

Green Pass and COVID-19 Vaccine Booster Shots in Israel – A More ‘Realistic’ Empirical Assessment Analyzing the Airport Data

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Abstract

The document describes analysis that is based on data published on September 25, 2021, by the Israeli Ministry of Health (MOH) on its control dashboard about returning Israelis through the national airport, including the respective numbers of Vaccinated and Unvaccinated individuals and the number of positive COVID-19 cases identified in each cohort. The data reflect the modified definitions of Vaccinated and Unvaccinated status after the Pfizer booster shot, based on which the new eligibility for a Green Pass is determined. More importantly, this is a unique setting where the Vaccinated and Unvaccinated individuals are all tested in (almost) the same intensity, which allows a more objective assessment of both the booster and Green Pass efficacy in preventing infections.

The analysis suggests that the rate of infections among the Vaccinated cohort is only 1.61-fold (about 40 percent) smaller than the one among the Unvaccinated cohort. This implies that the absolute number of infected individuals in the Vaccinated groups is likely to be comparable to the number in the Unvaccinated. The conclusion is that the new Green Pass is likely to be ineffective in preventing infection spread, and could even put high risk individuals at risk. Moreover, the analysis also suggests that the relative protection of the booster shot against infection is likely to be significantly smaller than the advertised 10-11-fold (over 90 percent) by the MOH, probably around or even less than 2.75-fold (about 65 percent). This analysis highlights the fundamental methodological problems in the current efficacy assessment by the MOH and calls for further and more open assessment.

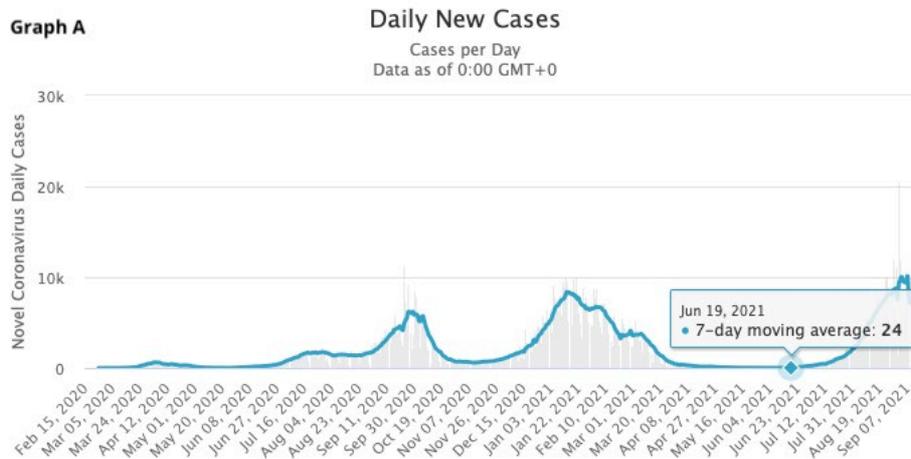
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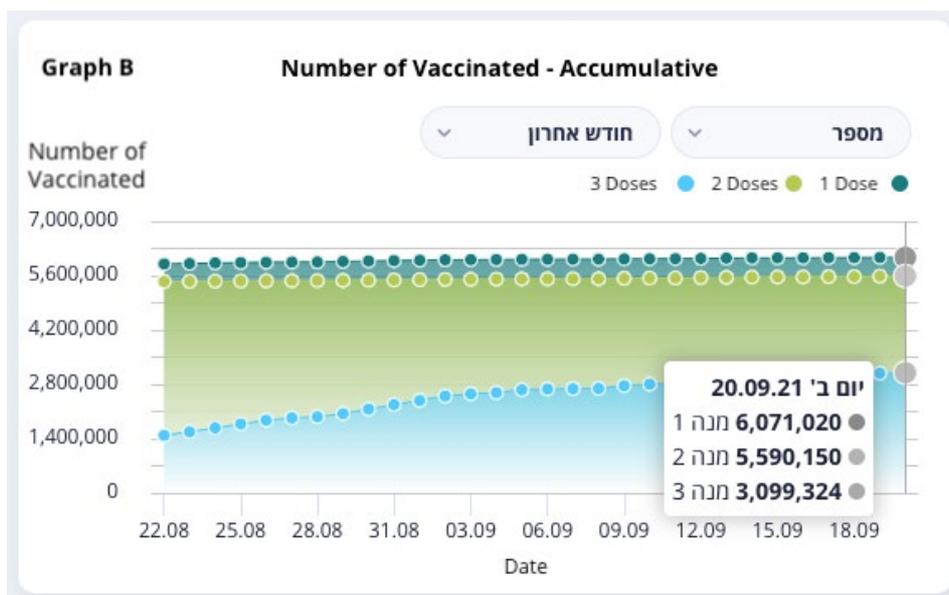
Background

Since the 3rd week of June 2021 Israel has been experiencing another wave of COVID-19 infections, as seen in Graph A⁴.



This wave has continued in spite the implementation of a strict “Green Pass” policy that required any unvaccinated individuals above the age of 3 to show a recent (last 24 hours) negative COVID-19 test in order to be able to enter restaurants, shows, sport events and other public settings and events. In fact, similar policy is now implemented by many work places.

Due to the rapidly increasing number of confirmed cases and resulting hospitalizations and deaths, the Ministry of Health (MOH) has concluded⁵ that the Pfizer-BioNTech vaccine’s efficacy is waning over time to the extent that it is necessary to administer a booster shot (3rd dose of the Pfizer-BioNTech vaccine). On July 30, 2021, Israel launched an aggressive booster vaccination campaign starting with the over 60 population and rapidly expanding to all ages above 12. As of September 20, 2021, the booster shot was administered to nearly 3.1 million people as can be seen in the Graph B⁶.

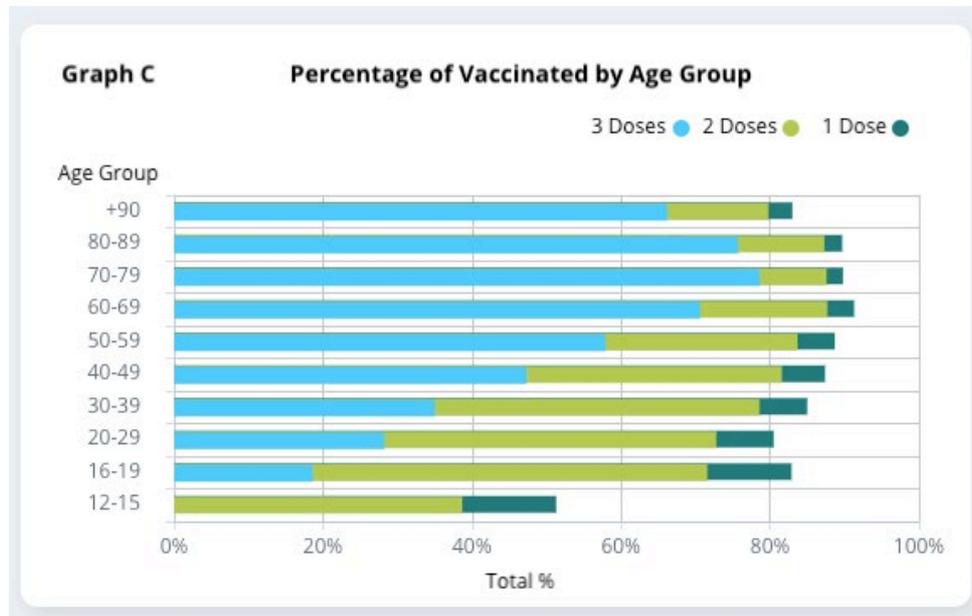


⁴ Taken from <https://www.worldometers.info/coronavirus/country/israel/>

⁵ Waning immunity of the BNT162b2 vaccine: A nationwide study from Israel <https://www.medrxiv.org/content/10.1101/2021.08.24.21262423v1.full-text>

⁶ Taken from the Israel MOH dashboard: <https://datadashboard.health.gov.il/COVID-19/>

As can be seen from Graph C⁷, as of September 20, 74% of the over 60 population received the booster. Similarly, 58% of the 50-59 population, 47% of the 40-49, 35% of the 30-39 population, 28% of the 20-29 population and 19% of the 16-19 population.



The New Green Pass Eligibility in Israel

Following the aggressive booster vaccination campaign, as of October 3, 2021 the Israel MOH has changed the eligibility criteria⁸ for Green Pass holders, requiring anyone that received the second dose of the Pfizer vaccine more than 6 months ago to get vaccinated with a booster shot or otherwise lose their Green Pass. Additionally, individuals who recovered more than 6 months ago will also be required to vaccinate. To summarize this change, the new definition of Vaccinated and Unvaccinated is as follows:

Vaccinated:

- Anyone who has received the 3rd dose (booster) more than 7 days ago.
- Anyone who has received 2 doses more than 7 days ago, but less than 6 months ago.
- Anyone who recovered after testing positive (PCR test), or shows recovery signals on a serological test within the last 6 months, or has received 1 dose more than 7 days ago.

Unvaccinated:

- Anyone who did not receive 2 doses at least 7 days ago. (note that this includes completely unvaccinated individuals).
- Anyone who has received their 2nd dose more than 6 months ago.

The Israel MOH justifies the epidemiologic rationale of the new Green Pass policy based on several studies that show that the protection of the initial 2 doses of the Pfizer vaccine against infection wanes over time⁹ and that the booster presumably regains this protection level back.

⁷ Taken from the Israel MOH dashboard: <https://datadashboard.health.gov.il/COVID-19/>

⁸ <https://www.gov.il/he/departments/news/29082021-01>

⁹ Waning of BNT162b2 vaccine protection against SARS-CoV-2 infection in Qatar (<https://www.medrxiv.org/content/10.1101/2021.08.25.21262584v1>)

Thus, it is effectively 'safe' to let Vaccinated individuals (based on the new definition) to enter public settings with no tests and require Unvaccinated individuals (again see above) to be tested.

In particular, on Sep. 15, 2021 a group of researchers, including Dr. Sharon Alroy-Preis, Head of Public Health Services in Israel Ministry of Health (MOH) published a study of the booster efficacy¹⁰ based on data collected by the MOH during the campaign. The study asserts that the booster achieves a 11.3 (95% confidence interval [CI], 10.4 to 12.3) relative reduction in the risk of COVID-19 infection¹¹ among the over 60 population, compared to the original 2 vaccine doses.

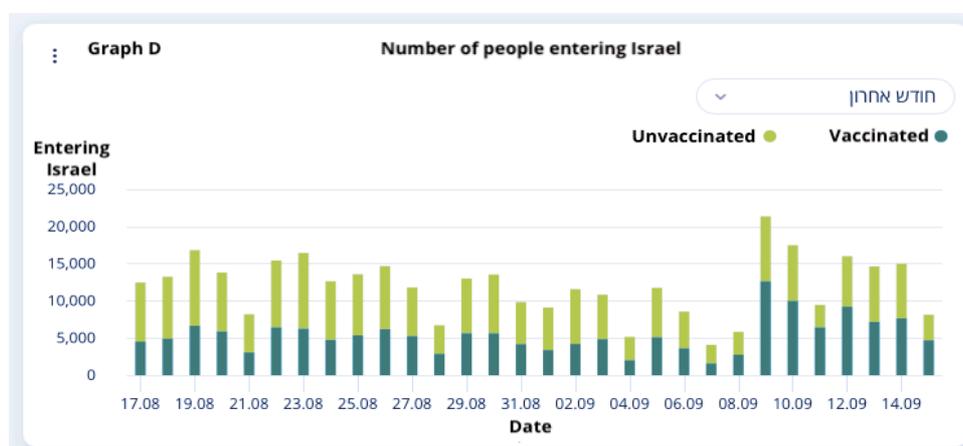
Overall, the paper follows 1,137,804 individuals ages 60 or older, who were eligible for a booster dose (who received their second dose before March 1, 2021) between July 30 (when the booster campaign was launched) and August 31, 2021. The study compares the rates of infection and severe COVID-19 outcomes per person-days at risk between two cohorts to estimate the booster efficacy, using Poisson regression, adjusting for possible confounding factors.

Unfortunately, there are multiple methodological problems with this study, the most significant of which is the fact that there is no appropriate control for the number of **respective tests** conducted among the members of each cohort. Moreover, the resulting respective positivity rates are not reported. This is a major potential source of an upward bias of the booster efficacy against infection, since there are all reasons to assume that the booster cohort was tested in significantly lower intensity, and in fact there are data in the MOH paper itself to support this assumption. The different intensity is the result of both individual behavior (i.e., individuals who are vaccinated with the booster will be less concerned about infections and will test less frequently) as well as the MOH testing policy.

Estimating of the Green Pass Efficacy Based on Data from Israel Airport

Recently, the MOH introduced a new "widget" to the public online Control Dashboard¹² that presents detailed data on individuals entering into Israel. The data includes information on the vaccination status as well as the number of positive cases as a function of the vaccination status.

Graphs D & E present the aforementioned 'widgets' in the MOH Dashboard related to the individuals that indeed provide, for each day, the exact number in each group, as well as the number of positive cases, whereas positive cases constitute of individuals who tested positive within the first 10 days of their return date. **Note that in spite of the difference in testing between the two groups of Vaccinated and Unvaccinated mentioned above, at least in this setting all individuals must take a test upon entering Israel.**



¹⁰ Protection of BNT162b2 Vaccine Booster against Covid-19 in Israel

<https://www.nejm.org/doi/full/10.1056/NEJMoa2114255>

¹¹ The study also reports the rate of severe illness was lower by a factor of 19.5 (95% CI, 12.9 to 29.5).

¹² <https://datadashboard.health.gov.il/COVID-19/general>

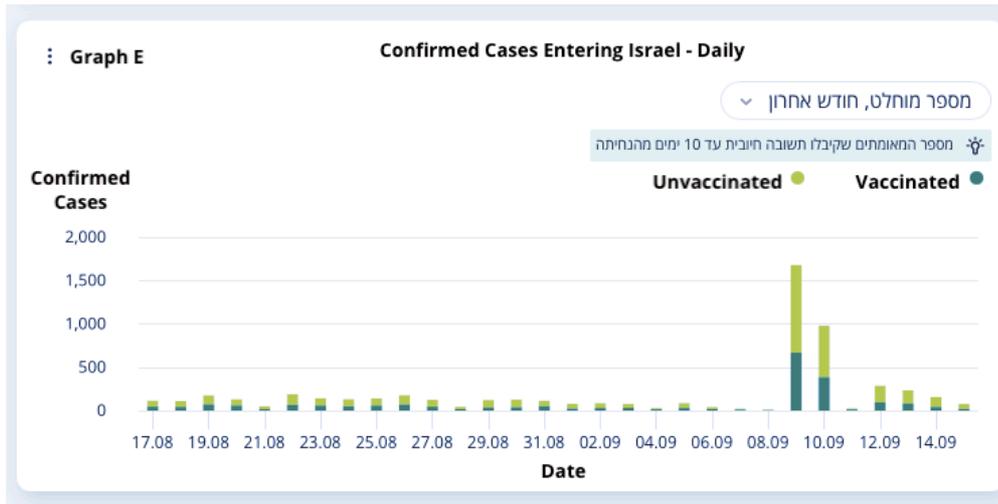


Table 1¹³ below shows the respective data of the above-mentioned airport widget (as published by end of September on the MOH control dashboard) for 45 days throughout September 25, 2021. There were 3016 confirmed cases among 314,369 Vaccinated, which is 0.96% positivity rate. Additionally, there were 4776 confirmed cases among 308,494 Unvaccinated which is 1.55% positivity rate. This implies that the relative risk of infection among the Vaccinated is reduced by a factor of 1.61, which is significantly lower than the 11.3-fold reduction estimate presented in the MOH's paper.

Furthermore, it is important to note September 9-10, 2021 as unique days that capture an event where thousands of Orthodox Jews returned from Uman (Ukraine) and many falsified hundreds of PCR results prior to coming back to Israel. These two days represent an outlier and omitting them and the following 10 days (accounting for the 10 day period after arrival over which they consider positive cases) from the analysis further reduces the estimated efficacy of the booster vaccine to 1.35.

Based on high booster vaccination rates, it is reasonable to assume that at least 40 percent of the newly defined Vaccinated cohort (see above) are vaccinated with a booster and most of the rest are more recently vaccinated individuals with 2 doses. If one takes a conservative assumption that the relative protection of the individuals who are vaccinated with 2 doses (less than 6 months ago) is at least 20 percent (1.25-fold), it follows that the relative protection of the booster is at most 2.75-fold (about 65 percent). In fact, assuming that the booster shot indeed provides protection of 11-fold implies that those vaccinated with 2 doses have no additional relative protection (less than 1-2 percent).

All of these conclusions follow from the fact that the overall relative efficacy of the Vaccinated cohort seems to be around 1.61-fold and the insight that the relative protection of the Vaccinated cohort is closely approximated by the weighted average (based on the relative proportion within the Vaccinated cohort) of the respective relative protection of each of the sub-cohort (boosters and 2 doses). Considering the recovered individuals who are known to have extremely high protection against infection will make this analysis even less favorable with respect to the booster efficacy.

¹³ Table 1 was created on Sep 25, 2021 to reflect the most current data.

Group A: "Vaccinated"

Pos A: the number of confirmed cases (absolute number) among Group A

Group B: "Unvaccinated"

Pos B: the number of confirmed cases (absolute number) among Group B

More generally, the analysis above makes it very clear that the Green Pass policy epidemiological rationale is highly questionable. Considering all individuals over 12 who are vaccine-eligible, the current Vaccinated cohort is 1.6 times larger than the Unvaccinated cohort. Thus, the absolute number of infected individuals from the Vaccinated cohort is likely to be at least as large as the number within the Unvaccinated cohort. Moreover, since these individuals will not be tested and be less likely to have symptoms or attribute their symptoms to being infected with the COVID-19 virus, it is quite likely that they will interact with many more contacts and run a significant risk to infect others. This risk is underscored by consistent findings that vaccinated individuals, once infected, can have high viral load¹⁴.

In conclusion, the analysis above suggests that the relative protection against infection between the individuals in the newly defined Vaccinated and Unvaccinated cohorts based on the new Green Pass policy is only 1.61 (about 40 percent) or even less. This suggests that unless the protection of the 2 doses have completely waned within less than 6 months, the relative protection of the booster shot is significantly lower than the MOH estimates of 11-fold (over 90 percent), probably at most 2.75-fold (about 65 percent).

Equally the analysis raises fundamental questions regarding the rationale of imposing the new Green Pass policy as it seems that it is not going to be effective in truly eliminating infections, especially considering the expected decline in the booster efficacy over time. In fact, the Green Pass policy could encourage the wrong perception within high risk patients that they are protected around vaccinated individuals, whereas those can be infected and infect them.

¹⁴ Shedding of Infectious SARS-CoV-2 Despite Vaccination
(<https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4>)

Table 1 was created on Sep 25, 2021 to reflect the most current data.

Table 1: Confirmed Cases Entering Israel

Date	Group A	Pos A	Group B	Pos B
10-08-2021	8756	89	10444	78
11-08-2021	6116	87	8600	121
12-08-2021	6293	77	9300	106
13-08-2021	5847	68	6884	71
14-08-2021	3460	46	4860	63
15-08-2021	8803	78	10837	99
16-08-2021	6109	55	8780	89
17-08-2021	4524	45	7937	68
18-08-2021	4909	42	8340	66
19-08-2021	6654	69	10168	106
20-08-2021	5887	56	7924	73
21-08-2021	3061	15	5140	34
22-08-2021	6419	65	9011	124
23-08-2021	6253	56	10200	86
24-08-2021	4751	49	7879	81
25-08-2021	5365	56	8214	84
26-08-2021	6199	68	8483	109
27-08-2021	5263	45	6535	79
28-08-2021	2872	16	3855	27
29-08-2021	5629	35	7385	86
30-08-2021	5627	37	7918	90
31-08-2021	4170	51	5664	62
01-09-2021	3369	22	5744	55
02-09-2021	4200	29	7384	56
03-09-2021	4836	31	5993	44
04-09-2021	2018	14	3129	15
05-09-2021	5107	29	6653	57
06-09-2021	3623	17	4930	22
07-09-2021	1574	10	2524	13
08-09-2021	2758	7	3065	8
09-09-2021	12609	745	8750	1123
10-09-2021	9991	446	7490	713
11-09-2021	6419	18	3044	15
12-09-2021	9223	118	6786	242
13-09-2021	7166	95	7485	182
14-09-2021	7657	61	7336	144
15-09-2021	4687	28	3456	70
16-09-2021	10	1	7	0
17-09-2021	9946	23	5521	32
18-09-2021	9271	13	3777	14
19-09-2021	13527	34	7926	50
20-09-2021	12319	20	7151	32
21-09-2021	8134	7	4051	18
22-09-2021	11907	7	5565	13
23-09-2021	14279	15	6969	27
24-09-2021	14466	16	5407	23
25-09-2021	12306	5	3993	6
Total:	314369	3016	308494	4776
	% Positive	0.96%	% Positive	1.55%
			Average Ratio:	1.61

Group A: "Vaccinated"

Pos A: the number of confirmed cases (absolute number) among Group A

Group B: "Unvaccinated"

Pos B: the number of confirmed cases (absolute number) among Group B