The Israeli Public Emergency Council For Covid-19 Crisis

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Position Paper – COVID-19 Vaccine for Children

Summary

1. The US Food and Drug Administration (FDA) has granted an emergency use authorization for the Pfizer vaccine against COVID-19 in children. This situation necessitates an in-depth discussion of the possible benefits of the vaccine vs. the possible risks, as well as an examination of the question of the emergency situation that has been invoked to justify this authorization.
2. The role of the vaccine is presented, sometimes in scientific publications and sometimes in the media, as having 3 beneficial components: reducing severe morbidity and mortality in children, prevention of the late side effects of the virus (PIMS and "Long COVID"), and environmental protection through the prevention of infection and the creation of herd immunity.
3. Severe morbidity and mortality in children due to COVID-19 is rare, and in healthy children without risk factors, it is even rarer. **The risk of severe illness as a result of COVID in healthy children is no different from the risk of severe disease from normal winter viruses**, and is in fact lower as a result of COVID-19 (including the Delta variant).
4. **There is no evidence that the vaccine is effective in preventing long-term COVID-19-related phenomena (PIMS or Long COVID)**, as according to scientific publications, these phenomena may occur even after asymptomatic infection with the disease (keeping in mind that the ability of the vaccine to prevent asymptomatic infection has not been tested in Pfizer studies, and its efficacy in this regard appears to be low and short lived). In addition, there are case-studies, in both the scientific literature and the media, of the **appearance of a PIMS-like syndrome after vaccination (MIS-V)**, as well as cases of PIMS that appeared after infection with COVID-19 also among vaccinated individuals.
5. Data from vaccination campaigns worldwide so far indicate that **the vaccine is ineffective in creating herd immunity**, and that its ability to reduce its spread is very limited and short-lived.
6. The vaccine against COVID-19 causes various side effects, most of them mild and a few of them severe, but at rates that were not observed in previous vaccinations. Beyond that, **there are still significant knowledge gaps regarding the side effects of the vaccine**, and especially regarding long-term side effects.
7. In light of the balance of benefits and risks, and especially in light of the rarity of serious illness in children at this time and in light of existing information regarding the side effects of the vaccine, **the Council sees no room for a sweeping vaccination of all children.**
   However, the council **recommends encouraging vaccination in children who are in risk groups**: these children constitute a small group among children but constitute a significant percentage of the serious COVID-19 morbidity in children.
   In addition, the Council reiterates the importance of the vaccine in older at-risk populations, in light of ample evidence of the benefits of the vaccine in preventing severe COVID-19 illness in that group. Vaccinating at-risk populations will significantly reduce severe illness and death from COVID-19, even in the case of additional pandemic waves, thus preventing excessive burdens on the medical system.
8. **The Council opposes any means of pressure, sanctions or incentives (including the green pass)**, which are designed to lead individuals to make medical decisions based on considerations that are not purely medical.
9. Despite the disappointment with the vaccine's inability to prevent the spread of the virus, Israel and the world must readjust the expectations and goals associated with the vaccine and **adopt a policy that internalizes the knowledge that COVID-19 will accompany us for years to come**, and should be approached—epidemiologically, medically and socially—as we treat other viral diseases.

   The council has a coherent plan for managing the COVID-19 crisis, which approaches public health in the broadest sense of the word.

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Introduction

The US Food and Drug Administration (FDA) has recently issued a permit for emergency use of the Pfizer vaccine against COVID-19 in children aged 5-11. This approval is in addition to the emergency approval given earlier for children aged 12-15, and the approval given to those aged 16 and over. Related scientific studies, as well as the media coverage, have brought to the public a great deal of overwhelming and sometimes contradictory information. Beyond that, in addition to medical considerations according to which a person should decide whether to vaccinate their children, additional technical considerations concerning the "green pass" have been introduced—so that people are pushed in an unprecedented way to perform a medical act out of direct and indirect government pressure. In this document, we will examine the data relevant to the issue of vaccinating children in order to make the most up-to-date and balanced information accessible. The document will review the risks to children from COVID-19 and examine the significance of the vaccine in dealing with them.

We will try to answer 4 basic questions that need to be answered when making a decision to vaccinate a child against COVID-19:

1. Does the vaccine protect children from COVID-19, especially from serious illness and mortality?

2. Does the vaccine prevent long-term effects of COVID-19, PIMS and Long COVID?

3. Is the vaccine required to protect others ("grandma and grandpa")?

4. Is the vaccine safe for children?

From the answers to these questions, and from the resulting balance of benefits and risks, every citizen will be able to make a decision about their children and to consent—or refuse—from a position of knowledge and informed opinion.

Finally, we will present the recommendation of the Council members regarding the vaccination of children, in light of the available data.

Part 1 - The role of the vaccine in preventing morbidity and mortality in children

One of the important features of the new COVID-19 virus is its variable effect depending on age and on the co-morbidities of the infected person, which are the main risk factors for serious illness and death as a result of the virus [1, 2]. Accordingly, children are in the lowest risk group, due to both their age and the paucity of co-morbidities in the young population. **In fact, the risk of a healthy child to develop severe illness as a result of COVID-19 are at least 1000 times lower than the risk of an individual over the age of 70 to develop severe illness [3-5]**. A comprehensive review published in the leading journal *Nature* based on data from the UK government that included all child deaths in the UK between March 2020 and February 2021 found that in the whole of England, where about 13 million children live, COVID-19 was a contributing factor to the deaths of 25 children. Of these, 15 had severe and life-threatening co-morbidities, and 4 others had chronic diseases. This means that out of 13 million children, 6 healthy children died - 1 out of 2 million healthy children. In addition, the review found that ethnic minorities (of African or Asian descent) were 2.5 times more likely to be represented compared to their part in the population, and were therefore at a higher risk compared to the general population of children [6].

It is known and agreed upon that COVID-19 is essentially not a childhood disease, and that the vast majority of children experience the disease without difficulty. A study conducted in Israel for a year following children's hospitalizations and emergency-room visits found that COVID-19 is usually a mild illness in children, even in children hospitalized due to

COVID-19: Over 80% of the population of children hospitalized due to COVID-19 had a mild illness. All children in this study, including those whose illness was defined as severe, made a full recovery [7].

However, there is no doubt that rarely, there are children who are severely affected by the disease. When dealing with the assessment of severe illness in children, a number of factors must be taken into account. Data varies across the world due to different definitions, sampling methods, and differences in timing in relation to the waves of the virus and the time that passes between the waves. Another factor that complicates the true picture of the morbidity rate, as has already emerged from scientific and media publications in Israel [7-9] and in the world [10], is that **many of the children who were hospitalized and defined as sick with COVID-19 were not hospitalized due to COVID-19**, but COVID-19 was detected in them as a result of a PCR test performed on each patient, regardless of the reason for hospitalization.

A survey of the total hospitalization of children, conducted by the Ministry of Health until the end of October 2021, reported about 200 children who have reached a severe or critical state. In some of them, as explained before, the severe state was not due to COVID-19 [9, 12]. World data, as also presented by Pfizer, show that the significant majority of these children, who end up hospitalized and have severe illness, are children who suffer from co-morbidities [3, 13, 14]. Thus, the chances of a child to become infected and reach a severe condition in Israel are lower than 1 in 15,000 (0.0006%, about 200 out of 3 million children) [5], and if the child is healthy, their chances of developing severe illness are even lower. Beyond that, according to data released by the Ministry of Health during the discussion of the pandemic response team [15], especially in the age group to be vaccinated now, ages 5-11, **the annual risk of severe illness is less than 1:40,000** (42 out of 1.1 million over 18 months), and if it is a child without co-morbidities, the risk is likely significantly lower.

In the United States as well, this segment of the population, aged 5-11, is the most "robust" segment of the population against COVID-19, with low hospitalization rates compared to children at other age groups.

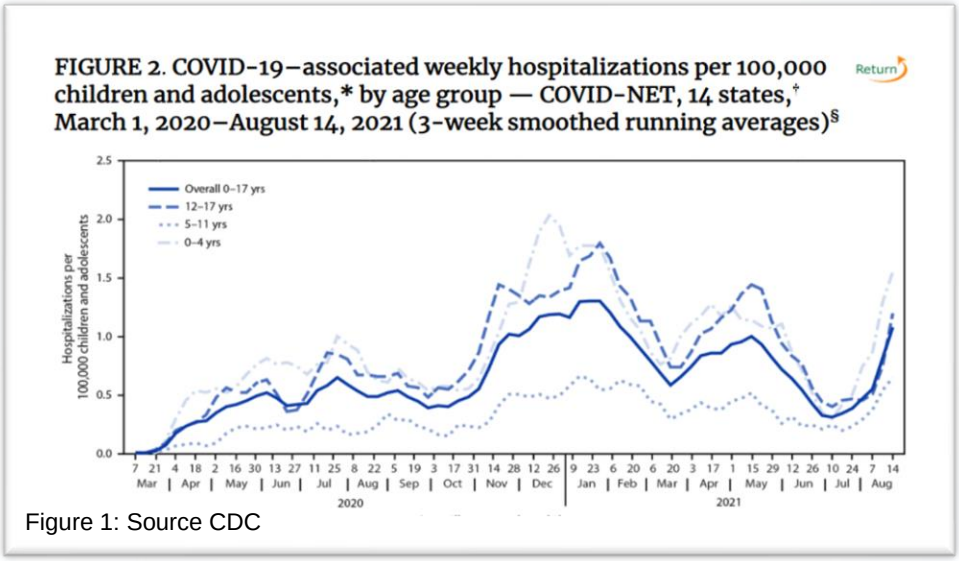

Figure 1: Source CDC

Another broad review, based on data from the UK government, found that the risk of children to be infected and hospitalized in an intensive-care unit due to COVID-19 stood at about 1 in 48,000 children in 2020 [17].

In recent months, there have been many reports in the media of an increase in the risk for children to develop severe illness due to the Delta variant [18]. However, data from Public Health England (PHE) and from the Australian National Centre for Immunisation Research and Surveillance (NCIRS) show that the situation is entirely different—the rates of those requiring emergency rooms and hospitalization are lower among patients infected with the Delta strain compared to those of the British strain [19, 20].

It is thus not surprising that in two studies by the Pfizer company that examined the effect of the vaccine on children (ages 5-11 and 12-15), which together included about 4,500 children, **not a single case of severe illness or death occurred—neither in the vaccinated group nor in the unvaccinated control group**. These two Pfizer studies tested the participating children for COVID-19 only when they complained of relevant symptoms, and therefore the study did not examine the spread of the virus or asymptomatic infection. The study was able to show effectiveness in that a lower number of children developed any symptoms due to infection with COVID-19 after receiving the vaccine. It is likely, even though this was not proven, that the vaccine will reduce direct severe illness in this age group, but in view of the rarity of severe illness

in children, the significance of the vaccine (to what extent and for how long) in preventing severe illness in children is unclear [23].

Due to the media prominence of the COVID-19 pandemic, the public has internalized a harsh picture of the effects of COVID-19 on children. From the objective data, **it is clear that the risk to children from COVID-19 is lower than the risk posed to them by ordinary winter illnesses** [24], which put a much greater burden on the medical system [25], and which claim the lives of about 10 children in Israel every year [26].

Part 2 - The role of the vaccine in preventing long-term complications as a result of infection with COVID-19

Two different syndromes are sometimes described as "post-COVID:" the first is Long COVID, and the second is Pediatric Inflammatory Multisystem Syndrome (PIMS) or, as it is called in the United States, Multisystem Inflammatory Syndrome in Children (MISC).

To understand the meaning and role of the vaccine in these syndromes, some detail about what is known about these syndromes shall be provided:

Long COVID

Most children and adolescents infected with COVID-19 do not experience any symptoms at all or experience only mild symptoms. The natural course of the illness in children and in adults concludes, most often, in **full recovery within 2-6 weeks** [27]. In some cases, patients have reported symptoms that have lasted weeks or months after the end of the illness, a phenomenon that has been called Long COVID (or Post COVID) [28].

The symptoms do not necessarily depend on the severity of the initial disease and may appear even after an asymptomatic infection. Even though these are not life-threatening symptoms, much research is directed to the subject due to possible implications for quality of life. The syndrome, whose definition is still contested, may encompass a wide range of nonspecific symptoms, such as fatigue, headaches, muscle aches, difficulty concentrating, loss of sense of taste or smell, shortness of breath, diarrhea and stomach aches, rashes or fever [30. 31]. The individual suffering that may be caused to patients, sometimes over long periods of time, should not be taken lightly.

At the same time, these conditions are well known in medicine and are not unique to COVID-19. Post-viral syndromes (that is, which appear after a viral illness) are observed and pass also after ordinary winter illnesses - the most well-known of which is Mono caused by EBV and CMV viruses, but the same phenomena also occur after common viral infections, such as enterovirus [32]. In fact, it is **not clear to what extent there is a difference between Long COVID and similar syndromes from other viruses** [33], beyond heightened scientific and public attention [34]. The British National Institute for Health Research (NIHR) reviewed the scientific literature on the subject and found that **many studies conducted on the syndrome exposed many biases** due to reliance on self-reporting and online questionnaires, short follow-up times and small sample sizes. Moreover, many of the studies (some of which have received a great deal of media coverage) did not pass peer review at all and were not published in scientific journals [31,33].

Therefore, it is not surprising that despite the large investment, there is still great difficulty in drawing clear conclusions about the prevalence and clinical significance of the syndrome, as also emerged in the discussion of the pandemic response team [35]. A number of up-to-date studies show that the incidence and significance of the syndrome is significantly lower from what the health authorities initially feared, and **especially in children, in whom the incidence of symptoms is lower than in adults** [36]. Other studies found a very low incidence (2%) of mild symptoms (such as headaches and fatigue), which usually lasted several weeks after infection with the virus [37]. Furthermore, other studies that followed for many months ongoing symptoms in children did not find significant differences between children who tested positive for the virus and children who did not contract it [38, 39]. One of the studies raised the possibility that psychological factors associated with lockdowns and isolation may result in the appearance of symptoms [39]. A study published in JAMA (the Journal of the American Medical Association) found that the very belief of a person that they are infected predicts Long-COVID symptoms—even in cases in which they are not infected at all. In this study, the only symptom found to be significantly different between those found to be infected based on a serological test and those who believed that they had been infected was impaired sense of smell [40].

Multisystem Inflammatory Syndrome – MIS-C/PIMS

Multisystem Inflammatory Syndrome, PIMS or MISC, is a syndrome that rarely appears several weeks after recovery from the virus and resembles in some of its characteristics other multisystem inflammatory syndromes that are known to medicine and that are treatable, such as Kawasaki disease. In this syndrome, there is a turbulent overactivity of the immune system, which manifests itself in multi-systemic inflammation that might affect, among other things, the gastrointestinal tract, the nervous system, the heart, blood vessels, and the respiratory system [42].

As with Long COVID, it is difficult to know the true prevalence of PIMS in the population, for a variety of reasons: One reason is that the diagnostic criteria are not uniform, and there is controversy as to whether evidence of previous COVID infection

is a sufficiently specific criterion, when hundreds of millions of people have contracted the virus [41]. Another reason stems from the great difficulty in knowing the true number of verified cases in the population, and therefore the prevalence of the syndrome among individuals who have recovered (in Israel, for instance, a serological survey by the Israel Center for Disease

Control at the Ministry of Health conducted in June) found that more than double the number of children than previously thought contracted COVID, which further lowers the prevalence of the syndrome [43]). A third reason for assessing the prevalence of the syndrome is due to the fact that certain groups of children are at increased risk (e.g. ethnic origin such as African-American or Hispanic, or being overweight) [44, 46-7].

Given these limitations, it is possible to assess the numbers published in Israel and around the world:

In the United States it was estimated that the prevalence of the syndrome is about 1 in 3,200 confirmed cases, but this study group included a significant over-representation of Hispanic and African-American children (62%), who are at increased risk for PIMS [44], as indicated above. In the UK, the risk of a child who tested positive for COVID to develop PIMS is 1 in 5,000 [47]. The data of the Ministry of Health [15] indicate a prevalence of 1 in 35,000. In light of these data, **the risk for a child to contract COVID-19 and to subsequently develop PIMS is smaller than 1 in 20,000** [5], and is most likely even significantly lower, with worldwide reports indicating rates of 1 per 40,000-50,000 children [17,45].

Similar to other inflammatory syndromes known to the world of medicine, PIMS can also be treated effectively, **and with early and appropriate treatment, the prospects of recovery from it are excellent in the vast majority of cases**.

It is important to add that despite repeated media reports of an increase in the incidence of PIMS cases as a result of the Delta variant [48], the data does not show any increase: in Israel, the COVID National Information and Knowledge Center reported 120 PIMS cases from March 2020 to the end of May 2021 (before the Delta variant) [49]. In early November 2021, it reported 30 more cases [50], which seems to indicate the same incidence rate also during the fourth "Delta" wave.

From data from the US Center for Disease Control, as well as from the statements of senior researchers in the field, it seems that the prevalence of the syndrome is even diminishing [51, 52] (Figure 2).

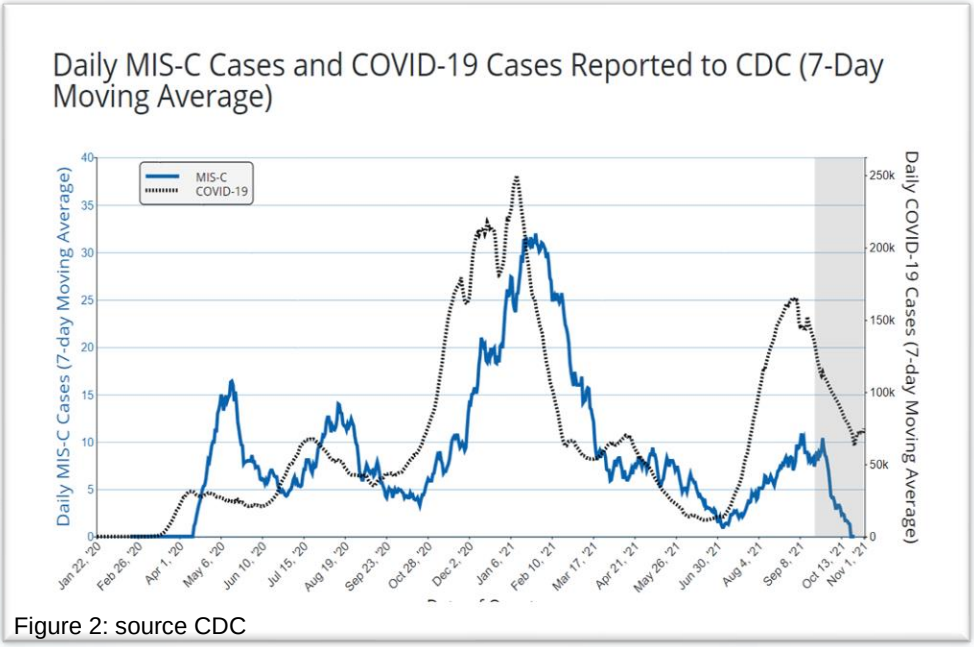

Figure 2: source CDC

The role and significance of the vaccine in the prevention of Long Covid and PIMS

With regard to the place of the vaccine in the face of these syndromes, it is of great importance to note that both Long COVID and PIMS may occur among children who were found positive for the virus but were asymptomatic [15, 38, 42]. Since the vaccine is not intended to prevent asymptomatic infection, Pfizer's clinical study did not investigate this matter (as will be detailed in the next part), and it seems that the vaccine does not effectively prevent asymptomatic infection/transmission effectively. Thus, there is no research-based backing to the claim that the vaccine will help prevent PIMS or Long COVID [53], as also noted in the discussion of the pandemic response team [15]. Beyond that, there are reports from both the scientific literature and the media, of the development of PIMS shortly after receiving the COVID-19 vaccine (MIS-V) and also of the development of PIMS in vaccinated individuals who contracted COVID-19 after being vaccinated [54-58]. Since PIMS-like cases were observed even after vaccination, caution is warranted in vaccinating children as long as the exact mechanism of this phenomenon is not well understood [59].

Since the vaccine is not intended to prevent asymptomatic disease, it has not been studied for that purpose, and probably does not prevent it effectively. Thus, there is no research-based backing to the claim that the vaccine will help prevent PIMS or Long COVID. There are reports of the development of PIMS in vaccinated individuals, both shortly after vaccination (also with no infection) and after infection, despite being vaccinated.

Part 3 - The contribution of vaccinating children to herd immunity and to the protection of the population

In the beginning of the epidemic, there was a concern that children constituted the significant vector through which the virus spread (as happens in the case of influenza [60]). In accordance with this notion, many countries around the world shut down education systems for a period of time. Within a few months, however, it became clear, through analysis of epidemiological investigations and epidemiological information that children were not a major transmission engine of the pandemic. The results, in Israel and around the world, show that children are less contagious than adults [45, 61].

Data published by the Pediatrics Association show that only about 10% of cases of infection in older individuals (over the age of 65) originated from children (Figure 3). In addition, studies examining the subject, including a survey examining 191 countries, found no association between the reopening of schools and increase in cases [63, 64]. Also in the UK, the picture that emerges is that **infections among children are "a mirror image" of background infection in the community as a whole** [65] (Figure 4). Data from the Ministry of Health clearly show that when cases drop in the population as a whole, it also drops among the very young age groups that have not been vaccinated [5].

Period of test	18.06.2021-20.10.2021											
	AGE OF CONNFIRMED CASE											
unknown	75+	65-74	55-64	45-54	35-44	25-34	18-24	13-17	9-12	5-8	0-4	
0	29	138	198	361	2460	2656	310	363	1085	2606	3598	0-4
4	45	190	286	1241	4686	2444	322	1232	4237	10823	4363	5-8
2	68	203	263	2168	4881	1329	681	2727	12328	5549	2559	9-12
3	60	130	364	2062	2407	376	1147	4746	2861	1703	851	13-17
3	57	152	885	1714	551	1083	3100	1115	656	401	593	18-24
7	156	577	1517	923	1409	5475	1309	552	1770	3848	5715	25-34
5	315	904	728	1344	4565	1589	769	2921	5697	6545	4808	35-44
4	539	478	914	2900	1299	940	2028	2395	2541	1786	861	45-54
3	381	659	2012	901	519	1231	880	433	305	355	389	55-64
2	496	1440	626	290	521	416	125	117	144	191	191	65-74
9	1062	479	356	343	212	104	42	42	58	55	31	75+
1	6	6	2	7	8	15	4	2	7	6	7	unknown
43	3214	5356	8151	14254	23518	17658	10717	16645	31689	33868	23966	

Age of source of infection

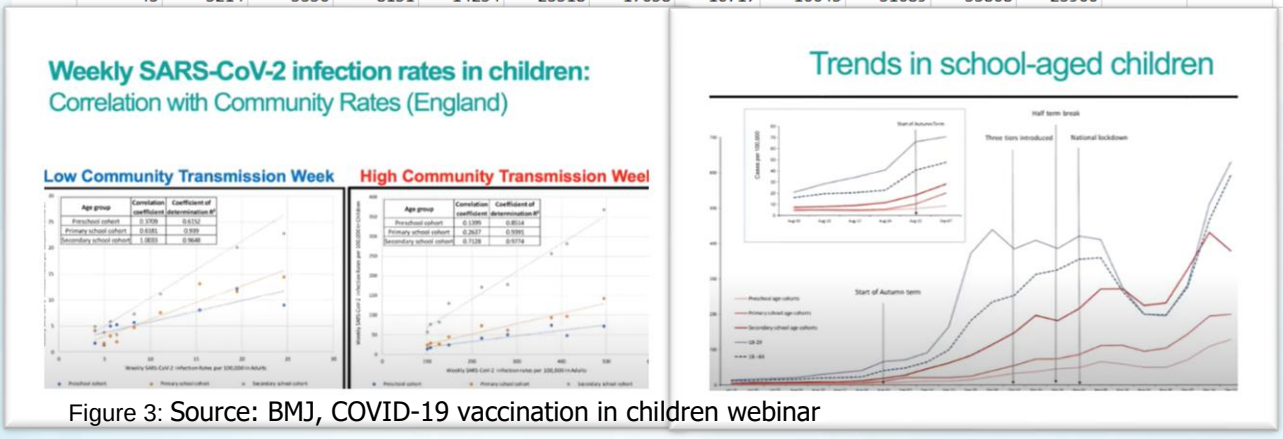

Figure 3: Source: BMJ, COVID-19 vaccination in children webinar

Even though it is clear that children are not "ticking bombs", as a senior physicians called them in the media [66], it is clear that they are still a part of the cycles of transmission, and they might get and transmit COVID-19. The effectiveness of the vaccine thus has to be determined in this respect.

First, a distinction must be made between two concepts which are often confused in the media, and even among official bodies, thus leading to a public discourse that is not evidence based. The first term is **infection**, which describes a situation in which a particular individual is infected with the virus, regardless of whether or not they developed symptomatic disease. The second concept is called "contagion" in the media, but it actually means transmission, which describes a situation in which an individual who already contracted the virus spreads it in the population by infecting other individuals. These two concepts are not identical, and the experimental method to test them is also different: to test infection, it is sufficient to have information about confirmed cases (symptomatic or asymptomatic), but the correct way to test transmission is to follow confirmed cases through contact tracing (which is the gold standard for the study of transmission) [67]. The distinction between these two concepts is important, as none of the three Pfizer studies in children, adolescents, and adults that formed the basis for approval of the COVID-19 vaccine has tested the spread of the virus. The Pfizer studies administered a COVID-test only to individuals who developed symptoms, so only infection was studied, and in only a partial way (as mentioned, only in individuals who developed symptoms) [21, 22, 68].

The subject of transmission was not studied in the randomized controlled studies that formed the basis for the emergency authorization, as required by the FDA [69]. Therefore, **the statement that the vaccine prevents transmission lacks scientific validity**. As evidence, many studies conducted after vaccination in large populations have contradicted the assumption that the vaccine prevents transmission, and many of them show that vaccinated individuals can spread the virus at a rate that is not significantly different from non-vaccinated individuals, and even carry the same viral load as non-vaccinated individuals [70-73], a measure used to assess the spreading potential of the virus [74]. In this context, it is important to explain that the large-scale studies conducted in Israel after the vaccination campaign, which were reported on in the media as proving a decrease in transmission (i.e., the spread of the virus) [75], did not measure it at all, but measured infection [76-78].

Theoretically, it is possible to use the relative proportion of vaccinated confirmed cases out of all confirmed cases as an approximation of the spread of the virus. However, given the green-pass policy in Israel, non-vaccinated individuals are tested significantly more extensively than vaccinated individuals who are not required to undergo routine testing (as also noted in some of the studies of the Ministry of Health themselves [76]). Therefore, the data and studies published by the Ministry of Health can not be a reliable indicator for the issue of transmission.

In contrast, a large-scale study examining asymptomatic infection in Qatar, where vaccinated individuals are also routinely tested (in contrast to Israel), found that the effectiveness of the Pfizer vaccine against asymptomatic infection fades within approximately 3 months, while the protection from severe illness lasts longer [79]. In a largescale study that examined 68 countries, **no connection was found between the rate of vaccination in a population and the number of cases that appear within it** [80]. This is also reflected in information coming from countries where the level of vaccination is very high (such as Iceland, Gibraltar, Singapore and in which others), in which epidemic waves are still occurring [81].

Thus, although the subject has not yet been studied in children aged 5-11, from the information collected in the other age groups and from real-world data, it follows that **the effectiveness of the vaccine in preventing the spread of the virus is low and short-term**, and therefore the vaccine is not useful in order to protect other people in the environment. In other words, the power of the vaccine in its original purpose: prevention of symptomatic or severe disease, that is, personal protection of the vaccinated individual.

This means that **the vaccine does not create herd immunity**. Unfortunately, the protection provided by the vaccine is not strong enough to prevent it outbreaks (in contrast to the measles vaccine, for example). Nevertheless, beyond the fact that children do not pose a significant risk to their environment and especially for fully vaccinated adults at high risk, vaccinating children will not provide a real additional protective layer for older adults in the population beyond the protection provided by the vaccines that those older adults took.

In general, it should be noted that in medicine it is not acceptable to provide medical treatment to a person for the benefit of another person, and this is a deviation from accepted ethical norms. This matter also came up in the discussion of the pandemic response team that discussed the issue of vaccinating children [15].

The information gathered indicates that the vaccine has low and short-term efficacy to prevent the spread of the virus. Because of this, the vaccine does not have the ability to create herd immunity or to create a true additional layer of protection to at-risk populations. The power of the vaccine is in its original purpose: prevention of a severe illness, i.e., the personal protection of the vaccinated individual.

Part 4 - Vaccine Safety for Children

At the beginning of the discussion on safety, it is important to note the uncertainty and the large knowledge gaps that exist regarding the vaccine, a drug developed and marketed at unprecedented speed. Despite widespread claims in the media that the vaccine is "safe beyond doubt" [82], that side effects appear only in the first weeks following vaccination [83, 84] and that "there is no reason that the vaccine would work differently from other vaccines that we have been using since the eighteenth century" [85], in the leaflet for individuals being vaccinated issued by Pfizer itself, it is explicitly stated that the **Pfizer COVID-19 vaccine for children has not yet gone through all the stages of clinical research related to the reporting of side effects, and there may be serious and unpredictable side effects that have not yet been detected** [86]. In addition, the vaccine was approved for emergency use only for ages 16 and younger or as a third dose at all ages [87], and the permanent approval given for two vaccine doses in ages 16 and over was given exceptionally (as indicated on the permit issued by the FDA) while conducting a number of ongoing safety studies. These studies are expected to last several years, with the aim of examining the prevalence and clinical significance of the side effect of pre-myocarditis, as well as following pregnant women and newborns until 2025. It is worth mentioning that myocarditis was added to the side effects of the vaccine only in June 2021, half a year after the vaccine was already given to millions of Israelis [89].

Myocarditis

This condition, which was discovered, as noted above, only after the vaccine was approved for distribution, was investigated by a special committee set up by the Ministry of Health. The findings of the investigation indicate that the prevalence of the condition increases in young people, especially in males aged 16-19 who were vaccinated with the second dose [90, 91].

According to the findings of the committee, this is one case for every 6,600 vaccinated individuals at that age group, **which is 13.6 times the expected prevalence in that age group**, according to data from previous years. Also, this significant number is probably an underestimation, as noted by the head of the committee, as well as by other sources that described a prevalence of about 1 in 3,000 to 1 in 6,000. CDC data also show that in the United States, an increase in myocarditis events was observed: 20-40 times more among young vaccinated individuals compared to the prevalence in the population [94].

While myocarditis events that occurred were often mild and passing, the phenomenon as a whole is significant, requires close monitoring, and may result in severe outcomes, as the report of the information and knowledge centre has indicated. This is evidenced by the death of a twenty-year-old woman, which was included in the findings of the committee of the Ministry of Health. Also, from CDC data it appears that in a three-month study following children who suffered from myocarditis after the Pfizer vaccine, only 30% of children (12-17) have made full recovery, with the other 70% are still experiencing symptoms or limitations to their physical activity [14].

Beyond the immediate risks, there is no way to determine the long-term consequences of myocarditis, for the purpose of negating residual damage to the heart muscle, as also noted in the discussion of the pandemic response team.

Additional side effects

Although myocarditis has been extensively covered in the media, it is not the only side effect of concern. Since the collection of information about side effects in Pfizer's clinical study is not yet complete, additional side effects may be detected. Already, there are a number of significant phenomena suspected to be related to the vaccine:

1. Following reports in Israel and around the world regarding the link between the vaccine and menstrual disorders [98, 99], the National Institutes of Health (NIH) in the United States announced that it will fund 5 large-scale studies about this topic [100]. Given the possible link between menstrual disorders and fertility disorders, it would be irresponsible to accuse women that their reports are creating "publicity bias" on social media [101], just as it would be irresponsible to argue that "there is no evidence" that the vaccine affects female fertility, as claimed in the media.
2. Various immunological and inflammatory symptoms that appeared after vaccination have been repeatedly reported in the scientific literature. Among them was the appearance of a rare and life-threatening hematologic disorder (TTP) that was diagnosed with significantly increased incidence than expected [102, 103], the eye inflammation Uveitis, the postponing of corneal implants (it was even suggested to wait for a few months between the vaccination and the corneal implant) [105, 106], Herpes-zoster outbreaks [107, 108], inflammatory and autoimmune disorders of the nervous system [109, 110], paralysis of facial nerves and Gillian-Barre syndrome [112-114].
3. Increase in events of hypercoagulability, conditions such as obstructive and venous skin blockages, pulmonary embolism and more [115-116].

4. Repeated case descriptions of renal injury [117-123], which led the European Medicines Agency (EMA) to come out with a statement that it will look more deeply into the issue, as well as the Israeli Ministry of Health to note that the issue is under investigation.
5. There are indications that receiving the vaccine after recovery from COVID-19 leads to more significant adverse effects [125]. This is of great importance, in light of the fact that antibody tests indicate that many children had COVID-19 without knowing it [43], and therefore vaccinating them without knowing that they have recovered increases the risk of adverse effects.

It should be noted that on the website of the Israeli Ministry of Health itself one can find a directive from the Director General from May 2021 defining the number of contraindications to giving another dose, out of concern that those conditions are related to the vaccine or may be exacerbated as a result of the vaccine. They include severe cardiovascular, hematological and neurological effects, such as Gillian Barre Syndrome, acute encephalitis, encephalitis or meningitis, and clotting events such as strokes, deep vein thrombosis (DVT) and pulmonary embolism (PE). It should be noted that these phenomena are not mentioned in the information sheet for people receiving the vaccine on the Ministry of Health website, as is customary to do with medications.

It is very important to note that some of these phenomena are rare and the prevalence of others is unknown, but this only highlights the information gaps that exist and the need to continue to monitor side effects in a thorough and systematic fashion, and of course to opt for careful, humble and, above all, transparent approaches.

It is of great importance to recognize that there is an under-reporting of COVID-19 vaccine adverse effects, both in Israel, as stated in the documents of the Ministry of Health itself [127] and in the world [128]. The US Vaccine Adverse Effects Reporting System (VAERS) is indeed a passive system that suffers from significant under-reporting, but it allows for transparent and detailed reporting. In Israel, the reporting system is affected by awkwardness and lack transparency. This is reflected in the reports of the vaccine monitoring committee, from which a strange picture emerged according to which the number of phenomena suspected to be vaccine adverse effects was in serious decline compared to the corresponding period in the years before the vaccine, such as a decrease of 1000 times in the number Myocardial infarctions[29]. The apparent implication, according to these reports, is that the vaccine protects not only from COVID-19, but also against dozens of other serious medical conditions that are unrelated to COVID-19. Since this is outside the boundaries of what is medically reasonable, it raises significant doubts about the reliability of the reports, whether due to the way that data were corrected or to the way that they were analyzed.

In view of the under-reporting of the phenomena that occur around the administration of the vaccine, and especially in light of serious phenomena (such as Myocarditis) significantly appearing after the start of the vaccination campaign, it is clear that more caution is needed and more attention needs to be paid to adverse effects. It is important to note that due to their low incidence and unpredictability, the recognition that adverse effects are caused by the vaccine may take a long time, as happened in the case of the discovery of the connection between narcolepsy and the swine-flu vaccine [130].

When discussing the current emergency authorization for vaccinating children aged 5-11, it should be remembered that in the study that Pfizer submitted to the FDA only 1,500 children who received the vaccine participated, and they were followed for two months. These data do not allow any picture to be obtained regarding the risk of serious side effects, such as Myocarditis, which may occur in an incidence of less than 1 in 1,500 and after more than 2 months following the vaccine, as was mentioned in the protocol submitted by Pfizer itself to the committee representing the FDA [131].

Many questions are still open about vaccine safety, which is evident in the FDA's requirement to conduct a number of longitudinal studies for the purpose of deepening the knowledge around certain adverse effects.

The under-reporting of these adverse effects also makes it difficult to obtain the full picture regarding vaccine safety. Beyond Myocarditis, a number of concerns have arisen regarding disorders of the hormonal, immune, and central and peripheral nervous systems, as well as problems in blood vessels and in coagulation, in the kidneys and in the skin.

There are differences in knowledge about the frequency and significance of the phenomena, but this emphasizes the need to opt for a careful, humble and, most importantly, transparent, approach.

Part 5 – Summary of the balance of benefit versus risk in vaccinating children against COVID-19

The choice to use a vaccine approved in an emergency procedure is not a trivial decision. The use of any drug, and certainly a vaccine that is still in the process of being tested, and has already demonstrated the potential for serious adverse effects that are not observed in other vaccines, requires an in-depth and rigorous risk-benefit analysis when it come to administering the vaccine.

Three questions about vaccine benefit are weighted against the question of vaccine safety:

1. Will the vaccine reduce severe illness and death in children? Severe illness is rare in children, and, in healthy children, it is even more rare. The COVID-19 mortality rate for children without risk factors is lower than the mortality rate from ordinary winter illnesses. To prevent a single case of serious illness or death, tens of thousands of children must be vaccinated, which clearly puts the safety issue at a higher priority.

2. Will the vaccine prevent long-term phenomena? The honest, clear and decisive answer is, no one knows. Since these adverse effects are possible even after asymptomatic infection, and since the vaccine's ability to prevent asymptomatic infection is probably low, there is no evidence that the vaccine will be useful on that front.

3. Will vaccinating children help protect the community and help to achieve herd immunity? Data emerging from studies on vaccinating other age groups (12 years of age and older) in many countries around the world shows that the vaccine will not significantly prevent the spread of the disease and that it will not create herd immunity. "Grandpa and Grandma" are vaccinated with 3 doses, thus getting a good protective "envelope" against severe illness and death as a result of COVID-19. The contribution of immunizing children to this protection, in the same vaccine that has only a limited and passing ability to prevent transmission, is marginal.

4. Is the vaccine safe for children? To many questions regarding the safety of the vaccine in general and its safety for children in particular, there is still no answer, but we do know about the incidence of significant adverse effects at a much higher rate than other vaccines [132], the most prominent of which is myocarditis. Other symptoms such as menstrual disorders and neurological side effects still require confirmation and interpretation.

An example of the balance of benefits and risks in a vaccination may be seen in the following comparison: The morbidity burden from myocarditis following a vaccine is so significant that in a risk-benefit analysis conducted by the CDC, it was found that if we vaccinate one million children aged 5-11, 67 intensive-care hospitalizations of children due to COVID would be prevented, but 57 children will be hospitalized in intensive care due to myocarditis. This is without taking into account the hospitalizations that may result from other adverse effects. This means that for every 100,000 children who receive the vaccine, only one hospitalization in intensive care is expected to be prevented. And this is, again, without taking into account risks from other adverse effects, as well as the fact that a vaccinated child could suffer adverse effects as a result of the vaccine—and also be infected with COVID-19 (as the vaccine does not provide full protection against transmission) and perhaps as a result of the illness to suffer from Long COVID or PIMS.

Other studies presented a similar balance of benefits and risk—to prevent the serious illness of one child, it is necessary to vaccinate and to expose to potential adverse effects tens of thousands or maybe even hundreds of thousands of children [133]. Another example of examining the balance of harms and benefits emerges from the Pfizer study itself in children 5-11, which shows that indeed there were fewer COVID-19 infections among vaccinated children compared to unvaccinated children, but when all symptoms are examined, without regard to their origin, it emerges that **children in the vaccinated group suffered from significantly higher rates of symptoms**, including headaches, fever and fatigue [21]. And so it emerges from the Pfizer study that as opposed to 13 children in the unvaccinated control group who suffered from symptoms such as fever, headaches and fatigue, over 200 children in the vaccinated group suffered from fever, headaches and fatigue following the vaccine.

A number of health authorities in different countries around the world have found the benefit-risk balance associated with the COVID-19 vaccine inadequate and have taken various steps to reduce the risk: Britain, Hong Kong and Taiwan, for example, give only one dose to children aged 12-15 [134-136]. A large number of European countries have already stopped the Moderna vaccines for people younger than 30 because of the risks involved in vaccinating young people [137]. The FDA reports a similar incidence of adverse effects between Pfizer and Moderna [94], although there are studies that show higher risks associated with Moderna. In either case, if caution is taken in vaccinating individuals under 30, extra caution must be taken when vaccinating children younger than 12, in light of the data that in the primary vaccination campaign (16 and older), the younger were the most vulnerable.

When we come to summarize the balance of benefits and risks, it must be said that the safety profile of the vaccine is not clear enough yet, especially when it comes to the child population. Extra care must be taken when calculating the expected benefit of the vaccine in the face of the potential harm that may be caused from it, in the short or long term. It should be noted that also the potential consequences of COVID-19 in the long run are unknown, but as of today, the data show that the risk for a child to develop known serious side effects from the COVID vaccine in the medium run is not significantly

different from the risk to a child without risk factors to develop serious illness as a result of COVID. In children, the vaccine has been shown to prevent mild symptomatic illness, but not to prevent transmission, infection, symptoms or complications (such as PIMS.)

It should also be noted that choosing to wait to vaccinate children also carries benefits for those 99.9% of children who, when infected with COVID-19, will experience a mild form of the disease, will develop natural immunity and will thus enjoy broader and more long term protection compared to repeated infection, which will also provide a broader "envelope" of protection against new variants.

The safety profile of the vaccine is not clear enough yet, especially regarding the children. Extra care must be taken when calculating the expected benefit of the vaccine in the face of the potential harm that may be caused from it, in the short or long term.

As of today, the data show that the risk for a child to develop serious side effects from the COVID vaccine is not significantly different from the risk that a child without risk factors to develop serious illness as a result of COVID. The vaccine does not promise protection against PIMS or Long COVID and does not contribute to herd immunity or to protecting vulnerable people.

Council recommendation

Close to a year into the vaccination campaign, it can be said that the vaccine seems to be effective in reducing severe illness and death due to COVID-19 within the adult population. Data about the vaccines' ability to prevent transmission and create herd immunity are disappointing.

In view of the very low rates of severe illness and death in children, and in light of the lack of safety data of the vaccine in that age group, **the risk-benefit balance does not justify a sweeping vaccination of the entire population of children**.

Ethically, the meaning of the first commandment in the Hippocratic oath "First, do no harm" is that if we are unsure that a new treatment will create a balance of risks and benefits that weighs clearly in favour of benefits for the patience—we must refrain from administering that treatment.

Balance of risks whose clinical significance is clearly in favor of treatment - we must refrain from giving this treatment.

The council vigorously opposes the aggressive manner in which the child vaccination campaign is being carried out. The pressure campaign directed at parents and children, including the green pass, is offensive and immoral.

The following cannot be overemphasized: **we condemn any element of coercion around the vaccine**, direct or indirect. Contrary to what has been stated by various representatives, the green pass is a coercive measure that is not medically or epidemiologically justified; it is morally wrong, violates the basic values of medicine, harbours resistance precisely because of the use of coercion, and at the same time - produces a false representation of a safe environment because vaccinated individuals can also infect and be infected. Along with the concern for health, human rights, ethics and moral values must also be preserved in a democratic state.

The data show that most cases of severe illness occurred in children in medically at-risk populations. Accordingly, the Council believes that vaccination should be recommended for children who are in the group of diseases which are defined as a risk factor for severe COVID illness.

From the approach of shared decision making with the patient, the Council believes that parents who are interested in vaccinating their children should be allowed to do so after receiving a full, reliable and transparent explanation, as is customary in medicine, about the benefits of the vaccine versus vaccine safety.

Beyond that, the Council calls for a change in the procedures that have created a situation in which a 12-year-old child receives a dose 3 times higher than an 11-year-old child, a situation that is not at all acceptable in the world of pediatrics.

As more information accumulates about the effectiveness of the vaccine and the profile of side effects, the Council will re-examine its position on the issue.

The Council emphasizes that according to the ethical rules of modern medicine, a decision to get vaccinated is a personal decision of the child and their parents, and there is no legitimacy to exerting pressure on them, either directly or indirectly, whether through sanctions or through incentives.

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The council reiterates that the call to vaccinate the child population for the health of others is controversial to say the least, and forcing immunization for this purpose is unprecedented.

Such a call is the beginning of a slippery slope, inconsistent with accepted medical practice, and constitutes a deviation from the rules of ethics that guide medical treatment.

Based on the data known today, the risk-benefit analysis does not justify a sweeping vaccination of the entire population of children.

This is not the case for children at risk, who are more vulnerable to a severe illness, and for whom vaccination is recommended.

No means of coercion or pressure, direct or indirect, should be used to motivate a parent to make a medical decision about vaccinating their children in a manner that is not based solely on health considerations.

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