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Supplementary appendix

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Online Supplementary Material

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Supplemental Table 1. Healthcare Common Procedure Coding System (HCPCS)/ Current Procedural Terminology (CPT)and National Drug Codes (NDC) for COVID-19 vaccines as of June 15, 2021.

Description	Coding System	Code
PFIZER-BIONTECH COVID-19 VACCINE - bnt162b2 injection, suspension	NDC	59267007801
bnt162b2 3ug/.2mL INTRAMUSCULAR INJECTION, SUSPENSION	NDC	59267007802
bnt162b2 3ug/.2mL INTRAMUSCULAR INJECTION, SUSPENSION	NDC	59267007804
SARS-CoV-2 (COVID-19) vaccine, mRNA-BNT162b2 0.1 MG/ML Injectable Suspension	NDC	59267100001
SARS-CoV-2 (COVID-19) vaccine, mRNA-BNT162b2 0.1 MG/ML Injectable Suspension	NDC	59267100002
SARS-CoV-2 (COVID-19) vaccine, mRNA-BNT162b2 0.1 MG/ML Injectable Suspension	NDC	59267100003
PFIZER-BIONTECH COVID-19 VACCINE - bnt162b2 injection, suspension	NDC	59267102501
bnt162b2 .225mg/2.25mL INTRAMUSCULAR INJECTION, SUSPENSION	NDC	59267102502
bnt162b2 .225mg/2.25mL INTRAMUSCULAR INJECTION, SUSPENSION	NDC	59267102503
bnt162b2 .225mg/2.25mL INTRAMUSCULAR INJECTION, SUSPENSION	NDC	59267102504
PFIZER-BIONTECH COVID-19 VACCINE - bnt162b2 injection, suspension	NDC	59267105501
bnt162b2 10ug/.2mL INTRAMUSCULAR INJECTION, SUSPENSION	NDC	59267105502
bnt162b2 10ug/.2mL INTRAMUSCULAR INJECTION, SUSPENSION	NDC	59267105504
Pfizer-Biontech Covid-19 Vaccine	CPT4	91300
Pfizer-BioNtech Covid-19 Vaccine (Ready to Use)	CPT4	91305
Pfizer-BioNTech Covid-19 Pediatric Vaccine	CPT4	91307
Pfizer-Biontech Covid-19 Vaccine Administration - First Dose	CPT4	0001A
Pfizer-BioNtech Covid-19 Vaccine (Ready to Use) Administration - First Dose	CPT4	0051A
Pfizer-BioNTech Covid-19 Pediatric Vaccine Administration - First Dose	CPT4	0071A
Pfizer-Biontech Covid-19 Vaccine Administration - Second Dose	CPT4	0002A
Pfizer-BioNtech Covid-19 Vaccine (Ready to Use) Administration - Second Dose	CPT4	0052A
Pfizer-BioNTech Covid-19 Pediatric Vaccine Administration - Second Dose	CPT4	0072A
Pfizer-Biontech Covid-19 Vaccine Administration - Third Dose	CPT4	0003A
Pfizer-BioNtech Covid-19 Vaccine (Ready to Use) Administration - Third Dose	CPT4	0053A
Pfizer-Biontech Covid-19 Vaccine Administration - Booster	CPT4	0004A
Pfizer-BioNtech Covid-19 Vaccine (Ready to Use) Administration - Booster	CPT4	0054A
SARS-CoV-2 (COVID-19) vaccine, mRNA-1273 0.2 MG/ML Injectable Suspension	NDC	80777027310
SARS-CoV-2 (COVID-19) vaccine, mRNA-1273 0.2 MG/ML Injectable Suspension	NDC	80777027315
SARS-CoV-2 (COVID-19) vaccine, mRNA-1273 0.2 MG/ML Injectable Suspension	NDC	80777027398
SARS-CoV-2 (COVID-19) vaccine, mRNA-1273 0.2 MG/ML Injectable Suspension	NDC	80777027399
Moderna Covid-19 Vaccine	CPT4	91301
Moderna Covid-19 Vaccine (Low Dose)	CPT4	91306
Moderna Covid-19 Vaccine Administration - First Dose	CPT4	0011A
Moderna Covid-19 Vaccine Administration - Second Dose	CPT4	0012A
Moderna Covid-19 Vaccine Administration - Third Dose	CPT4	0013A
Moderna Covid-19 Vaccine (Low Dose) Administration - Booster	CPT4	0064A

Covid-19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only covid-19 vaccine administration is performed at the patient's home	CPT4	M0201

Abbreviations: CPT=Current Procedural Terminology; NDC=National Drug Code.

Supplemental Table 2. Select descriptive characteristics of COVID-19 vaccinees aged 18–64 years in four databases

Characteristics	Data Partner 1		Data Partner 2		Data Partner 3		Data Partner 4	
	n	%	n	%	n	%	n	%
Total vaccinated enrollees	***6,245,406***	***100%***	***2,169,398***	***100%***	***3,573,097***	***100%***	***3,160,468***	***100%***
Total of myocarditis/pericarditis	***154***		***64***		***94***		***99***	
Age (years)								
18-25	806,375	13%	289,902	13%	485,590	14%	390,543	12%
26-35	997,268	16%	403,765	19%	588,293	16%	598,488	19%
36-45	1,276,890	20%	473,587	22%	753,812	21%	721,733	23%
46-55	1,492,251	24%	497,423	23%	856,577	24%	751,041	24%
56-64	1,672,622	27%	504,721	23%	888,825	25%	698,663	22%
Missing/Unknown	--	--	--	--	--	--	--	--
Sex								
Male	3,339,168	53%	1,148,857	53%	1,898,171	53%	1,654,341	52%
Female	2,906,238	47%	1,020,541	47%	1,674,926	47%	1,506,127	48%
Missing/Unknown	--		--		--		--	
Urban/Rural								
Urban	--	--	2,065,668	95%	3,117,269	87%	2,987,073	95%
Rural	--	--	94,754	4%	455,366	13%	168,825	5%
Missing/Unknown	--	--	8,976	0%	462	0%	4,570	0%
Prior COVID-19 diagnosis since April 1, 2020	439,508	7%	148,500	7%	237,519	7%	222,820	7%

Note: Percentages may not add up to 100% due to rounding.

* Prior COVID-19 diagnosis was identified via International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) code U07.1

Supplemental Table 3 (corresponding to Figure 1). Observed and expected number of myocarditis/pericarditis events within 1–7 days following vaccination and O/E Ratios by brand, age, gender, and database

	BNT162b2					mRNA-1273				
	Number of events		Rate (per 100,000 person-days)			Number of events		Rate (per 100,000 person-days)		
	O	E	O	E	O/E Ratio [95% CI]	O	E	O	E	O/E Ratio [95% CI]
18–25 years										
Data Partner 2										
Any dose (Male)	11	1·02	1·07	0·10	10·74 [5·36, 19·21]	5	0·55	0·90	0·10	9·07 [2·95,21·17]
Any dose (Female)	2	0·53	0·17	0·04	3·78 [0·46,13·66]	3	0·28	0·48	0·04	10·83 [2·23,31·64]
Data Partner 3										
Any dose (Male)	18	1·86	1·06	0·11	9·69 [5·74,15·31]	10	1·00	1·09	0·11	9·97 [4·78,18·33]
Any dose (Female)	4	0·89	0·20	0·04	4·47 [1·22,11·45]	2	0·47	0·19	0·04	4·21 [0·51,15·21]
Data Partner 4										
Any dose (Male)	10	2·08	0·73	0·15	4·80 [2·30,8·82]	14	1·05	2·01	0·15	13·30 [7·27,22·31]
Any dose (Female)	9	0·97	0·54	0·06	9·28 [4·24,17·62]	1	0·49	0·12	0·06	2·06 [0·05,11·48]
26–35 years										
Data Partner 2										
Any dose (Male)	5	1·30	0·35	0·09	3·85 [1·25,8·97]	3	0·74	0·37	0·09	4·06 [0·84,11·85]
Any dose (Female)	1	0·75	0·06	0·05	1·33 [0·03,7·40]	1	0·39	0·12	0·05	2·56 [0·06,14·25]
Data Partner 3										
Any dose (Male)	9	2·09	0·44	0·10	4·30 [1·96,8·16]	6	1·23	0·50	0·10	4·89 [1·80, 10·65]
Any dose (Female)	1	1·07	0·04	0·05	0·93 [0·02,5·19]	0	0·61	0·00	0·05	0·00[0·00,6·05]
Data Partner 4										
Any dose (Male)	12	3·09	0·56	0·14	3·88 [2·00,6·77]	7	1·69	0·60	0·14	4·14 [1·67,8·54]
Any dose (Female)	1	1·45	0·04	0·06	0·69[0·02,3·85]	1	0·75	0·08	0·06	1·34 [0·03,7·47]
36–45 years										
Data Partner 2										
Any dose (Male)	3	1·77	0·18	0·10	1·70 [0·35,4·97]	2	1·02	0·21	0·10	1·97 [0·24,7·11]

	BNT162b2					mRNA-1273				
	Number of events		Rate (per 100,000 person-days)			Number of events		Rate (per 100,000 person-days)		
	O	E	O	E	O/E Ratio [95% CI]	O	E	O	E	O/E Ratio [95% CI]
Any dose (Female)	6	1·41	0·31	0·07	4·26 [1·56,9·27]	0	0·79	0·00	0·07	0·00 [0·00,4·69]
Data Partner 3										
Any dose (Male)	6	2·63	0·23	0·10	2·28 [0·84,4·97]	6	1·61	0·37	0·10	3·72 [1·37,8·10]
Any dose (Female)	2	1·98	0·07	0·07	1·01 [0·12,3·65]	0	1·19	0·00	0·07	0·00 [0·00,3·09]
Data Partner 4										
Any dose (Male)	3	3·65	0·12	0·14	0·82 [0·17,2·40]	6	2·07	0·41	0·14	2·90 [1·07,6·32]
Any dose (Female)	5	2·25	0·17	0·08	2·22 [0·72,5·18]	0	1·23	0·00	0·08	0·00 [0·00,3·01]
46–55 years										
Data Partner 2										
Any dose (Male)	2	2·34	0·11	0·13	0·85 [0·10,3·09]	2	1·44	0·19	0·13	1·39 [0·17,5·01]
Any dose (Female)	3	1·80	0·15	0·09	1·66 [0·34,4·86]	2	1·09	0·17	0·09	1·83 [0·22,6·60]
Data Partner 3										
Any dose (Male)	4	3·40	0·14	0·12	1·18 [0·32,3·02]	2	2·24	0·10	0·12	0·89 [0·11,3·23]
Any dose (Female)	1	2·89	0·03	0·09	0·35 [0·01,1·93]	6	1·90	0·28	0·09	3·16 [1·16, 6·88]
Data Partner 4										
Any dose (Male)	5	3·78	0·19	0·14	1·32 [0·43,3·09]	1	2·26	0·06	0·14	0·44 [0·01, 2·46]
Any dose (Female)	7	2·62	0·24	0·09	2·67 [1·07,5·50]	1	1·52	0·06	0·09	0·66 [0·02,3·66]
56–64 years										
Data Partner 2										
Any dose (Male)	3	2·79	0·18	0·16	1·08 [0·22,3·15]	1	1·94	0·08	0·16	0·52 [0·01,2·88]
Any dose (Female)	8	2·18	0·43	0·12	3·67 [1·58,7·23]	1	1·50	0·08	0·12	0·67 [0·02,3·72]
Data Partner 3										
Any dose (Male)	5	4·52	0·17	0·15	1·11 [0·36,2·58]	3	3·35	0·14	0·15	0·90 [0·18, 2·62]
Any dose (Female)	5	3·49	0·16	0·11	1·43 [0·47,3·35]	4	2·60	0·17	0·11	1·54 [0·42,3·94]
Data Partner 4										
Any dose (Male)	5	4·18	0·21	0·18	1·20 [0·39,2·79]	4	2·78	0·25	0·18	1·44 [0·39,3·69]

	BNT162b2					mRNA-1273				
	Number of events		Rate (per 100,000 person-days)			Number of events		Rate (per 100,000 person-days)		
	O	E	O	E	O/E Ratio [95% CI]	O	E	O	E	O/E Ratio [95% CI]
Any dose (Female)	5	2·91	0·20	0·12	1·72 [0·56,4·01]	2	1·90	0·12	0·12	1·05 [0·13,3·80]
Overall										
Data Partner 2										
Any dose (Male)	24	9·05	0·32	0·12	2·65 [1·70,3·94]	13	5·48	0·28	0·12	2·37 [1·26,4·06]
Any dose (Female)	20	6·58	0·23	0·08	3·04 [1·86,4·70]	7	3·85	0·14	0·08	1·82 [0·73,3·75]
Data Partner 3										
Any dose (Male)	42	14·32	0·34	0·12	2·93 [2·11,3·96]	27	9·16	0·35	0·12	2·95 [1·94,4·29]
Any dose (Female)	13	10·17	0·09	0·07	1·28 [0·68,2·19]	12	6·43	0·14	0·07	1·87 [0·96,3·26]
Data Partner 4										
Any dose (Male)	35	16·80	0·31	0·15	2·08 [1·45,2·90]	32	9·80	0·49	0·15	3·27 [2·23,4·61]
Any dose (Female)	27	10·13	0·22	0·08	2·67 [1·76,3·88]	5	5·71	0·07	0·08	0·88 [0·28,2·04]

O=Observed rate after vaccination in the databases; E=Expected rate in the absence of vaccination, i.e., incidence rates estimated within each database in 2019 stratified by sex and age; Expected rate is not available in Data Partner 1 as the database population is a subset of the whole population having observed biologics use or meeting other inclusion criteria. CI=confidence interval;

Supplemental Table 4. Observed and expected number of myocarditis/pericarditis events within 1–7 days following vaccination and O/E Ratios among males 18–25 years by brand, dose number, and database**

	BNT162b2					mRNA-1273				
	Number of events		Rate (per 100,000 person-days)			Number of events		Rate (per 100,000 person-days)		
	O	E	O	E	O/E Ratio [95% CI]	O	E	O	E	O/E Ratio [95% CI]
Data Partner 2										
Dose 1	1	0·57	0·18	0·10	1·76 [0·04,9·83]	1	0·31	0·32	0·10	3·22 [0·08,17·96]
Dose 2	10	0·46	2·17	0·10	21·85 [10·48,40·18]	4	0·24	1·65	0·10	16·61 [4·53,42·54]
Any Dose	11	1·02	1·07	0·10	10·74 [5·36, 19·21]	5	0·55	0·90	0·10	9·07 [2·95,21·17]
Data Partner 3										
Dose 1	5	1·03	0·53	0·11	4·83 [1·57,11·28]	3	0·57	0·57	0·11	5·27 [1·09, 15·40]
Dose 2	13	0·82	1·72	0·11	15·77 [8·40,26·97]	7	0·43	1·76	0·11	16·13 [6·49,33·24]
Any Dose	18	1·86	1·06	0·11	9·69 [5·74,15·31]	10	1·00	1·09	0·11	9·97 [4·78,18·33]
Data Partner 4										
Dose 1	2	1·15	0·26	0·15	1·74 [0·21,6·28]	4	0·59	1·03	0·15	6·80 [1·85,17·40]
Dose 2	8	0·93	1·30	0·15	8·57 [3·70, 16·89]	10	0·46	3·26	0·15	21·53 [10·33,39·60]
Any Dose	10	2·08	0·73	0·15	4·80 [2·30,8·82]	14	1·05	2·01	0·15	13·30 [7·27,22·31]

** Data Partner 1 observed versus expected rates are not displayed due to background rates in this data partner only being estimated among a select population; O=Observed rate after vaccination in the databases; E=Expected rate in the absence of vaccination, i.e., incidence rates estimated within each database in 2019 stratified by sex and age; Expected rate is not available in Data Partner 1 as the database population is a subset of the whole population having observed biologics use or meeting other inclusion criteria; CI=confidence interval;

Supplemental Table 5. Direct head-to-head comparison of mRNA-1273 and BNT162b2, incidence rates (IRs) and incidence rate ratios (IRRs) comparing the risk of myocarditis/pericarditis following 1–7 days of vaccination, for females aged 18–25 years by brand, dose number, and database

	BNT162b2			mRNA-1273			mRNA-1273 vs. BNT162b2	
	Number of vaccine doses	Number of observed events	IR per 100, 000 person-days[95% CI]	Number of vaccine doses	Number of observed events	IR per 100,000 person-days [95% CI]	IRR [95% CI]	Excess Risk [95% CI]
Data Partner 1								
Any dose	537504	11	0·27 [0·14,0·50]	254242	7	0·40 [0·20,0·80]	1·48 [0·60,3·63]	9·05 [-16·30,34·40]
Dose 1	298625	3	0·11 [0·04,0·36]	140287	3	0·28 [0·09,0·87]	2·46 [0·49,12·22]	11·46 [-19·90,42·81]
Dose 2	238879	8	0·49 [0·24,1·00]	113955	4	0·54 [0·20,1·43]	1·10 [0·33,3·66]	3·34 [-48·79,55·46]
Data Partner 2								
Any dose	184986	2	0·15 [0·04,0·58]	94998	3	0·43 [0·13,1·38]	2·90 [0·5,16·74]	19·52 [-30·21,69·26]
Dose 1	101866	1	0·11 [0·02,0·84]	52966	1	0·23 [0·03,1·67]	2·00 [0·12,32·13]	7·95 [-59·51,75·41]
Dose 2	83120	1	0·18 [0·03,1·26]	42032	2	0·67 [0·17,2·72]	3·80 [0·34,41·94]	34·65 [-75·76,145·06]
Data Partner 3								
Any dose	310127	4	0·17 [0·07,0·41]	161650	2	0·18 [0·04,0·71]	1·06 [0·20,5·73]	0·70 [-26·40,27·80]
Dose 1	171200	0	0·0 [NE,NE]	90709	1	0·16 [0·02,1·15]	NE [NE,NE]	NE [NE,NE]
Dose 2	138927	4	0·34 [0·12,0·99]	70941	1	0·18 [0·03,1·32]	0·53 [0·06,4·78]	-11·04 [-70·02,47·95]
Data Partner 4								
Any dose	253007	9	0·51 [0·27,0·97]	127254	1	0·12 [0·02,0·85]	0·23 [0·03,1·85]	-27·66 [-68·32,13·01]
Dose 1	141603	2	0·20 [0·05,0·82]	72107	0	0·00 [NE,NE]	0·00 [NE,NE]	NE [NE,NE]
Dose 2	111404	7	0·89 [0·42,1·89]	55147	1	0·25 [0·04,1·82]	0·29 [0·04,2·34]	-44·26 [-127·06,38·53]
Meta-Analysis								
Any dose	1285624	26	0·28 [0·16,0·48]	638144	13	0·33 [0·19,0·56]	1·21 [0·52,2·81]	3·67 [-10·60,17·94]
Dose 1	713294	6	0·11 [0·04,0·31]	356069	5	0·26 [0·10,0·71]	2·33 [0·58,9·36]	10·51 [-13·15,34·18]
Dose 2	572330	20	0·52 [0·31,0·88]	282057	8	0·45 [0·23,0·91]	0·91 [0·38,2·19]	-4·84 [-43·23,33·55]

CI=confidence interval; IR=incidence rate; IRR=incidence rate ratio; NE=not estimated.
Excess Risk = Difference in incident cases per million doses between mRNA-1273 and BNT162b2 (reference) based on adjusted incidence rates, assuming 7 days at risk.
Any dose models adjusted for urban/rural residency status (Data Partner 2, Data Partner 3, Data Partner 4), COVID-19 diagnosis prior to vaccination (Data Partner 1, Data Partner 2, Data Partner 4), and week of vaccination (all databases). Dose 1 models adjusted for COVID-19 prior to vaccination (Data Partner 1,

Data Partner 2), urban/rural residency status (Data Partner 3), and week of vaccination (all databases). Dose 2 models adjusted for urban/rural residency status (Data Partner 2, Data Partner 4), COVID-19 prior to vaccination (Data Partner 2, Data Partner 4), and week of vaccination (all databases).

Supplemental Table 6. Direct head-to-head comparison of mRNA-1273 and BNT162b2, incidence rates (IRs) and incidence rate ratios (IRRs) comparing the risk of myocarditis/pericarditis following 1–7 days of vaccination, for males aged 18–35 years by brand, dose number, and database

	BNT162b2			mRNA-1273			mRNA-1273 vs. BNT162b2	
	Number of vaccine doses	Number of observed events	IR per 100, 000 person-days [95% CI]	Number of vaccine doses	Number of observed events	IR per 100,000 person-days [95% CI]	IRR [95% CI]	Excess Risk [95% CI]
Data Partner 1								
Any dose	964263	34	0·49 [0·32,0·75]	534213	24	0·67 [0·44,1·03]	1·37 [0·75,2·51]	12·74 [-9·26,34·75]
Dose 1	534287	7	0·19 [0·09,0·40]	291979	4	0·21 [0·08,0·56]	1·11 [0·32,3·80]	1·40 [-18·98,21·78]
Dose 2	429976	27	0·90 [0·61,1·33]	242234	20	1·24 [0·80,1·92]	1·37 [0·77,2·45]	23·55 [-22·00,69·09]
Data Partner 2								
Any dose	378025	16	0·59 [0·33,1·05]	206861	8	0·56 [0·27,1·17]	0·95 [0·37,2·42]	-2·00 [-37·70,33·70]
Dose 1	207639	2	0·14 [0·03,0·56]	114264	1	0·13 [0·02,0·93]	0·96 [0·09,10·61]	-0·40 [-46·31,45·52]
Dose 2	170386	14	1·21 [0·71,2·07]	92597	7	1·13 [0·54,2·38]	0·93 [0·38,2·31]	-5·85 [-80·59,68·88]
Data Partner 3								
Any dose	580336	27	0·60 [0·39,0·90]	322397	16	0·66 [0·40,1·10]	1·12 [0·58,2·14]	4·84 [-24·93,34·60]
Dose 1	319620	8	0·33 [0·16,0·67]	179137	6	0·47 [0·21,1·06]	1·44 [0·50,4·18]	10·07 [-25·57,45·71]
Dose 2	260716	19	0·95 [0·59,1·53]	143260	10	0·91 [0·48,1·72]	0·96 [0·45,2·07]	-2·55 [-54·27,49·18]
Data Partner 4								
Any dose	535419	22	0·59 [0·37,0·97]	285457	21	1·11 [0·68,1·80]	1·86 [0·94,3·70]	35·86 [-3·62,75·34]
Dose 1	298863	6	0·28 [0·12,0·63]	160218	4	0·37 [0·14,0·98]	1·31 [0·37,4·65]	6·06 [-28·99,41·11]
Dose 2	236556	16	1·00 [0·61,1·64]	125239	17	2·02 [1·25,3·26]	2·02 [1·02,4·01]	71·59 [-4·48,147·66]
Meta-Analysis								
Any dose	2458043	99	0·56 [0·44,0·71]	1348928	69	0·75 [0·57,0·99]	1·33 [0·94,1·88]	13·22 [-7·95,34·39]

CI=confidence interval; IR=incidence rate; IRR=incidence rate ratio.
Excess Risk = Difference in incident cases per million doses between mRNA-1273 and BNT162b2 (reference) based on adjusted incidence rates, assuming 7 days at risk.
Any dose models adjusted for urban/rural residency status (Data Partner 3, Data Partner 4), COVID-19 diagnosis prior to vaccination (all databases), and week of vaccination (all databases). Dose 1 models adjusted for urban/rural residency status (Data Partner 3), COVID-19 prior to vaccination (Data Partner 1, Data Partner 3, Data Partner 4), and week of vaccination (all databases). Dose 2 models adjusted for urban/rural residency status (Data Partner 3, Data Partner 4), COVID-19 prior to vaccination (all databases), and week of vaccination (all databases).

Supplemental Table 7. Direct head-to-head comparison of mRNA-1273 and BNT162b2, incidence rates (IRs) and incidence rate ratios (IRRs) comparing the risk of myocarditis/pericarditis restricted to IP and OP/ED events following 1–7 days of vaccination, for males aged 18–25 years by brand, dose number, and database

	BNT162b2			mRNA-1273			mRNA-1273 vs. BNT162b2	
	Number of vaccine doses	Number of observed events	IR per 100, 000 person-days [95% CI]	Number of vaccine doses	Number of observed events	IR per 100,000 person-days [95% CI]	IRR [95% CI]	Excess Risk [95% CI]
Data Partner 1								
Any dose	449020	18	0·57 [0·35,0·94]	211821	9	0·64 [0·33,1·25]	1·11 [0·48,2·60]	4·62 [-32·47,41·70]
Dose 1	250271	3	0·17 [0·05,0·53]	117192	2	0·26 [0·06,1·03]	1·51 [0·25,9·07]	6·04 [-32·09,44·17]
Dose 2	198749	15	1·15 [0·69,1·91]	94629	7	1·14 [0·54,2·40]	1·00 [0·41,2·44]	-0·38 [-77·74,76·97]
Data Partner 2								
Any dose	159435	9	0·81 [0·43,1·52]	84586	4	0·70 [0·29,1·69]	0·87 [0·29,2·57]	-7·47 [-75·18,60·23]
Dose 1	87769	1	0·17 [0·02,1·25]	47301	1	0·30 [0·04,2·29]	1·74 [0·11,28·22]	8·95 [-93·19,111·09]
Dose 2	71666	8	1·67 [0·83,3·37]	37285	3	1·22 [0·39,3·78]	0·73 [0·19,2·75]	-31·59 [-177·67,114·49]
Data Partner 3								
Any dose	262536	12	0·57 [0·31,1·05]	139732	7	0·64 [0·34,1·22]	1·12 [0·46,2·74]	4·94 [-40·20, 50·08]
Dose 1	145109	3	0·28 [0·09,0·90]	78572	1	0·18 [0·02,1·28]	0·62 [0·06,6·03]	-7·49 [-70·73, 55·76]
Dose 2	117427	9	0·94 [0·47,1·88]	61160	6	1·20 [0·52,2·76]	1·28 [0·45,3·60]	18·29 [-79·82, 116·41]
Data Partner 4								
Any dose	209473	9	0·64 [0·34,1·19]	106271	9	1·29 [0·67,2·47]	2·02 [0·83,4·95]	45·67 [-27·53,118·87]
Dose 1	116908	1	0·10 [0·01,0·76]	59925	2	0·38 [0·08,1·74]	3·95 [0·36,43·71]	20·03 [-41·85,81·92]
Dose 2	92565	8	1·29 [0·64,2·57]	46346	7	2·27 [1·08,4·77]	1·76 [0·64,4·87]	68·76 [-72·59, 210·11]
Meta-Analysis								
Any dose	1080464	48	0·63 [0·47,0·84]	542410	29	0·79 [0·56,1·13]	1·25 [0·79,1·98]	11·40 [-17·92,40·72]

CI=confidence interval; IR=incidence rate; IRR=incidence rate ratio.
Excess Risk = Difference in incident cases per million doses between mRNA-1273 and BNT162b2 (reference) based on adjusted incidence rates, assuming 7 days at risk.
Any dose models adjusted for urban/rural residency status (Data Partner 3, Data Partner 4), COVID-19 diagnosis prior to vaccination (Data Partner 1, Data Partner 3, Data Partner 4), and week of vaccination (all databases). Dose 1 models adjusted for urban/rural residency status (Data Partner 3), COVID-19 prior to vaccination (Data Partner 1, Data Partner 3, Data Partner 4), and week of vaccination (all databases). Dose 2 models adjusted for urban/rural residency status (Data Partner 3, Data Partner 4), COVID-19 prior to vaccination (Data Partner 3), and week of vaccination (all databases).

Supplemental Table 8. Direct head-to-head comparison of mRNA-1273 and BNT162b2, incidence rates (IRs) and incidence rate ratios (IRRs) comparing the risk of myocarditis/pericarditis restricted to IP and OP/ED events following 1–7 days of vaccination, for males aged 18–35 years by brand, dose number, and database

			BNT162b2		mRNA-1273		mRNA-1273 vs. BNT162b2	
	Number of vaccine doses	Number of observed events	IR per 100, 000 person-days [95% CI]	Number of vaccine doses	Number of observed events	IR per 100,000 person-days [95% CI]	IRR [95% CI]	Excess Risk [95% CI]
Data Partner 1								
Any dose	964263	22	0·32 [0·20,0·50]	534213	12	0·33 [0·19,0·60]	1·06 [0·51,2·21]	1·27 [-15·42, 17·96]
Dose 1	534287	5	0·13 [0·05,0·32]	291979	2	0·10 [0·03,0·41]	0·79 [0·15,4·11]	-1·89 [-18·17, 14·40]
Dose 2	429976	17	0·58 [0·36,0·95]	242234	10	0·63 [0·34,1·17]	1·07 [0·49,2·35]	3·06 [-33·20, 39·32]
Data Partner 2								
Any dose	378025	12	0·45 [0·24, 0·84]	206861	5	0·35 [0·14,0·91]	0·79 [0·25,2·50]	-6·52 [-37·92, 24·88]
Dose 1	207639	1	0·08 [0·01,0·53]	114264	1	0·13 [0·02,0·95]	1·75 [0·11,28·26]	3·90 [-48·60, 56·40]
Dose 2	170386	11	0·95 [0·52, 1·74]	92597	4	0·64 [0·24,1·72]	0·68 [0·22,2·13]	-21·39 [-91·58, 48·80]
Data Partner 3								
Any dose	580336	15	0·32 [0·17,0·59]	322397	12	0·47 [0·28,0·80]	1·48 [0·67, 3·23]	10·58 [-12·58, 33·74]
Dose 1	319620	5	0·22 [0·09,0·54]	179137	4	0·31 [0·11, 0·85]	1·44 [0·38,5·41]	6·64 [-23·21, 36·50]
Dose 2	260716	10	0·46 [0·24,0·89]	143260	8	0·66 [0·32,1·38]	1·45 [0·57, 3·69]	14·44 [-26·90, 55·79]
Data Partner 4								
Any dose	535419	15	0·42 [0·24, 0·72]	285457	15	0·80 [0·42, 1·52]	1·92 [0·83,4·47]	26·76 [-6·00, 59·52]
Dose 1	298863	1	0·04 [0·01, 0·30]	160218	2	0·14 [0·03, 0·65]	3·75 [0·34,41,47]	7·36 [-20·87, 35·60]
Dose 2	236556	14	0·88 [0·52, 1·48]	125239	13	1·55 [0·90, 2·68]	1·77 [0·83, 3·77]	47·17 [-21·16, 115·50]
Meta-Analysis								
Any dose	2458043	64	0·36 [0·28,0·48]	1348928	44	0·47 [0·32,0·68]	1·30 [0·85, 1·98]	7·38 [-6·19, 20·96]

CI=confidence interval; IR=incidence rate; IRR=incidence rate ratio.
Excess Risk = Difference in incident cases per million doses between mRNA-1273 and BNT162b2 (reference) based on adjusted incidence rates, assuming 7 days at risk.
Any dose models adjusted for urban/rural residency status (Data Partner 3, Data Partner 4), COVID-19 diagnosis prior to vaccination (Data Partner 1, Data Partner 3, Data Partner 4), and week of vaccination (all databases). Dose 1 models adjusted for urban/rural residency status (Data Partner 3), COVID-19 prior to vaccination (Data Partner 1, Data Partner 3, Data Partner 4), and week of vaccination (all databases). Dose 2 models adjusted for urban/rural residency status (Data Partner 3, Data Partner 4), COVID-19 prior to vaccination (Data Partner 3), and week of vaccination (all databases).

Supplemental Table 9. Direct head-to-head comparison of mRNA-1273 and BNT162b2, incidence rates (IRs) and incidence rate ratios (IRRs) comparing the risk of myocarditis/pericarditis following 1–21 days of vaccination, for males aged 18–25 years by brand, dose number, and database

	BNT162b2			mRNA-1273			mRNA-1273 vs. BNT162b2	
	Number of vaccine doses	Number of observed events	IR per 100, 000 person-days [95% CI]	Number of vaccine doses	Number of observed events	IR per 100,000 person-days [95% CI]	IRR [95% CI]	Excess Risk [95% CI]
Data Partner 1								
Any dose	449020	42	0·48 [0·33,0·70]	211821	24	0·59 [0·36,0·97]	1·23 [0·66,2·30]	25·28 [5·22,45·33]
Dose 1	250271	10	0·21 [0·11,0·38]	117192	7	0·31 [0·15,0·64]	1·49 [0·57,3·91]	23·19 [1·74,44·65]
Dose 2	198749	32	0·84 [0·59,1·19]	94629	17	0·94 [0·58,1·51]	1·12 [0·62,2·02]	21·19 [-18·37,60·75]
Data Partner 2								
Any dose	159435	12	0·37 [0·19,0·70]	84586	7	0·42 [0·22,0·80]	1·13 [0·45,2·84]	11·99 [-16·95,40·92]
Dose 1	87769	1	0·06 [0·01,0·39]	47301	1	0·11 [0·01,0·75]	1·92 [0·12,30·68]	11·16 [-25·96,48·27]
Dose 2	71666	11	0·78 [0·43,1·41]	37285	6	0·82 [0·37,1·84]	1·06 [0·39,2·86]	9·47 [-53·83,72·77]
Data Partner 3								
Any dose	262536	24	0·44 [0·29,0·68]	139732	14	0·49 [0·29,0·83]	1·12 [0·57,2·19]	13·02 [-10·45,36·49]
Dose 1	145109	8	0·27 [0·13,0·54]	78572	5	0·32 [0·13,0·76]	1·17 [0·38,3·60]	12·51 [-14·46,39·48]
Dose 2	117427	16	0·66 [0·40,1·09]	61160	9	0·71 [0·37,1·38]	1·08 [0·48,2·45]	11·54 [-31·96,55·04]
Data Partner 4								
Any dose	209473	15	0·35 [0·22,0·56]	106271	18	0·87 [0·54,1·38]	2·47 [1·28,4·76]	109·96 [77·32,142·59]
Dose 1	116908	5	0·20 [0·08,0·49]	59925	5	0·43 [0·18,1·02]	2·08 [0·60,7·18]	48·35 [13·45,83·25]
Dose 2	92565	10	0·54 [0·29,1·00]	46346	13	1·43 [0·83,2·46]	2·65 [1·16,6·05]	186·80 [125·36,248·23]
Meta-Analysis								
Any dose	1080464	93	0·42 [0·34,0·53]	542410	63	0·59 [0·44,0·81]	1·43 [0·98,2·10]	38·13 [14·73,61·52]

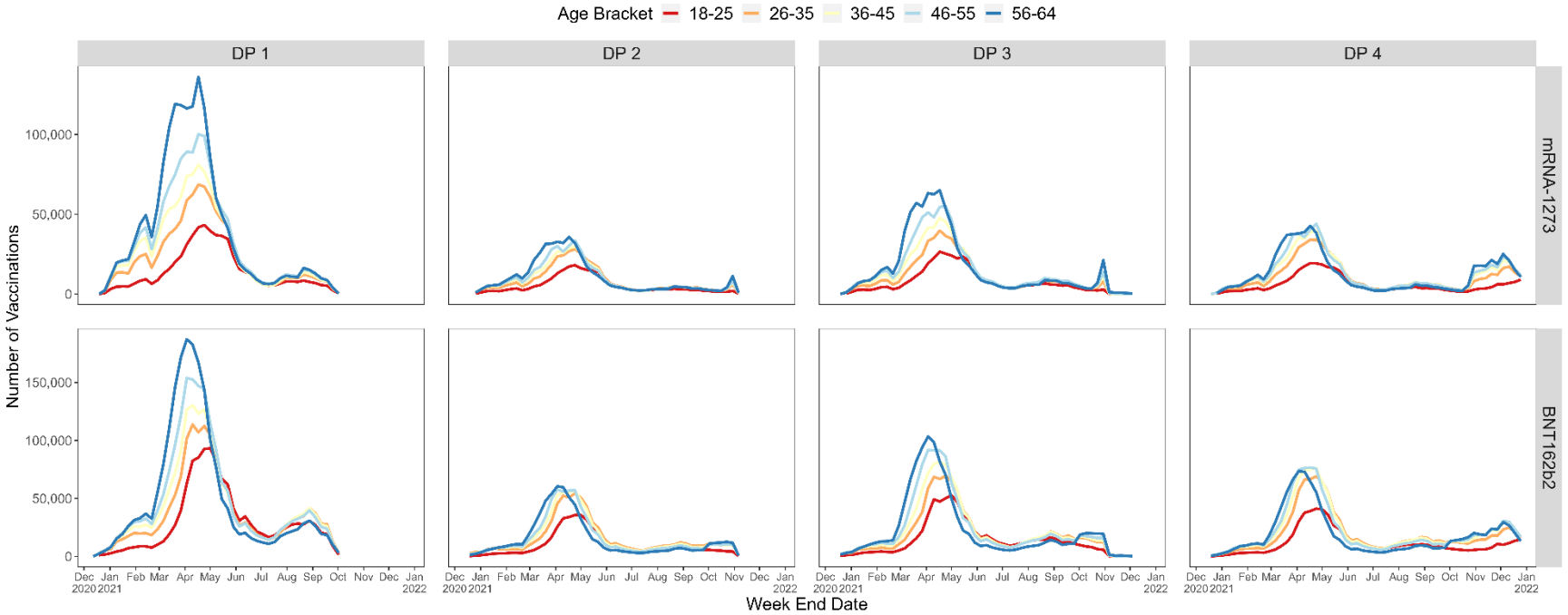
CI=confidence interval; IR=incidence rate; IRR=incidence rate ratio.
Excess Risk = Difference in incident cases per million doses between mRNA-1273 and BNT162b2 (reference) based on adjusted incidence rates, assuming 21 days at risk.
Any dose models adjusted for urban/rural residency status (Data Partner 2,Data Partner 3, Data Partner 4), COVID-19 diagnosis prior to vaccination (all databases), and week of vaccination (all databases). Dose 1 models adjusted for urban/rural residency status (Data Partner 3, Data Partner 4), COVID-19 prior to vaccination (all databases), and week of vaccination (all databases). Dose 2 models adjusted for urban/rural residency status (Data Partner 2, Data Partner 3, Data Partner 4), COVID-19 prior to vaccination (all databases), and week of vaccination (all databases).

Supplemental Table 10. Direct head-to-head comparison of mRNA-1273 and BNT162b2, incidence rates (IRs) and incidence rate ratios (IRRs) comparing the risk of myocarditis/pericarditis following 1–42 days of vaccination, for males aged 18–25 years by brand, dose number, and database

	BNT162b2			mRNA-1273			mRNA-1273 vs. BNT162b2	
	Number of vaccine doses	Number of observed events	IR per 100, 000 person-days [95% CI]	Number of vaccine doses	Number of observed events	IR per 100,000 person-days [95% CI]	IRR [95% CI]	Excess Risk [95% CI]
Data Partner 1								
Any dose	449020	50	0·38 [0·27,0·53]	211821	31	0·45 [0·30,0·68]	1·19 [0·70,2·02]	38·04 [24·40,51·67]
Dose 1	250271	14	0·24 [0·14,0·41]	117192	9	0·27 [0·14,0·52]	1·10 [0·47,2·54]	23·58 [6·41,40·75]
Dose 2	198749	36	0·49 [0·35,0·68]	94629	22	0·62 [0·41,0·94]	1·26 [0·74,2·15]	54·21 [32·36,76·06]
Data Partner 2								
Any dose	159435	17	0·35 [0·21,0·57]	84586	10	0·36 [0·21,0·61]	1·03 [0·50,2·13]	16·09 [-4·97,37·15]
Dose 1	87769	3	0·14 [0·04,0·43]	47301	4	0·29 [0·11,0·76]	2·09 [0·47,9·34]	49·82 [22·17,77·48]
Dose 2	71666	14	0·52 [0·31,0·88]	37285	6	0·43 [0·19,0·95]	0·83 [0·32,2·15]	-37·70 [-72·38,-3·01]
Data Partner 3								
Any dose	262536	32	0·38 [0·27,0·53]	139732	16	0·33 [0·21,0·53]	0·88 [0·50,1·58]	-1·76 [-17·26,13·74]
Dose 1	145109	13	0·35 [0·20,0·61]	78572	6	0·26 [0·11,0·57]	0·73 [0·28,1·92]	-1·08 [-22·77,20·60]
Dose 2	117427	19	0·40 [0·25,0·63]	61160	10	0·40 [0·22,0·75]	1·02 [0·47,2·19]	3·05 [-20·31,26·41]
Data Partner 4								
Any dose	209473	18	0·28 [0·18,0·44]	106271	21	0·61 [0·38,0·96]	2·19 [1·14,4·19]	123·59 [101·66,145·51]
Dose 1	116908	5	0·17 [0·07,0·41]	59925	7	0·41 [0·20,0·86]	2·42 [0·77,7·62]	76·92 [49·63,104·21]
Dose 2	92565	13	0·36 [0·21,0·63]	46346	14	0·79 [0·47,1·34]	2·17 [1·02,4·63]	179·67 [144·86,214·49]
Meta-Analysis								
Any dose	1080464	117	0·35 [0·29,0·43]	542410	78	0·43 [0·33,0·56]	1·23 [0·84,1·80]	39·36 [22·82,55·90]

CI=confidence interval; IR=incidence rate; IRR=incidence rate ratio.
Excess Risk = Difference in incident cases per million doses between mRNA-1273 and BNT162b2 (reference) based on adjusted incidence rates, assuming 42 days at risk.
Any dose models adjusted for urban/rural residency status (Data Partner 2,Data Partner 3, Data Partner 4), COVID-19 diagnosis prior to vaccination (all databases), and week of vaccination (all databases). Dose 1 models adjusted for urban/rural residency status (Data Partner 2,Data Partner 3, Data Partner 4), COVID-19 prior to vaccination (all databases), and week of vaccination (all databases). Dose 2 models adjusted for urban/rural residency status (Data Partner 2,Data Partner 3, Data Partner 4), COVID-19 prior to vaccination (all databases), and week of vaccination (all databases).

Supplemental Figure 1. mRNA-1273 and BNT162b2 COVID-19 Accrual by Week, 18–64 years



Data cutoff date: Data Partner 1 (9/30/2021), Data Partner 2 (10/31/2021), Data Partner 3 (11/4/2021), Data Partner 4 (12/25/2021)
Figure displays Dose 1, Dose 2, and other doses. Vaccine counts for recent dates may be underestimated due to data delay.

Appendix. Person-Time Adjustment for Observation Delay

Person-time attributed to each vaccination will be adjusted for observation delay ($time_{adj}$). The adjustment will be performed by segmenting study time for each vaccination by weeks of delay relative to the data cut date, and then multiplying the time by an estimated proportion of 'data completeness' obtained from historical data. Within each stratum defined by vaccine, age, sex, and other covariates, the adjusted time will be calculated as follows:

$$time_{adj} = \sum_{t=1}^{s} \sum_{i=1}^{n_t} \sum_{w=0}^{T_i} l_{stiw} P(s,t,w)$$

Where:

- s represents the study time period (e.g., study week) at which the analysis is planned (e.g., $s = 15$)
- t in 1 … s.
- n_t is the number of subjects vaccinated during time period t. Ineligible doses due to lack of enrollment or having an AESI in the cleaning period will be excluded.
- i in 1 … n_t.
- T_i represents the exposed weeks at risk following a dose (i.e., within the AESI-specific risk window) for subject i.
- w in 0 … T_i . Study weeks in which AESIs occur are represented by $t + w$, with $t + 0$ being the same study week as the vaccine dose, $t + 1$ the next week, etc.
- l_{stiw} in 0 … 7 is the number of exposed days following a vaccine dose in study week w post vaccine dose for a patient identified by i, t in the group based on data at observation week s.
- If the dose is administered on day 5 of study week t, then the first 1–2 days of 1–42 days post-vaccination risk window would occur in $w = 0$ post dose (with $l_{sti}(w=0) = 2$). The next 3–9 days would occur in week $w = 1$ post dose (with $l_{sti}(w=1) = 7$), etc.
- The occurrence of a second dose may contribute additional exposed time but overlapping time will not be double counted. For example, if the risk window length is 42 days, a second dose 22 days after the first dose will result in an overall risk period of 1 to (42 + 42 – 21 overlap) = 63 days. In the case when the gap

between doses is larger than the risk interval post first dose, the follow-up after the first dose would be censored at the end of the planned risk window and restarted at the second dose.

- $P(s,t,w)$ is the proportion of AESIs occurring in study week $t + w$ that would be observed by week s. This adjustment factor adjusts for the observation delay due to the use of partially accrued data.
- Cumulative proportion of data completeness will be estimated from myocarditis or pericarditis events in 2019 data.
- To account for variability in the observation delay adjustment for short delays (0–1 weeks), only events and person time 2 or more weeks delayed relative to the data cut date will be included in the analysis.