

## Supplemental Online Content

Hu M, Wong HL, Feng Y, et al. Safety of the BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine in children aged 5 to 17 years. *JAMA Pediatr*. Published online May 22, 2023. doi:10.1001/jamapediatrics.2023.1440

**eTable 1.** Database Descriptions

**eTable 2.** Codes for COVID-19 Vaccine Administrations, Utilized in Claims and IIS data

**eTable 3.** Outcomes, Age Groups, Settings, Clean Windows, Risk Windows, and Analysis Type for the Pediatric Population (Ages 5-17)

**eTable 4.** Sequential Testing Results in Health Plan Members Aged 5-17 years by Outcome Following BNT162b2 All Doses (Primary Series, Dose 1, Dose 2, and Third/Booster Dose) in CVS Health, HealthCore, and Optum Databases

**eTable 5.** Descriptive Outcome Counts, Overall and by Data Partners

### **eReferences**

This supplemental material has been provided by the authors to give readers additional information about their work.

**eTable 1. Database Descriptions**

Database	Description	Claims Type	Update frequency	Data Lag, Time to 80% Completeness <sup>a</sup>	Enrollees Ages 5-17 years <sup>b</sup>	Count of IIS Jurisdictions Incorporated into Analysis
CVS Health	CVS Health Clinical Trial Services (CVS CTS) transforms enrollment, demographic, and medical and drug claims data, for individuals enrolled from January 2018 forward in Aetna commercial including Affordable Care act (ACA) Marketplace, and Medicare Advantage health plans into a patient-centered, comprehensive Common Data Model (CDM).	Fully Adjudicated	Monthly	~ 3-4 months for IP claims, 2-3 months for OP claims, and 1-2 months for professional claims	5-11 years: > 1.5 million 12-15 years: > 991k 16-17 years: > 558k	14
Optum Pre-adjudicated Claims	The Optum data includes enrollment, prescription drug and pre-adjudicated hospital and physician health insurance claims. The pre-adjudicated claims database includes claims for privately insured and Medicare Advantage enrollees. Hospital and physician claims undergo initial processing on a daily basis from a large number of providers across the US who accept patients with health insurance.	Pre-Adjudicated	Bi-Weekly	~ 1-2 months for IP, OP, and professional claims	5-11 years: > 1.3 million 12-15 years: > 840k 16-17 years: > 429k	18
HealthCore	HealthCore, Inc. is a wholly-owned, research subsidiary of Elevance Health, Inc., a holding company owning several large US health plans associated with Anthem Blue Cross Blue Shield. HealthCore has a US population database including individually insured by commercial and Medicare Advantage plans, the HealthCore Integrated Research Environment (HIRE), with longitudinal data on health plan enrollees.	Fully Adjudicated	Monthly	~ 2-3 months for IP claims and 1-2 months for OP and professional claims	5-11 years: > 1.8 million 12-15 years: > 1.2 million 16-17 years: > 647k	0

<sup>a</sup> Data lag based on 2020 claims delay distribution

<sup>b</sup> Average number of annual enrollees in a given age category between 2018-2020

**eTable 2. Codes for COVID-19 Vaccine Administrations, Utilized in Claims and IIS data**

HCPCS/CPT Code	CVX Codes (IIS-Specific)	Manufacturer	Name	Age Group	Vaccine Administration Code	NDC 11 Labeler Product ID (Vial)	Dosing Interval
NA	NA	Pfizer	Pfizer-BioNTech COVID-19 Vaccine	16+ years	NA	00069-2025-01 00069-2025-10 00069-2025-25	NA
91308	219	Pfizer	Pfizer-BioNTech COVID-19 Vaccine	6 month - 5 years	0081A (1st dose)	59267-0078-01 59267-0078-02 59267-0078-04	-21+ days between dose 1 and dose 2
					0082A (second dose)		
91307	218	Pfizer	Pfizer-BioNTech COVID-19 Pediatric Vaccine	5-11 years	0071A (1st dose)	59267-1055-01 59267-1055-02 59267-1055-04	-21+ days between dose 1 and dose 2 -For immunocompromised, 21+ days between dose 1 and dose 2, and 28+ days between dose 2 and additional primary dose (dose 3)
					0072A (2nd dose)		
					0073A (3rd dose)		
					0074A (booster dose)		
91305	217	Pfizer	Pfizer-BioNTech COVID-19 Vaccine	12+ years	0051A (1 <sup>st</sup> dose)	59267-1025-01 59267-1025-02 59267-1025-03 59267-1025-04	-21+ days between dose 1 and dose 2 and 5+ months between dose 2 and third/booster dose - For immunocompromised, 21+ days between dose 1 and dose 2, 28+ days between dose 2 and dose 3. Additionally, booster dose recommended 3+ months after primary series
					0052A (2 <sup>nd</sup> dose)		
					0053A (3 <sup>rd</sup> dose)		
					0054A (booster dose)		

HCPCS/CPT Code	CVX Codes (IIS-Specific)	Manufacturer	Name	Age Group	Vaccine Administration Code	NDC 11 Labeler Product ID (Vial)	Dosing Interval
91300	208	Pfizer	Pfizer-BioNTech COVID-19 Vaccine	12+ years	0001A (1 <sup>st</sup> dose)	59267-1000-01 59267-1000-02 59267-1000-03	-21+ days between dose 1 and dose 2 and 5+ months between dose 2 and third/booster dose - For immunocompromised, 21+ days between dose 1 and dose 2, 28+ days between dose 2 and dose 3. Additionally, booster dose recommended 3+ months after primary series
					0002A (2 <sup>nd</sup> dose)		
					0003A (3 <sup>rd</sup> dose)		
					0004A (booster dose)		

**eTable 3. Outcomes, Age Groups, Settings, Clean Windows, Risk Windows, and Analysis Type for the Pediatric Population (Ages 5-17)**

Outcome	Setting	Clean Window	Risk Window	Analysis Type
<b>Pediatric Outcomes</b>				
Myocarditis/ Pericarditis	IP, OP/PB	365 days	1-7 days <sup>[1]</sup>	Descriptive and Sequential Testing
	IP, OP/PB	365 days	1-21 days <sup>[2]</sup>	Descriptive and Sequential Testing
	IP, OP-ED	365 days	1-7 days <sup>[1]</sup>	Descriptive and Sequential Testing
	IP, OP-ED	365 days	1-21 days <sup>[2]</sup>	Descriptive and Sequential Testing
Guillain-Barré syndrome (GBS)	IP- primary position only	365 days	1-42 days <sup>[3,4]</sup>	Descriptive Only
Multisystem inflammatory syndrome in children (MIS-C)	IP, OP-ED	365 days	1-42 days <sup>[5]</sup>	Descriptive Only
Encephalitis / myelitis / encephalomyelitis	IP	183 days	1-42 days <sup>[6]</sup>	Descriptive and Sequential Testing
Transverse myelitis	IP, OP-ED	365 days	1-42 days <sup>[7]</sup>	Descriptive Only
Anaphylaxis	IP, OP-ED	30 days	0-1 day <sup>[8,9]</sup>	Descriptive and Sequential Testing
Common thromboses with thrombocytopenia	[Definition below]**	365 days	1-28 days <sup>[10]</sup>	Descriptive and Sequential Testing
Unusual site thrombosis (broad)with thrombocytopenia- cerebral and abdominal thrombosis	[Definition below]**	365 days	1-28 days <sup>[11]</sup>	Descriptive Only
Seizures/Convulsions	IP, OP-ED	42 days	0-7 days <sup>[12]</sup>	Descriptive and Sequential Testing
Bell's palsy	IP, OP/PB	183 days	1-42 days <sup>[13]</sup>	Descriptive and Sequential Testing
Deep vein thrombosis (DVT)	IP, OP/PB	365 days	1-28 days <sup>[14-16]</sup>	Descriptive and Sequential Testing
Pulmonary embolism (PE)	IP, OP/PB	365 days	1-28 days <sup>[14-16]</sup>	Descriptive and Sequential Testing
Disseminated intravascular coagulation (DIC)	IP, OP-ED	365 days	1-28 days <sup>[17]</sup>	Descriptive and Sequential Testing
Immune thrombocytopenia (ITP)	IP, OP/PB	365 days	1-42 days <sup>[18,19]</sup>	Descriptive and Sequential Testing
Kawasaki disease	IP, OP/PB	365 days	1-28 days <sup>[20,21]</sup>	Descriptive Only
Narcolepsy	IP, OP/PB	365 days	1-42 days <sup>[22-24]</sup>	Descriptive and Sequential Testing
Appendicitis	IP, OP-ED	365 days	1-42 days <sup>[25,26]</sup>	Descriptive and Sequential Testing
Non-hemorrhagic stroke	IP	365 days	1-28 days <sup>[27,28]</sup>	Descriptive and Sequential Testing
Hemorrhagic stroke	IP	365 days	1-28 days <sup>[27,28]</sup>	Descriptive Only
Acute myocardial infarction	IP	365 days	1-28 days <sup>[27,28]</sup>	Descriptive Only

*Definitions: Clean Window is defined as an interval used to define incident outcomes where an individual enters the study cohort only if the outcome of interest did not occur during that interval. Risk Window is defined as an interval during which occurrence of the outcome of interest will be included in the analyses.*

*Setting Definitions: IP refers to inpatient facility claims. OP-ED refers to a subset of outpatient facility claims occurring in the emergency department. OP/PB refers to all outpatient facility claims, and professional/provider claims except those professional/provider claims with a laboratory place of service. For myocarditis/pericarditis, analyses were performed using two different risk windows (1-7 days; 1-21 days) and two different care settings (inpatient, outpatient and provider services; inpatient and outpatient-emergency department) based on clinician input and available literature*

*\*All outcomes were identified using ICD-10-CM Diagnosis codes.<sup>29</sup> The classification of outcomes into those to be monitored descriptively and those monitored via sequential testing is based on the availability of estimable background rates for the outcomes and the expected frequency of events*

*\*\* Both Common thromboses with thrombocytopenia and Unusual site thrombosis (broad) with thrombocytopenia are combined outcomes consisting of a thrombotic event (made up of other events such as acute myocardial infarction, deep vein thrombosis etc.) and a thrombocytopenia event (defined in the IP, OP/PB setting). The overall setting definition for each outcome depends on individual setting definitions for each of these components*

**eTable 4. Sequential Testing Results in Health Plan Members Aged 5-17 years by Outcome Following BNT162b2 All Doses (Primary Series, Dose 1, Dose 2, and Third/Booster Dose) in CVS Health, HealthCore, and Optum Databases**

Outcome	Dose	Age Group	CVS				HCI				Optum			
			# of Doses	Outcomes	Person-Time (Days)	RR	# of Doses	Outcomes	Person-Time (Days)	RR	# of Doses	Outcomes	Person-Time (Days)	RR
Anaphylaxis	Primary Series	5-11	739,974	<11	1,478,203	3.50	727,202	<11	1,449,597	5.39	680,186	0	1,348,722	0.00
		12-15	689,683	<11	1,378,721	3.95	772,261	<11	1,542,848	0.87	669,816	<11	1,337,763	5.50
		16-17	349,440	<11	698,487	4.78	393,066	<11	785,267	1.48	337,391	<11	673,972	3.95
	Dose 1	5-11	391,692	<11	782,495	3.30	404,716	<11	807,094	4.81	371,307	0	735,473	0.00
		12-15	365,895	<11	731,399	2.48	425,137	<11	849,202	1.58	360,549	<11	719,866	7.67
		16-17	187,361	<11	374,491	8.92	221,794	<11	443,014	2.63	185,157	<11	369,815	7.20
	Dose 2	5-11	348,282	<11	695,708	3.73	322,486	<11	642,503	6.14	308,879	0	613,249	0.00
		12-15	323,788	<11	647,322	5.61	347,124	0	693,646	0.00	309,267	<11	617,897	2.98
		16-17	162,079	0	323,996	0.00	171,272	0	342,253	0.00	152,234	0	304,157	0.00
	Dose 3	5-11	13,611	0	23,369	0.00	1,481	0	2,929	0.00	21,450	0	32,023	0.00
		12-15	96,975	<11	192,972	10.17	66,312	<11	131,608	11.11	86,087	0	170,125	0.00
		16-17	66,162	0	131,909	0.00	45,560	0	90,677	0.00	55,445	<11	110,204	12.24
Appendicitis	Primary Series	5-11	602,964	65	19,346,774	1.13	604,588	45	19,727,071	0.74	572,135	48	18,187,457	0.70
		12-15	572,563	90	18,568,541	1.10	652,741	88	21,526,254	0.87	565,049	87	18,251,418	0.94
		16-17	291,301	44	9,505,378	0.99	334,608	55	11,200,565	1.01	285,726	47	9,336,794	0.89
	Dose 1	5-11	318,219	27	7,902,725	1.13	335,279	21	8,916,128	0.74	310,350	25	7,865,129	0.84
		12-15	301,730	29	7,378,691	0.89	356,294	42	9,243,397	0.97	302,196	41	7,529,320	1.07
		16-17	155,214	20	3,875,060	1.10	186,911	27	5,072,915	1.10	155,615	17	4,028,348	0.75
	Dose 2	5-11	284,745	38	11,444,049	1.12	269,309	24	10,810,943	0.73	261,785	24	10,322,328	0.62
		12-15	270,833	61	11,189,850	1.24	296,447	46	12,282,857	0.80	262,853	47	10,722,098	0.86
		16-17	136,087	24	5,630,318	0.91	147,697	28	6,127,650	0.93	130,111	30	5,308,446	1.00
	Dose 3	5-11	11,438	0	124,510	0.00	1,339	0	45,888	0.00	19,033	0	369,675	0.00
		12-15	86,036	11	3,355,000	0.83	63,891	<11	2,482,199	0.74	79,497	<11	3,073,489	0.55
		16-17	57,772	<11	2,289,307	0.81	43,066	<11	1,697,120	0.83	50,525	15	1,951,045	1.43

Bell's palsy	Primary Series	5-11	675,779	13	21,785,514	1.17	673,161	12	22,150,403	1.01	635,935	<11	20,175,890	0.53
		12-15	623,855	14	20,275,128	1.08	709,401	22	23,491,552	1.18	615,692	11	19,893,989	0.57
		16-17	314,933	<11	10,298,281	0.74	360,346	<11	12,108,973	0.78	308,945	<11	10,096,665	0.84
	Dose 1	5-11	357,777	<11	8,944,746	0.87	374,144	<11	10,005,282	1.28	345,766	<11	8,760,032	0.24
		12-15	328,898	<11	8,079,623	0.97	386,972	<11	10,101,801	1.01	329,457	<11	8,231,955	0.50
		16-17	167,972	<11	4,216,467	0.61	201,636	<11	5,513,254	0.38	168,583	<11	4,378,145	1.11
	Dose 2	5-11	318,002	<11	12,840,768	1.38	299,017	<11	12,145,121	0.78	290,169	<11	11,415,858	0.75
		12-15	294,957	<11	12,195,505	1.28	322,429	<11	13,389,751	1.32	286,235	<11	11,662,034	0.62
		16-17	146,961	<11	6,081,814	1.05	158,710	<11	6,595,719	1.11	140,362	<11	5,718,520	0.64
	Dose 3	5-11	12,471	0	164,697	0.00	1,441	0	50,751	0.00	20,761	0	409,823	0.00
		12-15	91,094	<11	3,623,831	0.93	66,062	<11	2,656,746	1.10	83,933	<11	3,243,633	1.66
		16-17	62,499	<11	2,503,089	1.08	45,412	<11	1,825,062	0.63	54,106	<11	2,086,728	0.60
Common thromboses with thrombocytopenia <sup>a</sup>	Primary Series	5-11	603,631	0	15,063,681	0.00	605,189	0	15,253,024	0.00	572,768	0	14,156,025	0.00
		12-15	573,509	0	14,326,988	0.00	653,821	<11	16,493,102	1.51	566,008	0	14,069,963	0.00
		16-17	291,770	<11	7,309,572	3.28	335,214	0	8,514,719	0.00	286,191	0	7,151,741	0.00
	Dose 1	5-11	318,571	0	7,281,081	0.00	335,610	0	7,872,732	0.00	310,689	0	7,096,078	0.00
		12-15	302,226	0	6,810,180	0.00	356,881	0	8,241,243	0.00	302,702	0	6,848,840	0.00
		16-17	155,466	<11	3,530,834	3.40	187,251	0	4,401,614	0.00	155,870	0	3,578,004	0.00
	Dose 2	5-11	285,060	0	7,782,600	0.00	269,579	0	7,380,292	0.00	262,079	0	7,059,947	0.00
		12-15	271,283	0	7,516,808	0.00	296,940	<11	8,251,859	3.02	263,306	0	7,221,123	0.00
		16-17	136,304	<11	3,778,738	3.17	147,963	0	4,113,105	0.00	130,321	0	3,573,737	0.00
	Dose 3	5-11	11,446	0	89,279	0.00	1,341	0	33,982	0.00	19,048	0	291,412	0.00
		12-15	86,169	0	2,293,118	0.00	63,983	0	1,724,614	0.00	79,622	0	2,092,120	0.00
		16-17	57,851	0	1,553,697	0.00	43,144	0	1,163,968	0.00	50,629	0	1,327,042	0.00
Deep vein thrombosis (DVT)	Primary Series	5-11	603,606	0	15,062,839	0.00	605,162	0	15,252,307	0.00	572,759	0	14,155,801	0.00
		12-15	573,474	<11	14,325,938	0.24	653,791	<11	16,492,356	1.19	565,957	0	14,068,697	0.00
		16-17	291,691	<11	7,307,399	0.30	335,152	<11	8,513,141	1.14	286,133	<11	7,150,307	0.34
	Dose 1	5-11	318,556	0	7,280,652	0.00	335,593	0	7,872,323	0.00	310,683	0	7,095,938	0.00
		12-15	302,208	0	6,809,690	0.00	356,865	<11	8,240,878	1.43	302,674	0	6,848,207	0.00
		16-17	155,423	0	3,529,742	0.00	187,219	<11	4,400,848	1.77	155,836	<11	3,577,199	0.34



	Dose 2	5-11	285,050	0	7,782,187	0.00	269,569	0	7,379,984	0.00	262,076	0	7,059,863	0.00
		12-15	271,266	<11	7,516,248	0.45	296,926	<11	8,251,478	0.95	263,283	0	7,220,490	0.00
		16-17	136,268	<11	3,777,657	0.58	147,933	<11	4,112,293	0.47	130,297	<11	3,573,108	0.34
	Dose 3	5-11	11,446	0	89,251	0.00	1,339	0	33,926	0.00	19,046	0	291,366	0.00
		12-15	86,161	0	2,292,866	0.00	63,976	0	1,724,418	0.00	79,614	<11	2,091,896	1.69
		16-17	57,840	0	1,553,387	0.00	43,134	0	1,163,714	0.00	50,621	0	1,326,846	0.00
Disseminated intravascular coagulation (DIC)	Primary Series	5-11	603,622	0	14,973,673	0.00	605,194	<11	15,099,403	4.09	572,773	0	14,102,730	0.00
		12-15	573,509	0	14,304,512	0.00	653,820	0	16,440,576	0.00	566,010	0	14,053,504	0.00
		16-17	291,775	0	7,298,174	0.00	335,215	0	8,488,263	0.00	286,198	0	7,144,258	0.00
	Dose 1	5-11	318,566	0	7,238,894	0.00	335,613	0	7,813,485	0.00	310,692	0	7,067,211	0.00
		12-15	302,226	0	6,798,069	0.00	356,881	0	8,212,755	0.00	302,703	0	6,838,690	0.00
		16-17	155,469	0	3,524,012	0.00	187,252	0	4,385,669	0.00	155,874	0	3,573,645	0.00
	Dose 2	5-11	285,056	0	7,734,779	0.00	269,581	<11	7,285,918	8.81	262,081	0	7,035,519	0.00
		12-15	271,283	0	7,506,443	0.00	296,939	0	8,227,821	0.00	263,307	0	7,214,814	0.00
		16-17	136,306	0	3,774,162	0.00	147,963	0	4,102,594	0.00	130,324	0	3,570,613	0.00
	Dose 3	5-11	11,444	0	87,578	0.00	1,341	0	32,828	0.00	19,048	0	230,388	0.00
		12-15	86,170	0	2,248,385	0.00	63,982	0	1,665,851	0.00	79,622	<11	2,062,986	10.82
		16-17	57,854	0	1,536,756	0.00	43,144	0	1,139,733	0.00	50,630	0	1,317,447	0.00
Encephalitis / myelitis / encephalomyelitis	Primary Series	5-11	675,862	<11	21,498,513	0.83	673,262	0	21,766,827	0.00	636,003	0	20,177,981	0.00
		12-15	623,934	<11	20,201,159	1.65	709,494	<11	23,353,158	1.14	615,778	<11	19,896,658	0.62
		16-17	315,002	<11	10,263,177	1.29	360,397	0	12,041,649	0.00	308,985	0	10,097,982	0.00
	Dose 1	5-11	357,821	0	8,833,757	0.00	374,206	0	9,883,921	0.00	345,807	0	8,761,121	0.00
		12-15	328,944	0	8,041,758	0.00	387,018	0	10,027,824	0.00	329,507	<11	8,233,208	1.50
		16-17	168,011	0	4,196,563	0.00	201,662	0	5,473,212	0.00	168,607	0	4,378,790	0.00
	Dose 2	5-11	318,041	<11	12,664,756	1.44	299,056	0	11,882,906	0.00	290,196	0	11,416,860	0.00
		12-15	294,990	<11	12,159,401	2.75	322,476	<11	13,325,334	1.99	286,271	0	11,663,450	0.00
		16-17	146,991	<11	6,066,614	2.18	158,735	0	6,568,437	0.00	140,378	0	5,719,192	0.00
	Dose 3	5-11	12,473	0	134,559	0.00	1,441	0	47,953	0.00	20,764	0	409,895	0.00
		12-15	91,108	0	3,473,475	0.00	66,067	0	2,508,168	0.00	83,940	0	3,243,927	0.00
		16-17	62,513	0	2,441,902	0.00	45,421	0	1,765,174	0.00	54,118	0	2,087,194	0.00

Immune thrombocytopenia (ITP)	Primary Series	5-11	603,512	<11	19,489,519	2.09	605,104	<11	19,960,730	1.91	572,717	<11	18,205,909	1.49
		12-15	573,435	<11	18,629,280	1.08	653,693	12	21,635,214	2.53	565,907	<11	18,279,130	0.85
		16-17	291,710	<11	9,535,013	1.00	335,123	<11	11,256,120	1.78	286,147	<11	9,350,455	0.60
	Dose 1	5-11	318,509	<11	7,961,202	2.04	335,563	<11	8,994,830	2.38	310,663	<11	7,872,969	0.57
		12-15	302,187	<11	7,406,353	1.09	356,812	<11	9,297,471	1.96	302,645	<11	7,540,525	0.41
		16-17	155,435	<11	3,889,573	0.82	187,203	<11	5,103,168	3.29	155,845	<11	4,034,298	0.46
	Dose 2	5-11	285,003	<11	11,528,317	2.13	269,541	<11	10,965,900	1.51	262,054	<11	10,332,940	2.20
		12-15	271,248	<11	11,222,927	1.07	296,881	<11	12,337,743	2.95	263,262	<11	10,738,605	1.16
		16-17	136,275	<11	5,645,440	1.12	147,920	<11	6,152,952	0.54	130,302	<11	5,316,157	0.70
	Dose 3	5-11	11,441	0	150,770	0.00	1,340	0	47,511	0.00	19,043	0	369,817	0.00
		12-15	86,150	0	3,430,922	0.00	63,971	0	2,573,226	0.00	79,614	0	3,078,046	0.00
		16-17	57,838	<11	2,320,008	1.43	43,127	<11	1,735,767	2.09	50,620	<11	1,954,814	1.94
Myocarditis/Pericarditis (1-21 day risk window, all settings)	Primary Series	5-11	603,585	<11	12,485,896	3.44	605,143	<11	12,561,157	3.03	572,742	<11	11,698,334	4.35
		12-15	573,445	31	11,941,308	<b>10.62*</b>	653,742	23	13,640,542	<b>9.06*</b>	565,967	35	11,700,690	<b>10.19*</b>
		16-17	291,721	28	6,071,623	<b>12.65*</b>	335,160	23	6,990,316	<b>7.44*</b>	286,151	13	5,912,687	<b>3.47*</b>
	Dose 1	5-11	318,545	<11	6,590,589	3.25	335,584	<11	6,969,330	1.80	310,676	<11	6,341,416	3.20
		12-15	302,195	<11	6,282,142	2.60	356,836	<11	7,433,347	2.89	302,684	<11	6,254,311	<b>4.90*</b>
		16-17	155,443	<11	3,228,595	<b>5.10*</b>	187,217	<11	3,897,594	4.07	155,846	<11	3,217,800	0.98
	Dose 2	5-11	285,040	<11	5,895,307	3.67	269,559	<11	5,591,827	4.59	262,066	<11	5,356,918	5.72
		12-15	271,250	<11	5,659,166	<b>19.53*</b>	296,906	<11	6,207,195	<b>16.45*</b>	263,283	<11	5,446,379	<b>16.26*</b>
		16-17	136,278	<11	2,843,028	<b>21.21*</b>	147,943	<11	3,092,722	<b>11.68*</b>	130,305	<11	2,694,887	<b>6.45*</b>
	Dose 3	5-11	11,443	0	94,226	0.00	1,341	0	27,092	0.00	19,047	0	249,882	0.00
		12-15	86,157	<11	1,753,863	2.52	63,977	<11	1,320,089	14.01	79,609	<11	1,588,091	4.47
		16-17	57,844	<11	1,180,160	<b>9.93*</b>	43,134	<11	885,705	5.63	50,621	<11	1,007,613	4.90
Myocarditis/Pericarditis (1-7 day risk window, all settings)	Primary Series	5-11	603,585	<11	4,201,903	5.10	605,143	<11	4,218,557	8.94	572,742	<11	3,965,884	10.26
		12-15	573,445	22	4,005,827	<b>22.44*</b>	653,742	14	4,569,263	<b>16.43*</b>	565,967	26	3,943,897	<b>22.44*</b>
		16-17	291,721	22	2,037,440	<b>29.60*</b>	335,160	19	2,341,915	<b>18.31*</b>	286,151	11	1,993,951	<b>8.72*</b>
	Dose 1	5-11	318,545	<11	2,218,337	4.81	335,584	<11	2,340,724	5.33	310,676	<11	2,150,922	4.72
		12-15	302,195	<11	2,110,944	1.93	356,836	0	2,494,047	0.00	302,684	<11	2,109,334	6.45
		16-17	155,443	<11	1,085,398	7.58	187,217	<11	1,307,806	6.91	155,846	<11	1,085,979	2.91

	Dose 2	5-11	285,040	<11	1,983,566	5.43	269,559	<11	1,877,833	13.54	262,066	<11	1,814,962	16.85	
		12-15	271,250	<11	1,894,883	<b>45.33*</b>	296,906	14	2,075,216	<b>36.17*</b>	263,283	<11	1,834,563	<b>40.83*</b>	
		16-17	136,278	<11	952,042	<b>54.68*</b>	147,943	<11	1,034,109	<b>32.71*</b>	130,305	<11	907,972	<b>15.66*</b>	
	Dose 3	5-11	11,443	0	48,031	0.00	1,341	0	9,287	0.00	19,047	0	107,282	0.00	
		12-15	86,157	<11	594,686	7.41	63,977	<11	445,495	<b>40.59*</b>	79,609	<11	544,542	13.05	
		16-17	57,844	<11	400,044	<b>29.22*</b>	43,134	<11	299,708	8.20	50,621	<11	347,047	14.22	
	Myocarditis/Peri carditis (1-21 day risk window, IP, OP-ED)	Primary Series	5-11	603,627	0	12,415,336	0.00	605,187	<11	12,519,919	16.62	572,773	<11	11,698,984	3.49
			12-15	573,501	19	11,924,350	<b>22.98*</b>	653,800	12	13,627,693	<b>16.86*</b>	566,007	21	11,701,527	<b>18.64*</b>
			16-17	291,767	22	6,063,130	<b>20.76*</b>	335,210	15	6,983,839	<b>9.07*</b>	286,174	<11	5,913,153	<b>4.98*</b>
Dose 1		5-11	318,568	0	6,554,190	0.00	335,609	<11	6,950,073	14.71	310,693	0	6,341,772	0.00	
		12-15	302,223	0	6,272,569	0.00	356,870	0	7,425,502	0.00	302,703	<11	6,254,710	4.98	
		16-17	155,466	<11	3,223,290	<b>8.87*</b>	187,249	<11	3,893,432	4.35	155,858	<11	3,218,052	2.61	
Dose 2		5-11	285,059	0	5,861,146	0.00	269,578	<11	5,569,846	19.10	262,080	<11	5,357,212	7.62	
		12-15	271,278	19	5,651,781	<b>48.61*</b>	296,930	12	6,202,191	<b>37.07*</b>	263,304	<11	5,446,817	<b>34.34*</b>	
		16-17	136,301	<11	2,839,840	<b>34.24*</b>	147,961	<11	3,090,407	<b>15.01*</b>	130,316	<11	2,695,101	<b>7.81*</b>	
Dose 3		5-11	11,446	0	68,786	0.00	1,341	0	26,861	0.00	19,048	0	249,884	0.00	
		12-15	86,167	<11	1,714,547	9.72	63,982	<11	1,305,505	35.96	79,616	0	1,588,218	0.00	
		16-17	57,854	<11	1,166,224	16.47	43,143	<11	879,636	10.98	50,629	<11	1,007,781	4.33	
Myocarditis/Peri carditis (1-7 day risk window, IP, OP-ED)	Primary Series	5-11	603,627	0	4,176,754	0.00	605,187	<11	4,207,157	48.87	572,773	<11	3,966,101	10.29	
		12-15	573,501	19	3,999,983	<b>68.36*</b>	653,800	<11	4,565,641	<b>41.78*</b>	566,007	19	3,944,177	<b>50.01*</b>	
		16-17	291,767	18	2,034,590	<b>50.55*</b>	335,210	13	2,340,241	<b>23.39*</b>	286,174	<11	1,994,109	<b>14.77*</b>	
	Dose 1	5-11	318,568	0	2,205,071	0.00	335,609	<11	2,335,146	43.40	310,693	0	2,151,041	0.00	
		12-15	302,223	0	2,107,581	0.00	356,870	0	2,491,770	0.00	302,703	<11	2,109,467	9.84	
		16-17	155,466	<11	1,083,649	15.82	187,249	<11	1,306,721	6.45	155,858	<11	1,086,063	7.75	
	Dose 2	5-11	285,059	0	1,971,683	0.00	269,578	<11	1,872,011	55.92	262,080	<11	1,815,060	22.49	
		12-15	271,278	19	1,892,402	<b>144.90*</b>	296,930	<11	2,073,871	<b>92.06*</b>	263,304	<11	1,834,710	<b>96.22*</b>	
		16-17	136,301	<11	950,941	<b>90.11*</b>	147,961	<11	1,033,520	<b>44.75*</b>	130,316	<11	908,046	<b>23.17*</b>	
	Dose 3	5-11	11,446	0	23,687	0.00	1,341	0	9,233	0.00	19,048	0	107,284	0.00	
		12-15	86,167	<11	579,688	28.38	63,982	<11	441,307	102.61	79,616	0	544,585	0.00	

		16-17	57,854	<11	394,604	<b>48.16*</b>	43,143	<11	297,977	31.73	50,629	<11	347,103	12.56
Narcolepsy	Primary Series	5-11	603,613	<11	19,492,848	3.00	605,180	<11	19,963,122	0.47	572,762	0	18,207,458	0.00
		12-15	573,450	<11	18,629,851	0.50	653,703	<11	21,635,586	0.73	565,952	<11	18,280,657	0.76
		16-17	291,655	<11	9,533,109	0.82	335,066	<11	11,254,465	0.76	286,088	<11	9,348,810	0.60
	Dose 1	5-11	318,562	<11	7,962,580	1.82	335,604	<11	8,995,962	1.02	310,686	0	7,873,597	0.00
		12-15	302,195	<11	7,406,603	0.94	356,822	<11	9,297,814	1.41	302,671	<11	7,541,252	0.31
		16-17	155,400	<11	3,888,553	0.67	187,163	<11	5,102,168	0.48	155,815	<11	4,033,705	0.46
	Dose 2	5-11	285,051	<11	11,530,268	3.82	269,576	0	10,967,160	0.00	262,076	0	10,333,861	0.00
		12-15	271,255	<11	11,223,248	0.21	296,881	<11	12,337,772	0.21	263,281	<11	10,739,405	1.08
		16-17	136,255	<11	5,644,556	1.15	147,903	<11	6,152,297	0.99	130,273	<11	5,315,105	0.70
	Dose 3	5-11	11,446	0	150,873	0.00	1,341	0	47,553	0.00	19,046	0	369,915	0.00
		12-15	86,162	<11	3,431,411	1.46	63,976	0	2,573,404	0.00	79,609	<11	3,077,909	0.78
		16-17	57,831	<11	2,319,748	1.77	43,124	<11	1,735,642	3.82	50,607	<11	1,954,338	0.48
Non-hemorrhagic stroke	Primary Series	5-11	603,620	0	14,973,614	0.00	605,190	<11	15,182,777	2.44	572,772	0	14,156,125	0.00
		12-15	573,510	0	14,304,561	0.00	653,814	0	16,468,867	0.00	566,004	0	14,069,866	0.00
		16-17	291,775	<11	7,298,163	1.65	335,217	0	8,502,438	0.00	286,197	<11	7,151,916	0.99
	Dose 1	5-11	318,565	0	7,238,863	0.00	335,611	<11	7,844,822	4.61	310,691	0	7,096,122	0.00
		12-15	302,226	0	6,798,090	0.00	356,878	0	8,227,890	0.00	302,701	0	6,848,826	0.00
		16-17	155,470	<11	3,524,039	3.42	187,253	0	4,394,094	0.00	155,873	0	3,578,081	0.00
	Dose 2	5-11	285,055	0	7,734,751	0.00	269,579	0	7,337,955	0.00	262,081	0	7,060,003	0.00
		12-15	271,284	0	7,506,471	0.00	296,936	0	8,240,977	0.00	263,303	0	7,221,040	0.00
		16-17	136,305	0	3,774,124	0.00	147,964	0	4,108,344	0.00	130,324	<11	3,573,835	1.98
	Dose 3	5-11	11,446	0	87,634	0.00	1,341	0	33,429	0.00	19,048	0	291,412	0.00
		12-15	86,169	0	2,248,357	0.00	63,983	0	1,697,487	0.00	79,623	0	2,092,148	0.00
		16-17	57,855	<11	1,536,784	8.80	43,144	<11	1,152,674	21.01	50,632	0	1,327,126	0.00
Pulmonary embolism (PE)	Primary Series	5-11	603,628	0	15,109,619	0.00	605,187	0	15,312,029	0.00	572,776	0	14,156,230	0.00
		12-15	573,504	<11	14,338,531	1.06	653,808	0	16,512,834	0.00	566,002	<11	14,069,828	0.56
		16-17	291,724	<11	7,314,350	1.58	335,190	<11	8,524,694	1.79	286,159	0	7,150,951	0.00
	Dose 1	5-11	318,569	0	7,303,427	0.00	335,608	0	7,897,662	0.00	310,694	0	7,096,199	0.00
		12-15	302,224	0	6,816,484	0.00	356,874	0	8,252,689	0.00	302,699	0	6,848,786	0.00

		16-17	155,442	<11	3,533,778	2.18	187,238	<11	4,407,873	2.61	155,851	0	3,577,578	0.00
	Dose 2	5-11	285,059	0	7,806,192	0.00	269,579	0	7,414,367	0.00	262,082	0	7,060,031	0.00
		12-15	271,280	<11	7,522,047	2.02	296,934	0	8,260,145	0.00	263,303	<11	7,221,042	1.10
		16-17	136,282	<11	3,780,572	1.02	147,952	<11	4,116,821	0.93	130,308	0	3,573,373	0.00
	Dose 3	5-11	11,446	0	113,843	0.00	1,341	0	34,377	0.00	19,048	0	291,412	0.00
		12-15	86,168	0	2,319,678	0.00	63,983	0	1,746,941	0.00	79,622	0	2,092,120	0.00
		16-17	57,847	<11	1,563,040	2.60	43,141	0	1,173,213	0.00	50,627	0	1,326,986	0.00
Seizures/convulsions	Primary Series	5-11	732,503	15	5,804,883	1.81	721,478	24	5,748,418	1.79	676,710	12	5,356,934	1.33
		12-15	685,589	17	5,467,492	1.60	768,292	20	6,136,727	1.11	666,728	13	5,310,571	1.16
		16-17	347,431	11	2,770,390	1.63	391,217	17	3,123,757	1.27	335,928	<11	2,675,382	0.91
	Dose 1	5-11	388,213	<11	3,076,139	2.26	401,399	<11	3,199,876	1.98	369,270	<11	2,922,238	1.22
		12-15	363,843	<11	2,900,710	1.42	422,576	<11	3,375,193	0.91	358,999	<11	2,859,080	1.33
		16-17	186,243	<11	1,484,375	2.22	220,499	<11	1,760,130	1.33	184,243	<11	1,467,105	1.04
	Dose 2	5-11	344,290	<11	2,728,744	1.29	320,079	<11	2,548,542	1.53	307,440	<11	2,434,696	1.46
		12-15	321,746	<11	2,566,782	1.81	345,716	<11	2,761,534	1.36	307,729	<11	2,451,491	0.97
		16-17	161,188	<11	1,286,015	1.28	170,718	<11	1,363,627	1.20	151,685	<11	1,208,277	0.76
	Dose 3	5-11	13,572	0	34,157	0.00	1,476	0	11,690	0.00	21,413	0	141,013	0.00
		12-15	96,123	<11	747,307	3.04	66,287	<11	527,774	0.73	85,908	<11	672,632	1.44
		16-17	65,777	<11	516,066	0.86	45,550	0	361,811	0.00	55,387	0	434,725	0.00

Abbreviation: RR, rate ratio; IP, inpatient; OP-ED, Outpatient Emergency Department

Optum data through 6/25/2022, HealthCore data through 5/6/2022, CVS data through 5/31/2022

\*indicates the outcome has signaled in the data.

Cell sizes 1-10 were masked for confidentiality

**eTable 5. Descriptive Outcome Counts, Overall and by Data Partners**

Outcome	All Data Partners		HealthCore (data through 5/6/22)		CVS (data through 5/31/22)		Optum (data through 6/25/22)	
	# of Vaccine Doses	# of Outcomes	# of Vaccine Doses	# of Outcomes	# of Vaccine Doses	# of Outcomes	# of Vaccine Doses	# of Outcomes
<b>AMI</b>	4,904,152	<11	1,703,210	<11	1,625,585	<11	1,575,357	0
<b>GBS</b>	4,904,135	<11	1,703,207	<11	1,625,574	<11	1,575,354	<11
<b>Hemorrhagic Stroke</b>	4,904,039	<11	1,703,163	<11	1,625,548	<11	1,575,328	<11
<b>Kawasaki Disease</b>	4,903,075	55	1,702,843	12	1,625,217	19	1,575,015	24
<b>MIS-C</b>	4,903,902	14	1,703,107	<11	1,625,518	<11	1,575,277	<11
<b>Transverse Myelitis</b>	4,904,143	<11	1,703,206	<11	1,625,584	0	1,575,353	<11
<b>Unusual Site Thromboses</b>	4,904,140	<11	1,703,209	<11	1,625,582	0	1,575,349	0

Cell sizes 1-10 were masked for confidentiality

## eReferences

1. Oster ME, Shay DK, Su JR, et al. Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021. *JAMA*. 2022; 327(4): 331–340.
2. Klein N. Myocarditis Analyses in the Vaccine Safety Datalink: Rapid Cycle Analyses and “Head-to-Head” Product Comparisons. Presentation at: Advisory Committee on Immunization Practices; October, 2021.
3. Dodd CN, Romio SA, Black S, et al. International collaboration to assess the risk of Guillain Barré Syndrome following Influenza A (H1N1) 2009 monovalent vaccines. *Vaccine*. 2013; 31(40): 4448-4458.
4. Schonberger LB, Bregman DJ, Sullivan-Bolyai JZ, et al. Guillain-Barré syndrome following vaccination in the national influenza immunization program, United States, 1976–1977. *American Journal of Epidemiology*. 1979; 110(2): 105-123.
5. Hennon TR, Penque MD, Abdul-Aziz R, et al. COVID-19 associated Multisystem Inflammatory Syndrome in Children (MIS-C) guidelines; a Western New York approach. *Progress in Pediatric Cardiology*. 2020; 57: 1-6.
6. Pellegrino P, Carnovale C, Perrone V, et al. Acute disseminated encephalomyelitis onset: evaluation based on vaccine adverse events reporting systems. *PloS one*. 2013; 8(10): e77766.
7. Agmon-Levin N, Kivity S, Szyper-Kravitz M, Shoenfeld Y., Transverse myelitis and vaccines: a multi-analysis. *Lupus*. 2009; 18(13): 1198-1204.
8. Rüggeberg JU, Gold MS, Bayas J-M, et al., Anaphylaxis: case definition and guidelines for data collection, analysis, and presentation of immunization safety data. *Vaccine*. 2007; 25(31): 5675-5684.
9. Su JR, Moro PL, Ng CS, Lewis PW, Said MA, Cano MV. Anaphylaxis after vaccination reported to the Vaccine Adverse Event Reporting System, 1990-2016. *Journal of Allergy and Clinical Immunology*. 2019; 143(4): 1465-1473.
10. Pishko AM, Bussel JB, Cines DB. COVID-19 vaccination and immune thrombocytopenia. *Nature Medicine*. 2021; 27: 1145–1146 .
11. Whitworth H, Sartain SE, Kumar R, et al. Rate of thrombosis in children and adolescents hospitalized with COVID-19 or MIS-C. *Blood*. 2021; 138(2): 190-198.
12. Duffy J, Weintraub E, Hambidge SJ, et al. Febrile seizure risk after vaccination in children 6 to 23 months. *Pediatrics*. 2016; 138(1). e20160320.
13. Renoud L, Khouri C, Revol B, et al. Association of Facial Paralysis With mRNA COVID-19 Vaccines: A Disproportionality Analysis Using the World Health Organization Pharmacovigilance Database. *JAMA Internal Medicine*. 2021; 181(9): 1243–1245.
14. Kearon C. Natural history of venous thromboembolism. *Circulation*. 2003; 107(23\_suppl\_1): I-22-I-30.
15. Kearon C, Akl EA. Duration of anticoagulant therapy for deep vein thrombosis and pulmonary embolism. *Blood*. 2014; 123(12): 1794-1801.
16. Vickers E.R, McClure DL, Naleway AL, et al. Risk of venous thromboembolism following influenza vaccination in adults aged 50 years and older in the Vaccine Safety Datalink. *Vaccine*. 2017; 35(43): 5872-5877.

17. Tang N, Li D, Wang X, Sun Z . Abnormal coagulation parameters are associated with poor prognosis in patients with novel coronavirus pneumonia. *Journal of Thrombosis Haemostasis*. 2020; 18(4): 844-847.
18. Black C, Kaye JA, Jick H. MMR vaccine and idiopathic thrombocytopenic purpura. *British Journal of Clinical Pharmacology*. 2003; 55(1): 107-111.
19. D'alò GL, Zorzoli E, Capanna A, et al. Frequently asked questions on seven rare adverse events following immunization. *Journal of Preventive Medicine Hygiene*. 2017; 58(1): E13.
20. Baker MA, Baer B, Kulldorff M, et al. Kawasaki disease and 13-valent pneumococcal conjugate vaccination among young children: A self-controlled risk interval and cohort study with null results. *PLOS Medicine*. 2019; 16(7): e1002844.
21. Yung CF, Ma X, Cheung YB, Oh BK, Soh S, Thoon KC. Kawasaki Disease following administration of 13-valent pneumococcal conjugate vaccine in young children. *Scientific Reports*. 2019; 9(1): 1-7.
22. Duffy J, Weintraub E, Vellozzi C, DeStefano F . Narcolepsy and influenza A (H1N1) pandemic 2009 vaccination in the United States. *Neurology*. 2014; 83(20): 1823-1830.
23. Montplaisir J, Petit D, Quinn M-J, et al. Risk of narcolepsy associated with inactivated adjuvanted (AS03) A/H1N1 (2009) pandemic influenza vaccine in Quebec. *PloS one*. 2014; 9(9): e108489.
24. Sarkanen TO, Alakuijala APE, Dauvilliers YA, Partinen MM. Incidence of narcolepsy after H1N1 influenza and vaccinations: Systematic review and meta-analysis. *Sleep Medicine Reviews*. 2018; 38: 177-186.
25. Donahue JG, Kieke BA, Lewis EM, et al. Near Real-Time Surveillance to Assess the Safety of the 9-Valent Human Papillomavirus Vaccine. *Pediatrics*. 2019; 144(6): e20191808.
26. GeeJ, Naleway A, Shui I et al. Monitoring the safety of quadrivalent human papillomavirus vaccine: findings from the Vaccine Safety Datalink. *Vaccine*. 2011; 29(46): 8279-84.
27. Al Qudah Z, Abukwaik W, Souayah N. Stroke after Vaccination in United States. A Report from the CDC/FDA Vaccine Adverse Event Reporting System. [1990–2010] (P01.009). *Neurology*. 2012; 78(Meeting Abstracts 1): P01.009-P01.009.
28. Smeeth L, Thomas SL, Hall AJ, Hubbard R, Farrington P, Vallance P. Risk of myocardial infarction and stroke after acute infection or vaccination. *New England Journal of Medicine*. 2004; 351(25): 2611-2618.
29. Center for Biologics Evaluation and Research, BEST Initiative (2021, February 10). COVID-19 Vaccine Safety Protocol Supplemental. <https://bestinitiative.org/wp-content/uploads/2021/02/C19-Vaccine-Safety-Protocol-Supplemental-2021.xlsx>. Published 2021.