משרד הבריאות
לחיים בריאים יותר

Adverse events following vaccination COVID-19

Data updated March 31st 2021

Division of Epidemiology

Public health services

Ministry of Health Israel

Sources of adverse events reports

Sources of adverse events reports include:

- Hospitals
- HMOs
- Emergency Medical Services - MDA (for individuals who are vaccinated in nursing homes)
- The Medical Department and the Patient Safety Unit at the MoH
- Israeli Defense Forces (IDF)

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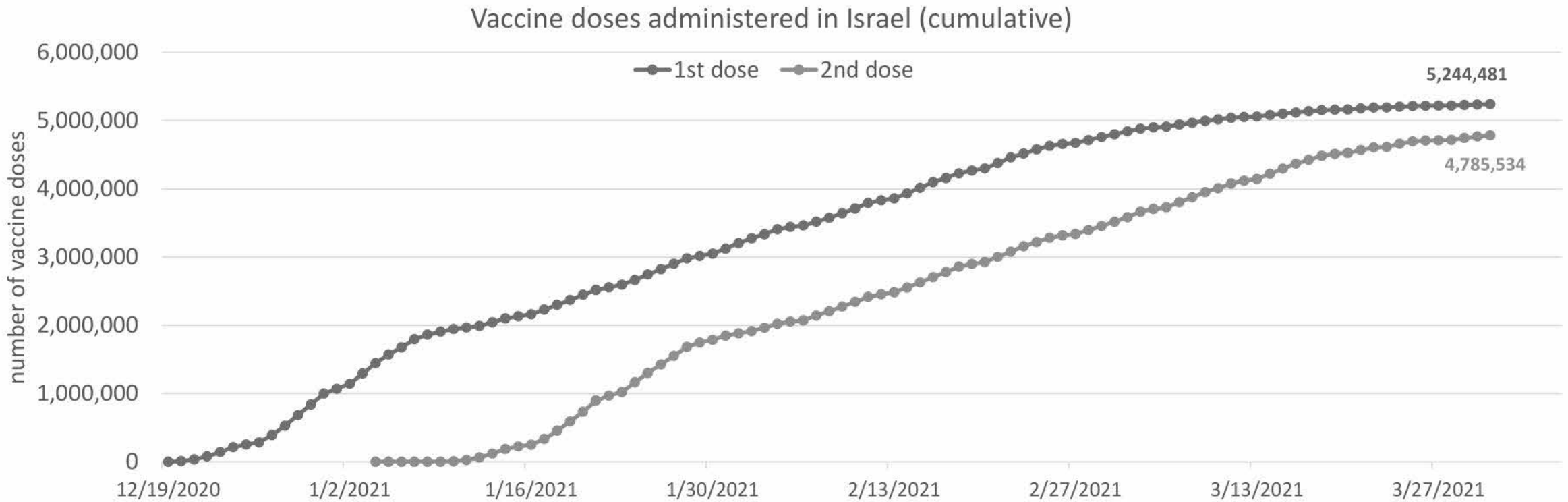
Vaccine doses administered in Israel



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Distribution of vaccine recipients according to age

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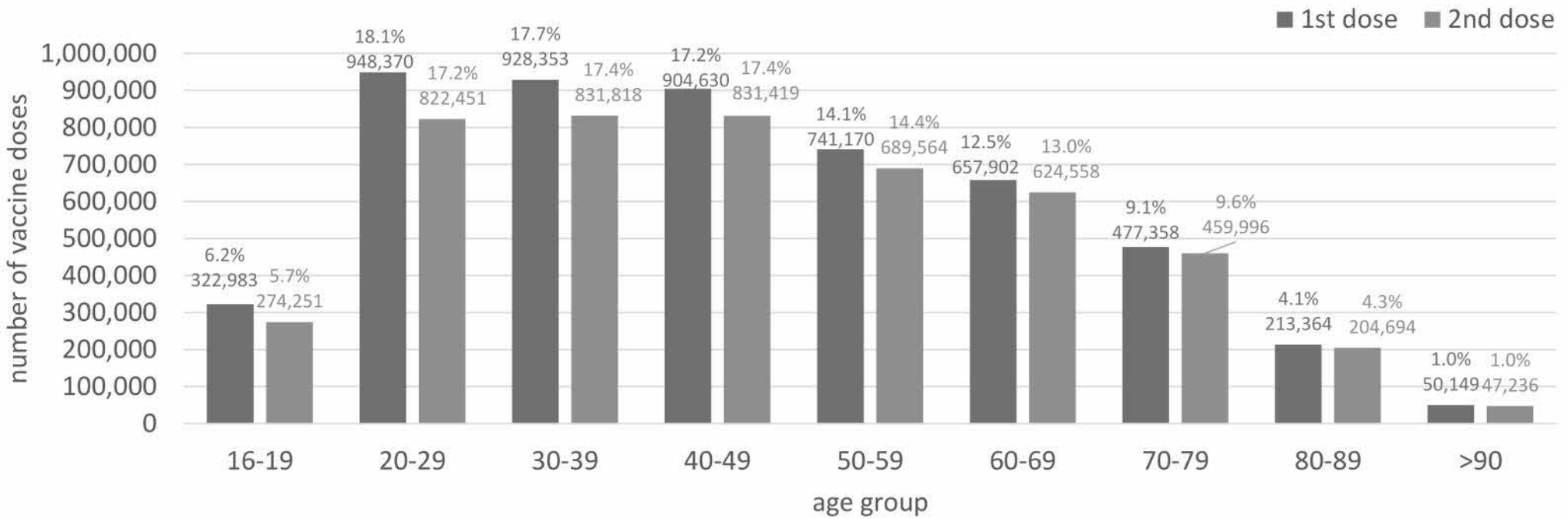

AgeGroup	16-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90<
Vaccine coverage by age group 1st dose	55.3%	72.9%	77.6%	82.3%	87.2%	88.7%	97.3%	94.6%	97.4%
Vaccine coverage by age group 2nd dose	47.0%	63.2%	69.5%	75.7%	81.1%	84.2%	93.7%	90.8%	91.7%

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Age and sex distribution among vaccine recipients and those who reported adverse events - FIRST DOSE

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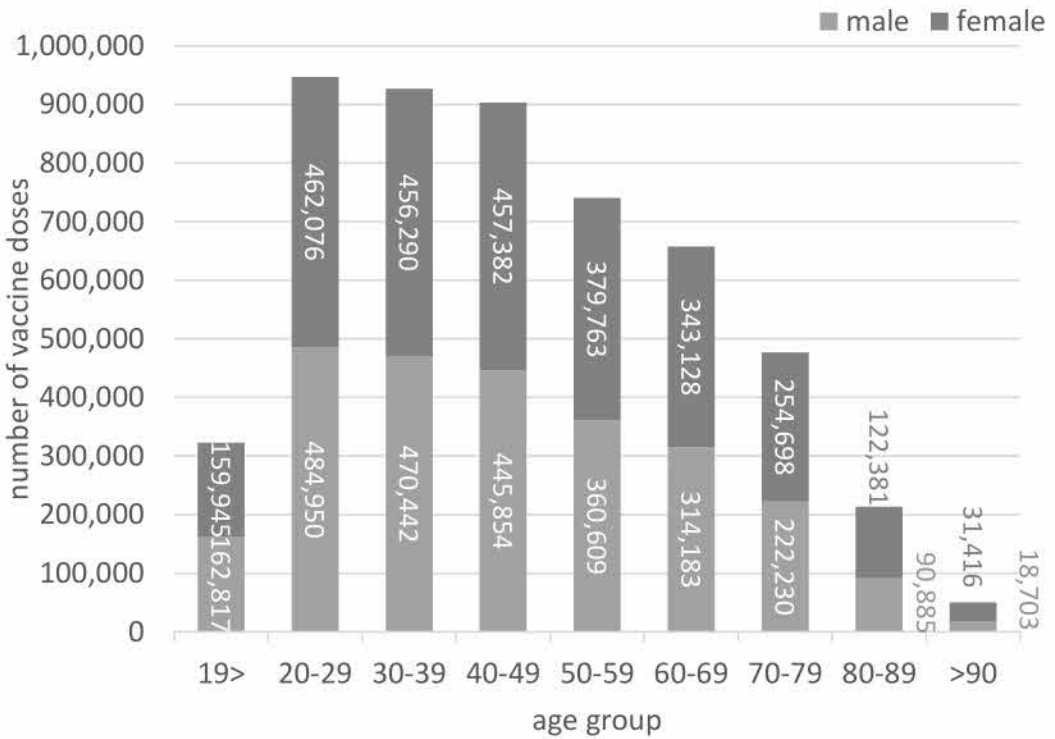
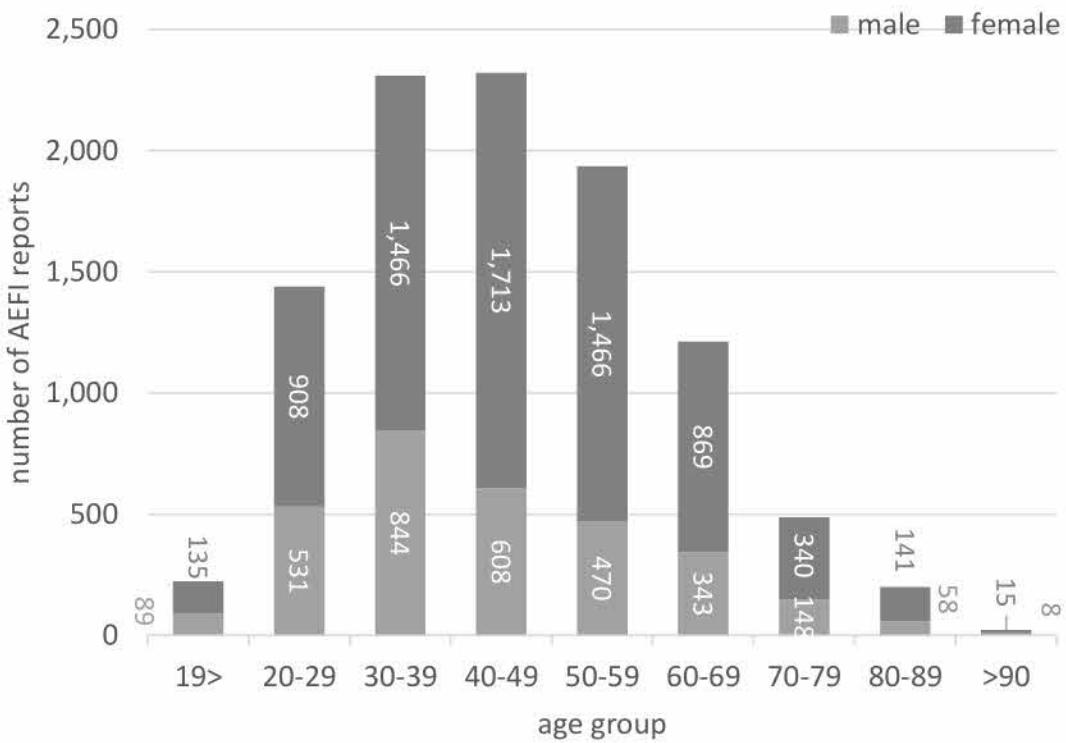
Distribution according to age group and sex among recipients of first vaccine dose.



Distribution according to age group and sex among individuals reporting adverse events following first dose vaccination.



Women and younger individuals are more likely to report adverse reactions following vaccination relative to their proportion among the vaccine recipient population

Updated 31/03/2021

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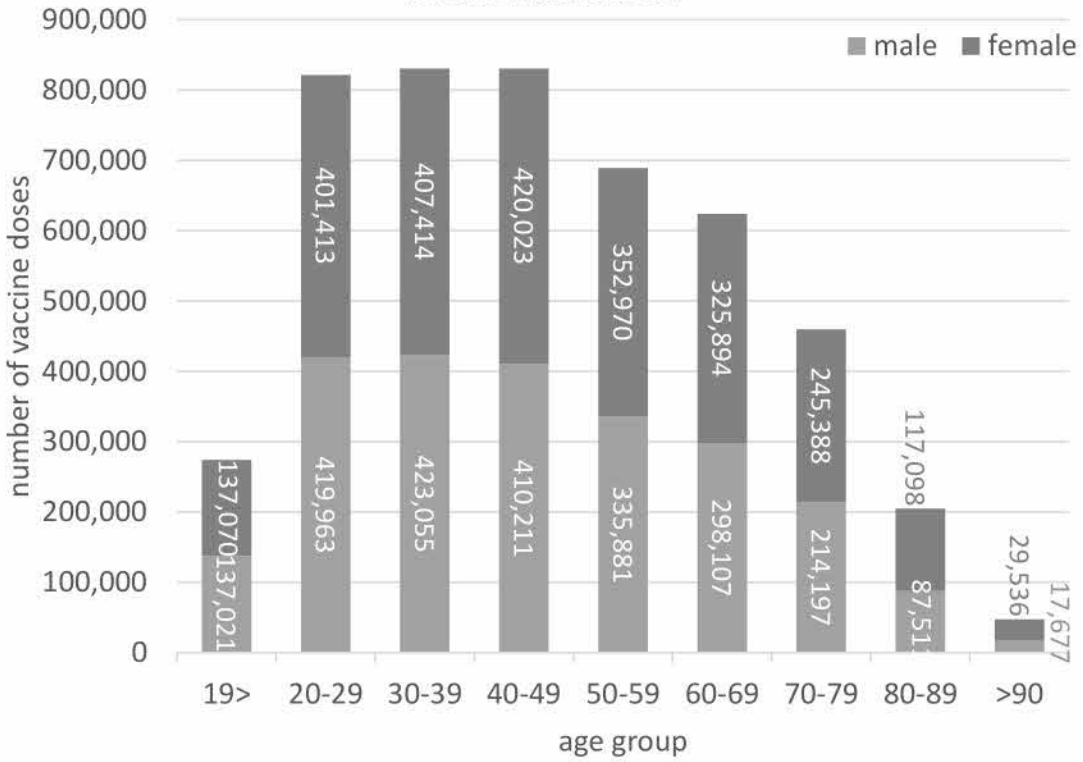
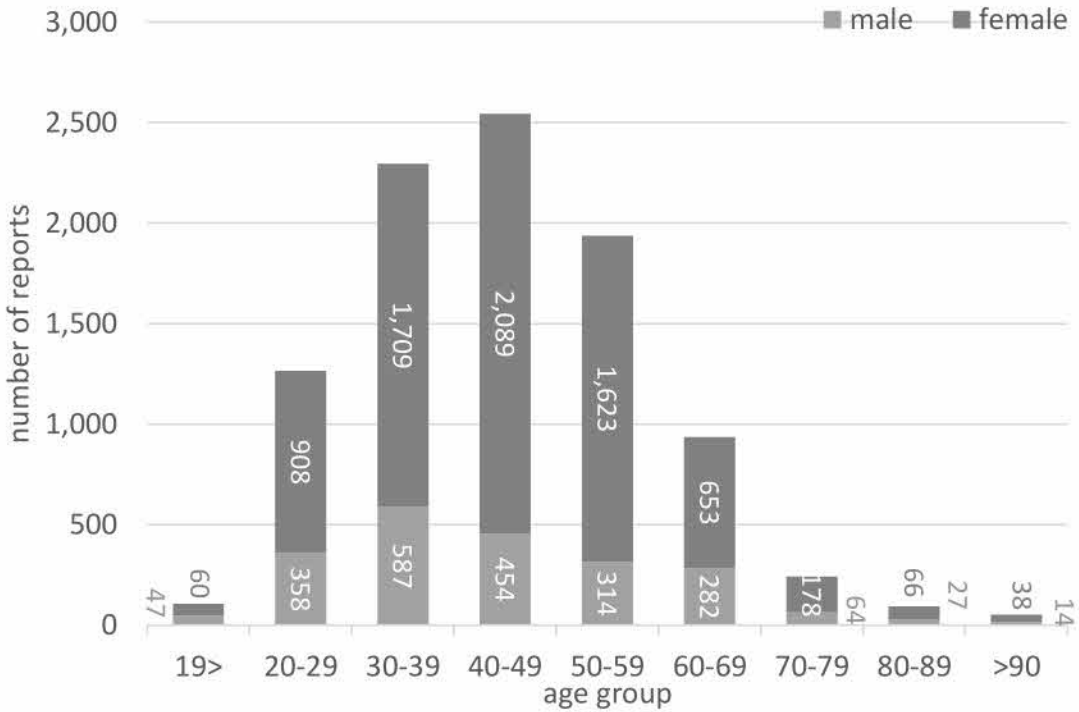
Age and sex distribution among vaccine recipients and those who reported adverse events - SECOND DOSE

משרד הבריאות

Distribution according to age group and sex among recipients of second vaccine dose.



Distribution according to age group and sex among individuals reporting adverse events following second dose vaccination



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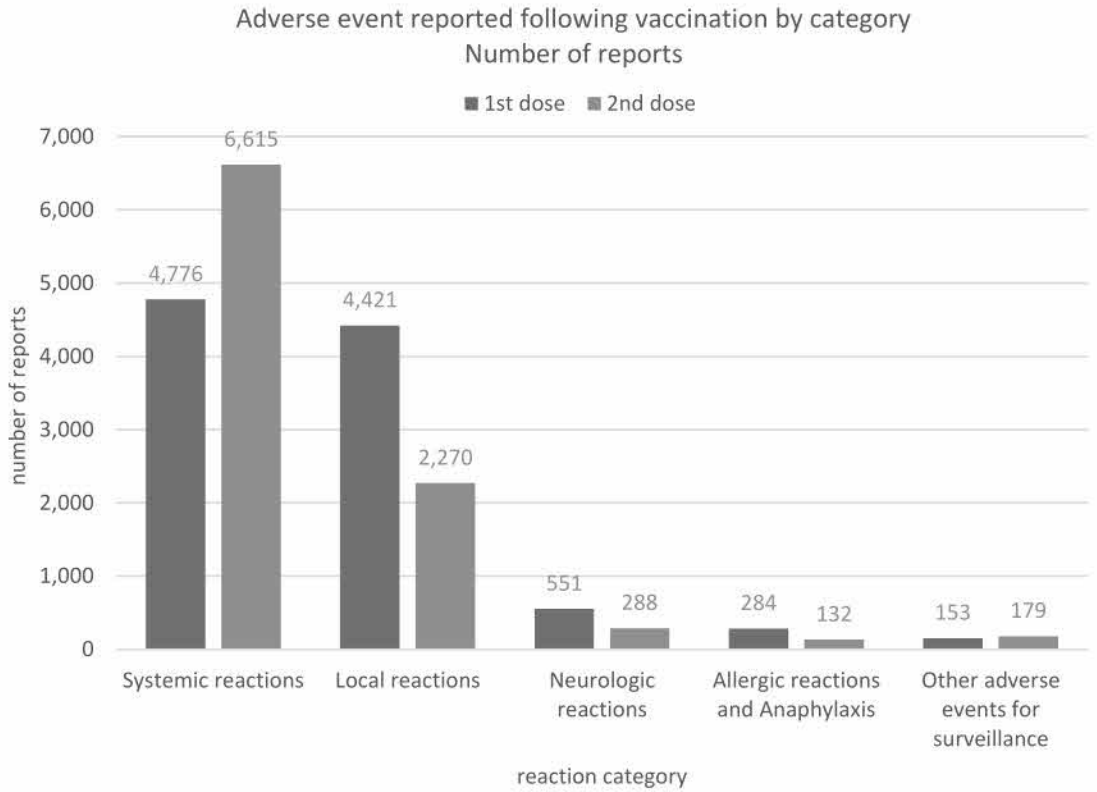
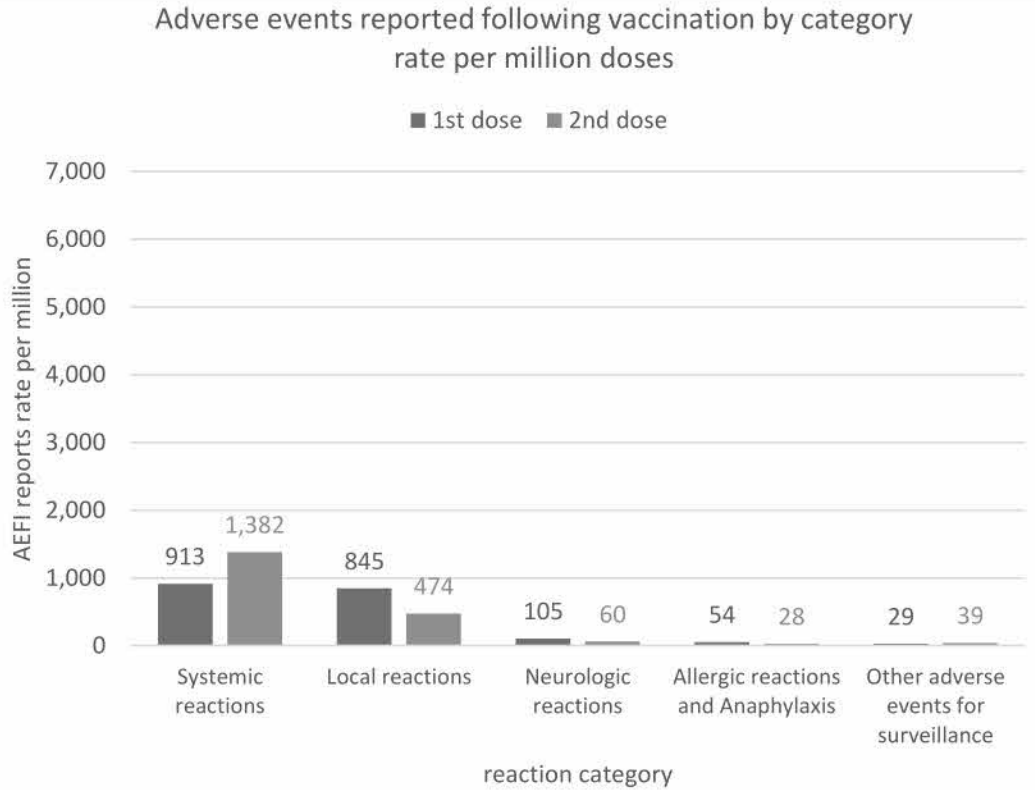
Adverse events following vaccination by category





Reports among vaccine recipients
1st dose: 5,244,481 2nd dose: 4,785,534

Updated 31/03/2021

Data is based on adverse events reported to the MoH I Some individuals reported more than one adverse event

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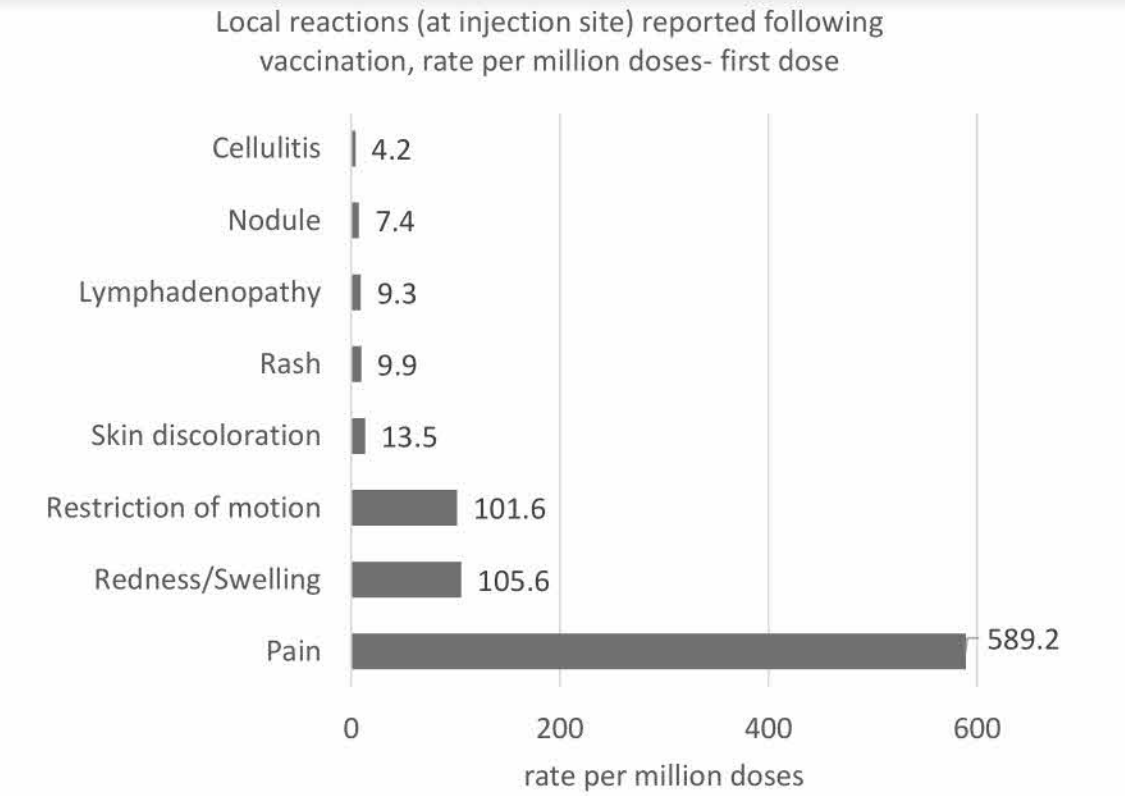
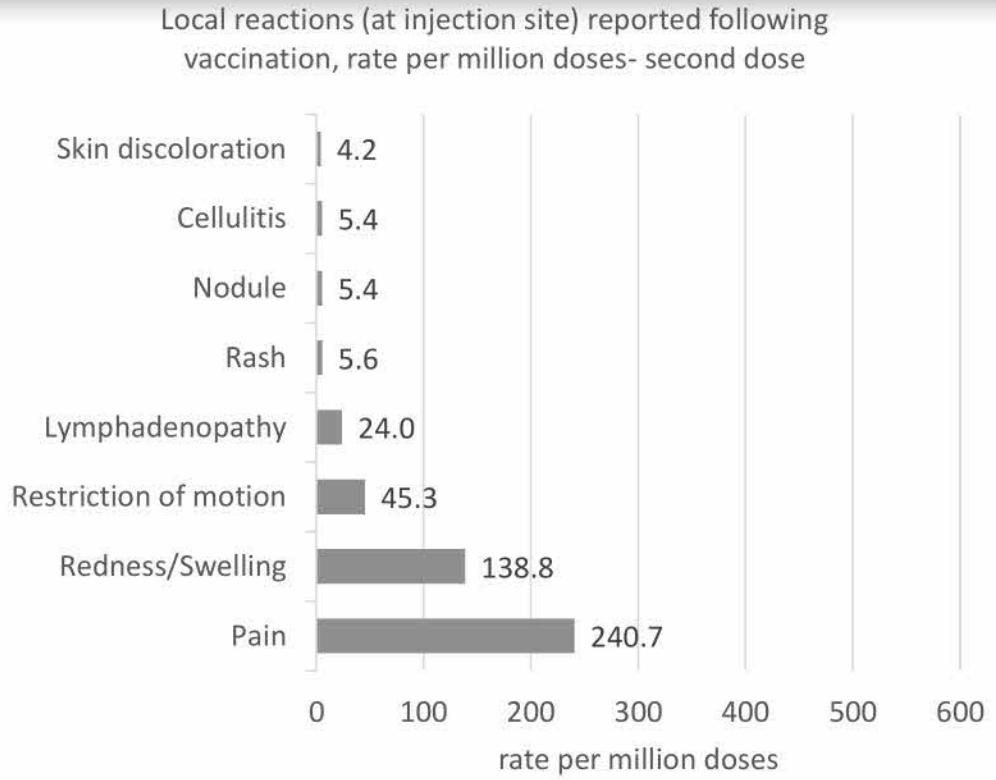
Local reactions



Rate per million vaccine doses out of 5,244,481 vaccine 1st dose recipients



Rate per million vaccine doses out of 4,785,534 vaccine 2nd dose recipients

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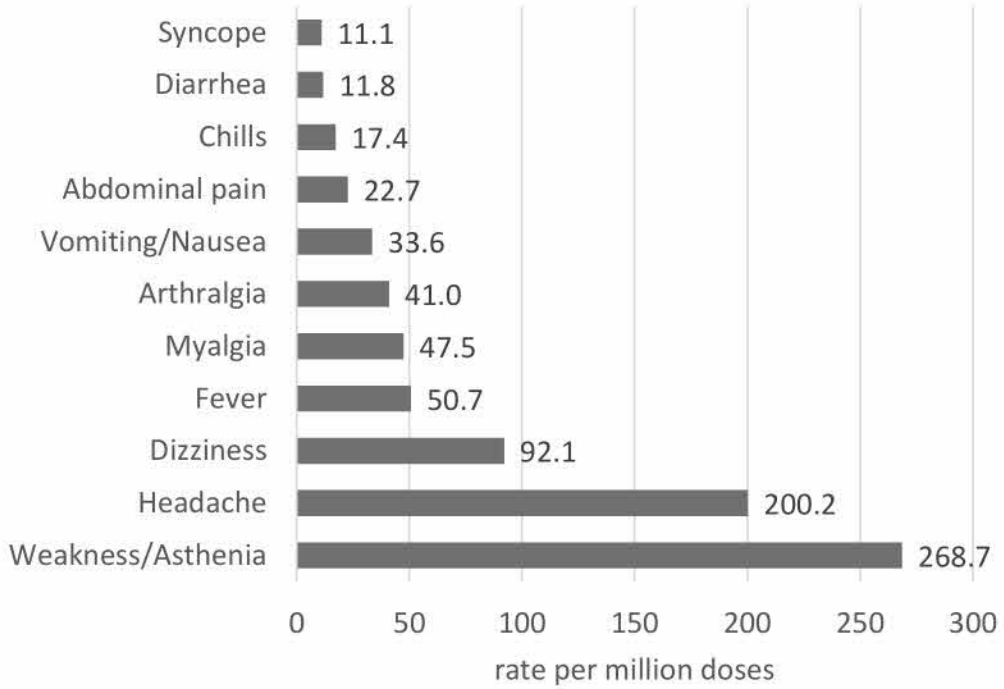
Systemic reactions

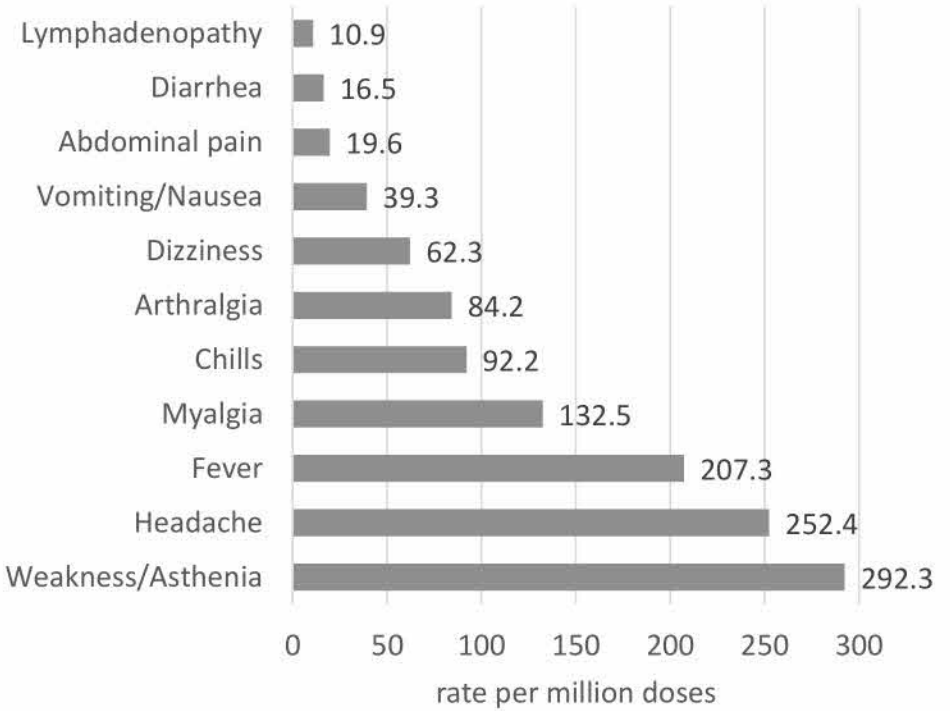
משרד הבריאות

General reactions reported following immunization, rate per million doses- first dose



Rate per million vaccine doses out of 5,244,481 vaccine 1st dose recipients

General reactions reported following immunization, rate per million doses- second dose



Rate per million vaccine doses out of 4,785,534 vaccine 2nd dose recipients

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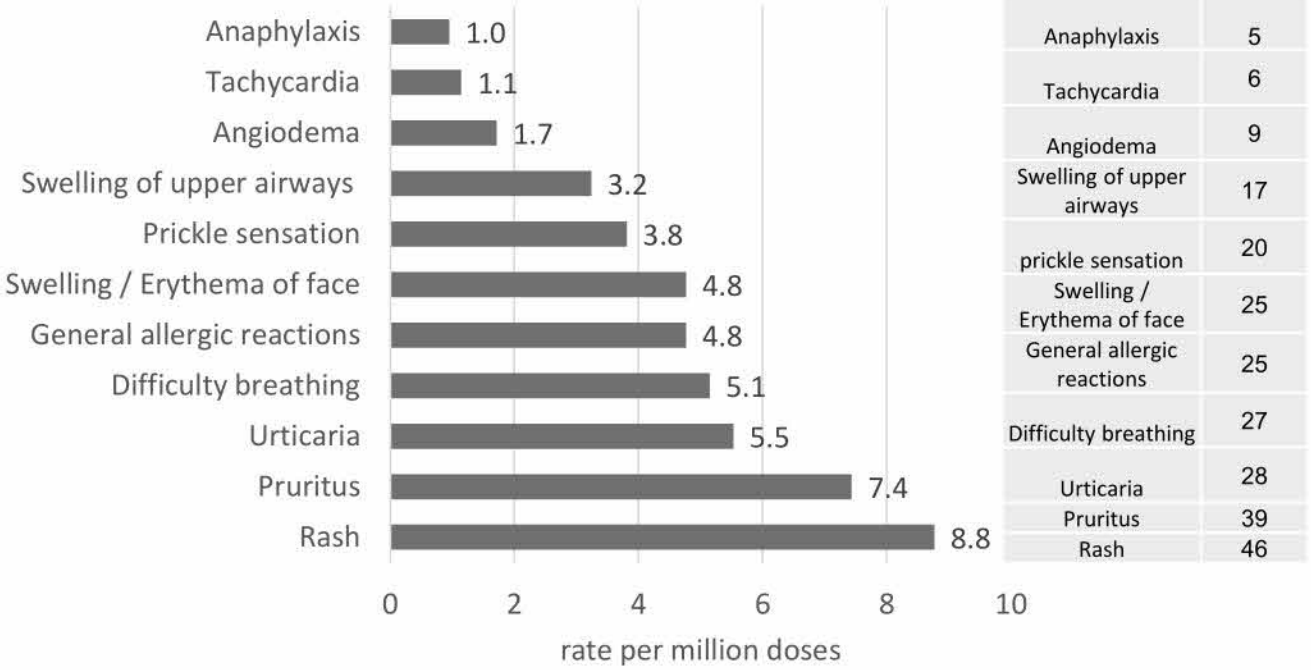
Allergic reactions

משרד הבריאות

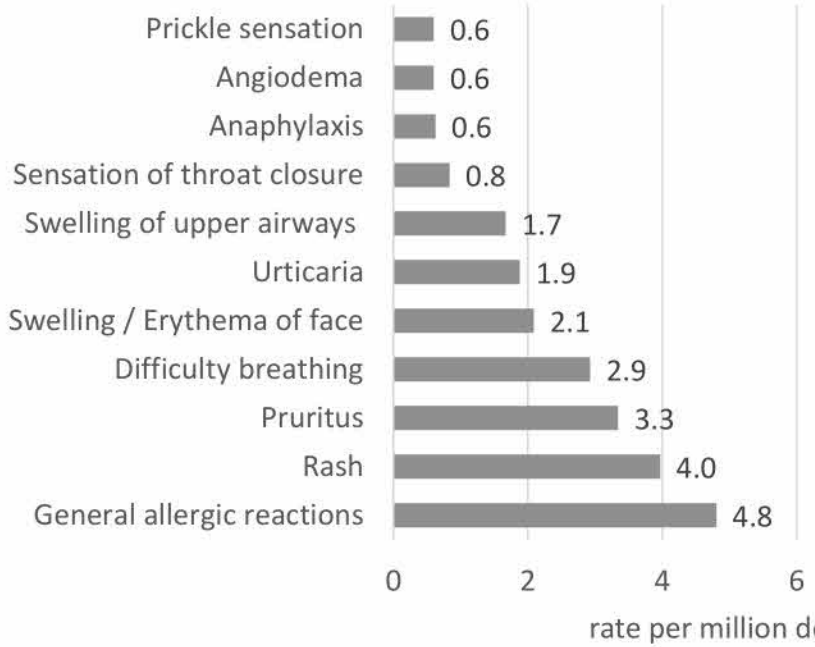
Allergic reactions reported following vaccination, rate per million vaccine doses- first dose



Number of allergic reactions reported 1st dose	
Anaphylaxis	5
Tachycardia	6
Angiodema	9
Swelling of upper airways	17
prickle sensation	20
Swelling / Erythema of face	25
General allergic reactions	25
Difficulty breathing	27
Urticaria	28
Pruritus	39
Rash	46

Rate per million vaccine doses out of 5,244,481 vaccine 1st dose recipients

Allergic reactions reported following vaccination, rate per million vaccine doses- second dose



Number of allergic reactions reported 2nd dose	
prickle sensation	3
Angiodema	3
Anaphylaxis	3
Sensation of throat closure	4
Swelling of upper airways	8
Urticaria	9
Swelling / Erythema of face	10
Difficulty breathing	14
Pruritus	16
Rash	19
General allergic reactions	23

Rate per million vaccine doses out of 4,785,534 vaccine 2nd dose recipients

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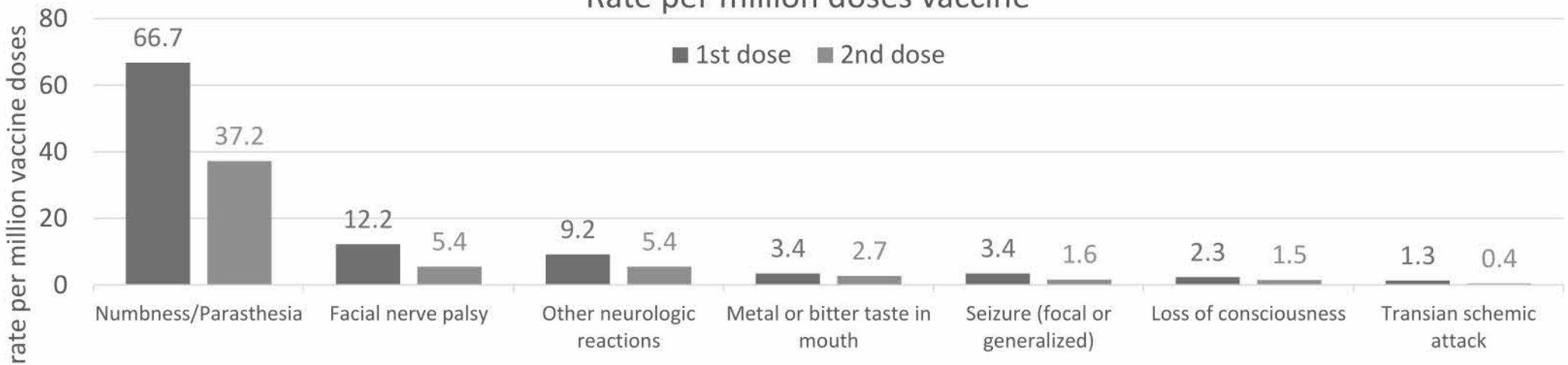
Neurologic reactions

Number of neurologic reactions reported

	Numbness/ Parasthesia	Facial nerve palsy	Other neurologic reactions	Metal or bitter taste in mouth	Seizure (focal or generalized)	Loss of consciousness	Transian ischemic attack
1st dose	350	64	48	18	18	12	7
2nd dose	178	26	25	13	8	7	2

Rate of neurological reactions reported following vaccination
Rate per million doses vaccine



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Neurologic reactions

משרד הבריאות

		Bell's palsy (1 case pregnant)		Blurred vision		Sudden sensorineural hearing loss		Abducens nerve palsy		Vertigo		Occulomotor nerve palsy		Trigeminal neuralgia		Seizures		Transiant Ischemic Attack		Guillain Barré syndrome (1 case exacerbation)		Multiple sclerosis (1 case exacerbation, 1 new case)		Brachial plexitis	
		1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose
Age group	<20	1	1													2	1								
	20-29	3	2		1	1								1		2	1	1		1					
	30-39	7	2	3		1	1									2	1								
	40-49	13	5	2	3		2			1						1	5	1				1			
	50-59	11	10	6	1	2	1				1					2				1					
	60-69	16	4	2		1	1	1	1	1	2	1				1		1		1	1			1	
	70-79	9	2			1			1							4		1	1	1		1			
	80-89	4				1	2		1							4		3							
	>90																		1						
	Total	**64**	**26**	**13**	**5**	**7**	**7**	**1**	**3**	**2**	**3**	**1**		**1**		**18**	**8**	**7**	**2**	**4**	**1**	**2**		**1**	
Follow-up second dose		**38**	Not relevant	**10**	Not relevant	**5**	Not relevant	**1**	Not relevant	**0**	Not relevant	**1**	Not relevant	**1**	Not relevant	**12**	Not relevant	**6**	Not relevant	**1**	Not relevant	**2**	Not relevant	**1**	Not relevant
Expected number of cases in population age 16 and older, for same time period of vaccination project and same population group		168	128	51	39	180	135	41	30	465	341	17	12	41	31	1372	1018	1258	920	139	110	334	260	13	9

The observed numbers are compared to the morbidity data in hospitalized patients from 2017-2019 which includes morbidity data reported among all individuals 16 years and older from the corresponding periods – *i.e* morbidity cases following the first and second dose is compared to morbidity cases in hospitalized patients from December - March and January - March respectively.
NOTE: In addition to the data presented in the table, the MoH monitors other reactions for which expected numbers cannot be presented.

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Other adverse events of interest

משרד הבריאות

Other AEs of interest following vaccination (rate per million vaccine doses) compared to expected rates in the general population according to morbidity data from the corresponding periods of years 2017-2019

Other adverse events of interest	Medical diagnosis	AE rates following first dose (Dec-Mar)	Expected rates (hospitalization data Dec-Mar 2017-2019)	AE rates following second dose (Jan-Mar)	Expected rates (hospitalization data Jan-Mar 2017-2019)
Hematological	Thrombocytopenia	0.6	26.9	0.4	21.0
	Purpura	0.2	21.2	Not reported	15.2
Infections	Sepsis	0.2	71.1	Not reported	53.5
	Herpes zoster	3.4	44.2	3.6	33.4
	Herpes simplex	1.3	15.2	1.3	10.5
	Necrotizing Fasciitis	0.2	6.5	Not reported	4.8
Neurological	Transiant Ischemic Attack	1.3	201.8	0.4	147.6
	Encephalitis	0.2	1.4	Not reported	1.1
	Diplopia (double vision)	0.4	9.3	0.6	6.8
	Acute hearing loss	1.3	28.9	1.5	21.6
	Shoulder weakness and severe pain	0.2	2.1	Not reported	1.5
	Facial weakness and severe pain	0.2	6.6	Not reported	5.0
	Blurred vision	2.5	8.2	1.0	6.3
	Vertigo	0.4	59.7	0.6	43.3
	Guillian barre syndrome	0.8	22.3	0.2	17.7

Note: Despite normalization to the number of vaccinees, observed and expected rates cannot be directly compared, because the observed cases are counted differently than the expected ones. The observed cases count morbidity within a time window of a defined event (vaccine administration). The expected cases are calculated by the cumulative incidence over several calendar months. However, the expected cases do give a general order of magnitude for comparison of morbidity following vaccine administration.

The observed rates are compared to the morbidity data in hospitalized patients from 2017-2019 which includes morbidity data reported among all individuals 16 years and older from the corresponding periods – *i.e* morbidity rates following the first and second dose is compared to morbidity rates in hospitalized patients from December - March and January - March respectively.
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Other adverse events of interest

Other AEs of interest following vaccination (rate per million vaccine doses) compared to expected rates in the general population according to morbidity data from the corresponding periods of years 2017-2019

Other adverse events of interest	Medical diagnosis	AE rates following first dose (Dec-Mar)	Expected rates (hospitalization data Dec-Mar 2017-2019)	AE rates following second dose (Jan-Mar)	Expected rates (hospitalization data Jan-Mar 2017-2019)
Cardiovascular	Myocardial infarction	0.6	746.1	0.2	554.1
	Heart failure	0.4	859.2	Not reported	648.6
	Subarachnoid hemorrhage	0.2	19.9	Not reported	14.2
	Vasculitis	Not reported	7.3	0.2	4.5
	Pericarditis	1.0	48.7	2.1	36.6
	Myocarditis (including Perimyocarditis)	1.1	21.3	11.7	15.6
	Cardiac tamponade	0.2	3.8	Not reported	2.5
	Venous thrombosis (DVT)	Not reported	65.2	0.6	48.1
	Superficial venous thrombosis	Not reported	3.6	0.2	2.7
	Atrial Fibrillation	0.4	560.4	0.6	414.3
	Stroke	1.0	649.1	0.2	475.6
	Pulmonary embolism	0.2	78.0	0.2	56.4
	Pericardial effusion	0.4	33.9	0.2	26.8
Ophthalmological	Retinopathy	0.2	0.8	Not reported	0.5
Rheumatology	Arthritis	Not reported	252.7	0.2	191.6

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Other adverse events of interest

משרד הבריאות

Other AEs of interest following vaccination (rate per million vaccine doses) compared to expected rates in the general population according to morbidity data from the corresponding periods of years 2017-2019

Other adverse events of interest	Medical diagnosis	AE rates following first dose (Dec-Mar)	Expected rates (hospitalization data Dec-Mar 2017-2019)	AE rates following second dose (Jan-Mar)	Expected rates (hospitalization data Jan-Mar 2017-2019)
Pregnant (rate calculated out of women ages 16-49 whom received the vaccine)	Missed abortion	1.3	1909.4	Not reported	1473.1
	IUFD	1.3	71.6	Not reported	53.8
	CMV	Not reported	3.8	0.7	3.2
Respiratory	Pleuritis	0.2	2.4	Not reported	1.7
	Pulmonary edema	Not reported	259.8	0.2	196.0
	Severe acute respiratory syndrome	Not reported	177.5	0.2	132.9
Organ damage	Acute liver damage	0.2	3.9	Not reported	2.8
	Acute kidney damage	0.2	227.4	Not reported	168.7
Other	Erythema Multiforme	0.2	3.4	Not reported	2.6
	Loss of smell (anosmia)/loss of taste (ageusia)	1.3	1.8	1.0	1.2
	Appendicitis	Not reported	315.9	0.2	235.3
	Acute thyroiditis	Not reported	2.4	0.2	1.9
	Multiple sclerosis (1 relapse and 1 new diagnosis)	0.4	53.6	Not reported	41.8
	Hemorrhagic cystitis	0.2	4.9	Not reported	3.9
	rhabdomyolysis	Not reported	20.6	0.2	16.0

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Myocarditis following vaccination

To date, 62 cases of myocarditis following vaccination have been reported

Myocarditis after first dose (N=6)

- 4 males, 2 females
- 1 case myocarditis, 5 cases of Perimyocarditis
- 4 events occurred within 10 days of receiving the vaccine,1 event occurred within 2 weeks and 1 event occurred within 3 weeks following vaccination.
- 3 cases with comorbidities (HTN, dyslipidemia)
- All cases were discharged from the hospital and are under observation in the community
- 2 cases received a second dose with no adverse reactions reported

Myocarditis after second dose (N=56)

- 50 males and 6 females
- 37 cases of Myocarditis, 19 cases of Perimyocarditis
- 23 events occurred within 10 days of receiving the vaccine, 2 events occurred within 2 weeks, 1 events occurred within 3 weeks, 2 events occurred within 4 weeks following vaccination.
- 28 cases with comorbidities (HTN, smoking, asthma, dyslipidemia, DM, hypercholesterolemia)
- 53 cases were discharged from the hospital and are under observation at community level. 1 case is under investigation, 2 cases died (1 case fulminant myocarditis, 1 case is still under investigation)
- None of the cases reported adverse reactions after receipt of the first dose

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Pericarditis following vaccination

To date, 15 cases of Pericarditis following vaccination have been reported

Pericarditis after first dose (N=5)

- 3 males, 2 females
- All events occurred within 4 days of receiving the vaccine.
- 2 cases with comorbidities (history of Pericarditis, heart valve)
- All cases were discharged from the hospital and are under observation in the community
- 3 cases received a second dose with no adverse reactions reported

Pericarditis after second dose (N=10)

- 6 males and 4 females
- 8 events occurred within 7 days of receiving the vaccine, 1 events occurred within 3 weeks, 1 events occurred within 5 weeks following vaccination.
- 8 cases with comorbidities (HTN, obesity, hypercholesterolemia, dyslipidemia, renal disease)
- 9 cases were discharged from the hospital and are under observation at community level. 1 is under investigation.
- None of the cases reported adverse reactions after receipt of the first dose

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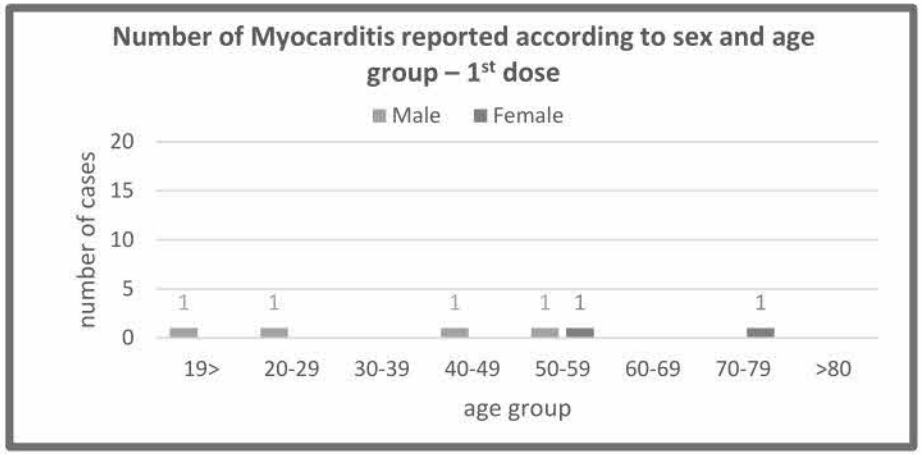
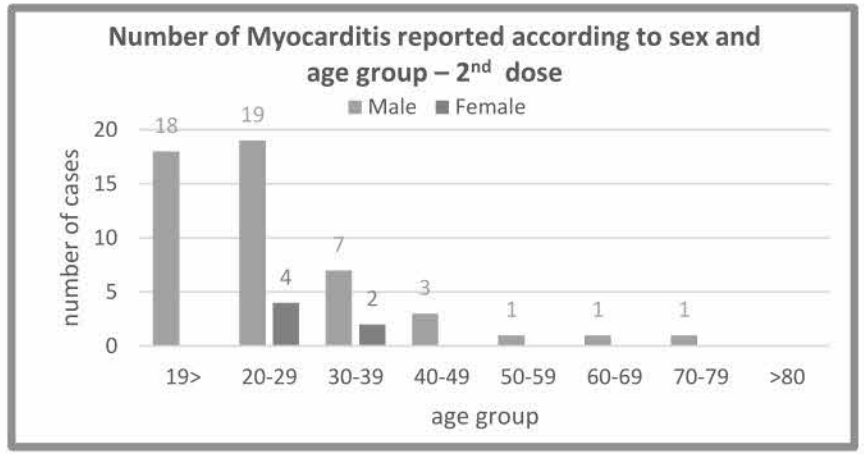
Myocarditis / Pericarditis following vaccination

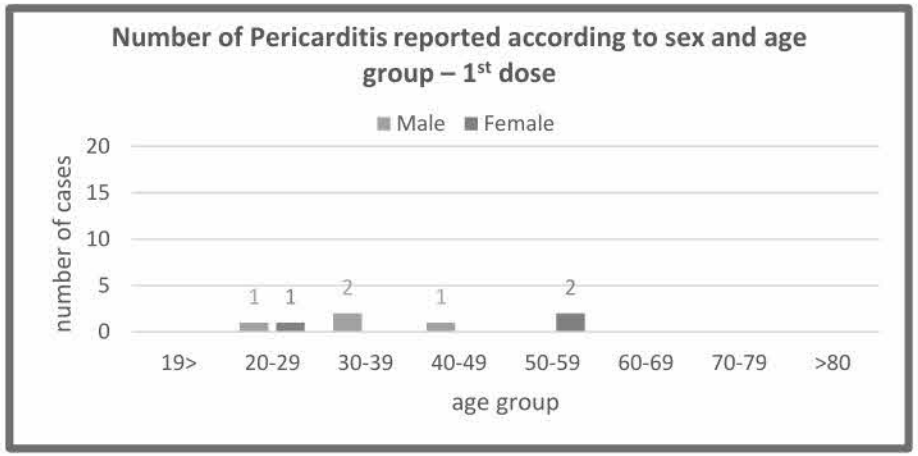
משרד הבריאות

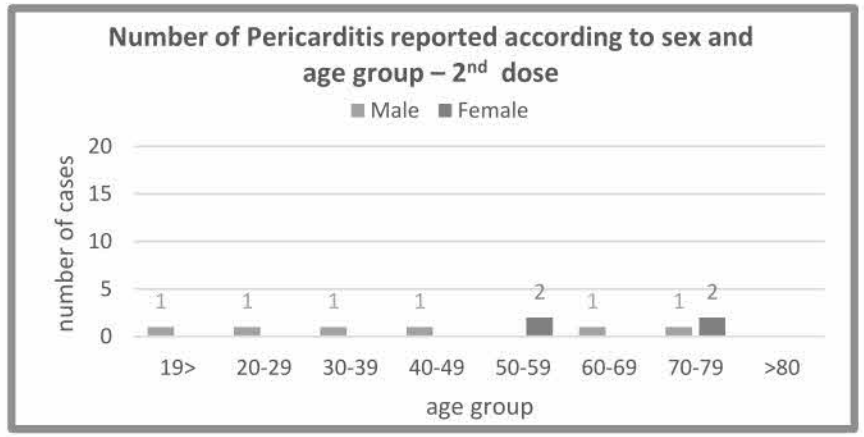
Myocarditis / Perimyocarditis





Pericarditis





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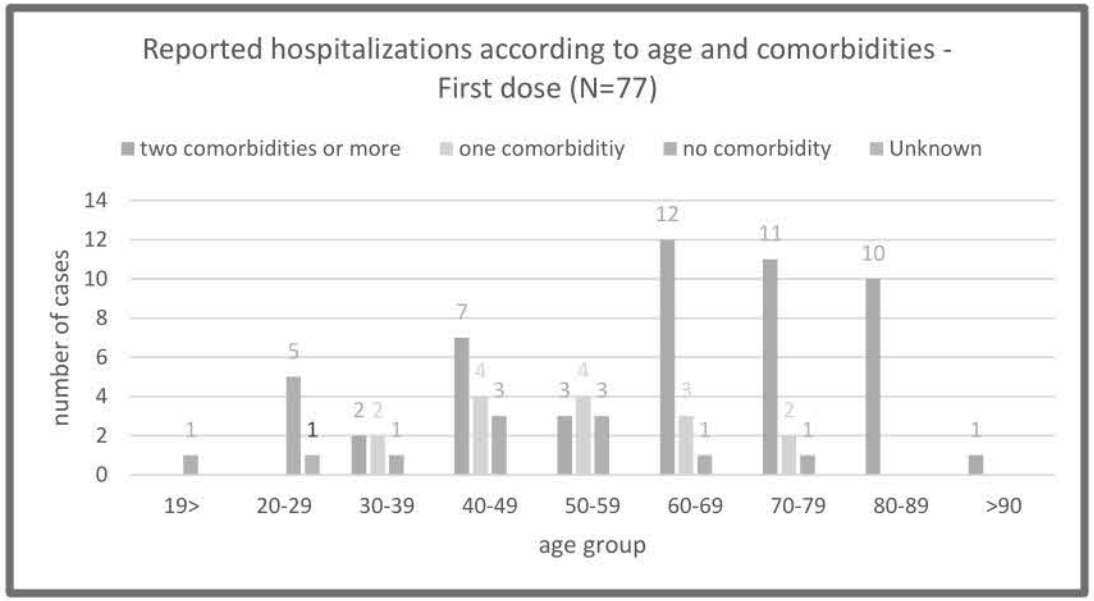
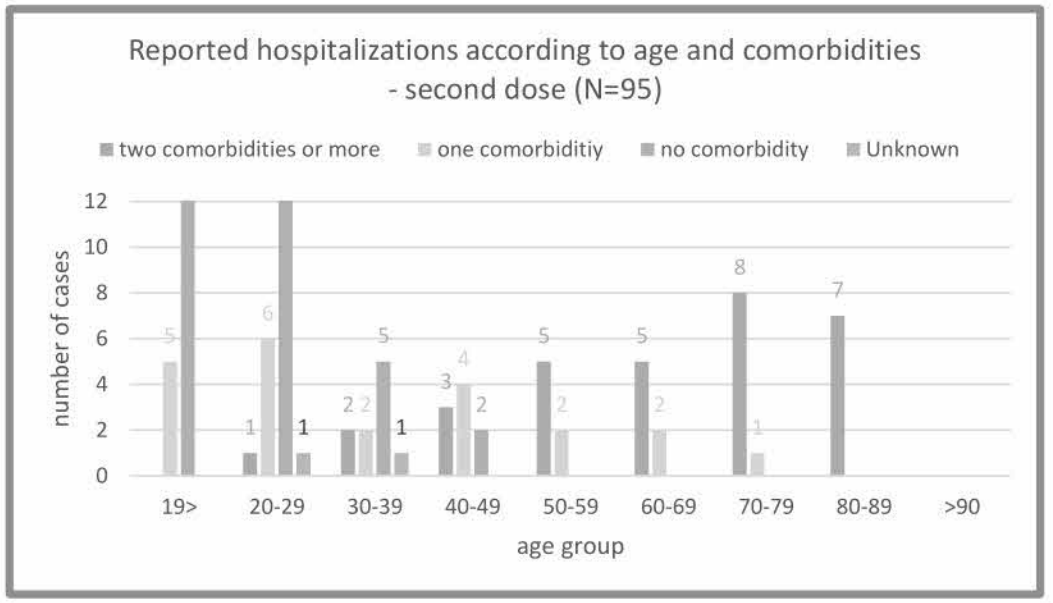
לחיים בריאים יותר

Hospitalizations reported following vaccination





Among 77 hospitalizations following receiving the first dose , 34 cases were related to neurological diseases out of which 30 cases had comorbidities, 25 hospitalization were related to underlying cardiovascular diseases out of which 18 had comorbidities, 6 hospitalizations were related to allergic reactions, 2 infectious and 7 hospitalizations were related to other underlying diseases. 3 hospitalizations were related to pregnancy complications.

Among 95 hospitalization following receiving the second dose , 75 cases were related to cardiovascular diseases and of those 38 were with significant underlying diseases. 10 hospitalizations were related to underlying neurological diseases and of those 8 were with significant underlying diseases and 4 hospitalizations were related to underlying respiratory diseases, and 8 hospitalizations were related to other underlying diseases.

Reports among vaccine recipients
1st dose: 5,244,481 2nd dose: 4,785,534

Data is based on adverse events reported to the MoH

Updated 31/03/2021

משרד הבריאות
לחיים בריאים יותר

Deaths reported following vaccination

- **48 persons were reported to die in proximity to vaccination (up to 30 days following vaccination).**
- **42 deaths occurred within 10 days following vaccination**
- **Out of 48 reported cases, 14 are <60 y old:**
  - **2 were diagnosed in ER with myocarditis (1 case fulminant myocarditis, 1 case still under investigation)**
  - **2 PM in cases of sudden death excluded myocarditis in one and showed blocked LAD.**
  - **10 cases are under investigation: relatively young persons with sudden death.**

Reports among vaccine recipients
1st dose: 5,244,481 2nd dose: 4,785,534

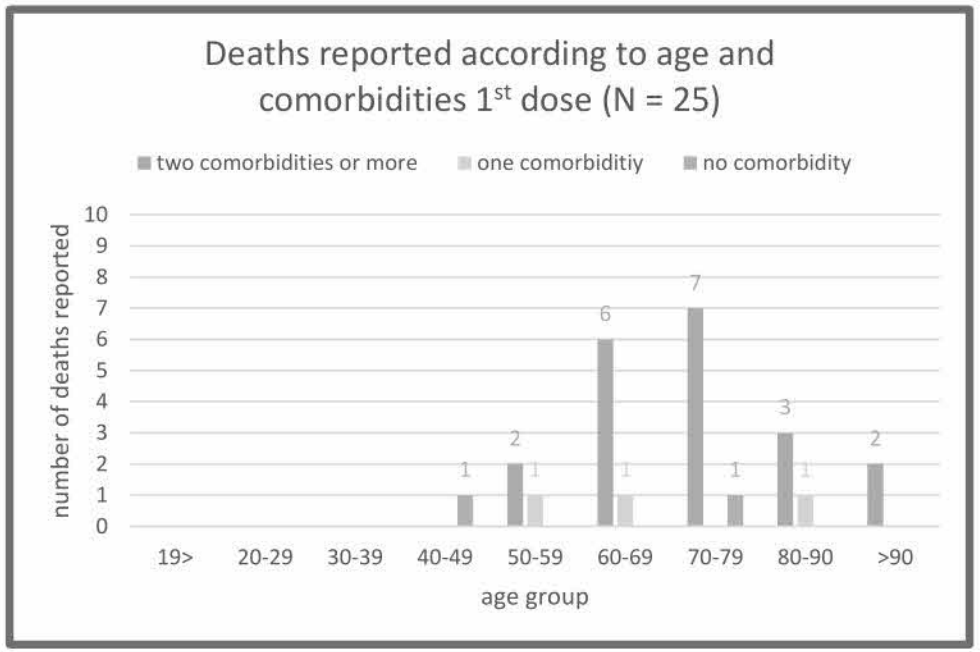
Data is based on adverse events reported to the MoH

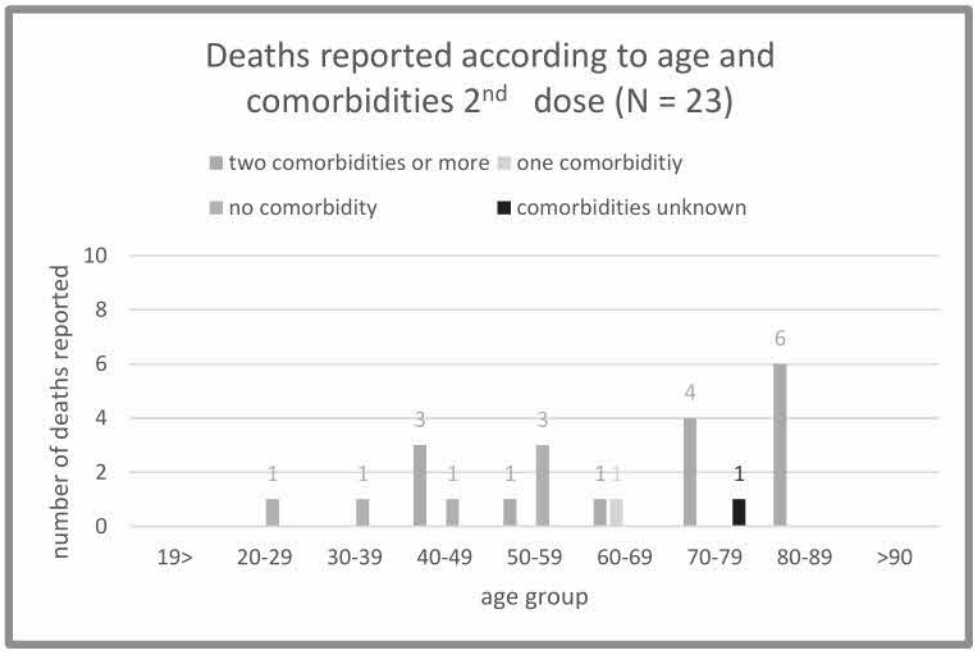
Updated 31/03/2021

R-2024-00044 A-00000749473 "UNCLASSIFIED" 11/21/2024

משרד הבריאות
לחיים בריאים יותר

Deaths reported following vaccination





Reports among vaccine recipients
1st dose: 5,244,481 2nd dose: 4,785,534

Data is based on adverse events reported to the MoH

Updated 31/03/2021

משרד הבריאות
לחיים בריאים יותר

Deaths reported following vaccination observed and expected

משרד הבריאות

Age group	Mortality cases reported following 1st dose	Mortality cases expected all causes (Dec-Mar)	Sudden death reported following 1st dose	Sudden death expected (Dec-Mar)	Mortality cases reported following 2nd dose	Mortality cases expected all causes (Jan-Mar)	Sudden death reported following 2nd dose	Sudden death expected (Jan-Mar)	Total cases reported
Male									
20-29	0	74	0	0	0	48	0	0	0
30-39	0	108	0	0	1	72	1	0	1
40-49	0	235	0	1	4	165	4	1	4
50-59	2	564	2	5	3	392	2	4	5
60-69	4	1220	1	5	2	865	0	3	6
70-79	6	2353	0	6	1	1727	0	3	7
80<	3	4349	0	9	3	3153	0	6	6
Female									
20-29	0	30	0	0	1	20	0	0	1
30-39	0	59	0	0	0	41	0	0	0
40-49	1	139	1	0	0	95	0	0	1
50-59	1	336	1	1	1	235	1	1	2
60-69	3	773	0	1	0	561	0	1	3
70-79	2	1714	1	4	4	1252	0	3	6
80<	3	5398	0	13	3	3889	0	10	6
Total	**25**	**17,352**	**6**	**45**	**23**	**12,515**	**8**	**32**	**48**

The overall mean of expected total deaths in the population of Israel 2015-2018, for December-March for the first dose, and January-March for the second dose, normalized for the number of vaccinated persons.

Note: Despite normalization to the number of vaccinees, observed and expected rates cannot be directly compared, because the observed cases are counted differently than the expected ones. The observed cases count deaths within a time window of a defined event (vaccine administration). The expected cases are calculated by the cumulative incidence over several calendar months. However, the expected cases do give a general order of magnitude for comparison of deaths following vaccine administration.

No specific signal associated with all causes of death and specifically sudden death

Data is based on adverse events reported to the MoH

Updated 31/03/2021

משרד הבריאות
לחיים בריאים יותר

משרד הבריאות
מינהל הרוקחת

COVID-19 vaccination Israel
"BACK TO LIFE"

משרד הבריאות
לחיים בריאים יותר

משרד הבריאות

Adverse events following vaccination COVID-19

Data updated March 31st 2021

Division of Epidemiology

Public health services

Ministry of Health Israel

משרד הבריאות
לחיים בריאים יותר

Sources of adverse events reports

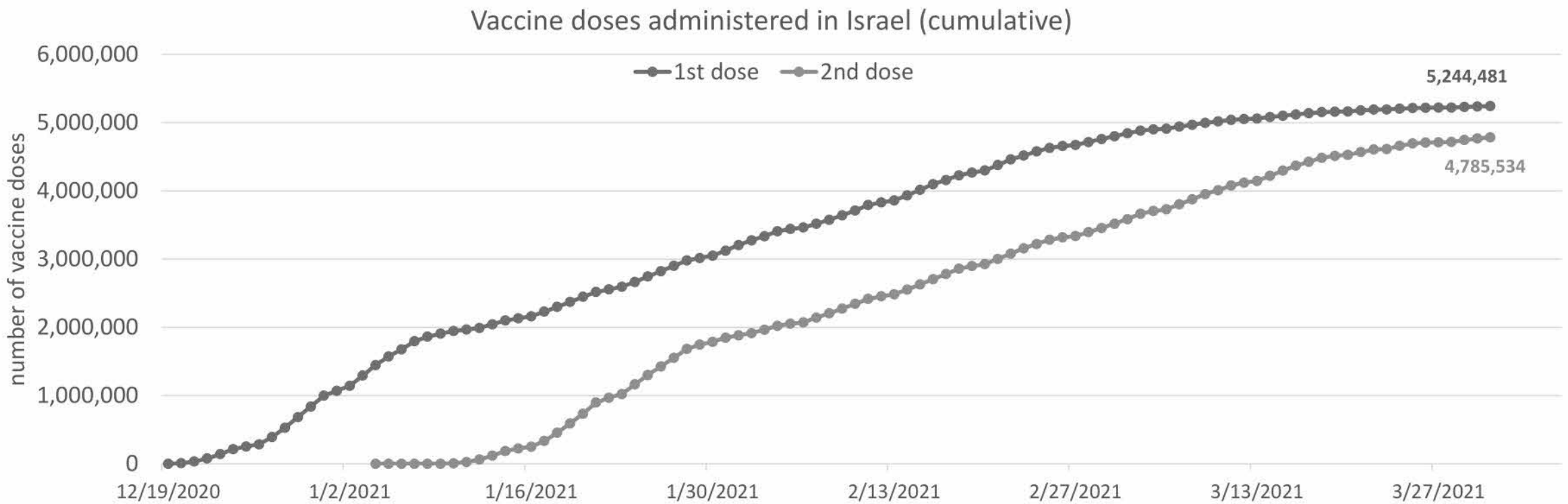
משרד הבריאות

Sources of adverse events reports include:

- Hospitals
- HMOs
- Emergency Medical Services - MDA (for individuals who are vaccinated in nursing homes)
- The Medical Department and the Patient Safety Unit at the MoH
- Israeli Defense Forces (IDF)

משרד הבריאות
לחיים בריאים יותר

Vaccine doses administered in Israel

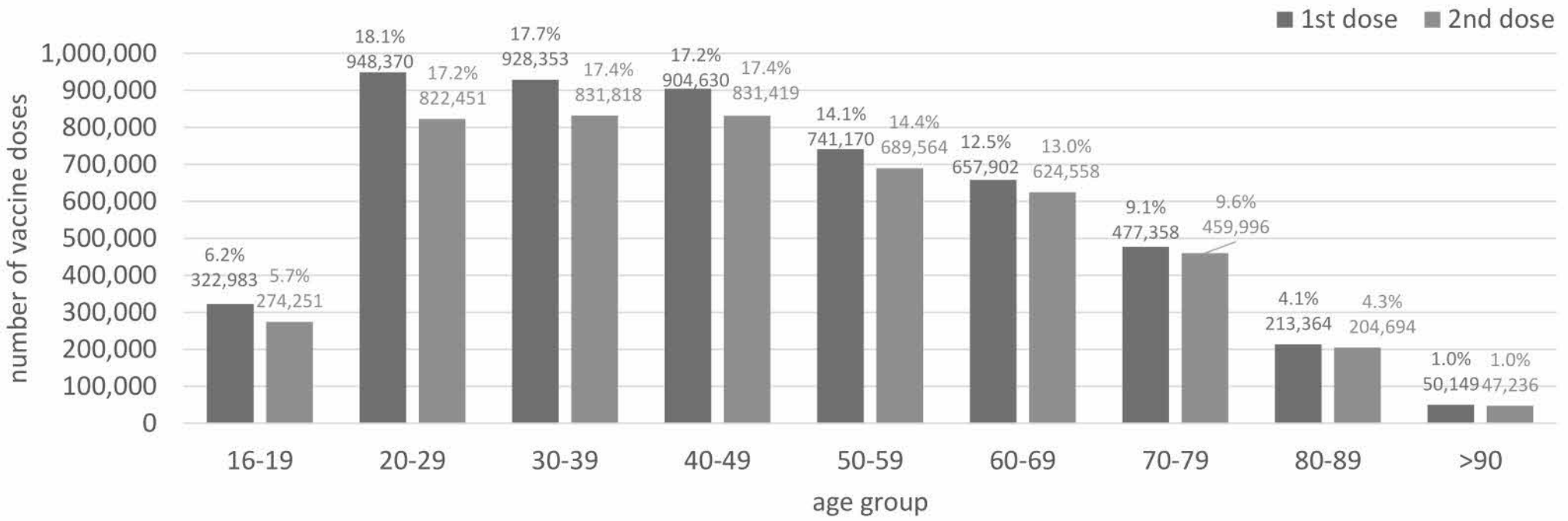


Updated 31/03/2021

משרד הבריאות
לחיים בריאים יותר

Distribution of vaccine recipients according to age

משרד הבריאות



AgeGroup	16-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90<
Vaccine coverage by age group 1st dose	55.3%	72.9%	77.6%	82.3%	87.2%	88.7%	97.3%	94.6%	97.4%
Vaccine coverage by age group 2nd dose	47.0%	63.2%	69.5%	75.7%	81.1%	84.2%	93.7%	90.8%	91.7%

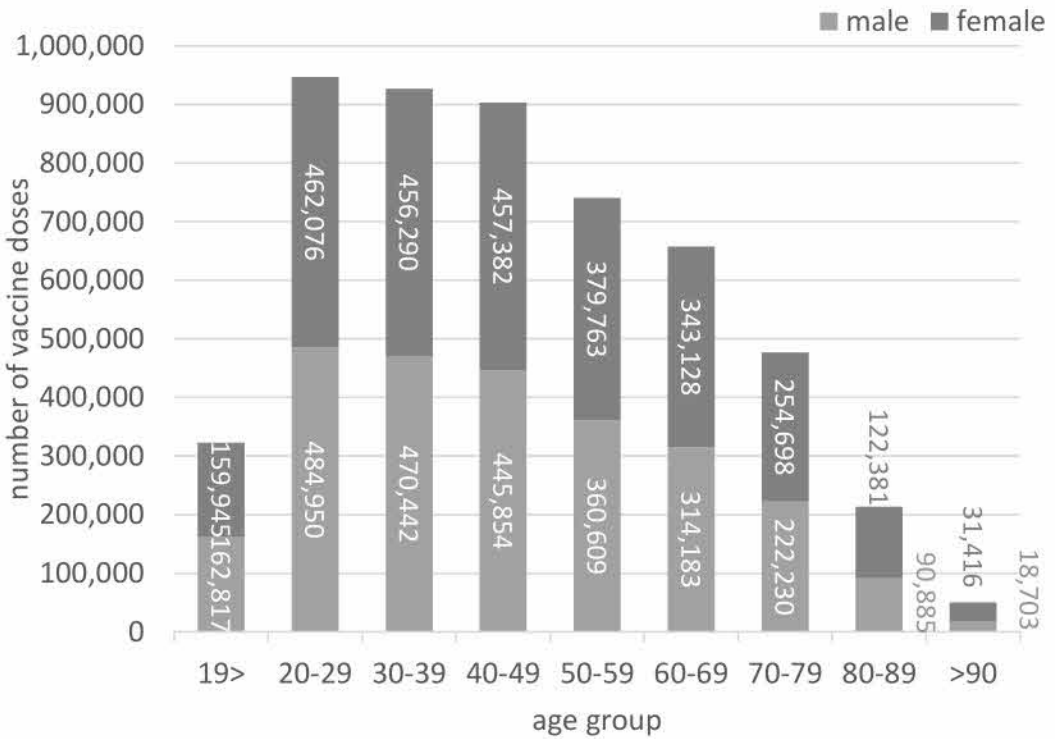
Updated 31/03/2021

משרד הבריאות
לחיים בריאים יותר

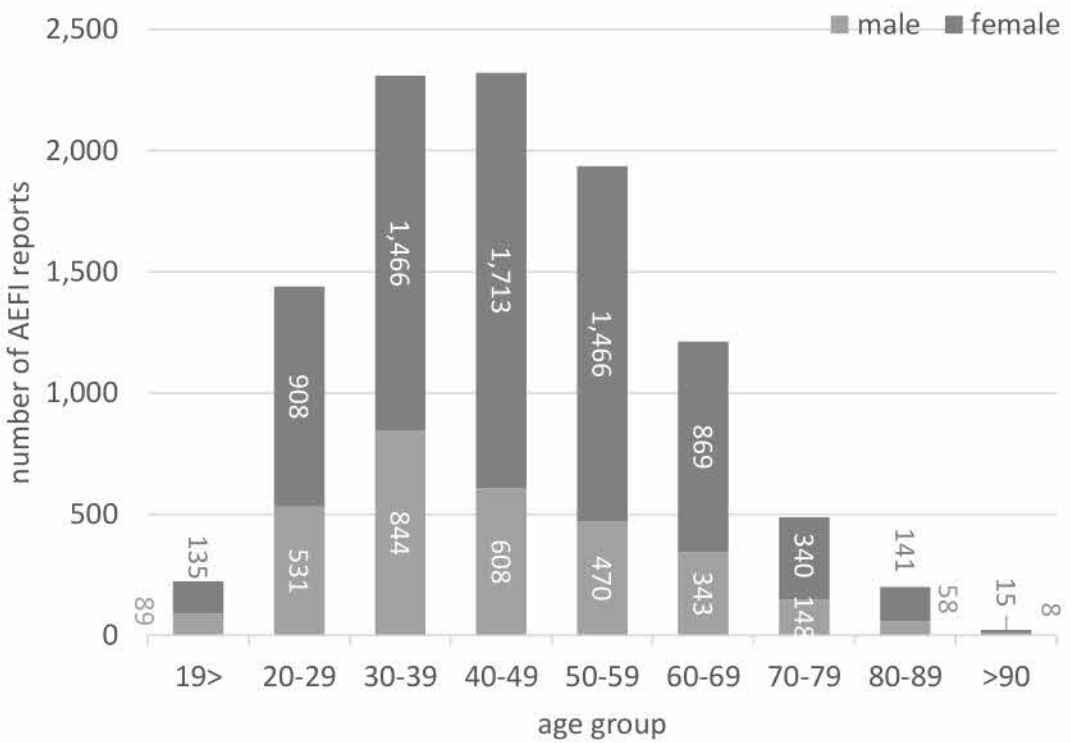
Age and sex distribution among vaccine recipients and those who reported adverse events - FIRST DOSE

משרד הבריאות

Distribution according to age group and sex among recipients of first vaccine dose.



Distribution according to age group and sex among individuals reporting adverse events following first dose vaccination.



Women and younger individuals are more likely to report adverse reactions following vaccination relative to their proportion among the vaccine recipient population

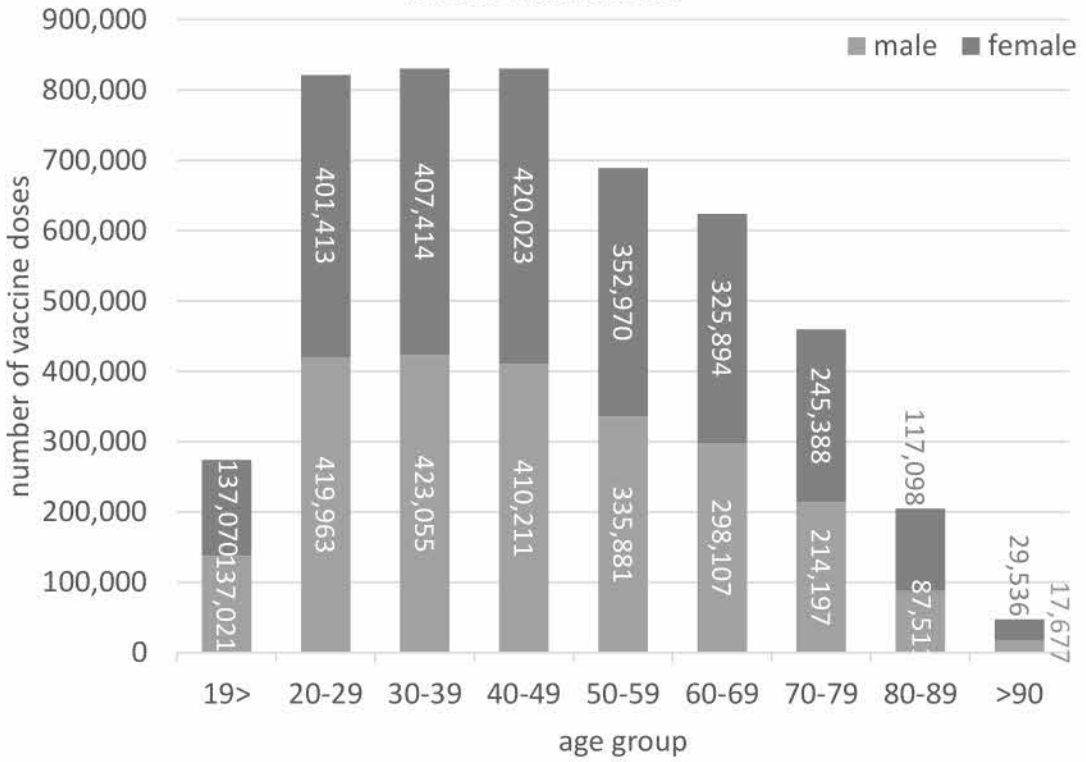
Updated 31/03/2021

משרד הבריאות
לחיים בריאים יותר

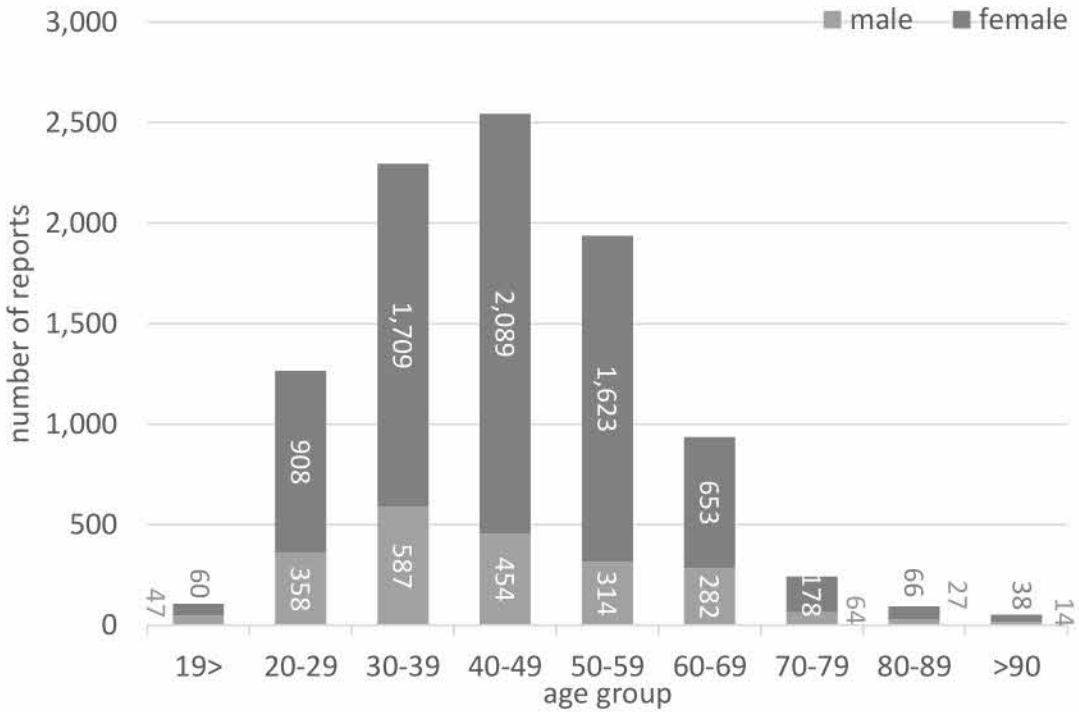
Age and sex distribution among vaccine recipients and those who reported adverse events - SECOND DOSE

משרד הבריאות

Distribution according to age group and sex among recipients of second vaccine dose.



Distribution according to age group and sex among individuals reporting adverse events following second dose vaccination



Women and younger individuals are more likely to report adverse reactions following vaccination relative to their proportion among the vaccine recipient population

Updated 31/03/2021

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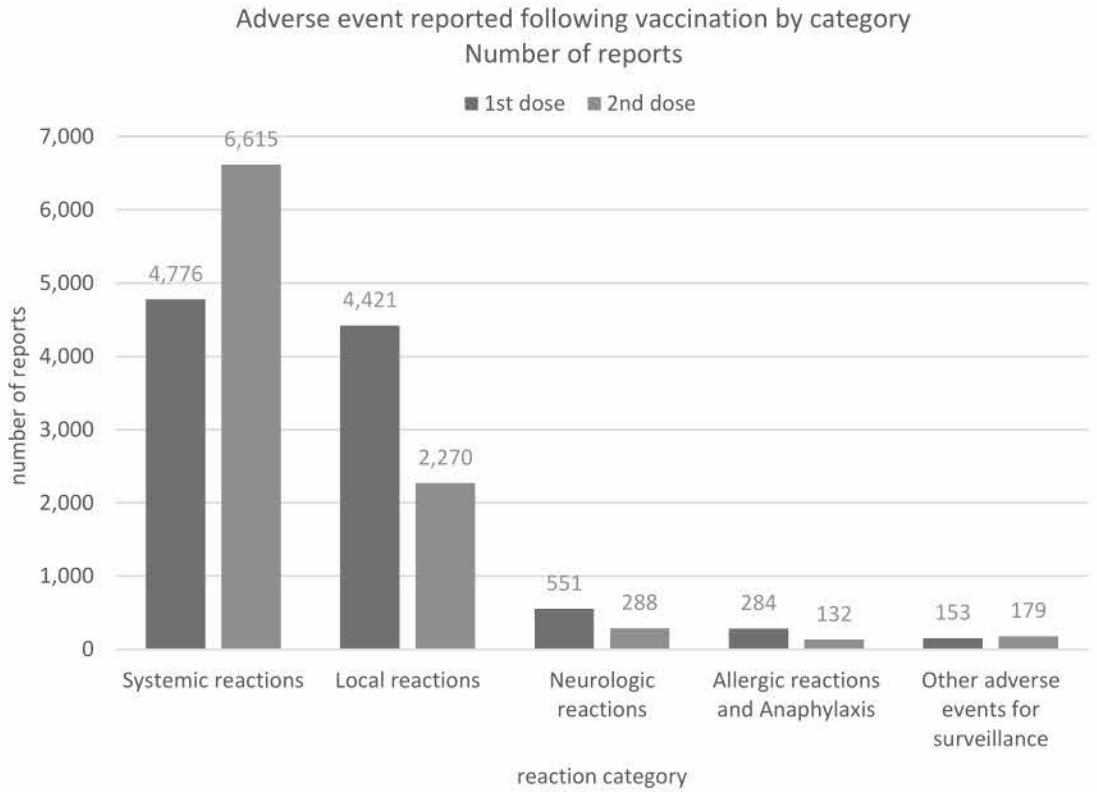
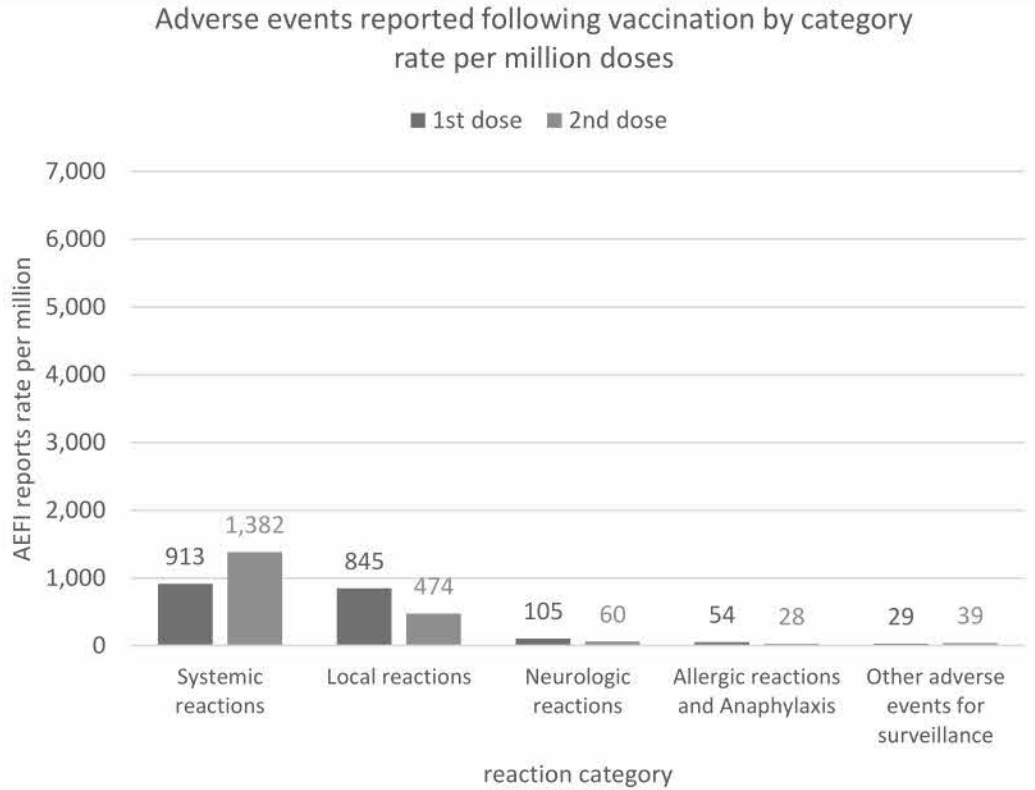
משרד הבריאות
לחיים בריאים יותר

Adverse events following vaccination by category





Reports among vaccine recipients
1st dose: 5,244,481 2nd dose: 4,785,534

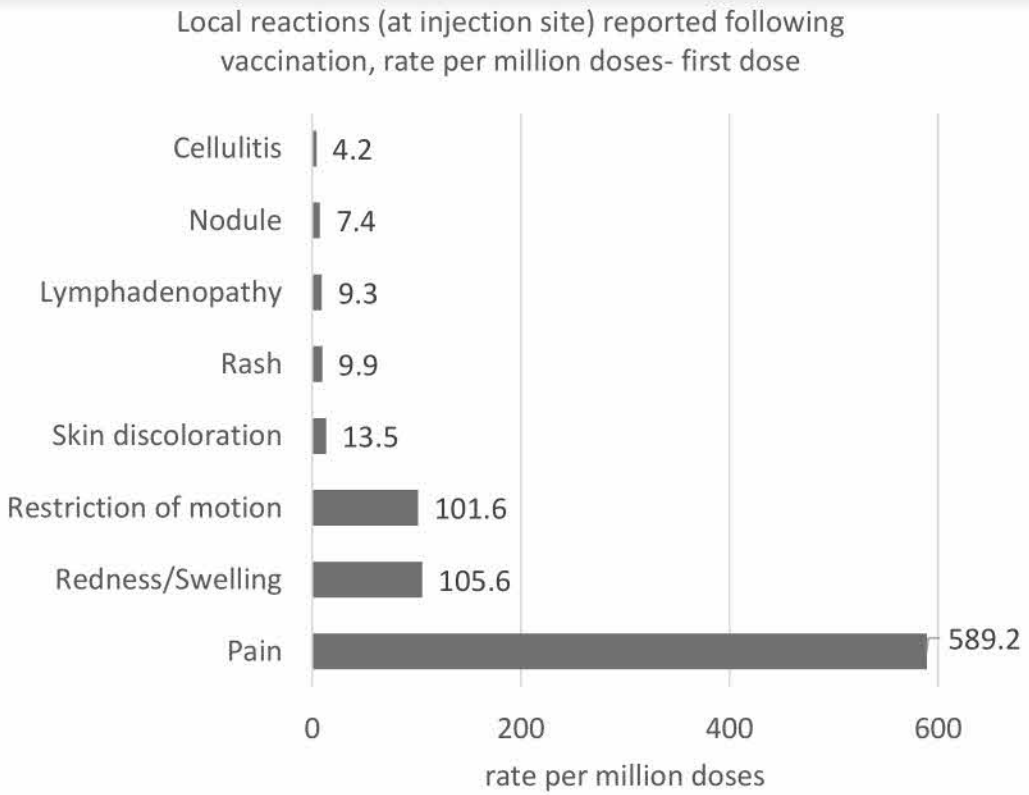
Updated 31/03/2021

Data is based on adverse events reported to the MoH I Some individuals reported more than one adverse event

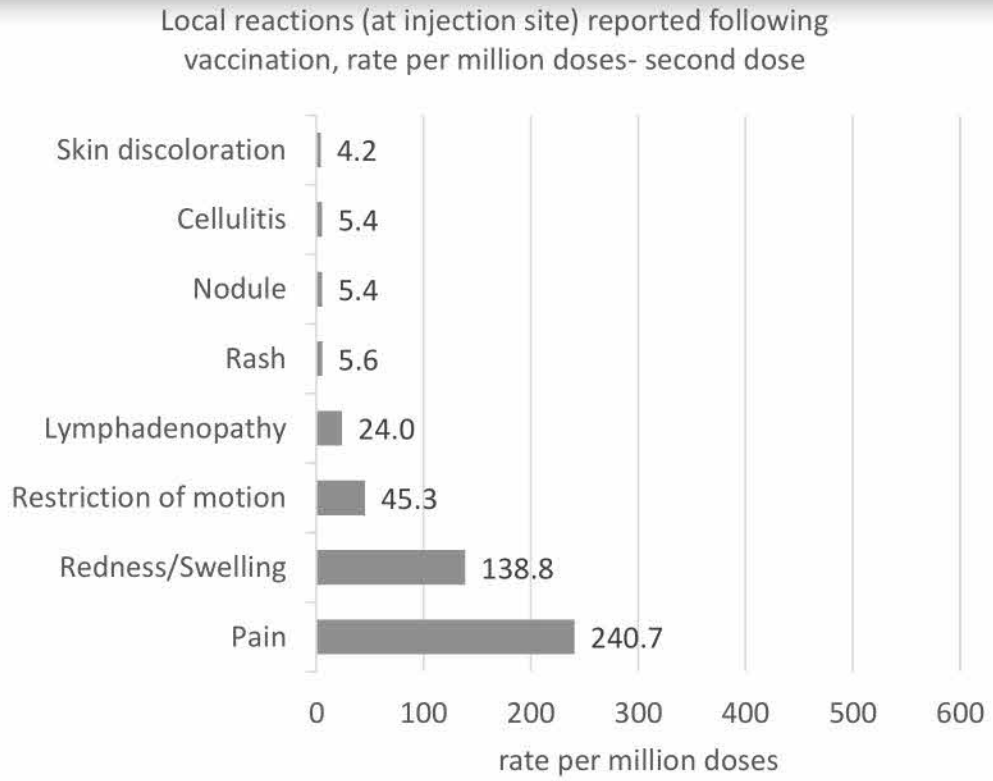
R-2024-00044 A-00000749473 "UNCLASSIFIED" 11/21/2024

משרד הבריאות
לחיים בריאים יותר

Local reactions



Rate per million vaccine doses out of 5,244,481 vaccine 1st dose recipients



Rate per million vaccine doses out of 4,785,534 vaccine 2nd dose recipients

Updated 31/03/2021

Data is based on adverse events reported to the MoH I Some individuals reported more than one adverse event

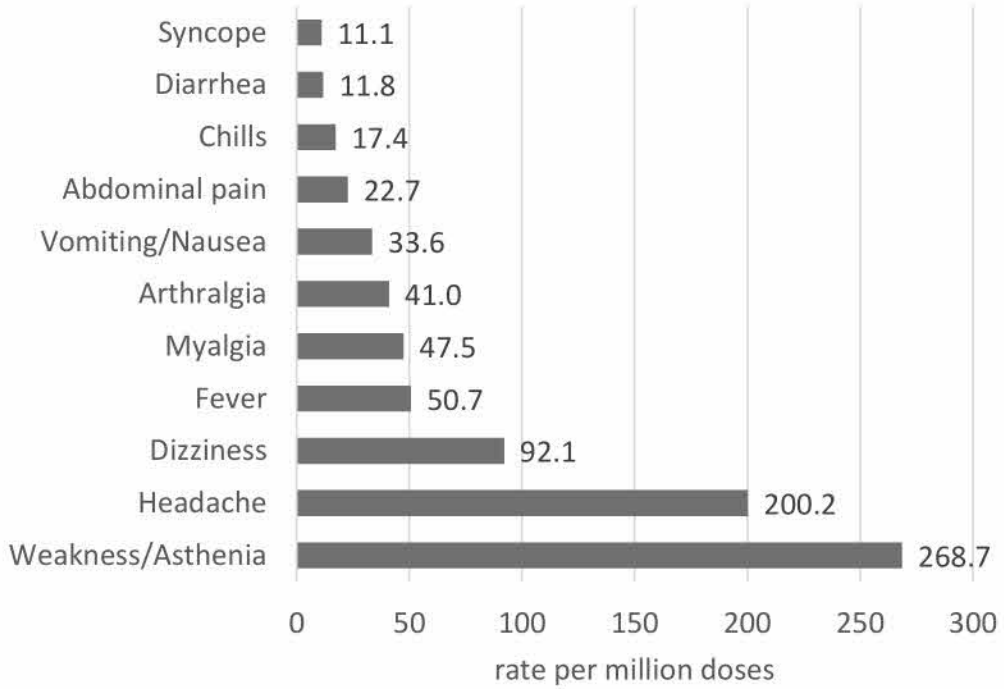
משרד הבריאות
לחיים בריאים יותר

R-2024-00044 A-00000749473 "UNCLASSIFIED" 11/21/2024

Systemic reactions

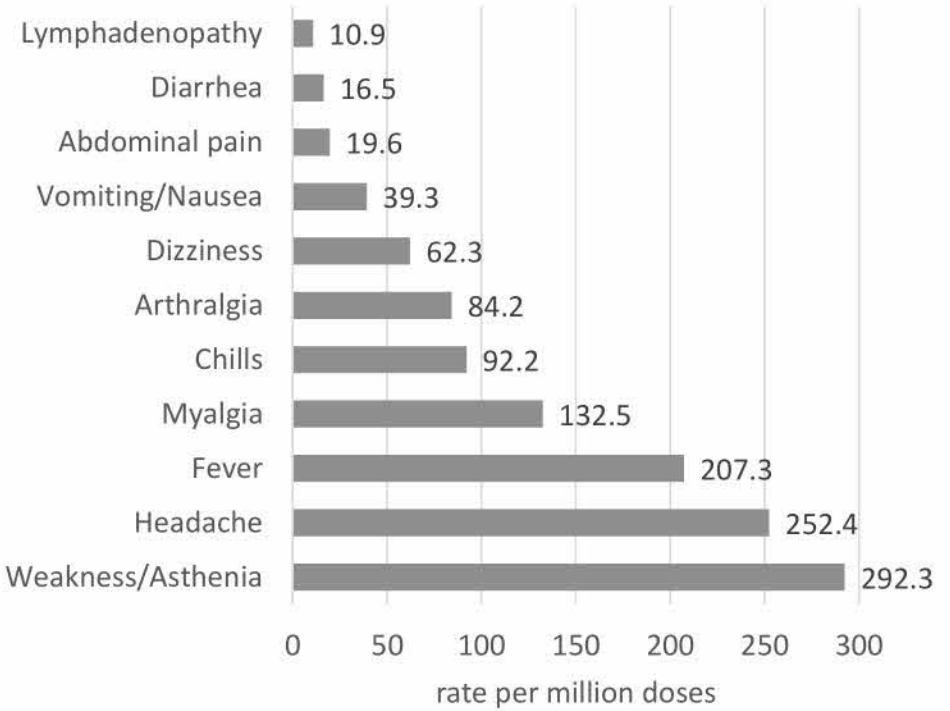
משרד הבריאות

General reactions reported following immunization, rate per million doses- first dose



Rate per million vaccine doses out of 5,244,481 vaccine 1st dose recipients

General reactions reported following immunization, rate per million doses- second dose



Rate per million vaccine doses out of 4,785,534 vaccine 2nd dose recipients

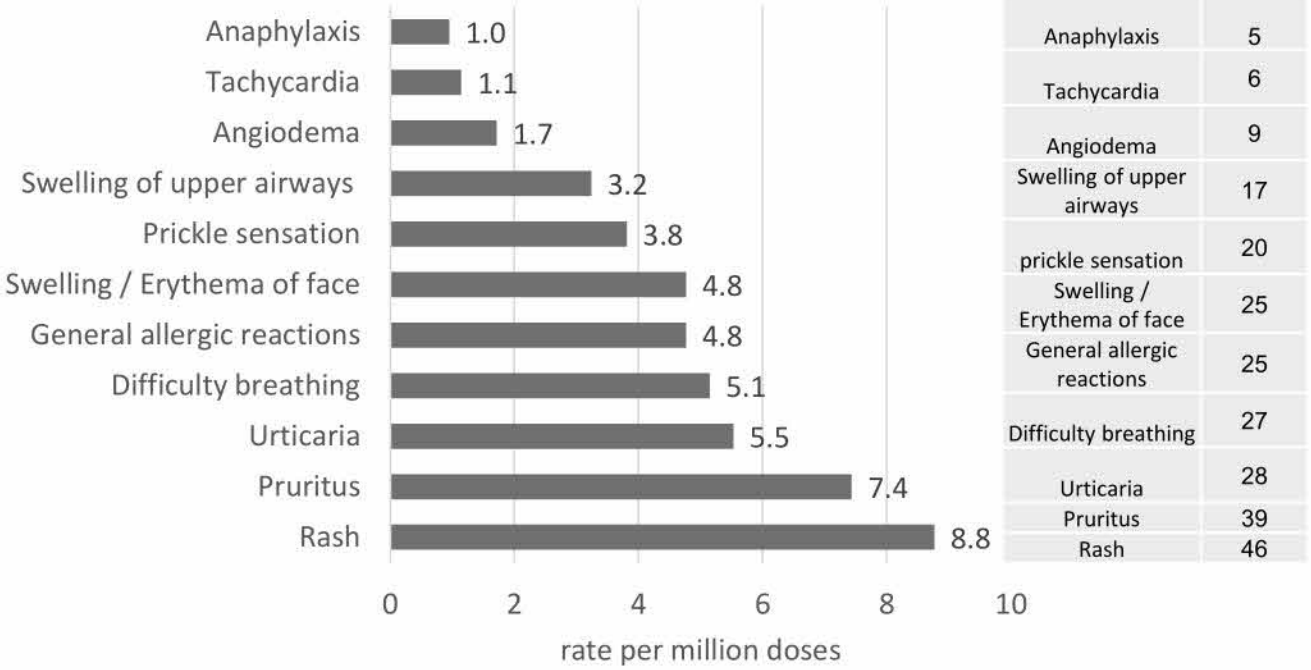
Updated 31/03/2021

Data is based on adverse events reported to the MoH I Some individuals reported more than one adverse event

R-2024-00044 A-00000749473 "UNCLASSIFIED" 11/21/2024

Allergic reactions

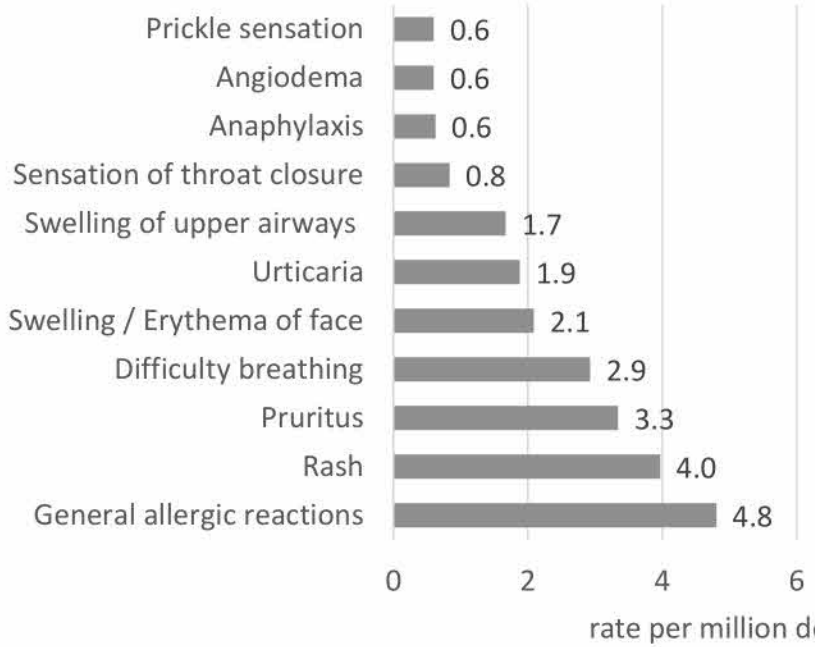
Allergic reactions reported following vaccination, rate per million vaccine doses- first dose



Number of allergic reactions reported 1st dose	
Anaphylaxis	5
Tachycardia	6
Angiodema	9
Swelling of upper airways	17
prickle sensation	20
Swelling / Erythema of face	25
General allergic reactions	25
Difficulty breathing	27
Urticaria	28
Pruritus	39
Rash	46

Rate per million vaccine doses out of 5,244,481 vaccine 1st dose recipients

Allergic reactions reported following vaccination, rate per million vaccine doses- second dose



Number of allergic reactions reported 2nd dose	
prickle sensation	3
Angiodema	3
Anaphylaxis	3
Sensation of throat closure	4
Swelling of upper airways	8
Urticaria	9
Swelling / Erythema of face	10
Difficulty breathing	14
Pruritus	16
Rash	19
General allergic reactions	23

Rate per million vaccine doses out of 4,785,534 vaccine 2nd dose recipients

Updated 31/03/2021

Data is based on adverse events reported to the MoH I Some individuals reported more than one adverse event

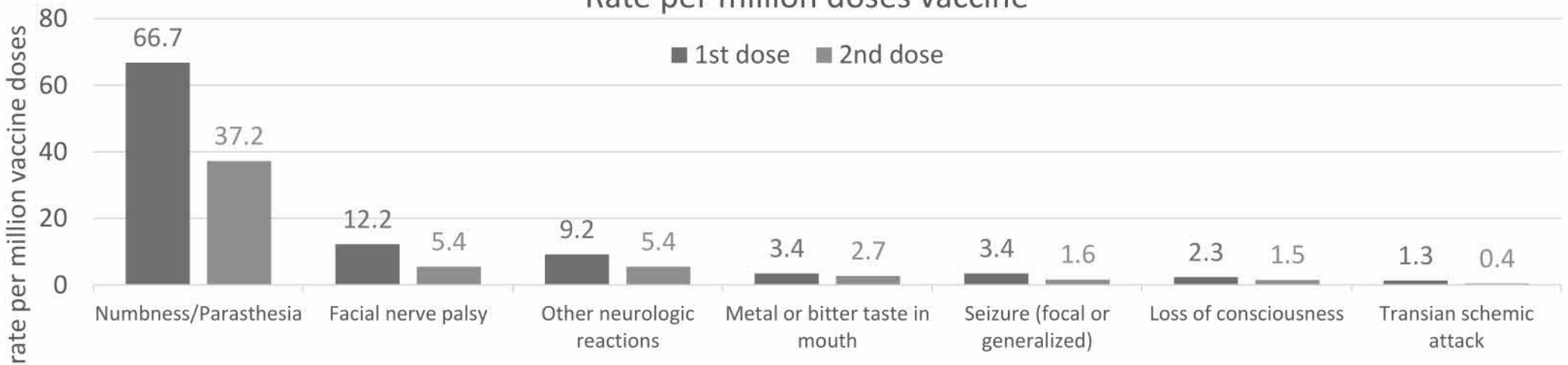
משרד הבריאות
לחיים בריאים יותר

Neurologic reactions

Number of neurologic reactions reported

	Numbness/ Parasthesia	Facial nerve palsy	Other neurologic reactions	Metal or bitter taste in mouth	Seizure (focal or generalized)	Loss of consciousness	Transian ischemic attack
1st dose	350	64	48	18	18	12	7
2nd dose	178	26	25	13	8	7	2

Rate of neurological reactions reported following vaccination
Rate per million doses vaccine



Updated 31/03/2021

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משרד הבריאות
לחיים בריאים יותר

R-2024-00044 A-00000749473 "UNCLASSIFIED" 11/21/2024

Neurologic reactions

משרד הבריאות

		Bell's palsy (1 case pregnant)		Blurred vision		Sudden sensorineural hearing loss		Abducens nerve palsy		Vertigo		Occulomotor nerve palsy		Trigeminal neuralgia		Seizures		Transiant Ischemic Attack		Guillain Barré syndrome (1 case exacerbation)		Multiple sclerosis (1 case exacerbation, 1 new case)		Brachial plexitis	
		1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose
Age group	**<20**	1	1													2	1								
	20-29	3	2		1	1								1		2	1	1		1					
	30-39	7	2	3		1	1									2	1								
	40-49	13	5	2	3		2			1						1	5	1				1			
	50-59	11	10	6	1	2	1				1					2				1					
	60-69	16	4	2		1	1	1	1	1	2	1				1		1		1	1			1	
	70-79	9	2			1			1							4		1	1	1		1			
	80-89	4				1	2		1							4		3							
	>90																		1						
	Total	**64**	**26**	**13**	**5**	**7**	**7**	**1**	**3**	**2**	**3**	**1**		**1**		**18**	**8**	**7**	**2**	**4**	**1**	**2**		**1**	
Follow-up second dose		**38**	Not relevant	**10**	Not relevant	**5**	Not relevant	**1**	Not relevant	**0**	Not relevant	**1**	Not relevant	**1**	Not relevant	**12**	Not relevant	**6**	Not relevant	**1**	Not relevant	**2**	Not relevant	**1**	Not relevant
Expected number of cases in population age 16 and older, for same time period of vaccination project and same population group		**168**	**128**	**51**	**39**	**180**	**135**	**41**	**30**	**465**	**341**	**17**	**12**	**41**	**31**	**1372**	**1018**	**1258**	**920**	**139**	**110**	**334**	**260**	**13**	**9**

The observed numbers are compared to the morbidity data in hospitalized patients from 2017-2019 which includes morbidity data reported among all individuals 16 years and older from the corresponding periods – *i.e* morbidity cases following the first and second dose is compared to morbidity cases in hospitalized patients from December - March and January - March respectively.
NOTE: In addition to the data presented in the table, the MoH monitors other reactions for which expected numbers cannot be presented.

Updated 31/03/2021

Data is based on adverse events reported to the MoH I Some individuals reported more than one adverse event

משרד הבריאות
לחיים בריאים יותר

R-2024-00044 A-00000749473 "UNCLASSIFIED" 11/21/2024

Other adverse events of interest

משרד הבריאות

Other AEs of interest following vaccination (rate per million vaccine doses) compared to expected rates in the general population according to morbidity data from the corresponding periods of years 2017-2019

Other adverse events of interest	Medical diagnosis	AE rates following first dose (Dec-Mar)	Expected rates (hospitalization data Dec-Mar 2017-2019)	AE rates following second dose (Jan-Mar)	Expected rates (hospitalization data Jan-Mar 2017-2019)
Hematological	Thrombocytopenia	0.6	26.9	0.4	21.0
	Purpura	0.2	21.2	Not reported	15.2
Infections	Sepsis	0.2	71.1	Not reported	53.5
	Herpes zoster	3.4	44.2	3.6	33.4
	Herpes simplex	1.3	15.2	1.3	10.5
	Necrotizing Fasciitis	0.2	6.5	Not reported	4.8
Neurological	Transiant Ischemic Attack	1.3	201.8	0.4	147.6
	Encephalitis	0.2	1.4	Not reported	1.1
	Diplopia (double vision)	0.4	9.3	0.6	6.8
	Acute hearing loss	1.3	28.9	1.5	21.6
	Shoulder weakness and severe pain	0.2	2.1	Not reported	1.5
	Facial weakness and severe pain	0.2	6.6	Not reported	5.0
	Blurred vision	2.5	8.2	1.0	6.3
	Vertigo	0.4	59.7	0.6	43.3
	Guillian barre syndrome	0.8	22.3	0.2	17.7

Note: Despite normalization to the number of vaccinees, observed and expected rates cannot be directly compared, because the observed cases are counted differently than the expected ones. The observed cases count morbidity within a time window of a defined event (vaccine administration). The expected cases are calculated by the cumulative incidence over several calendar months. However, the expected cases do give a general order of magnitude for comparison of morbidity following vaccine administration.

The observed rates are compared to the morbidity data in hospitalized patients from 2017-2019 which includes morbidity data reported among all individuals 16 years and older from the corresponding periods – *i.e* morbidity rates following the first and second dose is compared to morbidity rates in hospitalized patients from December - March and January - March respectively.
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Data is based on adverse events reported to the MoH

Updated 31/03/2021

R-2024-00044 A-00000749473 "UNCLASSIFIED" 11/21/2024

משרד הבריאות
לחיים בריאים יותר

Other adverse events of interest

Other AEs of interest following vaccination (rate per million vaccine doses) compared to expected rates in the general population according to morbidity data from the corresponding periods of years 2017-2019

Other adverse events of interest	Medical diagnosis	AE rates following first dose (Dec-Mar)	Expected rates (hospitalization data Dec-Mar 2017-2019)	AE rates following second dose (Jan-Mar)	Expected rates (hospitalization data Jan-Mar 2017-2019)
Cardiovascular	Myocardial infarction	0.6	746.1	0.2	554.1
	Heart failure	0.4	859.2	Not reported	648.6
	Subarachnoid hemorrhage	0.2	19.9	Not reported	14.2
	Vasculitis	Not reported	7.3	0.2	4.5
	Pericarditis	1.0	48.7	2.1	36.6
	Myocarditis (including Perimyocarditis)	1.1	21.3	11.7	15.6
	Cardiac tamponade	0.2	3.8	Not reported	2.5
	Venous thrombosis (DVT)	Not reported	65.2	0.6	48.1
	Superficial venous thrombosis	Not reported	3.6	0.2	2.7
	Atrial Fibrillation	0.4	560.4	0.6	414.3
	Stroke	1.0	649.1	0.2	475.6
	Pulmonary embolism	0.2	78.0	0.2	56.4
	Pericardial effusion	0.4	33.9	0.2	26.8
Ophthalmological	Retinopathy	0.2	0.8	Not reported	0.5
Rheumatology	Arthritis	Not reported	252.7	0.2	191.6

Note: Despite normalization to the number of vaccinees, observed and expected rates cannot be directly compared, because the observed cases are counted differently than the expected ones. The observed cases count morbidity within a time window of a defined event (vaccine administration). The expected cases are calculated by the cumulative incidence over several calendar months. However, the expected cases do give a general order of magnitude for comparison of morbidity following vaccine administration.

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Updated 31/03/2021

משרד הבריאות
לחיים בריאים יותר

R-2024-00044 A-00000749473 "UNCLASSIFIED" 11/21/2024

Other adverse events of interest

Other AEs of interest following vaccination (rate per million vaccine doses) compared to expected rates in the general population according to morbidity data from the corresponding periods of years 2017-2019

Other adverse events of interest	Medical diagnosis	AE rates following first dose (Dec-Mar)	Expected rates (hospitalization data Dec-Mar 2017-2019)	AE rates following second dose (Jan-Mar)	Expected rates (hospitalization data Jan-Mar 2017-2019)
Pregnant (rate calculated out of women ages 16-49 whom received the vaccine)	Missed abortion	1.3	1909.4	Not reported	1473.1
	IUFD	1.3	71.6	Not reported	53.8
	CMV	Not reported	3.8	0.7	3.2
Respiratory	Pleuritis	0.2	2.4	Not reported	1.7
	Pulmonary edema	Not reported	259.8	0.2	196.0
	Severe acute respiratory syndrome	Not reported	177.5	0.2	132.9
Organ damage	Acute liver damage	0.2	3.9	Not reported	2.8
	Acute kidney damage	0.2	227.4	Not reported	168.7
Other	Erythema Multiforme	0.2	3.4	Not reported	2.6
	Loss of smell (anosmia)/loss of taste (ageusia)	1.3	1.8	1.0	1.2
	Appendicitis	Not reported	315.9	0.2	235.3
	Acute thyroiditis	Not reported	2.4	0.2	1.9
	Multiple sclerosis (1 relapse and 1 new diagnosis)	0.4	53.6	Not reported	41.8
	Hemorrhagic cystitis	0.2	4.9	Not reported	3.9
	rhabdomyolysis	Not reported	20.6	0.2	16.0

Note: Despite normalization to the number of vaccinees, observed and expected rates cannot be directly compared, because the observed cases are counted differently than the expected ones. The observed cases count morbidity within a time window of a defined event (vaccine administration). The expected cases are calculated by the cumulative incidence over several calendar months. However, the expected cases do give a general order of magnitude for comparison of morbidity following vaccine administration.

The observed rates are compared to the morbidity data in hospitalized patients from 2017-2019 which includes morbidity data reported among all individuals 16 years and older from the corresponding periods – *i.e* morbidity rates following the first and second dose is compared to morbidity rates in hospitalized patients from December - March and January - March respectively.
NOTE: In addition to the data presented in the table, the MoH monitors other reactions for which expected rates cannot be presented.

Data is based on adverse events reported to the MoH

Updated 31/03/2021

R-2024-00044 A-00000749473 "UNCLASSIFIED" 11/21/2024

משרד הבריאות
לחיים בריאים יותר

Myocarditis following vaccination

משרד הבריאות

To date, 62 cases of myocarditis following vaccination have been reported

Myocarditis after first dose (N=6)

- 4 males, 2 females
- 1 case myocarditis, 5 cases of Perimyocarditis
- 4 events occurred within 10 days of receiving the vaccine,1 event occurred within 2 weeks and 1 event occurred within 3 weeks following vaccination.
- 3 cases with comorbidities (HTN, dyslipidemia)
- All cases were discharged from the hospital and are under observation in the community
- 2 cases received a second dose with no adverse reactions reported

Myocarditis after second dose (N=56)

- 50 males and 6 females
- 37 cases of Myocarditis, 19 cases of Perimyocarditis
- 23 events occurred within 10 days of receiving the vaccine, 2 events occurred within 2 weeks, 1 events occurred within 3 weeks, 2 events occurred within 4 weeks following vaccination.
- 28 cases with comorbidities (HTN, smoking, asthma, dyslipidemia, DM, hypercholesterolemia)
- 53 cases were discharged from the hospital and are under observation at community level. 1 case is under investigation, 2 cases died (1 case fulminant myocarditis, 1 case is still under investigation)
- None of the cases reported adverse reactions after receipt of the first dose

Data is based on adverse events reported to the MoH

Updated 31/03/2021

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משרד הבריאות
לחיים בריאים יותר

Pericarditis following vaccination

משרד הבריאות

To date, 15 cases of Pericarditis following vaccination have been reported

Pericarditis after first dose (N=5)

- 3 males, 2 females
- All events occurred within 4 days of receiving the vaccine.
- 2 cases with comorbidities (history of Pericarditis, heart valve)
- All cases were discharged from the hospital and are under observation in the community
- 3 cases received a second dose with no adverse reactions reported

Pericarditis after second dose (N=10)

- 6 males and 4 females
- 8 events occurred within 7 days of receiving the vaccine, 1 events occurred within 3 weeks, 1 events occurred within 5 weeks following vaccination.
- 8 cases with comorbidities (HTN, obesity, hypercholesterolemia, dyslipidemia, renal disease)
- 9 cases were discharged from the hospital and are under observation at community level. 1 is under investigation.
- None of the cases reported adverse reactions after receipt of the first dose

Data is based on adverse events reported to the MoH

Updated 31/03/2021

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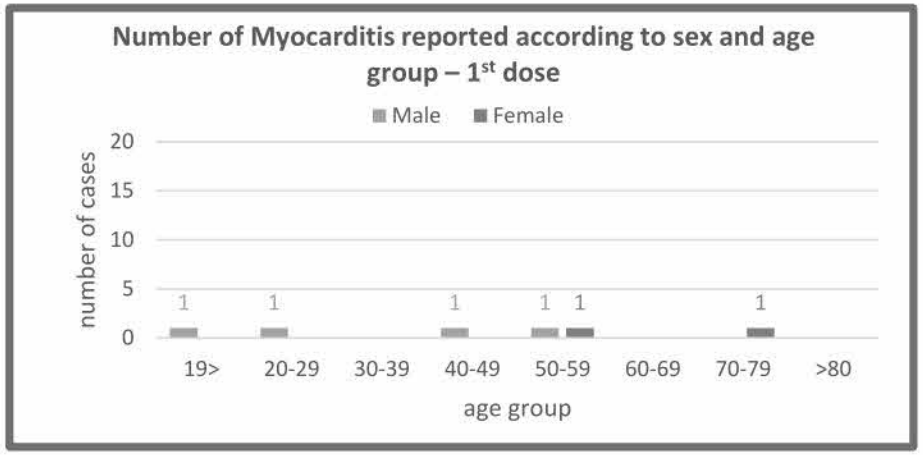
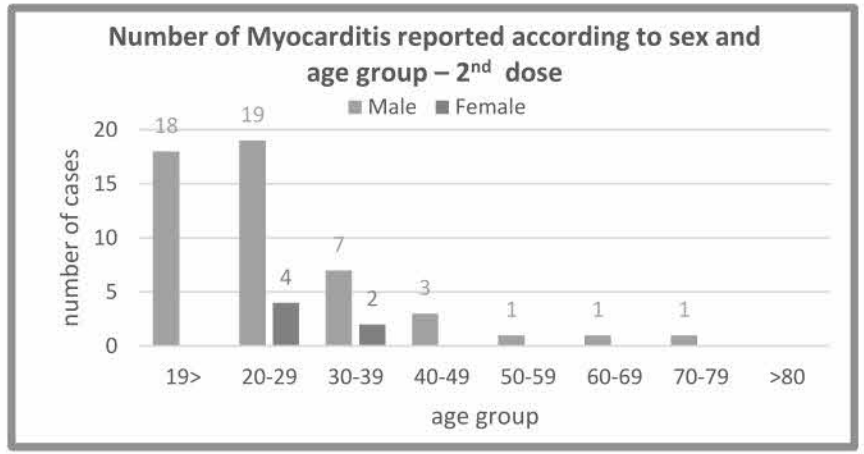
משרד הבריאות
לחיים בריאים יותר

Myocarditis / Pericarditis following vaccination

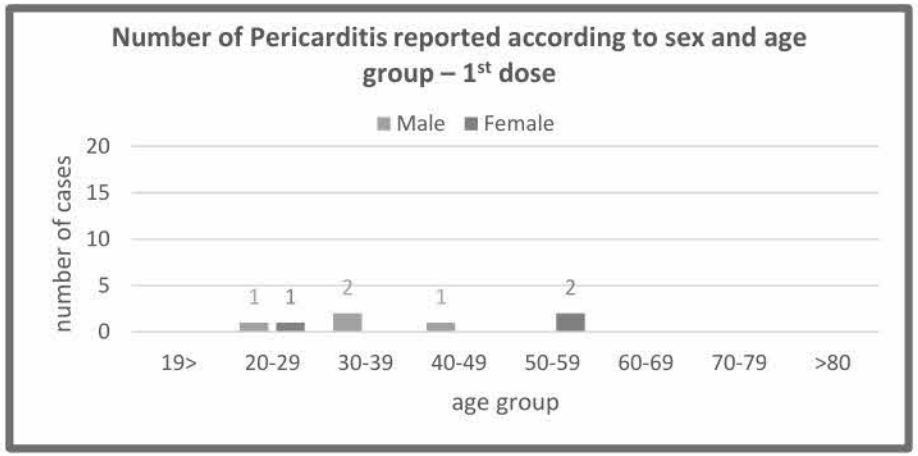
משרד הבריאות

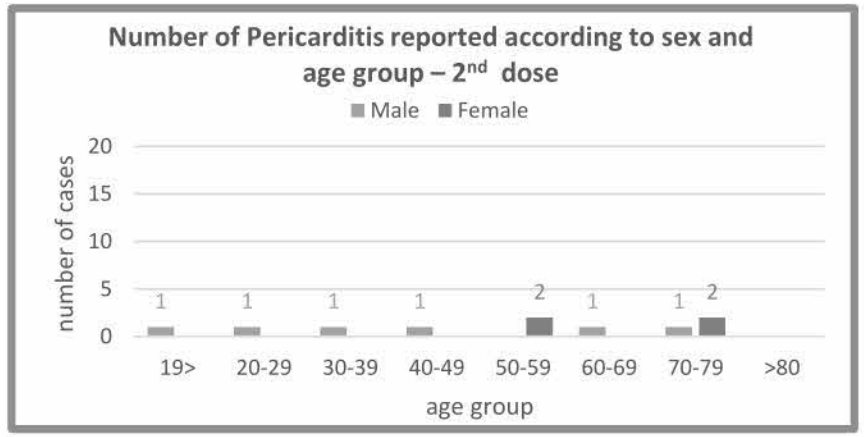
Myocarditis / Perimyocarditis





Pericarditis





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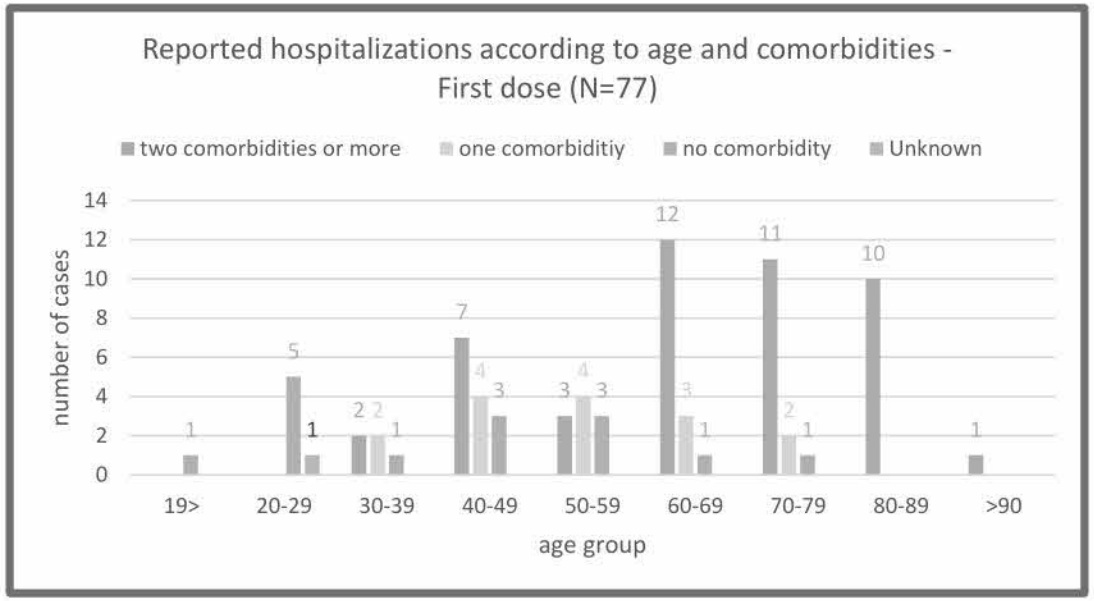
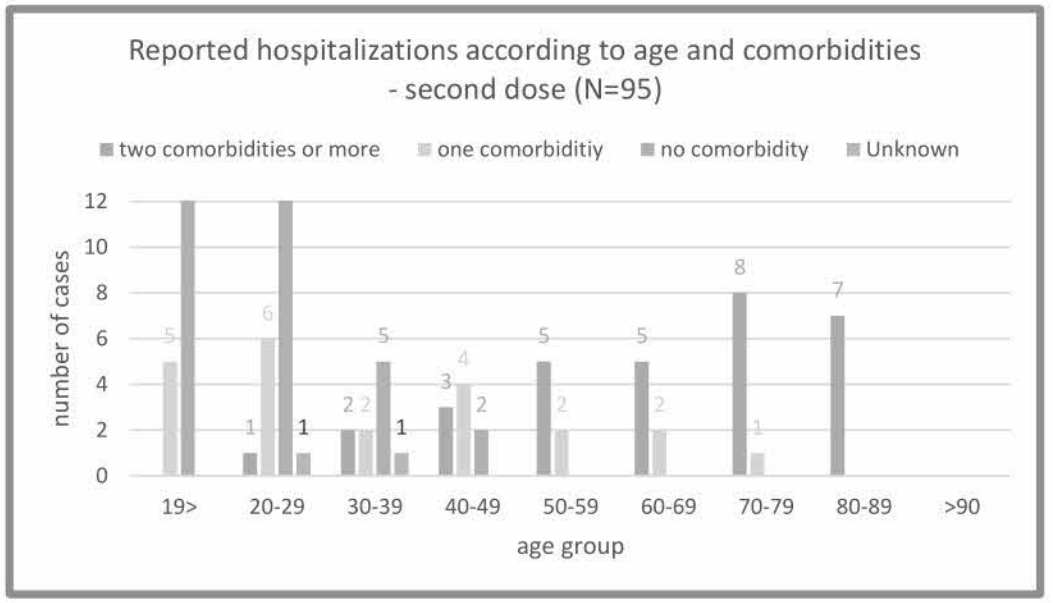
משרד הבריאות
לחיים בריאים יותר

Hospitalizations reported following vaccination





Among 77 hospitalizations following receiving the first dose , 34 cases were related to neurological diseases out of which 30 cases had comorbidities, 25 hospitalization were related to underlying cardiovascular diseases out of which 18 had comorbidities, 6 hospitalizations were related to allergic reactions, 2 infectious and 7 hospitalizations were related to other underlying diseases. 3 hospitalizations were related to pregnancy complications.

Among 95 hospitalization following receiving the second dose , 75 cases were related to cardiovascular diseases and of those 38 were with significant underlying diseases. 10 hospitalizations were related to underlying neurological diseases and of those 8 were with significant underlying diseases and 4 hospitalizations were related to underlying respiratory diseases, and 8 hospitalizations were related to other underlying diseases.

Reports among vaccine recipients
1st dose: 5,244,481 2nd dose: 4,785,534

Data is based on adverse events reported to the MoH

Updated 31/03/2021

משרד הבריאות
לחיים בריאים יותר

Deaths reported following vaccination

משרד הבריאות

- **48 persons were reported to die in proximity to vaccination (up to 30 days following vaccination).**
- **42 deaths occurred within 10 days following vaccination**
- **Out of 48 reported cases, 14 are <60 y old:**
  - **2 were diagnosed in ER with myocarditis (1 case fulminant myocarditis, 1 case still under investigation)**
  - **2 PM in cases of sudden death excluded myocarditis in one and showed blocked LAD.**
  - **10 cases are under investigation: relatively young persons with sudden death.**

Reports among vaccine recipients
1st dose: 5,244,481 2nd dose: 4,785,534

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Updated 31/03/2021

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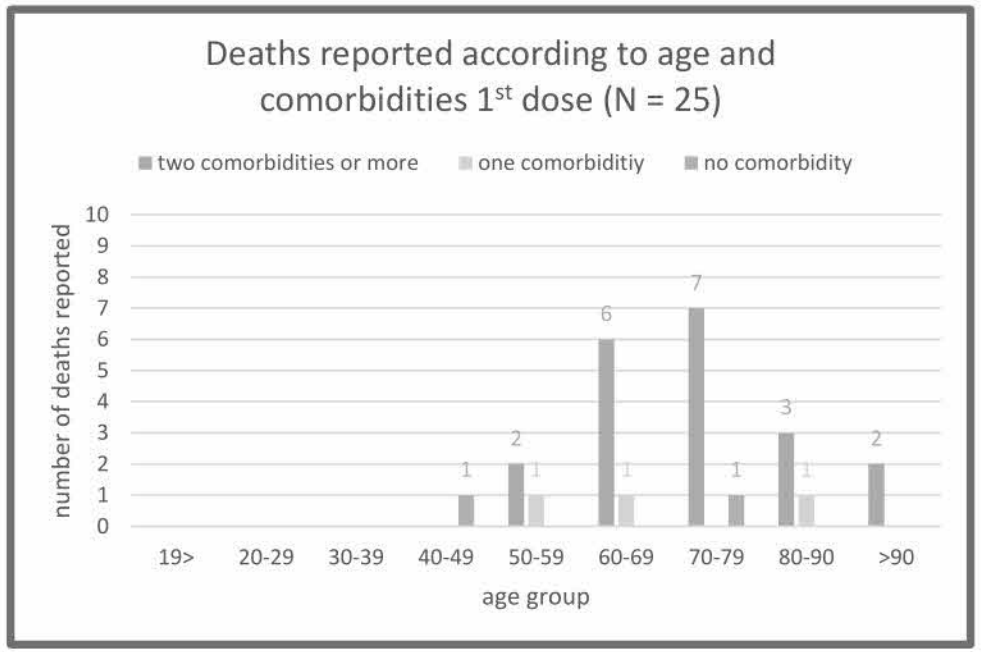
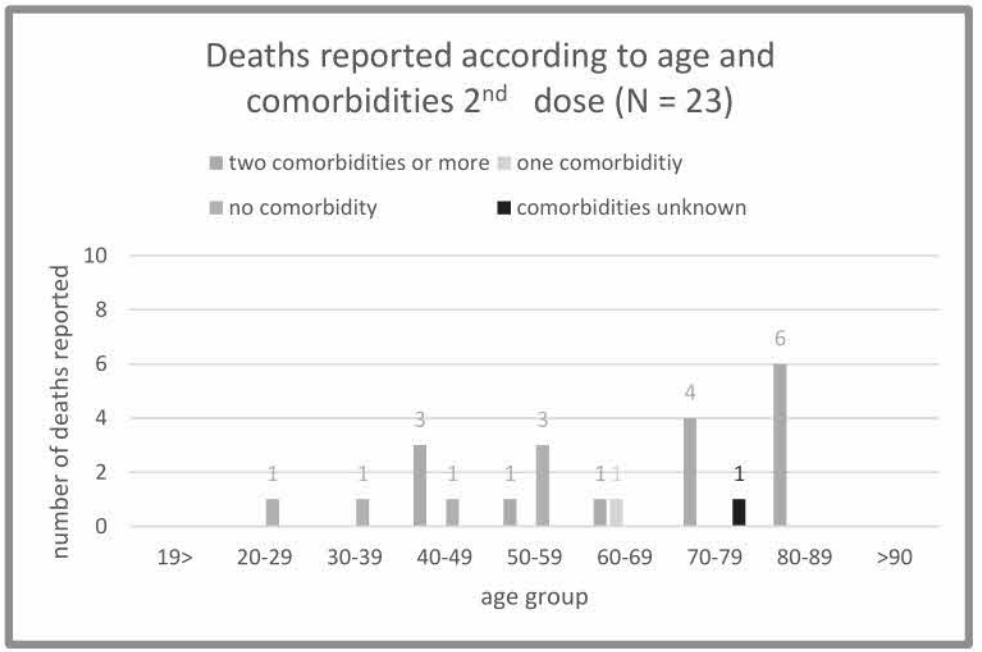
משרד הבריאות
לחיים בריאים יותר

Deaths reported following vaccination





Reports among vaccine recipients
1st dose: 5,244,481 2nd dose: 4,785,534

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Updated 31/03/2021

משרד הבריאות
לחיים בריאים יותר

Deaths reported following vaccination observed and expected

משרד הבריאות

Age group	Mortality cases reported following 1st dose	Mortality cases expected all causes (Dec-Mar)	Sudden death reported following 1st dose	Sudden death expected (Dec-Mar)	Mortality cases reported following 2nd dose	Mortality cases expected all causes (Jan-Mar)	Sudden death reported following 2nd dose	Sudden death expected (Jan-Mar)	Total cases reported
Male									
20-29	0	74	0	0	0	48	0	0	0
30-39	0	108	0	0	1	72	1	0	1
40-49	0	235	0	1	4	165	4	1	4
50-59	2	564	2	5	3	392	2	4	5
60-69	4	1220	1	5	2	865	0	3	6
70-79	6	2353	0	6	1	1727	0	3	7
80<	3	4349	0	9	3	3153	0	6	6
Female									
20-29	0	30	0	0	1	20	0	0	1
30-39	0	59	0	0	0	41	0	0	0
40-49	1	139	1	0	0	95	0	0	1
50-59	1	336	1	1	1	235	1	1	2
60-69	3	773	0	1	0	561	0	1	3
70-79	2	1714	1	4	4	1252	0	3	6
80<	3	5398	0	13	3	3889	0	10	6
Total	**25**	**17,352**	**6**	**45**	**23**	**12,515**	**8**	**32**	**48**

The overall mean of expected total deaths in the population of Israel 2015-2018, for December-March for the first dose, and January-March for the second dose, normalized for the number of vaccinated persons.

Note: Despite normalization to the number of vaccinees, observed and expected rates cannot be directly compared, because the observed cases are counted differently than the expected ones. The observed cases count deaths within a time window of a defined event (vaccine administration). The expected cases are calculated by the cumulative incidence over several calendar months. However, the expected cases do give a general order of magnitude for comparison of deaths following vaccine administration.

No specific signal associated with all causes of death and specifically sudden death

Data is based on adverse events reported to the MoH

Updated 31/03/2021

משרד הבריאות
לחיים בריאים יותר

משרד הבריאות
מינהל הרוקחת

COVID-19 vaccination Israel
“BACK TO LIFE”