The fourth wave of COVID-19 breakout in Israel – Alternative analysis: The efficacy of vaccination protocols in preventing serious disease and death vs. increased COVID-19 morbidity and mortality following booster vaccination

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Abstract

Background: During the months of August-October Israel has experienced the fourth wave of COVID-19 outbreak. This outbreak resulted in major increases in COVID-19 hospitalizations and mortality. At the beginning of this outbreak, Israel had one of the highest rates of two-dose Pfizer vaccination (2D protocol) and was beginning a vigorous campaign to promote a third-injection booster of the vaccine (3D protocol).

Purpose: The official serious illness and deaths records were analyzed in order to assess the efficacy of the 2D and 3D protocols in preventing serious illness or death due to COVID-19 infection

Methods: All raw data were obtained from the official Ministry of Health records (Data Dashboard). The same source was used to estimate the size of the relevant populations. The data for serious illness or mortality were normalized to sizes of the relevant populations on a daily basis.

Results and Conclusions: The 2D protocol alone, or followed by third-dose booster, significantly protected the relevant populations against serious illness (5 and 3-fold, respectively) and death (3.4 and 2.2-fold, respectively). However, this alternative analysis indicated that there was no protective advantage of the 3D over the 2D protocol. Actually, the protective effect of the 2D protocol against serious illness, and death in particular, appeared to exceed by a large factor that of the 3D protocol. Importantly, there was an unexpected early and prolonged rise in COVID-19 mortality in the 3D population. These results are discordant with the official statistics of the Ministry of Health and with some of the results presented in the scientific literature. Moreover, the kinetics of serious illness or mortality was spiking instead of the expected monotonous rise and decline, suggesting additional factors involved.

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Competing Interest Statement

No competing interests.

Funding Statement

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Author Declarations

I confirm all relevant ethical guidelines have been followed and there were no necessary IRB and/or ethics committee approvals.

Yes

The details of the IRB/oversight body that provided approval or exemption for the research described are given below:

COVID-19 Data Hub

I confirm that there were no necessary patient/participant consents and the therefore no appropriate institutional forms have been archived, and that any patient/participant/sample identifiers were not included or known to the author.

Yes

I understand that all clinical trials and any other prospective interventional studies must be registered with an ICMJE-approved registry, such as ClinicalTrials.gov. I confirm that any such study reported in the manuscript has been registered and the trial registration ID is provided (note: if posting a prospective study registered retrospectively, please provide a statement in the trial ID field explaining why the study was not registered in advance).

Not relevant

I have followed all appropriate research reporting guidelines and uploaded the relevant EQUATOR Network research reporting checklist(s) and other pertinent material as supplementary files, if applicable.

Yes

The COVID-19 pandemic presented many countries, especially those with aging population, with a nation-wide health systems crisis and significant pandemic mortality. Traditional pandemic control measures failed to achieve the desired effect. The emergence of COV-19 spike proteins mRNA-based vaccinations put a potentially powerful tool to combat the COVID-19 pandemic at the disposal of governmental health authorities. Israel was the first country to adopt this tool on a nation-wide scale and since January 2021 promulgated a sweeping vaccination campaign. Various measures, including institution of the Green Pass, were employed to coerce the population that has not been fully vaccinated (i.e. by the 3D protocol) to follow the MOH pronouncements. By the end of July 2021 Israel entered its fourth wave of COVID-19 flare-up and concurrently initiated a third-dose booster aimed at all population aged 12 and older. Daily updated Israel MOH DataDashboard (1) presented statistics that, taken *bona fide*, clearly demonstrated that vaccinated population was eminently protected against serious illness and death. Similarly, early studies argued that vaccinations and various other measures (e.g. lockdowns) were effective to limit the spread the pandemic (2). The booster policy was promulgated based on the numerous scientific reports that demonstrated that the observed immunity to COVID-19 and the anti-spike protein serological titer rapidly waned following the regular two-dose vaccination (3-5). The booster effectiveness was recently reviewed in a British Medical Journal editorial (6). There was also increasing amount of evidence strongly suggesting that the 2D-vaccinated population was open to COVID-19 infection, serious illness, and even death (3-5). The authorities argued (without rigorous proof) that the 2D-infected could infect others upon contact, whereas the 3D-vaccinated were much less infectious.

The government sources and diverse medical profession pundits hailed the booster as a major protective measure against serious disease and death due to COVID-19 infection with little if any vaccination side-effects and supported this position by widely publicized epidemiological study (3). Recently, children aged 5-11 were approved for vaccination by the Pfizer reduced-dose children vaccine. As a results, Israel is now one of the leading countries in respect of the proportion of vaccinated (2D protocol of the Pfizer vaccine) and "fully vaccinated", i.e. by the 3D protocol, population. The Israeli vaccination push was spearheaded by the Israeli Ministry of Health (MOH) with overwhelming support of numerous medical experts, media, and scientific publications originating predominantly from the Israeli public health organizations and even the MOH senior personnel. The overall message was: 1. The Pfizer vaccine (used almost exclusively in Israel) is highly effective in preventing serious illness and death. 2. The vaccine is largely side-effects free and the extremely rare side effects are predominantly light and temporary. 3. Even asymptomatic COVID-19 infection carries significant dangers of late debilitating conditions, including "Long-COVID" and PIMS, especially in children and young adults populations. The first message was reflected in the extensive daily updated-statistical report published by the MOH (1). Similar messages were promulgated by most reports of no excessive serious side-effects (e.g. in Ontario, Canada (7)).

A small but vocal minority of physicians and scientists responded to the MOH and State-sponsored campaign by claiming that the premises on which the state and MOH are basing their pro-vaccination stance are faulty, inaccurate, and even outright untrue. Probably the most striking estimate of vaccinations-related mortality can be found in the analysis of US (CDC) and European (euromomo.eu) data by Pantazatos and Seligman (8). Their model points at 146K to 187K vaccine-associated US deaths of all causes between February and August, 2021.
This study was undertaken in order to examine the efficacy of the 2D Pfizer vaccination and the additional booster to ameliorate the onset of serious illness and mortality in the Israeli population during the fourth outbreak of the COVID-19 pandemic.

Methods

All statistical data detailing the numbers of seriously ill (SI) or dead due to COVID-19 infection were downloaded from the official Israeli Ministry of Health site (1). The new SI and new dead daily reports were normalized to the respective population size (SI or dead per 100,000) starting at August 1, 2021 and terminating at November 9, 2011. The daily estimates of the sizes of the three relevant populations were calculated in the following way: The number of individuals that have been "fully vaccinated" (i.e. three vaccine doses) was obtained directly from the MOH DataDashboard (4). The number of individuals that received only two doses of the vaccine was calculated by subtracting the number of all those vaccinated three times from those vaccinated two times. The number of unvaccinated individuals was obtained by calculating the number of individuals that received no vaccination, or only a single dose, and subtracting from it the number of children under the age of 12 (estimated at 1.994 million (9)). It is important to stress that the percent vaccinated that is reported in the DataDashboard refers to the entire Israeli population, including children up to the age 12, who at the period examined here have not been yet approved for vaccination. The status and population size of individuals who recovered from COVID-19, or recovered and were vaccinated at least once are unavailable from the DataDashboard. Population sizes at the first and the last day of the examined period are shown in Table 1.

Population/Date	**Aug 1 2021**	**November 9 2021**
Vaccinated 3D	**0.05**	**4.00**
Vaccinated 2D	**5.34**	**1.75**
Unvaccinated	**1.91**	**1.56**

Table 1 Respective populations at August 1st and November 9th, in millions

To avoid the variability that resulted from low number of reported new SI or dead (including no new SI or dead on a significant proportion of the examined period), the data were smoothed by converting them to running averages with a period of 7 days, resulting in 101 days of consecutive follow-up. Hence, the data actually start on August 7, 2021.

Statistical analyses were performed using two-tailed Student's t-test assuming identical distribution. Two populations were considered to be significantly different when $p<0.05$.

Results

The seriously ill (SI)

The raw data and the normalized data of the three relevant populations are shown in Figs. 1A-C.

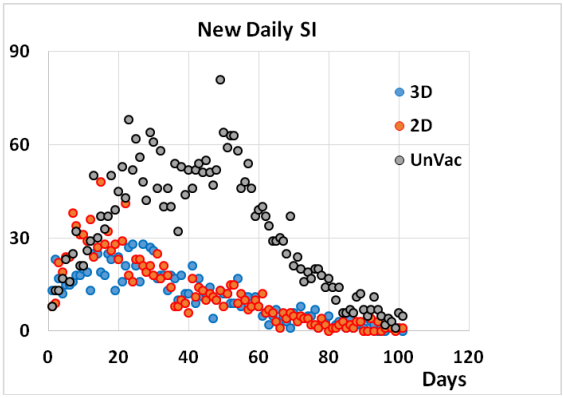
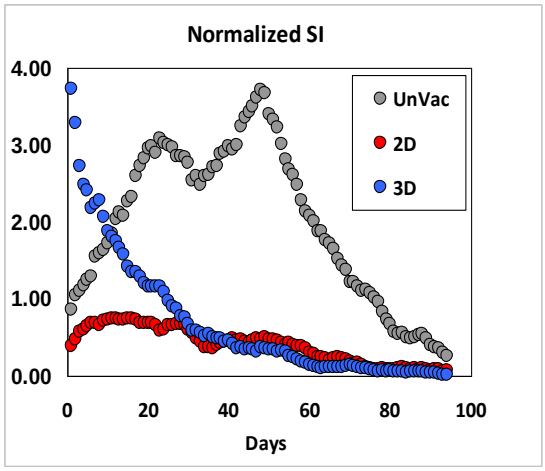
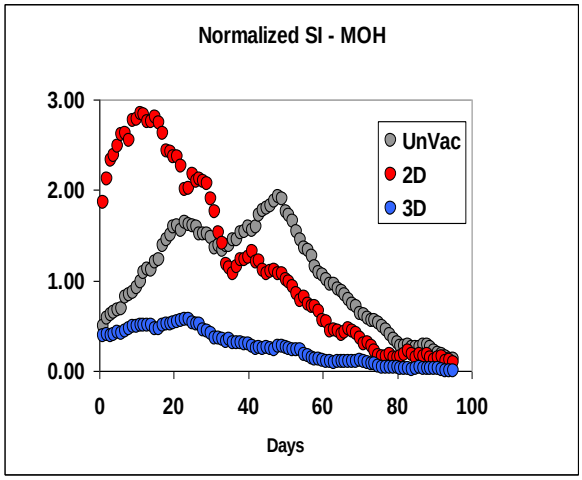


Fig. 1A Number of new daily reported SI. 2D – population that received only two doses of vaccine, 3D – 2D with a third booster dose, UnVac – Unvaccinated, including those that received a single dose, but excluding children under 12 years of age



1B



1C

Fig.1B-(This report),1C-(MOH): SI daily normalized to populations sizes (per 100,000). For labels, see Fig.1A.

The unvaccinated population exhibited a close to symmetrical curve with similar rates of onset and decay and an apparent distribution into two bell-shape curves, peaking around 20 and 50 days of the wave. Both the vaccinated by 2D and the 3D protocol populations exhibited more rapid onset followed by early monotonous decay (Fig. 1A). The unvaccinated population exhibited two distinct peaks and much higher rate of SI, culminating at close to 4 per 100,000. The 2D-vaccinated exhibited a much lower and much shallower curve. Interestingly, the population that received the booster exhibited very high initial rate, that rapidly decreased to much lower values. For approximately the last two months of the wave, both the 2D- and the 3D-vaccinated populations exhibited similar decreasing rates of new SI cases. There were statistically significant differences among the three populations ($p<0.002$ for all comparisons).

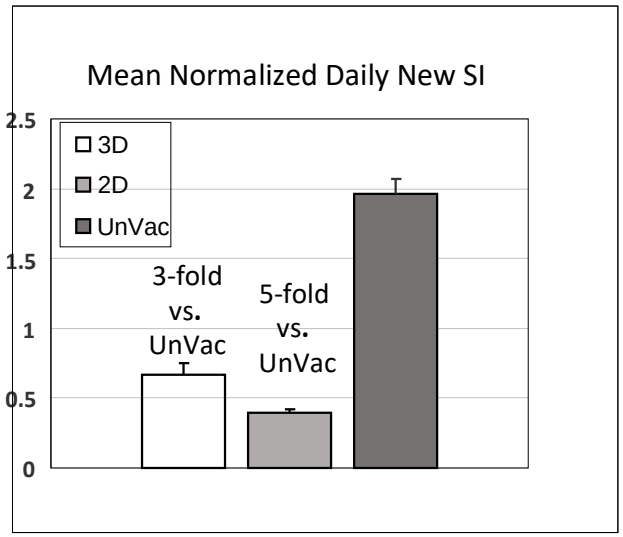


Fig. 2 Mean normalized new daily SI. The bars represent standard error. For labels see Fig. 1A.

Those who received the 2D protocol were better protected against SI than those who received the additional booster (5- vs. 3-fold, respectively).

The MOH data, treated in the same way, are shown in Fg. 1C.

COVID-19 daily mortality

Figs. 3A-C Kinetics of mortality in the three populations of interest.

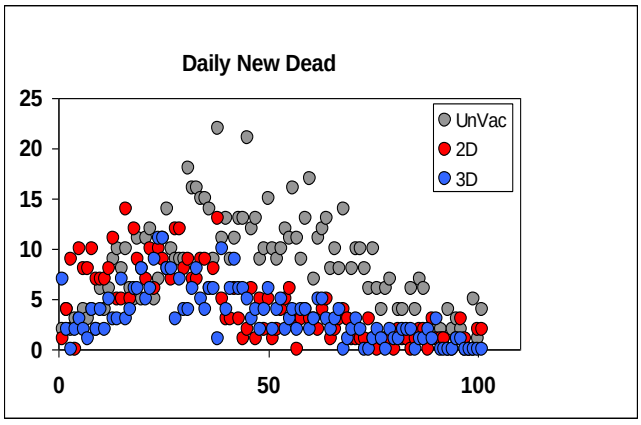
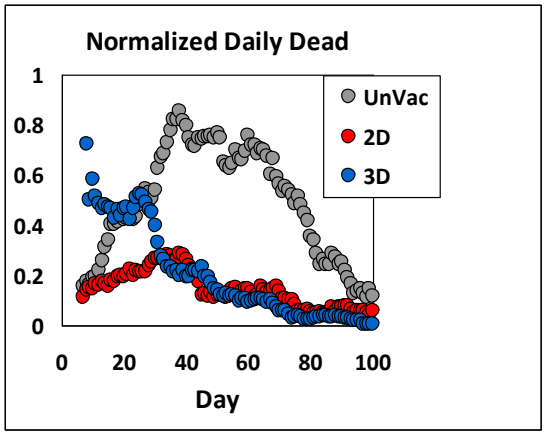
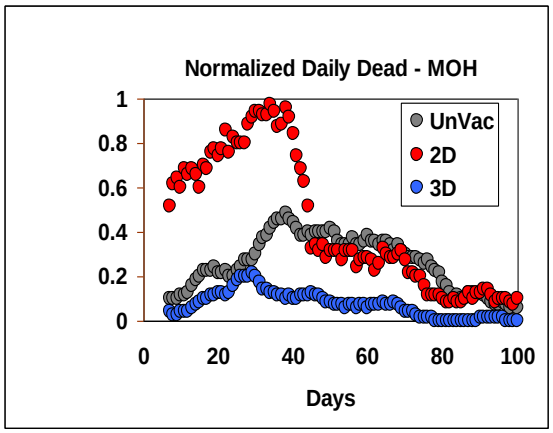


Fig. 3A Raw mortality data of the three populations of interest. For labels see Fig. 1A.



3B



3C

Fig. 3B((This report), C(MOH)) normalized (per 100,000) mortality scores. For labels see Fig. 1A.

In Fig. 3B, the smoothed data (running average, period of 7 days) was normalized to the sizes of the relevant populations (per 100,000). The kinetics of the 2D- and 3D-vaccinated and the unvaccinated populations were identical to the kinetics of the cognate SI populations (see Fig. 1B), albeit with more variability. The behavior of the 3D population exhibited relatively high (0.7-0.5/100,000) mortality level during the first month of the outbreak, and then gradually decreased. From day 70 and on the two populations were virtually indistinguishable. The unvaccinated population followed a generally symmetrical distribution with a small peak at the 40-days point and another, less pronounced at the 60-days point. From day 26 and on, the unvaccinated population exhibited significantly higher ($p<0.0001$) normalized mortality than the two vaccinated populations. The mean normalized mortality data are shown in Fig. 4. Those vaccinated by the 2D protocol were significantly better protected than those who received the additional booster (3.4- vs. 2.2-fold), the three populations were statistically different, $p<0.0001$ for the three comparisons).

The MOH analysis of the mortality data (Fig. 3C) differed from the analysis presented here (Fig. 3B), both in extent and pattern. Similarly to the kinetics of the SI, MOH analysis shows very high initial mortality of the 2D population vs. low mortality of the 3 D segment.

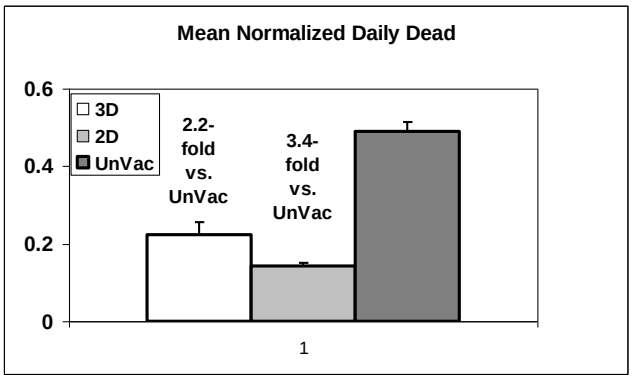


Fig.4 Mean normalized mortality scores. Bars represent standard error. For labels see Fig. 1A.

The data describing the behavior of the three populations were analyzed to show the proportion of SI who died. The daily ratio (Fig. 5) exhibited marked variability with three peaks in the 3D populations, four distinct peaks for the 2D-vaccinated population, and four relatively flat peaks for the unvaccinated. The mortality rates of the SI were lowest in the unvaccinated population.

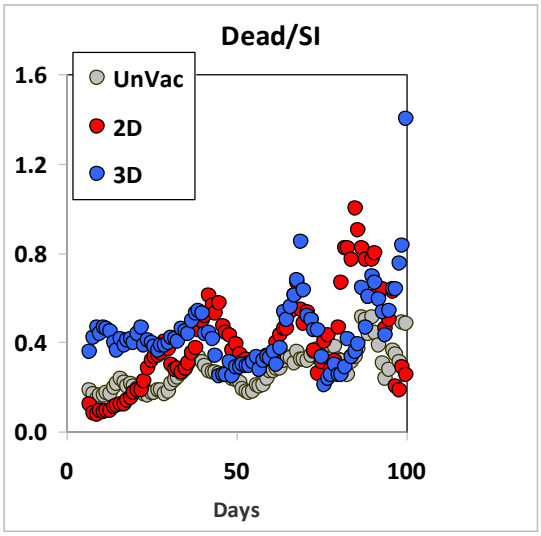


Fig. 5 Proportion of the newly reported deaths to the newly reported SI on a daily basis. For labels see Fig. 1A.

The mean ratios of the three populations are shown in Fig. 6. The 2D- and 3D-vaccinated populations exhibited a higher ratio between mortality and serious illness (45±2 and 40±2%, respectively), the unvaccinated the lowest (28±1%). There was no significant difference between the 2D and the 3D populations.

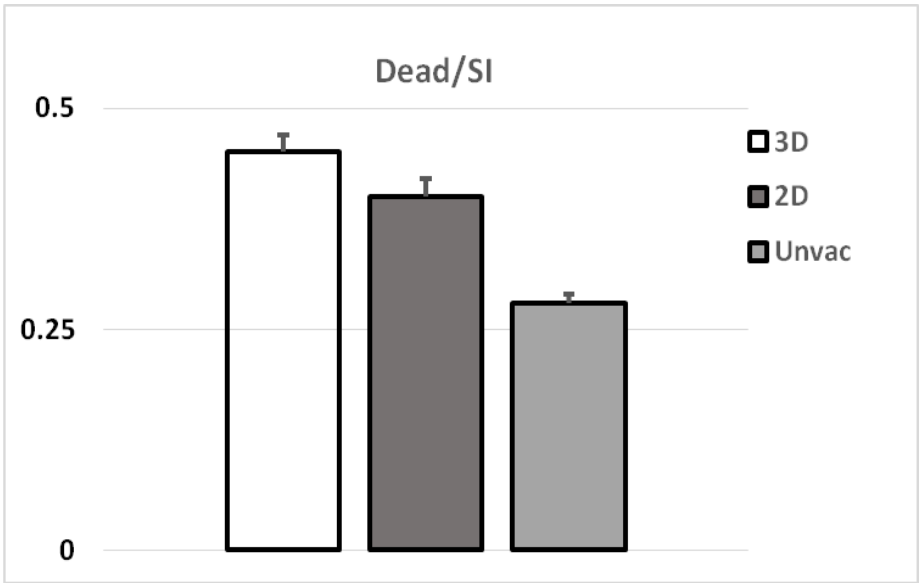


Fig. 6 Mean ratios of the daily reported new deaths and new SI. Bars represent standard error. For labels see Fig. 1A.

Discussion

Analysis of the protective effects of COVID-19 Pfizer vaccine during the fourth outbreak of the epidemic is a complex task. Due to the aggressive vaccination policy of the Israeli MOH, it resembles an attempt to understand a dynamic situation from a time-lapse movie. At the beginning of the outbreak (defined arbitrarily here as August 1st, 2021) a large proportion of the Israeli population (5.4 million, 74% of the eligible population) was already vaccinated by the 2D protocol. At that time point, the MOH embarked on vigorous program of a third, booster injection. By November 9, the last day analyzed in this report, the booster population reached 4.0 million (54.9% of the eligible population), while the 2D population decreased to 1.75 million. When I include in my analysis factors like the time elapsed since the injections, with immunity apparently on the increase in the recently vaccinated and waning in those vaccinated three or more months earlier, rigorous analysis is evidently impossible. Nevertheless, certain general questions can be answered with a reasonable degree of confidence.

1. Did vaccinations protect the population from SI? The answer is definitively positive. Both the 2D (0.4±0.02/100,000) and the 3D (0.67±0.08/100,000) populations exhibited markedly lower normalized SI rates than the unvaccinated population (1.97±0.1/100,000). The population vaccinated with 2D protocol was better protected than those that received the booster (4.95-fold vs. 2.95-fold, respectively, when compared with the unvaccinated population). Hence the booster actually appeared to decrease the efficacy of the 2D protocol by 40%.
2. Did vaccinations protect the population from COVID-19 death? Again, the answer is positive. Both the 2D (0.08±0.01/100,000) and the 3D (0.21±0.02/100,000) populations exhibited markedly lower normalized mortality rates than the unvaccinated population (0.49±0.2/100,000). The population vaccinated with 2D protocol was much better protected than those who also received the booster (3.4-fold versus 2.2-fold, respectively, when compared with the unvaccinated population). Since the overwhelming majority of SI and dead derive from the elderly population, the normalized values in these populations should increase, but the overall trends should not change in a meaningful way.
3. Do vaccinations protect against death of the SI? Our analysis shows that the proportion of deaths in the SI population was 28% in the unvaccinated, 45% in the booster, and 40% in the 2D population. Although the data are not sufficient for exact calculations, the low mortality of the 2D and the unvaccinated may reflect the higher proportion of young individuals within this group. Although the 2D protocol appeared to excel in preventing SI, it was much less efficacious in preventing death of those already seriously ill.

The dynamic situation is reflected in the time course of new SI and death. Both parameters exhibited the expected rise and fall only for the unvaccinated population. There were distinct two peaks in the normalized daily reported SI, and these two peaks were present also in the daily reported mortality, though less accentuated. The gradual and symmetrical kinetics of the two peaks indicated that they did not reflect changes in definitions or corrections of accounting errors. Interestingly, the trough of the two waves of morbidity and mortality in the unvaccinated population coincides with the onset of the rapid decrease in the morbidity and mortality of the 3D (this report) or 2D (MOH) populations (see below). The best interpretation appears to be a fusion of two consecutive waves of the epidemic, reflecting two different populations or two modes of infection in the same population. It is tempting to speculate that the second wave (peaking at approximately beginning of October) followed the High Holidays period of September. The 2D-vaccinated population followed a rapid, shallow rise in the kinetics of SI and a slow prolonged

decay. The most surprising finding was the curious kinetics of the booster population. It began with very high SI and mortality values, which, approximately 30 days after the beginning of the booster campaign, exhibited a rapid decrease and were then virtually indistinguishable from 2D population kinetics. Similar behavior is seen in the MOH data, except it characterizes the 2D population. I cannot offer a satisfactory explanation for the curious early kinetics of the booster population. There are both scientific and anecdotal reports of increased COVID-19 mortality of the recently vaccinated (10-15) and the kinetics seems to support this interpretation. The overall shape argues against low numbers artifact despite the rapid decay matching the increase in the number of individuals that received the booster injection. Similar finding have been recently published by Neil et al. (10), who analyzed the UK COVID-19 mortality report. The authors state that confounding mortality statistics stem from "…combination of systemic miscategorisation of deaths between the different categories of unvaccinated and vaccinated; delayed or non-reporting of vaccinations; systemic underestimation of the proportion of unvaccinated; and/or incorrect population selection for Covid deaths."

Another unexplained finding is the spiking kinetics of the ratio of mortality to SI. In the unvaccinated population it exhibits a series of four shallow peaks with a period of 21-22 days. The population that received the 2D protocol displayed four distinct peaks with periods of 13, 28 and 17 days. The booster population displayed also four peaks with similar periods. The spiking kinetics of this ratio could have been attributed to reporting protocols, but the varying periods, the different dates of the peaks, and the close-to-symmetrical shapes of the spikes argue against this type of artifact.

The last point is the most unexpected and possibly contentious – the major discrepancies between the analysis of the data in the present report and that shown in the MOH DataDashboard. For the SI population, the MOH data show much lower normalized numbers for the unvaccinated and a significantly higher numbers for the 2D- vaccinated. Moreover, the kinetics of the booster-vaccinated population is entirely different from my calculated data. These discrepancies are reflected in totally different averages in the three groups (Table 2). Similarly, for the mortality profiles, the MOH presents numbers that show much higher normalized numbers for the unvaccinated and the 2D-vaccinated populations and correspondingly lower values for the booster population. Overall, the MOH presentation favors the booster over the 2D and unvaccinated population.

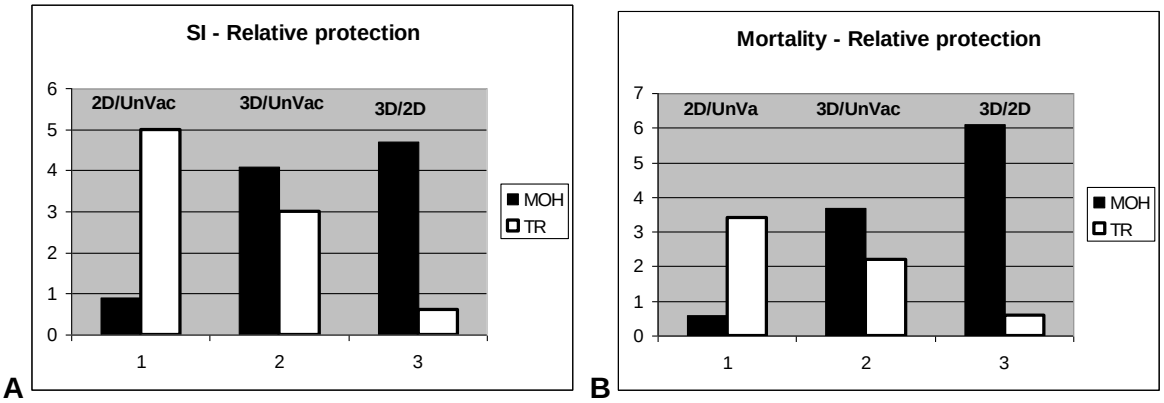


Fig.7A,B Comparison of the data reported in MOH Data. Dashboard (MOH) and the analysis in this report (TR) for the protection factor for SI (A) and mortality (B). The columns represent the values of the ratios of the three populations – 2D two-dose vaccinated; 3D –two dose vaccinated with a third booster dose; UnVac – unvaccinated or vaccinated with a single dose.

Since the absolute numbers of seriously ill and dead are indisputable, the differences between the analysis in this report and the MOH presentations could be accounted for only by different

estimates of the relevant populations. To reflect the numbers presented by MOH there should have been a large shift of population size from the 2D to the 3D class. It remains to be seen how these calculations have been done by MOH personnel. One of the questions that arise is where and how the recovered were categorized. This is a relatively large population of more than 1.3 million and it may affect the calculations in a meaningful way. However, the MOH site (1) does not deal at all with this population. Another question is whether the booster population was considered immediately "fully vaccinated", or did it require a delay period of an unknown duration (seven days according to unofficial reports). If this population was indeed considered by MOH still as “vaccinated but invalid” (i.e. 2D), than the increased morbidity and mortality following the third dose of the vaccine would appear in the 2D statistics, as it indeed does in the MOH analysis. Otherwise, there is no explanation of the major discrepancies between our analysis and that of MOH. Whatever the actual methods of analysis, it seems obvious that there was a major increase in COVID-19 morbidity and mortality associated with the onset of the booster campaign. The only plausible explanation is a sharp increase in morbidity and mortality during a short period following the booster shot. Indeed, Kostoff et al. (11) report similar findings in their analysis of mortality following vaccination in the US. Their Fig. A1 shows a large spike of mortality on days 1-3 post vaccination followed by a rapid exponential decline over time and is very similar to Fig. 1B in this report. Some non-scientific publications argue that the apparent increase in morbidity and mortality following vaccination could be explained by a confounding bias - older people with more severe co-morbidities would those targeted for early round of vaccination. This indeed may be the case, however hard data to examine this interpretation are unavailable.

Taking the data *bona fide* "as is", one can calculate two theoretical values- how many lives were saved by vaccinations, and how many lives were not saved due to refusal of vaccinations. The differences between this report and the MOH data can be clearly demonstrated by this kind of representation.

	Calculated # of lives saved by vaccinations	
	2D	**3D**
TR	**1056**	**408**
MOH	**-176**	**916**
	Calculated # of lives not saved by vaccinations	
	2D	**3D**
TR	**578**	**-444**
MOH	**-546**	**598**

Table 2. Theoretical calculations of lives saved and lives not saved during the fourth outbreak of COVID-19 epidemic in Israel. Calculations based on analyses presented in this report (TR) or MOH (3). The values represent the number of individuals who would have died if not vaccinated by the 2D or 3D protocols, and numbers of dead individuals in the unvaccinated population who might have been saved by the 2D or the 3D protocols. Negative numbers indicate a condition under which more, rather than less, deaths would have occurred.

In conclusion, vaccinations do work and prevent serious illness and death. However, the calculations presented in this report suggest that there is major difference between the 2D and the 3D protocols, with a significant advantage of 2D over 3D. There is a major discrepancy of these values and those published in MOH (1), which dramatically favor the 3D over the 2D protocol. These differences should be investigated, since they form the background mandate for

the booster vaccination drive. Further stratification of the SI and mortality data into decades should make this type of analysis more meaningful in terms of public health decision making. Importantly, the initial significantly higher morbidity and mortality from COVID-19, as well as from all causes, at the early period of initiating the booster protocol should be urgently investigated. Seneff and Nigh (16) point at the pitfalls of mRNA-based vaccines. Ontario AEFI reported 931 hospital admissions with 8 vaccine-correlated deaths, with additional 26 deaths under investigation in a total of 2.5 million vaccination events, i.e. 0.05% reports defined as “of special interest”(7). Moreover, there is increasing evidence of pathology reports that point at direct and indirect association between recent vaccinations and unexplained mortality ((12,17). In comparison, Hong Kong Public Health authorities conclude, in a detailed report, that there were no credible reports of vaccine-related mortality (18). In this respect, there are baffling reports of a decrease in all causes, non-COVID-19 mortality following vaccination (19,20). The most curious analysis claims that vaccination prevented all cause mortality in the US by a factor of an order of magnitude (21). These findings, if confirmed, might reflect the confounding bias of the altered behavior patterns of the vaccinated population. It is obvious that both types of reports (i.e. increased vs. decreased mortality) cannot coexist. An interesting analysis by Norman Fenton that demonstrates how lags between actual events and the time of their reporting can create false efficacy perception (22). This does not, however, affect the present report, whereas it deals with analysis of virtually the entire fourth wave of COVID-19 outbreak. Although these conflicting data and diametrically opposed analyses are often presented in non-peer-reviewed journals and in the media, it is obvious that public health interest mandates an open and evidence-based discussion.

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