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reply-to: Robert W Malone MD from Who is Robert Malone <reply+2cr95r&doii8&&172dc289e0f57c9e3ef71fe1184644bb251386b574a6ecaee64eccf0625f3d3e@mg1.substack.com>

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date: Mar 6, 2024, 11:46 AM

subject: COVID-19 vaccines’ effectiveness and safety exaggerated in clinical trials & observational studies, academics find

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[**COVID-19 vaccines’ effectiveness and safety exaggerated in clinical trials & observational studies, academics find**](https://substack.com/app-link/post?publication_id=583200&post_id=142359327&utm_source=post-email-title&utm_campaign=email-post-title&isFreemail=false&r=doii8&token=eyJ1c2VyX2lkIjoyMjk3ODczNiwicG9zdF9pZCI6MTQyMzU5MzI3LCJpYXQiOjE3MDk3NDM1ODksImV4cCI6MTcxMjMzNTU4OSwiaXNzIjoicHViLTU4MzIwMCIsInN1YiI6InBvc3QtcmVhY3Rpb24ifQ.0s_Q66iD-P_8UiVOoQMY5vRloh4mlBaCTfI504l9lsQ)

By RAPHAEL LATASTER, PHD

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| [READ IN APP](https://open.substack.com/pub/rwmalonemd/p/covid-19-vaccines-effectiveness-and?utm_source=email&redirect=app-store" \t "_blank) |

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By: Raphael Lataster, PhD

An unofficial series of 4 crucially important medical journal articles, 2 by me, appearing in major academic publisher Wiley’s *Journal of Evaluation in Clinical Practice* reveals that claims made about COVID-19 vaccines’ effectiveness and safety were exaggerated in the clinical trials and observational studies, which significantly impacts risk-benefit analyses. Also discussed are the concerning topics of myocarditis, with evidence indicating that this one adverse effect alone means that the risks outweigh the benefits in the young and healthy; and perceived negative effectiveness, which indicates that the vaccines increase the chance of COVID-19 infection/hospitalisation/death, to say nothing about other adverse effects.

Whilst already planning for a holiday overseas on the advice of my treating team, I fortuitously was invited to share my research and discuss my ongoing persecution alongside brilliant and courageous doctors, scientists, academics, lawyers, and activists, such as [Dr Robert Malone](https://substack.com/redirect/48068172-3309-48d0-9186-a2f4f91813de?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg" \t "_blank), who declared this research to be “excellent”, and “some of the best work, academically, in reevaluating the data”, culminating in an invitation to testify for [US Senator Ron Johnson](https://substack.com/redirect/128a4754-1dec-4177-9330-ee014a9e5672?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg). So for those who are here because of the associated videos, and anyone else interested in this topic, please enjoy this much more detailed summary.

**Introduction**

In early 2023 pharmacy researcher Peter Doshi, one of the editors of the prestigious *British Medical Journal*, and contributor to the excellent Fraiman et al. analysis on the mRNA vaccine clinical trials ([source](https://substack.com/redirect/bfdd37a0-41ec-4087-aad5-5eddd7a3c14e?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg), [OTN entry](https://substack.com/redirect/ad95dc3f-ff1e-4b48-a363-2cefe8dce732?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg)), published an important study (Article 1, [source](https://substack.com/redirect/e91149c2-6f26-461b-bc04-643718c7b338?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg), [OTN entry](https://substack.com/redirect/8de3af4b-a4bc-4f03-b4fe-8ac82e008e22?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg)) with statistician Kaiser Fung and biostatistician Mark Jones on biases in observational studies of COVID-19 vaccines. The highlight was the discussion on the case-counting window bias, which affects effectiveness estimates. Building on this effort, misinformation researcher and former pharmacist Raphael Lataster (that’s me) published a paper (Article 2, [source](https://substack.com/redirect/d9fe9f0d-c457-496c-9f19-a2afb95b6fd3?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg), [OTN entry](https://substack.com/redirect/3d8b0394-0f75-45d3-a8e9-c1d54bd97b5b?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg)) noting that, amongst other things, such counting window issues could also affect estimates of safety in observational studies.

Doshi and Fung then returned serve with a discussion (Article 3, [source](https://substack.com/redirect/60bdde12-86cb-49f3-8e45-d0548ce4fefc?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg), [OTN entry](https://substack.com/redirect/d86689d7-a9ca-4eff-9999-734d519b2608?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg)) on how case-counting window issues also affected estimates of effectiveness in the Pfizer and Moderna clinical trials. Ending the unofficial series, Lataster produced an article (Article 4, [source](https://substack.com/redirect/86021169-e157-46d0-9556-dc2cb5dabe51?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg), [OTN entry](https://substack.com/redirect/59607e0e-992e-44b4-baa6-7d3cc697ec92?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg)) explaining that the clinical trials also were plagued with adverse effect counting window issues which likely led to exaggerated safety estimates. Together, these 4 articles make clear that claims made about COVID-19 vaccines’ effectiveness and safety were exaggerated in the clinical trials and observational studies, whilst also finding time to discuss myocarditis and perceived negative effectiveness, meaning that **new risk-benefit analyses are very much needed**.

**Exaggerated effectiveness in observational studies**

In Article 1 Doshi, Fung, and Jones discuss several biases present in observational studies that are likely contributing to inaccurate estimates of the effectiveness of the mRNA COVID-19 vaccines. The most concerning is the “case-counting window bias”, which concerns the 7 days, 14 days, or even 21 days after the jab where we are meant to overlook jab-related issues, such as COVID infections, for some odd reason as “the vaccine has not had sufficient time to stimulate the immune system”. This may strike you as quite bizarre since all of the ‘fully vaccinated’ must go through the process of being ‘partially vaccinated’, sometimes even more than once. To make matters worse, the unvaccinated do not get such a ‘grace period’, meaning that there is also a clear bias at play. In an example using data from Pfizer’s clinical trial, the authors show that thanks to this bias, a vaccine with effectiveness of 0%, which is confirmed in the hypothetical clinical trial, could be seen in observational studies as having effectiveness of 48%. That’s obviously a huge chunk of the stated effectiveness, and higher than the effectiveness of the jabs after only a few months. This looks bad, but don’t worry, it gets worse. Much worse.

In Article 2 the cheeky Lataster declared that Doshi’s team has actually understated things. The case-counting window bias is often accompanied by a definitional bias, referring to the curious definitions used for terms like ‘vaccinated’ and ‘unvaccinated’. He refers to situations where COVID cases in the (partially) vaccinated are not just ignored, but shifted over to the unvaccinated groups. Note that issues in the unvaccinated are not ever attributed to the vaccinated, because of course not. Building on the earlier example, Lataster estimates that “a vaccine with 0% effectiveness” could actually be “perceived as having 65% effectiveness”, the vast majority of the stated effectiveness of the vaccines. Keep in mind the 50% threshold necessary for FDA approval. Already concerned? We’re only getting started.

**Exaggerated safety in observational studies**

Still with Article 2, Lataster notes that counting window issues can also affect estimates of safety in observational studies, which would be important when comparing the overall health of the vaccinated and unvaccinated, as may be appropriate when looking into “the mysterious rise in non-COVID excess deaths post-pandemic”. In Article 4 Lataster appears to have provided an example of just that, discussing a Johns Hopkins study ignoring many adverse effects in the vaccinated, with the very narrow counting windows apparently missing both very early adverse events (such as deaths by anaphylactic shock) and adverse effects occurring months and years after the final dose (such as myocarditis, including cardiovascular deaths). That study was critiqued further by the unfunded Lataster in Oxford University Press’ influential *American Journal of Epidemiology* ([source](https://substack.com/redirect/48042776-150a-477f-87d4-f224889e044b?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg), [OTN entry](https://substack.com/redirect/99e7de67-819a-4217-8648-9a09b9acfb42?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg)), prompting an underwhelming and churlish response from the team from the Bill Gates and Big Pharma funded Johns Hopkins Bloomberg School of Public Health ([source](https://substack.com/redirect/2d7345a0-7791-41ab-8d96-fb37eebb2a3d?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg), [OTN entry](https://substack.com/redirect/efb7a348-1439-4fe2-9bdc-91c2bc954827?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg)).

**Exaggerated effectiveness in clinical trials**

In Article 3 Doshi and Fung shift focus from observational studies to the clinical trials. What they found was concerning: “While both our commentary and Lataster’s critique focus on observational study designs, concerns about case counting windows also extend to the original phase 3 randomised trials of COVID-19 vaccines.” They discovered that COVID case counting “only began once participants were 7 days (Pfizer) or 14 days (Moderna) post Dose 2, or approximately 4–6 weeks after Dose 1”. The obvious implication being: “Decisions on when to initiate the case counting window affected calculations of vaccine efficacy. Because cases occurring in the 4–6 weeks between Dose 1 and the case counting window were excluded, reported vaccine efficacy against COVID-19 (the primary endpoint) at the time of Emergency Use Authorization was higher than what would have been calculated had all COVID-19 cases after Dose 1 been included, as in a conventional Intent-to-Treat analysis.” They also found that “different case counting windows” were used at different times, which just coincidentally happened to yield better results.

Lataster again couldn’t help himself in following up in Article 4 with a suggestion that Doshi’s team may have again understated things, since “numerous issues with the clinical trials and FDA briefing documents had gone unmentioned. For example, there are a significant number of trial participants lost to follow-up, and Pfizer also acknowledged ‘3410 total cases of suspected but unconfirmed COVID-19 in the overall study population’ in the FDA briefing document on their vaccine trial, split almost evenly between the treatment and placebo groups, which would have drastically brought down treatment efficacy estimates.” To illustrate, just 5 COVID cases in the vaccinated vs 95 cases in the unvaccinated looks impressive. But 1,005 COVID cases in the vaccinated vs 1,095 cases in the unvaccinated, not so much. In this way, a product with less than 10% effectiveness can be made to look over 90% effective. Anything can be claimed with manipulated data. 69% of all people know that.

**Exaggerated safety in clinical trials**

Apart from the concerning “significant number of trial participants lost to follow-up” Article 4 notes many other issues with the clinical trials, likely leading to exaggerated estimates of safety. The counting windows for adverse effects in the clinical trials were incredibly short, going against long-established norms, especially with the treatment and placebo groups quickly merged (which renders long-term safety analyses in the clinical trials impossible), and the reliance on unsolicited reporting, as well as the opinions of researchers paid by the vaccine manufacturers (like how cardiovascular deaths were written off as unrelated to the jab when we now know the jab does cause cardiovascular deaths). Lataster notes that “deceased trial participants will not be contacting the researchers to describe their issues”.

Wrap your head around that one. Someone in the vaccinated group dies, thanks to the jab. They’re not exactly in a position to call Pfizer and say, “Yeah, your jab killed me. Sorry, it’s really hot down here and I’m only wearing a towel. I said your jab killed me! Right. Make sure you report it. Okay, see you soon.” As a result, such deaths are not included in the data, and with relatively few adverse event reports the jab is declared safe. You’ve just been scienced! It’s a bit like how we can’t refer to many of the adverse event reports submitted to government agencies as they’re [perpetually unverified](https://substack.com/redirect/f844791b-a553-46c1-9cb0-da129e9c80be?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg).

[For more eye-opening revelations on safety in the clinical trials, read the aforementioned Fraiman et al., and also Benn et al., which reveals that the mRNA vaccine clinical trials showed no death benefit, which was supposedly the whole point of the jabs, and even a death deficit ([source](https://substack.com/redirect/eb31bd97-ba76-4ac9-bf4f-671b6fdfd5ef?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg), [OTN entry](https://substack.com/redirect/e6114335-41e3-43fe-9223-7c902590934b?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg)). Yes, that means what you think it means. More people died in the vaccinated groups. Typically because of supposedly unrelated cardiovascular issues. Note that in a proper randomised controlled trial discrepancies in outcomes are due to the treatment. So which is it? Are these additional deaths caused by the vaccines, or are these trials not properly randomised and controlled, meaning their positive conclusions are baseless? Can’t have it both ways.]

**Myocarditis**

Just one aspect of the safety of the COVID-19 vaccines is myocarditis. In Article 4 Lataster cited increasing research on myocarditis that alone appears to indicate that the risks of the jabs outweigh the benefits in at least the young and healthy, when comparing to British government data on the numbers needed to vaccinate in various groups to produce positive outcomes, the topic of his *BMJ Open* rapid response ([source](https://substack.com/redirect/b4816240-5354-4811-9857-5ad3df4f40fe?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg), [OTN entry](https://substack.com/redirect/af2d3011-285b-4447-b22c-71b9f573b94a?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg)).

Lataster further revealed that Pfizer acknowledges myocarditis risks and limitations of their study. And also that Pfizer is currently running a trial, again plagued by questionable counting windows, to “determine if COMIRNATY is safe and effective, and if there is a myocarditis/pericarditis association that should be noted” ([source](https://substack.com/redirect/c068a5fd-10f6-4551-a5bf-ffdf67f19303?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg), [OTN entry](https://substack.com/redirect/9a5bee62-7dfd-4f15-962c-517a7dc7962a?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg)). Wouldn’t this information have been handy before they jabbed billions of people, and before the jabs were universally declared “safe and effective”, and before people - [like Lataster](https://substack.com/redirect/caffb26f-2dd1-4519-80f9-678850d04678?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg) - were fired and demonised for not submitting?

**Negative effectiveness**

As if that all were not enough, Lataster also mentions what may be the most distressing issue around the jabs in Article 2, [negative effectiveness](https://substack.com/redirect/00432b26-d18f-4808-8515-5ba957eda1c8?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg) (keep following the negative effectiveness links backwards in time to go through the many OTN entries on this issue). This is where, apart from all the (other) known and unknown adverse effects, the vaccines appear to increase the risk of COVID-19 infection and/or hospitalisation and/or death. Clearly not what one gets vaccinated for. There would be no analysis of the risks vs the benefits possible. We would only have risks upon risks.

Lataster shows how, with the biases discussed in Articles 1 & 2, “a vaccine with −100% effectiveness, meaning that it makes symptomatic COVID-19 infection twice as likely, can be perceived as being 47% effective”. Furthermore, “Repeated calculations will show that moderate vaccine effectiveness is still perceived even with actual vaccine effectiveness figures of −1000% and lower.” In other words, the possibility that the vaccines were always negatively effective, and only appeared effective due to incomplete data, poor methods, short counting windows, and even [outright fraudulent practices](https://substack.com/redirect/abd714a1-5291-477d-bdb4-86b88e99fa0e?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg), is very much on the table. Interestingly, even the *BMJ*, one of the most prestigious medical journals in the world, appears to be aware of perceived negative effectiveness, publishing, amongst others, a rapid response on the topic by Lataster ([source](https://substack.com/redirect/ce309eaf-5d53-41e6-b8f1-4d53b60aee60?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg), [OTN entry](https://substack.com/redirect/94205e1f-16f1-4856-baf5-84d874dda16d?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg)).

**Conclusion**

All the key points discussed here are in ‘the science’ we are continuously told to trust, peer-reviewed research by qualified medical doctors, scientists, and academics, publishing in proper medical journals. No wild speculations or conspiracy theories necessary. Yet there is more than enough here to, as Lataster states in Article 4, “nullify the claim that the benefits of the vaccines still outweigh the risks in all populations”.

Any time you look at the evidence behind claims that the COVID-19 vaccines are safe and effective, **check for the definitions of the unvaccinated and the vaccinated.** **If there aren’t any the studies are invalid.** If there are definitions, ensure that the definitions pass the smell test. If these definitions

* ignore what’s going on in the ‘partially vaccinated’ and/or
* assign COVID cases or adverse effects in the vaccinated to the unvaccinated

then the studies are invalid. As of right now it appears that almost all of the studies backing up the claims about the COVID-19 vaccines being safe and effective **are indeed invalid**. Apart from definitions, the claim that these products are safe when there is exactly 0 long-term safety data is, you guessed it, **invalid**. Heck, in pharmacy school I was taught that you can never really say that a pharmaceutical product is safe, which rings so true now after the [pholcodine debacle](https://substack.com/redirect/98ff06cd-9ec1-4425-98e0-9791c536b45e?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg) [Pholcodine withdrawn] . And we haven’t even talked about the massive conflicts of interest involved, regulatory capture, and so forth (it may be best to discuss the publicly available financial data that reveals that a handful of people own the major drug companies - and provide most of the funding for the drug regulators, tobacco companies, left-wing and right-wing news outlets, clean energy and dirty energy companies, all the major tech companies, the largest investment firms, and worst of all, both major brands of cola, [on another day](https://substack.com/redirect/b8e3f5c3-a905-4ecc-a4e6-02ec74a46c39?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg)).

But don’t worry. As more people catch on we can at least look forward to most politicians doing absolutely nothing and headlines like this in mainstream news outlets: “Okay, the Evidence for the COVID-19 Vaccines Is Pretty Bad. Here’s Why That’s a Good Thing.”

Okay then.

Extra: Peter Doshi (University of Maryland) continues to do great work on the vaccines as a *BMJ* editor and researcher, which he records on his [university webpage](https://substack.com/redirect/e14bb203-5b29-4c1d-b0fc-49fd29e7da00?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg). Raphael Lataster (University of Sydney) continues to undertake such research, particularly as he is effectively forced to continue building his case/s against his former employer, which he makes freely available to the public on his [OTN website](https://substack.com/redirect/78f2883c-b969-4c2a-9d23-6d72ea23c2d6?j=eyJ1IjoiZG9paTgifQ.91g_34VRuzI_MLkPmRIGM0gm4tNgR1dQS7br89dPnSg).

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