The Efficacy of COVID-19 Vaccine Boosters against Severe Illness and Deaths: Scientific Fact or Wishful Myth?

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ABSTRACT

The medical narrative justifying the global vaccination campaign has changed throughout the coronavirus disease 2019 (COVID-19) crisis. While the primary narrative focused on the proclaimed excellent ability of the novel mRNA vaccines to *prevent infections* and (therefore) to attenuate the spread of the pandemic, policymakers today (March 2023) acknowledge the poor vaccine efficacy (VE) of contemporary booster doses against infections but insist that the boosters are still capable of providing long-term protection against severe illness and deaths (as if the two types of protection do not depend on each other).

We examine the evidence behind this modified narrative through an in-depth evaluation of representative and high-profile data from: (1) the formal, phase 3 clinical trials by Pfizer and Moderna, which preceded the FDA's emergency use authorization (EUA); (2) the observational studies from Israel ("the world's lab," as termed by Pfizer officials), which examined the efficacy of the fourth dose at about the time the FDA authorized this second booster; and (3) the publicly available, real-life dashboards of pandemic statistics.

This investigation encountered multiple *methodological and representational constraints*, including short, and sometimes arbitrary or uneven follow-up periods; uneven exclusion criteria and COVID-19 testing levels; selection biases; and selective report of results. But most importantly, the documented, *conditional probability of death and severe illness* (i.e., the percentage of severe illness and death cases among those infected with the virus) did **not** differ between the treatment and the control groups of the various clinical and observational efficacy studies.

Altogether, the representative data examined in this article do not lend convincing support to the notion that the current booster doses offer protection against severe illness and deaths that extends significantly beyond their temporary and fragile protection against infections.

Considering the already known poor efficacy against infections and transmission and the ever-growing concerns over serious, vaccine-associated adverse outcomes, the findings of this meticulous scientific investigation challenge the current (modified) narrative and serve as an urgent call for the medical community to reconsider the balance between the benefits and the risks of the newly developed COVID-19 vaccines.

Introduction

Following the emergency use authorization (EUA) of the U.S. Food and Drug Administration (FDA) to administer novel mRNA vaccines on Dec 11, 2020, mass vaccination has become the leading coping strategy in the battle against COVID-19. However, the official medical narrative broadcast to the public to justify this campaign has undergone a dramatic change. While the primary narrative, at the beginning of the campaign, focused on the ability of the vaccines to *prevent COVID-19 infections* and (therefore) to attenuate the spread of the pandemic, today (March 2023), the leading medical justification revolves around the proclaimed vaccine efficacy (VE) against severe illness and deaths.[1] This article explores the scientific validity of this modified narrative, but first we need to review its chronological evolution.

The Early Medical Narrative

"When you get vaccinated", stated Dr. Anthony Fauci, the Chief Medical Advisor to the President of the U.S., on May 16, 2021, *"you not only protect your own health…, but also you contribute to the community health by preventing the spread of the virus throughout the community… You become a dead end to the virus."*[2] This basic narrative, according to which the mRNA vaccines are capable of preventing COVID-19 infections, originated in the article that portrayed the pivotal, phase 3 clinical trial by Pfizer. This article was published in the *New England Journal of Medicine* (*NEJM*) one day before the FDA's EUA (on Dec 10, 2020), and it explicitly declared that the newly developed vaccine "was 95% effective in preventing COVID-19."[3] Complementing this straightforward narrative of this high-impact study (which is currently cited more than 11,000 times, according to Google Scholar), vaccinated individuals were believed to be almost completely protected from the virus, and the few infections that did occur were termed by the Centers for Disease Control and Prevention (CDC) *"vaccine breakthrough infections,"*[4] as if these infections managed to penetrate the strong defensive wall of the vaccines.

Notably, throughout the pandemic, this "protection against infection" narrative served as the medical justification for the various governmental restrictions that were implemented on the unvaccinated populations, and many still view this type of VE as the primary desirable outcome of the vaccines. For example, Pfizer CEO Albert Bourla declared on May 25, 2022, that the goal of the new vaccines they were developing to cope with COVID-19 variants *"is to prevent the sickness—and that will maximize the chances to do well, and that will maximize the chances that people that you love, not to get infected. You vaccinate, not only for yourself. You vaccinate also to protect society, particularly to protect those that you love the most because they are the ones that you are together."*[5]

A Narrative Shift

Around September 2021, when the Delta variant became predominant, we identified a narrative shift towards VE against

severe illness and deaths.[6] Surprisingly, the outbreak of the new variants, including the eruption of the highly infectious Omicron variant in November 2021, as well as the ever-growing evidence regarding vaccine breakthroughs and poor VE against infections,[4,7-12] did not cause policymakers to pause and reconsider the very usefulness of the vaccines. Instead, many started to claim that the justification to keep administering booster doses of the vaccines should revolve around their presumed protection against severe illness and deaths.[1]

Corresponding with this modified narrative, on Jan 10, 2022, Pfizer's CEO explained that *"the three doses with a booster, they offer reasonable protection against* ***hospitalization and deaths****. Against deaths, I think very good, and* ***less protection*** *against infection"* [emphasis added].[13] Similarly, Dr. Fauci stated in a perspective article published in *NEJM* that *"vaccination has also been unable to prevent 'breakthrough' infections, allowing subsequent transmission to other people* ***even when*** *the vaccine prevents severe and fatal disease"* [emphasis added].[14, p 298] This new rationale, which created a dichotomy between the two types of protection (as if they do not depend on each other) seemed to receive scientific support from a large *NEJM* study from Israel that found that the *"protection [of the fourth dose] against confirmed infection appeared short-lived,* ***whereas*** *protection against severe illness did not wane during the study period"* [emphasis added].[12, p 1712]

But how valid is this modified narrative? Does the accumulating scientific literature about the second booster (i.e., the fourth dose) of the mRNA COVID-19 vaccine really support the notion that the two types of protection are independent from each other, and that the VE against severe illness and deaths remains intact long after the (now known) rapid decline in the VE against infections? To answer these questions, we conducted a rigorous review of representative and high-profile data from three types of sources: (1) the formal, phase 3 clinical trials by Pfizer and Moderna, which preceded the FDA's emergency use authorization, (2) the observational studies from Israel ("the world's lab"[15]), which examined the efficacy of the fourth dose at about the time the FDA authorized to administer this second booster, and (3) the contemporary dashboards of pandemic statistics that distinguish the COVID-19 from historical pandemics.[16]

Factual Evidence from the Phase 3 Clinical Trials

One might (falsely) assume that the key questions we presented above were already answered in the founding, phase 3, randomized control trials (RCTs) by Pfizer and Moderna that were published in the *NEJM*.[3,17] After all, longitudinal RCTs are considered to be the gold standard in biomedical research, and these phase 3 clinical trials specifically served as the scientific foundation for FDA's decision to provide an EUA to administer the newly developed mRNA COVID-19 products. Nevertheless, the reported results in these trials, although promising, still cannot be interpreted as evidence that support the modified medical narrative whereby VE against severe illness remains intact long after the decline in the VE against infection.

Apparently, these key clinical trials were not designed to investigate the most important outcome of VE against deaths,[18] and the rare death cases could not be interpreted.[11] Even the 6-month follow-up study by Pfizer did not yield significant differences in deaths from all causes between vaccinated individuals (N = 15 deaths out of 21,720 participants) and unvaccinated individuals (N = 14 deaths out of 21,728 participants).[19] In fact, the open-label stage of the study (when the blind condition was terminated following the FDA approval) yielded five additional deaths, all among vaccinated individuals, three among the original treatment group and two among the placebo group who were given the real vaccine during this open-label stage. Correspondingly, a recent overview by Benn and colleagues showed that total mortality did not differ between the treatment (vaccine) and the placebo groups of the phase 3 RCTs by Moderna or Pfizer.[20]

In the same way, the VE against severe illness, which was reported in these clinical trials, is difficult to interpret due to the rarity of hospital admissions. Pfizer's trial, for example, did not include any reports of hospital admissions.[11] The reported VE against severe illness is also difficult to interpret in light of the potentially biased testing[21] and uneven exclusion criteria[22] that undermined the internal validity of these phase 3 clinical trials. For example, 311 participants were excluded from the treatment arm of Pfizer's study, compared with only 60 participants in the placebo arm of the study, without satisfactory rationale for these uneven exclusions, thus raising concerns that the excluded populations might have suffered severe reactions, whether from the vaccine, or from the coronavirus.

The Importance of 'Conditional Probability' in the Assessment of VE against Severe Illness

In addition to the fact that the founding phase 3 clinical trials cannot be relied on to derive conclusions about VE against severe illness, these trials did not produce convincing evidence that the VE against severe illness may exist independently from the observed VE against infections, despite Moderna's claim about 100% VE against severe illness.[17] To explain this last assertion that concerns the key efficacy measurement of "conditional probability," we ought to take a scientific step backward.

Theoretically speaking, when a study finds indications for high VE against infections, it also typically obtains reduced numbers of severe illness cases in its treatment arm compared with the control arm. Consider, for example, a research scenario whereby 10 participants from the vaccine group were infected by the virus compared with 100 participants from the placebo group. Assuming equal numbers of participants in each group, the observed infections in this hypothetical study may indicate a high VE against infections. However, what if (typically about two weeks later) one out of the 10 participants (10%) from the vaccine group developed severe illness compared with 10 out of the 100 participants (10%) from the placebo group? In this scenario, the difference in numbers (1 versus 10) is essentially a byproduct of the vaccine's efficacy against infections. It does not teach us what will happen in cases in which the vaccine fails to protect against infections, like the situation we face today. To prove the independent VE against severe illness, the study's findings should indicate that the *conditional probability* of severe illness in the vaccine group (i.e., the percentage of severe illness among infected participants only) is significantly lower than the conditional probability of severe illness (among

infected participants only) in the placebo group. This has not been the case in the founding clinical trials by Pfizer and Moderna.

The sample sizes of the clinical trials that preceded the FDA's EUA, with their fantastic reported results claiming 95% efficacy against COVID-19, do not provide any insights regarding the vaccines' efficacy against severe illness. Only very few infection cases were reported in the vaccine arms of these studies (eight in Pfizer's trial and 11 in Moderna's trial), thus restricting our ability to derive insights based on the conditional probability of severe illness among these participants (one case of severe illness in Pfizer's trial and zero cases in Moderna's trial, which led the researchers to claim efficacy of 100% VE against severe illness). If anything, the Pfizer trial actually raises the concern that, in cases where the vaccine does not protect against infection, the prevalence of severe illness might be larger among individuals who received the vaccine compared with those who did not. This is because one out of the eight infected participants (12.5%) developed severe illness in the vaccine group compared with nine out of the 162 infected participants (5.6%) in the placebo group. Of course, these percentage estimates should be cautiously interpreted as they derive from very small numbers, as explained above.

Factual Evidence from Contemporary Observational Studies

Without convincing evidence from the formally designed, randomized, and controlled clinical trials, we are left with the observational studies that investigated the efficacy of the fourth dose of the vaccine (i.e., the second booster) in real-life settings. Although observational studies are even more vulnerable to unwanted biases (e.g., failures to take into account the lower, real-life testing levels for COVID-19 of vaccinated individuals compared with the unvaccinated),[23-25] when they are conducted properly they provide opportunities to increase the generalizability of the results to wide and diverse populations, to estimate the waning immunity of the vaccines over time, and to detect rare adverse outcomes of the vaccines.[26-27] Correspondingly, and perhaps also due to the medical uncertainties that characterized the COVID-19 crisis, the FDA relied on such observational studies to authorize the *fourth dose* of the vaccine (on Mar 29, 2022). Indeed, the FDA's news release describing this authorization[28] brings only one observational study by Regev et al.[29] as evidence for the efficacy of the fourth dose, but it states that "additional information on effectiveness [was] submitted by the companies." Since the news release did not include citations or links to this "additional information," we gathered the fourth-dose studies that were published around the time period of the FDA's authorization (March-April 2022). These studies were conducted in Israel—the world's "hot-spot" for COVID-19 vaccination research, or "the world's lab," as it was called by Pfizer officials.[15] Israel was the first country to approve the administration of this second booster (even before the FDA's official authorization) and to examine its efficacy in real-life settings through the large observational studies discussed below.

The Study by Regev et al., 2022

The news release announcing the FDA's authorization of the fourth dose to older and immunocompromised individuals included an explicit statement that "a second booster… improves protection against severe COVID-19."[28] Surprisingly, however, the sole scientific source mentioned to support this straightforward statement was a (small-size) Israeli study by Regev et al. at Sheba Medical Center,[29] which had not yielded encouraging efficacy results. Not only did this study (published in the *NEJM* about 2 weeks before the FDA's authorization on Mar 16, 2022) fail to address severe illness or to investigate the populations at risk for which the FDA approved the fourth dose, but its findings were also interpreted by the authors themselves as indication that the fourth dose "may have only marginal benefits."[29] This is because the observed VE against infections in this study ranged from 11% to 30%, for Moderna's and Pfizer's vaccines, respectively, and was statistically *insignificant* for both vaccines.

Notably, the poor results of this study regarding infections could have created an interesting scientific opportunity to assess the VE against severe COVID-19 outcomes, since the booster group included similar numbers of infected participants as the control group (see the theoretical discussion above on the importance of 'conditional probability' in the assessment of VE against severe illness). However, even in this unique case, the reported VE against symptomatic disease (between 31% to 43% for Moderna and Pfizer, respectively) is much below the minimum required vaccine efficacy, as determined by the World Health Organization,[30] and was, once again, *not* statistically significant. Notice that the authors do not report whether these VE scores are significant, but a review of the relevant figure in the study's supplementary material reveals that the 95% Confidence Intervals of the second booster group overlaps with the 95% Confidence Intervals of the control group. Of course, severe illness and deaths, as mentioned above, were not even assessed in this study, thus preventing us from calculating their conditional probability and deriving conclusions about these important outcomes.

The Study by Arbel et al., 2022

A preprint article by Arbel et al. concerning the fourth dose[31] was uploaded to Research Square on Mar 24, 2022, five days before the FDA's authorization. It was formally published about a month later in *Nature Medicine*.[32]

The preprint described a retrospective cohort study, which yielded a significant decrease in death cases (*Adjusted Hazard Ratio* = 0.22) among the 328,597 participants aged 60-100 who received the second booster, compared with the 234,868 participants who remained with the first booster only. However, this study suffers from major limitations that do not allow us to derive real-life conclusions based on its results. First, participants who were infected during the seven-day period from the second booster were removed from the sample—a methodological decision that might be justified theoretically, but de facto obscures actual death rates among the treatment group. Second, "participants were censored [from the study] in cases of death from any cause,"[31, p 7] and the data about death cases from all causes (i.e., not only the COVID-19 related deaths) were not reported despite the fact that the authors had access to "hospital reports regarding the cause of death."[31, p 4] This misrepresentation does not allow us to estimate the actual benefit-risk balance. Third, as explicitly acknowledged by the

authors, "it is possible that participants in this study died from other causes but were reported as death due to COVID-19 because they happened to have been SARS-Cov-2 positive when they died."[31, pp 4-5] Fourth, plain COVID-19 infection rates were not reported—a non-conventional omission, which does not allow us to evaluate the exact VE against deaths beyond the (short-term) protection against infections, using conditional probability estimates as discussed above. Finally, and most importantly, a key failure in the assessment of the outcome measure of the study (i.e., COVID-19 deaths) undermines its entire conclusions.

Whereas the follow-up of participants in the control group, who never received the second booster, lasted 40 days, over the entire period of this study (Jan 10–Feb 20, 2022), the follow-up of participants in the treatment group started seven days after they received the second booster (at a varying time point, all throughout the 40 days period of the study) and ended at the same time as the control group. A calculation of the weighted average of days in this follow-up, based on the available information in the preprint,[31, p 13] suggests that participants in the experimental second booster group were followed for about 22 days only. This calculation includes 9,247 who were not followed at all, since they only received the second booster five or fewer days before the termination of the study. The description of the study design implies that the actual follow-up of death cases continued up until Feb 27, 2022. If this is the case, then seven follow-up days should be added to both the treatment group and the control group. This uneven follow-up is problematic even if it is considered as a covariate in the statistical analysis, since the estimated number of days from the appearance of the first symptoms to death typically ranges from six to 41 days (median = 14).[33]

The Study by Bar-On et al., 2022

A large observational study by Bar-On et al. concerning 1,252,331 Israeli individuals older than 60 appeared in the *NEJM* on Apr 5, 2022, several days after the FDA's authorization.[12] Aside from the fourth-dose treatment group, this study had two control groups, a group of participants who received only three doses of the vaccine, and a designated "internal control group" that received four doses but was followed only during the first three to seven days when the vaccines are not presumed to be effective. The authors considered this group to be an improved control group because it had socio-demographic characteristics equivalent to the treatment group whereas the more general, three-dose control group had increased numbers of low-income minorities, which might bias the rates of severe illness. The key finding of this study was that Pfizer's fourth dose vaccine remained effective against severe illness six weeks from its administration, despite quick attenuation in its protection against infections—attenuation that started in about the fifth week and continued to drop so that, by the eighth week of the study, the VE against infections completely disappeared. To our knowledge, this was the first time that researchers reported results from which readers may deduce that the VE of the fourth dose against severe illness is above and beyond its efficacy against infections (i.e., not just a by-product of the VE against infections).

Notably, however, the validity of this finding is limited to an exceptionally narrow time window of one or two weeks, as severe illness was only monitored up until the *sixth week* from vaccination—that is, two weeks less than the follow-up period of infections, which ended after the *eighth week*, and demonstrated efficacy reduction from the *fifth week* onward. The justification provided for these uneven monitoring periods was "to minimize the effects of missing outcome data due to delays in reporting PCR or antigen test results and to allow time for the development of severe illness." Even if we disregard this strong limitation, when the precise efficacy rates against severe illness are calculated, while taking into account the uneven monitoring periods, the findings do not support the far-reaching conclusion of this study.

Based on Table 1 in that article,[12] Wohl and Leibowitz, for example, calculated that the conditional probability of severe illness (i.e., the percentage of severe illness cases from the total number of infections) in the treatment group is not significantly different from the conditional probability in the control groups, for individuals aged 60-69 years.[34] In response, Bar-On et al. offered three potential reasons why this calculation might be incorrect, but they still avoided the key problematic characteristic of the study, that is, the uneven monitoring period. Although their Table 1 presents 355 cases of severe illness out of 44,325 cases of infections in the experimental, fourth-dose group of the study, as can be seen in their Table 2, only 38,288 infections occurred during the second-to-sixth week period, when the parallel follow-up period of severe illness was conducted. This means that, regardless of age, the *real* conditional probability of severe illness in the treatment group was 0.927% (355 of 38,288 infections), just a little less than the conditional probability in the "internal control group," which was followed during the first three-to-seven days after vaccination. The conditional probability of severe illness in this internal control group (114 out of 10,531 infections) was 1.082%, thus teaching us that, when infected, the genuine reduction in the risk for severe illness following the administration of the fourth dose is quite minor, probably statistically insignificant, and limited to a period of one or two weeks.

We could not calculate the exact prevalence of severe illness in the crude, three-dose control group because the weekly distribution of infections in this group was not provided in the article and our requests to be given this information were not answered. However, from the information that was presented about this control group, in which 1,210 out of 111,780 infected participants (1.08%) developed severe illness over the entire period of the study, we learn that this group had a similar or perhaps a slightly larger prevalence of severe disease. These conditional probability rates echo an earlier preprint study by Bar-On et al.,[35] which was cited in the Briefing Document presented to the FDA prior to the approval of the first booster (the third dose). The 2-dose control group of this study consisted of 330 severe cases out of 3,473 infection cases (9.5%) and the booster treatment group consisted of 32 severe cases out of 313 infection cases (10.2%). Clearly, such results cannot be used to disprove the reasonable and straightforward assumption that the VE reduction against infections (from the fifth week onward) is probably followed by an equivalent reduction in the VE against severe illness and death (about two weeks later as discussed above).

The Study by Magen et al., 2022

Magen et al. estimated the efficacy of the fourth dose of Pfizer's vaccine from Jan 3 to Feb 18, 2022, in a study published in the *NEJM* two weeks after the FDA's four-dose authorization on April 13, 2022.[36] The follow-up period in this study lasted less than 47 days. The vaccination time points varied between participants, and the actual follow-up periods were confined to days 7 to 30 from vaccination, with no explanation given for the termination of the observation at the 30th day. The median number of follow-up days was 26, thus limiting the findings regarding infections to about 19 days after the reduction of the first 7 days. But more importantly, findings regarding deaths, which typically occur about 14 days after first symptoms,[33] are limited to (up to) nine days among the 2,838 participants who were infected at day 7, two days among the 2,170 who were infected at day 14, and zero days among the remaining sample.

It is possible then that the observed efficacy against deaths simply reflects the initial and temporary efficacy against infections. In this study, the daily efficacy against infections (45%) reached a peak of about 62% at about day 18, declined to about 40% at day 30, and probably kept declining to zero efficacy at day 56, as illustrated in the previously discussed study by Bar-On et al.[12] In this study, Magen et al. did not provide a daily efficacy figure for deaths (or other outcomes, aside from infections) and did not disprove the plain assumption that the decline in VE against infection was followed by an equivalent decline in the VE against deaths about two weeks later.

Factual Evidence from the Public Dashboards

Without convincing scientific evidence regarding the VE of the fourth dose of the mRNA COVID-19 vaccines, it seems that the public, and perhaps even medical officials, learn about VE against severe illness and deaths from ongoing and uncontrolled data from dashboards of pandemic statistics. In contrast to historical pandemics, the COVID-19 and the measures taken to attenuate its spread are constantly monitored through designated dashboards with running statistics that give a sense of objectivity and control at times of uncertainties.[16] However, data from these popular dashboards should be carefully interpreted.

Given their nature, which is not scientifically controlled, dashboards of pandemic statistics are exposed to multiple distortions. Examples include: (1) failure to control for socio-demographic confounders; (2) failure to control for unwanted effects of prior treatments; (3) asymmetric testing for COVID-19 such that unvaccinated patients are tested significantly more than the vaccinated (as discussed above in the observational studies section); and (4) non-COVID-related severe diseases that are counted as cases of severe COVID-19 upon positive testing, which is conducted in an uneven manner. There are, of course, additional real-life characteristics that impair the validity of dashboard-based information; however, here we discuss in detail only two (major) problems in the contemporary trend to derive insights from, and implement public-health measures based on non-scientifically controlled dashboards.

First, dashboard data are vulnerable to mistakes and unjustified alterations, as can be seen in the following example. To overcome the aforementioned bias of uneven testing levels through which real-life prevalence of COVID-19 tests is significantly higher among unvaccinated individuals compared with vaccinated individuals (because of the selective restrictions),[23-25] Koren, Altuvia, and Levi analyzed dashboard data about passengers who entered Israel through the country's international airport during August through October 2021. In this unique setting, where both vaccinated and unvaccinated individuals were tested for COVID-19 upon entering the country, the dashboard data indicated a significantly smaller VE against infections (only 35%) than the conventional VE rates, which were openly declared at that time by the Israeli Ministry of Health.[37] These low VE rates derived, among other reasons, from the *reversed efficacy* that was observed in the first month whereby significantly more vaccinated individuals were infected compared with unvaccinated individuals. Regrettably however, as the second author of the current article noticed, within only 24 hours from the first publication of these findings, the relevant dashboard data was altered completely, in a retrospective manner, to include many fewer positive COVID-19 tests among the vaccinated passengers and many more positive COVID-19 tests among the unvaccinated passengers.[38] Soon afterward, Yariv Hammer, an Israeli social activist, reported that the Israeli Ministry of Health has removed the entire slot that presented this unique information from the country's main entrance gate from the dashboard.[39]

The second major problem in dashboard data (aside from the multiple problems that were mentioned above in such uncontrolled and non-randomized datasets) is that the most important COVID-related information, that is the specific dataset of at-risk, old-age populations (where the vast majority of severe illness and deaths occur), is severely skewed. At the beginning of the global vaccination campaign, Israel has been leading the world in daily vaccine doses administered per person, and the current percentage of completely unvaccinated individuals among the elderly is negligible. According to the Israeli dashboard, as of October 2022, only about four percent of the Israeli population over the age of 70 were considered completely unvaccinated (in February 2023 the dashboard even reported zero percentage of unvaccinated—an improbable number that also indicates of the poor reliability of the dashboard data). Nevertheless, despite these small numbers of unvaccinated elderly persons, they are repeatedly referred to as the "baseline" control group from which we presume to learn about the VE against severe illness and deaths.

Aside from the fact that this small group of unvaccinated elderly does not account for the major load on the Israeli health system, it cannot be viewed as a proper control group. At this age, the reasons for not getting the vaccines usually do not involve ideological opposition. It is likely that the majority of these patients could not receive the vaccine because they were unable to reach health facilities (e.g., disabled elderly who are confined to their homes) or because they were too fragile to receive the injections (i.e., an immediate vaccine reaction might have been more dangerous to them compared with the risk for future COVID-19 infections).

We also know from the previously discussed study by Bar-On et al. that low-income minorities tend to be less vaccinated than others,[12] and it is fairly reasonable to assume that this distinct small group of unvaccinated elderly includes

disproportionate numbers of individuals from the weakest strata of the population. Thus, even if the presented data in dashboards of pandemic statistics were reliable (a problematic assumption as shown above), the increased levels of severe illness and deaths in these specific populations should probably be attributed to their primary health condition rather than to their vaccination status. In other words, rates of severe illness and deaths (even if not due to COVID-19) are expected to be higher in these selected four percent, and it is unwise to derive general conclusions regarding the vaccines' efficacy based on their observed (poor-to-begin-with) health status. This *selection bias* problem, as discussed above, is exactly why we have to conduct longitudinal randomized controlled trials (RCTs)—to make sure that the vaccine group and the placebo group comprise, more or less, the same type of population, including similar rates of healthy and less healthy individuals. RCTs are also critically needed to distinguish the proclaimed effects of the vaccines from the potentially beneficial outcomes of prior infections by COVID-19 and early ambulatory treatments against severe illness and deaths.[40-42]

Counterbalancing Risks

Though a detailed consideration of the risks of the vaccines is beyond the scope of this paper, they need to be mentioned here to complete the scientific picture and allow readers to balance the unfounded efficacy of the vaccines discussed in this article with their known risks. Aside from the potential evolvement of dangerous variants following intense immune pressure exerted by mass vaccination,[43,44] numerous studies raise concrete concerns over multiple, and in many cases serious, adverse outcomes,[45-47] including cardiovascular,[48-60] immunological,[61-63] and neurological reactions. Thus, we join previous cautionary calls[64-66] that emphasize the urgent need to reassess the balance between the benefits and the risks of the COVID-19 vaccines.

Summary

With the accumulating evidence regarding vaccine breakthroughs and rapid decline in VE against infections, the official medical narrative has changed. The modified justification for the continuation of the vaccination campaign now revolves around the alleged protection of the vaccines against severe illness and deaths. However, the representative data from the various sources examined here, including the founding clinical trials by Pfizer and Moderna, the nationwide observational studies from Israel on the fourth dose, and the pandemic dashboards, do **not** provide convincing evidence that the booster doses of the mRNA vaccines can offer longstanding protection against severe illness and deaths that extends significantly beyond the temporary and fragile protection against infections.

Of course, the current article cannot replace a comprehensive systematic review of all the available studies on the efficacy of the COVID-19 vaccines. However, in scientific discourse, a single "black swan" (i.e., negative instance that does not fit in with a given theory) may falsify a universal claim, as well put by Sir Karl Popper; and this article presented numerous such black swans.

The *multiple methodological and representational limitations* (e.g., the exceptionally short or uneven follow-up periods, the real-life differences in testing levels, the selection bias problem, and the data corruption) alongside the *equivalent conditional probabilities of mortality/severe illness cases* in both the treatment and the control groups of the various studies challenge the validity of the new (modified) narrative, thus leaving the global vaccination campaign without proper scientific justification.

Conclusion

The widely accepted medical narrative today, as if the booster doses of the mRNA vaccines prevent severe illness and deaths despite their failure to protect against infections, lacks scientific support. It is more likely that this proclaimed efficacy against severe illness and deaths is merely a wishful myth, which has no empirically grounded evidence. We therefore openly call for an immediate, even if temporary cessation of the vaccination campaign until real evidence is available, especially considering the critical safety signals, which seem to be downplayed unjustifiably in the medical and scientific discourse.

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