

Report of the State Comptroller of Israel | May 2024

A Collection of Reports Concerning the Coronavirus

Vaccination of the Population Against the Coronavirus



# Vaccination of the Population Against the **Coronavirus**

#### **Background**

One of the primary ways to eradicate epidemics is through vaccination. Developing the vaccine against the Coronavirus and getting its approval quickly was crucial in coping with the Covid-19 pandemic. The development process of a routine vaccine is lengthy and can last 10-15 years, while its approval process can last about eight months or even more. Conversely, developing vaccines against Covid-19 took 12-24 months, and in December 2020, the vaccine manufacturers received a special emergency authorization (EUA – Emergency Use Authorization) from the American Food and Drug Administration (FDA).

The outbreak of the Covid-19 pandemic was a rare and unusual event with unique characteristics that occurred under conditions of uncertainty and required dynamic management and the use of non-routine work methods suitable for emergencies and allowing quick responses to the changing reality. In Israel, the vaccination campaign against the Coronavirus began in December 2020, and Israel was one of the first countries in the world to vaccinate against the virus. In December 2020, the first vaccine dose was given to the entire elderly population (over 60), medical staff, populations at risk, and others. Following that, with the receipt of the appropriate approvals from the Ministry of Health, the vaccine was also given to people of younger ages: in January 2021, vaccination began for those aged 16 and over; In June 2021, for ages 12-15; In November 2021 for ages 5-11. With the persistence of the pandemic, it was found that its effectiveness decreased after about six months from administering the second vaccine dose. Israel was the first country in the world to vaccinate with a third vaccination dose ("booster") - from the end of July 2021. From the beginning of the vaccination campaign at the end of December 2020 until the end of March 2021, within about three months, over half of the population in Israel aged 16 and over was vaccinated with two vaccination doses. By January 2023, about 82% of the population aged 16 and over had been vaccinated. From the beginning of the vaccination campaign until the audit end date (November 2022), the state invested about NIS 3.9 billion in the procurement of vaccines.

Given the significant importance of vaccinating the population against the Coronavirus during the Covid-19 pandemic, the state increased vaccination rates to minimize the spread of the pandemic as much as possible. These actions, led by the Ministry of Health, played a key role in saving the lives of thousands of Israelis. Among the factors that may affect the rate of vaccination in the population is the public's trust in the health system - including in the process of formulating the recommendations of the Epidemic Management Team (EMT), the concern



of the side effects of the Covid-19 vaccine and the false information that has been disseminated on the Covid-19 vaccines.

This report, conducted before the outbreak of the 'Swords of Iron' war, deals with a specific area – the population vaccination against an epidemic. With a forward-looking view, the report focuses on the lessons to be learned from the vaccination process for the state's effective coping with extreme health events. Still, lessons can also be learned from it to prepare for coping with emergency events in general.

#### **Key Figures**

#### 86%

of the population over the age of 12 were vaccinated with the first vaccine dose, compared to 61% who were vaccinated with the third vaccine dose (as of January 2023)

## 65.2%

of the population received two vaccination doses, compared to 72.9% in the European Union and compared to a world average of 63% (as of November 2022)

# 59.6%

of the population received the third vaccination dose, compared to 60.6% in the European Union and compared to a world average of 33% (as of November 2022)

## 60%-62%

the rate of those who receive the third vaccination dose among those aged 60 and over in the local authorities examined in the Arab and ultra-Orthodox sectors, compared to 86% in the general population

#### 25%

of the participants in the survey conducted by the Government Advertising Agency (GAA) in July 2022 stated that none of the bodies they were asked about in the survey (including experts in the health system, the government, and the Home Front Command) were perceived reliable for issuing instructions

### 31%

of the participants in the GAA survey in December 2021 stated that side effects they or others experienced were an obstacle to their getting vaccinated with the second and third doses of the vaccine

# 33,000

anonymous reports of side effects were received from the general public in 2021, which the Ministry of Health did not process nor analyze

## 18%

the side effects report rate that occurred close to receiving Covid-19 vaccinations, which were recorded in the Ministry of Health's systems, out of the reports submitted to the Ministry by medical sources (about 62,000 out of about 354,200 reports)

## 101 members

of the Epidemic Management Team (EMT) during the Covid-19 pandemic, with the right to vote. In comparison, in the United States, the **Advisory Committee** on Vaccines numbered 57 members, with 20 of them having the right to vote, and in Australia, there were 23 members, with 15 of them having the right to vote

### about 47%

of the EMT members (48 out of 101 members) hold positions in the Ministry of Health and may participate in votes on the Ministry of Health's recommendations

# 77%

the parents' rate who were exposed to claims regarding the damage that childhood vaccinations in general (and not just the Covid-19 vaccine) may cause, as noted in the GAA survey from August 2022

### about **57%**

of the parents who participated in the GAA survey from August 2022 expressed concern of permanent damage to their children as a result of vaccinations in general, compared to about 46% of parents in 2016



#### **Audit Actions**



From November 2021 to November 2022, the State Comptroller's Office examined the health system's operations in vaccinating the population against the Coronavirus. The audit included the population rate vaccinated; The EMT's activity, and in particular the vaccination of the population1; The gathering of data and information on side effects from the medical teams in the Health Maintenance Organizations (HMOs) and hospitals, as well as from the general public and the handling of these reports; The Ministry of Health investigating the reports; And the National Information Directorate and the Ministry of Health's contending with false information ('fake news') disseminated about the Covid-19 vaccines. The audit was conducted at the Ministry of Health, the hospitals, the HMO's, and the National Information Directorate at the Prime Minister's Office. Completion examinations were carried out until January 2023 at the Ministry of Finance and the IDF.

## **Key Findings**





The Vaccination Rate Among the General Population — from the beginning of the vaccination campaign in December 2020, the rate of people receiving two vaccination doses in Israel increased sharply until the end of March 2021, when the vaccination rate reached 50.9% of the general population. This compared to the European Union, with a 5.1% vaccination rate at the same time, and a world average of 1.8%. Israel was the second country in vaccination rates (after Gibraltar). However, the rate of people vaccinated in Israel began to decline from that date. The vaccination rate in Israel by the end of November 2022 of those receiving two vaccination doses was 65.2%, compared to 72.9% in the European Union and a global average of 63%. By the end of November 2022, over 80% of the population in Canada and Italy had been vaccinated with two doses of the vaccine. A similar trend was also raised about the third vaccine in Israel, which was the first to vaccinate with this vaccine, there was a sharp increase in the rate of those vaccinated when the administration of the third vaccine dose began. At the end of November 2022, the vaccination rate in Israel with the third dose was 59.6%, compared to 60.6% in the European Union and a world average of 33%. By that

The audit of the EMT's activity, and in particular with regard to the vaccination of the population, ended in November 2022

time, over 75% of the population had been vaccinated in Canada, Germany, and Italy with the third dose of the vaccine.

The Vaccination Rate Amongst the Population Aged 60 and Over, and Particularly in the Ultra-Orthodox and Arab Society – those 60 years old and over were defined as a population at risk, where the rates of severe morbidity and mortality were high. The rate of people aged 60 and over, vaccinated with the first vaccination dose out of this age group was 97%, and the rate of people vaccinated from the Arab and ultra-Orthodox sectors in the local authorities examined was 88% and 84%, respectively. With the administration of the additional doses of the vaccine, there was a significant decrease in the willingness of those aged 60 and over to be vaccinated, and with the third dose of vaccine, it occurred mainly in the local authorities examined in the Arab and ultra-Orthodox sectors. Amongst the general population, there was a drop of eight percentage points, while in local authorities in the Arab sector, there was a drop of 22 percentage points, and in local authorities in the ultra-orthodox sector, there was a drop of 14 percentage points. Furthermore, the gap between the rate of those vaccinated in the different populations grew higher between the first vaccination dose and the fourth vaccination dose - in the first vaccination, the gap between the general population and between the local authorities examined in Arab and ultra-Orthodox sectors was 9 and 13 percentage points, respectively; This gap grew until it reached 34 and 26 percentage points, respectively, with the fourth dose of vaccine.

#### **Gathering Data and Information About the Side Effects of** the Covid-19 Vaccine

The Ministry of Health gathered data on the side effects from several reporting channels, including from the vaccine manufacturers, as well as within the framework of the information sharing agreement with Pfizer Inc.; From medical entities including the HMOs, the hospitals, Magen David Adom and the IDF; From the general public; From the international medical community; From Israeli and international scientific studies; And from surveys conducted. The medical entities transferred most of the reports through an interface with the Ministry's computerized system – the Nahlieli system<sup>2</sup> (the Ministry of Health's vaccination database). Furthermore, the Ministry of Health also investigated the side effects of the vaccines through scientific publications based on Big Data gathered by Israeli and international authorities, as well as through two surveys carried out by the Ministry of Health on vaccinations and additional surveys carried out by the HMOs.

Nahlieli - Israeli National Vaccination Management.



# Below are the Deficiencies Regarding the Gathering of Reports on Side Effects in Israel:

- Gathering Reports on the Side Effects from the Medical Teams in the HMOs and Hospitals the Ministry of Health's computerized systems did not record about 82% of the information of about 354,200 reports that were forwarded to it by medical sources, due to technical malfunctions in the interface with the Nahlieli system:
  - Clalit Health Services (Clalit) although the Clalit HMO insures over half of the country's population (about 51%), which requires special attention to the work interfaces between the HMO and the Ministry of Health, the Ministry of Health and Clalit did not regulate the transfer of reports from Clalit and their receipt in full by the Ministry. As a result, about 279,300 reports from the Clalit indicated that it had been transferred to the Ministry (the majority of the HMOs' reports about 85%) were not recorded by the Ministry of Health's systems. Until December 2023, there was still no agreement between the Ministry of Health and Clalit regarding the number of reports that Clalit transferred to the Ministry. The gap between the Ministry's position on the number of reports on side effects received from Clalit (about 245,600) and Clalit's position on the number of reports it forwarded to the Ministry (about 289,800) is about 44,200 reports. Moreover, the Ministry of Health only recorded 185 out of 1,000 (18.5%) reports from the Clalit hospitals in its systems.
  - Leumit Health Services (Leumit) from December 2020 to May 2022, Leumit did not report any side effects from the vaccine to the Ministry of Health through the Nahlieli interface. Following the audit's question on the subject in May 2022, Leumit began to transmit for the first time the 89 reports it had for the entire period. As for the Ministry of Health, it did not turn to Leumit during the period above to set up the interface with Nahlieli and deliver reports. The Ministry of Health and Leumit did not regulate the transfer of the reports on the side effects to the Ministry of Health through the Nahlieli interface throughout the entire period.
  - Maccabi Health Services (Maccabi) in the first year the population was vaccinated against the Coronavirus (from December 2020 to December 2021) Maccabi did not forward reports of side effects to the Ministry of Health. Due to a technical fault in Maccabi's interface, in its first transfer in December 2021, about 3,000 reports were not recorded by the Ministry of Health, and the Ministry returned these reports with instructions to correct them. However, Maccabi did not return the corrected reports to the Ministry, and the Ministry did not demand to receive them.

The Ministry of Health established a computerized tool (interface with Nahlieli) to gather information from medical sources about the side effects; however, the tool only partially

contributed to this goal. Hence, the Ministry of Health formed the situation report of the side effects and the safety of the vaccines, based on about 55,000 reports received and recorded from medical sources and the reports received from the additional channels listed above.

- Gathering Direct Reports About Side Effects from the Public the Ministry of Health did not process 33,000 reports it received from the general public about side effects in 2021 and did not analyze them. Furthermore, due to the shortcoming of anonymous reporting, the Ministry of Health could not go back to those reporting to verify data or obtain details. Even in cases where the informants left contact information, it was impossible to get back to them to confirm the reporting data or to obtain additional information. The limited workforce available to the Epidemiology Division at the Ministry of Health did not allow the identification and tracking of reports in which identifying details were provided.
- Data Management in the Epidemiology Division at the Ministry of Health the concentration of data on side effects was done by the Ministry of Health on a collation file of side effects, using electronic worksheets (Excel files) and not through a dedicated system that orderly manages the data. The files are stored on the Ministry of Health's network and are accessible to authorized persons as determined by the Ministry. The access of those authorized to the file is direct, and their identification is not required, not through a password to the file, and even more so, not through multi-factor authentication. The actions performed on the files were not documented or recorded in a particular file (Log file). Therefore, it is impossible to track the identity of the authorized and unauthorized who have performed actions on the files and to trace intentional errors or vulnerabilities. In other words, even though it is a file that contains sensitive and essential data, its management method does not allow for the detection of irregular actions performed in it or the provision of alerts about them. Hence, it is impossible to intelligently identify a suspicion of a significant side effect worthy of examination from among all the reports and issuing warnings about them - a 'red flag' mechanism. Due to the shortage of personnel in the Epidemiology Division, the management and updating of the Excel files are done by limited personnel.
- Investigation of the Information from Medical Entities (HMOs, Hospitals, the IDF, Vaccination Complexes, and Other Medical Institutions such as Geriatric and Psychiatric Hospitals) Regarding the Vaccine's Side Effects - most of about 55,000 reports that the Ministry received after data cleansing from medical entities (mainly the medical staff at the HMOs and hospitals) was about minor symptoms, such as chills and pain at the injection site, but there were also more significant symptoms that required investigation such as reports of menstrual disorders among women (about 200 reports) that were not investigated close to the actual reporting date. In practice, the Ministry investigated about 1,000 side effects, about a quarter of which (275 cases) were myocarditis and pericarditis (inflammation of the pericardium), most involving



patient hospitalization. Moreover, five of the 11 general-government hospitals did not receive requests for feedback from the Ministry of Health. With three others, feedback was given in a few cases, or feedback was given, especially concerning myocarditis. In conclusion that the investigation done by the Ministry was incomplete.

- **The Public's Trust in Public Bodies Regarding the Issuing of the Covid-19 Guidelines** according to the Government Advertising Agency in July 2022, the Ministry of Health experts are perceived as the most reliable to the survey participants. In July 2022, about a fifth to a third of the participants among the various populations considered the Ministry of Health experts as reliable for the issue of instructions during the Covid-19 pandemic. However, 25% of all the survey participants stated in July 2022 that none of the bodies they were asked about were considered reliable for issuing instructions. According to a breakdown by population, among the general population 24%, in the ultra-Orthodox sector, this rate was exceptionally high, at 37%, and in the Arab sector, the rate was 21%. Furthermore, only 5% of all survey participants stated that they perceive the government as reliable for passing instructions. To preserve trust in the Ministry of Health experts, ensuring that the decision-making procedures, in general, and on the subject of vaccinations in particular, are perceived by the public as reliable, to the extent possible, is critical.
- The Composition of the Epidemic Management Team (EMT) and its Eligible Voters the EMT is the official advisory body to the Director General of the Ministry of Health on the outbreaks of epidemics and their treatment. In February 2021, the members of the Advisory Committee for Covid-19 Vaccines were integrated into the EMT, and the EMT's composition (the consolidated team) included 101 members, all considered eligible voters. In comparison, a similar advisory committee in the United States has 57 members, with 20 of them having the right to vote, and an advisory committee in Australia comprised 23 members, 15 of whom have the right to vote. Almost all the members of the advisory committees in the United States and in Australia who are eligible voters are health experts, and in the EMT in Israel, about a third of those who have such right to vote are not health experts. Moreover, about half (about 47%) of the EMT members (the consolidated team) (48 members out of the 101 members) hold positions in the Ministry of Health and may vote on the Ministry of Health's recommendations.
- The Number of Participants in the EMT Deliberations and the Broadcast of the EMT Deliberations the EMT meetings (the consolidated team) were attended by most of the members, many dozens of participants. These deliberations ranged from 154 minutes to 200 minutes, so the possible duration of talking time for each participant in the deliberations presented ranged between one and a half to two and a half minutes per participant. Such a large number of participants in the EMT deliberations (the consolidated team) may hinder holding in-depth discussions among all the participants.

Furthermore, the publicity of the EMT deliberations was not regulated before and during the Covid-19 pandemic. At the beginning of November 2021, an open public deliberation of the EMT (the consolidated team) was held on the vaccination of children aged 5 to 11; The deliberations were broadcast live on the internet. Apart from this discussion, the other 113 EMT deliberations were not broadcast live. For comparison, in the United States, the CDC Advisory Committee hold its deliberations in public (live).

Regulating the EMT's Activity - the EMT's operation procedure does not fully regulate its activity. A comparison between the EMT's operation procedure and the operation procedure of the CDC Advisory Committee in the United States indicates that, except for the role of the committee, all the other components that were examined (the term of office of the voting members, the composition of the committee and the voting rights of its members, the structure of the working groups, the method for examining the information presented before the committee, the publicity of the discussions and the procedure for selecting the topics for the committee's deliberations) are regulated in the CDC Advisory Committee operation procedure, but are not regulated, or partially regulated, in the EMT's operation procedure. These components are also not regulated in the updated draft of the procedure from 2022.

#### Contending with False Information ('fake news') Regarding Covid-19 vaccines

- the Ministry of Health and the National Information Directorate for Combating Covid-19 did not explain to the public how to contend with false information on the Coronavirus, especially when it comes to Covid-19 vaccines. Apart from one informational campaign that dealt with responsible consumption of information, they did not conduct awareness campaigns on identifying false information and the possible ways to deal with it, did not distribute guidelines to the public on the issue, and did not publish the available reporting tools on false information. Furthermore, the National Information Directorate and the Ministry of Health did not formulate a strategy for dealing with false information and did not operate an orderly and systematic mechanism for handling it. They did not develop an orderly and structured plan of action for dealing with false information, including setting guidelines for handling such information and defining all the factors that should be involved in handling it; there was no orderly mechanism for locating the false information, managing its registration, describing the threat posed by it and the level of its possible impact on the public, and monitoring the handling of any false information found.

The Effect of the Covid-19 Pandemic on Public Perspective Regarding Routine **Vaccinations** – in 2017, during routine vaccinations, the rate of vaccinated children in Israel was one of the highest in the world. For example, about 99% of toddlers in Israel were vaccinated with the first dose against measles, mumps, and rubella (MMR), and about 99% completed four polio vaccines (the inactivated vaccine). A GAA survey from August 2022 regarding the attitudes and perceptions of parents on the vaccinations for children, and in particular a comparison between the attitudes of parents in 2016 and



the attitudes of parents in 2022 (with the persistence of the Covid-19 pandemic), indicate that in 2022 the exposure rate of the parents who participated in the survey to claims regarding the harm that vaccines may cause was 18 percentage points higher than in 2016 (about 59% in 2016, compared to about 77% in 2022). This increase may affect the public's willingness to be vaccinated. Indeed, it was raised that there was a noticeable decrease in the number of vaccinated children in these years.



The Operation of the Health System During the Covid-19 Pandemic – the Ministry of Health, which was required to manage the complex Covid-19 pandemic, worked diligently and with full commitment and dedication to find diverse solutions to the changing needs. The health system treated thousands of Covid-19 patients and encouraged the population to be vaccinated.

An In-Depth Investigation of Myocarditis - the Ministry of Health initiated the gathering and investigation of myocarditis reports. Israel was the first country in the world to diagnose the link between myocarditis and the Covid-19 vaccines. Furthermore, Israel presented the findings of active monitoring to the global vaccine manufacturers and health authorities worldwide, leading to their decision to investigate the phenomenon in depth and examine the issue, according to their data.

The Activity of the EMT and the Ministry of Health Employees' Involved in Gathering Reports on the Side Effects and Their Investigation — their activity in an event with national ramifications was carried out in real-time while dedicating time and efforts, in addition to fulfilling their routine duties.

#### **Key Recommendations**



控 It is recommended that the Ministry regulate an intelligent system to manage, monitor, and control the reports on the side effects received from various sources – the community, hospitals, and the public. It is recommended that the system operate routinely and, in an emergency - for example, during the outbreak of a pandemic (a widespread epidemic), that it reliably and efficiently manages the reports, thus enabling an analysis of the data received and extracting insights from there. It is recommended that within the framework of the intelligent system, components for the management of reports in real-time will be included, among other things, through an alert of multiple reports regarding a particular phenomenon ('red flags'), and that it will be possible to monitor changes made to the data. In a forward-looking view regarding monitoring vaccines that will be developed and provided to the public, the Ministry of Health should examine whether the resources

allocated to monitoring side effects, particularly the workforce, are sufficient to ensure monitoring as required.



To benefit from the hundreds of thousands of reports gathered by the HMOs and to enhance public trust, it is recommended that the Ministry of Health enter the missing data into its systems, analyze the complete data, and cooperate with the HMOs to complete the definition of the interface with Nahlieli; It is further recommended that the Ministry examine the number of side effects reported by the medical institutions compared to the number of vaccinated people in each institution and accordingly instruct the relevant institutions to transmit data on side effects as required. It is additionally recommended that the Ministry of Health can return to the reports it received from the public. Thus, the Ministry can learn more about the frequency of side effects, compare them with data from around the world, and identify the side effects that require addressing.



It is recommended that the Ministry of Health examine the composition of the EMT members, particularly the identity of those eligible to vote and their expertise. It is further recommended that the Ministry of Health expand and update the EMT's operation procedure so that it includes reference to other significant aspects of the operation of an advisory committee while adjusting the operation procedure to the State of Israel's needs, providing the required flexibility of operation and that it consider regulating the public nature of the EMT deliberations. It is further recommended that the Ministry of Health establish in the operation procedure the mechanism for determining the optimal composition of participants in the EMT deliberations so that it is adapted to the issues expected to be discussed and their complexity, similar to what is customary in comparable bodies worldwide.



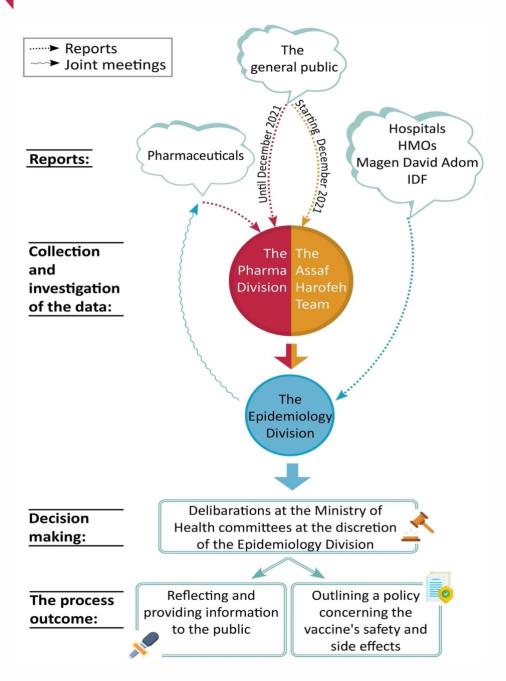
It is recommended that the National Information Directorate formulate a strategy and operational doctrine to combat the spread of false information in civil emergencies such as a pandemic outbreak and share this with relevant government ministries, particularly the Ministry of Health, and other relevant parties involved in preparing for civil emergencies. It is further recommended that it define the resources and the budgetary sources required for this. It is recommended that the National Information Directorate consider including in its plan the establishment of a headquarters for the coordination of national information activities, the establishment of dedicated action teams for civil matters, which will consist of representatives from the relevant government ministries (such as the Ministry of Health) and other relevant factors. These action teams will, among other things, deal with false information. Alternatively, it is recommended to consider operating a separate headquarters for monitoring and rebutting false information in the civil field.



Given the downward trend in the rate of children vaccinated with routine vaccines that followed the Covid-19 pandemic, it is recommended that the Ministry of Health restore and maintain the high vaccination rate of children as it was on the eve of the crisis, considering the parents concern of the side effects of vaccines on children.

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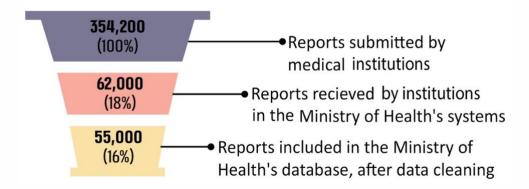
The Ministry of Health's Reporting, Gathering, and Investigation Channels of the Side Effects



According to data from the Ministry of Health, processed by the Office of the State Comptroller.



#### Medical Institutions' Reports to the Ministry of Health on **Side Effects**



According to data from the Ministry of Health and medical sources regarding reports from the HMOs, hospitals, the IDF, vaccination complexes, and other medical institutions (such as geriatric hospitals and psychiatric hospitals), processed by the Office of the State Comptroller.

The diagram indicates that the Ministry of Health's computerized systems did not record about 82% of the information of about 354,200 reports forwarded by medical sources (62,000 were received, 18% of the scope of reports submitted by the medical sources). About 55,000 reports (about 16% of all) were recorded and their dada cleansed in the Ministry of Health's collation file of side effects from the beginning of the vaccination campaign until the audit end date. It should be noted that about 55,000 reports received by the Ministry, concerned mild symptoms, such as chills and pain at the injection site.



## **Summary**

Vaccinating the population against the Coronavirus was one of the main tools to cope with the virus, and Israel, led by the Ministry of Health, was one of the first countries in the world to vaccinate against it, significantly contributing to saving the lives of thousands of Israelis. The implementation of the vaccination campaign by the health system, especially in the first months of the campaign, prevented harm to public health, and it is even accurate to say that it saved the lives of many, especially those who were defined as a population at risk - the elderly and those suffering from serious underlying diseases. It also ensured the return of the economy to full activity. The public's trust in the health system (including in the process of formulating the recommendations of the Epidemic Management Team), the concern about the side effects of the Covid-19 vaccine, and the false information that was spread about the Covid-19 vaccines - all of these were some of the factors that could affect the vaccination of the population. Increasing public trust in the health system; Learning lessons from the Covid-19 pandemic regarding the vaccination of the population, and particularly the formulation of a strategy and plan to combat false information; And future preparation to contend with pandemic events - all of these are essential aspects in the Ministry of Health's ability to ensure that the citizens of the State of Israel receive the necessary vaccines to protect their health.