". Besides my doubt about comparability given the lack of essential information, why the authors wrote "than expected"? I would have bet whatever I have that the rate was lower than that estimated for a background mortality for two reasons: 1) under-reporting and 2) background mortality include death for any cause while VAERS includes only deaths that have been somehow associated with the immunization. The authors included an interpretation similar to mine in the "limitations" section. So they likely expected this results as well.

Reviewer #6: Thank you for the opportunity to review this paper. It is an interesting an important piece of research.

I would like to have seen very clear research questions rather than a broad aim of "We review VAERS and v-safe data during the first 6 months of the U.S. vaccination program, when >298 million doses of mRNA COVID-19 vaccines were administered."

There is a lot of data so I would like to see a a STROBE Statement—Checklist of items that should be included in reports of cohort studies, and a CONSORT style flow chart showing for each vaccine the flow e.g. Overall recipients at dose 1, then at dose 2, and how many recipients reported through VAERS and how many completed V-safe survey reports from days 0-7 - split by vaccine type. This will make it easier to follow the tables.

All VAERS reports for mRNA vaccines were submitted and processed from December 14, 2020 through June 14, 2021, inclusive of any interval from vaccination to event report. Could this mean that some recipients were not followed up for the full 6 weeks post dose, e.g. had their vaccine in early June?

Vsafe participants receive text messages that link to web-based health check-in surveys following vaccination, initially daily (days 0-7), then at longer intervals post vaccination. The system resets to the initial survey frequency after entry of another dose. Does this mean that the information relates to either dose 1 or dose 2.

Table 1: I would recommend this table only show the descriptive characteristics of the vaccine recipients, not the the outcomes e.g. Reports, Signs or symptoms most frequently reported, nonserious, and Signs or symptoms most frequently reported, serious. Linking to above, this should be by dose (e.g. Table 5 could replace this). Did all those who are presented in Table 5 as having first dose, then be those who also had their second does e.g. for BNT162b2 vaccine second doses=1,861,599 from 2,150,068 who had first dose - or are could these be a different groups?

Table 2 shows the Reports (as in Table 1) and Reports of adverse events of special interest. It should also include Signs or symptoms most frequently reported, nonserious, and Signs or symptoms most frequently reported, serious (as presented in Table 2).

Deaths were recorded as in the 7 days and 42 days (6 weeks) post vaccination - needs to split by dose 1 and 2. Time interval to death following vaccination was available for 4,119 reports (92·1%); median time interval was 10·0 days (range: 0—161 days). The greatest number of death reports occurred on day 1 (10·5%) and day 2 (7·0%) following vaccination (Supplemental Figure 1). There are clear differences between vaccines here. This might be better as a Kaplan Meier plot and as there are apparent differences by vaccine type - could survival analysis be done here to compare them, adjusting for characteristics and allowing for censoring.

Of the 4,472 reports of deaths analyzed, 2,087 (46·7%) were reported following BNT162b2 and 2,385 (53·3%) following mRNA-1273 - should any statistical comparison made here, adjusting by recipient characteristics? e.g. Females accounted for 42·6% of reported deaths (can this be split by vaccine type), and adjustments are needed as in Table 1 44.0% and 41.4% of the recipients were female.

During the analytic period, VAERS received and processed a total of 340,522 reports: 164,669 following BNT162b2 and 175,816 following mRNA-1273 vaccination (Table 1). Were these individual participants or could one recipient report more than once? How many recipients did not report e.g. had no side effects?

During the analytic period, 7,914,583 mRNA COVID-19 vaccine recipients enrolled in v-safe and completed at least one post-vaccination health survey during days 0-7 (Table 5). What is this as a proportion? A total of 6,775,515 participants completed at least one survey during day 0-7 after dose (3,455,778 following BNT162b2; 3,319,737 following mRNA-1273). Why do these numbers not match?

A clear limitation of this data is a lack of analysis on the time from vaccine (dose 1 and/or dose 2), and time to side effect or adverse event. Also a lack of statistical comparison between the vaccines as there are some differences - however if the aim is not to compare vaccines, splitting the sessions by vaccine might make the paper easier to read.

TECHNICAL INFORMATION:

When you submit the revised paper, please provide the following:

1. One "clean" copy of your manuscript
2. One copy where your changes are highlighted (tracked changes).
3. A separate, point by point response to the editorial and referee comments typed immediately following each specific point above. Please do not use boxes for responses.
4. Any images and/or tables (even if no revisions have been made).

Please do NOT include a copy of your original manuscript. All text files should be supplied as MS Word files.

Please also supply the word count for the body of your paper and your abstract (word count for the body of your paper should not include abstract, references, figures or tables).

To enable readers to better appreciate research findings and to encourage full and transparent reporting of outcomes, *The Lancet* family journals offer to publish a webaddress in accepted paper that links to the study's protocol on the author's institutional website (see Lancet 2009; 373: 992). This is particularly encouraged for randomised controlled trials, but is welcome for all types of research.

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Yours sincerely,

Phoebe Hall
Senior Editor
The Lancet Infectious Diseases

From: "Menschik, David" <[redacted]
To: "Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)" <[redacted]
Cc: "Baer, Bethany" <[redacted]
Bcc: "Menschik, David" <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond
Date: Fri, 10 Sep 2021 11:52:45 -0000
Importance: Normal
Attachments: mRNA_6mo_safety_review-update98forOS_9921.docx

Hi Hannah,

Bethany and I have edits for the data mining limitations section on page 13 of the attached draft manuscript. Please see attached and glad to discuss if any questions.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, September 09, 2021 3:44 PM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Sounds like a plan!

Hannah

From: Menschik, David <[redacted]
Sent: Thursday, September 9, 2021 3:41 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks – working with Bethany now on new data mining limitation language and will share with you in near future. I'll wait to run changes by my leadership for clearance until you advise me that no further substantive edits are forthcoming prior to submission.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Thursday, September 09, 2021 3:33 PM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Definitely
Here's the latest version – the discussion has gotten a little messy so if you can excuse some of the part that is clearly still in revision.

Hannah

From: Menschik, David <[redacted]
Sent: Thursday, September 9, 2021 3:01 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks Hannah!
Given the current stage of the manuscript, would we be able to add an additional data mining limitation to the manuscript?
Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, September 09, 2021 2:20 PM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Dear David,
Thanks so much for writing. The manuscript has moved through CDC clearance rather quickly but we've decided to revise some of the analysis about reported deaths to make it more meaningful/interpretable.
Will definitely send you an updated version of the manuscript as this evolves.

Thanks so very much for your continued engagement on this,
Hannah

From: Menschik, David <[redacted]
Sent: Thursday, September 9, 2021 1:32 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Hope all well on your end. Wondering if there is any status update for this manuscript?

Best,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, August 05, 2021 2:48 PM
To: Baer, Bethany <[redacted]
Cc: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Excellent!! I hope you had a nice leave. On my end, we're ***almost*** through the CDC clearance process – will keep you posted!

Hannah

From: Baer, Bethany <[redacted]
Sent: Thursday, August 5, 2021 2:44 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Cc: Menschik, David (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,
I was on leave for several weeks, so I realize my response is a little delayed. I have caught up on the email exchanges between you and David. I have reviewed the manuscript you sent on July 21st and the minor changes you mentioned in the email below. I, Bethany Baer, approve submission of the manuscript titled 'Reactogenicity and Adverse Events during the First Six Months of mRNA COVID-19 Vaccination in the United States: A Prospective Observational Study of Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe ' to clearance and to journal publication."

Thank you for all of your hard work on this!
Bethany

From: Menschik, David <[redacted]
Sent: Thursday, July 29, 2021 3:37 PM
To: Rosenblum, Hannah (CDC) <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

I agree that these are not substantive changes and will send you the authorship agreement statement shortly.
Thanks so much to you and other teammates for all the amazing work on this very impressive paper!

Congratulations on this key milestone!
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, July 29, 2021 3:33 PM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi David,
Thanks for asking and sorry I didn't write to you about this earlier.
Several small changes were made since you saw the draft (and I'm not sure what you consider substantive so I'll just list them all here):

1. A previously supplemental table about impressions of deaths was moved to a main table (Table 4)
2. The previous table 9 had duplicate data as Figure 2 so that table was moved to supplemental

3. We split 'serious reports' and 'non serious reports' by meddra PT code in Table 2 to more accurately reflect the breakdown.
4. A sentence was added in the discussion stating that the serious /nonserious report distribution is similar to other adult vaccines (since there was concern that we didn't include enough about adverse events in the discussion).

Thank you so so much for all of your responses, feedback and work on this.
Warm regards,
Hannah

From: Menschik, David <[redacted]
Sent: Thursday, July 29, 2021 3:26 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks Hannah! Can you please confirm that there were no substantive edits since the version cleared at FDA (or else share these edits)?

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, July 29, 2021 3:22 PM
To: Gee, Julianne M (CDC) [redacted] Liu, Ruiling (CDC) [redacted] Marquez, Paige L (CDC) [redacted]; Zhang, Bi C (CDC) [redacted]; Strid, Penelope (CDC) <[redacted]; Abara, Winston E (CDC) [redacted] Mcneil, Michael M (CDC) [redacted]; Myers, Tanya R (CDC) [redacted]; Hause, Anne M (CDC) <[redacted]; Menschik, David <[redacted] Baer, Bethany <[redacted] Su, John (CDC) [redacted]; Shimabukuro, Tom (CDC) <[redacted]; Shay, David K (CDC) [redacted]
Subject: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond
Importance: High

Dear co-authors,

Thank you so much for all of your hard work and feedback on the 6 month safety review manuscript. The manuscript has been revised based on all of your feedback, and we're in a good position to submit to CDC clearance.

Please double check your names/degrees to make sure I haven't made any mistakes and that you are listed appropriately.

If you agree with submission of the draft in its current form, please reply with "I, **NAME**, approve submission of the manuscript titled 'Reactogenicity and Adverse Events during the First Six Months of mRNA COVID-19 Vaccination in the United States: A Prospective Observational Study of Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe ' to clearance and to journal publication."

We are planning to submit to the journal *Lancet ID* and the formatting of the draft matches their requirements.

All the very best,
Hannah

Hannah G. Rosenblum, MD
Epidemic Intelligence Service Officer

HPV Team, Viral Vaccine-Preventable Diseases Branch
Division of Viral Diseases, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: "Menschik, David" <[redacted]
To: "Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)" [redacted]
Cc: "Baer, Bethany" <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond
Date: Fri, 10 Sep 2021 19:08:29 -0000
Importance: Normal

Hmm… you should have seen the earlier iterations of this! ☺ Yes, it should say "disproportionality" -autocorrect strikes again! Thanks for correcting that…
Our goal was to simplify as much as possible while not losing key concepts and this is where we landed after working the sentence over…
I think you've got the main point that if the comparison group is enriched with so many mRNA COVID-vaccine reports, that it becomes very difficult to exceed the EB05>2 alert threshold even for an adverse event that may be associated with mRNA vaccines – thus data mining has blind spots and this is why it's so good to have so many complimentary vaccine safety surveillance systems (e.g., VSD) that can cover different blind spots of other systems…
Happy to have a phone call if helpful to explain the importance of including specific words or anything else…

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)[redacted]
Sent: Friday, September 10, 2021 2:51 PM
To: Menschik, David <David.Menschik[redacted]
Cc: Baer, Bethany <Bethany.Baer[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi David,
Certainly will pass along the draft when ready for clearance at FDA!

In looking the additional sentence over in more detail, it seems pretty technical. If I'm understanding correctly, you're saying that the sheer volume of COVID-19 vaccine reports basically washes out the possibility of finding disproportionality (I think it should say disproportionality instead of disproportionately right?)

Do you think you can simplify the sentence so it would be understandable for the average clinician reader?

Hannah

From: Menschik, David <[redacted]
Sent: Friday, September 10, 2021 10:46 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thank you Hannah for all your efforts. Once you advise that paper is ready to clear at FDA, will be very helpful, if possible, to have a version with indication of where specific changes were made from prior cleared version, so that we can do our best to optimize time to re-clear here…

Wishing you an enjoyable weekend,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Friday, September 10, 2021 9:21 AM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

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Thank you David and Bethany!

Hannah

From: Menschik, David <[redacted]
Sent: Friday, September 10, 2021 7:53 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Bethany and I have edits for the data mining limitations section on page 13 of the attached draft manuscript. Please see attached and glad to discuss if any questions.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, September 09, 2021 3:44 PM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

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Sounds like a plan!

Hannah

From: Menschik, David <[redacted]
Sent: Thursday, September 9, 2021 3:41 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks – working with Bethany now on new data mining limitation language and will share with you in near future. I'll wait to run changes by my leadership for clearance until you advise me that no further substantive edits are forthcoming prior to submission.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, September 09, 2021 3:33 PM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Definitely
Here's the latest version – the discussion has gotten a little messy so if you can excuse some of the part that is clearly still in revision.

Hannah

From: Menschik, David <[redacted]
Sent: Thursday, September 9, 2021 3:01 PM
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Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks Hannah!
Given the current stage of the manuscript, would we be able to add an additional data mining limitation to the manuscript?
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Thanks so very much for your continued engagement on this,
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Hi Hannah,

Hope all well on your end. Wondering if there is any status update for this manuscript?

Best,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, August 05, 2021 2:48 PM
To: Baer, Bethany <[redacted]
Cc: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Excellent!! I hope you had a nice leave. On my end, we're ***almost*** through the CDC clearance process – will keep you posted!

Hannah

From: Baer, Bethany <[redacted]
Sent: Thursday, August 5, 2021 2:44 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Menschik, David (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,
I was on leave for several weeks, so I realize my response is a little delayed. I have caught up on the email exchanges between you and David. I have reviewed the manuscript you sent on July 21st and the minor changes you mentioned in the email below. I, Bethany Baer, approve submission of the manuscript titled 'Reactogenicity and Adverse Events during the First Six Months of mRNA COVID-19 Vaccination in the United States: A Prospective Observational Study of Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe ' to clearance and to journal publication."

Thank you for all of your hard work on this!
Bethany

From: Menschik, David <[redacted]
Sent: Thursday, July 29, 2021 3:37 PM
To: Rosenblum, Hannah (CDC) <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

I agree that these are not substantive changes and will send you the authorship agreement statement shortly.
Thanks so much to you and other teammates for all the amazing work on this very impressive paper!

Congratulations on this key milestone!
David

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Hi David,
Thanks for asking and sorry I didn't write to you about this earlier.
Several small changes were made since you saw the draft (and I'm not sure what you consider substantive so I'll just list them all here):

1. A previously supplemental table about impressions of deaths was moved to a main table (Table 4)
2. The previous table 9 had duplicate data as Figure 2 so that table was moved to supplemental
3. We split 'serious reports' and 'non serious reports' by meddra PT code in Table 2 to more accurately reflect the breakdown.
4. A sentence was added in the discussion stating that the serious /nonserious report distribution is similar to other adult vaccines (since there was concern that we didn't include enough about adverse events in the discussion).

Thank you so so much for all of your responses, feedback and work on this.
Warm regards,
Hannah

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To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks Hannah! Can you please confirm that there were no substantive edits since the version cleared at FDA (or else share these edits)?

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, July 29, 2021 3:22 PM
To: Gee, Julianne M (CDC) <[redacted] Liu, Ruiling (CDC) [redacted] Marquez, Paige L (CDC) [redacted]; Zhang, Bi C (CDC) <[redacted]; Strid, Penelope (CDC) <[redacted]; Abara, Winston E (CDC) [redacted]; Mcneil, Michael M (CDC) [redacted] Myers, Tanya R (CDC) [redacted] Hause, Anne M (CDC) [redacted] Menschik, David <[redacted] Baer, Bethany <[redacted]; Su, John (CDC) [redacted]; Shimabukuro, Tom (CDC) <[redacted] Shay, David K (CDC) <[redacted]
Subject: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond
Importance: High

Dear co-authors,

Thank you so much for all of your hard work and feedback on the 6 month safety review manuscript. The manuscript has been revised based on all of your feedback, and we're in a good position to submit to CDC clearance.

Please double check your names/degrees to make sure I haven't made any mistakes and that you are listed appropriately.

If you agree with submission of the draft in its current form, please reply with "I, **NAME**, approve submission of the manuscript titled 'Reactogenicity and Adverse Events during the First Six Months of mRNA COVID-19 Vaccination in the United States: A Prospective Observational Study of Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe ' to clearance and to journal publication."

We are planning to submit to the journal *Lancet ID* and the formatting of the draft matches their requirements.

All the very best,
Hannah

Hannah G. Rosenblum, MD
Epidemic Intelligence Service Officer

HPV Team, Viral Vaccine-Preventable Diseases Branch
Division of Viral Diseases, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: "Menschik, David" <[redacted]>
To: "Baer, Bethany" <[redacted]>
Bcc: "Menschik, David" <[redacted]>
Subject: FW: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond
Date: Thu, 23 Sep 2021 10:48:09 -0000
Importance: High
Attachments: mRNA_6mo_safety_review-update_92121_forclearance_clean.docx; Blackline_Comparison_Reactogenicity_and_Adverse_Events_during_the_First_Six_Months_of_mRNA_COVID.docx; Blackline_Comparison_Reactogenicity_and_Adverse_Events_during_the_First_Six_Months_of_mRNA_COVID(1).docx

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Hi Bethany,

Attached is the new clean manuscript and there is no redline version per below. I created a "blackline version" of the manuscript (comparing previous clean version with this clean version; attached) and it appears that there are substantive changes that will require re-clearance.
I'm not satisfied with the late changes to the data mining limitation section. Recent version said:

> EB data mining has multiple limitations[22] including that an absence of a disproportionality alert does not rule out presence of a safety problem. Additionally, since most reports received during this surveillance period involved COVID-19 vaccines, disproportionately scores (which are adjusted by year to control for time-dependent, potentially confounding, exposure and outcome variables) can be muted by COVID-19 vaccine reports contributing substantially to the comparator group, particularly if both mRNA COVID-19 vaccines are associated with the same adverse event.

New version says:

> A limitation of EB data mining[22] is low sensitivity; that is, absence of a disproportionality alert does not rule out a possible adverse event. A new concern with disproportionality scores, which are adjusted by year to control for time-dependent confounders, is that during the study period most VAERS reports were for COVID-19 vaccinations. As all VAERS reports are used for vaccine-event comparisons in EB data mining, potential associations with mRNA COVID-19 vaccines plausibly could be missed.

This is inadequate since there are many limitations to data mining and they are only pointing out 'low sensitivity' which is not accurate. If you agree, would advise revising to:

> EB data mining has multiple limitations[22,23] including that the absence of a disproportionality alert does not rule out a possible corresponding adverse event. A new concern with disproportionality scores, which are adjusted by year to control for time-dependent confounders, is that during the study period most VAERS reports were for COVID-19 vaccinations. As all VAERS reports are used for vaccine-event comparisons in EB data mining, potential associations with mRNA COVID-19 vaccines plausibly could be missed.

I'm ok with the other data mining parts (including slimming down the results section) and deferring on non-data mining parts of the paper (for which we were not involved).

Any additional edits or thoughts welcome.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Wednesday, September 22, 2021 2:36 PM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi David and Bethany,

I hope all is well. Please see attached for a new version of the vaccine safety 6 month manuscript. A few notes:

- One of the comments in CDC clearance was about the analysis and framing of reports of deaths in the discussion, so part of what took so long to revise and edit was that we opted to significantly change how death reports appear. (Table 4, specifically, is new and compared reports of death from a pre-print paper by CDC authors.)
- You'll also notice that we've taken out some of the details about EB mining in the results. **I hope this is okay with both of you**- as you know, there is a ton of data in this paper, and we left the information that summarized the findings, without going into details that didn't necessarily add to the overall messages of the manuscript- welcome your thoughts about this. You'll see that I've kept everything in the methods/discussion as well as the references that you suggested.

There have been significant edits at this point, and I certainly defer to you about whether the paper should go back into formal FDA clearance. About my ideal timeline- the draft is currently back in CDC clearance- I'm hoping that it is cleared in the next few days, and then I can begin to prep for manuscript submission in the next week or so.

Let me know if it would be helpful to have a short call to go through some of these changes in more detail.

Thanks so very much,
Hannah

From: "Menschik, David" <[redacted]
To: "Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)" [redacted]
Cc: "Baer, Bethany" <[redacted]
Bcc: "Menschik, David" <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond
Date: Thu, 23 Sep 2021 12:21:44 -0000
Importance: Normal

Good morning Hannah,

There are substantive changes and this will ultimately have to go through clearance at FDA.

Regarding the limitations section, previously accepted version said:

> EB data mining has multiple limitations[22] including that an absence of a disproportionality alert does not rule out presence of a safety problem. Additionally, since most reports received during this surveillance period involved COVID-19 vaccines, disproportionately scores (which are adjusted by year to control for time-dependent, potentially confounding, exposure and outcome variables) can be muted by COVID-19 vaccine reports contributing substantially to the comparator group, particularly if both mRNA COVID-19 vaccines are associated with the same adverse event.

New version says:

> A limitation of EB data mining[22] is low sensitivity; that is, absence of a disproportionality alert does not rule out a possible adverse event. A new concern with disproportionality scores, which are adjusted by year to control for time-dependent confounders, is that during the study period most VAERS reports were for COVID-19 vaccinations. As all VAERS reports are used for vaccine-event comparisons in EB data mining, potential associations with mRNA COVID-19 vaccines plausibly could be missed.

This is inadequate since there are many limitations to data mining and paper is only pointing out 'low sensitivity' which is not accurate. We recommend revising to:

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OK with the other data mining parts (including slimming down the results section) and deferring on non-data mining parts of the paper (for which we were not involved).

Please let us know if the proposed revision is acceptable and if so, please provide an updated clean version for our clearance process.

Best,
David

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Sent: Wednesday, September 22, 2021 2:36 PM
To: Menschik, David <[redacted]

Cc: Baer, Bethany <[redacted]
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Let me know if it would be helpful to have a short call to go through some of these changes in more detail.

Thanks so very much,
Hannah

From: Menschik, David <[redacted]
Sent: Wednesday, September 15, 2021 9:29 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks Hannah!

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Wednesday, September 15, 2021 8:56 AM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

This look great- I've kept that reference in and kept all of your language.
So appreciate your work on this- and will forward on a 'clean' and 'modified' version ASAP!
All the best,

Hannah

From: Menschik, David <[redacted]
Sent: Wednesday, September 15, 2021 8:46 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Thanks! I certainly understand the desire to simplify and be economical with words. I've attached a slightly revised version which Bethany has not had a chance to review yet and copying her here in case she has further thoughts.
I think it is important to make reference to the Martin article (reference #22) which mentions several important VAERS data mining limitations so the reader does not overestimate what data mining can do (see attached for suggested placement). I changed 'driven towards the null" to "muted" and removed "if there is a class effect" and removed the immediately following parenthesis and "e.g.," to highlight main concern of potentially missing a PT that is associated with both mRNA vaccines.

Please see attached and let me know what you think.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Wednesday, September 15, 2021 8:01 AM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi David,
Thanks and sorry for the lack of response. I had rewritten with a similar tightening – additionally, I had deleted "particularly if there is a class-effect" or do you think that clarification is needed?
Senior authors on our team are looking through it today, so hopefully will be ready for re-clearance later this week.
Will forward on as soon as possible.
Thanks a million,

Hannah

From: Menschik, David <[redacted]
Sent: Wednesday, September 15, 2021 7:59 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Hopefully no issues with the new language provided yesterday though if so please advise.
Also wondering If you have a general estimate on when this paper will be ready for re-clearance?

Thanks,
David

From: Menschik, David
Sent: Tuesday, September 14, 2021 5:17 AM
To: Rosenblum, Hannah (CDC) [redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

To simplify, the previously language could be replaced with:

> "Additionally, since most reports received during this surveillance period involved COVID-19 vaccines, disproportionately scores (which are adjusted by year to control for time-dependent, potentially confounding, exposure and outcome variables) can be driven towards the null by COVID vaccine reports contributing substantially to the comparator group, particularly if there is a class-effect (e.g., if multiple COVID vaccines are associated with the same adverse event)."

Does this help?

Thanks,
David

From: Menschik, David <[redacted]
Sent: Friday, September 10, 2021 3:08 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hmm… you should have seen the earlier iterations of this! ☺ Yes, it should say "disproportionality" -autocorrect strikes again! Thanks for correcting that…
Our goal was to simplify as much as possible while not losing key concepts and this is where we landed after working the sentence over…
I think you've got the main point that if the comparison group is enriched with so many mRNA COVID-vaccine reports, that it becomes very difficult to exceed the EB05>2 alert threshold even for an adverse event that may be associated with mRNA vaccines – thus data mining has blind spots and this is why it's so good to have so many complimentary vaccine safety surveillance systems (e.g., VSD) that can cover different blind spots of other systems…
Happy to have a phone call if helpful to explain the importance of including specific words or anything else…

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Friday, September 10, 2021 2:51 PM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi David,
Certainly will pass along the draft when ready for clearance at FDA!

In looking the additional sentence over in more detail, it seems pretty technical. If I'm understanding correctly, you're saying that the sheer volume of COVID-19 vaccine reports basically washes out the possibility of finding disproportionality (I think it should say disproportionality instead of disproportionately right?)

Do you think you can simplify the sentence so it would be understandable for the average clinician reader?

Hannah

From: Menschik, David <[redacted]
Sent: Friday, September 10, 2021 10:46 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thank you Hannah for all your efforts. Once you advise that paper is ready to clear at FDA, will be very helpful, if possible, to have a version with indication of where specific changes were made from prior cleared version, so that we can do our best to optimize time to re-clear here…

Wishing you an enjoyable weekend,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Friday, September 10, 2021 9:21 AM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thank you David and Bethany!

Hannah

From: Menschik, David <[redacted]
Sent: Friday, September 10, 2021 7:53 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Bethany and I have edits for the data mining limitations section on page 13 of the attached draft manuscript. Please see attached and glad to discuss if any questions.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, September 09, 2021 3:44 PM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Sounds like a plan!

Hannah

From: Menschik, David <[redacted]
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To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks – working with Bethany now on new data mining limitation language and will share with you in near future.
I'll wait to run changes by my leadership for clearance until you advise me that no further substantive edits are forthcoming prior to submission.

Thanks,
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Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Definitely
Here's the latest version – the discussion has gotten a little messy so if you can excuse some of the part that is clearly still in revision.

Hannah

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Thanks Hannah!
Given the current stage of the manuscript, would we be able to add an additional data mining limitation to the manuscript?
Thanks,
David

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Will definitely send you an updated version of the manuscript as this evolves.

Thanks so very much for your continued engagement on this,
Hannah

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Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Hope all well on your end. Wondering if there is any status update for this manuscript?

Best,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)[redacted]
Sent: Thursday, August 05, 2021 2:48 PM
To: Baer, Bethany <[redacted]
Cc: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Excellent!! I hope you had a nice leave. On my end, we're ***almost*** through the CDC clearance process – will keep you posted!

Hannah

From: Baer, Bethany <[redacted]
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To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)[redacted]
Cc: Menschik, David (FDA/CBER) <[redacted]
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Hi Hannah,
I was on leave for several weeks, so I realize my response is a little delayed. I have caught up on the email exchanges between you and David. I have reviewed the manuscript you sent on July 21st and the minor changes you mentioned in the email below. I, Bethany Baer, approve submission of the manuscript titled 'Reactogenicity and Adverse Events during the First Six Months of mRNA COVID-19 Vaccination in the United States: A Prospective Observational Study of Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe ' to clearance and to journal publication."

Thank you for all of your hard work on this!
Bethany

From: Menschik, David <[redacted]
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To: Rosenblum, Hannah (CDC) <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

I agree that these are not substantive changes and will send you the authorship agreement statement shortly.
Thanks so much to you and other teammates for all the amazing work on this very impressive paper!

Congratulations on this key milestone!
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, July 29, 2021 3:33 PM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi David,
Thanks for asking and sorry I didn't write to you about this earlier.
Several small changes were made since you saw the draft (and I'm not sure what you consider substantive so I'll just list them all here):

1. A previously supplemental table about impressions of deaths was moved to a main table (Table 4)
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Thank you so so much for all of your responses, feedback and work on this.
Warm regards,
Hannah

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Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks Hannah! Can you please confirm that there were no substantive edits since the version cleared at FDA (or else share these edits)?

Thanks,
David

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To: Gee, Julianne M (CDC) [redacted] Liu, Ruiling (CDC) [redacted] Marquez, Paige L (CDC) [redacted] Zhang, Bi C (CDC) [redacted]; Strid, Penelope (CDC) <[redacted] Abara, Winston E (CDC) [redacted] Mcneil, Michael M (CDC) <[redacted]; Myers, Tanya R (CDC) [redacted]; Hause, Anne M (CDC) [redacted]; Menschik, David <[redacted] Baer, Bethany <[redacted]; Su, John (CDC) <[redacted]; Shimabukuro, Tom (CDC) <[redacted] Shay, David K (CDC) <[redacted]
Subject: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond
Importance: High

Dear co-authors,

Thank you so much for all of your hard work and feedback on the 6 month safety review manuscript. The manuscript has been revised based on all of your feedback, and we're in a good position to submit to CDC clearance.

Please double check your names/degrees to make sure I haven't made any mistakes and that you are listed appropriately.

If you agree with submission of the draft in its current form, please reply with "I, **NAME**, approve submission of the manuscript titled 'Reactogenicity and Adverse Events during the First Six Months of mRNA COVID-19 Vaccination in the United States: A Prospective Observational Study of Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe ' to clearance and to journal publication."

We are planning to submit to the journal *Lancet ID* and the formatting of the draft matches their requirements.

All the very best,
Hannah

Hannah G. Rosenblum, MD
Epidemic Intelligence Service Officer

HPV Team, Viral Vaccine-Preventable Diseases Branch
Division of Viral Diseases, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: "Menschik, David" <[redacted]
To: "Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)" [redacted]
Cc: "Baer, Bethany" <[redacted] "Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)" <[redacted] "Shay, David K (CDC)" [redacted]
Bcc: "Menschik, David" <[redacted]
Subject: RE: [EXTERNAL] RE: 6 month safety review-COI form- please fill out and send back by COB 10/21
Date: Sat, 23 Oct 2021 12:42:24 -0000
Importance: High
Embedded: unnamed; unnamed(1)

Hi Hannah,

The version you sent below is not the same version as the clean copy you sent on 10/5/21 (per attached) addressing FDA edits/comments from the clearance process.
e.g., on page 5, regarding data mining methods, manuscript states, "This statistical method calculates observed to expected MedDRA PT pairings by comparing a specific vaccine-MedDRA PT pair to all vaccine-PT pairs in VAERS, adjusting for age, sex, and year of vaccination." when expected to state, "This statistical method calculates observed to expected MedDRA PT pairings by comparing a specific vaccine-MedDRA PT pair to all vaccine-PT pairs in VAERS, adjusting for age, sex, and year received."

Please advise ASAP.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)[redacted]
Sent: Friday, October 22, 2021 9:52 AM
To: Gee, Julianne M (CDC) [redacted] Liu, Ruiling (CDC) [redacted] Marquez, Paige L (CDC [redacted] Zhang, Bi C (CDC) <[redacted] Strid, Penelope (CDC) [redacted] Abara, Winston E (CDC [redacted] Mcneil, Michael M (CDC) [redacted] Myers, Tanya R (CDC) <[redacted]; Hause, Anne M (CDC) <[redacted] Menschik, David <[redacted]; Baer, Bethany <[redacted]; Su, John (CDC) <[redacted]>; Shimabukuro, Tom (CDC) <[redacted]; Shay, David K (CDC) <[redacted]; Markowitz, Lauri (CDC) <[redacted]>
Subject: [EXTERNAL] RE: 6 month safety review-COI form- please fill out and send back by COB 10/21

Good morning all,
Attached is a copy of the clean version that is being submitted for posting to medRxiv.
Thanks to all of you for your hard work on this.

Hannah

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)
Sent: Wednesday, October 20, 2021 6:16 PM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) [redacted] Liu, Ruiling (CDC/NIOSH/WTCHP) <[redacted] Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR) [redacted] Strid, Penelope (CDC/DDNID/NCCDPHP/DRH) [redacted] Abara, Winston E.

(CDC/DDID/NCHHSTP/DSTDP) [redacted]; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) [redacted]; Hause, Anne M. (CDC/DDID/NCEZID/DHQP) <[redacted]
Menschik, David (FDA/CBER) <[redacted]; Baer, Bethany (FDA/CBER) <[redacted]
Su, John (CDC/DDID/NCEZID/DHQP) [redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [redacted]
Shay, David (CDC/DDID/NCIRD/ID) <[redacted]; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[redacted]
Subject: 6 month safety review-COI form- please fill out and send back by COB 10/21

Dear co-authors,

Thanks so so much for all of your hard work and feedback on the 6 month safety review manuscript. The paper has been through CDC and FDA clearance, and is in final revision stages. Our plan is to submit to the medRxiv pre-print server, to be followed by journal submission shortly therefore.

I will send a revised draft for all of you to review in the next day or two- **in the meantime, could you please complete and return the attached COI form with your name, the date and any disclosures by COB tomorrow, 10/21/21?**

Thanks so very much,
Hannah

Hannah G. Rosenblum, MD
Epidemic Intelligence Service Officer

HPV Team, Viral Vaccine-Preventable Diseases Branch
Division of Viral Diseases, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: "Menschik, David" <[redacted]
To: "Alimchandani, Meghna" <[redacted]
Cc: "Baer, Bethany" <[redacted]
Bcc: "Menschik, David" <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond
Date: Tue, 28 Sep 2021 11:26:20 -0000
Importance: Normal
Attachments: mRNA_6mo_safety_review-2021-09-26_CLEAN_DT_.docx; mRNA_COIVD19_vaccine_six_month_safety_review_Clearance_092721_DT_KJW.pdf

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Meghna,

I caught another error on page 5 – pretty sure data mining is adjusted based on year received (i.e., when the VAERS report was received) not year of vaccination – this is what we had in prior version and somehow they changed it. The attached version has the correction.

Bethany and I have a meeting with Commonwealth this afternoon and will confirm then…

Thanks,
David

From: Menschik, David
Sent: Tuesday, September 28, 2021 6:49 AM
To: Alimchandani, Meghna <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: FW: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Meghna,

Sorry for the multiple emails.
Assuming you haven't started yet, for clearance purposes, please replace manuscript with attached version (this has one new change: I included a PT example per Deb's suggestion)

Thanks,
David

From: Menschik, David
Sent: Tuesday, September 28, 2021 5:32 AM
To: Alimchandani, Meghna <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Meghna,

In case you haven't started clearing this paper, I'm attaching an updated version based on the version Deb forwarded below with a footnote superscript (#23) added for data mining limitations on page 13.

Thanks,
David

From: Menschik, David
Sent: Monday, September 27, 2021 2:42 PM
To: Welsh, Kerry <[redacted]; Alimchandani, Meghna <[redacted]
Cc: Baer, Bethany <[redacted]; Thompson, Deborah <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thank you very much for the rapid turnaround Kerry!

Meghna: I'm attaching the version with Deb's comments for your convenience – thanks!

From: Welsh, Kerry <[redacted]
Sent: Monday, September 27, 2021 2:33 PM
To: Thompson, Deborah <[redacted] Menschik, David <[redacted]
Cc: Alimchandani, Meghna <[redacted]; Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

No clearance issues. Here's the signed clearance form for Meghna.

Best,
Kerry

From: Thompson, Deborah <[redacted]
Sent: Monday, September 27, 2021 12:38 PM
To: Menschik, David <[redacted]
Cc: Welsh, Kerry <[redacted]; Alimchandani, Meghna <[redacted] Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks, David. I've sent it on to Kerry.

Thanks,

Deb

From: Menschik, David <[redacted]
Sent: Monday, September 27, 2021 12:31 PM
To: Thompson, Deborah <[redacted]
Cc: Welsh, Kerry <[redacted]; Alimchandani, Meghna <[redacted]; Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Deb,

Thanks so much for the rapid turn-around!
Attached is the clearance form for you to please sign and then pass on to Kerry along with the attached manuscript edits.

Kerry: after you review, please forward to Meghna and cc me

Thanks!
David

From: Thompson, Deborah <[redacted]
Sent: Monday, September 27, 2021 12:09 PM
To: Baer, Bethany <[redacted]; Menschik, David <[redacted]
Cc: Welsh, Kerry <[redacted]; Alimchandani, Meghna <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks, Bethany and David. I've re-reviewed as well and had a couple of minor comments (and found same missing word/typo😊). Please send the updated clearance form when you have a chance and I can sign.

Thanks!

Deb

From: Baer, Bethany <[redacted]
Sent: Monday, September 27, 2021 9:54 AM
To: Menschik, David <[redacted]
Cc: Thompson, Deborah <[redacted]; Welsh, Kerry <[redacted]>; Alimchandani, Meghna <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi David,
I have read the new version and am okay going to clearance. Thank you so much, Deb, Kerry, and Meghna.

I did see a minor typo/missing word on pg. 11, line 7 where it says "Reports of seeking medical care after mRNA vaccine were rare; v-safe did not which symptoms prompted the participant to seek medical care." That shouldn't affect clearance but I'll pass the info back to the first author.
Thanks,
Bethany

From: Menschik, David <[redacted]
Sent: Monday, September 27, 2021 7:59 AM
To: Baer, Bethany <[redacted]
Cc: Thompson, Deborah <[redacted]; Welsh, Kerry <[redacted]; Alimchandani, Meghna <[redacted]
Subject: FW: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Bethany,

Attached please find the revised version of the mRNA vaccine review paper that needs re-clearance. The second attachment is a black-line version I created to show differences with the prior version that was cleared.

I'm ok with the data mining portions (with one exception below) which was the focus of our contribution to this paper. Once you give the ok, we can begin the clearance process here. CDC says it's already cleared there and requesting expedited clearance here so I'm copying Deb and Kerry who cleared this last time as a heads up.

Thanks,
David

From: Menschik, David
Sent: Monday, September 27, 2021 5:54 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

I noticed that the statement, "EB data mining has multiple limitations,[22] including that…" is missing reference #23 as discussed (i.e., should reference both 22 and 23) – can you please revise accordingly and send us back a clean copy?

Thanks,
David

From: "Menschik, David" <[redacted]
To: "Baer, Bethany" <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond
Date: Wed, 15 Sep 2021 13:28:24 -0000
Importance: Normal

Thanks!

From: Baer, Bethany <[redacted]
Sent: Wednesday, September 15, 2021 9:26 AM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Yes, the edits are fine with me.
Thanks,
Bethany

From: Menschik, David <[redacted]
Sent: Wednesday, September 15, 2021 9:04 AM
To: Baer, Bethany <[redacted]
Subject: FW: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

these tweaks ok with you?

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Wednesday, September 15, 2021 8:56 AM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

This look great- I've kept that reference in and kept all of your language.
So appreciate your work on this- and will forward on a 'clean' and 'modified' version ASAP!
All the best,

Hannah

From: Menschik, David <[redacted]
Sent: Wednesday, September 15, 2021 8:46 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Thanks! I certainly understand the desire to simplify and be economical with words. I've attached a slightly revised version which Bethany has not had a chance to review yet and copying her here in case she has further thoughts.
I think it is important to make reference to the Martin article (reference #22) which mentions several important VAERS data mining limitations so the reader does not overestimate what data mining can do (see attached for suggested placement). I changed 'driven towards the null" to "muted" and removed "if there is a class effect" and removed the immediately following parenthesis and "e.g.," to highlight main concern of potentially missing a PT that is associated with both mRNA vaccines.

Please see attached and let me know what you think.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Wednesday, September 15, 2021 8:01 AM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi David,
Thanks and sorry for the lack of response. I had rewritten with a similar tightening – additionally, I had deleted "particularly if there is a class-effect" or do you think that clarification is needed?
Senior authors on our team are looking through it today, so hopefully will be ready for re-clearance later this week.
Will forward on as soon as possible.
Thanks a million,

Hannah

From: Menschik, David <[redacted]
Sent: Wednesday, September 15, 2021 7:59 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Hopefully no issues with the new language provided yesterday though if so please advise.
Also wondering If you have a general estimate on when this paper will be ready for re-clearance?

Thanks,
David

From: Menschik, David
Sent: Tuesday, September 14, 2021 5:17 AM
To: Rosenblum, Hannah (CDC) <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

To simplify, the previously language could be replaced with:

> "Additionally, since most reports received during this surveillance period involved COVID-19 vaccines, disproportionately scores (which are adjusted by year to control for time-dependent, potentially confounding, exposure and outcome variables) can be driven towards the null by COVID vaccine reports contributing substantially to the comparator group, particularly if there is a class-effect (e.g., if multiple COVID vaccines are associated with the same adverse event)."

Does this help?

Thanks,
David

From: Menschik, David <[redacted]
Sent: Friday, September 10, 2021 3:08 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hmm… you should have seen the earlier iterations of this! ☺ Yes, it should say "disproportionality" -autocorrect strikes again! Thanks for correcting that…
Our goal was to simplify as much as possible while not losing key concepts and this is where we landed after working the sentence over…
I think you've got the main point that if the comparison group is enriched with so many mRNA COVID-vaccine reports, that it becomes very difficult to exceed the EB05>2 alert threshold even for an adverse event that may be associated with mRNA vaccines – thus data mining has blind spots and this is why it's so good to have so many complimentary vaccine safety surveillance systems (e.g., VSD) that can cover different blind spots of other systems…
Happy to have a phone call if helpful to explain the importance of including specific words or anything else…

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Friday, September 10, 2021 2:51 PM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi David,
Certainly will pass along the draft when ready for clearance at FDA!

In looking the additional sentence over in more detail, it seems pretty technical. If I'm understanding correctly, you're saying that the sheer volume of COVID-19 vaccine reports basically washes out the possibility of finding disproportionality (I think it should say disproportionality instead of disproportionately right?)

Do you think you can simplify the sentence so it would be understandable for the average clinician reader?

Hannah

From: Menschik, David <[redacted]
Sent: Friday, September 10, 2021 10:46 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]

Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thank you Hannah for all your efforts. Once you advise that paper is ready to clear at FDA, will be very helpful, if possible, to have a version with indication of where specific changes were made from prior cleared version, so that we can do our best to optimize time to re-clear here…

Wishing you an enjoyable weekend,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Friday, September 10, 2021 9:21 AM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thank you David and Bethany!

Hannah

From: Menschik, David <[redacted]
Sent: Friday, September 10, 2021 7:53 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Bethany and I have edits for the data mining limitations section on page 13 of the attached draft manuscript. Please see attached and glad to discuss if any questions.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, September 09, 2021 3:44 PM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Sounds like a plan!

Hannah

From: Menschik, David <[redacted]
Sent: Thursday, September 9, 2021 3:41 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks – working with Bethany now on new data mining limitation language and will share with you in near future. I'll wait to run changes by my leadership for clearance until you advise me that no further substantive edits are forthcoming prior to submission.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)[redacted]
Sent: Thursday, September 09, 2021 3:33 PM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Definitely
Here's the latest version – the discussion has gotten a little messy so if you can excuse some of the part that is clearly still in revision.

Hannah

From: Menschik, David <[redacted]
Sent: Thursday, September 9, 2021 3:01 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks Hannah!
Given the current stage of the manuscript, would we be able to add an additional data mining limitation to the manuscript?
Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, September 09, 2021 2:20 PM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Dear David,
Thanks so much for writing. The manuscript has moved through CDC clearance rather quickly but we've decided to revise some of the analysis about reported deaths to make it more meaningful/interpretable.
Will definitely send you an updated version of the manuscript as this evolves.

Thanks so very much for your continued engagement on this,
Hannah

From: Menschik, David <[redacted]
Sent: Thursday, September 9, 2021 1:32 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Hope all well on your end. Wondering if there is any status update for this manuscript?

Best,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, August 05, 2021 2:48 PM
To: Baer, Bethany <[redacted]
Cc: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Excellent!! I hope you had a nice leave. On my end, we're ***almost*** through the CDC clearance process – will keep you posted!

Hannah

From: Baer, Bethany <[redacted]
Sent: Thursday, August 5, 2021 2:44 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Menschik, David (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,
I was on leave for several weeks, so I realize my response is a little delayed. I have caught up on the email exchanges between you and David. I have reviewed the manuscript you sent on July 21st and the minor changes you mentioned in the email below. I, Bethany Baer, approve submission of the manuscript titled 'Reactogenicity and Adverse Events during the First Six Months of mRNA COVID-19 Vaccination in the United States: A Prospective Observational Study of Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe ' to clearance and to journal publication."

Thank you for all of your hard work on this!
Bethany

From: Menschik, David <[redacted]
Sent: Thursday, July 29, 2021 3:37 PM
To: Rosenblum, Hannah (CDC) [redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

I agree that these are not substantive changes and will send you the authorship agreement statement shortly.
Thanks so much to you and other teammates for all the amazing work on this very impressive paper!

Congratulations on this key milestone!
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, July 29, 2021 3:33 PM

To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi David,
Thanks for asking and sorry I didn't write to you about this earlier.
Several small changes were made since you saw the draft (and I'm not sure what you consider substantive so I'll just list them all here):

1. A previously supplemental table about impressions of deaths was moved to a main table (Table 4)
2. The previous table 9 had duplicate data as Figure 2 so that table was moved to supplemental
3. We split 'serious reports' and 'non serious reports' by meddra PT code in Table 2 to more accurately reflect the breakdown.
4. A sentence was added in the discussion stating that the serious /nonserious report distribution is similar to other adult vaccines (since there was concern that we didn't include enough about adverse events in the discussion).

Thank you so so much for all of your responses, feedback and work on this.
Warm regards,
Hannah

From: Menschik, David <[redacted]
Sent: Thursday, July 29, 2021 3:26 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks Hannah! Can you please confirm that there were no substantive edits since the version cleared at FDA (or else share these edits)?

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, July 29, 2021 3:22 PM
To: Gee, Julianne M (CDC) [redacted]; Liu, Ruiling (CDC) [redacted] Marquez, Paige L (CDC) [redacted] Zhang, Bi C (CDC) [redacted] Strid, Penelope (CDC) [redacted]; Abara, Winston E (CDC) [redacted] Mcneil, Michael M (CDC) [redacted]; Myers, Tanya R (CDC) [redacted]; Hause, Anne M (CDC) [redacted] Menschik, David <[redacted]; Baer, Bethany <[redacted]; Su, John (CDC) [redacted] Shimabukuro, Tom (CDC) [redacted]; Shay, David K (CDC) [redacted]
Subject: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond
Importance: High

Dear co-authors,

Thank you so much for all of your hard work and feedback on the 6 month safety review manuscript. The manuscript has been revised based on all of your feedback, and we're in a good position to submit to CDC clearance.

Please double check your names/degrees to make sure I haven't made any mistakes and that you are listed appropriately.

If you agree with submission of the draft in its current form, please reply with "I, **NAME**, approve submission of the manuscript titled 'Reactogenicity and Adverse Events during the First Six Months of mRNA COVID-19 Vaccination in the United States: A Prospective Observational Study of Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe ' to clearance and to journal publication."

We are planning to submit to the journal *Lancet ID* and the formatting of the draft matches their requirements.

All the very best,
Hannah

Hannah G. Rosenblum, MD
Epidemic Intelligence Service Officer

HPV Team, Viral Vaccine-Preventable Diseases Branch
Division of Viral Diseases, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: "Menschik, David" <[redacted]
To: "Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)" <[redacted]
Cc: "Baer, Bethany" <[redacted]>
Bcc: "Menschik, David" <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond
Date: Wed, 15 Sep 2021 12:45:52 -0000
Importance: Normal
Attachments: mRNA_6mo_safety_review-update98forOS_091521.docx

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Hi Hannah,

Thanks! I certainly understand the desire to simplify and be economical with words. I've attached a slightly revised version which Bethany has not had a chance to review yet and copying her here in case she has further thoughts.
I think it is important to make reference to the Martin article (reference #22) which mentions several important VAERS data mining limitations so the reader does not overestimate what data mining can do (see attached for suggested placement). I changed 'driven towards the null" to "muted" and removed "if there is a class effect" and removed the immediately following parenthesis and "e.g.," to highlight main concern of potentially missing a PT that is associated with both mRNA vaccines.

Please see attached and let me know what you think.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <qds8@cdc.gov>
Sent: Wednesday, September 15, 2021 8:01 AM
To: Menschik, David <[redacted]>
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi David,
Thanks and sorry for the lack of response. I had rewritten with a similar tightening – additionally, I had deleted "particularly if there is a class-effect" or do you think that clarification is needed?
Senior authors on our team are looking through it today, so hopefully will be ready for re-clearance later this week.
Will forward on as soon as possible.
Thanks a million,

Hannah

From: Menschik, David <[redacted]
Sent: Wednesday, September 15, 2021 7:59 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Hopefully no issues with the new language provided yesterday though if so please advise.
Also wondering If you have a general estimate on when this paper will be ready for re-clearance?

Thanks,
David

From: Menschik, David
Sent: Tuesday, September 14, 2021 5:17 AM
To: Rosenblum, Hannah (CDC) [redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

To simplify, the previously language could be replaced with:

> "Additionally, since most reports received during this surveillance period involved COVID-19 vaccines, disproportionately scores (which are adjusted by year to control for time-dependent, potentially confounding, exposure and outcome variables) can be driven towards the null by COVID vaccine reports contributing substantially to the comparator group, particularly if there is a class-effect (e.g., if multiple COVID vaccines are associated with the same adverse event)."

Does this help?

Thanks,
David

From: Menschik, David <[redacted]
Sent: Friday, September 10, 2021 3:08 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hmm… you should have seen the earlier iterations of this! ☺ Yes, it should say "disproportionality" -autocorrect strikes again! Thanks for correcting that…
Our goal was to simplify as much as possible while not losing key concepts and this is where we landed after working the sentence over…
I think you've got the main point that if the comparison group is enriched with so many mRNA COVID-vaccine reports, that it becomes very difficult to exceed the EB05>2 alert threshold even for an adverse event that may be associated with mRNA vaccines – thus data mining has blind spots and this is why it's so good to have so many complimentary vaccine safety surveillance systems (e.g., VSD) that can cover different blind spots of other systems…
Happy to have a phone call if helpful to explain the importance of including specific words or anything else…

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Friday, September 10, 2021 2:51 PM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi David,
Certainly will pass along the draft when ready for clearance at FDA!

In looking the additional sentence over in more detail, it seems pretty technical. If I'm understanding correctly, you're saying that the sheer volume of COVID-19 vaccine reports basically washes out the possibility of finding disproportionality (I think it should say disproportionality instead of disproportionately right?)

Do you think you can simplify the sentence so it would be understandable for the average clinician reader?

Hannah

From: Menschik, David <[redacted]
Sent: Friday, September 10, 2021 10:46 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thank you Hannah for all your efforts. Once you advise that paper is ready to clear at FDA, will be very helpful, if possible, to have a version with indication of where specific changes were made from prior cleared version, so that we can do our best to optimize time to re-clear here…

Wishing you an enjoyable weekend,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Friday, September 10, 2021 9:21 AM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thank you David and Bethany!

Hannah

From: Menschik, David <[redacted]
Sent: Friday, September 10, 2021 7:53 AM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Bethany and I have edits for the data mining limitations section on page 13 of the attached draft manuscript. Please see attached and glad to discuss if any questions.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Thursday, September 09, 2021 3:44 PM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Sounds like a plan!

Hannah

From: Menschik, David <[redacted]
Sent: Thursday, September 9, 2021 3:41 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD)[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks – working with Bethany now on new data mining limitation language and will share with you in near future. I'll wait to run changes by my leadership for clearance until you advise me that no further substantive edits are forthcoming prior to submission.

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, September 09, 2021 3:33 PM
To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Definitely
Here's the latest version – the discussion has gotten a little messy so if you can excuse some of the part that is clearly still in revision.

Hannah

From: Menschik, David <[redacted]
Sent: Thursday, September 9, 2021 3:01 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks Hannah!
Given the current stage of the manuscript, would we be able to add an additional data mining limitation to the manuscript?
Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, September 09, 2021 2:20 PM

To: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Dear David,
Thanks so much for writing. The manuscript has moved through CDC clearance rather quickly but we've decided to revise some of the analysis about reported deaths to make it more meaningful/interpretable.
Will definitely send you an updated version of the manuscript as this evolves.

Thanks so very much for your continued engagement on this,
Hannah

From: Menschik, David <[redacted]
Sent: Thursday, September 9, 2021 1:32 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

Hope all well on your end. Wondering if there is any status update for this manuscript?

Best,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, August 05, 2021 2:48 PM
To: Baer, Bethany <[redacted]
Cc: Menschik, David <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Excellent!! I hope you had a nice leave. On my end, we're ***almost*** through the CDC clearance process – will keep you posted!

Hannah

From: Baer, Bethany <[redacted]
Sent: Thursday, August 5, 2021 2:44 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Menschik, David (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,
I was on leave for several weeks, so I realize my response is a little delayed. I have caught up on the email exchanges between you and David. I have reviewed the manuscript you sent on July 21st and the minor changes you mentioned in the email below. I, Bethany Baer, approve submission of the manuscript titled 'Reactogenicity and Adverse Events during the First Six Months of mRNA COVID-19 Vaccination in the United States: A Prospective Observational Study of Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe ' to clearance and to journal publication."

Thank you for all of your hard work on this!
Bethany

From: Menschik, David <[redacted]
Sent: Thursday, July 29, 2021 3:37 PM
To: Rosenblum, Hannah (CDC) [redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi Hannah,

I agree that these are not substantive changes and will send you the authorship agreement statement shortly.
Thanks so much to you and other teammates for all the amazing work on this very impressive paper!

Congratulations on this key milestone!
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, July 29, 2021 3:33 PM
To: Menschik, David <[redacted]
Cc: Baer, Bethany <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Hi David,
Thanks for asking and sorry I didn't write to you about this earlier.
Several small changes were made since you saw the draft (and I'm not sure what you consider substantive so I'll just list them all here):

1. A previously supplemental table about impressions of deaths was moved to a main table (Table 4)
2. The previous table 9 had duplicate data as Figure 2 so that table was moved to supplemental
3. We split 'serious reports' and 'non serious reports' by meddra PT code in Table 2 to more accurately reflect the breakdown.
4. A sentence was added in the discussion stating that the serious /nonserious report distribution is similar to other adult vaccines (since there was concern that we didn't include enough about adverse events in the discussion).

Thank you so so much for all of your responses, feedback and work on this.
Warm regards,
Hannah

From: Menschik, David <[redacted]
Sent: Thursday, July 29, 2021 3:26 PM
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Baer, Bethany (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond

Thanks Hannah! Can you please confirm that there were no substantive edits since the version cleared at FDA (or else share these edits)?

Thanks,
David

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Thursday, July 29, 2021 3:22 PM
To: Gee, Julianne M (CDC) [redacted]; Liu, Ruiling (CDC) [redacted]; Marquez, Paige L (CDC) [redacted]; Zhang, Bi C (CDC) [redacted]; Strid, Penelope (CDC) [redacted]; Abara, Winston E (CDC) [redacted] Mcneil, Michael M (CDC) [redacted]; Myers, Tanya R (CDC) [redacted] Hause, Anne M (CDC) [redacted]; Menschik, David [redacted]; Baer, Bethany [redacted]; Su, John (CDC) [redacted]; Shimabukuro, Tom (CDC) [redacted]; Shay, David K (CDC) [redacted]
Subject: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond
Importance: High

Dear co-authors,

Thank you so much for all of your hard work and feedback on the 6 month safety review manuscript. The manuscript has been revised based on all of your feedback, and we're in a good position to submit to CDC clearance.

Please double check your names/degrees to make sure I haven't made any mistakes and that you are listed appropriately.

If you agree with submission of the draft in its current form, please reply with "I, **NAME**, approve submission of the manuscript titled 'Reactogenicity and Adverse Events during the First Six Months of mRNA COVID-19 Vaccination in the United States: A Prospective Observational Study of Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe ' to clearance and to journal publication."

We are planning to submit to the journal *Lancet ID* and the formatting of the draft matches their requirements.

All the very best,
Hannah

Hannah G. Rosenblum, MD
Epidemic Intelligence Service Officer

HPV Team, Viral Vaccine-Preventable Diseases Branch
Division of Viral Diseases, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: "Menschik, David" <[redacted]
To: "Su, John (CDC/DDID/NCEZID/DHQP)" [redacted]
Subject: data mining limitations
Date: Wed, 22 Sep 2021 16:33:23 -0000
Importance: Normal
Attachments: mRNA_6mo_safety_review-update98forOS_091521.docx

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Hi John,

In the mRNA vaccine review article that we're co-authors on, we recently expanded data mining limitations section as per attached work-in-progress draft (Hannah indicated acceptance of the language) and excerpt below for convenience:

> EB data mining has multiple limitations[22] including that an absence of a disproportionality alert does not rule out presence of a safety problem. Additionally, since most reports received during this surveillance period involved COVID-19 vaccines, disproportionately scores (which are adjusted by year to control for time-dependent, potentially confounding, exposure and outcome variables) can be muted by COVID-19 vaccine reports contributing substantially to the comparator group, particularly if both mRNA COVID-19 vaccines are associated with the same adverse event.

Thought it might be helpful to share this manuscript update with you, especially if folks on your end may be placing excess value on data mining alerts (EB05>2) or the absence of specific data mining alerts.

Best,
David

PS: If you'd like to discuss more, happy to do so by phone (better suited than email…)

Reactogenicity and Adverse Events during the First Six Months of mRNA COVID-19 Vaccination in the United States: A Prospective Observational Study of Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe

Hannah G. Rosenblum, MD[1,2]; Julianne M. Gee, MPH[1]; Ruiling Liu, PhD[1]; Paige L. Marquez, MSPH[1]; Bicheng Zhang, MS[1]; Penelope Strid, MPH[1], Winston E. Abara, MD[1]; Michael M. McNeil, MD, MPH[1]; Lauri E. Markowitz, MD[1]; Tanya R. Myers, PhD[1]; Anne M. Hause, PhD, MSPH[1]; John R. Su, MD, PhD[1]; Bethany Baer, MD[3]; David Menschik, MD, MPH[3]; Tom T. Shimabukuro, MD, MPH, MBA[1], David K. Shay, MD, MPH[1]

[1]CDC COVID-19 Response Team, Centers for Disease Control and Prevention, Atlanta, Georgia

[2]Epidemic Intelligence Service, Centers for Disease Control and Prevention, Atlanta, Georgia

[3]Food and Drug Administration, Silver Spring, Maryland

Corresponding author: Julianne Gee [redacted]

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 Food and Drug Administration (FDA)

Acknowledgements

We wish to acknowledge the following contributors: CDC: Amelia Jazwa, Tara Johnson, Charles Licata, Stacey Martin; FDA: Jane Baumblatt, Deborah Thompson, Kerry Welsh, Narayan Nair, Kosal Nguon (Commonwealth Informatics); v-safe participants; Oracle v-safe development team. Mention of a product or company name is for identification purposes only and does not constitute endorsement by the CDC or the FDA.

Target journal: Lancet ID

Manuscript word count: ***/3500

Abstract (word count: 233/250)

Background: In December 2020, two mRNA-based COVID-19 vaccines were authorized for use in the United States. Vaccine safety was monitored using Vaccine Adverse Event Reporting System (VAERS), a national passive surveillance system, and v-safe, an active surveillance system.

Methods: VAERS and v-safe data from December 14, 2020—June 14, 2021 were analyzed. Empirical Bayesian data mining was used to identify disproportional reporting of events by vaccine in VAERS. Proportions of v-safe participants reporting local and systemic reactions or health impacts the week following first and second vaccine doses were determined.

Findings: During the analytic period, 298,792,852 total doses of mRNA vaccines were administered in the United States. VAERS received and processed 340,522 reports; 92·1% were classified as non-serious; 6·6%: serious, non-death; and 1·3% as death. Over half of 7,914,583 v-safe participants self-reported local and systemic reactogenicity, more frequently after dose 2. Injection-site pain, fatigue, and headache were most commonly reported during days 0–7 following vaccination. Reactogenicity was reported most frequently one day after vaccination and rapidly declined; most reported reactions were mild. More reports of being unable to work or do normal activities occurred after dose 2 (32·1%) than dose 1 (11·9%); <1% of participants reported seeking medical care after vaccination.

Interpretation: Safety data from >298 million doses of mRNA COVID-19 vaccine administered in the first 6 months of the U.S. vaccination program show the majority of reported adverse events were mild and short in duration.

Funding: No external sources of funding were used. CDC received nonfinancial technical support to develop and maintain the v-safe infrastructure from Oracle.

Commented [RH(1]: Note all death results/interpretation has been removed from abstract
Rosenblum, Hannah (CDC)
2021-09-08 10:30:00

Introduction

In December 2020, two messenger RNA (mRNA) coronavirus disease 2019 (COVID-19) vaccines (BNT162b2 developed by Pfizer-BioNTech and mRNA-1273 developed by Moderna) were granted Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) as 2-dose series and recommended for use by the Advisory Committee on Immunization Practices (ACIP).[1,2] The mRNA vaccine platform uses lipid nanoparticles as a carrier system for the mRNA which encodes the SARS-COV-2-spike protein. In clinical trials, both mRNA COVID-19 vaccines had acceptable safety profiles.[3,4] Reactogenicity (i.e., local and systemic reactions) was observed after receipt of vaccine in clinical trials of both vaccines; the most frequently reported symptoms included injection site pain, fatigue, and headache. Reactogenicity was more frequently reported following dose 2, and more common among participants aged <65 years.[3-5]

Commented [BR(2]: Sounds awkward as written. Actually, the lipid nanoparticles envelop the mRNA, which encodes the genetic sequence information for the viral SARS-CoV-2 spike protein. Another way to put it "The messenger RNA vaccine platform uses lipid nanoparticles as a carrier system for the mRNA which encodes the SARS-CoV-2 spike protein".
Office of Science
2021-08-11 07:50:00

Commented [RH(3R2]: thanks- has been edited
Rosenblum, Hannah (CDC)
2021-08-17 14:32:00

Post-authorization safety monitoring is necessary to better understand the safety profiles of mRNA-based COVID-19 vaccines in larger and more heterogeneous populations.[6] Phased administration of COVID-19 vaccines in the United States began with healthcare workers and residents of long-term care facilities and expanded to the general population by spring 2021; however, implementation plans varied by state.[7] The Vaccine Adverse Event Reporting System (VAERS), a spontaneous reporting (i.e., passive surveillance) system,[8] and v-safe,[9] a new active monitoring system, were the primary safety data sources used in initial reports of adverse events following administration of COVID-19 vaccines in the United States vaccination program.[10-11] Since the inception of the program, regular vaccine safety updates from these systems have been provided through websites, publications, and presentations to advisory committees.[10-14] Here, we review VAERS and v-safe safety data during the first six months of the U.S. vaccination program, when over 298 million doses of mRNA COVID-19 vaccines were administered.

Methods

VAERS

VAERS is an established, national spontaneous reporting system that serves as an early warning system for detecting potential safety problems for vaccines authorized or licensed in the United States.[8] Co-administered by Centers for Disease Control and Prevention (CDC) and FDA, VAERS accepts reports from health care providers, manufacturers, and the public. VAERS reports include information about the vaccinated person, type of vaccine administered, and the adverse event (AE) experienced. For this analysis, VAERS reports submitted and processed by June 14, 2021 were included.[15] Processed reports were those checked for data quality, de-duplicated, and coded using the Medical Dictionary for Regulatory Activities (MedDRA) terminology.[8] Each VAERS report may be assigned more than one MedDRA Preferred Term (PT); PTs do not necessarily indicate a medically confirmed diagnosis, and include signs and symptoms of illness and results of diagnostic tests.

Based on the Code of Federal Regulations,[16] VAERS reports were classified as serious if any of the following were documented: hospitalization, prolongation of existing hospitalization, permanent disability, life-threatening illness, congenital anomaly or birth defect, or death. Adverse events of special interest (AESI)[17] were selected for enhanced COVID-19 vaccine safety monitoring based on biologic plausibility, previous vaccine safety experience, and theoretical concerns related to COVID-19.[17] Death certificates and autopsy reports were requested for death reports. CDC physicians reviewed VAERS reports and available death certificates for each decedent to form an impression about cause of death. Causes of death were further categorized into the following groups, using the National Center for Health Statistics the 15 most common major *International Classification of Disease, Tenth Revision (ICD-10)* diagnostic categories reported on U.S. death certificates[18]: COVID-19 disease; other (i.e., diagnosis did not belong in one of the other pre-specified categories); or unknown/unclear if a likely cause could not be determined.

V-safe

V-safe is a voluntary smartphone-based system that uses text messaging and secure web-based surveys to actively monitor vaccine safety, and has been specifically designed to gather information about COVID-19 vaccine AEs, particularly for common local injection site and systemic reactions.[19] V-safe participants receive text messages that link to web-based health check-ins and respond to questions in surveys following vaccination, initially daily (days 0–7), then weekly (days 14–42) and lastly at 3, 6 and 12 months post vaccination. The system resets to the initial survey frequency after receipt of dose 2. We analyzed survey reports from days 0–7 for reactogenicity, severity[9] (mild, moderate, severe), and health impact (i.e., unable to perform normal daily activities, unable to work, and/or received care from a medical professional). Participants who reported receiving medical care were contacted by v-safe staff and VAERS reports were completed if clinically indicated.

Data analyses

We conducted descriptive analyses of available VAERS and v-safe data from December 14, 2020–June 14, 2021 following first and second doses of BNT162b2 and mRNA-1273 vaccines. For VAERS, bivariate analyses included sex, age groups, race/ethnicity, serious AEs, time from vaccination to reported death (i.e., onset interval) for death reports, cause of death for death reports, and vaccine type/manufacturer administered. Unadjusted, crude reporting rates to VAERS were calculated for AEs using the total number of doses of mRNA vaccine administered during the six-month period. COVID-19 vaccine administration data were provided through CDC's COVID-19 Data Tracker.[20]

Empirical Bayesian (EB) data mining was used to detect disproportional reporting of post-vaccine outcomes by vaccine received among all VAERS serious and non-serious reports received by June 14, 2021.[21] This statistical method calculates observed to expected PT pairings by comparing a specific vaccine-PT pair to all vaccine-PT pairs in VAERS, adjusting for age, sex, and year of vaccination.[22]

Commented [RH(4]: I removed crude everywhere else, but I think good to leave here- what do others think?
Rosenblum, Hannah (CDC)
2021-09-08 11:49:00

Commented [BR(5]: Required:
This is unclear to the general reader. Please clarify "disproportionately" to what.
Office of Science
2021-08-11 12:05:00

Commented [RH(6R5]: Thank you- this is a typo! It should have read "disproportionately" but rather "disproportionality" or as I have modified it to "disproportional reporting". Thank you!!
Rosenblum, Hannah (CDC)
2021-08-11 17:03:00

Commented [BR(7]: Required: It is unclear how the rate of expected PT pairings were determined. Please explain.
Office of Science
2021-08-11 09:45:00

Commented [RH(8R7]: Have expanded the phrase and re-checked the references as well as added another reference suggested by FDA. Thank you!

Rosenblum, Hannah (CDC)
2021-08-11 17:04:00

These ratios are ranked by the lower 5% bound of the EB geometric mean confidence interval (EB05) and a standard alert threshold of EB05 >2 was used. An EB05 >2 represents a high degree of confidence that a vaccine-PT pair was reported at least twice as frequently as expected. In addition to overall ratios, ratios were calculated for age group, sex, serious reports, and death reports.

V-safe participants who responded to at least one health check-in survey during day 0–7 after vaccination were included in analyses. Descriptive statistics were calculated for participants characteristics (sex, age, race/ethnicity), reaction (type and severity) and health impact by manufacturer, dose number, and number of days following vaccination.

SAS software, version 9.4 (SAS Institute; Cary, NC, USA) was used for analyses. Both VAERS and v-safe conduct surveillance as a public health function and are exempt from institutional review board review. Activities were reviewed by the CDC and were conducted in accordance with applicable federal law and CDC policy (See: 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.).

Results

During December 14, 2020–June 14, 2021, a total of 298,792,852 doses of mRNA COVID-19 vaccines were administered in the United States: 167,177,332 were BNT162b2 and 131,639,515 were mRNA-1273 (Supplemental Table 1). A greater proportion of vaccines were administered to females (53·2%) compared with males (45·8%). The median age at vaccination was 50 years (inter-quartile range [IQR]: 33–65) for BNT162b2 and 56 years (IQR: 39–68) for mRNA-1273, respectively. Non-Hispanic White persons accounted for 38·4% of vaccine recipients; however, race/ethnicity was unknown for 34·9% of all vaccine recipients.

VAERS

During the analytic period, VAERS received and processed a total of 340,522 reports: 164,669 were following BNT162b2 and 175,816 were following mRNA-1273 vaccine administration (Table 1). Of these reports, 92·1% were classified as non-serious, 6·6% were serious, not resulting in a death (non-death), and 1·3% were deaths. Seventy-two percent of reports were among females, and 45·3% of reports were among vaccine recipients aged 18–49 years; median age was 50 years (IQR: 36–64). Fifty percent of those reporting race/ethnicity identified as non-Hispanic White; for 22·1%, race/ethnicity was unknown. The most common MedDRA PTs among non-serious reports were headache (20·4%), fatigue (16·6%), pyrexia (16·3%), chills (15·7%), and pain (15·2%). The most common MedDRA PTs among serious reports were dyspnea (15·4%), death (14·1%), pyrexia (11·0%), fatigue (9·7%), and headache (9·5%). The reporting rate to VAERS was 1,049 non-serious reports per million doses, and 90 serious reports per million doses (Table 2). Among the pre-specified AESIs, reporting rates ranged from 0·1 narcolepsy reports per million doses administered to 32 COVID-19 disease reports per million doses administered.

There were 4,496 reports of death in VAERS (Table 3). After review, 24 reports were excluded because of miscoding of death or duplicate reporting. Of the 4,472 reports of deaths analyzed, 2,087 (46·7%) were reported following BNT162b2 and 2,385 (53·3%) following mRNA-1273. Females accounted for 42·6% of reported deaths; the median age of decedents was 76 years (IQR: 66–86). More than 80% of deaths were reported among individuals aged 60 years or older (reporting rate of death per million doses administered by age group: 60–69 years, 2·6; 70–79 years, 3·7; 80–89 years, 3·8; ≥90 years, 2·1).18·3% of decedents were identified as long-term care facility residents. Death certificates or autopsy reports were available for clinical review for 808 (18·1%) reports of deaths analyzed (Table 4). Among these 808 reports, causes of death were most commonly diseases of the heart (46·5%) and COVID-19 disease (12·6%). Causes of death among reports with death certificate or autopsy available are shown by age in Figure 1 and Supplemental Table 2. Among the 3,664 reports of death without a death certificate or

Commented [RH(9]: These figures/tables are new
Rosenblum, Hannah (CDC)
2021-09-08 11:54:00

autopsy, causes of death were most commonly unknown/unclear (54·1%), diseases of the heart (17·0%), and COVID-19 disease (8·7%). Supplemental Table 3 displays specific impressions within each category of cause of death, for all deaths, and for those with death certificate or autopsy. Time interval to death following vaccination was available for 4,119 reports (92·1%) and the median time interval was 10·0 days (range: 0—161 days) after vaccination. The greatest number of reports of deaths occurred on day 1 (10·5%) and day 2 (7·0%) following vaccination (Supplemental Figure 1).

Commented [RH(10]: Not sure if sentence needed
Rosenblum, Hannah (CDC)
2021-09-08 11:56:00

EB Data Mining

No adverse health outcome alerts were identified in EB data mining. However, five mRNA COVID-19 alerts with disproportionality (EB05>2) were identified during the surveillance period. For BNT162b2 vaccine, 'product preparation issue' alerted among all reports (EB05: 2·09; N=757), and among adults ≥65 years (EB05: 2·10; N=205), females (EB05: 2·03; N=394), and males (EB05: 2·01; N=350). Two terms for BNT162b2 vaccine alerted in adults ≥65 years: 'investigation' (EB05: 2.06; N=163) and 'weight' (EB05: 2·01; N=139). For mRNA-1273 vaccine, two terms alerted among all reports: 'poor quality product administered' (EB05: 2·43; N=1,506), and 'product temperature excursion issue' (EB05: 2·17; N=720).

v-safe

During the analytic period, 7,914,583 mRNA COVID-19 vaccine recipients enrolled in v-safe and completed at least one post-vaccination health survey during days 0–7 after vaccination (Table 5). The median age of v-safe participants was 50 years (IQR: 36–63), 62·9% were female, and 59·4% identified as non-Hispanic White. A total of 6,775,515 participants completed at least one survey during day 0–7 after dose 1 (3,455,778 following BNT162b2 and 3,319,737 following mRNA-1273). Of these participants, 68·6% reported a local injection site reaction and 52·7% reported a systemic reaction. Of the 5,674,420 participants who completed a survey after dose 2, a greater percentage reported an injection site

reaction (71·7%) and/or a systemic reaction (70·8%) (Table 6). Local injection site reactions were reported more frequently after mRNA-1273 (dose 1: 73·3%; dose 2: 78·4%) than after BNT162b2 (dose 1: 64·0%; dose 2: 65·3%). A similar pattern was found for systemic reactions after mRNA-1273 (dose 1: 54·3%; dose 2: 75·8%) versus BNT162b2 (dose 1: 51·3%; dose 2: 66·1%). The most frequently reported events after dose 1 of either mRNA vaccine included injection site pain (66·2%), fatigue (33·9%), and headache (27·0%); these reactions were also more frequent after dose 2: injection site pain (68·6%), fatigue (55·7%), headache (46·2%). Differences in proportions of reactogenicity by dose number were similar after stratifying by age group (<65 vs. ≥65 years) and sex. More reactogenicity was reported among younger participants aged <65 years and by females. (Supplemental Table 4).

Proportions of reported severity of reactions by manufacturer, dose number, and day since vaccination are shown in Figure 2. The majority of reported symptoms were mild. Participants reported moderate and severe reactogenicity most commonly on day 1 after dose 2 of either vaccine. The proportion of participants who reported symptoms was greatest on day 1 and then decreased on subsequent days. The highest proportion of participants reported severe symptoms on day 1 following dose 2 of mRNA-1273 (Supplemental Table 6). On all other days, proportions of participants reporting severe symptoms did not exceed 3.0% for any individual symptom (Supplemental Tables 5 and 6).

Reported health impact was greater following dose 2 of either mRNA vaccine (32·1%) compared with dose 1 (11·9%) and after mRNA-1273 of either dose compared with BNT162b2 (Table 6). After dose 1 of either mRNA vaccine, 9·7% of participants were unable to do normal activities and 4·5% were unable to work. After dose 2 of BNT162b2, 20·5% were unable to do normal activities, and 12·3% were unable to work. After dose 2 of mRNA-1273, 32·8% were unable to do normal activities, and 20·0% were unable to work. Less than 1·0% reported receiving medical care after receiving either dose from either manufacturer. Fewer participants reported an emergency room visit (dose 1: 0·1%; dose 2: 0·2%) or hospitalization (dose 1: 0·03%; dose 2: 0·04%).

When stratified by sex, females reported a health impact more frequently than males, peaking on day 1 after vaccination (Supplemental Figure 2). Following dose 2 of mRNA-1273 vaccine, 41·4% of females reported in the day 1 survey an inability to perform normal activities, and 23·5% an inability to work. Among males receiving dose 2 of mRNA-1273 on the day 1 survey, 25·6% were unable to perform normal activity and 16·9% were unable to work (Supplemental Table 7).

Discussion

During the first six months of the U.S. COVID-19 vaccination program, over 298 million doses of mRNA vaccines were administered. COVID-19 vaccine safety in the United States has been monitored with well-established systems, including the Vaccine Safety Datalink[23] and VAERS, and a system developed specifically for COVID-19 vaccine safety monitoring, known as v-safe. The post-authorization safety profile for mRNA COVID-19 vaccines after six months of use in the United States is largely consistent with data presented in the pre-authorization clinical trials.[3,4] Data from U.S. safety monitoring systems have been presented regularly to ACIP's COVID-19 Vaccine Safety Technical Subgroup (VaST) work group[24] and at public ACIP meetings.[25] Data have been presented concerning cases of clinically serious AEs, including anaphylaxis,[13] thrombosis with thrombocytopenia syndrome (TTS),[26] myocarditis,[27] and Guillain-Barré Syndrome (GBS)[28] reported following receipt of COVID-19 vaccines. ACIP has assessed the benefit-risk balance of each of the currently authorized U.S. COVID-19 vaccines; these evaluations have not prompted any changes in U.S. COVID-19 immunization recommendations.[13,27,28]

Our main findings are similar to those obtained from diary-based reporting in pre-authorization clinical trials and early post-authorization reports – data from all reports demonstrate substantial local and systemic reactogenicity.[3-5,10,11] In both VAERS and v-safe, local injection site and systemic reactions were commonly reported, and in v-safe, transient reactions were reported more frequently following mRNA-1273 compared with BNT162b2, and more frequently following dose 2. Overall, females and individuals

aged <65 years reported AEs and reactions more frequently. These findings are similar to those from a large-scale study about reactogenicity conducted in the United Kingdom.[29] Host characteristics known to influence reactogenicity, including age, sex, and the presence of underlying medical conditions, might be associated with this pattern of findings.[30] Females have more vigorous antibody responses[31] to certain vaccines and also tend to report more severe local and systemic reactions to influenza vaccine.[32] Females may also be more likely than males to respond to surveys[33,34] and we hypothesize that younger individuals may be more comfortable with smartphone-based surveys and more likely to respond to survey questions.[35,36]

The impact of vaccination on daily life activities was most frequently reported on the first day after vaccination. Reports about the health impact measures used in v-safe, while self-assessed and subjective, correlate with reports about reactogenicity patterns: more health impact was reported by females than males, by participants aged <65 years compared with older participants, by persons receiving dose 2 compared with dose 1, and by those who received mRNA-1273 versus BNT162b2. Reports of seeking medical care (including telehealth and urgent care) after receipt of either dose of mRNA vaccine were rare, suggesting that reactogenicity was transient and manageable at home. Among those who did report seeking medical care, only a small proportion visited an emergency department or were hospitalized. Reactogenicity and its associated health effects, even if transient, may deter some persons from seeking vaccination. An April 2021 survey conducted by the Kaiser Family Foundation found that nearly half (48%) of unvaccinated adults aged <50 years expressed concern about missing work due to vaccine side effects; this concern was reported by 55% of unvaccinated Black adults and 64% of unvaccinated Hispanic adults.[37] Employees who are provided time off may be more likely to get vaccinated, even after controlling for other demographic factors that might influence vaccine uptake.[38] These data suggest that employee work policies that accommodate days off for vaccination and recovery from side effects may increase vaccination coverage.[39]

Increased public awareness, widespread promotion of VAERS, and outreach and education to healthcare providers about COVID-19 EUA AE reporting requirements are likely all contributing factors to the high volume of VAERS reports following mRNA COVID-19 vaccines as compared to established adult vaccinations.[8] For mRNA COVID-19 vaccines in this six-month period, VAERS has processed and received more than six times the number of average reports per year (typically 50,000 reports are received per year for all vaccines in all age groups).For example, the number of reports of death in VAERS following mRNA vaccine in this period exceeds the number of deaths reported to VAERS for all other vaccines in a summary report from 1997–2013 by eight times.[40] The concentrated reporting of deaths on days 1 and 2 following vaccination may represent reporting bias, as the likelihood to report a serious AE may increase when it occurs in close temporal proximity to vaccination.

Comparing deaths reported to VAERS following mRNA vaccination by cause to national mortality data[41] is challenging, as more common causes of deaths in younger individuals (for example, accidents or suicide) may be less likely to be reported to VAERS. The overrepresentation of diseases of the heart as cause of death in general may be driven by non-specific causes of death on death certificates such as cardiac arrest or cardiopulmonary arrest, which are terminal events, but might be chosen if no immediate explanation is available. Additional studies are needed to characterize deaths in VAERS …???

During the 6-month period we analyzed, patterns of reports to VAERS are similar to other vaccines that are routinely administered to adults and the majority of reported events were non-serious.[42,43,44,45] None of the EB data mining alerts suggested an unexpected vaccine safety problem. Serious AEs have been detected following receipt of COVID-19 vaccines during U.S. safety monitoring and reviewed in detail.[26-28] Early reports of anaphylaxis prompted recommendations about specific clinical management including screening and recommendation of a post-observation period following vaccination.[46] After myocarditis was observed following mRNA vaccination,[47,48] particularly in males aged <30 years, CDC issued clinical guidance and management recommendations,[49] and presented a benefit-risk assessment to ACIP.[27] The risk of TTS[26] and GBS[28] is elevated following receipt of Janssen COVID-19 vaccine (Ad26.COV2.S) and have not been associated with mRNA COVID-19 vaccines to date.

Commented [RH(11]: include total number of vaers reports yearly to highlight overall magnitude through 6 months?
Rosenblum, Hannah (CDC)
2021-09-07 14:51:00

Commented [S(12R11]: Yes, i think that's a good idea
Shay, David (CDC/DDID/NCIRD/ID)
2021-09-08 08:02:00

Commented [RH(13R11]: Tried to use CDC wonder for this and did some literature search, but unable to find a readily available resource to cite- wondering if comparing to the # of deaths is enough to make this point

Rosenblum, Hannah (CDC)
2021-09-08 10:37:00

Commented [RH(14R11]: Received this data from Paige- not sure If I can cite Wonder- asking her…
Rosenblum, Hannah (CDC)

Commented [BR(15]: Required:
Rates per million doses administered is not the same as rates per million persons vaccinated. Rates per doses can

Commented [RH(16R15]: Thanks so much – we've removed the text about rate comparisons for the reasons you outlined

Commented [RH(17]: Framing around deaths evaluated after pediatric vaccination-
Vaers hasn't been used to evaluate deaths following

Commented [BR(18]: Required:
This reporting may also reflect a true event. This hypothesis can easily be tested in VAERS. Please discuss whether a

Commented [RH(19R18]: I don't think the other VAERS published data I've seen focuses on the timing of reported deaths so I'm not sure how easily tested this is—any

Commented [S(20R18]: the temp scan results may help here. also, please note that the total number of deaths reported to VAERS following Covid vaccination is far larger

Commented [RH(21R18]: Have the # of deaths exceeded by 8 times in this period—but still not sure how to address OS here- could use help here

Commented [RH(22]: This paragraph is really where I could use some help – I tried to sum some of what we've discussed, and Tom pointed out in his last email- but I feel

Commented [RH(23]: I think this paragraph should come before the deaths paragraph now.
Rosenblum, Hannah (CDC)

Commented [BR(24]: Editorial:
Redundant to say "observation of a post-observation". Please revise.

Commented [RH(25R24]: Thank you - edited
Rosenblum, Hannah (CDC)
2021-08-11 17:07:00

This study has several strengths and several limitations. Strengths include a large sample size and comprehensive capture of national data from two complementary surveillance systems. Data on doses administered are available for estimating reporting rates for VAERS, as the U.S. government provides all COVID-19 and collects administration data from jurisdictions. Therefore, the reporting rates calculated here use the number of mRNA vaccine doses administered as a denominator,[50] while for other vaccines the only denominators available are doses distributed, which is variably larger than dose administered. V-safe data illustrating the effects of mRNA vaccination on daily activities and work during the week following vaccination provide new information has not previously available. Limitations include that VAERS data are based on passive surveillance, and may therefore be subject to underreporting, and variable or incomplete reporting.[8] For this analysis, reports of death in VAERS were individually reviewed by physicians and follow-up is ongoing to obtain additional records for reports of death missing death certificates, autopsy reports, or other medical records; however, not all other serious AE reports were individually reviewed. VAERS reports require interpretation to determine if AE reports meet clinical case definitions.[51] ~~Though~~ EB data mining has multiple limitations[22] including that ~~is used to screen for safety alerts,~~ an absence of a~~n~~ disproportionality alert does not rule out presence of a safety problem. Additionally, since most reports received during this surveillance period involved COVID-19 vaccines, disproportionately scores (which are adjusted by year to control for time-dependent, potentially confounding, exposure and outcome variables) can be muted by COVID-19 vaccine reports contributing substantially to the comparator group, particularly if both mRNA COVID-19 vaccines are associated with the same adverse event. Routine screening of VAERS reports may also not be sensitive enough to pick up true associations, particularly if they occur in specific age groups. V-safe is voluntary and requires smartphone access. Participants are asked about pre-specified reactions; this report focused on the first 7 days post-vaccination. Because a subset of all vaccine recipients chose to participate in v-safe, the results likely are not generalizable to the entire vaccinated population in the United States. Participants in v-safe may also be lost to follow up as there is not a requirement for continuous enrollment.

Commented [BR(26]: Please explain if the v-safe system allows for free text reporting in addition to a list of predefined adverse events.
Office of Science
2021-08-11 10:53:00

Commented [RH(27R26]: Thanks added
Rosenblum, Hannah (CDC)
2021-08-11 17:07:00

Commented [BR(28]: Consider including another limitation of this report: it focused only on AE reported in v-safe for the first 7 days post-vaccination.
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Commented [RH(29R28]: Added to limitations
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2021-08-11 17:07:00

During the first six months of the U.S. COVID-19 vaccination program, more than 50% of the eligible population received at least one dose of COVID-19 vaccine.[20] VAERS and v-safe data from this period demonstrate a post-authorization safety profile for mRNA COVID-19 vaccines that is consistent with pre-authorization trials[3,4] and early post-authorization surveillance reports.[10,11] Serious AEs have been identified following mRNA vaccinations; however, based on the most current information, these events are rare. Vaccines are the most effective tool to preventing serious COVID-19 disease outcomes and the benefits of immunization in preventing serious morbidity and mortality clearly favor vaccination.[26-28] VAERS and v-safe, two complementary surveillance systems, will continue to provide data needed to inform immunization policy makers, medical and immunization providers, and the public about the safety of COVID-19 vaccination.

Research in context

Evidence before this study

We searched PubMed for articles published through July 12, 2021, using the terms ("BNT162b2" or "mRNA-1273" or "mRNA COVID-19 vaccine") AND ("reactogenicity" or "side-effects" or "adverse effects" or "health impact") not restricted by language or type of publication. Among 100 results, publications describing the health impacts following vaccination by BNT162b2 or mRNA-1273 are limited. Available literature from the United States included reports of manufacturer-sponsored phase 1–3 clinical trials. Additionally, we found seven published articles from the United States, one published article from United Kingdom and two preprints from the United States investigating reactogenicity and adverse events in mRNA vaccination. These articles discussed reactogenicity and adverse events following mRNA vaccination. No study included the period through June 2021.

Added value of this study

In this large, observational study, we assessed reactogenicity, health impact, and adverse events reported following mRNA COVID-19 vaccination during the first six months of the U.S. vaccination program. We found that reported reactions to mRNA vaccination were mostly mild in severity and transient in duration, and the great majority of reports were non-serious. Reactions and health impact were reported more frequently in females compared to males, and in individuals aged <65 years compared to older individuals. Health impact information for adults from v-safe is presented here for the first time. Deaths, overall and for specific causes by age, were reported.

Implications of all the available evidence

The findings from complementary surveillance systems from the first six months of mRNA vaccination in the United States are consistent with pre-authorization clinical trials and early post-authorization reports. Mild-to-moderate transient reactogenicity should be anticipated, particularly among younger recipients and female recipients. As these data inform immunization policy recommendations and clinical considerations, the federal monitoring system continues to update the benefit-risk balance of vaccine

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Rosenblum, Hannah (CDC)
2021-08-17 14:37:00

recommendations, particularly in the setting of the association of specific serious adverse events and COVID-19 vaccination.

References

1. Oliver SE, Gargano JW, Marin M, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine - United States, December 2020. *MMWR Morbidity and mortality weekly report 2020*; **69**(50): 1922-4.

2. Oliver SE, Gargano JW, Marin M, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine - United States, December 2020. *MMWR Morbidity and mortality weekly report* 2021; **69**(5152): 1653-6.

3. Polack FP, Thomas SJ, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *The New England Journal of Medicine* 2020; **383**(27): 2603-15.

4. Baden LR, El Sahly HM, Essink B, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *The New England Journal of Medicine* 2021; **384**(5): 403-16.

5. Anderson EJ, Rouphael NG, Widge AT, et al. Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults. *New England Journal of Medicine* 2020; **383**(25): 2427-38.

6. Chen RT, Davis RL, Rhodes PH. Special methodological issues in pharmacoepidemiology studies of vaccine safety. In: Strom BL, editor. Pharmacoepidemiology. 4th John Wiley & Sons; Sussex: 2005

7. Dooling K, McClung N, Chamberland M, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine - United States, 2020. *MMWR Morbidity and mortality weekly report* 2020; **69**(49): 1857-9.

8. Shimabukuro TT, Nguyen M, Martin D, DeStefano F. Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). *Vaccine* 2015; **33**(36): 4398-405.

9. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

10. Gee J, Marquez P, Su J, et al. First Month of COVID-19 Vaccine Safety Monitoring - United States, December 14, 2020-January 13, 2021. *MMWR Morbidity and mortality weekly report* 2021; **70**(8): 283-8.

11. Chapin-Bardales J, Gee J, Myers T. Reactogenicity Following Receipt of mRNA-Based COVID-19 Vaccines. *JAMA* 2021; **325**(21): 2201-2.

12. Shimabukuro TT, Cole M, Su JR. Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021. *JAMA* 2021; **325**(11): 1101-2.

13. Shay DK, Gee J, Su JR, et al. Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine - United States, March-April 2021. *MMWR Morbidity and mortality weekly report* 2021; **70**(18): 680-4.

14. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. *MMWR Morbidity and mortality weekly report* 2021; **70**(2): 46-51.

15. https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html

16. Code of Federal Regulations Title 21
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr

17. https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf

18. https://www.cdc.gov/nchs/nvss/leading-causes-of-death.htm

19. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

20. https://covid.cdc.gov/covid-data-tracker/#datatracker-home 21. Szarfman A, Machado SG, O'Neill RT. Use of screening algorithms and computer systems to efficiently signal higher-than-expected combinations of drugs and events in the US FDA's spontaneous reports database. Drug Saf 2002; **25**(6): 381-92.

22. Martin, D, Menschik D, Bryant-Genevier M, Ball R. Data mining for prospective early detection of safety signals in the Vaccine Adverse Event Reporting System (VAERS): a case study of febrile seizures after a 2010-2011 seasonal influenza virus vaccine. *Drug Saf.* 2013; Jul:**36**(7):547-56.

23. https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html

24. https://www.cdc.gov/vaccines/acip/work-groups-vast/index.html

25. https://www.cdc.gov/vaccines/acip/meetings/index.html

26. MacNeil JR, Su JR, Broder KR, et al. Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients - United States, April 2021. *MMWR Morbidity and mortality weekly report* 2021; **70**(17): 651-6.

27. Gargano JW, Wallace M, Hadler SC, et al. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices - United States, June 2021. *MMWR Morbidity and mortality weekly report* 2021; **70**(27): 977-82.

28. Rosenblum HG, Hadler SC, Moulia D et al. Use of COVID-19 Vaccines After Reports of Adverse Events Among Adult Recipients of Janssen (Johnson & Johnson) and mRNA COVID-19 Vaccines (Pfizer-BioNTech and Moderna): Update from the Advisory Committee on Immunization Practices – United States, July 2021. *MMWR Morbidity and mortality weekly report* 2021: **70**(32); 1094-1099.

29. Menni C, Klaser K, May A, et al. Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID Symptom Study app in the UK: a prospective observational study. *Lancet Infect Dis.* 2021; **21**(7):939-949

30. Hervé C, Laupèze B, Del Giudice G, Didierlaurent AM, Tavares Da Silva F. The how's and what's of vaccine reactogenicity. *NPJ Vaccines* 2019;**4**: 39.

31. Zimmermann P, Curtis N. Factors That Influence the Immune Response to Vaccination. *Clin Microbiol Rev* 2019; **32**(2).

32. Klein SL, Jedlicka A, Pekosz A. The Xs and Y of immune responses to viral vaccines. *Lancet Infect Dis* 2010; **10**(5): 338-49.

33. Pathiravasan CH, Zhang Y, Trinquart L, et al. Adherence of Mobile App-Based Surveys and Comparison With Traditional Surveys: eCohort Study. *J Med Internet Res* 2021; **23**(1): e24773.

34. Guo X, Vittinghoff E, Olgin JE, Marcus GM, Pletcher MJ. Volunteer Participation in the Health eHeart Study: A Comparison with the US Population. *Sci Rep* 2017; 7(1): 1956.

35. Millar MM, Elena JW, Gallicchio L, et al. The feasibility of web surveys for obtaining patient-reported outcomes from cancer survivors: a randomized experiment comparing survey modes and brochure enclosures. *BMC Med Res Methodol* 2019; **19**(1): 208.

36. Messer BL, Dillman DA. Surveying the General Public over the Internet Using Address-Based Sampling and Mail Contact Procedures. *Public Opinion Quarterly* 2011; **75**(3): 429-57.

37. https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-april-2021/

38. https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-june-2021/

39. https://www.whitehouse.gov/briefing-room/statements-releases/2021/04/21/fact-sheet-president-biden-to-call-on-all-employers-to-provide-paid-time-off-for-employees-to-get-vaccinated-after-meeting-goal-of-200-million-shots-in-the-first-100-days/

40. Moro PL, Arana J, Cano M, Lewis P, Shimabukuro TT. Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997-2013. Clin Infect Dis 2015; 61(6): 980-7.

41. Murphy SL, Xu J, Kochanek KD, Arias E, Tejada-Vera B. Deaths: Final Data for 2018. Natl Vital Stat Rep 2021; **69**(13): 1-83.

42. Miller ER, Lewis P, Shimabukuro TT, et al. Post-licensure safety surveillance of zoster vaccine live (Zostavax®) in the United States, Vaccine Adverse Event Reporting System (VAERS), 2006-2015. *Human vaccines & immunotherapeutics* 2018; **14**(8): 1963-9

43. Moro PL, Haber P, McNeil MM. Challenges in evaluating post-licensure vaccine safety: observations from the Centers for Disease Control and Prevention. *Expert Review of Vaccines* 2019; **18**(10): 1091-101

44. Haber P, Moro PL, Ng C, et al. Safety review of tetanus toxoid, reduced diphtheria toxoid, acellular pertussis vaccines (Tdap) in adults aged ≥65 years, Vaccine Adverse Event reporting System (VAERS), United States, September 2010-December 2018. *Vaccine* 2020; **38**(6): 1476-80

45. Woo EJ, Moro PL. Postmarketing safety surveillance of quadrivalent recombinant influenza vaccine: Reports to the vaccine adverse event reporting system. *Vaccine* 2021; **39**(13): 1812-7.

46. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fanaphylaxis-management.html

47. Abu Mouch S, Roguin A, Hellou E, et al. Myocarditis following COVID-19 mRNA vaccination. Vaccine 2021.

48. Marshall M, Ferguson ID, Lewis P, et al. Symptomatic Acute Myocarditis in Seven Adolescents Following Pfizer-BioNTech COVID-19 Vaccination. *Pediatrics* 2021 Jun 4;e2021052478. *Online ahead of print*

49. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html

50. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/distributing/first-doses.html

51. https://vaers.hhs.gov/data/dataguide.html

52. https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html

***Table* 1: Characteristics of reports received and processed by Vaccine Adverse Events Reporting System (VAERS) for mRNA COVID-19 vaccines—December 14, 2020–June 14, 2021**

	Both mRNA vaccines† (n=340,522)	BNT162b2 vaccine (n=164,669)	mRNA-1273 vaccine (n=175,816)
Reports			
Non-serious adverse event reports	313,499 (92·1)	150,486 (91·4)	162,977 (92·7)
Serious reports, including death	27,023 (7·9)	14,183 (8·6)	12,839 (7·3)
Serious, non-death adverse event reports	22,527 (6·6)	12,078 (7·3)	10,448 (5·9)
Death	4,496 (1·3)	2,105 (1·3)	2,391 (1·4)
Sex			
Female	246,085 (72·3)	116,587 (70·8)	129,475 (73·6)
Male	88,311 (25·9)	45,157 (27·4)	43,140 (24·5)
Unknown	6,126 (1·8)	2,925 (1·8)	3,201 (1·8)
Age (years)			
16–17	6,874 (2·0)	3,283 (2·0)	3,591 (2·0)
18–49	154,171 (45·3)	76,385 (46·4)	77,773 (44·2)
50–64	84,949 (24·9)	40,367 (24·5)	44,572 (25·4)
65–74	49,755 (14·6)	20,048 (12·2)	29,702 (16·9)
75–84	21,418 (6·3)	9,021 (5·5)	12,392 (7·1)
≥85	7,595 (2·2)	3,564 (2·2)	4,027 (2·3)
Unknown	15,760 (4·6)	12,001 (7·3)	3,759 (2·1)
Race/Ethnicity			
Hispanic/Latino	23,480 (6·9)	11,217 (6·8)	12,260 (7·0)
Non-Hispanic			
White	169,877 (49·9)	73,398 (44·6)	96,469 (54·9)
Black	10,446 (3·1)	5,104 (3·1)	5,342 (3·0)
Asian	10,172 (3·0)	5,038 (3·1)	5,131 (2·9)
American Indian or Alaska Native	1,414 (0·4)	615 (0·4)	799 (0·5)
Native Hawaiian or Other Pacific Islander	441 (0·1)	209 (0·1)	232 (0·1)
Multiple races	3,542 (1·0)	1,578 (1·0)	1,964 (1·1)
Other races	1,684 (0·5)	808 (0·5)	876 (0·5)
Unknown race	2,593 (0·8)	1,422 (0·9)	1,171 (0·7)
Unknown ethnicity			
White	28,787 (8·5)	15,497 (9·4)	13,289 (7·6)
Black	4,189 (1·2)	2,524 (1·5)	1,662 (1·0)
Asian	2,435 (0·7)	1,396 (0·9)	1,039 (0·6)
American Indian or Alaska Native	724 (0·2)	348 (0·2)	375 (0·2)
Native Hawaiian or Other Pacific Islander	105 (0·03)	56 (0·03)	49 (0·03)
Multiple races	590 (0·2)	301 (0·2)	289 (0·2)
Other races	4,709 (1·4)	2,838 (1·7)	1,870 (1·1)
Unknown race and ethnicity	75,334 (22·1)	42,320 (25·7)	32,999 (18·8)
Signs or symptoms most frequently reported, non-serious*			
Headache	64,064 (20·4)	30,907 (20·5)	33,154 (20·3)
Fatigue	52,048 (16·6)	24,805 (16·5)	27,241 (16·7)
Pyrexia	51,023 (16·3)	22,185 (14·7)	28,837 (17·7)
Chills	49,234 (15·7)	21,638 (14·4)	27,595 (16·9)
Pain	47,745 (15·2)	21,506 (14·3)	26,238 (16·1)
Nausea	37,333 (11·9)	18,066 (12·0)	19,267 (11·8)
Dizziness	37,257 (11·9)	20,307 (13·5)	16,950 (10·4)
Pain in extremity	31,753 (10·1)	14,098 (9·4)	17,653 (10·8)
Injection site pain	28,949 (9·2)	10,462 (7·0)	18,487 (11·3)
Injection site erythema	22,351 (7·1)	2,991 (2·0)	19,360 (11·9)
Signs or symptoms most frequently reported, serious*			
Dyspnea	4,175 (15·4)	2,210 (15·6)	1,965 (15·3)
Death‡	3,802 (14·1)	1,753 (12·4)	2,039 (15·9)
Pyrexia	2,986 (11·0)	1,469 (10·4)	1,517 (11·8)
Fatigue	2,608 (9·7)	1,395 (9·8)	1,213 (9·4)
Headache	2,567 (9·5)	1,360 (9·6)	1,207 (9·4)
Chest pain	2,300 (8·5)	1,310 (9·2)	990 (7·7)
Nausea	2,228 (8·2)	1,160 (8·2)	1,068 (8·3)
Pain	2,222 (8·2)	1,195 (8·4)	1,027 (8·0)
Asthenia	2,194 (8·1)	1,084 (7·6)	1,110 (8·6)
Dizziness	2,069 (7·7)	1,111 (7·8)	958 (7·5)

Data are n (%).
*Symptoms refers to MedDRA preferred terms (PTs) and are ordered by most frequently reported for both vaccines. MedDRA PTs are not mutually exclusive.
†Total includes reports without a vaccine manufacturer listed.
‡Not all reports of death were coded with the MedDRA PT of 'death'

***Table* 2: Frequency and reporting rates of adverse events of special interest reported to Vaccine Adverse Event Reporting System (VAERS) by recipients of mRNA COVID-19 vaccine—December 14, 2020–June 14, 2021**

	Both mRNA vaccines		BNT162b2 vaccine		mRNA-1273 vaccine	
	n	Reports per million doses*	n	Reports per million doses†	n	Reports per million doses‡
Non-serious adverse event reports	313,499	1,049·2	150,486	900·2	162,977	1,238·1
Serious reports, including death	27,023	90·4	14,183	84·8	12,839	97·5
Serious, non-death adverse event reports	22,527	75·4	12,078	72·2	10,448	79·4
Reports§ of adverse events of special interest**						
COVID-19	9,344	31·3	7,184	43·0	2,160	16·4
Coagulopathy††	4,320	14·5	2,343	14·0	1,977	15·0
Seizure	2,733	9·1	1,478	8·8	1,255	9·5
Stroke‡‡	1,937	6·5	981	5·9	955	7·3
Bells' Palsy	1,918	6·4	1,057	6·3	861	6·5
Anaphylaxis	1,639	5·5	972	5·8	667	5·1
Myopericarditis	1,307	4·4	813	4·9	494	3·8
Acute Myocardial Infarction	1,118	3·7	610	3·6	508	3·9
Appendicitis	383	1·3	258	1·5	125	1·0
Guillain-Barré Syndrome	293	1·0	154	0·9	139	1·1
Multisystem Inflammatory Syndrome in Adults	119	0·4	60	0·4	59	0·4
Transverse Myelitis	98	0·3	55	0·3	43	0·3
Narcolepsy	21	0·1	12	0·1	9	0·1

*298,792,852 doses of mRNA vaccine were administered in the study period.
†167,177,332 doses of BNT162b2 vaccine were administered in the study period.
‡131,639,515 doses of mRNA-1273 vaccine were administered in the study period.
§These represent reports, not confirmed by case definition.
**Reported death is an adverse event of special interest but counts appear in following tables. Events are not mutually exclusive.
††Coagulopathy is an aggregate term capturing three specific adverse events: 1) thrombocytopenia, 2) deep venous thrombosis/pulmonary embolism, and 3) disseminated intravascular coagulopathy.
‡‡No vaccine manufacturer was provided for one report of stroke.

***Table* 3: Characteristics of deaths reported to Vaccine Adverse Event Reporting System (VAERS) by recipients of mRNA COVID-19 vaccine—December 14, 2020–June 14, 2021**

	Both mRNA vaccines (n=4,472*)		BNT162b2 vaccine (n=2,087)		mRNA-1273 vaccine (n=2,385)	
	n (%)	Reports per million doses†	n (%)	Reports per million doses‡	n (%)	Reports per million doses §
Sex						
Female	1,906 (42·6)	6·4	918 (44·0)	5·5	988 (41·4)	7·5
Male	2,486 (55·6)	8·3	1,117 (53·5)	6·7	1,369 (57·4)	10·4
Unknown	80 (1·8)	0·3	52 (2·5)	0·3	28 (1·2)	0·2
Age (years)						
16–17	6 (0·1)	0·02	6 (0·3)	0·04	..	..
18–29	51 (1·1)	0·2	27 (1·3)	0·2	24 (1·0)	0·2
30–39	94 (2·1)	0·3	50 (2·4)	0·3	44 (1·8)	0·3
40–49	151 (3·4)	0·5	74 (3·5)	0·4	77 (3·2)	0·6
50–59	328 (7·3)	1·1	132 (6·3)	0·8	196 (8·2)	1·5
60–69	765 (17·1)	2·6	354 (17·0)	2·1	411 (17·2)	3·1
70–79	1,118 (25·0)	3·7	497 (23·8)	3·0	621 (26·0)	4·7
80–89	1,128 (25·2)	3·8	529 (25·3)	3·2	599 (25·1)	4·6
≥90	637 (14·2)	2·1	302 (14·5)	1·8	335 (14·0)	2·5
Unknown	194 (4·3)	0·6	116 (5·6)	0·7	78 (3·3)	0·6

*Of 4,496 deaths, 24 were excluded as they could not be confirmed or were duplicate reports upon review.
†298,792,852 doses of mRNA vaccine were administered in the study period.
‡167,177,332 doses of BNT162b2 vaccine were administered in the study period.
§131,639,515 doses of mRNA-1273 vaccine were administered in the study period.

***Table* 4: Most common causes of death among reports received and processed by Vaccine Adverse Event Reporting System (VAERS) following mRNA COVID-19 vaccination (n=4,472)—December 14, 2020–June 14, 2021**

	Death or autopsy certificate available			No death certificate or autopsy available		
ICD-10 Major Group	**Both mRNA vaccines** (n=808)	**BNT162b2 vaccine** (n=401)	**mRNA-1273 vaccine** (n=407)	**Both mRNA vaccines** (n=3,664)	**BNT162b2 vaccine** (n=1,686)	**mRNA-1273 vaccine** (n=1,978)
All reported deaths						
Diseases of the heart	376 (46·5)	161 (40·1)	215 (52·8)	622 (17·0)	296 (17·6)	326 (16·5)
COVID-19 disease	102 (12·6)	62 (15·5)	40 (9·8)	317 (8·7)	178 (10·6)	139 (7·0)
Other	68 (8·4)	38 (9·5)	30 (7·4)	141 (3·8)	68 (4·0)	73 (3·7)
Cerebrovascular diseases	53 (6·6)	28 (7·0)	25 (6·1)	207 (5·6)	101 (6·0)	106 (5·4)
Dementia	41 (5·1)	20 (5·0)	21 (5·2)	9 (0·2)	3 (0·2)	6 (0·3)
Chronic lower respiratory diseases	28 (3·5)	17 (4·2)	11 (2·7)	29 (0·8)	10 (0·6)	19 (1·0)
Malignant neoplasms	27 (3·3)	15 (3·7)	12 (2·9)	68 (1·9)	42 (2·5)	26 (1·3)
Unknown/unclear	27 (3·3)	9 (2·2)	18 (4·4)	1,984 (54·1)	844 (50·1)	1,140 (57·6)
Septicemia	23 (2·8)	12 (3·0)	11 (2·7)	72 (2·0)	47 (2·8)	25 (1·3)
Influenza and pneumonia	22 (2·7)	18 (4·5)	4 (1·0)	113 (3·1)	52 (3·1)	61 (3·1)
Accidents/unintentional injuries	11 (1·4)	3 (0·7)	8 (2·0)	22 (0·6)	8 (0·5)	14 (0·7)
Renal disease	8 (1·0)	5 (1·2)	3 (0·7)	25 (0·7)	7 (0·4)	18 (0·9)
Hematologic disease, other than malignancy	7 (0·9)	5 (1·2)	2 (0·5)	19 (0·5)	9 (0·5)	10 (0·5)
Pneumonitis due to solids and liquids	6 (0·7)	3 (0·7)	3 (0·7)	8 (0·2)	5 (0·3)	3 (0·2)
Diabetes mellitus	4 (0·5)	1 (0·2)	3 (0·7)	6 (0·2)	4 (0·2)	2 (0·1)
Chronic liver disease and cirrhosis	4 (0·5)	3 (0·7)	1 (0·2)	7 (0·2)	4 (0·2)	3 (0·2)
Intentional self-harm	1 (0·1)	1 (0·2)	0 (0·0)	15 (0·4)	8 (0·5)	7 (0·4)

Data are n (%).

(new) Table 5: **Observed deaths vs. expected deaths in a 7-day risk period (need footnotes to Abara paper)**

Commented [RH(32]: Note this is the 5th VAERS table (compared to 2 v-safe and 1 v-safe figure) and the 3rd table regarding death

Rosenblum, Hannah (CDC)
2021-09-09 10:39:00

	Expected		Observed (reported in VAERS)					
	All-cause death rates per million vaccinated persons		Both mRNA vaccines n (rate per vaccinated persons)		BNT162b2 vaccine n (rate per million doses administered)		mRNA-1273 vaccine n (rate per million doses administered)	
	Within 7 days of vaccination	Within 42 days of vaccination	Within 7 days of vaccination	Within 42 days of vaccination	Within 7 days of vaccination	Within 42 days of vaccination	Within 7 days of vaccination	Within 42 days of vaccination
Age (years)								
16–24**	14.2	85.1	14	26	9	17	5	9
25–34	25.5	152.7	32	56	18	31	14	25
35–44	37.4	224.5	54	97	28	47	26	50
45–54	77.0	461.7	118	200	55	91	63	109
55–64	169.8	1,018.6	247	453	99	201	148	252
65–74	343.2	2,059.4	457	878	207	385	250	493
75–84	857.2	5,143.0	412	908	180	396	232	512
≥85	2,601.4	15,608.3	437	980	202	448	235	532
Unknown	--	--	28	40	13	16	15	24
Total	165.6	993.3	1,799	3,638	811	1,632	988	2,006

*calculated from Abara paper per 10,000,000

**Abara paper is 15-24. Age 15 was not included in this paper

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***Table* 5: Demographic characteristics of v-safe participants reporting receipt of mRNA COVID-19 vaccine and completing at least one health survey 0-7 days after vaccination—December 14, 2020–June 14, 2021**

Characteristics	Both mRNA vaccines (n = 7,914,583)	BNT162b2 vaccine		mRNA-1273 vaccine	
		Dose 1 n=3,455,778	Dose 2 n=2,920,526	Dose 1 n= 3,319,737	Dose 2 n=2,753,894
Sex					
Female	4,975,209 (62·9)	2,150,068 (62·2)	1,861,599 (63·7)	2,073,542 (62·5)	1,779,200 (64·6)
Male	2,860,738 (36·1)	1,272,011 (36·8)	1,032,941 (35·4)	1,210,622 (36·5)	947,612 (34·4)
Other	8,872 (0·1)	4,027 (0·1)	3,464 (0·1)	3,443 (0·1)	2,947 (0·1)
Unknown	69,764 (0·9)	29,672 (0·9)	22,522 (0·8)	32,130 (1·0)	24,135 (0·9)
Age (years)					
16–17	73,347 (0·9)	63,865 (1·8)	38,530 (1·3)	946 (0·03)	473 (0·02)
18–49	3,791,839 (47·9)	1,726,465 (50·0)	1,431,627 (49·0)	1,505,760 (45·4)	1,219,210 (44·3)
50–59	1,500,981 (19·0)	653,799 (18·9)	574,422 (19·7)	627,214 (18·9)	531,200 (19·3)
60–64	739,381 (9·3)	315,404 (9·1)	279,350 (9·6)	316,768 (9·5)	270,831 (9·8)
65–74	1,344,721 (17·0)	516,227 (14·9)	452,928 (15·5)	643,663 (19·4)	557,279 (20·2)
≥75	464,314 (5·9)	180,018 (5·2)	143,669 (4·9)	225,386 (6·8)	174,901 (6·4)
Race/Ethnicity					
Hispanic	782,301 (9·9)	346,197 (10·0)	288,263 (9·9)	316,460 (9·5)	256,185 (9·3)
Non-Hispanic					
White	4,701,715 (59·4)	2,059,560 (59·6)	1,896,823 (64·9)	1,979,056 (59·6)	1,830,413 (66·5)
Black	443,938 (5·6)	202,598 (5·9)	176,164 (6·0)	178,981 (5·4)	153,667 (5·6)
Asian	467,932 (5·9)	215,713 (6·2)	196,173 (6·7)	154,498 (4·7)	138,793 (5·0)
American Indian or Alaska Native	27,899 (0·4)	11,161 (0·3)	9,194 (0·3)	13,486 (0·4)	11,410 (0·4)
Native Hawaiian or Other Pacific Islander	19,393 (0·2)	8,500 (0·2)	7,373 (0·3)	7,689 (0·2)	6,664 (0·2)
Multiple races	110,326 (1·4)	50,954 (1·5)	46,129 (1·6)	41,977 (1·3)	38,772 (1·4)
Other races	42,230 (0·5)	19,252 (0·6)	16,757 (0·6)	15,885 (0·5)	13,880 (0·5)
Unknown race	23,420 (0·3)	10,249 (0·3)	9,090 (0·3)	9,502 (0·3)	8,270 (0·3)
Unknown ethnicity*					
White	115,766 (1·5)	48,084 (1·4)	38,674 (1·3)	52,143 (1·6)	42,070 (1·5)
Black	26,865 (0·3)	11,602 (0·3)	8,570 (0·3)	11,993 (0·4)	8,406 (0·3)
Asian	33,146 (0·4)	14,134 (0·4)	11,844 (0·4)	11,356 (0·3)	9,153 (0·3)
American Indian or Alaska Native	3,142 (0·04)	1,206 (0·03)	848 (0·03)	1,582 (0·05)	1,151 (0·04)
Native Hawaiian or Other Pacific Islander	1,945 (0·02)	815 (0·02)	659 (0·02)	800 (0·02)	613 (0·02)
Multiple races	6,370 (0·1)	2,902 (0·1)	2,408 (0·1)	2,478 (0·1)	2,041 (0·1)
Other races	13,148 (0·2)	5,681 (0·2)	4,528 (0·2)	5,414 (0·2)	4,263 (0·2)
Unknown race and ethnicity*	129,647 (1·6)	56,481 (1·6)	45,410 (1·6)	54,969 (1·7)	44,340 (1·6)
Unavailable†	965,400 (12·2)	390,689 (11·3)	161,619 (5·5)	461,468 (13·9)	183,803 (6·7)
Pregnant at time of vaccination	86,801 (1·1)	39,884 (1·2)	39,163 (1·3)	25,255 (0·8)	25,428 (0·9)
Pregnancy test positive after vaccination	27,370 (0·3)	1,548 (0·04)	11,677 (0·4)	4,009 (0·1)	10,199 (0·4)

Data are n (%).

*Unknown indicates that v-safe participants selected unknown or preferred not to say.
†Unavailable refers to information that was not collected or missing in v-safe.

***Table 6*: Reported local and systemic reactions*, and reported health impact following mRNA COVID-19 vaccines reported days 0–7 after vaccination to v-safe, by manufacturer and dose—December 14, 2020 – June 14, 2021**

	Both mRNA vaccines		BNT162b2 vaccine		mRNA-1273 vaccine	
	Dose 1 (n=6,775,515)	Dose 2 (n=5,674,420)	Dose 1 (n=3,455,778)	Dose 2 (n=2,920,526)	Dose 1 (n=3,319,737)	Dose 2 (n=2,753,894)
Any injection site reaction	4,644,989 (68·6)	4,068,447 (71·7)	2,212,051 (64·0)	1,908,124 (65·3)	2,432,938 (73·3)	2,160,323 (78·4)
Injection site pain	4,488,402 (66·2)	3,890,848 (68·6)	2,140,843 (61·9)	1,835,398 (62·8)	2,347,559 (70·7)	2,055,450 (74·6)
Swelling	703,790 (10·4)	976,946 (17·2)	246,230 (7·1)	309,718 (10·6)	457,560 (13·8)	667,228 (24·2)
Redness	353,788 (5·2)	640,739 (11·3)	116,108 (3·4)	167,127 (5·7)	237,680 (7·2)	473,612 (17·2)
Itching	376,076 (5·6)	605,633 (10·7)	145,596 (4·2)	191,132 (6·5)	230,480 (6·9)	414,501 (15·1)
Any systemic reaction	3,573,429 (52·7)	4,018,920 (70·8)	1,771,509 (51·3)	1,931,643 (66·1)	1,801,920 (54·3)	2,087,277 (75·8)
Fatigue	2,295,205 (33·9)	3,158,299 (55·7)	1,127,904 (32·6)	1,475,646 (50·5)	1,167,301 (35·2)	1,682,653 (61·1)

Headache	1,831,471 (27·0)	2,623,721 (46·2)	893,992 (25·9)	1,189,444 (40·7)	937,479 (28·2)	1,434,277 (52·1)
Myalgia	1,423,336 (21·0)	2,478,170 (43·7)	653,821 (18·9)	1,085,365 (37·2)	769,515 (23·2)	1,392,805 (50·6)
Chills	631,546 (9·3)	1,680,185 (29·6)	263,617 (7·6)	642,856 (22·0)	367,929 (11·1)	1,037,329 (37·7)
Fever	642,092 (9·5)	1,679,577 (29·6)	274,650 (7·9)	656,454 (22·5)	367,442 (11·1)	1,023,123 (37·2)
Joint pain	642,006 (9·5)	1,440,927 (25·4)	285,812 (8·3)	591,877 (20·3)	356,194 (10·7)	849,050 (30·8)
Nausea	562,273 (8·3)	901,103 (15·9)	267,160 (7·7)	384,525 (13·2)	295,113 (8·9)	516,578 (18·8)
Diarrhea	383,576 (5·7)	419,044 (7·4)	190,542 (5·5)	198,618 (6·8)	193,034 (5·8)	220,426 (8·0)
Abdominal pain	233,511 (3·4)	359,107 (6·3)	113,872 (3·3)	158,251 (5·4)	119,639 (3·6)	200,856 (7·3)
Rash	85,766 (1·3)	99,878 (1·8)	41,565 (1·2)	42,662 (1·5)	44,201 (1·3)	57,216 (2·1)
Vomiting	55,710 (0·8)	91,727 (1·6)	25,336 (0·7)	36,761 (1·3)	30,374 (0·9)	54,966 (2·0)
With reported health impact*	808,963 (11·9)	1,821,421 (32·1)	361,834 (10·5)	740,529 (25·4)	447,129 (13·5)	1,080,892 (39·2)
Unable to do normal activity	658,330 (9·7)	1,501,679 (26·5)	290,207 (8·4)	598,584 (20·5)	368,123 (11·1)	903,095 (32·8)
Unable to work	305,709 (4·5)	911,366 (16·1)	135,063 (3·9)	360,411 (12·3)	170,646 (5·1)	550,955 (20·0)
Reported medical care	56,647 (0·8)	53,077 (0·9)	27,358 (0·8)	25,568 (0·9)	29,289 (0·9)	27,509 (1·0)
Telehealth	19,562 (0·3)	19,770 (0·3)	9,318 (0·3)	9,238 (0·3)	10,244 (0·3)	10,532 (0·4)
Clinic	18,671 (0·3)	16,793 (0·3)	9,109 (0·3)	8,487 (0·3)	9,562 (0·3)	8,306 (0·3)
Emergency visit	9,907 (0·1)	8,907 (0·2)	5,087 (0·1)	4,494 (0·2)	4,820 (0·1)	4,413 (0·2)
Hospitalization	1,896 (0·03)	2,053 (0·04)	915 (0·03)	1,001 (0·03)	981 (0·03)	1,052 (0·04)

Data are n (%).
*Reports of local and systemic reactions, and reports of health impact are not mutually exclusive.

Figure 1: Percent distribution of the 10 leading causes of death, by age, among reported deaths with death certificate or autopsy to Vaccine Adverse Event Reporting System (VAERS) December 14, 2020–June 14, 2021 following mRNA vaccination

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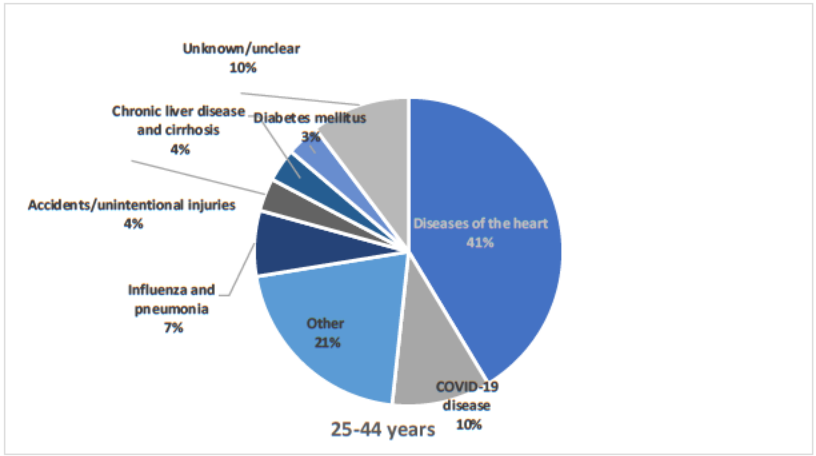
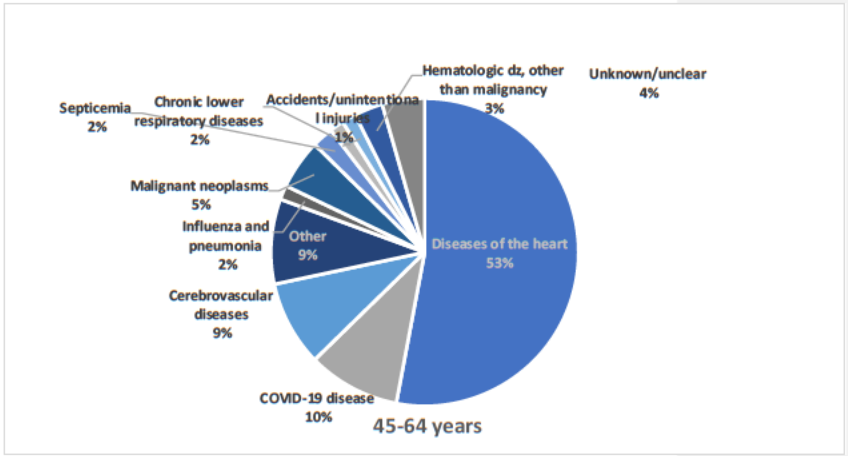
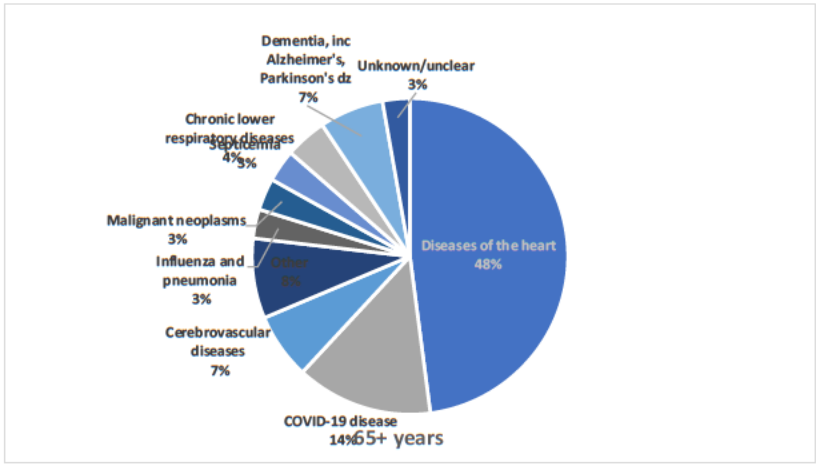
Data is captured in supplemental table 2
Rosenblum, Hannah (CDC)
2021-09-08 16:03:00







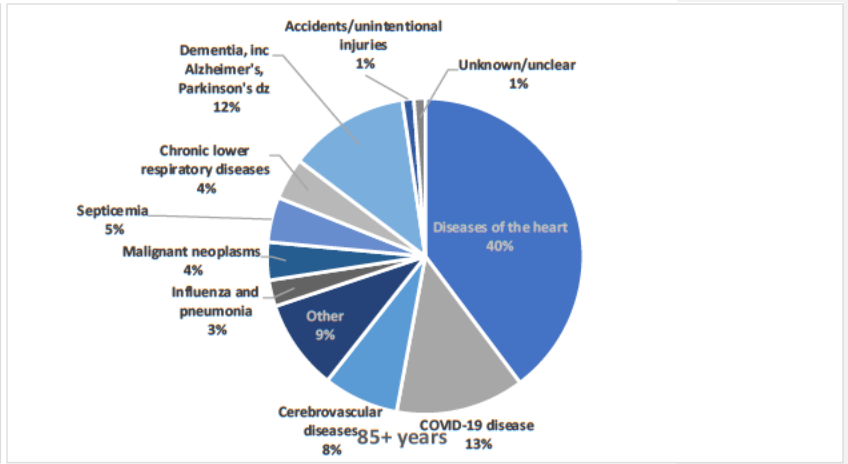
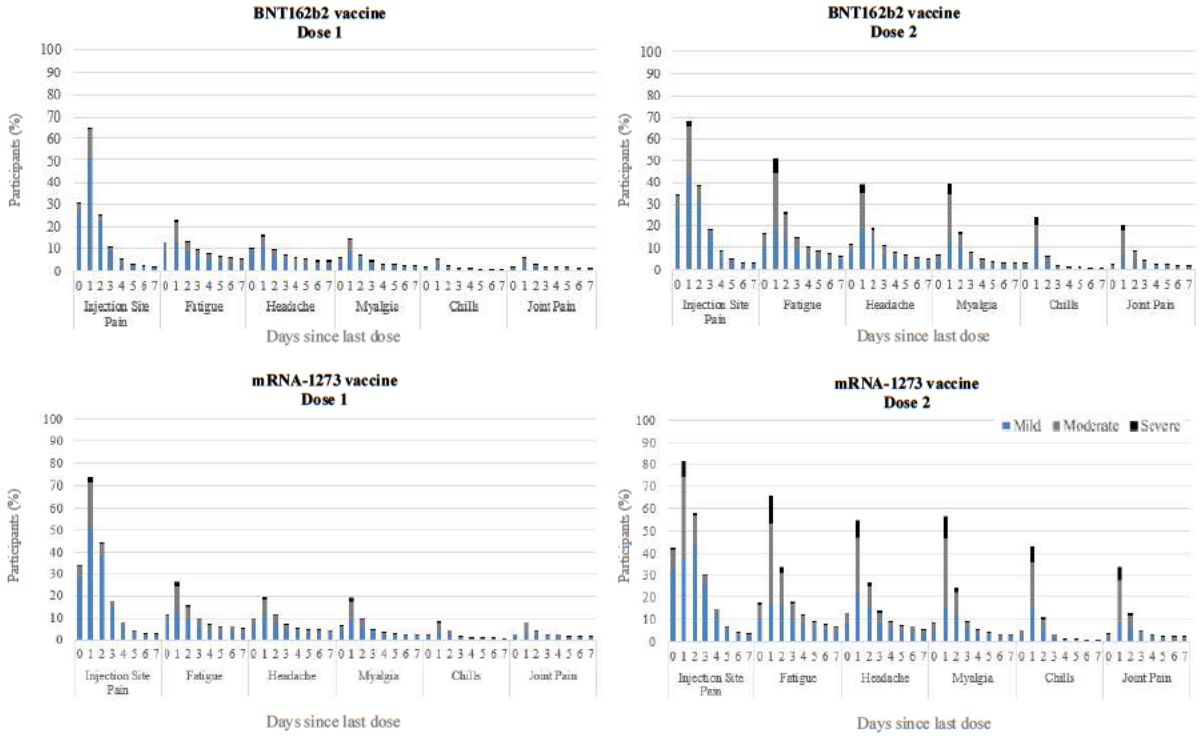


Figure 2: Local and systemic reactions* to mRNA COVID-19 vaccine reported in v-safe, by manufacturer, dose, days after vaccination, and severity†



*Top five reactions determined by reported frequency after second dose of both mRNA COVID-19 vaccines in v-safe, excluding fever because it was not rated mild, moderate, or severe.
†Mild was defined as "noticeable symptoms but they aren't a problem", moderate was defined as "symptoms that limit normal activities, and severe symptoms "make normal daily activities difficult or impossible"

Supplemental Table 1: mRNA COVID-19 vaccine doses administered in the United States—December 14, 2020–June 14, 2021

Characteristics	Both mRNA vaccines† (n=298,792,852)	BNT162b2 vaccine† (n=167,177,332)	mRNA-1273 vaccine† (n=131,639,515)
Sex			
Female	155,969,573 (53·2)	86,507,992 (53·5)	69,461,582 (52·8)
Male	134,373,958 (45·8)	73,768,602 (45·6)	60,605,356 (46·1)
Unknown	2,868,979 (1·0)	1,452,344 (0·9)	1,416,634 (1·1)
Age (years)			
16–17*	5,506,763 (1·8)	5,365,855 (3·2)	140,908 (0·1)
18–49	126,288,626 (42·3)	74,999,327 (44·9)	51,289,299 (39·0)
50–64	79,207,752 (26·5)	43,595,972 (26·1)	35,611,780 (27·1)
65–74	51,699,307 (17·3)	25,402,217 (15·2)	26,297,090 (20·0)
75–84	27,731,181 (9·3)	13,555,128 (8·1)	14,176,053 (10·8)
≥85	8,359,223 (2·8)	4,248,648 (2·5)	4,110,575 (3·1)
Unknown	23,995 (0·01)	10,185 (0·01)	13,810 (0·01)
Race/Ethnicity			
Hispanic	31,599,632 (10·8)	17,964,345 (11·1)	13,635,287 (10·4)
Non-Hispanic			
White	112,698,875 (38·4)	61,996,607 (38·3)	50,702,268 (38·6)
Asian	11,789,429 (4·0)	7,258,033 (4·5)	4,531,396 (3·4)
Black	16,848,436 (5·7)	9,665,586 (6·0)	7,182,849 (5·5)
American Indian or Alaska Native	1,738,938 (0·6)	842,263 (0·5)	896,674 (0·7)
Native Hawaiian or Other Pacific Islander	508,285 (0·2)	295,634 (0·2)	212,651 (0·2)
Multiple races	8,856,800 (3·0)	5,037,828 (3·1)	3,818,972 (2·9)
Other races	6,949,404 (2·4)	4,161,353 (2·6)	2,788,051 (2·1)
Unknown race and ethnicity	102,227,532 (34·9)	54,511,493 (33·7)	47,716,039 (36·3)

Data are n (%).
*mRNA-1273 vaccine was not authorized for individuals <18 years during this period, reported mRNA-1273 doses are either from clinical trials or were administered or reported in error
†Totals reflect the number of doses in age categories. Missing doses for sex and race/ethnicity are due to certain jurisdictions that report data in aggregate.

Supplemental Table 2: Causes of death among reported deaths to Vaccine Adverse Event Reporting System (VAERS) December 14, 2020–June 14, 2021 following mRNA vaccination, by age

Reports of death with death cert or autopsy	All	16-24		25-34		35-44		45-54		55-64		65-74		75-84		85+	
ICD-10 Major Group	808	n=4		n=5		n=24		n=37		n=101		n=171		n=202		n=264	
All		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Diseases of the heart	376	1	25.0	2	40.0	10	41.7	21	56.8	50	49.5	98	57.3	91	45.0	103	39.0
COVID-19 disease	102	1	25.0	1	20.0	2	8.3	2	5.4	11	10.9	19	11.1	32	15.8	34	12.9
Cerebrovascular diseases	53	0	0	0	0	0	0	4	10.8	8	7.9	8	4.7	13	6.4	20	7.6
Other	68	0	0	1	20.0	5	20.8	2	5.4	10	9.9	11	6.4	15	7.4	24	9.1
Influenza and pneumonia	22	0	0	0	0	2	8.3	0	0	2	2.0	4	2.3	7	3.5	7	2.7
Malignant neoplasms	27	0	0	0	0	0	0	2	5.4	5	5.0	2	1.2	8	4.0	10	3.8
Septicemia	23	0	0	0	0	0	0	1	2.7	2	2.0	2	1.2	6	3.0	12	4.5
Chronic lower respiratory diseases	28	0	0	0	0	0	0	0	0	2	2.0	11	6.4	4	2.0	11	4.2
Dementia, inc Alzheimer's, Parkinson's dz	41	0	0	0	0	0	0	0	0	1	1.0	1	0.6	7	3.5	32	12.1
Accidents/unintentional injuries	11	0	0	0	0	1	4.2	0	0	2	2.0	2	1.2	3	1.5	3	1.1
Renal dz, incl nephritis and chronic dz	8	0	0	0	0	0	0	1	2.7	0	0	3	1.8	3	1.5	1	0.4
Hematologic dz, other than malignancy	7	0	0	0	0	0	0	1	2.7	3	3.0	0	0	1	0.5	2	0.8
Intentional self-harm	1	1	25.0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pneumonitis due to solids and liquids	6	0	0	0	0	0	0	0	0	1	1.0	0	0	3	1.5	2	0.8
Chronic liver disease and cirrhosis	4	0	0	1	20.0	0	0	0	0	1	1.0	1	0.6	1	0.5	0	0
Diabetes mellitus	4	0	0	0	0	1	4.2	0	0	0	0	2	1.2	1	0.5	0	0
Unknown/unclear	27	1	25.0	0	0	3	12.5	3	8.1	3	3.0	7	4.1	7	3.5	3	1.1

***Supplemental Table 3*: Causes and impressions of death among reported deaths to Vaccine Adverse Event Reporting System (VAERS) December 14, 2020–June 14, 2021 following mRNA vaccination**

Commented [RH(34]: Combine 16-24 and 25-34? n=9
Rosenblum, Hannah (CDC)
2021-08-27 21:56:00

ICD-10 Major Group and impression	All reports of death	Reported deaths with death certificate or autopsy
All reported deaths, n	4,472	808
Diseases of the heart	998 (22.3)	376 (46.5)
Aortic dissection, aneurysm or aortitis	13 (0.3)	7 (0.9)
Arrhythmia	42 (0.9)	18 (2.2)
Atherosclerotic cardiovascular or hypertensive cardiovascular disease	129 (2.9)	98 (12.1)
Cardiac arrest	321 (7.2)	79 (9.8)
Cardiomyopathy or hypertrophy	17 (0.4)	12 (1.5)
Heart failure	104 (2.3)	47 (5.8)
Myocardial infarction	247 (5.5)	87 (10.8)
Myocarditis	4 (0.1)	0 (0.0)
Pulmonary embolism	84 (1.9)	17 (2.1)
Other cardiac cause	37 (0.8)	11 (1.4)
COVID-19 disease	419 (9.4)	102 (12.6)
Cerebrovascular diseases	260 (5.8)	53 (6.6)
Other	209 (4.7)	68 (8.4)
Disseminated herpes zoster	2 (0.04)	1 (0.1)
Drug overdose/intoxication	7 (0.2)	5 (0.6)
Failure to thrive	9 (0.2)	9 (1.1)
Gastrointestinal[*]	36 (0.8)	8 (1.0)
Hemorrhage/Hemorrhagic shock	4 (0.1)	2 (0.2)
Metabolic derangement	4 (0.1)	1 (0.1)
Multiorgan failure	28 (0.6)	7 (0.9)
Natural	2 (0.04)	2 (0.2)
Neurologic[†]	28 (0.6)	6 (0.7)
Obesity	2 (0.04)	2 (0.2)
Respiratory failure	63 (1.4)	22 (2.7)
Vaccine related[‡]	4 (0.1)	3 (0.4)
Influenza and pneumonia	135 (3.0)	22 (2.7)
Malignant neoplasms	95 (2.1)	27 (3.3)
Septicemia	95 (2.1)	23 (2.8)
Chronic lower respiratory diseases	57 (1.3)	28 (3.5)
Dementia	50 (1.1)	41 (5.1)
Accidents/unintentional injuries	33 (0.7)	11 (1.4)
Renal disease	33 (0.7)	8 (1.0)
Hematologic disease, other than malignancy	26 (0.6)	7 (0.9)
Intentional self-harm	16 (0.4)	1 (0.1)
Pneumonitis due to solids and liquids	14 (0.3)	6 (0.7)
Chronic liver disease and cirrhosis	11 (0.2)	4 (0.5)
Diabetes mellitus	10 (0.2)	4 (0.5)
Unknown/unclear	2,011 (45.0)	27 (3.3)

[†]Data are n (%) unless otherwise stated.
[*]Gastrointestinal includes gastrointestinal bleeding, bowel obstruction/perforation, mesenteric ischemia, pancreatitis.
[†]Neurologic includes amyotrophic lateral sclerosis, encephalopathy, hydrocephalus, Guillain-Barré syndrome, seizure.
[‡]Vaccine related includes systemic inflammatory response syndrome from vaccine reaction, anaphylaxis post-COVID-19 vaccination

Supplemental Table 4: Local and systemic reactions* 0–7 days after vaccination by sex, age, and dose number, reported in v-safe—December 14, 2020–June 14, 2021

	Female		Male		<65 years		≥65 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
	(n=4,223,610)	(n=3,640,799)	(n=2,482,633)	(n=1,980,553)	(n=5,210,221)	(n=4,345,643)	(n=1,565,294)	(n=1,328,777)
Any injection site reaction	3,095,194 (73·3)	2,792,488 (76·7)	1,498,108 (60·3)	1,235,278 (62·4)	3,835,618 (73·6)	3,290,206 (75·7)	809,371 (51·7)	778,241 (58·6)
Injection site pain	2,989,733 (70·8)	2,666,734 (73·3)	1,448,440 (58·3)	1,184,914 (59·8)	3,728,795 (71·6)	3,179,024 (73·2)	759,607 (48·5)	711,824 (53·6)
Swelling	539,793 (12·8)	771,962 (21·2)	154,980 (6·2)	194,033 (9·8)	604,868 (11·6)	812,126 (18·7)	98,922 (6·3)	164,820 (12·4)
Redness	283,345 (6·7)	529,175 (14·5)	66,134 (2·7)	104,933 (5·3)	295,413 (5·7)	512,516 (11·8)	58,375 (3·7)	128,223 (9·6)
Itching	299,407 (7·1)	504,016 (13·8)	72,095 (2·9)	95,356 (4·8)	309,607 (5·9)	466,319 (10·7)	66,469 (4·2)	139,314 (10·5)
Any systemic reaction	2,444,362 (57·9)	2,752,592 (75·6)	1,088,296 (43·8)	1,226,561 (61·9)	2,972,931 (57·1)	3,237,621 (74·5)	600,498 (38·4)	781,299 (58·8)
Fatigue	1,624,531 (38·5)	2,221,361 (61·0)	643,206 (25·9)	904,556 (45·7)	1,941,979 (37·3)	2,588,541 (59·6)	353,226 (22·6)	569,758 (42·9)
Headache	1,349,155 (31·9)	1,906,337 (52·4)	460,786 (18·6)	690,138 (34·8)	1,595,091 (30·6)	2,226,046 (51·2)	236,380 (15·1)	397,675 (29·9)
Myalgia	954,469 (22·6)	1,724,474 (47·4)	450,562 (18·1)	726,994 (36·7)	1,219,190 (23·4)	2,085,722 (48·0)	204,146 (13·0)	392,448 (29·5)
Chills	451,583 (10·7)	1,202,364 (33·0)	172,283 (6·9)	459,577 (23·2)	542,285 (10·4)	1,426,710 (32·8)	89,261 (5·7)	253,475 (19·1)
Fever	446,178 (10·6)	1,182,201 (32·5)	187,713 (7·6)	478,912 (24·2)	565,804 (10·9)	1,449,504 (33·4)	76,288 (4·9)	230,073 (17·3)
Joint pain	444,630 (10·5)	1,023,525 (28·1)	188,846 (7·6)	400,963 (20·2)	539,196 (10·3)	1,214,624 (28·0)	102,810 (6·6)	226,303 (17·0)
Nausea	447,766 (10·6)	728,730 (20·0)	106,872 (4·3)	161,455 (8·2)	500,782 (9·6)	794,450 (18·3)	61,491 (3·9)	106,653 (8·0)
Diarrhea	272,890 (6·5)	313,252 (8·6)	106,079 (4·3)	101,107 (5·1)	323,773 (6·2)	352,077 (8·1)	59,803 (3·8)	66,967 (5·0)
Abdominal pain	179,210 (4·2)	283,422 (7·8)	50,991 (2·1)	71,115 (3·6)	203,575 (3·9)	316,165 (7·3)	29,936 (1·9)	42,942 (3·2)
Rash	65,498 (1·6)	79,092 (2·2)	19,193 (0·8)	19,735 (1·0)	70,985 (1·4)	79,913 (1·8)	14,781 (0·9)	19,965 (1·5)
Vomiting	43,998 (1·0)	75,650 (2·1)	10,936 (0·4)	14,915 (0·8)	49,483 (0·9)	81,733 (1·9)	6,227 (0·4)	9,994 (0·8)

Data are n (%).
*Reports of local and systemic reactions are not mutually exclusive.

***Supplemental Table* 5: Most common local and systemic reactions* to mRNA COVID-19 vaccine reported in v-safe, by dose and severity,† 0-7 days after vaccination with BNT162b2 vaccine**

		Dose 1				Dose 2			
	Day	All, n	Severe	Moderate	Mild	All, n	Severe	Moderate	Mild
Injection site pain	0	2,272,335	2,533 (0·1)	80,358 (3·5)	599,511 (26·4)	1,766,510	4,359 (0·2)	94,156 (5·3)	503,779 (28·5)
	1	2,545,271	18,827 (0·7)	334,755 (13·2)	1,289,293 (50·7)	2,027,330	48,810 (2·4)	453,726 (22·4)	885,434 (43·7)
	2	2,545,434	4,356 (0·2)	62,838 (2·5)	565,455 (22·2)	2,116,614	10,391 (0·5)	126,741 (6·0)	680,408 (32·1)
	3	2,507,344	2,119 (0·1)	26,602 (1·1)	216,785 (8·6)	2,067,908	3,332 (0·2)	43,037 (2·1)	336,222 (16·3)
	4	2,436,977	1,420 (0·1)	16,710 (0·7)	102,077 (4·2)	2,028,926	1,820 (0·1)	20,548 (1·0)	149,408 (7·4)
	5	2,332,032	1,138 (0·05)	11,965 (0·5)	60,401 (2·6)	2,000,426	1,272 (0·1)	12,719 (0·6)	73,486 (3·7)
	6	2,249,409	909 (0·04)	8,901 (0·4)	40,597 (1·8)	2,000,472	1,106 (0·1)	11,008 (0·6)	46,707 (2·3)
	7	2,198,611	768 (0·03)	7,783 (0·4)	32,967 (1·5)	2,067,201	1,557 (0·1)	14,159 (0·7)	44,322 (2·1)
Fatigue	0	2,272,335	7,280 (0·3)	79,232 (3·5)	193,192 (8·5)	1,766,510	11,293 (0·6)	98,802 (5·6)	185,051 (10·5)
	1	2,545,271	35,734 (1·4)	229,606 (9·0)	326,015 (12·8)	2,027,330	135,581 (6·7)	523,998 (25·8)	373,601 (18·4)
	2	2,545,434	16,936 (0·7)	114,562 (4·5)	211,046 (8·3)	2,116,614	39,668 (1·9)	217,269 (10·3)	308,126 (14·6)
	3	2,507,344	10,636 (0·4)	74,341 (3·0)	145,114 (5·8)	2,067,908	15,361 (0·7)	104,673 (5·1)	193,174 (9·3)
	4	2,436,977	8,275 (0·3)	58,170 (2·4)	109,266 (4·5)	2,028,926	10,280 (0·5)	69,886 (3·4)	133,603 (6·6)
	5	2,332,032	7,062 (0·3)	49,739 (2·1)	88,721 (3·8)	2,000,426	8,089 (0·4)	55,840 (2·8)	103,919 (5·2)
	6	2,249,409	6,428 (0·3)	44,044 (2·0)	76,633 (3·4)	2,000,472	7,200 (0·4)	48,388 (2·4)	86,907 (4·3)
	7	2,198,611	6,027 (0·3)	40,428 (1·8)	67,168 (3·1)	2,067,201	7,528 (0·4)	46,669 (2·3)	78,361 (3·8)
Headache	0	2,272,335	3,394 (0·1)	42,501 (1·9)	167,985 (7·4)	1,766,510	5,217 (0·3)	52,759 (3·0)	144,892 (8·2)
	1	2,545,271	20,011 (0·8)	129,629 (5·1)	265,970 (10·4)	2,027,330	82,393 (4·1)	333,605 (16·5)	381,368 (18·8)
	2	2,545,434	10,458 (0·4)	69,347 (2·7)	162,658 (6·4)	2,116,614	24,063 (1·1)	134,054 (6·3)	249,895 (11·8)
	3	2,507,344	6,670 (0·3)	46,850 (1·9)	110,115 (4·4)	2,067,908	10,356 (0·5)	68,461 (3·3)	148,990 (7·2)
	4	2,436,977	5,552 (0·2)	38,319 (1·6)	85,635 (3·5)	2,028,926	7,238 (0·4)	47,550 (2·3)	103,204 (5·1)
	5	2,332,032	4,911 (0·2)	34,379 (1·5)	72,831 (3·1)	2,000,426	6,154 (0·3)	40,322 (2·0)	82,191 (4·1)
	6	2,249,409	4,733 (0·2)	31,540 (1·4)	64,890 (2·9)	2,000,472	5,467 (0·3)	35,177 (1·8)	69,168 (3·5)
	7	2,198,611	4,381 (0·2)	29,475 (1·3)	58,752 (2·7)	2,067,201	5,372 (0·3)	34,057 (1·6)	63,628 (3·1)
Myalgia	0	2,272,335	1,999 (0·1)	29,601 (1·3)	96,095 (4·2)	1,766,510	4,001 (0·2)	38,960 (2·2)	75,790 (4·3)
	1	2,545,271	18,440 (0·7)	136,939 (5·4)	219,125 (8·6)	2,027,330	101,801 (5·0)	408,637 (20·2)	293,241 (14·5)
	2	2,545,434	7,441 (0·3)	56,954 (2·2)	112,788 (4·4)	2,116,614	23,521 (1·1)	140,700 (6·6)	209,074 (9·9)
	3	2,507,344	4,200 (0·2)	33,605 (1·3)	65,696 (2·6)	2,067,908	6,925 (0·3)	54,206 (2·6)	100,982 (4·9)
	4	2,436,977	3,255 (0·1)	25,814 (1·1)	46,369 (1·9)	2,028,926	4,146 (0·2)	32,786 (1·6)	60,489 (3·0)
	5	2,332,032	2,831 (0·1)	22,598 (1·0)	37,598 (1·6)	2,000,426	3,239 (0·2)	25,326 (1·3)	44,242 (2·2)
	6	2,249,409	2,543 (0·1)	20,904 (0·9)	33,016 (1·5)	2,000,472	2,973 (0·1)	22,422 (1·1)	36,522 (1·8)
	7	2,198,611	2,504 (0·1)	19,474 (0·9)	30,222 (1·4)	2,067,201	3,379 (0·2)	23,046 (1·1)	33,563 (1·6)
Chills	0	2,272,335	879 (0·04)	8,246 (0·4)	34,000 (1·5)	1,766,510	2,091 (0·1)	14,428 (0·8)	38,195 (2·2)
	1	2,545,271	8,558 (0·3)	45,518 (1·8)	78,033 (3·1)	2,027,330	62,884 (3·1)	210,579 (10·4)	207,218 (10·2)
	2	2,545,434	3,371 (0·1)	18,659 (0·7)	36,412 (1·4)	2,116,614	11,744 (0·6)	51,490 (2·4)	76,276 (3·6)
	3	2,507,344	1,462 (0·1)	9,241 (0·4)	19,569 (0·8)	2,067,908	2,582 (0·1)	13,423 (0·6)	25,421 (1·2)
	4	2,436,977	1,051 (0·04)	6,915 (0·3)	13,967 (0·6)	2,028,926	1,336 (0·1)	7,424 (0·4)	14,223 (0·7)
	5	2,332,032	863 (0·04)	5,531 (0·2)	11,284 (0·5)	2,000,426	955 (0·05)	5,423 (0·3)	10,583 (0·5)
	6	2,249,409	779 (0·03)	5,048 (0·2)	9,932 (0·4)	2,000,472	851 (0·04)	4,763 (0·2)	9,029 (0·5)
	7	2,198,611	752 (0·03)	4,645 (0·2)	8,889 (0·4)	2,067,201	1,222 (0·1)	5,515 (0·3)	9,039 (0·4)
Joint pain	0	2,272,335	1,069 (0·05)	11,375 (0·5)	24,689 (1·1)	1,766,510	2,396 (0·1)	18,677 (1·1)	25,699 (1·5)
	1	2,545,271	9,676 (0·4)	61,691 (2·4)	69,532 (2·7)	2,027,330	55,446 (2·7)	225,949 (11·2)	137,601 (6·8)
	2	2,545,434	4,608 (0·2)	31,238 (1·2)	44,072 (1·7)	2,116,614	14,386 (0·7)	80,490 (3·8)	90,461 (4·3)
	3	2,507,344	2,675 (0·1)	19,912 (0·8)	29,313 (1·2)	2,067,908	4,624 (0·2)	32,971 (1·6)	46,467 (2·2)
	4	2,436,977	2,165 (0·1)	15,923 (0·7)	22,386 (0·9)	2,028,926	2,882 (0·1)	20,861 (1·0)	29,916 (1·5)
	5	2,332,032	1,999 (0·1)	13,922 (0·6)	18,869 (0·8)	2,000,426	2,341 (0·1)	16,528 (0·8)	23,366 (1·2)
	6	2,249,409	1,773 (0·1)	13,018 (0·6)	16,874 (0·8)	2,000,472	2,138 (0·1)	15,046 (0·8)	19,649 (1·0)
	7	2,198,611	1,686 (0·1)	12,245 (0·6)	15,605 (0·7)	2,067,201	2,462 (0·1)	15,782 (0·8)	18,678 (0·9)

Data are n (%) unless otherwise stated.

*Top five reactions determined by reported frequency after second dose of both mRNA COVID-19 vaccines in v-safe, excluding fever because it was not rated mild/moderate/severe. Symptoms are not mutually exclusive. †Mild was defined as "noticeable symptoms but they aren't a problem", moderate was defined as "symptoms that limit normal activities, and severe symptoms", and severe symptoms "make normal daily activities difficult or impossible".

***Supplemental Table* 6: Most common local and systemic reactions* to mRNA COVID-19 vaccine reported in v-safe, by dose and severity,† 0-7 days after vaccination with mRNA-1273 vaccine**

		Dose 1				Dose 2			
	Day	All, n	Severe	Moderate	Mild	All, n	Severe	Moderate	Mild
Injection site pain	0	2,112,380	4,971 (0·2)	113,992 (5·4)	595,108 (28·2)	1,656,723	11,174 (0·7)	155,045 (9·4)	535,260 (32·3)
	1	2,424,231	49,225 (2·0)	512,076 (21·1)	1,214,808 (50·1)	1,937,029	131,379 (6·8)	735,284 (38·0)	713,164 (36·8)
	2	2,474,399	13,723 (0·6)	152,289 (6·2)	932,770 (37·7)	2,035,773	26,351 (1·3)	268,371 (13·2)	890,618 (43·7)
	3	2,459,431	4,778 (0·2)	47,625 (1·9)	370,863 (15·1)	1,993,354	6,469 (0·3)	78,053 (3·9)	525,158 (26·3)
	4	2,390,709	2,881 (0·1)	25,370 (1·1)	148,288 (6·2)	1,960,829	3,393 (0·2)	33,315 (1·7)	239,358 (12·2)
	5	2,285,185	2,087 (0·1)	17,079 (0·7)	77,452 (3·4)	1,939,300	2,493 (0·1)	19,783 (1·0)	109,652 (5·7)
	6	2,196,757	1,512 (0·1)	12,520 (0·6)	50,245 (2·3)	1,949,754	2,496 (0·1)	18,002 (0·9)	61,677 (3·2)
	7	2,157,101	1,595 (0·1)	13,301 (0·6)	45,669 (2·1)	2,019,370	3,443 (0·2)	22,300 (1·1)	49,711 (2·5)
Fatigue	0	2,112,380	7,221 (0·3)	74,690 (3·5)	170,757 (8·1)	1,656,723	13,938 (0·8)	104,699 (6·3)	173,749 (10·5)
	1	2,424,231	54,659 (2·3)	275,510 (11·4)	315,454 (13·0)	1,937,029	240,342 (12·4)	706,424 (36·5)	330,245 (17·0)
	2	2,474,399	23,894 (1·0)	143,988 (5·8)	228,253 (9·2)	2,035,773	60,995 (3·0)	292,539 (14·4)	337,135 (16·6)
	3	2,459,431	11,711 (0·5)	78,023 (3·2)	147,930 (6·0)	1,993,354	19,031 (1·0)	126,765 (6·4)	213,889 (10·7)
	4	2,390,709	8,430 (0·4)	57,900 (2·4)	107,495 (4·5)	1,960,829	11,806 (0·6)	80,578 (4·1)	146,796 (7·5)
	5	2,285,185	7,252 (0·3)	48,602 (2·1)	86,144 (3·8)	1,939,300	9,238 (0·5)	61,449 (3·2)	110,778 (5·7)
	6	2,196,757	6,486 (0·3)	43,439 (2·0)	73,380 (3·3)	1,949,754	8,051 (0·4)	52,161 (2·7)	91,466 (4·7)
	7	2,157,101	6,309 (0·3)	41,022 (1·9)	65,817 (3·1)	2,019,370	8,702 (0·4)	50,008 (2·5)	80,798 (4·0)
Headache	0	2,112,380	3,475 (0·2)	40,930 (1·9)	153,086 (7·2)	1,656,723	6,812 (0·4)	58,638 (3·5)	143,161 (8·6)
	1	2,424,231	33,272 (1·4)	164,590 (6·8)	273,687 (11·3)	1,937,029	154,933 (8·0)	497,171 (25·7)	411,266 (21·2)
	2	2,474,399	15,614 (0·6)	91,066 (3·7)	186,713 (7·5)	2,035,773	39,797 (2·0)	195,074 (9·6)	311,816 (15·3)
	3	2,459,431	7,782 (0·3)	50,386 (2·0)	114,639 (4·7)	1,993,354	13,752 (0·7)	85,153 (4·3)	177,740 (8·9)
	4	2,390,709	5,818 (0·2)	38,567 (1·6)	86,140 (3·6)	1,960,829	8,903 (0·5)	56,974 (2·9)	120,773 (6·2)
	5	2,285,185	5,316 (0·2)	34,399 (1·5)	72,082 (3·2)	1,939,300	7,429 (0·4)	46,575 (2·4)	93,323 (4·8)
	6	2,196,757	4,732 (0·2)	31,891 (1·5)	63,922 (2·9)	1,949,754	6,576 (0·3)	40,092 (2·1)	77,243 (4·0)
	7	2,157,101	4,585 (0·2)	30,705 (1·4)	59,396 (2·8)	2,019,370	6,705 (0·3)	37,634 (1·9)	68,333 (3·4)
Myalgia	0	2,112,380	3,011 (0·1)	35,724 (1·7)	95,048 (4·5)	1,656,723	7,757 (0·5)	54,566 (3·3)	82,160 (5·0)
	1	2,424,231	38,950 (1·6)	197,871 (8·2)	226,700 (9·4)	1,937,029	198,988 (10·3)	610,812 (31·5)	292,422 (15·1)
	2	2,474,399	13,531 (0·5)	86,102 (3·5)	150,896 (6·1)	2,035,773	39,990 (2·0)	203,682 (10·0)	251,594 (12·4)
	3	2,459,431	5,264 (0·2)	38,086 (1·6)	74,647 (3·0)	1,993,354	9,143 (0·5)	65,042 (3·3)	114,111 (5·7)
	4	2,390,709	3,627 (0·2)	26,656 (1·1)	47,845 (2·0)	1,960,829	5,041 (0·3)	36,805 (1·9)	65,072 (3·3)
	5	2,285,185	2,989 (0·1)	22,955 (1·0)	37,471 (1·6)	1,939,300	3,796 (0·2)	27,445 (1·4)	45,771 (2·4)
	6	2,196,757	2,667 (0·1)	21,040 (1·0)	33,060 (1·5)	1,949,754	3,592 (0·2)	24,073 (1·2)	37,073 (1·9)
	7	2,157,101	2,731 (0·1)	20,799 (1·0)	31,659 (1·5)	2,019,370	4,415 (0·2)	25,026 (1·2)	33,652 (1·7)
Chills	0	2,112,380	1,395 (0·1)	10,125 (0·5)	35,178 (1·7)	1,656,723	4,685 (0·3)	23,091 (1·4)	45,194 (2·7)
	1	2,424,231	23,553 (1·0)	84,997 (3·5)	101,682 (4·2)	1,937,029	137,685 (7·1)	402,336 (20·8)	291,400 (15·0)
	2	2,474,399	7,601 (0·3)	33,238 (1·3)	52,246 (2·1)	2,035,773	23,939 (1·2)	90,569 (4·5)	113,067 (5·6)
	3	2,459,431	2,358 (0·1)	11,569 (0·5)	21,723 (0·9)	1,993,354	4,164 (0·2)	18,349 (0·9)	31,919 (1·6)
	4	2,390,709	1,374 (0·1)	7,398 (0·3)	14,470 (0·6)	1,960,829	2,100 (0·1)	9,271 (0·5)	16,372 (0·8)
	5	2,285,185	1,022 (0·04)	5,986 (0·3)	11,645 (0·5)	1,939,300	1,547 (0·1)	6,581 (0·3)	11,521 (0·6)
	6	2,196,757	838 (0·04)	5,231 (0·2)	10,167 (0·5)	1,949,754	1,500 (0·1)	6,158 (0·3)	9,622 (0·5)
	7	2,157,101	891 (0·04)	5,094 (0·2)	9,317 (0·4)	2,019,370	2,376 (0·1)	7,405 (0·4)	9,915 (0·5)
Joint pain	0	2,112,380	1,448 (0·1)	13,228 (0·6)	24,666 (1·2)	1,656,723	4,387 (0·3)	26,725 (1·6)	29,864 (1·8)
	1	2,424,231	20,384 (0·8)	92,808 (3·8)	79,034 (3·3)	1,937,029	115,152 (5·9)	375,004 (19·4)	163,832 (8·5)
	2	2,474,399	8,102 (0·3)	46,926 (1·9)	57,163 (2·3)	2,035,773	25,592 (1·3)	123,386 (6·1)	116,891 (5·7)
	3	2,459,431	3,509 (0·1)	23,226 (0·9)	33,006 (1·3)	1,993,354	6,277 (0·3)	41,550 (2·1)	55,855 (2·8)
	4	2,390,709	2,400 (0·1)	16,852 (0·7)	23,553 (1·0)	1,960,829	3,601 (0·2)	24,570 (1·3)	34,118 (1·7)
	5	2,285,185	2,010 (0·1)	14,447 (0·6)	19,143 (0·8)	1,939,300	2,831 (0·1)	18,829 (1·0)	25,132 (1·3)
	6	2,196,757	1,821 (0·1)	13,250 (0·6)	16,821 (0·8)	1,949,754	2,582 (0·1)	16,587 (0·9)	21,152 (1·1)
	7	2,157,101	1,874 (0·1)	13,157 (0·6)	16,230 (0·8)	2,019,370	3,240 (0·2)	17,390 (0·9)	19,800 (1·0)

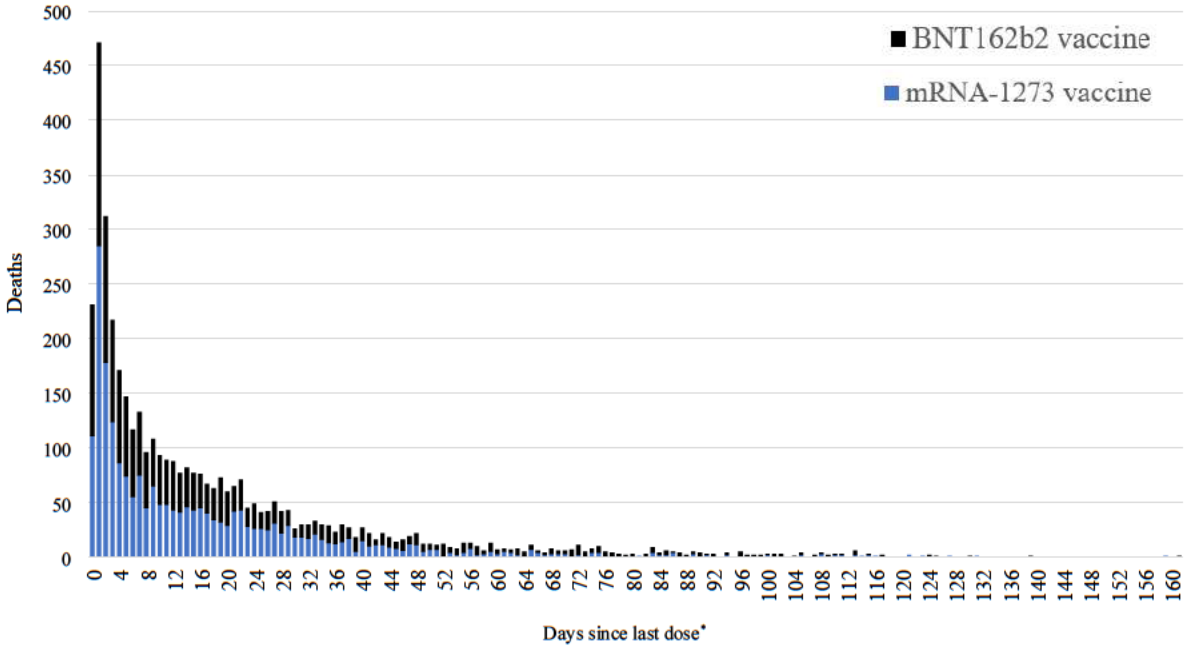
Data are n (%) unless otherwise stated.
*Top five reactions determined by reported frequency after second dose of both mRNA COVID-19 vaccines in v-safe, excluding fever because it was not rated mild/moderate/severe. Symptoms are not mutually exclusive. †Mild was defined as "noticeable symptoms but they aren't a problem", moderate was defined as "symptoms that limit normal activities, and severe symptoms", and severe symptoms "make normal daily activities difficult or impossible".

Supplemental Table 7: Reported health impact* 0-7 days after vaccination by mRNA COVID-19 vaccine manufacturer, dose, and sex reported in v-safe—December 14, 2020–June 14, 2021

	BNT162b2 vaccine						mRNA-1273 vaccine					
	Dose 1 (n=3,455,778)			Dose 2 (n=2,920,526)			Dose 1 (n=3,319,737)			Dose 2 (n=2,753,894)		
Sex/day	Unable to do normal activity	Unable to work	Reported medical care	Unable to do normal activity	Unable to work	Reported medical care	Unable to do normal activity	Unable to work	Reported medical care	Unable to do normal activity	Unable to work	Reported medical care
Female												
Day 0	29,039 (2·1)	11,480 (0·8)	2,486 (0·2)	38,593 (3·5)	18,411 (1·7)	1,567 (0·1)	30,334 (2·4)	10,888 (0·8)	2,099 (0·2)	48,485 (4·6)	22,274 (2·1)	1,471 (0·1)
Day 1	105,123 (6·6)	41,398 (2·6)	2,810 (0·2)	324,559 (24·9)	178,887 (13·7)	3,276 (0·3)	151,710 (10·0)	60,161 (4·0)	3,370 (0·2)	522,192 (41·4)	296,178 (23·5)	4,470 (0·4)
Day 2	53,456 (3·4)	22,016 (1·4)	2,912 (0·2)	121,302 (8·9)	67,628 (5·0)	3,335 (0·2)	74,193 (4·8)	31,936 (2·1)	3,432 (0·2)	188,421 (14·2)	107,761 (8·1)	3,767 (0·3)
Day 3	35,994 (2·3)	13,399 (0·9)	3,387 (0·2)	55,917 (4·2)	24,334 (1·8)	3,695 (0·3)	40,305 (2·6)	15,496 (1·0)	3,345 (0·2)	73,844 (5·7)	32,292 (2·5)	4,052 (0·3)
Day 4	28,877 (1·9)	10,799 (0·7)	3,572 (0·2)	36,450 (2·8)	14,154 (1·1)	3,377 (0·3)	29,880 (2·0)	10,773 (0·7)	3,351 (0·2)	43,833 (3·4)	16,702 (1·3)	3,541 (0·3)
Day 5	24,765 (1·7)	9,468 (0·6)	3,548 (0·2)	29,069 (2·3)	10,747 (0·8)	3,125 (0·2)	25,056 (1·7)	9,512 (0·7)	3,467 (0·2)	32,958 (2·6)	12,195 (1·0)	3,065 (0·2)
Day 6	22,401 (1·6)	9,187 (0·7)	3,621 (0·3)	25,167 (2·0)	9,669 (0·8)	3,157 (0·2)	22,502 (1·6)	9,271 (0·7)	3,733 (0·3)	28,146 (2·2)	10,840 (0·9)	3,133 (0·2)
Day 7	20,820 (1·5)	8,801 (0·6)	3,811 (0·3)	24,955 (1·9)	10,060 (0·8)	3,419 (0·3)	21,804 (1·6)	9,242 (0·7)	4,483 (0·3)	28,538 (2·2)	12,066 (0·9)	3,272 (0·3)
Male												
Day 0	8,905 (1·0)	5,711 (0·7)	569 (0·1)	11,137 (1·7)	8,208 (1·3)	380 (0·1)	8,954 (1·1)	5,339 (0·7)	479 (0·1)	13,450 (2·3)	8,955 (1·5)	337 (0·1)
Day 1	30,240 (3·2)	16,781 (1·8)	656 (0·1)	93,820 (13·3)	66,375 (9·4)	820 (0·1)	46,535 (5·3)	24,313 (2·8)	955 (0·1)	167,957 (25·6)	110,868 (16·9)	1,104 (0·2)
Day 2	13,698 (1·5)	7,846 (0·8)	767 (0·1)	29,528 (4·0)	21,766 (3·0)	768 (0·1)	21,696 (2·4)	12,307 (1·4)	836 (0·1)	47,601 (6·9)	33,333 (4·9)	785 (0·1)
Day 3	8,925 (1·0)	4,669 (0·5)	827 (0·1)	12,163 (1·7)	7,101 (1·0)	788 (0·1)	10,625 (1·2)	5,218 (0·6)	865 (0·1)	15,542 (2·3)	8,550 (1·3)	784 (0·1)
Day 4	7,267 (0·8)	3,667 (0·4)	967 (0·1)	7,978 (1·1)	4,250 (0·6)	843 (0·1)	7,670 (0·9)	3,801 (0·4)	867 (0·1)	9,428 (1·4)	4,613 (0·7)	754 (0·1)
Day 5	6,180 (0·7)	3,207 (0·4)	981 (0·1)	6,319 (0·9)	3,224 (0·5)	901 (0·1)	6,516 (0·8)	3,376 (0·4)	932 (0·1)	7,156 (1·1)	3,425 (0·5)	785 (0·1)
Day 6	5,696 (0·7)	3,019 (0·4)	1,022 (0·1)	5,790 (0·8)	2,902 (0·4)	868 (0·1)	5,829 (0·7)	3,107 (0·4)	1,035 (0·1)	6,433 (1·0)	3,146 (0·5)	793 (0·1)
Day 7	5,324 (0·7)	2,937 (0·4)	1,050 (0·1)	5,873 (0·8)	3,147 (0·4)	975 (0·1)	5,443 (0·7)	3,047 (0·4)	1,094 (0·1)	6,651 (0·9)	3,547 (0·5)	886 (0·1)

Data are n (%)†.
*Reports of health impacts are not mutually exclusive.
†Percent corresponds to number of respondents by sex and day.

***Supplemental Figure* 1: Number of reports of death per day following vaccination, by manufacturer, to Vaccine Adverse Event Reporting System (VAERS)—December 14, 2020–June 14, 2021**

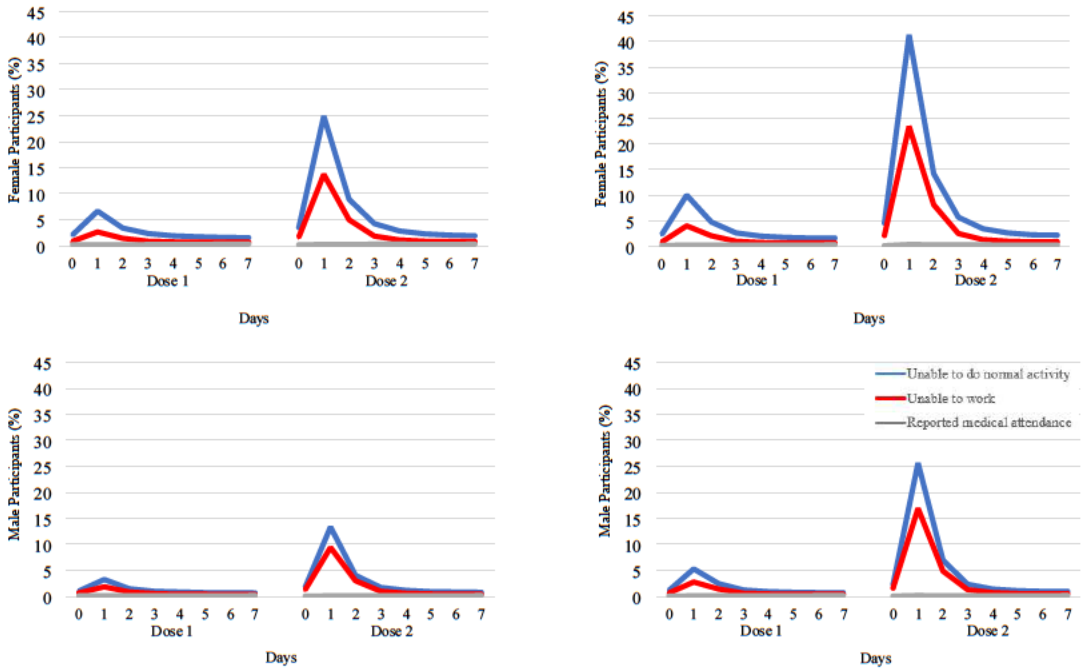


*x-axis reports through 161 days since last dose.

Commented [BR(35]: Editorial suggestion:
This wording sounds awkward and confusing. Please revise for clarity. Consider something like "Number of reports per day of onset" .....
Office of Science
2021-08-11 11:45:00

Commented [RH(36R35]: Thanks. done
Rosenblum, Hannah (CDC)
2021-08-31 12:09:00

***Supplemental Figure* 2: Reported health impact 0-7 days after mRNA COVID-19 vaccination by manufacturer, type of impact, and sex reported in v-safe—December 14, 2020–June 14, 2021**



Top left: Female participants reporting health impact after receiving BNT162b2 vaccine. *Top right:* Female participants reporting health impact after receiving mRNA-1273 vaccine. *Bottom left:* Male participants reporting health impact after receiving BNT162b2 vaccine. *Bottom right*: Male participants reporting health impact after receiving mRNA-1273 vaccine.