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# Revised: The Importance of Correct Infection and Exposure Pool Estimations when Making a Comparison Between COVID-19 Vaccine Injury Rates Among Vaccinees and COVID-19 Injury Rates Among Unvaccinated Individuals

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SUMMARY

On August 25, 2021 the above paper, Safety of the BNT162b2 mRNA COVID-19 Vaccine in a Nationwide Setting, was published in New England Journal of Medicine. Unfortunately, the study includes two method errors which make the comparison between COVID-19 vaccine injury rates and COVID-19 injury rates in it incorrect. More specifically, the vaccine injury rates among vaccinees are compared to disease injury rates among confirmed infected people when instead they should be compared to disease injury rates among the total pool of unvaccinated people. I'll here explain how come using highly adequate infection and exposure pool estimations when conducting such a comparative study is of utmost importance. I'll also carry out a more correct calculation of the total pool of unvaccinated people, based on official infection rate figures.

## Introduction

On August 25, 2021 the above paper, Safety of the BNT162b2 mRNA COVID-19 Vaccine in a Nationwide Setting, authored by Barda *et al* from the Israeli Clalit Research Institute (CRI), was published in New England Journal of Medicine [2]. The title of the paper describes its content very well, although in addition to investigating the occurence of various injuries following BNT162b2 mRNA COVID-19 vaccination, it also made a comparison between injury rates among vaccinees and COVID-19 injury rates among infected individuals.

I've now gone through and reviewed this paper and I'm sorry, but this study is not correct. That is, it contains two major method errors. First of all, the pool of people used as denominator when calculating the percentage of COVID-19 infected people who developed certain conditions due to the infection is greatly inadequate. Second, the vaccine injury rates among vaccinees were compared to disease injury rates among infected people when instead they should’ve been compared to disease injury rates among the total pool of unvaccinated people. These method inadequacies have serious consequences. I'll explain what I mean.

## Correct estimation of infection pool

When calculating the risk of developing a medical condition from an infectious disease, you need to make a correct assessment of how how large the pool of infected people is. And to do that, you need to make an *estimate*. Merely counting the number of people who've tested positive in a certain area isn't enough, as you need to include people who don't go test themselves because of being asymptomatic, or of not having the energy to do it due to their symptoms, or of lacking interest or knowledge about the infection et c. There may be many different reasons. This means you need to make an estimate, otherwise the denominator in the calculation of the percentage of infected people who develops the condition becomes incorrect.

I'll use the study Estimation of the Lethality for COVID-19 in Stockholm County published by the Swedish Public Health Agency as an example of a correctly calculated risk, based on an adequately defined denominator [3]. The fact that this was a calculation of the lethality percentage from COVID-19 and not the percentage of infection complications is irrelevant, the point is that the same mathematics used in this study should've been applied in the present CRI study. From the Swedish study, in translation:

"Recruitment was based on a stratified random sample of the population 0-85 years. In the survey we use, the survey for

Stockholm County was supplemented with a self-sampling kit to measure ongoing SARS-CoV-2-infection by PCR test. The sampling took place from March 26 until April 2 and 18 of a total of 707 samples were positive. The proportion of the population in Stockholm County which would test positive was thus estimated at 2.5%, with 95% confidence range 1.4-4.2%."

For a complex reason, which I won't go into but is described in the study text, one sometimes needs to use a slightly higher percentage when multiplying it with the total number of people in the pool, but that's of minor importance. Anyway, in this study they had to use the figure 3.1169% and when they multiplied it with the number of people in Stockholm County, 2 377 000, they got 74 089. This estimate was then the correct denominator to use when calculating the percentage of people who died from COVID-19 in Stockholm County during this time period.

The numerator was the number of people who died in Stockholm County with a strong suspicion of COVID-19 as a cause, which was 432, no incorrectness there either, as long as a suspected cause number, not a diagnosed cause number, is also used as the numerator when calculating the lethality from the COVID-19 vaccine when the infection lethality and vaccine lethality rates are compared.

So, what they found was that the lethality from COVID-19 in Stockholm County was 0.58%. This was a correct figure, as long as we keep in mind the fact that some of the suspected COVID-19 deaths may later have become diagnosed as unrelated to the infection.

The above is thus how the authors of the present study should've carried out their calculations but they didn't. From their text:

"Each day in this SARS-CoV-2 analysis, persons with a new diagnosis of SARS-CoV-2 infection were matched to controls who were not previously infected. As in the vaccine safety analysis, persons could become infected with SARS-CoV-2 after they were already matched as controls on a previous day, in which case their data would be censored from the control group (along with their matched SARS-CoV-2–infected person) and they could then be included in the group of SARS-CoV-2–infected persons with a newly matched control. Follow-up of each matched pair started from the date of the positive PCR test result of the infected member and ended in an analogous manner to the main vaccination analysis, this time ending when the control member was infected or when either of the persons in the matched pair was vaccinated."

I e, the selection pool for their SARS-CoV-2 analysis merely consisted of confimed infected persons. This excluded a considerable amount of infected persons in the total pool of roughly 3 million people of relevant age during the study period belonging to Clalit Health Services (CHS), the health care organization in question, who didn't go test themselves because of a number of reasons (being asymptomatic, not having the energy or interest for it, et c). In short, the pool of participants should've been added with a vast amount of both symptomatic and asymptomatic SARS-CoV-2 positive people who didn't develop these medic care necessitating conditions.

How large then, exactly, should the denominator have been? Well, the present study looked at the time period from March 1, 2020 to to May 24, 2021. What we need to do first, is to look at the official statistics of how many estimated new infections arose in Israel during these 15 months in question. And this figure is found by means of the statistical online resource Our World in Data, via the page presenting daily new estimated COVID-19 infections in Israel [4]. If we download the file and look at the figures, we find that the total number of estimated infections in the country during these 15 months amounted to 2 099 453. Prevalence studies of this period indicate that the adequate estimate to use here is the upper one [5].

If we then look at the data for confirmed infections in the country during this period, we see that they amounted to 839 689. This means that the estimated number of infections was 2.5 times higher than the number of confirmed. And this, in turn, means that we have to multiply the incorrect denominator in the study by 2.5 to get the correct denominator, which should've been used instead.

Further, in the CRI study's Figure 4, eleven adverse events after vaccination are chosen for comparison with the occurence of these after infection, and we find the following excess risk numbers associated with COVID-19: Arrhythmia 0.166%, acute kidney injury 0.125%, pulmonary embolism 0.062%, deep-vein thrombosis 0.043%, myocardial infarction 0.025%, pericarditis 0.011%, myocarditis 0.011%, intracranial hemorrhage 0.008%, appendicitis 0.004% and lymphadenopathy 0.003%. As for herpes zoster infection, the study found that COVID-19 reduced instead of increased the risk of acquiring it, with 0.009%.

Now, if we apply the laws of mathematics and recalculate these numbers, taking into account that the pool of participants should've been 2.5 times larger, we get the following, more correct figures: Arrhythmia 0.066%, acute kidney injury 0.050%, pulmonary embolism 0.025%, deep-vein thrombosis 0.017%, myocardial infarction 0.010%, pericarditis 0.004%, myocarditis 0.004%, intracranial hemorrhage 0.003%, appendicitis 0.002%, lymphadenopathy 0.001% and herpes zoster infection -0.013%.

I'd here like to interpose a recommendation of reading through the Swedish COVID-19 lethality study that I took up in the beginning of my text as a correct, comparative example

[3]. The PDF is easily translated into any language via Google Translate. This is the main paper that the Swedish equivalent to the Centers for Disease Control and Prevention, the Public Health Agency (Folkhälsomyndigheten), refers to when talking about COVID-19 lethality here and it's put up on one of the major information pages of their website. I really recommend reading all of it, because it explains so well and in such detail how come this model of denominator calculation without exception must be used in studies like these, which aim to investigate the rate of injuries/complications arising from an infectious illness.

**Correct estimation of exposure pool**

Let's continue to the second method error of the CRI paper. The vaccine injury rates among vaccinees were in the study compared to disease injury rates among infected people, when instead they should've been compared to disease injury rates among the total pool of unvaccinated people (the unvaccinated pool in the first part of the study is irrelevant as it merely constituted a COVID-19 negative control group, incomparable to a real life pool of unvaccinated people). From the paper:

"To place the magnitude of the adverse effects of the vaccine in context, we also estimated the effects of SARS-CoV-2 infection on these same adverse events during the 42 days after diagnosis."

Also, in the study's Figure 3 and Figure 4, injury rates among vaccinees and injury rates among infected people are directly compared. The problem is, this type of comparison simply cannot be done, i e, it's an incorrect comparison. This is because the alternative to taking a vaccine is to *not* take the vaccine, the alternative isn't to get the infection. Also, when comparing vaccinees to infected instead of unvaccinated, the risk/benefit assessment derived from these figures becomes greatly inadequate. I'll explain what I mean.

Let me start by taking the potentially crippling condition myocarditis as an example, a COVID-19 vaccine injury which has been extra noted in media lately since it primarily affects very young adults and teenagers, among which the increased risk after vaccination is around 0.02% [6]. According to the present study's data, there was a 0.003% increased risk of getting myocarditis after the vaccine, and since older individuals were included here, that's a correct figure. Further, according to the study's data, the increased risk of developing the condition after a confirmed COVID-19 infection was 0.011%. Since we in accordance with the laws of mathematics have corrected that figure though, it's now narrowed down to 0.004%.

However, when comparing the risk of developing medical condition X from taking vaccine Y with the risk of developing condition X from not taking vaccine Y, you can't compare a pool of vaccinees with a pool of infected people. Because when you take a vaccine, there's a 100% risk of getting the "infection" (in this case with viral RNA), while in the case of not taking the vaccine, it doesn't imply a 100% risk of getting the infection (with the virus), but a much lower risk.

And as we've seen, in Israel during the analysis period of the present paper, the accumulated number of estimated COVID-19 infections towards the end of the study period was 2 099 453. According to same source, Our World in Data, the accumulated number of estimated infections in the beginning of the period was 661. Based on the size of the country's population in 2021 [7] and in accordance with the laws of mathematics, this means that the infection risk was 0.007% in the beginning of the study period and 22% towards the end of it. Thus, the average infection risk during this period was 11%.

This means that we have to multiply the figure 0.004% by 0.11 to get the correct risk increase for people of acquiring myocarditis if they stayed unvaccinated. And this in turn means that the risk increase for COVID-19 derived myocarditis for people who didn't get the vaccine was as low as 0.0004%. Now we're suddenly in a whole different ballpark, as 0.003, the vaccine myocarditis risk increase figure, is 7.5 times as much as 0.0004. And this means that as for myocarditis, the risk of acquiring it was 7.5 times higher if you got vaccinated as opposed to if you abstained.

Further, we have to apply this recalculation to all the other recalculated COVID-19 related injury data in the study as well, given that the unvaccinated didn't have a 100% risk for infection but only 11%. What we then find, is that if you were unvaccinated, the correct COVID-19 derived risk increase figures for the eleven mentioned conditions were:

Arrhythmia 0.007%, acute kidney injury 0.006%, pulmonary embolism 0.003%, deep-vein thrombosis 0.002%, myocardial infarction 0.001%, pericarditis 0.0004%, myocarditis, as said, 0.0004% also, intracranial hemorrhage 0.0003%, appendicitis 0.0002%, lymphadenopathy 0.0001% and herpes zoster infection -0.014%.

Let's now look at the risk increase figures for COVID-19 vaccinated individuals according to the study. These were fully correctly calculated since there are no unregistered vaccinees and therefore the registered figure is to be used. For appendicitis, the vaccine generated risk increase was 0.005%, for myocardial infarction, it was 0.001%, for pericarditis, it was 0.001% as well, for myocarditis, it was, as mentioned, 0.003%, for herpes zoster infection, it was 0.016% and for lymphadenopathy, it was as high as 0.078%. For acute kidney injury, arrhythmia, deep-vein thrombosis, intracranial hemorrhage and pulmonary embolism, the vaccine related effect was slightly negative: -0.005%, -0.006%, -0.001%, -0.003% and -0.001%, respectively.

Now, what we find if we add all eleven vaccine related risk figures together and then compare that sum to the sum of all eleven risk figures for the unvaccinated group, is that the aggregated risk increase for the vaccinated individuals was as much as 14.7 times higher than the corresponding risk increase for the unvaccinated. For the vaccinated, the aggregated risk increase was 0.088%, while the figure for the unvaccinated was 0.006%, and it's worth underlining that these are all very serious afflictions (or, as for lymphadenopathy, can point to such).

Let me emphasize: The risk increase of acquiring a SARS-Cov-2 derived form of one or more of the eleven serious conditions focused on in this large study was *14.7 times higher for vaccinees than for unvaccinated individuals.*

One may object here and say that even if the vaccine increased the risk of developing a number of conditions, it also reduced the risks of developing a number of them. From the paper:

"The BNT162b2 vaccine appears to be protective against certain conditions such as anemia and intracranial hemorrhage. These same adverse events are also identified in this study as complications of SARS-CoV-2 infection, so it appears likely that the protective effect of the vaccine is mediated through its protection against undiagnosed SARS-CoV-2 infection, which may be undiagnosed either because of a lack of testing or because of false negative PCR results."

In the study's abstract, this is commented as well:

"In this study in a nationwide mass vaccination setting, the BNT162b2 vaccine was not associated with an elevated risk of most of the adverse events examined."

Well, that's something of a play with words, because if we look at Table 2 in the paper, where the entirety of adverse events associated with the vaccine is listed, we find that in total, the risk reduction for serious conditions generated by the vaccine was 0.04%, while the total risk increase for serious conditions generated by it was 0.14%; that is, a whole 3.5 times larger.

**Conclusion**

Interestingly, with their work including the abovementioned errors, these authors have actually provided scientific validation of the growing suspicion that the COVID-19 vaccinated state gives rise to various serious injuries to a much greater extent than does the unvaccinated (which is the opposite of the message of the paper) because even if the figures used for comparison with the vaccine injury figures are inadequate, the other figures in the study are most likely not.

Towards the end of the study, one of the problems discussed above is briefly mentioned:

"When a person decides to become vaccinated, this choice results in a probability of 100% for the vaccination, whereas the alternative of contracting SARS-CoV-2 infection is an event with uncertain probability that depends on the person, place, and time."

However, since omitting to include a calculation example with an adequate exposure pool, based on a correct infection pool and official infection rate figures has such a large impact on the main message of this paper - changing it from defining the COVID-19 vaccinated state as less injurious than the unvaccinated, to the opposite - merely briefly mentioning it towards the end like this, as one among several limitations of the study, is so greatly misleading that it constitutes an error in itself.

Finally, and most importantly, there's a reason why the method inadequacies discussed here have especially serious consequences in this particular case. That is, CDC, the major public health organization in the US and an organization with profound influence on public health officials worldwide, refers to this study and its figures in their documents as a source to support their view that the benefits of COVID-19 vaccinating the population outweigh the risks connected to it [8, 9]. Of course, had the present study been correctly performed, it would've pointed the CDC in the direction of determining the opposite; that the risks of vaccinating are far greater than abstaining.

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