משרד הבריאות
לחיים בריאים יותר

Survey of reported symptoms after a third vaccination
Of Pfizer against 19-COVID

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חטיבת טכנולוגיות רפואיות, מידע ומחקר
המרכז הלאומי לבקרת מחלות

introduction

On December 20, 2020, a Pfizer vaccine campaign against 19-COVID (Corona) began in Israel. By the end of March 2021

More than half of the population was vaccinated by 2 doses of the vaccine

The decrease in immunity over time and the emergence of new variants, led to a renewed increase in morbidity in Israel

In the summer of 2021

At the end of July 2021, the third vaccine (booster dose) of the vaccine was approved for anyone who has been vaccinated with two vaccines and who has passed

At least five months from the date of receiving the second vaccine

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The importance of the survey

From collecting data from reports of medical staff or self-reporting from the public regarding side effects

The vaccine (passive monitoring) appears to be under-reported; It is therefore important to characterize symptoms in the vicinity of the vaccine

Among impulse vaccinators actively through a dedicated survey

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Goals

General purpose

Examine the prevalence of symptoms that appeared within 21-30 days of the company's third vaccine (booster dose)

Pfizer against Corona among Israeli citizens aged 18+

Specific goals

Examine the prevalence of symptoms in the vicinity of the third vaccine by age and sex groups

Check the time of onset in relation to vaccination and duration, and compare with the effects of previous vaccines

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Methods

Survey type: **Retrospective cohort**

Survey population: Israeli citizens aged 18+ who were vaccinated 21-30 days before the interview

In Pfizer's booster vaccine

Inclusion criteria:

1. Citizens living in the community
2. Hebrew speakers

Exclusion criteria:

1. 19-COVID Recovery (Before Conducting the Survey)
2. Those who do not have a phone number for them
3. Those who have difficulty understanding and inability to be interviewed

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Sampling method:

The sample was taken from the Ministry of Health's vaccinated database, which includes data for all vaccinated people

To Corona and updated daily. From this database, only people with a telephone number to call were sampled (approximately 75% of the total

The database)

The sample for the survey was random and stratified by sex (male, female) and age groups (39-18, 59-40, 60+)

The survey received the approval of the Information Committee and the approval of the Supreme Helsinki Committee of the Ministry of Health

Data collection:

Telephone interviews by experienced surveyors / research assistants at MALBAM who have been trained, using a structured questionnaire

And computerized in Hebrew (CATI system)

A follow-up interview was conducted 7-12 weeks after the original survey, among 45 of the women who reported irregularities

Menstrual in the first survey (59 = N) using a structured questionnaire, to gather more information to characterize the phenomenon and duration

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Questionnaire contents:

1. Demographic characteristics: gender, age

2. Symptoms that appeared in close proximity to the vaccine divided into local, general, neurological, allergic symptoms

   And others, including a breakdown of the symptoms, the date of their onset, the duration of the symptoms and their severity

3. Background morbidity

Statistical methods:

The reported rates of symptoms were compared between sex and age groups (39-18, 59-40, 60+) using an accepted statistical test

Results

The survey included 2,068 interviews performed between 19.09.21 and the 25.10.21;
19 interviews were not included in the processing Statistical due to data missing.
In practice 2,049 Full interviews.

51% of respondents were men (1,044 = N) and

49% were women N = 1,005

Sample population divided evenly between

3 age groups (18- 9between 3, 59-40, 60+)

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	Total
Total sample	4,945
Not in the inclusion criteria	624
Total effective sample	4,321
No contact was made	1,427
People with whom contact could not be made (but 8 attempts were not completed)	347
Refused to attend	469
Partial interview	10
actually interviewed	2,068
Calculating Response Rate 1	2,068 / 4,321
Denominator = effective sample	47.8%=
Calculating Response Rate 2	2,068 / 2,894
Denominator = [effective sample - one that is not created With them any contact]	71.4%=

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Chronic morbidity rate and exacerbation throughout the sample

The condition / disease	Incidence of the disease N (%)	Report of exacerbation of the disease N (%)
Hypertension	(14.1) 285	(6.3) 18
Lung disease	(9.9) 201	(7.0) 14
diabetes	(7.5) 151	(9.3) 14
heart diseases	(5.4) 110	(5.4) 6
Anxiety disorder or depression	(4.5) 91	(26.4) 24
Autoimmune disease (such as arthritis)	(3.1) 62	(24.2) 15

* Percentage of respondents who reported exacerbation of the disease in the month after vaccination out of those who reported the existence of the disease

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Symptoms reported in close proximity to time (up to 21-30 days) for vaccination

Two-thirds (66.4%, 1,360 total) of the respondents reported that they had suffered from at least one phenomenon near the vaccine

The rate of reporting changed significantly by sex (more in women) and by age (more in young people) - similar to the findings of passive monitoring

	Rate of reporting at least one phenomenon	Significance Statistically
sex	**Men = 57.7%** **Women = 75.4%**	**P <0.05**
age	**39-18 = 71.4%** **59-40 = 69.9%** **60+ = 57.2%**	**P <0.05**

Nearly half (44.1%, 589 total) of the respondents who reported that they suffered from any phenomenon after the vaccine, also reported that as a result they had difficulty performing daily activities (more women, 50.9%, compared to men, 35.4%, 0.05 <p)

Individuals (0.5%, 6 total) of all respondents who reported suffering from any phenomenon after vaccination were hospitalized following the same phenomenon

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Telephone survey results, 2049 vaccinated

Local effects reported in close proximity to time (up to 21-30 days) for vaccination

About half (55.7%, 1,140 total) of the respondents reported that they had suffered from at least one local phenomenon near the vaccine

The rate of reporting changed significantly by sex (more in women) and by age (more in young people) - similar to the findings of passive monitoring

	At least one local phenomenon reporting rate	Significance
sex	**Men = 47.9%** **Women = 63.8%**	**P <0.05**
age	**39-18 = 61.6%** **59-40 = 58.9%** **60+ = 46.0%**	**P <0.05**

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	Ink rate And on a phenomenon Local a HAt least	Significance
sex	Men %47.9 Women %63.8	P <0.05
age	39-18 =% 61.6 59-40 =% 58.9 60+ =% 0. 46	P <0.05

Local reactions	Men n (%)	women n (%)	Total "about)% (n
Pain	(2. 46) 482	(62.5) 626	(54.2) 1,108
restriction In the hand movement	(0. 15) 156	(31.9) 317	(23.3) 473
swelling	(7.2) 75	(18.2) 182	(12.6) 257
Enlarged lymph nodes near the injection site	(6.1) 63	(12.3) 122	(9.1) 185
redness	(4.2) 39	(10.5) 92	(7.3) 131
Local rash	(1.8) 19	(1.9) 19	(1.9) 38
abscess (Abscess)	(0.2) 2	(1.4) 14	(0.8) 16

Other *	(0.2) 2	(0.4) 4	(0.3) 6

Telephone survey results, 2049 vaccinated

*** Includes: movement restriction in the hands and numbness in the injection area**

General (systemic) effects reported in close proximity to the vaccine (up to 21-30 days)

About half (48.6%, 995 total) of the respondents reported that they suffered from at least one general phenomenon near the vaccine

The rate of reporting changed significantly by sex (more in women) and by age (more in young people) - similar to the findings of passive monitoring

	The rate of reporting at least one general phenomenon	Significance
sex	**Men = 38.3%** **Women = 59.4%**	**P <0.05**
age	**39-18 = 54.5%** **59-40 = 53.8%** **60+ = 36.6%**	**P <0.05**

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General effects reported in close proximity to the vaccine (up to 21-30 days)

General effects	Men (%n)	Women (%n)	Total n)% (
Weakness / fatigue	) 32.4(333	) 52.9 (523	) 42.5 (856
Headache	) 17.9(184	) 34.9 (345	) 26.3 (529
Muscle pain / joint	) 17.9(184	) 33.9 (336	) 25.7 (520
chills	) 10.6(108	) 23.9 (236	) 17.1 (344
Temperature above 38.0 (c)	) 10.2(104	) 20.5 (202	) 15.2 (306
Dizziness / feeling Faint	) 5.0 (51	) 13.7 (135	) 9.3 (186
Vomiting / nausea	) 3.3 (34	) 10.6 (105	) 6.9 (139
Chest pain	) 4.0 (41	) 7.0 (69	) 5.5 (110
Digestion system problems *	) 3.9 (40	) 6.2 (61	) 5.0 (101
Enlarge lymph nodes (not near injection site)	) 2.5 (25	) 6.0 (59	) 4.2 (84
cough	) 3.7 (38	) 4.1 (40	) 3.9 (78
Anxiety response	) 1.5 (15	) 2.6 (26	) 2.0 (41
Other**	(0.2(21	) 1.9 (19	) 2.0 (40

* Includes: abdominal pain / constipation / diarrhea / heartburn

* * Includes: colds / phlegm / sore throat, focused effects in the legs (swelling / heaviness / weakness), low fever / feeling cold, sores in the mouth, hot flashes, hair loss, contractions in pregnant women, restlessness, insomnia, blurred consciousness and shortness of breath Breathing with effort.

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Telephone survey results, 2049 vaccinated

Neurological effects reported in close proximity to time (up to 21-30 days) for vaccination

A minority (4.5%, 91 total) of the respondents reported that they had suffered from at least one neurological phenomenon near the vaccine

The rate of reporting varied significantly by sex (more in women) but not by age - similar to the findings of passive monitoring

	The rate of reporting at least one neurological phenomenon	Significance
sex	**Men = 2.1%** **Women = 6.9%**	**P <0.05**
age	**39-18 = 3.7%** **59-40 = 5.1%** **60+ = 4.5%**	**P> 0.05**

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Telephone survey results, 2049 vaccinated

Neurological effects reported in close proximity to time (up to 21-30 days) for vaccination

A minority (4.5%, 91 total) of the respondents reported that they had suffered from at least one neurological phenomenon near the vaccine

The rate of reporting varied significantly by sex (more in women) but not by age - similar to the findings of passive monitoring

	The rate of reporting at least one neurological phenomenon	Of course KAnd
sex	Men =% 2.1 Women =% 6.9	0.05 < P
age	39-18 =% 3.7 59-40 =% 5.1 60+ =% 4.5	0.05>P

phenomena Neurologies	Men n)% (	NPut (n)%	Total n)% (
tingling sensation	) 1.5 (16	) 3. 5 (52	) 3.4 (68
Bells palsy	) 0.3 (3	)0.8 (8	) 0.5 (11
Blurred vision/ disturbance	) 0.5 (5	)0.6 (6	) 0.5 (11
Memory damage	) 0.3 (3	)0.5 (5	) 0.4 (8
Sharp interference in hearing	) 0.2 (2	)0.5 (5	) 0.4 (7
Convulsions	) 0.1 (1	)0.3 (3	) 0.2 (4
Loss of consciousness	) 0.0 (0	)0.3 (3	) 0.2 (3
Other*	) 0.1 (1	)0.4 (4	) 0.3 (5

* Includes: involuntary movements / tics in the eyes, vertigo

Telephone survey results, 2049 vaccinated

Allergic reactions reported in close proximity (up to 21-30 days) to receive the vaccine

A minority (3.9%, 80 total) of the respondents reported that they had suffered from at least one allergic phenomenon near the vaccine

The rate of reporting varied significantly by sex (more in women) but not by age - similar to the findings of passive monitoring

	The rate of reporting at least one allergic phenomenon	Significance
sex	**Men = 2.6%** **Women = 5.3%**	**P <0.05**
age	**39-18 = 3.8%** **59-40 = 4.1%** **60+ = 3.7%**	**P> 0.05**

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Telephone survey results, 2049 vaccinated

Allergic reactions reported in close proximity (up to 21-30 days) to receive the vaccine

A minority (3.9%, 80 total) of the respondents reported that they had suffered from at least one allergic phenomenon near the vaccine

The rate of reporting varied significantly by sex (more in women) but not by age - similar to the findings of passive monitoring

	Reporting rate on One allergic phenomenon at least	Significance
sex	Men = 2.6% Women = 5.3%	P <0.05
age	39-18 = 3.8% 59-40 = 4.1% 60+ = 3.7%	P> 0.05

Allergic reations*	Men n)% (	NPut (%n)	Total n)% (
Rash	) 1.3 (14	) 62. (26	) 2.0 (40
Skin irritation	) 1.1 (11	) 32. (23	) 1.7 (34
Breathing difficulties	) 1.0 (10	) 02. (20	) 1.5 (30
Facial/ throat swelling	) 0.5 (5	) 0.8 (8	) 0.6 (13

* No cases of anaphylaxis were reported in the sample

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Telephone survey results, 2049 vaccinated

Other effects reported in close proximity to time (up to 21-30 days) for vaccination

A minority (4.1%, 83 total) of the respondents reported that they had suffered from at least one other phenomenon near the vaccine

The rate of reporting changed significantly by sex (more in women) and by age (more in young people)

	The rate of reporting at least one other phenomenon	Significance
sex	**Men = 0.7%** **Women = 7.6%**	**P <0.05**
age	**39-18 = 6.6%** **59-40 = 4.5%** **60+ = 0.9%**	**P <0.05**

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Telephone survey results, 2049 vaccinated

Other effects reported in close proximity to time (up to 21-30 days) for vaccination

A minority (4.1%, 83 total) of the respondents reported that they had suffered from at least one other phenomenon near the vaccine

The rate of reporting changed significantly by sex (more in women) and by age (more in young people)

	Reporting rate on One other phenomenon at least	Significance
sex	Men = 0.7% Women = 7.6%	P <0.05
age	39-18 = 6.6% 59-40 = 4.5% 60+ = 0.9%	P <0.05

Other effects	Men n)% (	women n)% (	Total n)% (
Herpes simplex	) 0.0 (0	) 0.4 (4	) 0.2 (4
Herpes zoster	) 0.0 (0	) 0.3 (3	) 0.2 (3
Menstrual changes *	-	) 9.6 (59	-
Other**	) 0.7 (7	) 1.5 (15	) 1.1 (22

* Percentage of all women in the sample under the age of 54 years (N = 615)

* * The other most common symptoms included: eye problems (5 cases), change in sense of taste / smell (4 cases), myocarditis (one case)

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Follow-up interview in women who reported menstrual irregularities

The follow-up interview was conducted between 7-12 weeks after the first survey

47 (79.7%) of all 59 women aged 19-50 years who reported menstrual irregularity in the vicinity of vaccine 3 participated in the original survey.

From these,45 Entered into the data processing (2 were removed because their original report referred to previous vaccines and not the 3rd vaccine)

Of all the women who participated in the follow-up interview:

- **88.6% testified to a regular menstrual cycle before being vaccinated to Corona**
- **31.1% applied for medical treatment following the changes in the menstrual cycle**
- **9.1% were treated with medication as a result**
- **39.0% suffered from similar effects after previous vaccines against corona; However, most (67%) indicated that the symptoms passed before the third vaccine and returned after it**
- **About half of the women reported that the symptoms persist until the day of the additional survey**

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Follow-up interview - major changes reported in the menstrual cycle

The changes In the monthly cycle *	N (%)
Late Menstruation	) 37.8 (17
excessive Menstruation	) 31.1 (14
Early Menstruation	) 28.9 (13
Duration of bleeding Longer than usual	) 26.7 (12
Multiple menstruation in one month	) 24.4 (11
Strong pains during menstruation	) 20.0 (9
Weakening Menstrual bleeding	) 8.9 (4
No menstruation	) 6.7 (3
Duration of bleeding Shorter than usual	) 4.4 (2
Single irregular Bleeding after injection	) 2.2 (1
Reappearance of menstruation after disappearance	) 2.2 (1
Other**	) 8.9 (4

* More than one phenomenon could have been reported

* * Other = blood clots, decreased pain during menstruation, irregularity, and premenstrual syndrome that includes irritability and pain

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Date of appearance of all types of phenomena and duration

	Local effects N = 1,140 n (%)	Systemic N = 995 n (%)	Neurological N = 91 n (%)	Allergic symptoms N = 80 n (%)	Other N = 83 n (%)
Time of reaction					
Within an hour	) 9.4 (106	) 2.9 (28	) 15.7 (13	) 4.1 (3	) 4.1 (2
One hour – 24 hours	) 66.7 (752	) 56.9 (555	) 26.5 (22	) 31.1 (23	) 10.2 (5
1-7 days	) 23.0 (259	) 33.5 (327	) 28.9 (24	) 35.1 (26	) 38.8 (19
One week – one month	) 0.9 (10	) 6.7 (65	) 28.9 (24	) 29.7 (22	) 46.9 (23
Duration of the phenomenon					
Up to 24 hours	) 23.8 (269	) 26.8 (261	) 21.3 (19	) 9.2 (7	) 2.2 (1
Between 1-3 days	) 56.3 (636	) 42.7 (415	) 20.2 (18	) 25.0 (19	) 13.3 (6
Between 4-7 days	) 14.0 (158	) 11.8 (115	) 7.9 (7	) 18.4 (14	) 17.8 (8
Over a week	) 3.7 (42	) 6.0 (58	) 3.4 (3	) 14.5 (11	) 24.4 (11
Ongoing	) 2.1 (24	) 12.7 (124	) 47.2 (42	) 32.9 (25	) 42.2 (19

Telephone survey results, 2049 vaccinated

The severity of the symptoms

	Local N = 1,140 n (%)	Systemic N = 995 n (%)	Neurological N = 91 n (%)	Allergic symptoms N = 80 n (%)	Other effects N = 83 n (%)
Comparison of severity With previous dose					
Now milder	) 14.0 (157	) 15.3 (149	) 5.6 (5	) 6.7 (5	) 1.9 (1
Now more severe	) 21.1 (237	) 16.9 (165	) 12.4 (11	) 20.0 (15	) 9.4 (5
Similar	) 42.5 (478	) 25.2 (245	) 20.2 (18	) 10.7 (8	) 28.3 (15
Not comparable*	) 22.4 (252	) 42.6 (415	) 61.8 (55	) 62.7 (47	) 60.4 (32
Reporting taking medication	) 22.3 (252	) 43.9 (431	) 18.2 (16	) 43.4 (33	) 26.4 (14
Seek medical attention	) 3.0 (34	) 7.4 (72	) 21.6 (19	) 23.7 (18	) 30.2 (16

* Not comparable because they did not suffer from similar symptoms in previous vaccines

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summary of results

	noteLocal pests	A. And general defects	noteF Neurological time	Aand. worms Allergic	A. others Will appear
Percentage of Hsea Medve	56%	49%	4.5%	4%	4%
Men	48%	38%	2%	3%	1%
women	64%	59%	7%	5%	8%
The phenomena e Most sputum That	1. 2. aboutfather God 3. N Limitation of hand movement Local devaluation	1. Hwalsh / fatigue 2. Father about 3. Avi Muscles / about M.RPKim.	1. N Itching / tingling 2. FCialis 3. God Pharaoh / Blurred vision	1. A. You bloomed 2. Rd third 3. K Shea breathing	In women up to g To 54 - Changes in Wes A (10%)
Date of appearance The phenomenon	In most e Cases (about 90%) between Time to weekFrom the vaccine	In most e Cases (about 90%) between Time to weekFrom the vaccine	In most e Cases (about 60%) be late From to month From the Fun shelter	In most e Cases (about 65%) be late From to month Fun From the shelter	In most cases M (about 85%) be lateDay and D month From the vaccine
Duration of the God phenomen n	In most e Cases between1-3Days	In most e Cases betweenAn hour to 3 days	publicly (47%)Still drawn	publicly (33%)Still drawn	In most cases MOver a week After the vaccine or thatStill continued
To Reported by Netty A medicine	22%	44%	18%	43%	26%
Contact Tipu To medical	3%	7%	22%	24%	30%
Character Report FSimilar times in vaccines Previous	78% (By 9% 7The effects of the vaccine Current Not harder)	57% (At 3% 8 The effects of the vaccine Current Not harder)	38% (By 8% 8 The effects of the vaccine Current Not harder)	37% (At 0% 8 The effects of the vaccine Current Not harder)	40% (In 91% - e Vaccine effects The current does not kDrink more)

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Conclusions

1. Reporting of effects in the vicinity of the vaccine is more common in women and young people
2. Most of the symptoms reported within 21-30 days after the impulse vaccine against 19-COVID in 18+ year olds in Israel were local or general; Most did not seek medical attention, and by the end of the day to three days had passed
3. Neurological, allergic and other symptoms were much less common (about 4%); However 10% of women (up to age 54) who reported other symptoms suffered from menstrual irregularities
4. Neurological, allergic and other symptoms appeared over long periods of time from the vaccine (up to a month) and often persisted even at the time of questioning (21-30 days from the vaccine); More than one-fifth of those who reported these symptoms sought medical attention because of them
5. In most people who reported side effects of all kinds, the occurrence after the third vaccine was not more difficult compared to previous vaccines

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