

Covid-19 Vaccinations Do More Harm Than Good

Description

Now We Have It in Black And White

In July, Mörl, Günther and Rockenfeller published a high-profile paper in the peer-reviewed online journal Frontiers in Medicine [1]. They compared the number of adverse events in the five pivotal trials of the Covid-19 vaccine with the number of adverse events in the control groups, as well as the number of severe Covid-19 cases in both groups, and calculated a harm-benefit ratio. If this is less than 1, then the vaccines do more good than harm. If it is greater than 1, they do more harm than good. Only two studies had a harm-benefit ratio smaller than 1, but very close to 1 (0.9 and 0.6). The authors point out that it would probably be reasonable to expect a harm-benefit ratio much smaller than 0.1, that is, ten more severe courses among control cases than among vaccinated people.

Clearly, this is not the case. In the BioNTech study, the ratio is actually very large at 25. This means that 25 times more serious side effects are registered in the vaccination group than in the control group. In the Moderna study, the ratio of 1.1 is about the same, but also far from favourable. They do not interpret the Sputnik pivotal study because the ratio there is negative, which is hardly credible.

Now a new study has appeared in the main vaccination journal, „Vaccine“ (not to be confused with a journal with a similar name, „Vaccines“. „Vaccine“ is published by Elsevier, „Vaccines“ by the online publisher MDPI).

The study is co-authored by Peter Doshi, one of the associate editors of the British Medical Journal [2]. It was previously published as a preprint, before peer review [3].

This study uses the same data, namely the published data from the Pfizer-BioNTech and Moderna pivotal trials along with the online supplements, but also regulatory documents and documents from Federal Drug Agency (FDA) and Health Canada approval meetings. And it goes one step further: it uses such side effects that a priori had already been defined as „serious adverse events of special interest (SAESI)“ by a WHO advisory group in March 2020. These are side effects that were already known as particularly severe complications from SARS-CoV2 infections (vascular problems such as embolisms, for example) and as they were to be expected from other vaccines or from animal models.

The authors note that the pivotal studies did not even record side effects that were used at the same time to use

© Prof. Harald Walach

success (so-called „efficacy endpoints“). They were removed from the publications, for example, severe Covid-19 disease, 17 of which were removed from the Pfizer pivotal trial, one from the Moderna trial. (This means: they are in the original registration documents, but not in the publication.)

The Pfizer study showed a 36% higher risk of serious adverse events in the vaccination group, compared to the control group. In the Moderna study, the risk for vaccine subjects was 6% higher than in the control group, and in summary, the risk for both vaccines was 16% higher for subjects in the vaccine group to suffer severe side effects, compared to the control group.

To examine Serious Adverse Events of Special Interest (SAESI), the possible serious side effects defined in March 2020, the reported side effects were matched against this list, by two blinded researchers. This means that the researchers did not know which of these side effects had occurred in the control group or in the vaccination group. They then had to decide whether a side effect from the reporting table was a SAESI or not.

Of the 237 reported serious adverse events in all Pfizer and Moderna trials, 97% were SAESIs. Most side effects were visible as blood clotting disorders. In the Pfizer trials, more cardiovascular serious adverse events were reported in the vaccination groups than in the control groups, and one more case in the Moderna trial. Such SAESIs were 57% more common in the vaccinated subjects in the Pfizer study and 36% more common in the Moderna study, and together there were 43% more SAESIs with both vaccines reported by the vaccinated patients compared with the control patients.

I believe the key sentence is on page 3 of the online publication and on p. 5800 of the print publication under „ *3.4 Harm-Benefit Considerations*„:

„In the Moderna trial, the excess risk of serious AESIs (15.1 per 10,000 participants) was higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (6.4 per 10,000 participants). [3] In the Pfizer trial, the excess risk of serious AESIs (10.1 per 10,000) was higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (2.3 per 10,000 participants).“

In plain language:

Although the BioNTech-Pfizer vaccine has 2.3 fewer Covid-19 hospitalizations per 10,000 participants compared to placebo, the risk for those vaccinated to suffer a serious adverse event is significantly higher, nearly five times this benefit. In the Moderna study, the risk for those vaccinated to suffer a serious adverse event is more than twice as high as the benefit they can expect from preventing hospitalization through vaccination.

And don’t forget: Mortality reduction, the only reasonable outcome, has not been studied in any of the pivotal trials. Also the reported numbers of deaths in the study documents are not credible, as Günther and colleagues have calculated [4].

To put it even more clearly: the risk-benefit ratio of these vaccines is a disaster. The fact that we have not long since pulled the emergency brake here and stopped both the debate on compulsory vaccination and the licensing shows how unreasonable and medically ideologized the discourse around these substances is.

Where is the basis for recommending these vaccinations when it is clear that the expected side effects for those vaccinated exceed the expected benefits by a factor of two to five? What exactly is the argument of reason supposed to be, that one should not only be vaccinated, but vaccinated twice and then boostered several times? And not only in adults – the studies were all registration studies in people over 18 or over 16 – but also in children? Especially since a new analysis based on data from Public Health England has just appeared on the preprint server MedRxiv

© Prof. Harald Walach

, showing that vaccine effectiveness, i.e. the efficacy of booster vaccinations, is actually negative [5].

In any sane society, such data would be the immediate end of pharmacological or vaccine approval. The fact that these data not only fail to generate any excitement in the press, but so far appear to have no political consequences at all, shows how far the craziness has already spread.

Because:

- This data is not new. One can glean this information from the registration data. Doshi and colleagues point this out. FDA and other regulatory authorities should have reacted long ago.
- You don't have to study the regulatory documents. A simple calculation based on the published studies is enough to see: The risk-benefit calculation is negative.
- One forgets in all this: The side effects have been very cleverly defined by the study authors. For all side effects that appear immediately after vaccination, e.g. covid disease, deaths, paralysis, are not counted as side effects in the study protocols. Rather, these patients were excluded from further observation. Had these people been counted, the drama would have been immediately clear.

I point out that we had already named this problem early on, albeit based on a shakier data base, but very similar in substance [6, 7]. The study was retracted after a shitstorm from „Vaccines" and was republished. We repeated our warning recently [8]. No one in official positions listened. I was kicked out of the medical university in Pozna? because of this analysis, and the University of Witten put my visiting professorship on hold and eventually did not renew it. The authors of the Doshi working group are now calling for exactly what we also called for a year ago: careful, prospective monitoring of benefits and harms, because the passive systems, such as the side effect databases, are apparently insufficient.

I can only draw one conclusion from this and hope that at some point some moral-ethical sense of honour will stir among authority employees, public prosecutors or high officials: these vaccines are dangerous. They do not deliver what they promised. Further administration is tantamount to bodily harm. Anyone who visibly supports this in federal authorities and ministries is liable to prosecution, as far as my simple civil legal understanding goes.

I also think that we should not just go back to business as usual now – Ukraine war, inflation, bad weather – but that a very careful investigation must happen here so that something like this does not happen again.

Sources and literature

1. Mörl F, Günther M, Rockenfeller R. Is the Harm-to-Benefit Ratio a Key Criterion in Vaccine Approval? Frontiers in Medicine. 2022;9. doi: https://doi.org/10.3389/fmed.2022.879120.
2. Fraiman J, Erviti J, Jones M, Greenland S, Whelan P, Kaplan RM, et al. Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. Vaccine. 2022;40(40):5798-805. doi: https://doi.org/10.1016/j.vaccine.2022.08.036.
3. Fraiman J, Erviti J, Jones M, Greenland S, Whelan P, Kaplan RM, et al. Serious Adverse Events of Special Interest Following mRNA Vaccination in Randomized Trials. SSRN Preprint. 2022.
4. Günther M, Mörl F, Rockenfeller R. Where Have the Dead Gone? Frontiers in Medicine. 2022;9. doi: https://doi.org/10.3389/fmed.2022.837287.
5. Emani VR, Pallipuram VK, Goswami KK, Maddula KR, Reddy R, Nakka AS, et al. Increasing SARS-CoV2 cases, hospitalizations and deaths among the vaccinated elderly populations during the Omicron (B.1.1.529) variant surge in UK. medRxiv. 2022:2022.06.28.22276926. doi: https://doi.org/10.1101/2022.06.28.22276926

© Prof. Harald Walach

.

6. Walach H, Klement RJ, Aukema W. Retracted: The Safety of COVID-19 Vaccinations—We Should Rethink the Policy. Vaccines. 2021;9(7):693. doi: 10.3390/vaccines9070693. PubMed PMID: doi: https://doi.org/10.3390/vaccines9070693.
7. Walach H, Klement RJ, Aukema W. The Safety of COVID-19 Vaccinations — Should We Rethink the Policy? Science, Public Health Policy, and the Law. 2021;3:87-99. https://www.publichealthpolicyjournal.com/general-5.
8. Walach H, Klement RJ, Aukema W. The risk-benefit ratio of Covid-19 vaccines: Publication policy by retraction does nothing to improve it. Clinical and Translational Discovery. 2022;2(1):e35. doi: https://doi.org/10.1002/ctd2.35.

Date Created
22. September 2022

© Prof. Harald Walach