# Comment on the Retraction of Our Paper “The Safety of Covid-19 Vaccinations – We Should Rethink the Policy”

## Harald Walach, Rainer J. Klement

The Journal “Vaccines” retracted our paper “Walach, H., Klement, R. J., & Aukema, W. (2021). The Safety of COVID-19 Vaccinations—We Should Rethink the Policy. Vaccines, 9(7), 693. doi:10.3390/vaccines9070693” on July 2nd, following a retraction decision on July 1st (<https://www.mdpi.com/2076-393X/9/7/729/htm>). Thereby the Journal violated the ethical standards of good publishing. The publisher of the Journal, MDPI, states (<https://www.mdpi.com/ethics>):

“MDPI journals are members of the Committee on Publication Ethics ([COPE](https://publicationethics.org/)). We fully adhere to its [Code of Conduct](https://publicationethics.org/resources/code-conduct) and to its [Best Practice Guidelines](https://publicationethics.org/guidance/Guidelines).”

The retraction guidelines of COPE (<https://publicationethics.org/files/cope-retraction-guidelines-v2.pdf>, page 4) indicate the reasons for retractions. Retractions are usually not warranted if:

* The main findings of the work are still reliable and correction could sufficiently address errors or concerns
* An editor has inconclusive evidence to support retraction
* or is awaiting additional information such as from an institutional investigation for information about expressions of concern.

## The Journal and its Editors did not wait for our response before retraction

The Journal violated its own ethical code of conduct by not awaiting and not publishing our response to the concerns raised (see below). The time line was the following:

Our paper was published on June 24.

On June 25 (18:19, all times Central European Time) the journal received an email from LAREB, the Dutch health authority whose data we had used for our analysis.

On June 28 (08:59) I was forwarded this mail with the request to respond and the information that the journal would wait until our response was received.

On June 28 (13:06) the Journal notified us about the fact that “serious concerns” had been raised and that the Journal would publish an Expression of Concern that day or the next. The Journal did not wait for our response.

On June 29 (5:17) I told the Journal that we would send a statement that very day. The Journal responded at 9:43 with the request to send a statement soon. I answered that we would have a conference call at 4 pm to finalize it and send it afterwards. We sent our response that day at 19:11 with the request to publish it.

On July 1, time unknown, the decision to retract was taken, without formally or informally considering our response, nor answering it. We received a mail at 14:51 that day to notify us of the decision with the request. I was traveling without access to internet; my colleagues responded (20:44) that we do not agree and that we would send a formal response the next day.

On July 2, 12:21, the journal notified us that a retraction would be published together with our statement of disagreement. I did not receive a request to send a final comment. My colleagues responded promptly telling the journal that we would be sending a reply before business closure that day, at 17:00, and at 16:47 my coauthor Wouter Aukema sent a response.

What we observe is the following: The journal notified us with delay of 2 days about the content of the letter by Prof. van Puijenbroek, the head of pharmacovigilance at LAREB with a request to respond. While the content of the major concerns were published, our response was not.

We also observe: The decision to retract was taken without giving us due time to respond and without considering the fact that the major point of the concern was actually the causality implied by our language, and not any mistake in analysis (see below).

## The true reason seems to have been pressure on part of some editors of the journal

Unbeknownst to us, but obviously to others, a major reason for the retraction decision was the fact that six editors of the Journal, Florian Krammer of the Icahn School of Medicine at Mount Sinai (<https://labs.icahn.mssm.edu/krammerlab/dr-krammer/>), Katie Ewer from Oxford (<https://www.ox.ac.uk/news-and-events/find-an-expert/professor-katie-ewer-0>), Diane Harper of the University of Michigan (<https://medicine.umich.edu/dept/family-medicine/diane-m-harper-md-mph-ms>), Paul Licciardi from Australia (<https://www.mcri.edu.au/users/paul-licciardi>), Andrew Pekosz of the Bloomberg School of Public Health at Johns Hopkins (<https://hopkinsglobalhealth.org/faculty-research/faculty-directory/andrew-pekosz/>) and Helen Petousis-Harris of the University of Auckland https://unidirectory.auckland.ac.nz/profile/hpet002) resigned as Journal Editors or threatened resignation if the Journal did not retract our paper. The resignments were announced in social media first, and received major coverage in an article by Meredith Wadman in Science (<https://www.sciencemag.org/news/2021/07/scientists-quit-journal-board-protesting-grossly-irresponsible-study-claiming-covid-19>), published on July 1st, 4:00 pm EST, i.e. 22:00 CET.

Meredith Wadman interviewed one of us (H.W.) on that issue before here article, but did not reveal information about the resignments of editors in that conversation.

Whether or not Conflict of Interest might have been active in the background I would like to let readers decide: Katie Ewer was part of the team that developed the vector vaccine in Oxford, others such as Florian Krammer have received grants from industry involved with vaccine productions or from the Bill and Melinda Gates Foundation, which has a clearly expressed agenda in those vaccines (e.g. [https://www.mountsinai.org/about/newsroom/2019/researchers-receive-12-million-grant-to-develop-flu-vaccine-against-many-viral-strains](https://www.mountsinai.org/about/newsroom/2019/researchers-receive-12-million-grant-to-develop-flu-vaccine-against-many-viral-strains%20) ). The Bill and Melinda Gates Foundation also sponsors the publisher of the journal, and in the sponsoring agreement (<https://www.mdpi.com/about/announcements/1415>) it not only says that authors whose project are funded by BMGF can publish for free but that the foundation has also access to the submission system and can thus see what is being submitted.

## The timeline suggests that the Journal was not really interested in our response and that our response was irrelevant to the retraction

What we have described so far, mainly the timeline, suggests that there was never really an interest in awaiting our response and deciding fairly. The decision to retract was obviously taken before our response was evaluated, probably due to pressure.

## The main concern raised was an undue causal link of side-effect reports to vaccinations and a misrepresentation of data

Prof. Eugène von Puijenbroek raised the concern that we presented data that allow only association, namely those from the side-effects data base of Covid-19 vaccines, as causally linked to the vaccines and that we presented the data as if they were medically certified.

These two concerns we take seriously. We contend, though, that they could have been remedied by an addendum in which the wording would have been changed.

We also contend: It is clear that side-effect reports from any ADR-database are always associations and would have to be investigated for causalities. We said so, in the Discussion of our paper. We should have said it more clearly, and we could have corrected that in a correction. We agree that we could have used more diligent wording.

LAREB stated itself on its website that all reports were “investigated” (we quote the passages below in the verbatim version of our response to the Journal). We took this to mean: by personnel that is competent to distinguish between real effects and those in which causality can be ruled out with high confidence. We took LAREB at its word. Obviously we should not have done so.

Prof. van Puijenbroek stated in his letter of concern that the reports are unsystematic collections or practitioners and patients. In this he contradicts himself. In a statement (also quoted below) he made in the same year he says that roughly 60% of all ADR-reports come from market-authorization holders, and the rest from practitioners and patients.

## Wordings and interpretations could have been changed by an addendum or an amendment

So, the central concern could have been addressed by an addendum, or, in the case of an online-publication, by a change of wording or second version with amendments. This is what the ethical code of publishers would have suggested. We observe: The publisher did not abide by his own ethical code.

## The analysis was correct; the data, if weak, not ours; the conclusions an alarm signal

Retractions are normally warranted if data are fabricated or incorrect or wrongly analyzed. The data were from LAREB and from a published study. The analysis was correct. The data are weak, we do and did say that. But they are the best we currently have. The conclusion was an alarm signal to investigate the safety. It goes without saying: the risk-benefit ratio might decrease, if we have a study with a longer observation period, as deaths as a consequence of vaccinations occur quickly, while benefits might accrue over time. But we do not have the long- term observation of safety and risks that is actually necessary to make such an assessment. However, we also know that underreporting is a serious problem in pharmacovigilance data, and this probably also applies to vaccine-related side effects. We hope that our study raised at least as much concern to instigate a safety review and a good cohort study to assess safety.

## This is the response which we sent to the Journal on June 29, 2021:

*Response to „Incorrect use of data..” by Prof. Dr. Eugène van Puijenbroek”*

*Harald Walach, Rainer J. Klement & Wouter Aukema*

We are grateful to Prof. van Puijenbroek for raising his concerns. This starts a long-overdue debate on how to gauge the safety of COVID-19 vaccines. We would like to remind Prof. van Puijenbroek and all readers: These vaccines have had an emergency approval *without* the *necessary* safety data. Although we would agree with Prof. van Puijenbroek that the self-reporting system of side-effects for vaccines and other drugs is far from foolproof, it is the only data we have. So why should it not be put to use?

It is interesting to note that Prof. Puijenbroek, in his concern, describes the Lareb-ADR data as “spontaneous reporting”. In a statement in Regulatory Science 2021 (<https://www.regulatoryscience.nl/editions/2021/12/prof.-dr.-eugene-van-puijenbroek-on-the-nature-of-signals>; accessed 29th June 2021) he says:

“The Netherlands Pharmacovigilance Centre [Lareb](http://www.lareb.nl/) collected 34.000 reports of adverse drug reactions in 2019, of which 14.000 reports are submitted directly to Lareb by *healthcare professionals* and patients and more than 20.000 were forwarded by the *marketing authorisation holders*. These reports are assessed and analysed, which may lead to safety signals about adverse drug reactions. These are reported to and reviewed by the Medicines Evaluation Board (MEB), supporting the MEB in its decisions in pharmacovigilance in the Netherlands and Europe.” (typos and grammatical errors removed, else identical with webquote at the end of the article)

So, what is really true and what should we go by: Is it true that roughly 60% of the adverse drug reaction (ADR)-data come from market authorization holders, who, by law, are required to report, and is it true that the data are reviewed, as stated on the website and in this article, or are these informations only true in all other cases but not in the case of COVID-19 vaccines? It would be good to have clarity on this point. We assumed that what Lareb says about all other ADR reports is also true of COVID-19 ADR reports. If we were mistaken in this assumption, perhaps Lareb should clearly state: “ADR reports are reviewed and evaluated in all cases of ADR reports, but not with COVID-19 vaccines.” And, ideally, it should also give a reason, why this is so, if it is so.

Ideally the consequence of this debate is that someone sets up a systematic observational post-marketing surveillance study in a large number of vaccinated persons under public scrutiny to really document the side-effects that can be causally related to the vaccine. Currently we only have association, we agree, and we never said anything else. But the same is true with fatalities as consequences of SARS-CoV2-infections. The cases that are counted here as deaths are rarely vetted by autopsy or second opinion, but still counted as deaths due to COVID-19. And it is exactly this allegedly high number of COVID-19 related deaths that gave rise to an unprecedented sloppy regulation process that allowed new types of vaccines using a mechanism never before tested in humans to be widely distributed in the population. Prof. Puijenbroek basically argues that the largest vaccination experiment in the history of medicine cannot be assessed for safety and unforeseeable toxicities, because we should not use the ADR data for such inferences. In contrast, we argue that it is mandatory that those data which are at hand are used to gauge the safety, and this is what we have done.

We are happy to admit that these data are far from perfect. But we repeat: they are the only ones that are available.

We quoted LAREB itself which states on its website at the time we checked the data: “*All reports received are checked for completeness and possible ambiguities. If necessary, additional information is requested from the reporting party and/or the treating doctor. If necessary, additional information is requested from the reporting party and/or the treating doctor. The report is entered into the database with all the necessary information. Side effects are coded according to the applicable (international) standards. Subsequently an individual assessment of the report is made. The reports are forwarded to the European database (Eudravigilance) and the database of the WHO Collaborating Centre for International Drug Monitoring in Uppsala. The registration holders are informed about the reports concerning their product*.").

We took this statement to mean that those reports that are obviously without any foundation are taken out such that the final data-base is at least reliable to some degree. Would it not be like that, why else would one want to collect these data and make them public in the first place?

We are happy to concede that the data we used – the large Israeli field study to gauge the number needed to vaccinate and the LAREB data to estimate side-effects and harms – are far from perfect, and we said so in our paper. But we did not use them incorrectly. We used imperfect data correctly. We are not responsible for the validity and correctness of the data, but for the correctness of the analysis. We contend that our analysis was correct. We agree with LAREB that their data is not good enough. But this is not our fault, nor can one deduce incorrect use of data or incorrect analysis.

And we hope that this stimulates governments or university consortia to collect valid data to prove us wrong. We would be the first to be happy about that. But the challenge is out: Prove that the vaccines are safe! No one has done so. We say they are not and we used the best data currently at hand. Our usage was correct. If the data were not, whose fault is this?