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2022

Phenomena reported by the public in the vicinity of receiving a vaccine against the corona virus

09/12/2021-31/05/2022 for the period summarizing the report



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background

With the start of the corona vaccines in December 2020, the Ministry of Health worked to collect data on the safety of the vaccines in two

Ways:

1. Reports of symptoms that appear in close proximity to receiving a vaccine by a medical team, as is customary.
2. Possibility for the general public to report side effects on the ministry's website - a mechanism created specifically for the vaccination operation

the current

As time passed, it became clear that the manner of reporting on the ministry's website, which was an anonymous report in free text, made it difficult to check the reliability of the data and their meaning, their professional analysis and drawing conclusions. At the same time, the understanding has sharpened that there may be side effects that do not require medical treatment and it is necessary to improve the way the public reports on the site out of the great importance of reliable and complete information. In October 2021, the Ministry of Health began to build an identified questionnaire that allows the vaccinated person to easily fill out side effects by marking in predefined fields, in addition to detailing in free text. In addition, the Ministry recruited a dedicated team to monitor and analyze the data in cooperation with the Epidemiology Division to ensure that there is continuous and professional monitoring of the content appearing in the reports. The form went live in December 2021 with the start of vaccination of children aged 5-11 and was sent by the health insurance funds to the vaccinated. During the entire period, the team follows the public's reports and this report summarizes the reports received until May 2022. This reporting method complements the reports of the medical teams, followed by the Epidemiology Division, which are published periodically to the public on the Ministry of Health website.

The purposes of the surveillance

1. Locating and monitoring symptoms that minors do not necessarily seek medical treatment.
2. Increasing the sensitivity of monitoring events in close proximity to receiving the vaccine through the participation of the public
3. Contribution to the understanding of the various aspects of vaccine safety

The importance of reporting from the public

Detection of phenomena among the general public for which a medical professional is not always consulted

Detection of phenomena that were not known in the context of vaccines or rare phenomena

Monitoring of an increase in the rate of known phenomena

Completing the information received from medical teams

Allow self-reporting in free text and describe the phenomenon in detail

The professional staff

The clinical pharmacology and toxicology unit team from the "Shamir" medical center (Asaf Harofeh) received an appointment from the director general of the Ministry of Health to establish an increasing work group. The clinical pharmacology unit team consists of doctors, pharmacists, researchers and administrative staff who are skilled in collecting, processing, and analyzing phenomena that appear in close proximity to receiving care

I have been medicated for many years.



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highlights

The report is based on an analysis of spontaneous reports from the vaccinating public and/or parents of vaccinated children in an online form. The form included the option to mark phenomena in predetermined fields and free text.

The report presents all the cases that were reported in close proximity to the receipt of the vaccine against the corona virus, and does not necessarily indicate a causal relationship between the receipt of the vaccine and the reported phenomenon. A total of 973,134,18 doses of the vaccine against the corona virus were given in Israel. A total of 8054 reports were received in the online system, of which 6259 were valid reports - that is, identified, not duplicates that contained information about the phenomenon.

In all age groups, most of the reported symptoms (**70-90%** of all reports) were **general symptoms** (such as general weakness, fatigue, fever, headache) or **local symptoms** (such as redness, swelling, pain in the injection area) that appeared close to vaccination in each of the vaccine doses.

Other reported effects:

In children aged 5-11 years, about 10% of the reports were about **gastrointestinal symptoms**.

Also, a total of **24 events related to the cardiovascular system** were reported, which constitute **004.0%** of the 809,565 vaccine doses given.

In teenagers aged 12-17 years, 7-10% of the reports were about **gastrointestinal symptoms**.

which constitute **008.0%** of 097,718 vaccine doses given. Also, a total of **58 cases of changes in the menstrual cycle** were reported for vaccinations in this age group.

A total of **31 events related to the cardiovascular system** were reported, representing **002.0%** of the 450,480,1 vaccine doses administered.

In adults aged 18 years and older, 8-12% of the reports were about **changes in the menstrual cycle**, which is **03.0%** out of 349,620,4 vaccine doses given to vaccinated women aged 18-50 years (the oldest age at which a woman with menstrual changes was reported - age 50).

Also, a total of **830 events related to the cardiovascular system were reported**, representing **0.05%** of 714,088,16 vaccine doses given

Reports of myocarditis in all age groups (received from various sources) are described in the [safety presentation](#) of the Ministry of Health dated May 31, 2022

In conclusion,

The reported phenomena are known phenomena in the professional literature and were also found in the previous reports of the Ministry of Health, and it was not observed as a new phenomenon (new signal).



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General description of the system

The system for self-reporting of symptoms near the administration of the vaccine began to operate in December 2021.

The system is designed to collect reports from the general public regarding the phenomena that appeared in close proximity to receiving the vaccine against the new corona

¹ virus. The system allows the identification of new side effects that are unknown (signals)

It is important to note that the reported phenomena do not necessarily have a proven causal link to the vaccine. It is possible that certain phenomena would have occurred in any case and regardless of the vaccine. This is especially noticeable in the case where a large population is vaccinated that also includes vaccine recipients suffering from co-morbidities.

Definitions

• **Symptoms that appeared close to receiving a vaccine** - any medical event that occurs close to the time of receiving the vaccine, even if it is not necessarily causally related to the administration of the vaccine.

Proximity refers to a time period of up to 30 days from receiving the vaccine and for certain phenomena such as Galian Barre syndrome

up to 60 days.

• **General symptoms** - such as general weakness, fatigue, fever, headache, stomachache

• **Local effects** - effects that occurred in the injection area such as redness, swelling, pain

• **Allergic symptoms** - such as rash, itching, edema

• **Neurological phenomena** - such as circumscription (change in sensation on the surface of the skin), facialis (transient damage to the facial nerve), convulsions,

Loss of consciousness

• **Gastrointestinal effects** - abdominal pain, vomiting/nausea, diarrhea

• **Changes in menstruation** - prolongation of bleeding, increased bleeding, cessation of menstruation, changes in menstruation

• **Effects related to the cardiovascular system** - high blood pressure, chest pains

• **Loss of sense of taste and smell**

• **A significant or serious event (serious adverse event)** - a phenomenon that includes one or more of the situations

the following:

o A life-threatening condition (as assessed by the medical staff) or a condition that ended in death

o A condition requiring hospitalization or extending the duration of hospitalization

o Causing permanent disability

o A birth defect was diagnosed in the baby of a woman who was vaccinated during pregnancy

o A condition that requires urgent medical treatment (according to the assessment of the medical staff)

• The reports received as free text were analyzed by a staff member from the field of pharmacology who converted the text

The free form for a systematic and effective medical nomenclature, using the method:

- [MedDRA](#) - Medical Dictionary for Regulatory Activities

This is a dictionary used by the regulatory authorities and the pharmaceutical industry in the classification, evaluation and presentation of side effects and safety information

collected during the pre/post marketing activity.

¹ "Signal" is a hypothesis regarding the risk of a medicinal product, and the data and evidence that support it. The source of the data can be diverse.

The evidence in "Signal" is not conclusive, and is only a preliminary indication, since it may change substantially as more information accumulates.



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The manner of reporting

The reporting mechanism through the online form is part of the monitoring activity of phenomena close to receiving the vaccine against a virus

Corona. You can access the questionnaire form using the following link:

<https://corona.health.gov.il/symptoms/>

The characterization of the report is user-friendly and the time required to complete it is about 3 minutes. In order to complete the report, it is required to provide identification information for the purpose of verifying details and a declaration by the person filling out the form on the approval of information sharing.

The form is intended for reporting to one person. At the end of the report, the form can be filled out again for additional people (such as children under the age of 18).

The possibility to report is not limited in time, that is, it is possible to report retroactively. In addition, a person can report more than once, provided that the report will not be the same as what has already been reported. Below, appear Questions about a variety of symptoms that appeared from the day of receiving the vaccine until 30 days after. In the form, indicate the dose to which the reported symptoms refer.

The questionnaire enables the reporting of a wide variety of phenomena with structured questions in advance and, in addition, there is the option of reporting in free text in order to allow the description of the event beyond the structured questions or to report on an event that does not appear in the questionnaire.

It is important to note that one report can contain more than one phenomenon. In addition, the questionnaire allows reporting of medications and medical treatments taken for the phenomenon, in a period of 30 days from receiving the vaccine, as well as a description of the duration of the phenomenon.

The beginning of the use of the form (December 2021) was accompanied by a notice from the Ministry of Health about the possibility of reporting in this way.

It should be noted that the introduction of the form at this stage is part of drawing lessons from the experience gained in Israel. From the beginning of the vaccination campaign, reports were received from medical teams according to the instructions in the vaccination briefing. In addition, the need arose to allow the general public to directly report symptoms in the vicinity of receiving the vaccine without the need to contact a medical professional as is customary in the US and other countries.

Accordingly, an anonymous online form was launched that allows anyone to report symptoms. As the vaccination campaign progressed, data was received from the anonymous online form, but without the ability to professionally process and validate the data. Issues arose such as: duplicate reports, inability to return to the reporter to clarify missing information or for the purpose of follow-up, there was no verification with the reporter's vaccination data. As a result, it was decided to stop using the previous online form and replace it with a renewed form. The renewed, non-anonymous form came into use before the start of the vaccination campaign for ages 5-11.

The information was collected, concentrated and underwent ongoing evaluation by a dedicated team on behalf of the clinical pharmacology and toxicology unit, Shamir Medical Center (Asaf Harofeh) according to the appointment of the Ministry of Health. The team analyzed the information received through an online reporting form on the Ministry of Health website that came into effect during the month of December 2021.

The reports received were verified and cross-checked with KofH and Ministry of Health data. The data underwent refinement such as removing Empty reports and duplicate reports. **The reports were reviewed and summarized on a daily**, weekly and cumulative basis for the entire period, these summaries were sent to the Epidemiology Division.

A separate processing and analysis was performed for the reports received in the closed (predetermined) fields and the reports received as free text in the field designated for this purpose. Reports that contained phenomena described in the free text were converted into reports by categories

Based on the [MedDRA](#) classification.

Phenomena in children (ages 5-17) that required referral to the emergency room and/or hospitalization were discussed by a special committee of pediatricians appointed by the Ministry of Health. The team of experts examined every case of referral to the emergency room or hospital admission in children and teenagers and examined the possibility of a causal relationship to the vaccine. The committee included pediatricians specializing in various fields (such as: infectious diseases, cardiology, neurology, rheumatology, endocrinology, allergy, pharmacology) clinical and toxicology).

The details of the findings of all the significant phenomena reported in children can be found in the Ministry of Health's [safety presentation](#)

31.05.2022 from date



Vaccination data

An important part of monitoring phenomena in close proximity to vaccines is checking the rate of phenomena out of the total number of vaccines given. Therefore, the vaccination data up to 05/31/2022 was received from the Ministry of Health. A total of **973,134,18** doses of vaccine against the corona virus were given in Israel.

Table No. 1 : Distribution of total vaccine doses by manufacturer and dose number until 05/31/2022.

Total portions	Dish 4	Dish 3	Dish 2	portion 1	manufacturer
17,902,081	811,284	4,486,220	6,071,762	6,532,815	Pfizer
227,071	837	6,416	61,129	158,689	Modern
5,821	64	695	2,367	2,695	AstraZeneca

The Moderna and AstraZeneca vaccines were given only to adults (over 18 years of age). The Pfizer vaccine was also given to children and youth. Attached is

Table No. 2 summarizing the number of Pfizer vaccine doses given by age and dose number.

Table No. 2 : Distribution of total Pfizer vaccine doses by age groups and number of doses until 05/31/2022

Total portions	Dish 4	Dish 3	Dish 2	portion 1	age groups
565,809			236,868	328,941	Years 5-11
1,480,535	85	206,470	584,776	689,204	Years 12-17
15,855,737	811,199	4,279,750	5,250,118	5,514,670	and over 18 years



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The details of the phenomena reported in an online form in predetermined fields

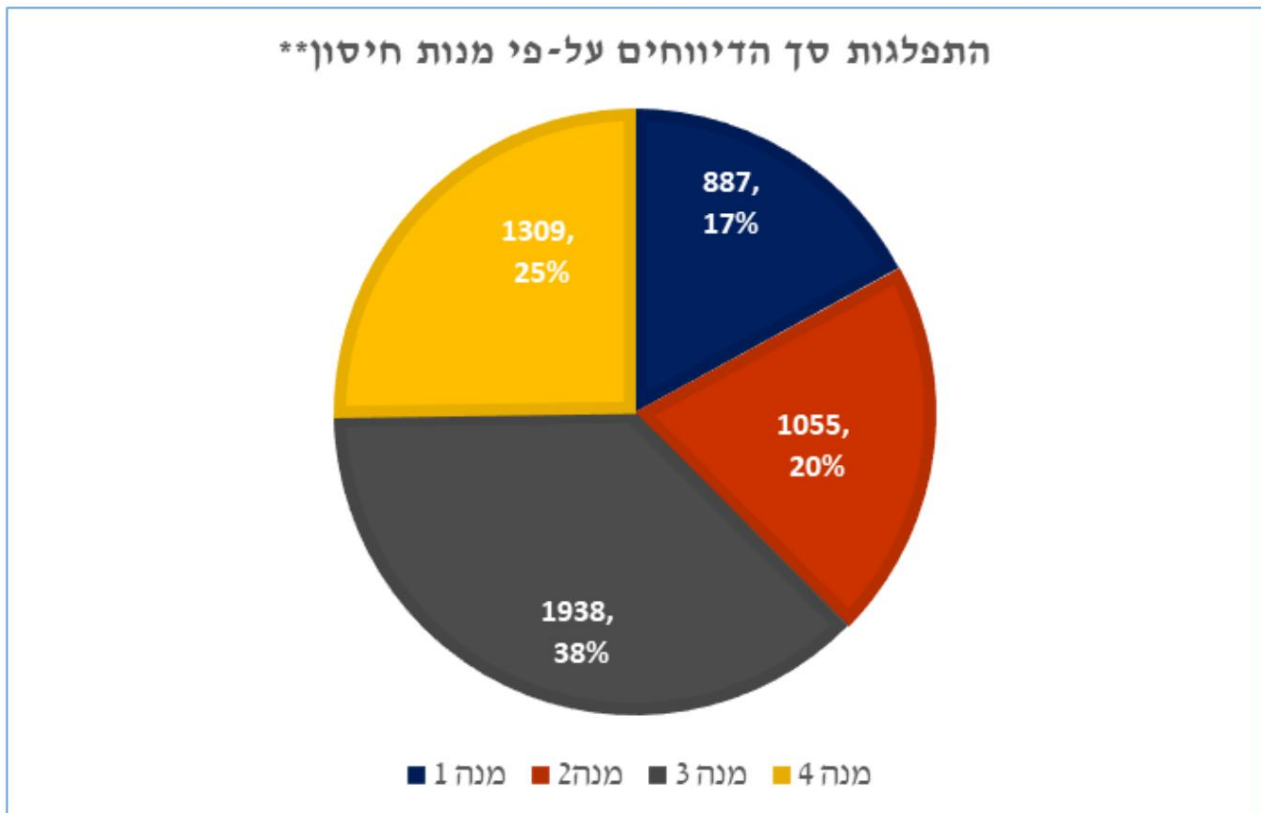


The summary of the findings is general

Between the dates 2022/05/31-2021/12/09 (inclusive), 8054 reports were received, of which **6259 were valid** - that is, identified reports, not duplicates, that contained information about the phenomenon. It is important to note that **one report can contain more than one phenomenon** and The reports refer to phenomena that occurred **before** the aforementioned date range.

About 61% of the reports were from women (or girls) and 39% from men (boys).

Chart 1 : The distribution of reports reported in an online form in predetermined fields according to vaccine dose



** For those for whom a vaccine dose was reported

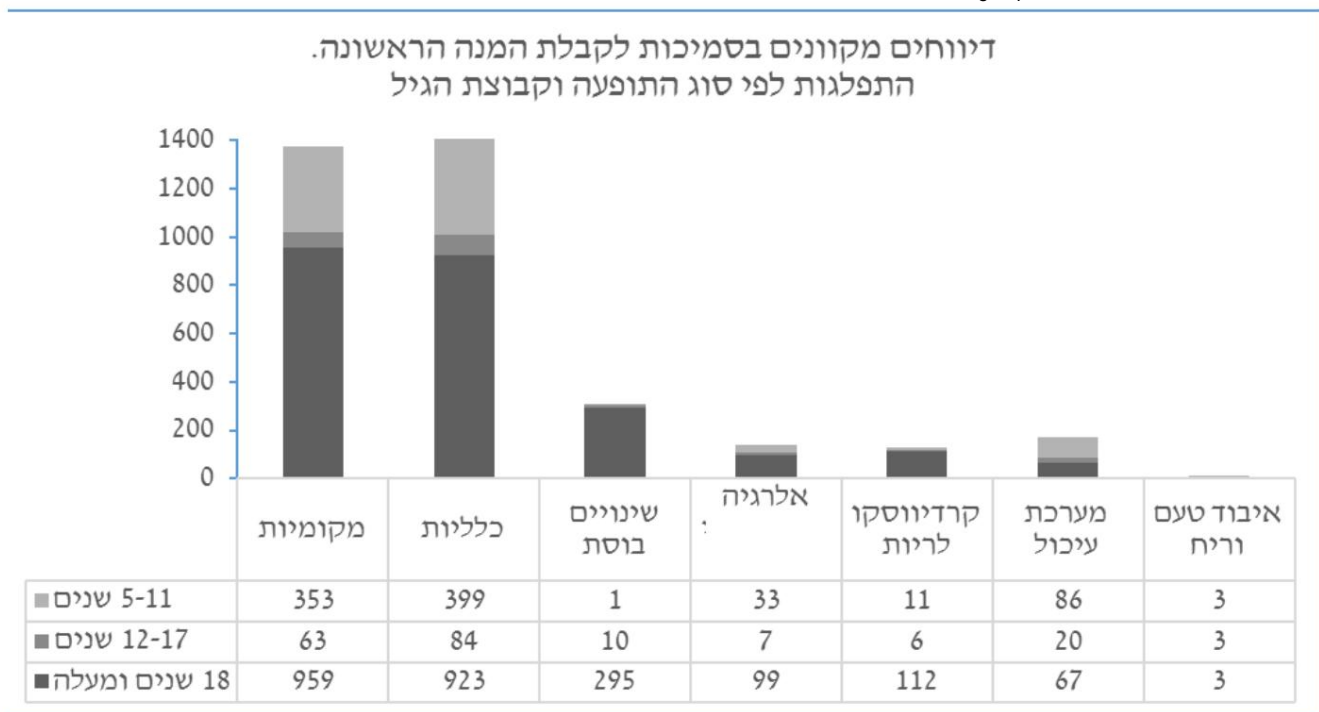


Symptoms reported in an online form (in predetermined fields) in close proximity to the first dose of the vaccine in the different age groups

As mentioned, until the date 2022/05/31, a total of **199,694,6 first vaccination doses (of all manufacturers) were given.**

Between the dates 2022/05/31-2021/12/09 (inclusive), **823,3** were reported in the online form for self-reporting Symptoms near **the first dose** in all age groups (in predetermined fields). **About 79%** of the symptoms were classified as **general symptoms (such as general weakness, fatigue, fever, headache) or local symptoms (such as redness, swelling, pain in the injection area).** Chart 2 : The

distribution of online reports (in predetermined fields) in the vicinity of receiving the first dose according to the type of phenomenon and age groups



At the **age of 5-11 years**, until 2022/05/31, a total of **941,328 first vaccine doses were given (Pfizer company only).** **898** phenomena were reported in an online form in predetermined fields, close to the first dose.

The number of reports in this age group is about 23% of all reports for the first dose.

About 85% of the symptoms reported in this age group were classified as **general symptoms (such as general weakness, fatigue, fever, headache) - They make up 12.0% of the 941,328 vaccine doses given, or local effects (such as redness, swelling, pain in the injection area) - which make up 11.0% of the 941,328 vaccine doses given.**

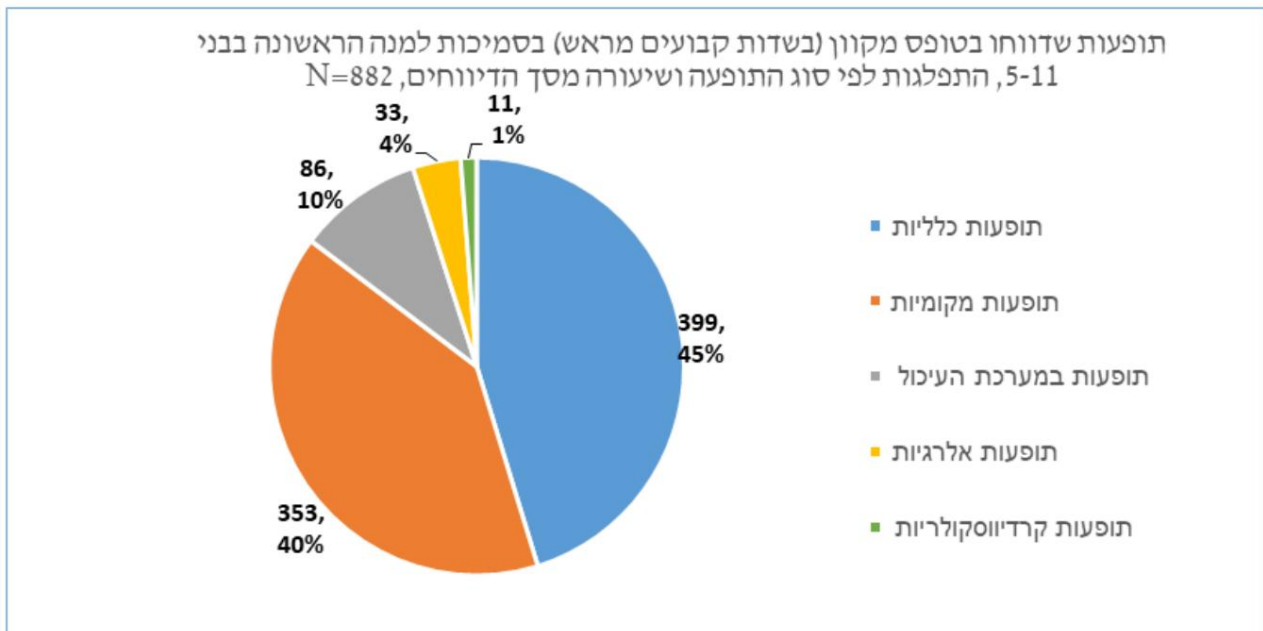
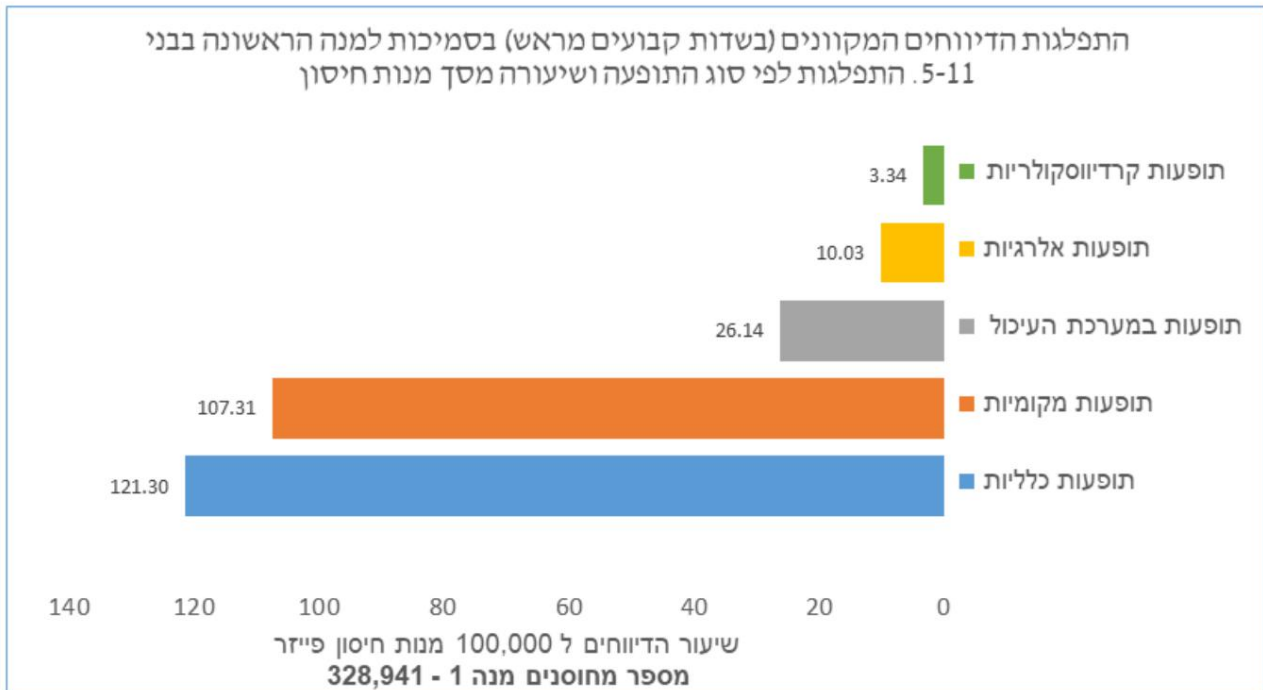
About 10% of the symptoms reported in this age group were classified as gastrointestinal symptoms (abdominal pain, vomiting/nausea, diarrhea) - **and they make up 03.0% of the 941,328 vaccine doses given.**

An additional 4% of the symptoms reported in this age group were classified as allergy symptoms (such as rash, itching, edema) - **they make up 01.0% of the 941,328 vaccine doses given.**

About 1% of the 11 symptoms out of the total of 898 symptoms reported in this age group, representing 003.0% of the 941,328 vaccine doses given, were classified as symptoms related to the cardiovascular system (high blood pressure, chest pain).



Diagram 3 : Phenomena reported in an online form (in predetermined fields) in the vicinity of the first dose in 5-11 year olds. Distribution according to the type of phenomenon and its rate (number per 100,000 vaccine doses)





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At the **age of 12-17 years**, until 05/31/2022, a total of **204,689 first vaccine doses were given (Pfizer only)**. 197 symptoms were reported in an online form in predetermined fields, close to the first dose (which constitutes 5% of all symptoms reported for this dose).

76% of the symptoms reported in this age group were classified as **general symptoms (such as general weakness, fatigue, fever, headache)** - they make up **01.0%** of the **204,689 vaccine doses given**, or **local symptoms (such as redness, swelling, pain in the injection area)** - which constitute **009.0%** of the **204,689 vaccine doses given**.

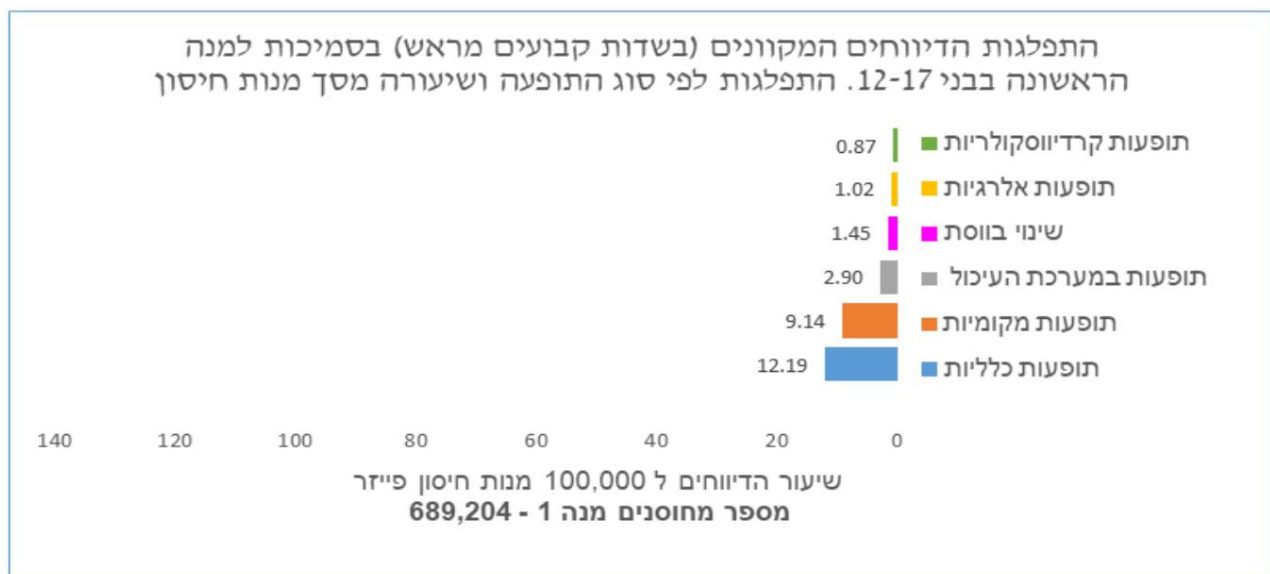
10% of the symptoms reported in this age group were classified as gastrointestinal symptoms (abdominal pain, vomiting/nausea, diarrhea) - **Make up 003.0% of the 204,689 vaccine doses given**.

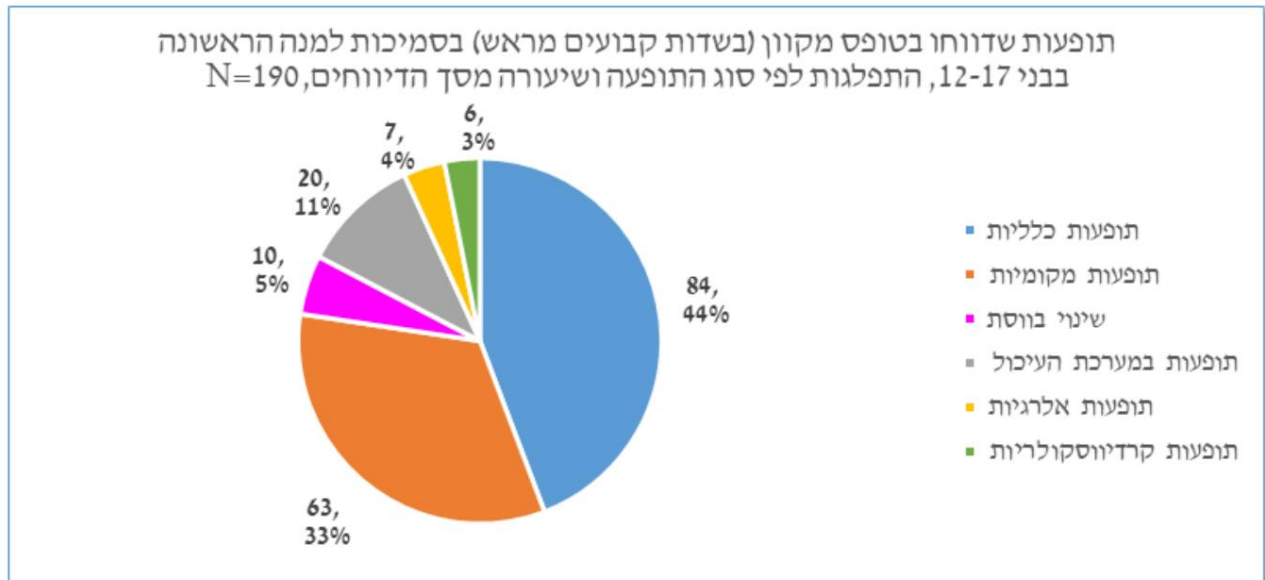
About 5% of all symptoms reported in this age group were classified as changes in menstruation (extension of bleeding, increased bleeding, cessation of menstruation, changes in menstruation). The rate of occurrence of changes in menstruation was calculated from the number of vaccine doses given to the vaccinated . **003.0% of the 523,334 vaccine doses given**.

About 4% of all symptoms reported in this age group were classified as allergic symptoms (such as rash, itching, edema) - **making up 001.0% Of the 204,689 vaccine doses given**.

About 3% of the symptoms reported in this age group were classified as symptoms related to the cardiovascular system - **accounting for 009.0% of the 204,689 vaccine doses given**.

Diagram 4 : Phenomena reported in an online form (in predetermined fields) near the first dose in 12-17 year olds. Distribution According to the type of phenomenon and its rate (number per 100,000 vaccine doses)





A total of **054,676,5** first vaccination doses were given to those **aged 18 and over**, until 2022/05/31 (all companies).

728.2 phenomena were reported in an online form in predetermined fields, close to the first dose (71% of all phenomena)

that were reported to this portion).

76% of the symptoms reported in this age group were classified as **general symptoms (such as general weakness, fatigue, fever, headache) and they make up 02.0% of the 054,676 vaccine doses given, or local symptoms (such as redness, swelling, pain in the injection area) which make up the % 02.0 out of 054,676,5 vaccine doses given.**

About 12% of all symptoms reported in this age group were classified as changes in menstruation (extension of bleeding, increased bleeding, cessation of menstruation, changes in menstruation). The rate of occurrence of changes in menstruation was calculated from the number of vaccine doses given to vaccinated women aged 18-50 (the oldest age at which Report on a woman with menstrual changes - 50 years old (- **and they make up 02.0% out of 393,767,1**

The vaccine doses given.

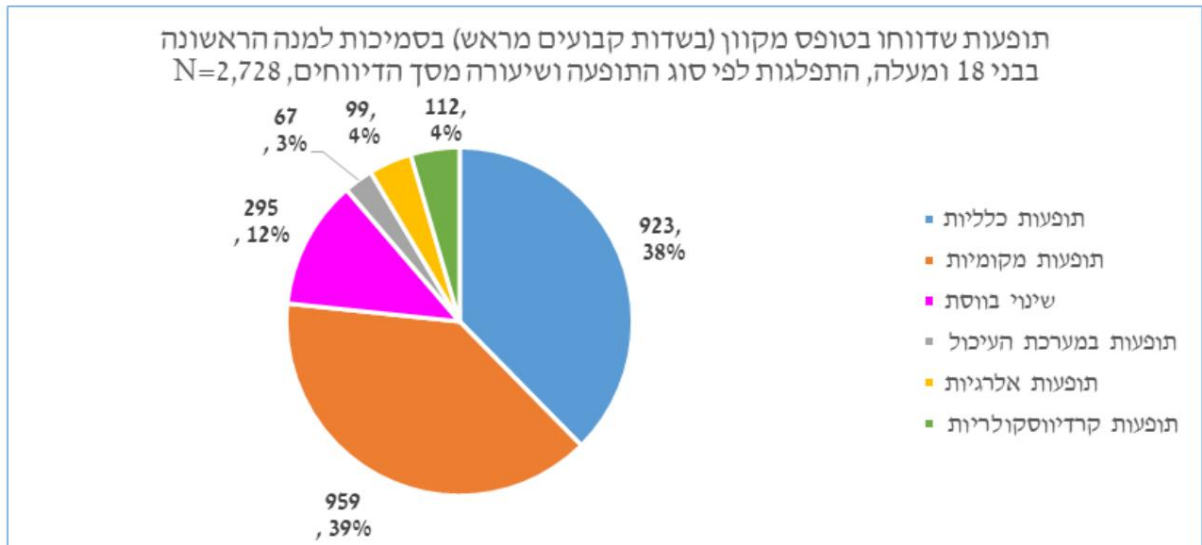
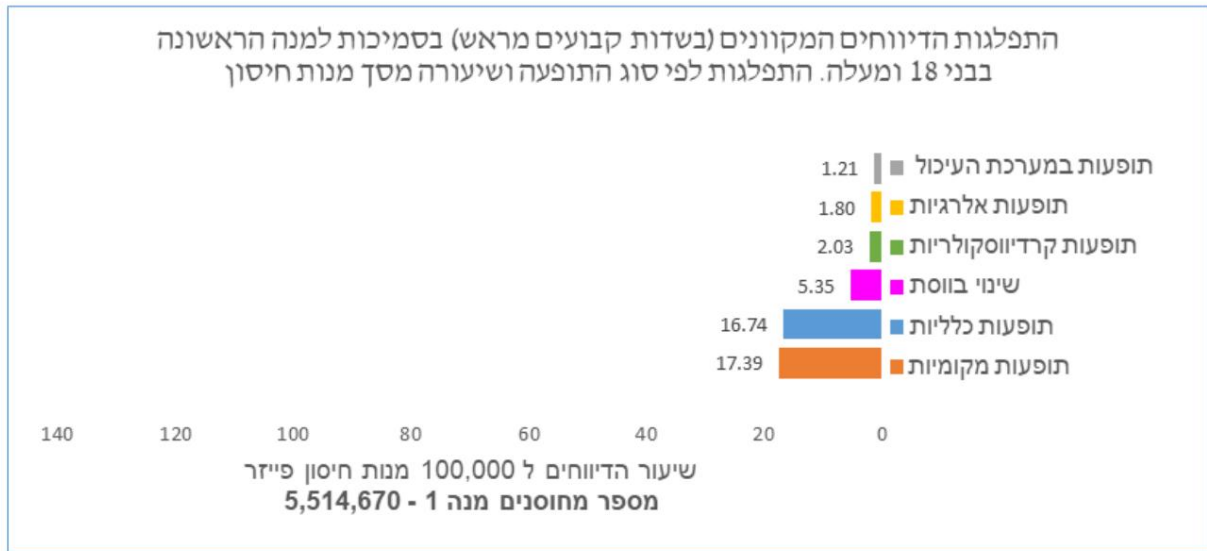
About 5% of the symptoms reported in this age group were classified as symptoms related to the cardiovascular system - **accounting for 002.0% of the 054,676.5 vaccine doses given.**

About 4% of all symptoms reported in this age group were classified as allergic symptoms (such as rash, itching, edema) - **making up 002.0% Out of 054,676,5 vaccine doses given.**

About 3% of all symptoms reported in this age group were classified as gastrointestinal symptoms (abdominal pain, vomiting/nausea, diarrhea) - **accounting for 001.0% of the 054,676.5 vaccine doses given.**



Diagram 5 : Phenomena reported in an online form (in predetermined fields) in the vicinity of the first dose in those aged 18 and over.
Distribution according to the type of phenomenon and its rate (number per 100,000 vaccine doses)





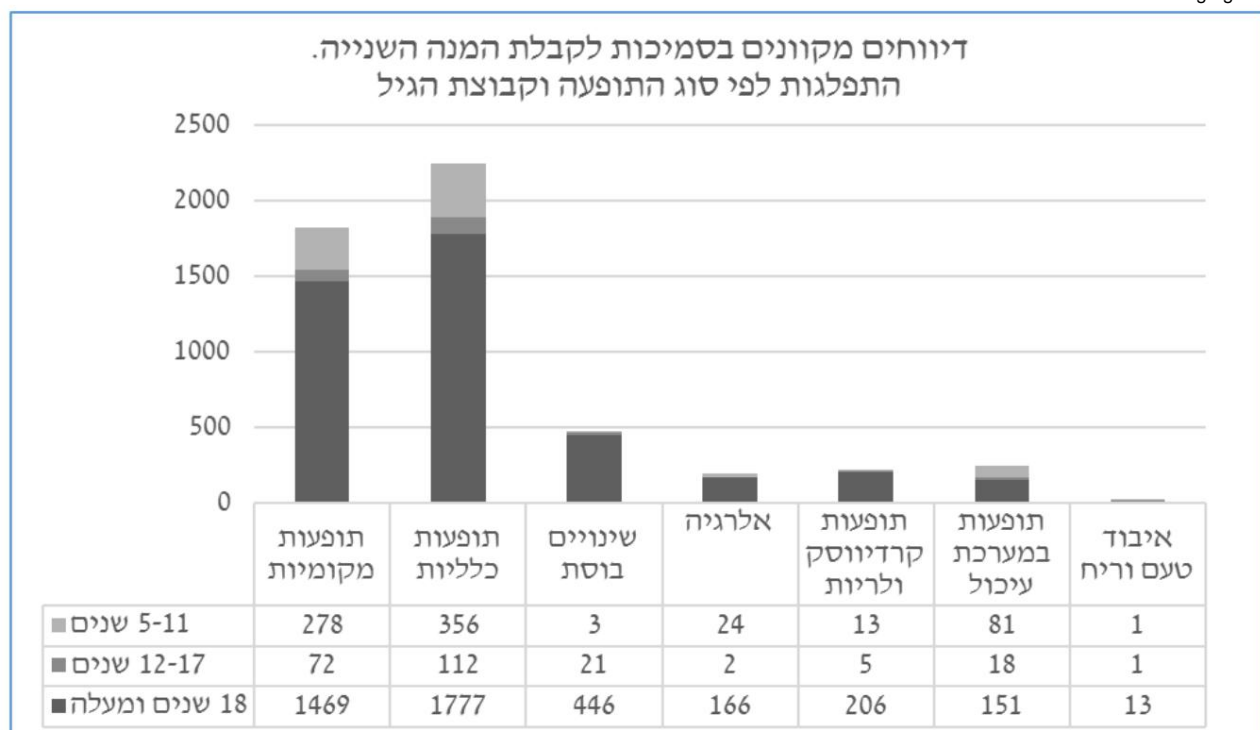
Symptoms reported in an online form (in predetermined fields) in the vicinity of the second dose of the vaccine in the different age groups

Until the date 05/31/2022, a total of **258,135,6 second vaccination doses were given (all companies)**.

215.5 phenomena were reported near the second dose in all age groups, in predetermined fields. Similar to the symptoms from the first dose, also in the second vaccination about 78% of symptoms were classified as "general" or "local" and 9%

Some of the reports were about menstrual changes.

Diagram 6 : The distribution of online reports (in predetermined fields) in the vicinity of receiving the second dose according to the type of phenomenon and age groups



In the 5-11 age group, until 05/31/2022, a total of **868,236 second vaccine doses were given (Pfizer company only)**. **756** symptoms were reported in an online form in predetermined fields, close to the second dose (which constitutes 14% of all symptoms reported for this dose) .

84% of the symptoms reported in this age group were classified as **general symptoms (such as general weakness, fatigue, fever, headache) - and they make up 15.0% of the 868,236 vaccine doses given, or local symptoms (such as redness, swelling, pain in the injection area)**

- representing 12.0% of the 868,236 vaccine doses given.

About 11% of the symptoms reported in this age group were classified as gastrointestinal symptoms (abdominal pain, vomiting/nausea, diarrhea)

- make up 03.0% of the 868,236 vaccine doses given.

3% of the symptoms reported in this age group were classified as allergic symptoms (such as rash, itching, edema) - accounting for 01.0% of the

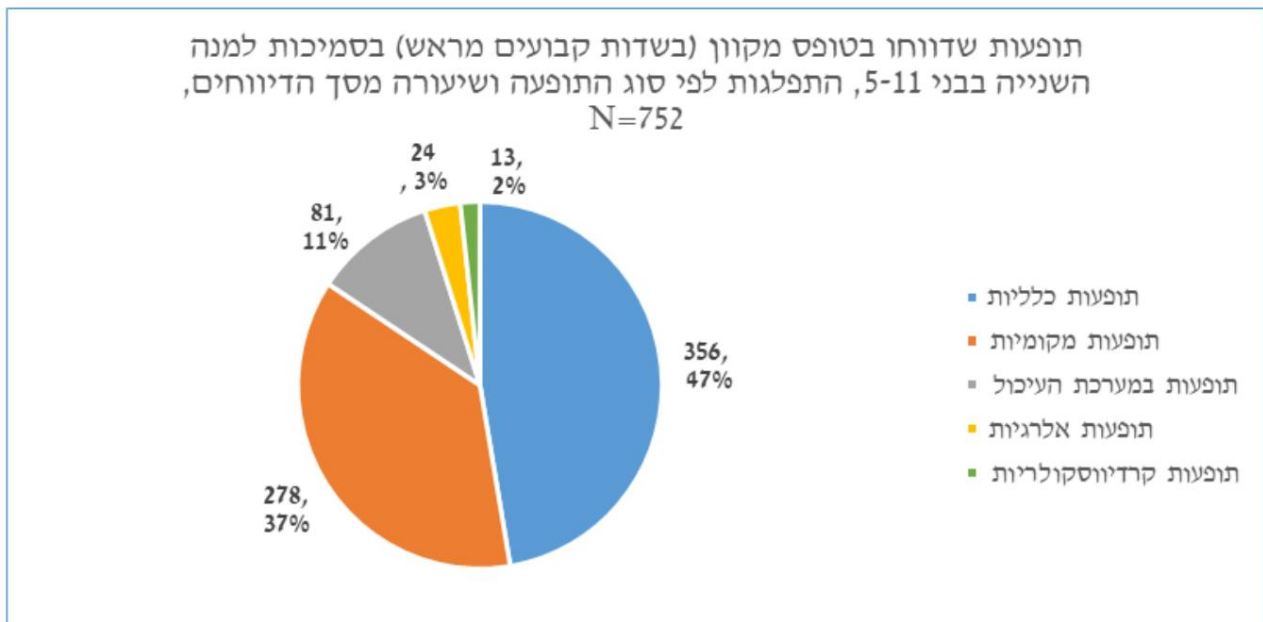
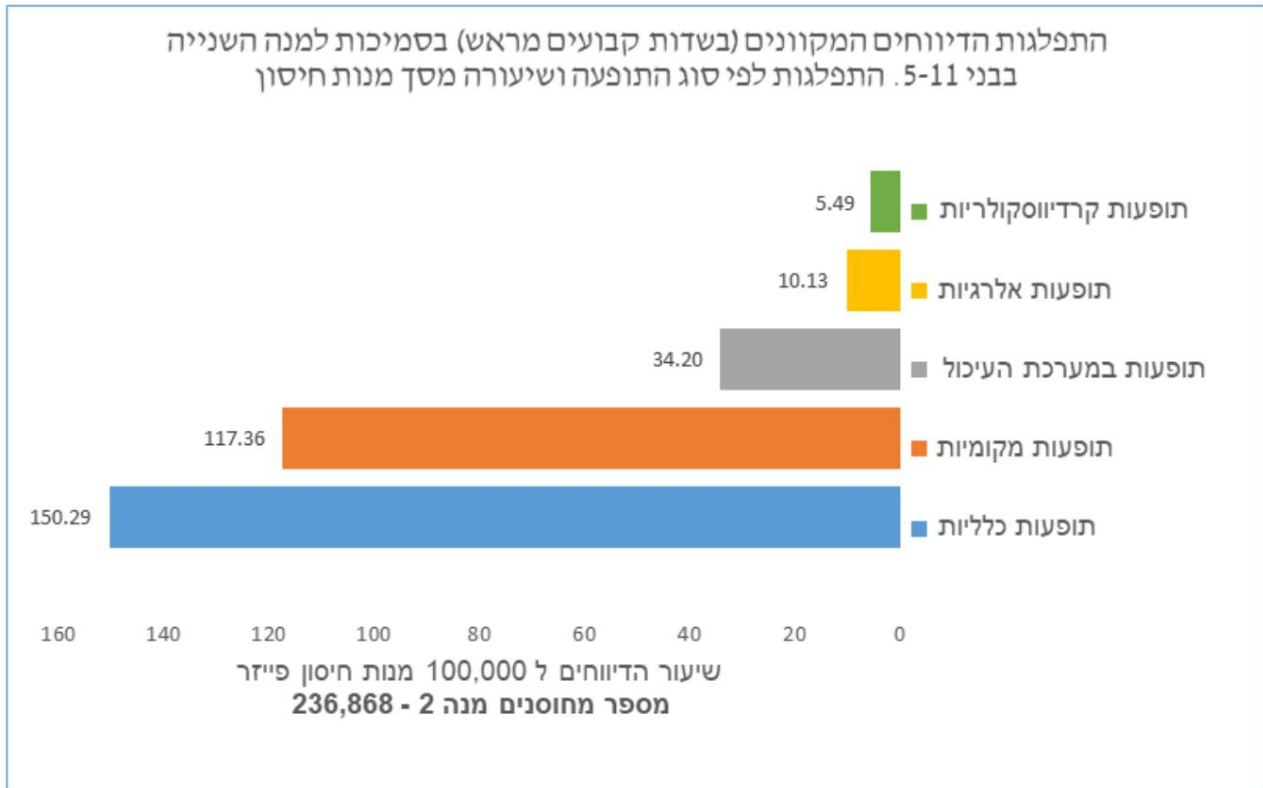
868,236 vaccine doses given.

About 2% of the symptoms reported in this age group were classified as symptoms related to the cardiovascular system - accounting for 005.0% of

the 868,236 vaccine doses given.



Figure 7 : Phenomena reported in an online form (in predetermined fields) in the vicinity of the second dose in 5-11 year olds. Distribution according to the type of phenomenon and its rate (number per 100,000 vaccine doses)



In the 12-17 age group, until 05/31/2022, a total of **776,584 second vaccine doses were given (Pfizer company only)**. 231 symptoms were reported in an online form in predetermined fields, close to the second dose (which constitutes 4% of all symptoms reported for this dose).

80% of the symptoms reported in this age group were classified as **general symptoms (such as general weakness, fatigue, fever, headache)** - and they make up **02.0%** of the 776,584 vaccine doses given, or local symptoms (such as redness, swelling, pain in the injection area) - representing **01.0%** of the 776,584 vaccine doses given.

9% of the symptoms reported in this age group were classified as changes in menstruation (extension of bleeding, increased bleeding, cessation of menstruation, changes in menstruation).

007.0% of the 088,284 vaccine doses given.

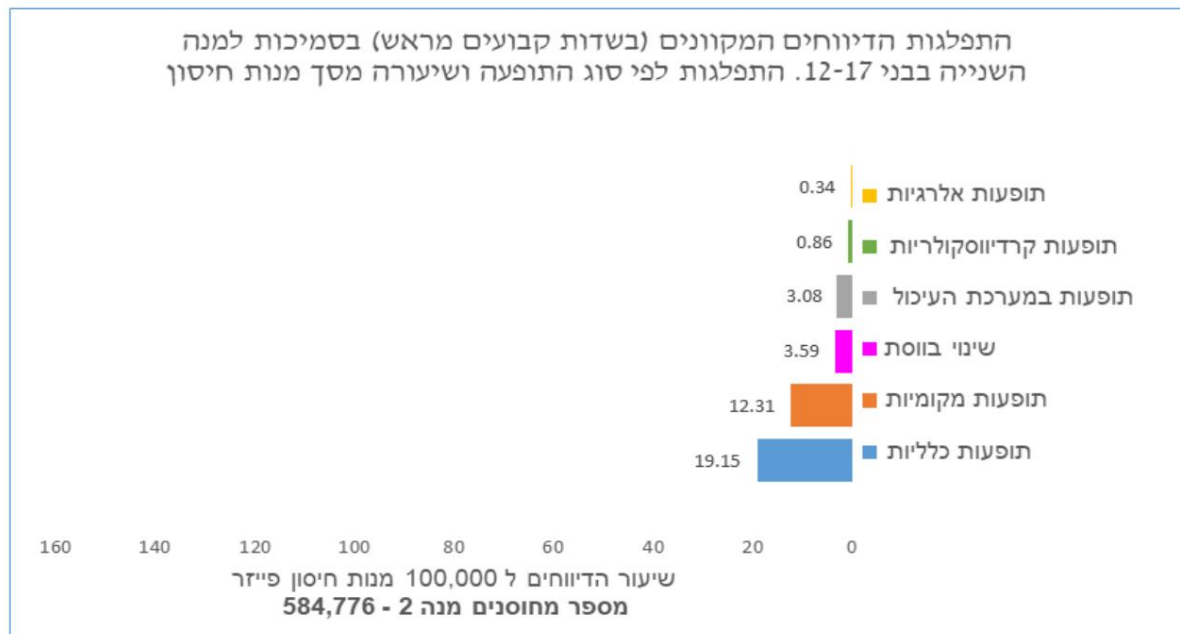
About 8% of the symptoms reported in this age group were classified as gastrointestinal symptoms (abdominal pain, vomiting/nausea, diarrhea)

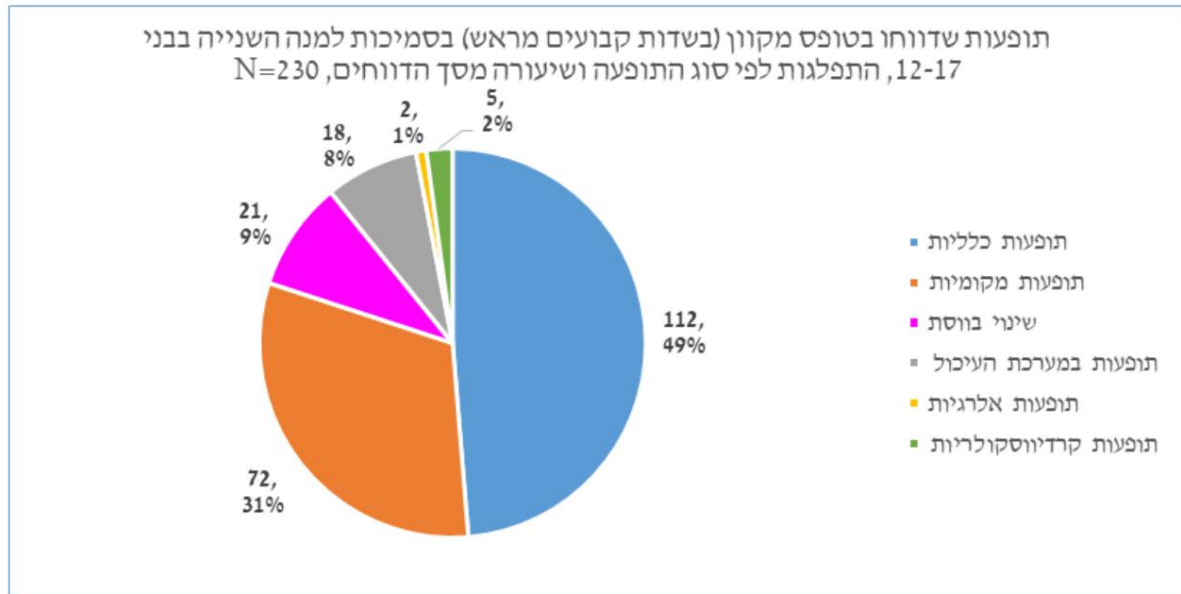
- Make up **003.0%** of the 776,584 vaccine doses given.

About 2% of the symptoms reported in this age group were classified as symptoms related to the cardiovascular system - making up **0008.0%** of

776,584 vaccine doses given.

Figure 8 : Phenomena reported in an online form (in predetermined fields) in the vicinity of the second dose in 12-17 year olds. Distribution according to the type of phenomenon and its rate (number per 100,000 vaccine doses)





In the age group of 18 years and older, until 05/31/2022, a total of 614,313,5 second vaccination doses were given (all companies). 228,4 symptoms were reported in an online form in predetermined fields, close to the second dose (which constitutes 81% of all symptoms reported per dose) this(.

About 77% of the symptoms reported in this age group were classified as general symptoms (such as general weakness, fatigue, fever, headache) - And they make up 03.0% of the 614,313.5 doses of vaccine given, or local symptoms (such as redness, swelling, pain in the injection area) - which make up 03.0% of the 614,313.5 doses of vaccine given.

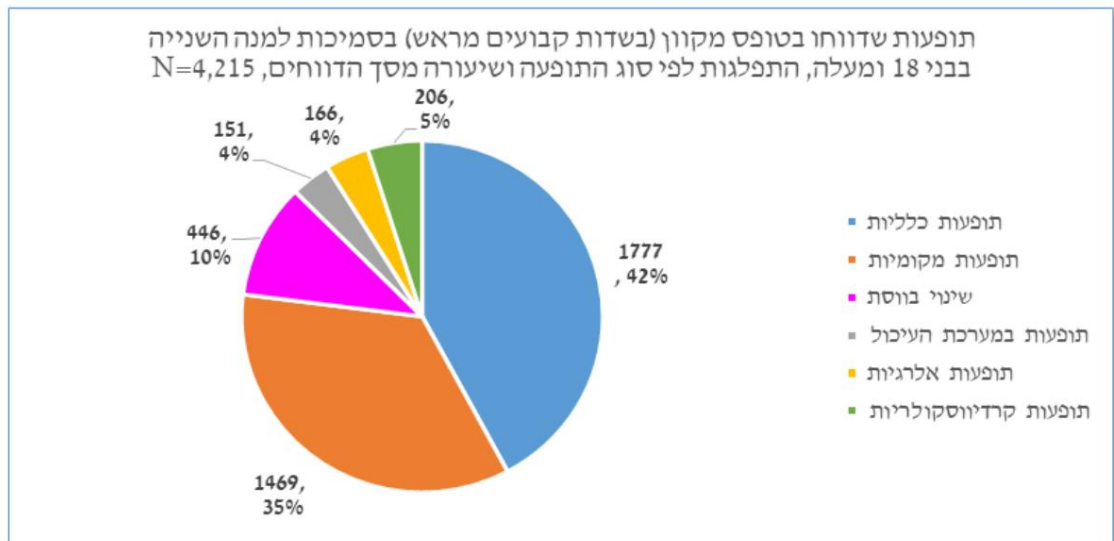
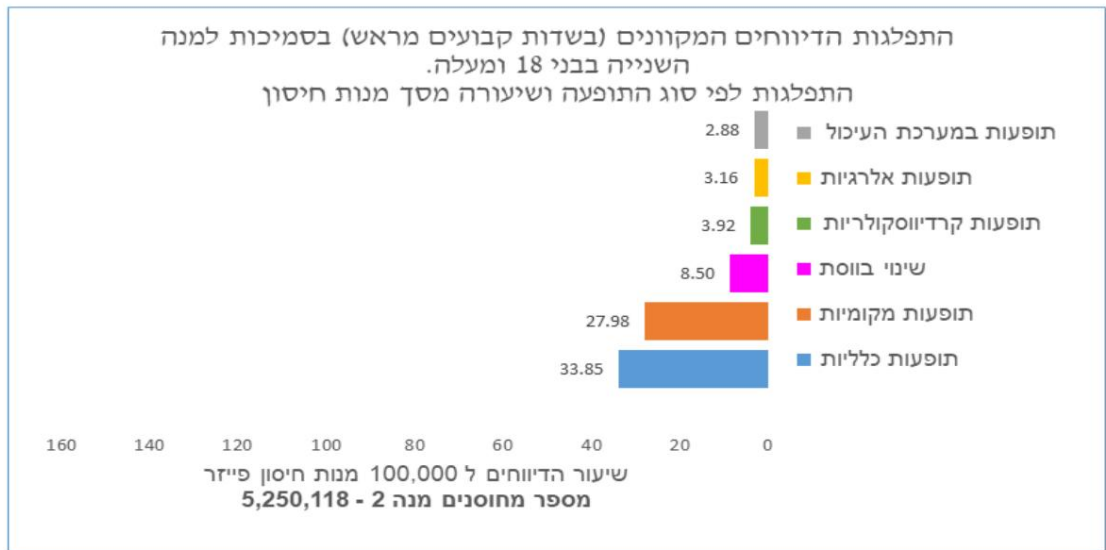
About 11% of all the symptoms reported in this age group were classified as changes in menstruation (extension of bleeding, increased bleeding, cessation of menstruation, changes in menstruation). The rate of appearance of changes in menstruation was calculated from the number of vaccine doses given to vaccinated women aged 18-50 (the oldest age at which Report on a woman with menstrual changes - 50 years old (- make up 03.0% of 898,613,1 The vaccine doses given.

About 5% of the symptoms reported in this age group were classified as symptoms related to the cardiovascular system - accounting for 004.0% of the 614,313,5 vaccine doses given.

About 4% of all symptoms reported in this age group were classified as allergic symptoms (such as rash, itching, edema) - making up 003.0% Of the 614,313,5 vaccine doses given.

About 4% of all symptoms reported in this age group were classified as gastrointestinal symptoms (abdominal pain, vomiting/nausea, diarrhea) - accounting for 0.003% of the 614,313.5 vaccine doses given.

Figure 9 : Phenomena reported in an online form (in predetermined fields) in the vicinity of the second dose in those aged 18 and over. Distribution according to the type of phenomenon and its rate (number per 100,000 vaccine doses)





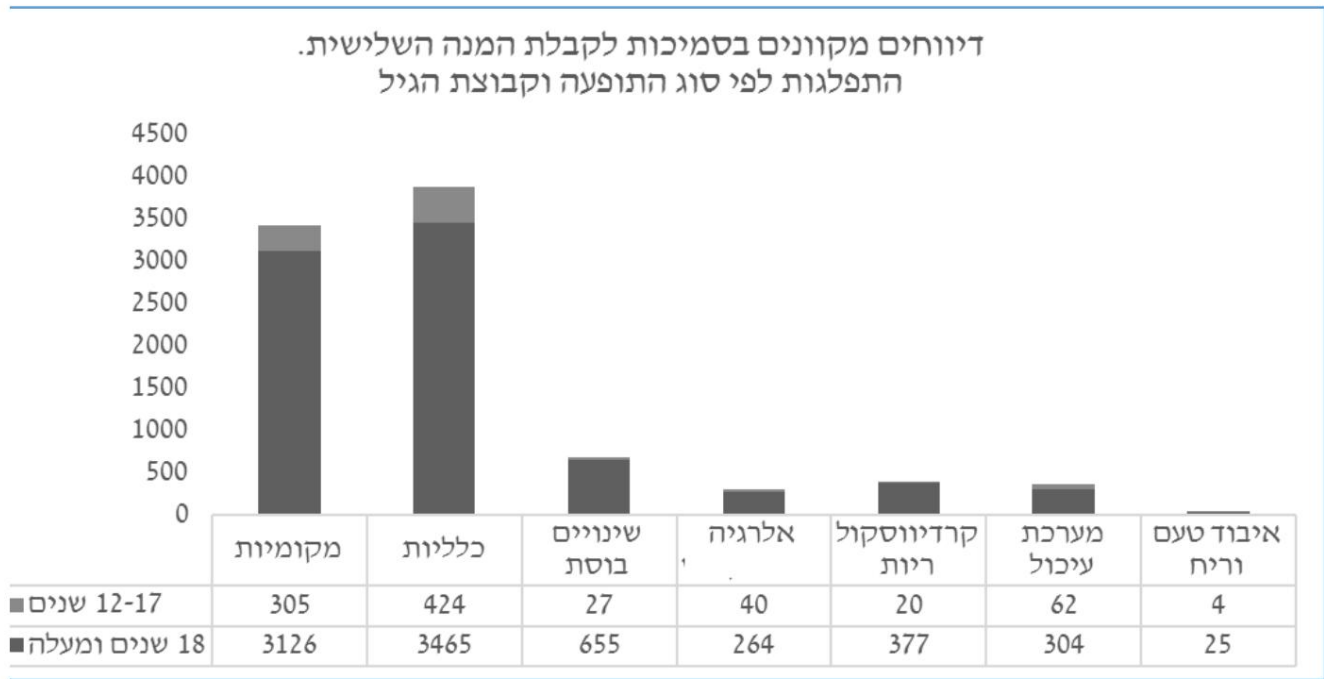
Symptoms reported in an online form (in predetermined fields) close to the third dose of the vaccine in the different age groups

Until the date 05/31/2022, a total of **331,493,4 doses of the third vaccine were given (all companies)**.

098,9 phenomena were reported in an online form in predetermined fields, near the third dose in adults and teenagers. Similar to the phenomena reported in the first and second doses, also in the The third, about 81% of the symptoms were classified as "general" or "local" and 8% of the reports were about menstrual changes. **Chart 10** :

The distribution of the online reports (in predetermined fields) in the vicinity of receiving the third dose by type

The phenomenon and age groups



In the age group of **12-17 years**, until 05/31/2022, a total of **470,206 doses of the third vaccine were given (Pfizer only)**. **882** symptoms were reported in an online form in predetermined fields, close to the third dose (which is about 10% of all the symptoms reported for the dose) this(.

83% of the symptoms reported in this age group were classified as **general symptoms (such as general weakness, fatigue, fever, headache)** and they make up **2.0%** of the **470,206 vaccine doses given**, or **local symptoms (such as redness, swelling, pain in the injection area)** - representing **15.0%** of the **470,206 vaccine doses given**.

About 7% of the symptoms reported in this age group were classified as gastrointestinal symptoms (abdominal pain, vomiting/nausea, diarrhea) - **Make up 03.0%** of the **470,206 vaccine doses given**.

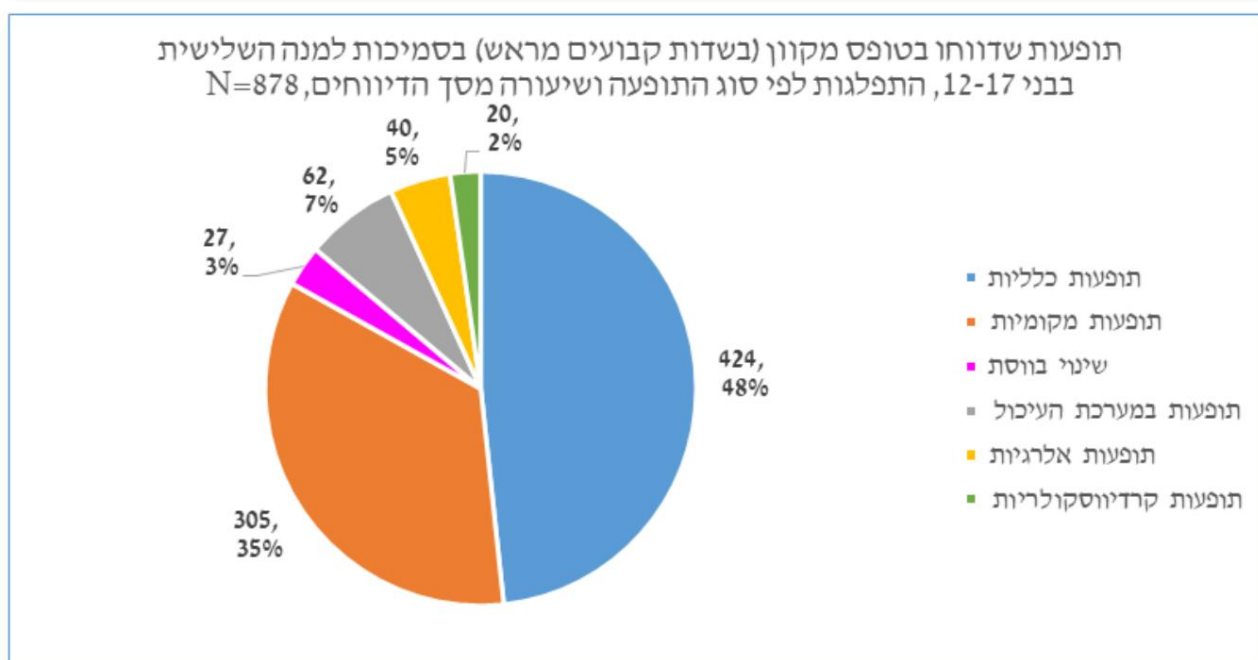
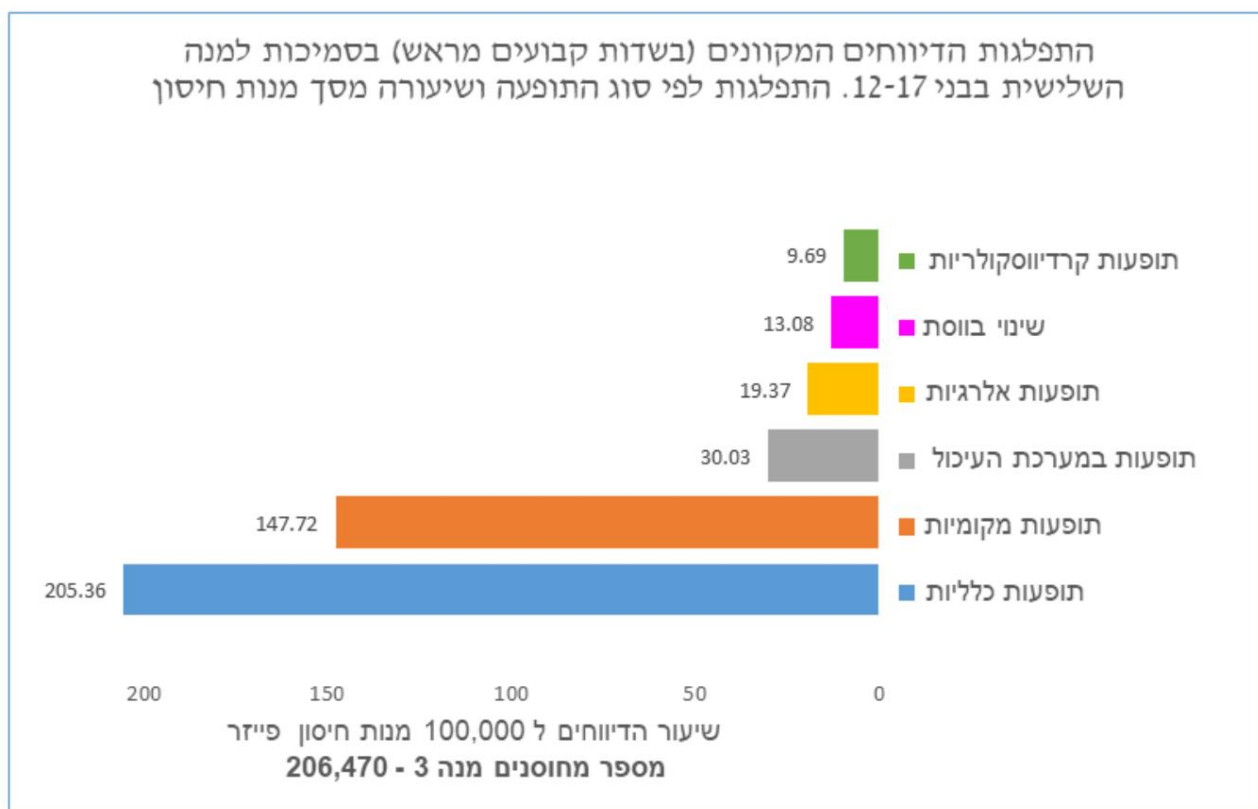
About 4% of all symptoms reported in this age group were classified as allergic symptoms (such as rash, itching, edema) - **making up 02.0%** Of the **470,206 vaccine doses given**.

3% of the symptoms reported in this age group were classified as changes in menstruation (extension of bleeding, increased bleeding, cessation of menstruation, changes in menstruation) .

Of the 447,99 vaccine doses given.

About 2% of the symptoms reported in this age group were classified as symptoms related to the cardiovascular system - **making up 009.0%** of the **470,206 vaccine doses given**.

Diagram 11 : Symptoms reported in an online form (in pre-set fields) near the third dose in 12-17 year olds.
Distribution according to the type of phenomenon and its rate (number per 100,000 vaccine doses)



In the age group of 18 years and older, until the date 05/31/2022, a total of 861,286,4 doses of the third vaccine were given (all companies). 216,8 symptoms were reported in an online form in predetermined fields, close to the third dose (which constitutes 90% of all the symptoms reported for the dose) this(80% of the symptoms reported in this age group were classified as general symptoms (such as general weakness, fatigue, fever, headache) - and they make up 08.0% of the 861,286,4 vaccine doses given, or local symptoms (such as redness, swelling, pain in the injection area) - which constitute 07.0% of the 861,286,4 vaccine doses given.

Approximately 8% of all symptoms reported in this age group were classified as changes in menstruation (extension of bleeding, increased bleeding, cessation of menstruation, changes in menstruation).

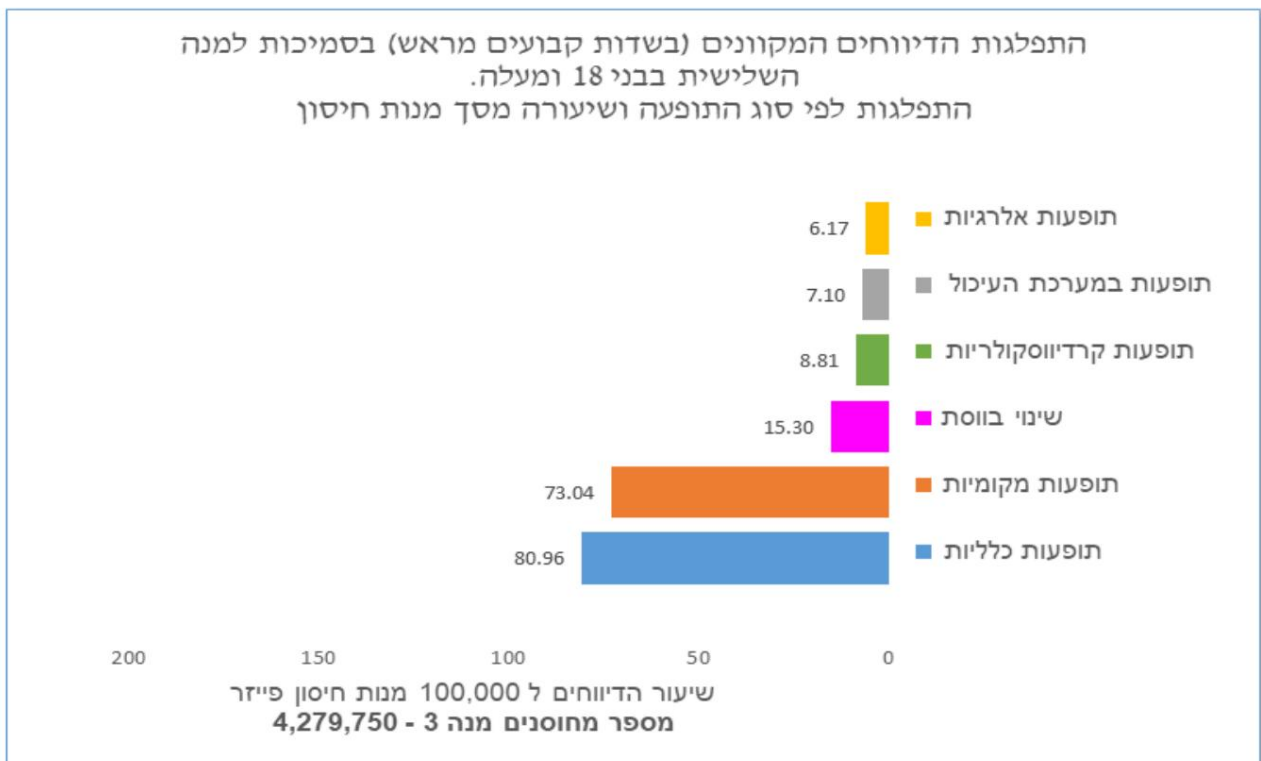
50 (the oldest age at which a woman with menstrual changes was reported - 50 years old) - **make up 05.0% of the 119,202,1 vaccine doses given.**

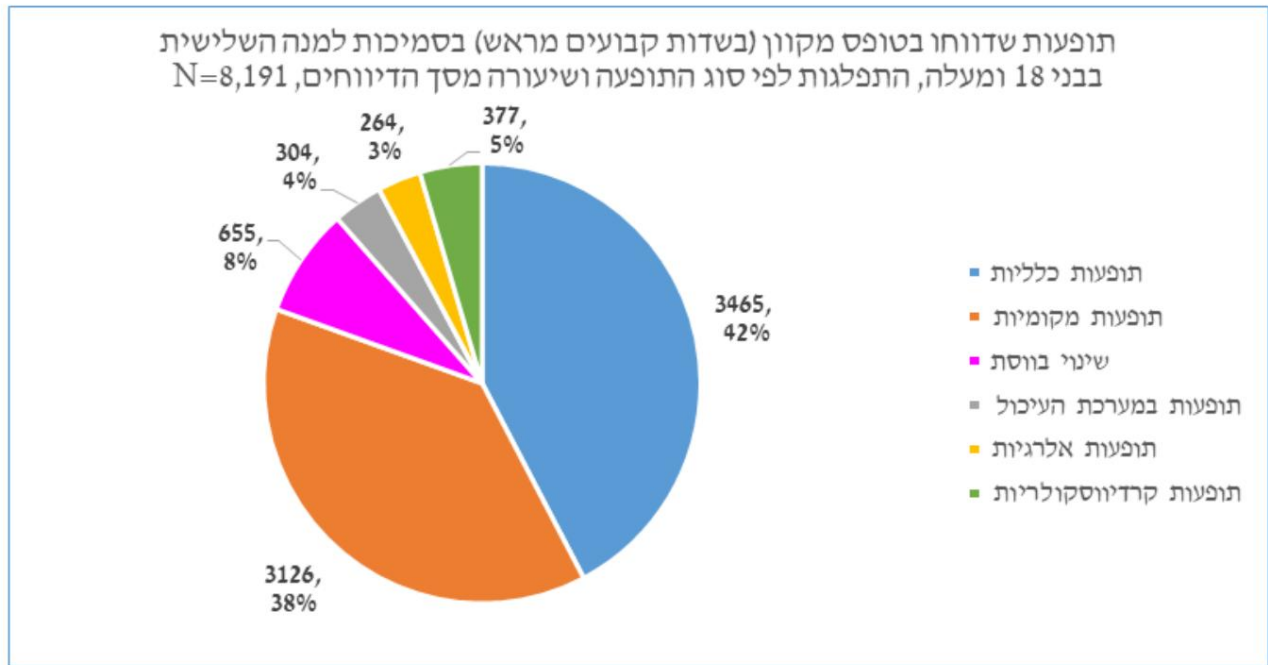
About 5% of the symptoms reported in this age group were classified as symptoms related to the cardiovascular system - **accounting for 0.09% of the 861,286.4 vaccine doses given.**

Approximately 4% of all symptoms reported in this age group were classified as gastrointestinal symptoms (abdominal pain, vomiting/nausea, diarrhea) - **representing 0.07% of the 4,861,286 doses of vaccine administered.**

About 3% of all symptoms reported in this age group were classified as allergic symptoms (such as rash, itching, edema) - **making up 006.0% Of the 861,286,4 vaccine doses given.**

Diagram 12 : Phenomena reported in an online form (in predetermined fields) in the vicinity of the third dose in those aged 18 and over. Distribution according to the type of phenomenon and its rate (number per 100,000 vaccine doses)





Symptoms reported in an online form (in predetermined fields) close to the fourth dose of the vaccine in the different age group

Until 05/31/2022, a total of 185,812 doses of the fourth vaccine were given (all companies).

723,4 symptoms were reported in an online form in predetermined fields, near the fourth dose, which was given to adults only. About 90% of the symptoms reported in this age group were classified As **general symptoms (such as general weakness, fatigue, fever, headache) - And they make up 25.0% of the 185,812 vaccine doses given, or local effects (such as redness, swelling, pain in the injection area) - which make up 26.0% of the 185,812 vaccine doses given.**

About 4% of all symptoms reported in this age group were classified as gastrointestinal symptoms (abdominal pain, vomiting/nausea, diarrhea) - **accounting for 03.0% of the 185,812 vaccine doses given.**

About 3% of the symptoms reported in this age group were classified as symptoms related to the cardiovascular system - **accounting for 02.0% of the 185,812 vaccine doses given.**

About 3% of all symptoms reported in this age group were classified as allergic symptoms (such as rash, itching, edema) - **making up 0.14% Of the 185,812 vaccine doses given.**

About 1% of all symptoms reported in this age group were classified as changes in menstruation (extension of bleeding, increased bleeding, cessation of menstruation, changes in menstruation).

50 (the oldest age at which a woman with menstrual changes was reported - 50 years old) - **make up 14.0% of 939,36 cases the vaccine given.**



Diagram 13 : The distribution of online reports (in predetermined fields) in the vicinity of receiving the fourth ration by type

The phenomenon and age groups

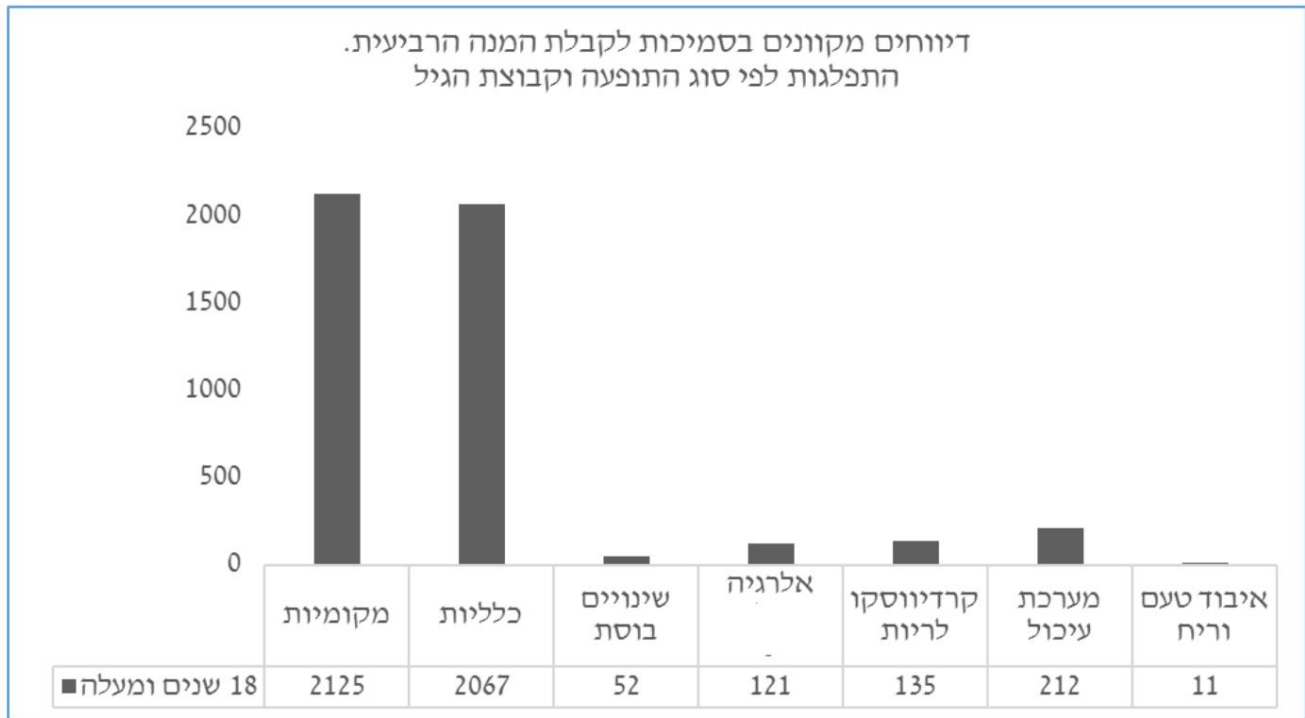
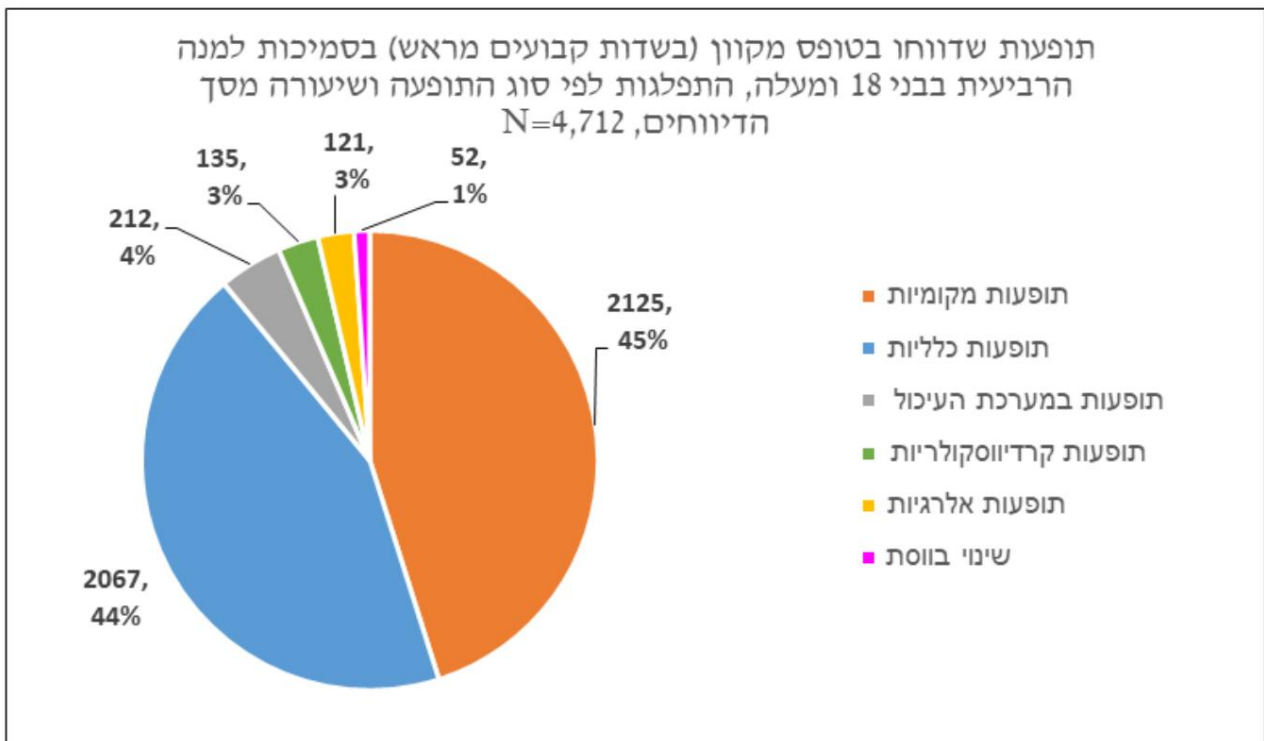
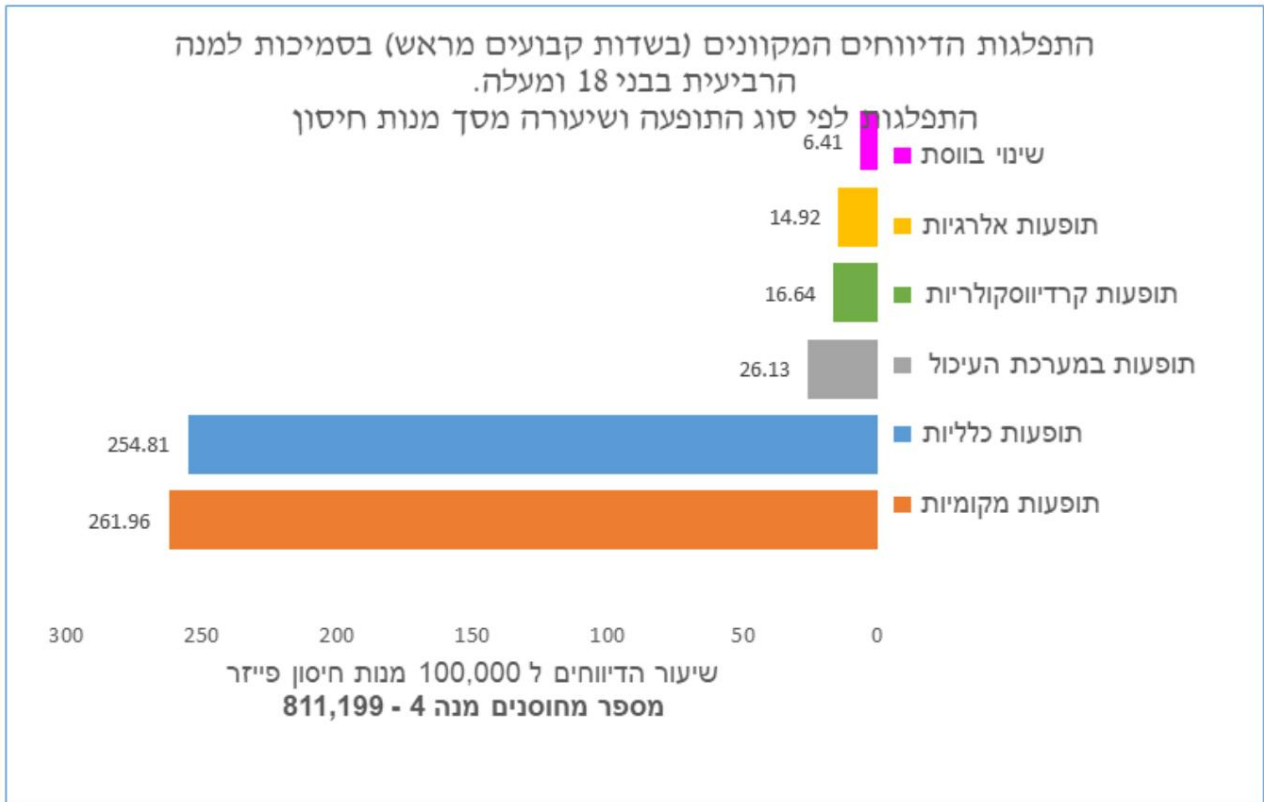


Figure 14 : Phenomena reported in an online form (in predetermined fields) in the vicinity of the fourth dose in those aged 18 and over.
 Distribution according to the type of phenomenon and its rate (number per 100,000 vaccine doses)

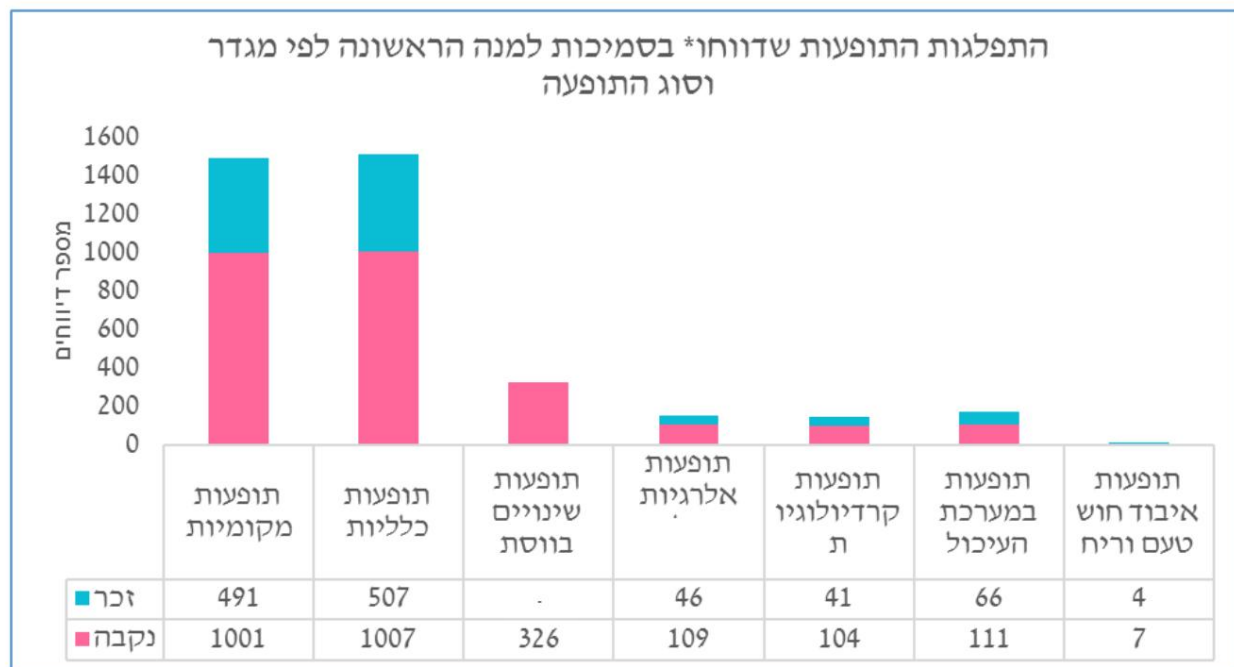



The details of the phenomena reported in an online form in predetermined fields in the distribution by gender*

* For reports regarding which the gender was reported.

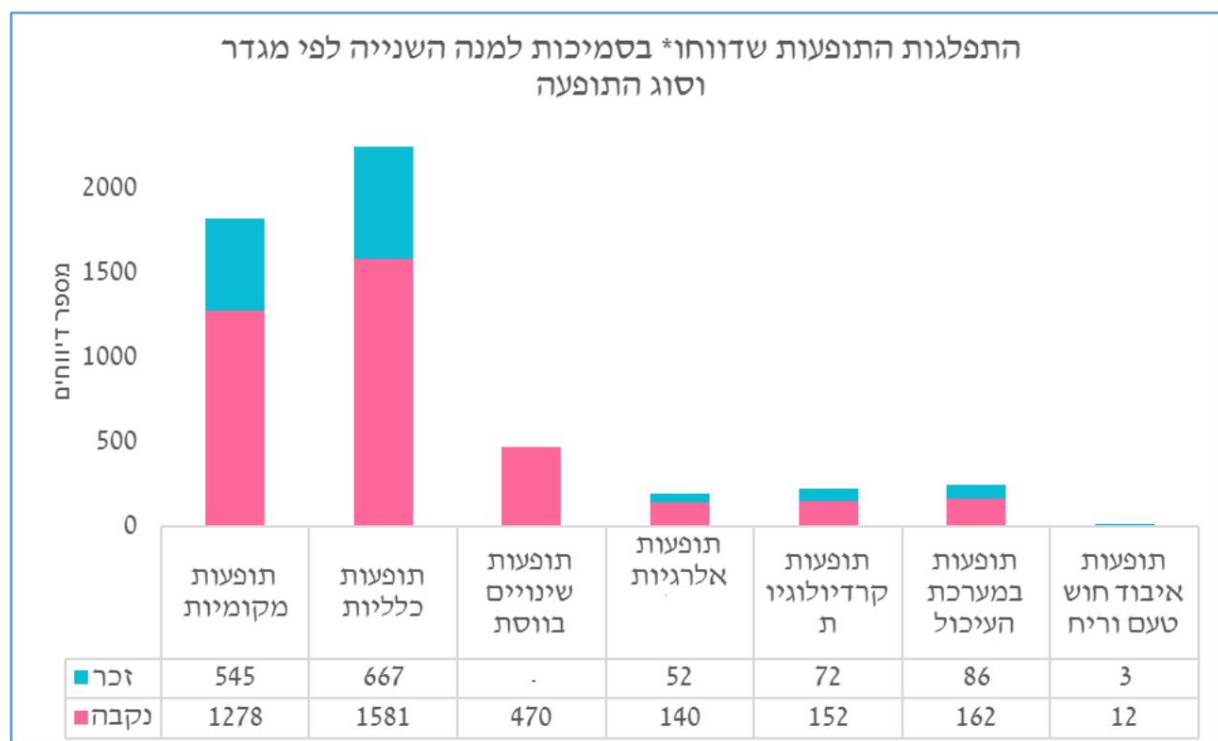
Between the dates 2022/05/31-2021/12/09 (inclusive), a total of 828 reports* (317 male, 511 female) were received in close proximity to the first dose, which included 820.3 phenomena.

Chart 15 : Distribution by gender of the types of phenomena that were reported in an online form (in predetermined fields) next to the portion the first



981 reports* (336 male, 645 female) in close proximity to the second dose, which included 220.5 phenomena.

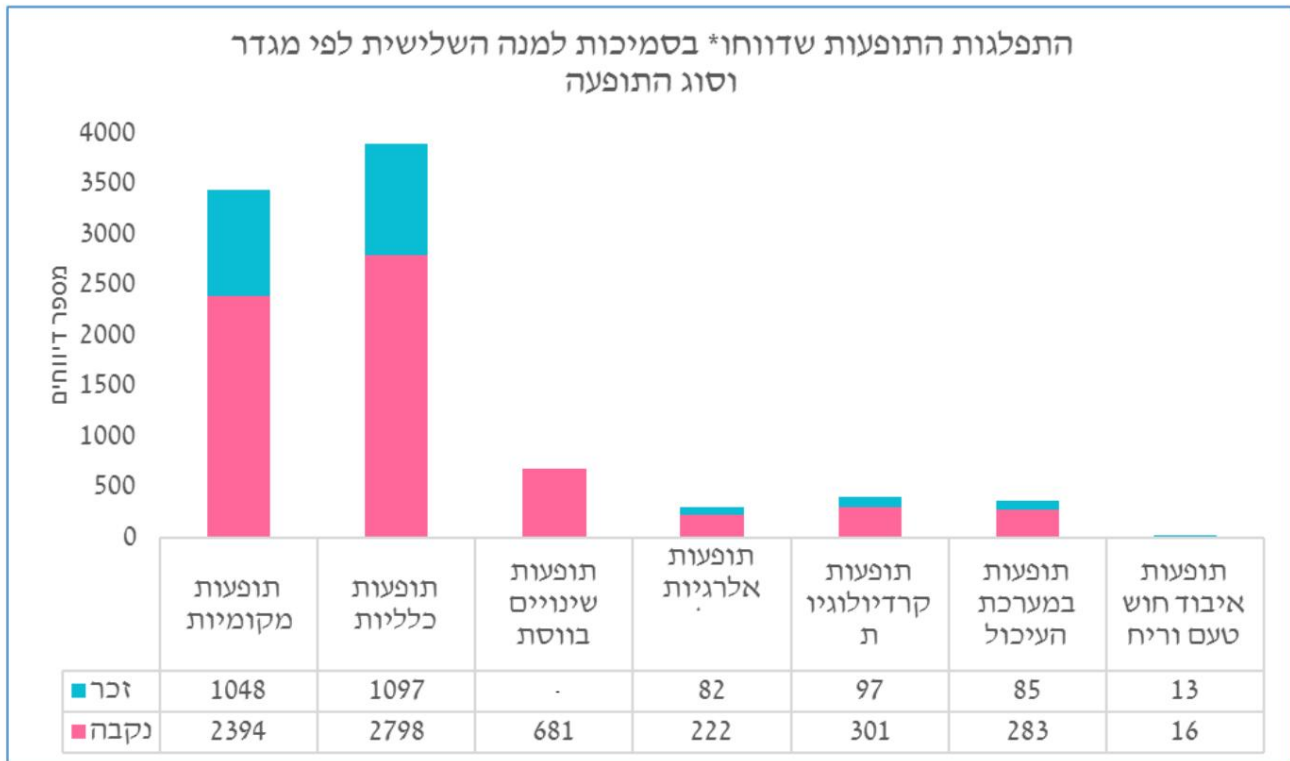
Figure 16 : Distribution by gender of the types of symptoms reported in an online form (in predetermined fields) in proximity to the dose the second



1854 reports* (685 male, 1169 female) in close proximity to the third dose, which included 117.9 phenomena.

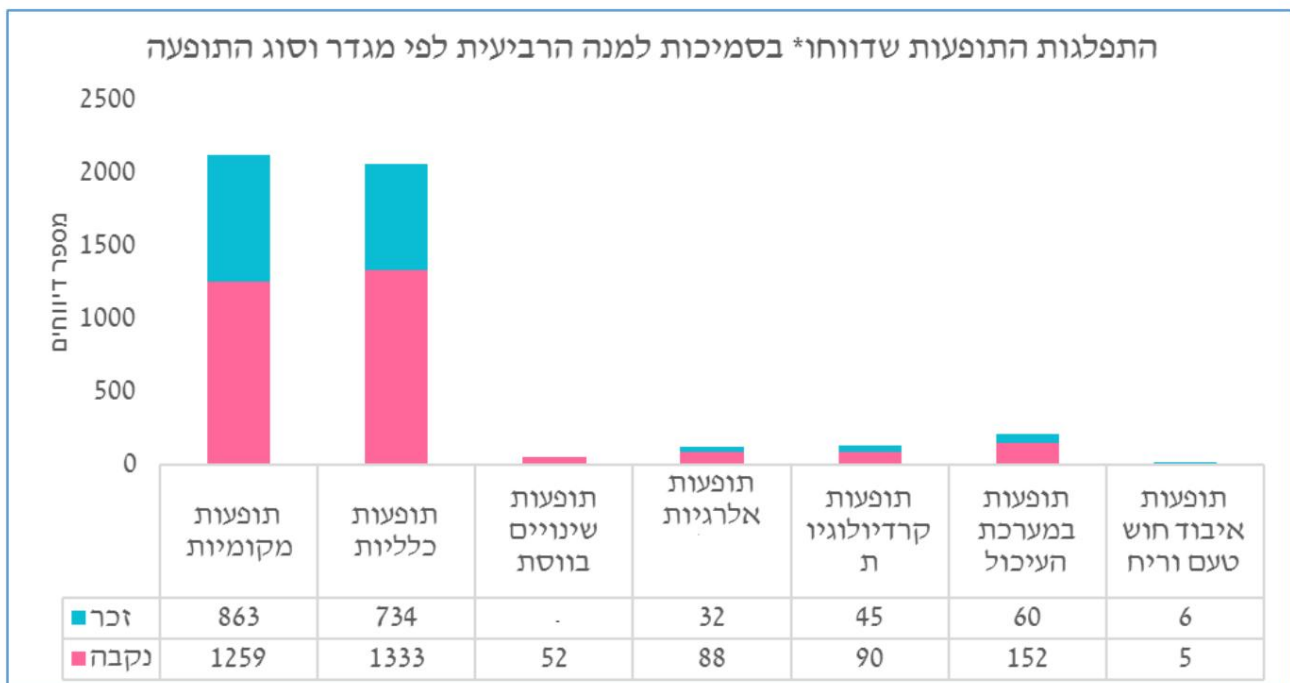


Figure 17 : Distribution by gender of the types of symptoms reported in an online form (in predetermined fields) in proximity to the dose the third



1289 reports* (619 male, 670 female) in close proximity to the fourth dose, which included 719.4 phenomena.

Figure 18 : Distribution by gender of the types of symptoms reported in an online form (in predetermined fields) in proximity to the dose the fourth





משרד
הבריאות
לחיים בריאים יותר



Details of the phenomena reported in an online form in free text fields



משרד
הבריאות
לחיים בריאים יותר



In addition to reporting phenomena in predetermined fields, there is a field in the online form for reporting phenomena as free text (text). The reports received as free text were analyzed by a staff member from the field of pharmacology and included conversion of the free text in the form into a systematic and valid medical nomenclature, using the Activities Regulatory for Dictionary Medical method - MedDRA After

converting the free text to medical nomenclature, the information was classified into medical categories. The phenomena that were reported as free text were classified into 22 categories (arranged in A-B order):

1. Oncological symptoms - diagnosis/exacerbation of an oncological disease

2. Allergic symptoms - allergic rash, anaphylaxis, etc. 3.

Endocrinological phenomena - hypo/hyperthyroidism, thyroiditis, Hashimoto's disease, etc. 4. Phenomena in the

menstrual cycle - irregularity in the menstrual cycle, delayed/early menstruation, heavy menstrual bleeding, etc. 5. Effects in the

sexual and reproductive system - impotence 6. Effects in

the digestive system/kidney and urinary system - nausea, abdominal pain, diarrhea, pain in the urinary tract, etc. 7. Effects in

the musculoskeletal system - muscle/joint pain, etc. 8. Effects in hearing and

balance Weight - tinnitus, hearing loss, etc. 9. Gynecological symptoms -

vaginal pain, ovarian cysts, endometriosis, etc. 10. Hematological symptoms - anemia, leukocytosis,

etc. 11. Vascular symptoms - bleeding, hypercoagulability, etc.

12. Infectious-inflammatory symptoms - Herpes, strep throat,

mastitis, etc. 13. General symptoms - fatigue, loss of appetite, weakness, etc. 14. Metabolic symptoms - hypo/

hyperglycemia, etc. 15. Obstetrical symptoms - miscarriage, birth

defect, growth retardation in a newborn, etc. 16 Laboratory

phenomena - findings in the blood/urine tests such as changes in hemoglobin, CRP,

coagulation factors, etc. 17. Neurological phenomena - dizziness, feeling numb, loss of consciousness, etc. 18. Skin phenomena

- baldness, night sweats, psoriasis, etc. 19. Ocular phenomena - Blurred vision,

inflammation of the eye, swelling of the eye, etc. 20. Psychiatric phenomena -

emotional instability, depression, restlessness, etc. 21. Kerad phenomena

Vascularity - high/low blood pressure, arrhythmias, pericarditis, etc. 22. Rheumatoid

symptoms - asthma, breathing difficulties, cough, etc.



The summary of the findings is general

Between the dates 2022/05/31-2021/12/09 (inclusive), **2075 phenomena** reported in the free text were classified.

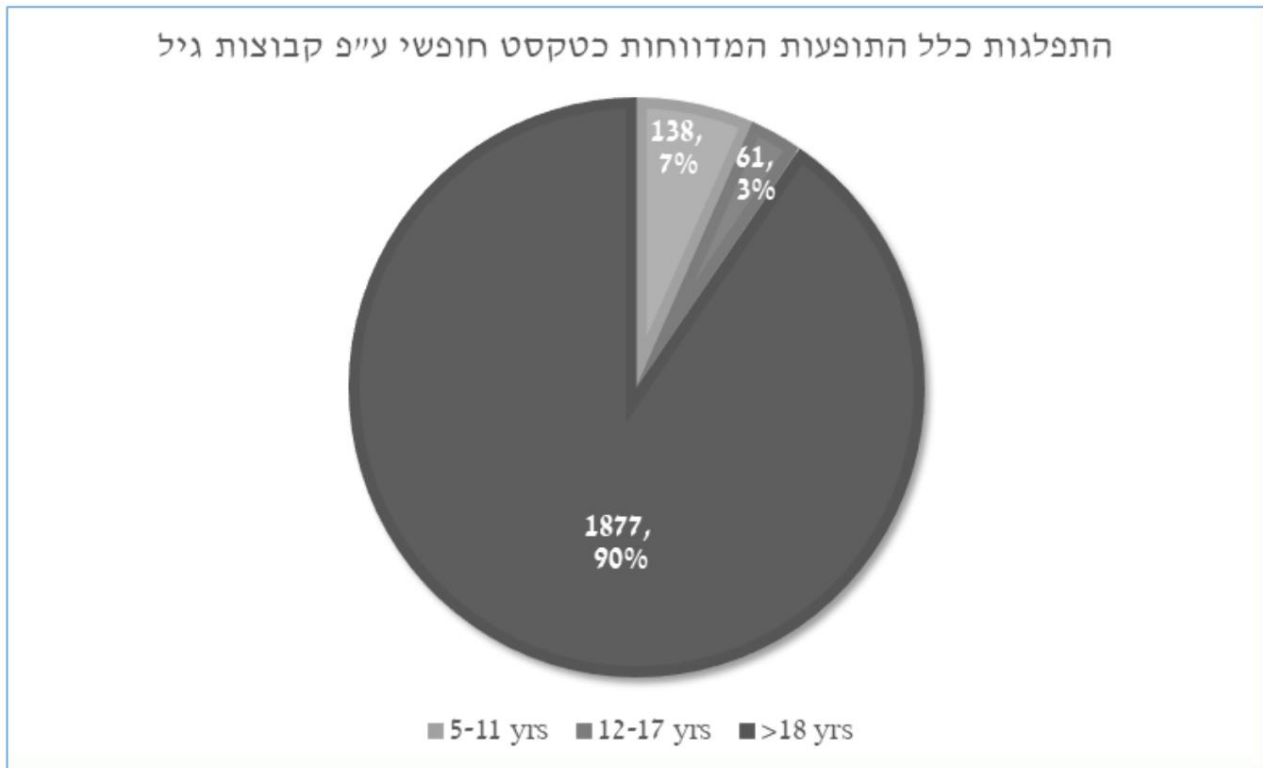
About 90% of the phenomena reported in the free text were of vaccinators 18 years of age and older.

About another 7% belonged to the 5-11 age group.

The remaining 3% refer to the age group of 12-17 years.

By gender, 73% of the reports (1505 reports) in free text were by women and 27% (570 reports) by men.

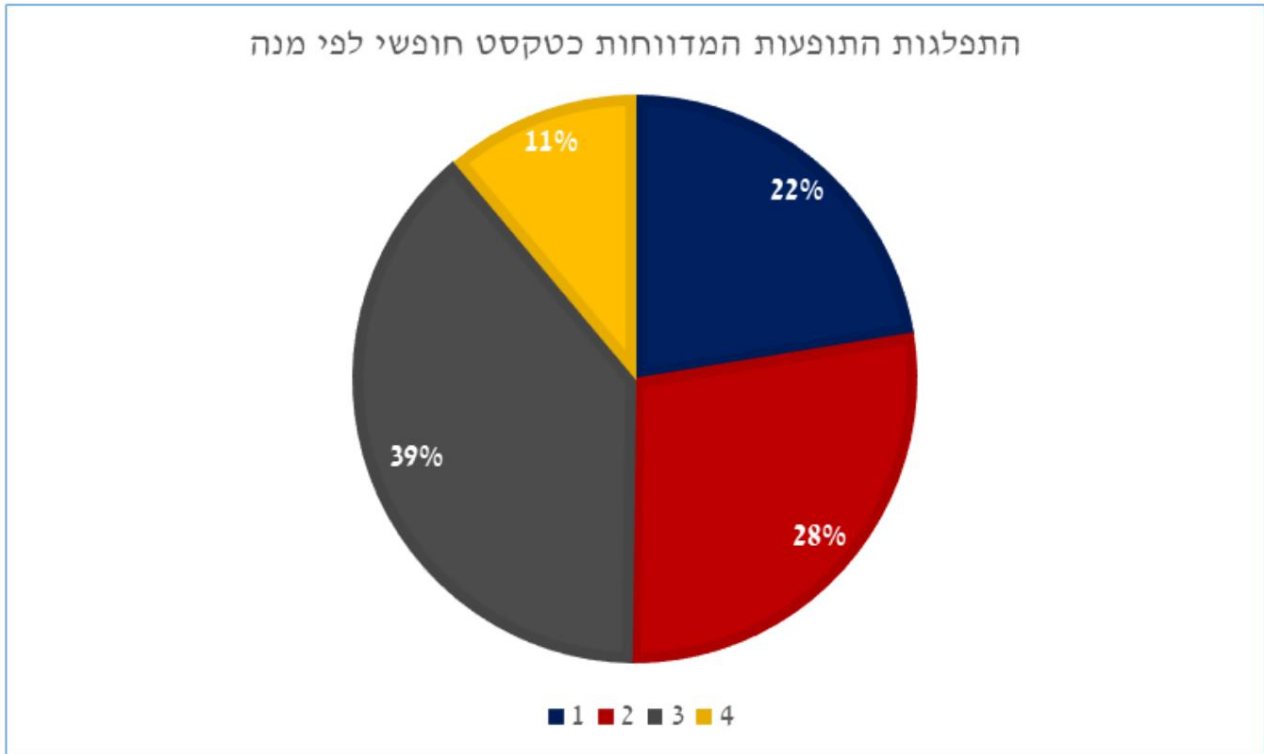
Diagram 19 : Distribution of all phenomena reported as free text according to age groups



In the division by the number of doses, 22% of the reports referred to symptoms in the vicinity of the first dose, 28% in the vicinity of the second dose, 39% in the vicinity of the third dose and 11% in the vicinity of the fourth dose.



Diagram 20 : The distribution of the phenomena reported as free text according to doses



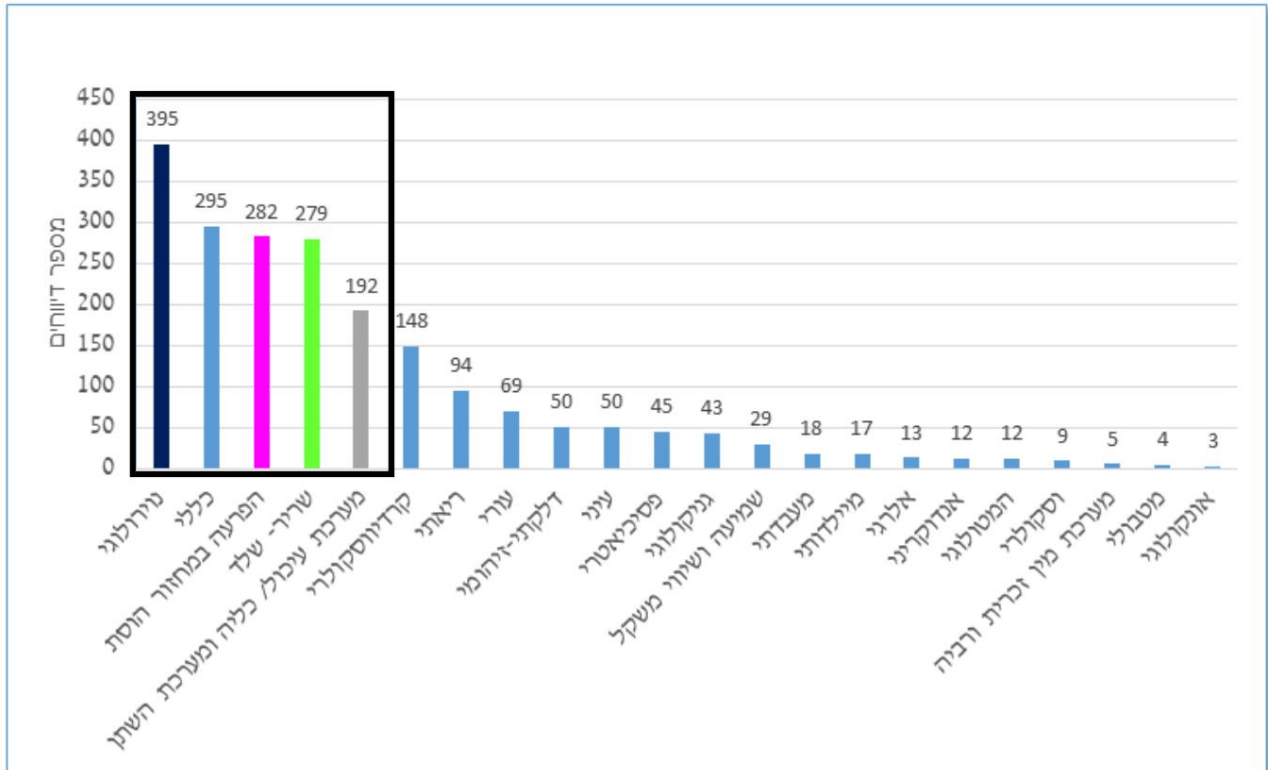
The **five** most common categories reported in the free text were **neurological** (395 reports, 19%), **general symptoms** (14%, 295), **menstrual cycle disorder** (13,282%), **musculoskeletal** (13,279%) and **digestive system, kidney and urine**) 9, 192%.) **These five categories together accounted for about 70% of all the phenomena reported in free text. Attached is a diagram that includes everything**

The reported categories.

It is important to note that **one report can contain more than one phenomenon** and some reports refer to phenomena that occurred **before**

The date range of the report

Diagram 21 : The distribution of the phenomena reported as free text into categories (detail of phenomena in the framework of diagrams 24-33)



Divided by gender, in women, approximately 54% of the most frequently reported symptoms were classified as neurological (27%) or menstrual cycle disorders (27%), 18% were classified as general, 17% were classified as musculoskeletal, another 11% were classified as belonging to the digestive/kidney system and urinary system. In men, among the commonly reported symptoms, 24% were classified as neurological, 23% were classified as general, 22% musculoskeletal, 17% as digestive, kidney and urinary system problems and 14% cardiovascular.

Diagram 22 : The distribution of the common symptoms in women reported as free text

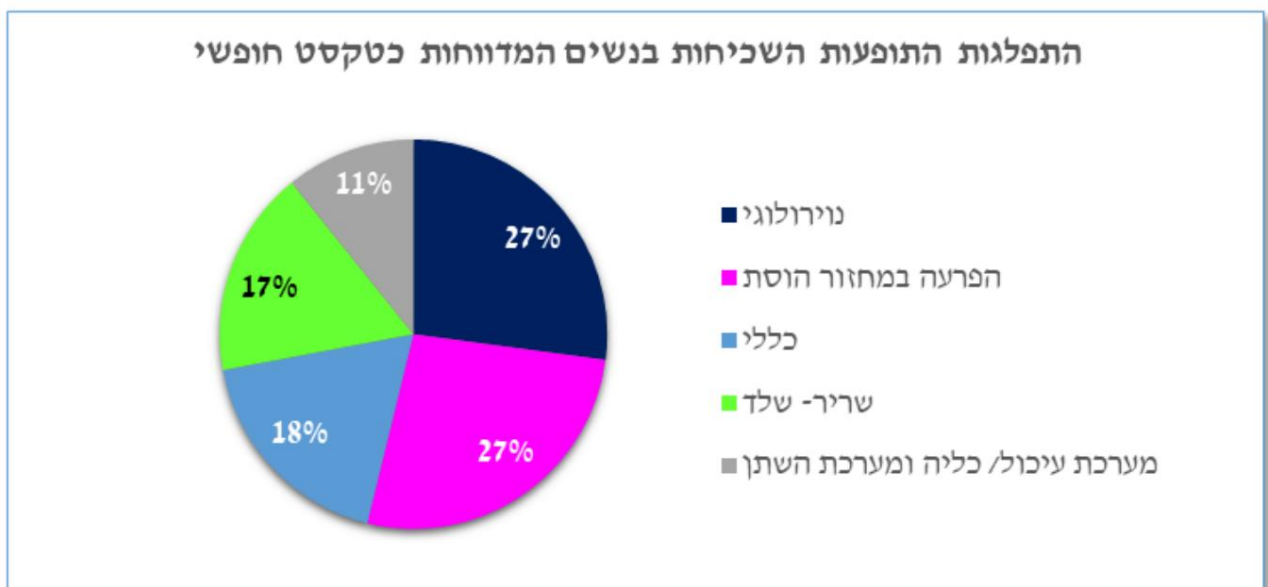
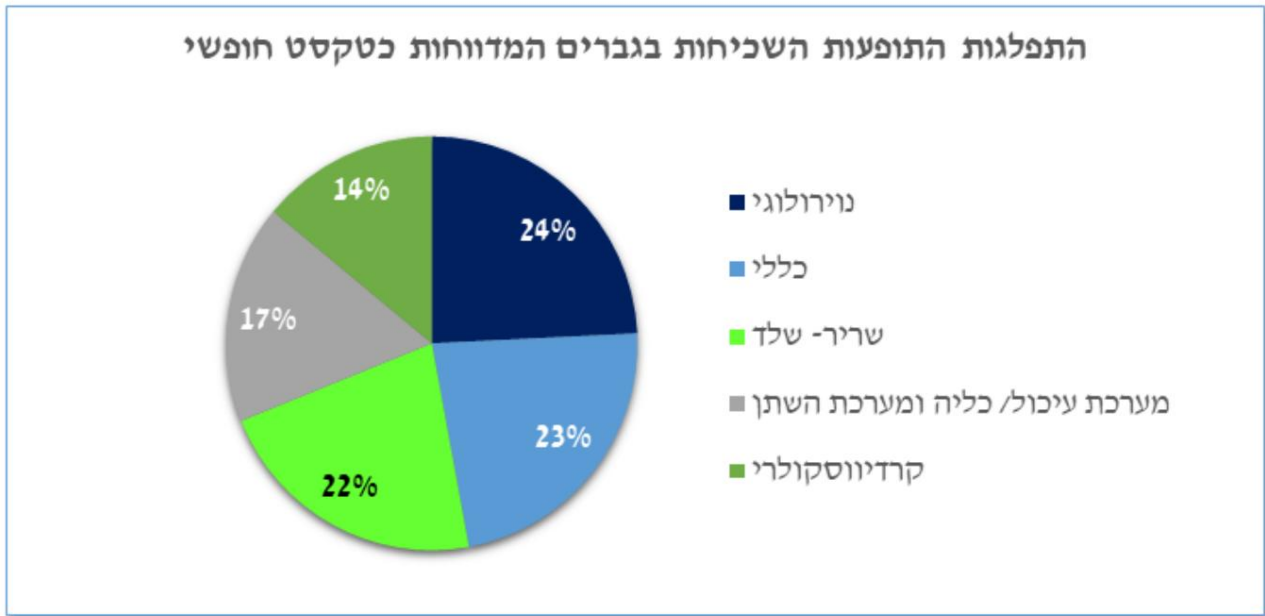




Diagram 23 : The distribution of the common symptoms in men reported as free text



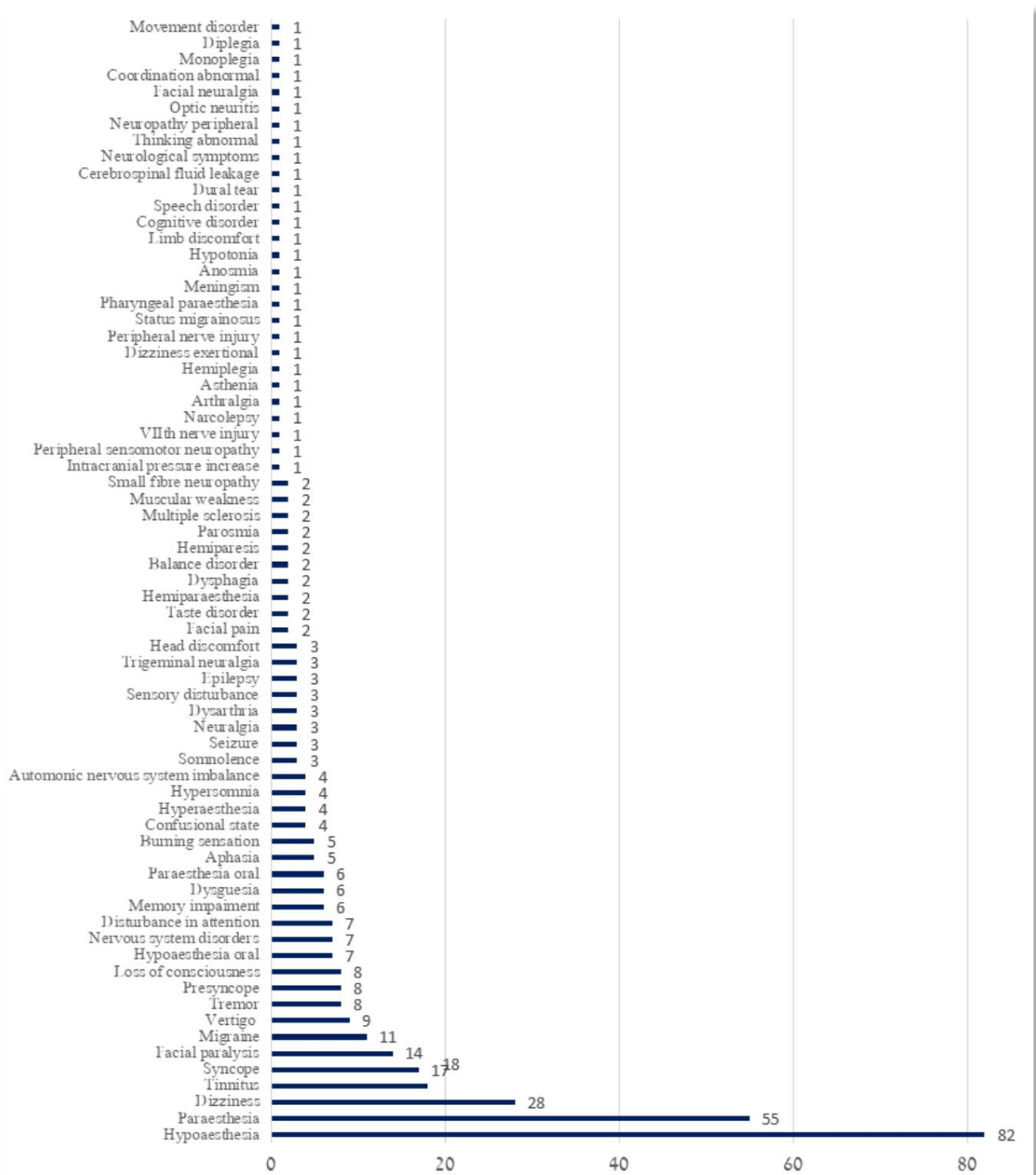
Neurological problems reported as free text

Between the dates 2022/05/31-2021/12/09 (inclusive), **395 neurological** phenomena were reported as free text (making up 20% of all the phenomena reported as free text), see details in chart no. 24.

72% were reported by women and 28% were reported by men.

365 cases (92%) of the phenomena were reported by adults, 8 cases (2%) by teenagers (12-17 years) and 22 cases (6%) were reported by children (5-11 years).

The distribution according to vaccine doses was 26% (79 cases) near the first dose, 27% (80 cases) near the second dose, 36% (106 cases) near the third dose and 11% (32 cases) near the fourth dose. **Diagram 24** : Distribution The neurological symptoms reported as free text are classified according to MedDRA





The following graph shows their distribution (into subcategories) according to MedDRA.

This segmentation allows identification of the specific phenomena and their frequency among all the phenomena belonging to this category.

In free text reports on neurological problems, 85 out of 395% (22) reports contained information on the duration of the phenomenon. In 57% (67) of the 85 cases, a phenomenon was reported that lasted for more than one month. **Figure 25** : Distribution of the duration of the neurological symptoms that lasted for more than a month, reported as free text



At the **age of 5-11 years** , two phenomena with a duration of 1-3 months were reported: sleepiness and tremors.

At the **age of 12-17 years** , one phenomenon was reported, neuralgia (nerve pain), with a duration of 6-12 months

In **adults aged 18 and over** , 4 phenomena were reported that lasted 1-3 months: 1 report of narcolepsy and 3 of circumcision.

In adults, 17 phenomena were reported with a duration of 3-6 months: 3 cases of hypoesthesia (numbness), 2 cases of paraesthesia, 2 cases of tinnitus, 2 cases of paralysis of the facial nerve, 2 cases of dizziness, and isolated reports of aphasia, confusion, pressure in the head,

Hyperesthesia, vertigo and tremor.

In adults, 17 phenomena were reported with a duration of 6-12 months: 5 cases of hypoesthesia (numbness), 2 cases of paraesthesia, 3 cases of tinnitus, 2 cases of aphasia and isolated reports of dizziness, facial nerve palsy, fainting, memory problems and general problems

in the nervous system.

In adults, 16 symptoms with a duration of 12 months or more were reported: 7 cases of hypoesthesia (numbness), and isolated reports of dizziness, tinnitus, aphasia, facial nerve paralysis, balance problems, neuralgia (nerve pain), neuropathic pain and sensation

burning.



Menstrual disorders reported as free text

Between the dates 2022/05/31-2021/12/09 (inclusive), **282 disturbances in the menstrual cycle** were reported as free text (which constitutes 18%) of all the phenomena reported as free text in women).

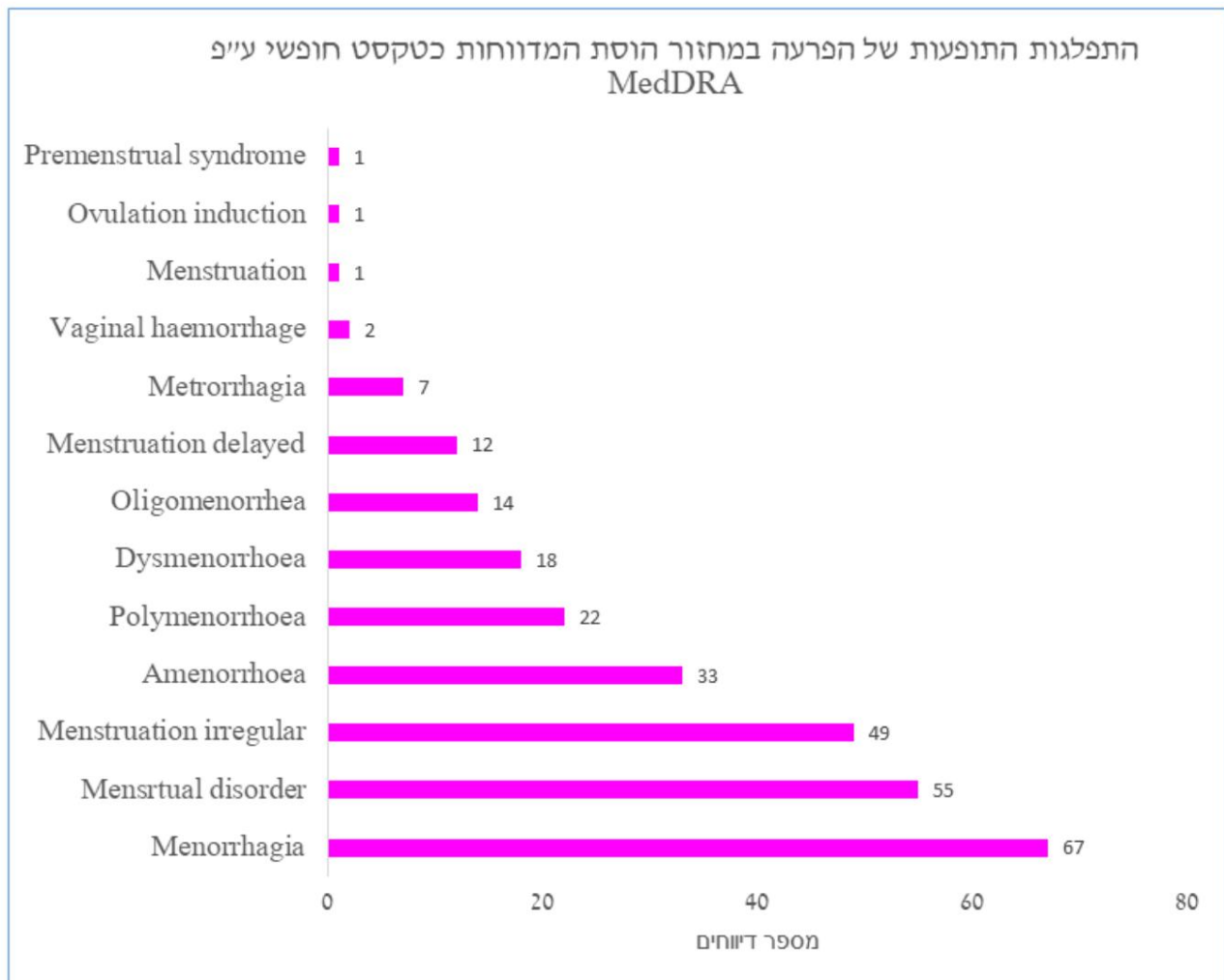
271 women (96%) of the phenomena were reported by adult women (over 18%), 9 cases (3) by girls (12-17 years old) and 1% (2)

cases) were reported in childhood (5-11

years). The distribution according to vaccine doses was 51 cases (21%) (close to the first dose, 80 cases (23%) (close to the second dose), 100

cases (41%) (close to the third dose and 11 cases) 5%) near the fourth portion. **Figure 26** : Distribution of symptoms

of menstrual cycle disorder reported as free text classified according to MedDRA



In free text reports about changes in the menstrual cycle, 88 out of 282% (31) reports contained information about the duration of the phenomenon.

In 83 cases out of the 88% (94), a phenomenon was reported that lasted more than one week.



Figure 27 : Distribution of duration of menstrual cycle disturbances that lasted more than a week reported as free text



In the age group of 5-11 years there were two reports (they did not contain information about the duration of the phenomenon). One report about the onset of the first period in a 10-year-old girl and one report about menstrual disruption in an 11-year-old girl

In the age group of 12-17 years , there was one report with a note on the duration of the phenomenon, about a break in menstruation in a 14-year-old girl.

In older women, there were 11 reports of effects lasting between a week and a month. 5 reports of increased bleeding, 2 reports of menstrual pain, 2 reports of a short menstrual period, 1 report of vaginal bleeding and 1 report of late menstruation.

In older women, there were 11 reports of effects lasting between 1-6 months. There were 16 reports of cessation of menstruation, 13 of disruptions in menstruation or irregular menstruation, 6 of increased bleeding, 2 reports of delayed menstruation, 2 reports of a deficiency in the amount or duration of menstruation, and 1 report of menstrual pain.

In older women, there were 7 reports of effects lasting more than 12 months. 4 reports of disturbances in menstruation and regularity, 1 report of increased menstruation, 1 report of a decrease in the number of menstrual days and 1 report of cessation of menstruation.



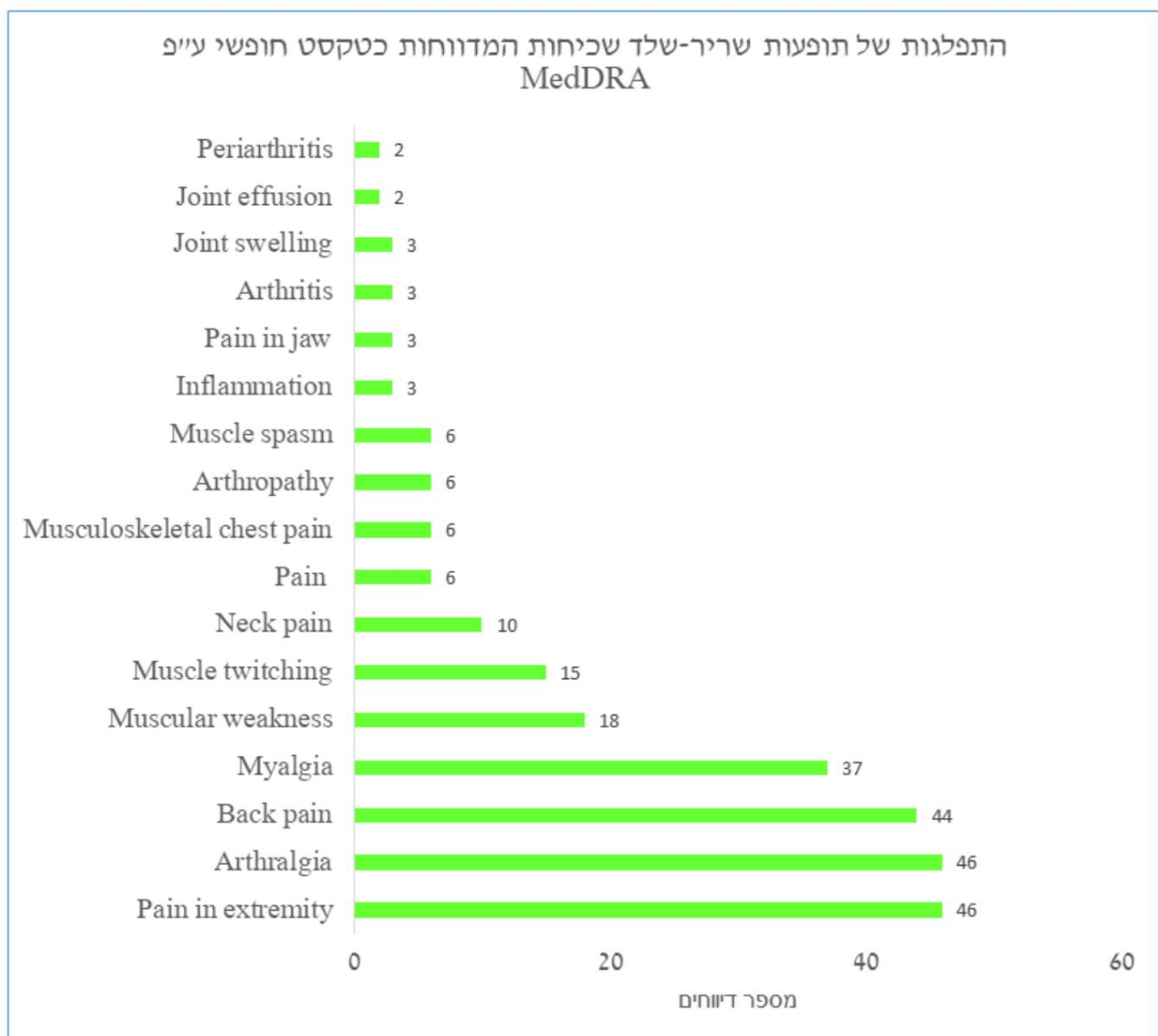
Musculoskeletal system reported as free text

Between the dates 2022/05/31-2021/12/09 (inclusive), **279 musculoskeletal** phenomena were reported as free text (making up 13% of all phenomena reported as free text).

65% were reported by women and 35% were reported by men.

261 cases (93%) of the phenomena were reported by adults, 8 cases (3%) by teenagers (12-17 years) and 10 cases (4%) were reported by children (5-11 years).

The distribution according to vaccine doses was 19% (44 cases) near the first dose, 24% (56 cases) near the second dose, 45% (104 cases) near the third dose and 12% (27 cases) near the fourth dose. **Diagram 28** : Distribution Musculoskeletal disorders reported as free text are classified according to MedDRA



In free text reports on musculoskeletal problems, 79 out of 279% (28) reports contained information on the duration of the phenomenon.

In 55% (70) cases out of the 79, a phenomenon was reported that lasted for more than two weeks.



Figure 29 : Distribution of duration of musculoskeletal symptoms that lasted more than two weeks reported as free text



In the age group of 5-11 years there was one report of between two weeks and a month of pain in the hand and one report with a duration of between 1-6 months of limb pain.

In the age group 12-17 years there were two reports with a duration of 6-12 months, one of bone pain and one of muscle and leg pain.

In adults, about 57% (29 cases) of the common symptoms, which were reported to last for more than two weeks, were classified as pain in a limb or joint, about 20% (10 cases) were classified as muscle pain, another 8% were classified as muscle spasms (4 cases) and - The remaining 16% (8 cases) were divided between neck pain, non-specific damage to the joint, swelling of the joint, bone pain

and more.



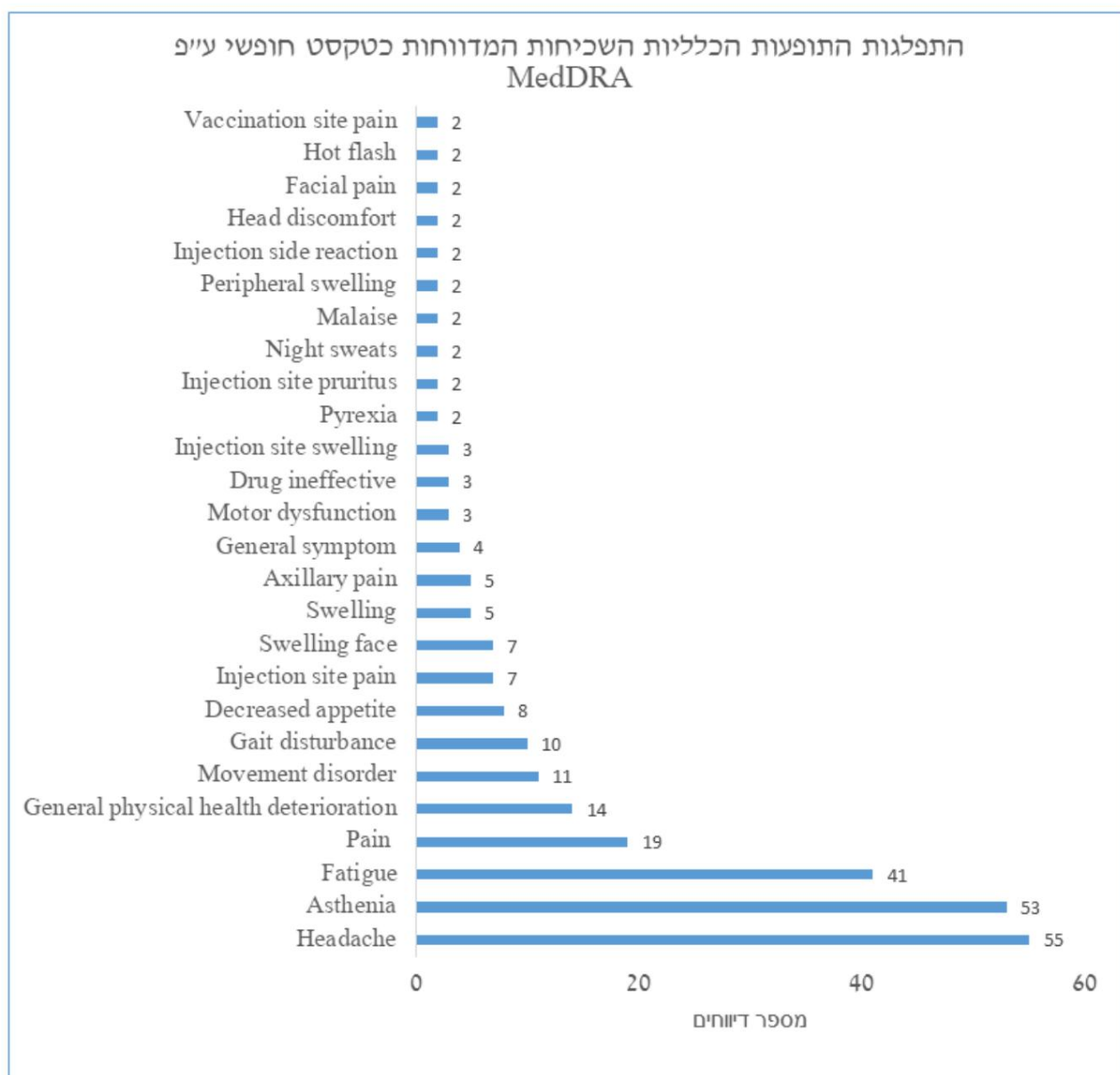
General phenomena reported as free text

Between the dates 2022/05/31-2021/12/09 (inclusive), **295 general** phenomena were reported as free text (making up 14% of all phenomena reported as free text).

65% were reported by women and 35% were reported by men.

272 reports (92%) of the phenomena were reported by adults, 11 reports (4%) by teenagers (12-17 years) and 12 reports (4%) were reported by children (5-11 years).

The distribution according to vaccine doses was 19% (42 reports) near the first dose, 26% (60 reports) near the second dose, 91% (40 reports) near the third dose, and 15% (35 reports) near the fourth dose. **Chart 30** : Distribution of symptoms Generalities reported as free text are classified according to MedDRA

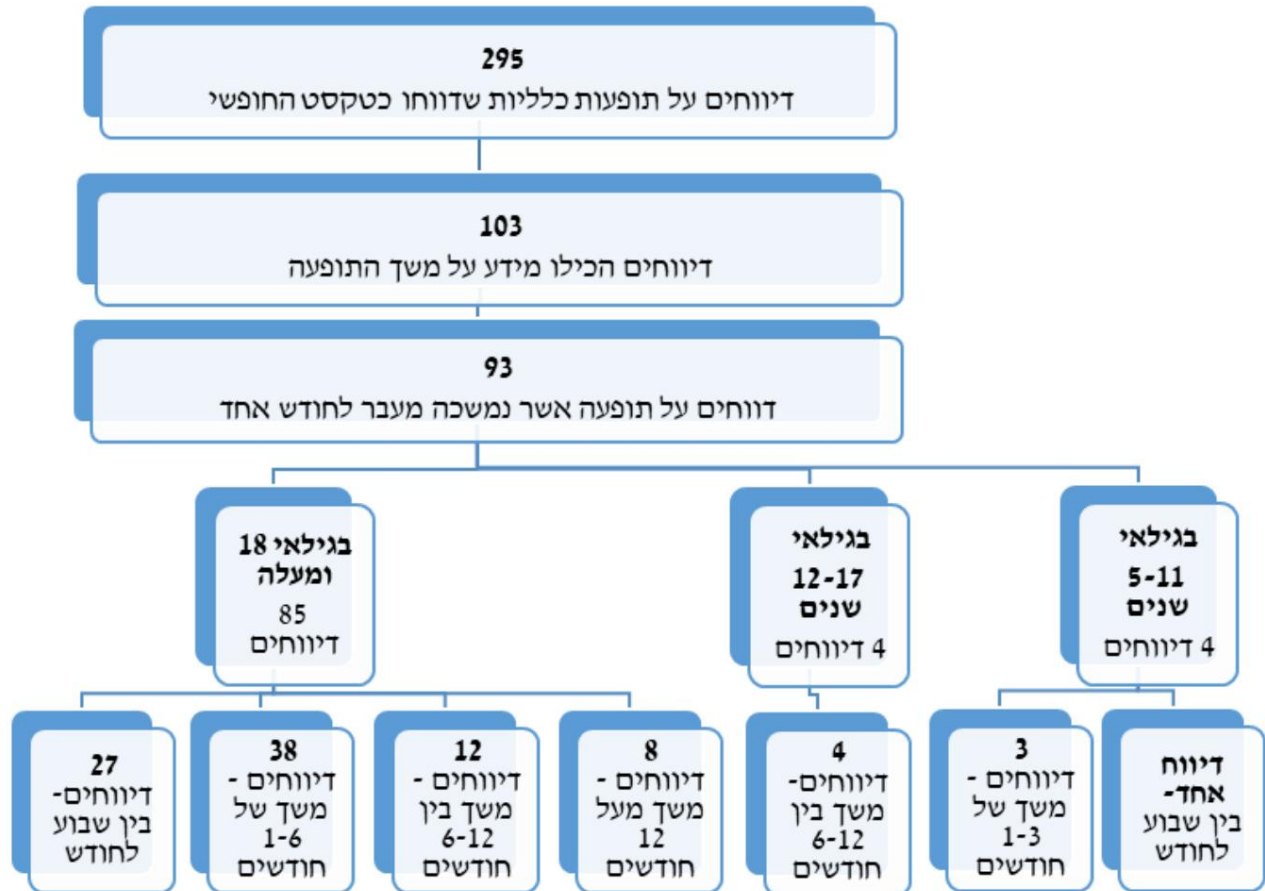


In free text reports on general phenomena, 103 out of 295 (35%) reports contained information on the duration of the phenomenon.

In 93% (90 cases out of the 103), a phenomenon was reported that lasted for more than a week.



Figure 31 : Distribution of duration of general phenomena that lasted more than a week, reported as free text



In the age group of 5-11 years , one phenomenon was reported on a headache that lasted between a week and a month and three individual reports on phenomena that lasted 1-3 months: weakness, fatigue and falls.

In the age group 12-17 years there were 4 reports of symptoms that lasted 6-12 months: weakness, fatigue, headaches and a general decrease in function.

In adults, about 55% of the common symptoms (47 cases), for which a duration of more than a week was reported, were classified as weakness, fatigue, or headache. About 19% (16 cases) were classified as pain, a general decrease in physical function, and impaired mobility. The remaining 25% (22 cases) were distributed among a variety of phenomena such as feeling sick, falls, swelling, hot flashes and more.



Digestive, renal and urinary systems reported as free text

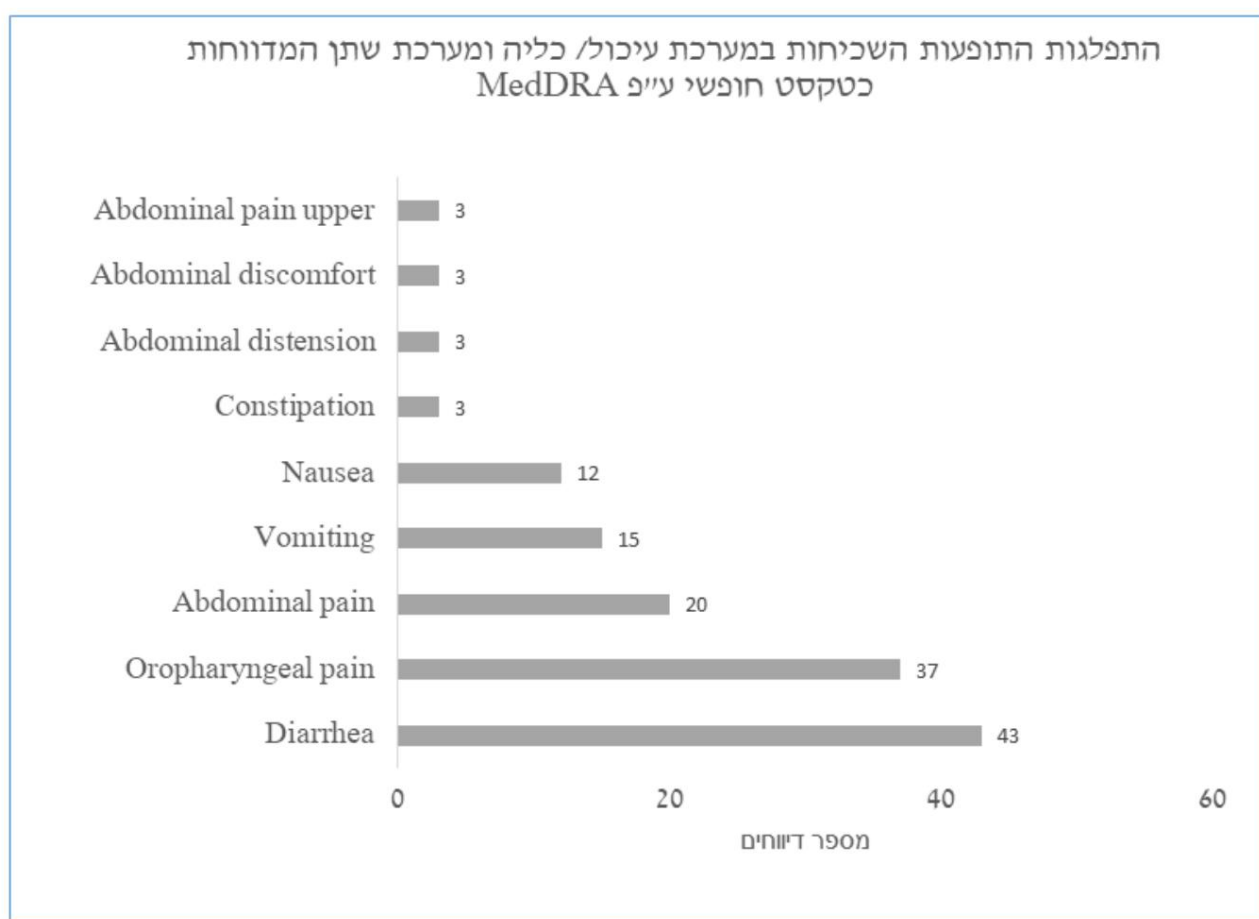
Between the dates 2022/05/31-2021/12/09 (inclusive), **192 phenomena in the digestive system, the kidney and the urine** were reported as free text (making up 9% of all the phenomena reported as free text).

60% were reported by women and 40% were reported by men.

76% (146) of the symptoms were reported by adults, 9% (5) by teenagers (12-17 years) and 37% (19%) reported by children (5-11 years). The distribution according to vaccine doses was 20% near the first dose (31 cases), 22% near the second dose (35).

cases), 38% near the third dose (60 cases) and 20% near the fourth dose (32 cases). **Chart 32** : Distribution of digestive, kidney and urinary system symptoms reported as free text classified according to

MedDRA



In free text reports about problems with the digestive system, kidney and urine, 23 reports out of 192 (12%) contained information about the duration of the phenomenon. In 18% (78) cases out of the 23, a phenomenon was reported that lasted for more than one week. Of the phenomena that can be determined to have lasted for over a week, 22% (4) of the reports indicated a duration of between a week and a month, over 44% (8) of the reports indicated a duration of 1-6 months, 28% (5) (other of the reports indicated a duration of between 6-12 months

And about 6% (1) more of the reports indicated a duration exceeding 12 months. **In**

the 5-11 age group there was one report of urinary frequency, a phenomenon that lasted between a week and a month.

In the age group 12-17 years there was one report of nausea lasting 6-12 months.

In **adults**, 8 cases of the most common gastrointestinal/kidney and urinary system symptoms, which were reported to last over a week, were classified as abdominal pain or diarrhea, 1 more were classified as nausea, the remaining 7 cases were distributed among a variety of symptoms such as excessive urination, constipation, nausea, dry mouth and more .



Figure 33 : Distribution of the duration of digestive, kidney and urinary system symptoms that lasted more than a week and are reported as text free



Summary

As mentioned, the reported phenomena are known phenomena in the professional literature and were also found in the previous reports of the Ministry of Health, and it was not observed as a new phenomenon (a new signal).

The Ministry of Health sees great importance in continuously monitoring the safety of vaccines in the State of Israel, analyzing the data, and providing complete and reliable information to the public in a transparent manner. The new system created for the purpose of receiving reports from the public was found to be effective and continues to be used by the office in the Corona vaccination campaign and other vaccination campaigns.

The office is committed to continuing to examine ways to improve the ongoing dialogue with the public, including continuous improvement of the reporting form in order to make data collection and analysis more accurate for the public.