In Search of Safety Signals – Let the Light Shine In

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Away from the mainstream media, controversy continues about the balance of risks and benefits of universal Covid vaccination.

The true status will continue to be in doubt so long as the health authorities keep the relevant information close to their chests instead of releasing it openly to the public.

This makes life difficult for policymakers who have to rely on bureaucratic intermediaries to give them advice, which is politically very difficult for them to disregard. But political advisers need to run their own checks on the available data so that their masters can hold the agency heads accountable. Let's try and do this using any data we can find from the various US surveillance systems.

There is particular doubt over the proportionality of COVID-19 vaccine adverse effects compared to previous vaccines. In their introduction to 'Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS)' Shimabukuro et al. explain that 'the proportion of

reports involving a specific adverse event and a specific vaccine can be compared to the proportion of reports involving the same adverse event and other vaccines.' So, this can and should be done, right?

In 2021, the CDC made a commitment to monitor and report on this, a commitment which has not been honored. They were supposed to track an indicator called the Proportional Reporting Ratio (PRR). The *Epoch Times* has shown that the agency changed its story three times in 2022 on whether it was conducting this monitoring: 'initially saying such analysis was outside the agency's purview, then saying the analysis was performed starting in 2021, then saying the analysis did not begin until 2022.'

The picture is further complicated by the fact that the CDC uses a fiendishly complicated-looking statistical equation to determine proportionality. Instead of calculating whether a particular adverse event is being reported more often than with previous vaccines, the CDC calculates whether a specific adverse event rate reported for the COVID vaccines is a higher proportion of total adverse events compared to previous vaccines.

In the equation, a and c are the specific adverse events, and b and d are the total adverse events:

PRR = [a/(a+b)]
[c/(c+d)]

The problem here is that if a particular adverse event (mortality for example) were, let's say, ten times greater with the COVID vaccines, the CDC's formula would not generate a signal if the vaccines produced ten times more adverse effects overall! It shows only whether a particular event is a higher proportion of the total and ignores whether the total is greater than with previous vaccines. Both higher figures could be driven by an extraneous external factor, but that would be speculative.

In any case, a search of the CDC site reveals no figures about the PRR of the COVID-19 vaccines. How can this be? It is a matter of vital public importance. Steve Kirsch has crunched the numbers using the CDC's unduly complex formula, and finds that even this generates a safety signal, but the CDC remains silent. His workings-out are available for scrutiny and rebuttal at his Substack site.

Information about the reporting rates of COVID-19 vaccines compared with other vaccines is generally very hard to find, which is itself remarkable and unacceptable. But there are some clues in the published literature from which policymakers can make some deductions.

In a previous Brownstone Institute article published on October 28, 2021, I observed:

> Searching through the data for the twenty years leading up to 2013, Moro et al. found a total of 2,149 reports, roughly 100 deaths per year. They concluded that this represents one reported death per million doses. The CDC found [MMWR October 13, 2021] that more than 403 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through October 6, 2021, during which time, VAERS received 8,638 reports of deaths. This translates to a rate of one reported death per 46,000 doses

It also equates to around 21 deaths per million for the COVID-19 vaccines compared to one per million for the previous vaccines. The rate quoted in MMWR (Morbidity and Mortality Weekly Report) for October 3, 2022 has gone up to 1 death for around 38,000 doses, or 26 deaths per million doses The trend is not going in the right direction.

The CDC's case on the VAERS mortality data rests on a study by Day et al. which found that:

> For all COVID-19 vaccines combined, the observed reporting rates for US death events was approximately 10 times lower than the expected all-cause death rate within seven days of vaccination and approximately 36 times lower than the expected all-cause death rate within 42 days of vaccination.

However, these rates are incommensurable, as the background rates are based on the total number of deaths from all causes, whereas VAERS is a passive reporting system, where the number of deaths reported is reliant on doctors, nurses and other carers taking the initiative to report. Thus, it could represent an unknown fraction of vaccine-related total deaths. The authors try to get around this problem by showing that reporting rates were higher than normal for the 2009 H1N1 inactivated pandemic influenza vaccine, suggesting that they may generally be higher in a well-publicized pandemic.

But in the COVID-19 pandemic there have been extreme pressures to support the universal vaccination campaign which were not present in previous pandemics. In any event, the fact remains that Day et al. are comparing definitive total background mortality with an unknown percentage of mortality occurring after COVID-19 vaccination.

Further evidence of the reporting rate for COVID-19 vaccines can be gleaned indirectly from a paper by Rosenblum et al., based on VAERS reports. Mortality rates are not stated in their narrative text but can be deduced from Table 2, which shows deaths reported between Dec 14, 2020, and June 14, 2021. Per million doses, there were 90.4 'serious reports, including death' per million and 75.4 'serious reports, excluding death.'

It follows therefore that the reporting rate for deaths must have been 15 per million, which is comparable with the 2021 MMRW figures quoted above, and which we can again contrast with the background reporting rate of one per million. Why do the distinguished authors not explicitly state this figure?

No conclusions can be drawn from the VAERS data about the number of deaths linked to vaccination, but the huge increase in reports is valid data in itself and urgently needs to be explained.

A second surveillance system used by CDC is the 'V-Safe' phone app. This data too has been hidden from view but was obtained by court order (after a long struggle) by the Informed Consent Action Network (ICAN) and made publicly available. Out of more than 10 million individuals who used the app, 1.2 million reported they were unable to conduct normal everyday activities after vaccination, 1.3 million missed work or school and 0.8 million (7.7%) required medical attention. Of course, those individuals who sadly died are unlikely to have reported this through their phone….

By comparison, the Australian figures show much lower figures for medical attention and much higher ones for missing work, study or routine duties, in this case broken down by dose (21% for Pfizer dose 2). Perhaps this indicates underlying cultural differences – it seems that us Aussies will take any excuse for a day off work and the Americans will take any opportunity to run to the doctor! The difference certainly highlights how dependent all these statistics are on data collection and processing protocols.

These results seem high and are difficult to benchmark. But by comparison, out of 330 participants in a trial of a combined hepatitis A/B vaccine, only one reported a Grade 3 reaction (i.e. preventing normal activities). In a trial of trivalent influenza vaccines (adjuvanted v. non-adjuvanted), out of 6,000 participants in the reactogenicity and safety cohort, 5.8% experienced a Grade 3 reaction. This contrasts with more than 11% in the V-Safe COVID-19 data.

There is a third safety monitoring system called 'Vaccine Safety Datalink' (VSD), which is a collaboration between the CDC and a number of hospitals. One study by Xu et al. found that 'non-COVID mortality' was lower in vaccinated individuals admitted to those hospitals compared to the unvaccinated. This was suggested to be caused by the 'healthy vaccinee effect:' people are less likely to get vaccinated while they are ill. This tells us nothing about the rate of mortality in the vaccinated population overall compared to the unvaccinated population. No VSD data about this has been made public.

The closest I can find to this is a VSD-based study by Klein et al. of particular adverse events, acute disseminated encephalomyelitis, anaphylaxis, encephalitis/myelitis, Guillain-Barré syndrome, immune thrombocytopenia, Kawasaki disease, narcolepsy, seizures, and transverse myelitis.

The headline results showed that these were not elevated; however, this is based on comparing two arbitrary time periods after vaccination (day 1 to day 21 and day 22 to day 42), not comparing vaccinated individuals with unvaccinated individuals. The authors do

acknowledge that with myocarditis/pericarditis, ‘Cases were significantly clustered within the 0 to 5 days after vaccination.’ This is surely a signal but is deemphasized.

They also did in fact conduct a ‘supplemental analysis’ comparing vaccinated and unvaccinated groups, the results of which are also deemphasized. This showed that the relative risk of myocarditis/pericarditis per 1 000 000 person-years was 9.83 during days 0 to 7 after vaccination, corresponding to 6.3 additional cases per million doses. ‘After dose 2, RR estimates were higher for both BNT162b2 and mRNA-1273 vaccines.’

So relative risk was nearly ten times higher in the first week, and higher still for dose 2. Why is this not mentioned in the abstract? The rationale is that the comparator groups for the primary analysis between the 3-week time periods were more likely to be similar, but this is hypothetical, and the elevated risk for one week is so high it is unlikely to be insignificant.

The other myocarditis/pericarditis evidence in the literature is consistent with this and also indicates that the results should be broken down by age group. For example, a study by Le Vu et al. of the nationwide French data (May to October 2021) found:

> We perform matched case-control studies and find increased risks of myocarditis and pericarditis during the first week following vaccination, and particularly after the second dose, with adjusted odds ratios of myocarditis of 8.1 (95% confidence interval [CI], 6.7 to 9.9) for the BNT162b2 and 30 (95% CI, 21 to 43) for the mRNA-1273 vaccine.
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> The largest associations are observed for myocarditis following mRNA-1273 vaccination in persons aged 18 to 24 years. Estimates of excess cases attributable to vaccination also reveal a substantial burden of both myocarditis and pericarditis across other age groups and in both males and females.

The essential issue for policymakers since 2020 has been how to reduce hospitalization peaks and how to reduce all-cause mortality.

There is an abundance of papers showing that the vaccines reduce mortality in COVID-19-positive people, based on particular slices of time. But the significance of this is limited by the uncertainty about deaths caused by as opposed to deaths with COVID-19 and the variability of pandemic data over time.

To obviate the uncertainty introduced by differing diagnosis and cause of death standards, policymakers need to focus on all-cause mortality. Voters want to know whether their risk of dying is increased or reduced after the intervention – they don’t normally care whether they die with this diagnosis or if that diagnosis is on the death certificate.

We know that ‘post-vaccine reactions’ leading to death are possible based on the few autopsy reports that have been published, such as this one originally published by the College of American Pathologists. So, the number of these deaths is more than one, but we

don’t know how much more. This is not acceptable, and agencies should be investigating.

There is also a paucity of papers showing that the vaccines reduce all-cause mortality, starting with the randomized clinical trials (RCTs) that led to them receiving emergency use authorization. Deaths were relatively evenly distributed between the vaccine groups and the placebo groups. Arguably, the trials were not sufficiently powered to detect a difference (not enough participants), but that still leaves us with the negative conclusion that they do not establish that the vaccines reduce all-cause mortality, the most important objective. Neither have other observational trials since.

The overall thrust of the surveillance evidence, the paucity of all-cause mortality evidence and the differential between cohort outcomes call into question government vaccination strategies based on a ‘one-size-fits-all’ model.

Policy in public health should be only made on the basis of the evidence available. The evidence available indicates that the strategy of universal vaccination of the whole population exposed some groups to unnecessary risk, and that a differentiated risk-based strategy would have led to better outcomes. Some countries are now belatedly moving in this direction at least for boosters.

And finally, we need far greater transparency about the data held by public agencies. They are reluctant to release it when they fear it will increase vaccination hesitancy. But the data probably *should* increase hesitancy in the cohorts at risk.

Let the light shine in!

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