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Editorial

If Vaccine Adverse Events Tracking Systems Do Not Support Causal Inference, then "Pharmacovigilance" Does Not Exist

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There are two messages from those who hold appointed offices or other influential positions in Public Health on long-term vaccine safety. The first message is that long-term randomized double-blinded placebo-controlled clinical trials are not necessary for the long-term study of vaccine safety because we have "pharmacovigilance"; i.e. long-term post-market safety surveillance that is supported by widely accessible, passive vaccine adverse events tracking systems.

The second message is that any use of those very same vaccine adverse events tracking systems that leads to the inference or conclusion that vaccines might cause serious adverse events or death is unsupported by such systems.

When the philosopher Sir Karl Popper described his demarcation between science and non-science, he introduced hypothetico-deduction as a compromise between inferences that use induction — that is, those that seek generalization — and inferences that use deduction — that is, those that we can make about the data that we have in hand.

In his formulation of his formal calculus of hypothetical deduction, Popper described that the appropriate way to seek generalizable knowledge using science is to pose a hypothesis and think of the most critical test that could, in principle, falsify (i.e. disprove) the hypothesis of interest if that hypothesis was, in fact, false.

After conducting the critical test of the hypothesis of interest, a scientist should then examine the evidence provided by the test and interpret the hypothesis and the background knowledge about the hypothesis in light of the new evidence from the critical test that could have demolished the hypothesis if it was, in fact, false.

Under the Popperian model of science, hypotheses that survive critical tests were and are considered to be corroborated. According to Popper, the degree to which the corroboration can be attributed is a function of how surprised the scientist conducting a critical test is to see the unexpected result (that a hypothesis survived a critical test). Of course, the introduction of null hypothesis significance testing allows us to focus on challenging the null hypothesis instead of the alternative hypothesis. Science is not the best argument that can explain the data; it's the process of approaching the truth asymptotically, with ever-increasing accuracy, by getting rid of possibilities that do not survive *bona fide* critical tests.

The key to the success of hypothetico-deduction, upon which virtually all science is now thought to be conducted, was the insistence that the test being applied to threaten the hypothesis was, in fact, a truly critical test of that hypothesis and not a weak test. Popper warned us that weak tests, which cannot truly jeopardize a particular hypothesis by potentially falsifying said hypothesis, can only provide weak corroboration.

When those seeking support for public health initiatives, such as a new vaccination program, offer evidence that long-term vaccine safety studies are well in hand due to the possibility of detecting adverse events that happened following vaccination, they are either (a) unaware that the vaccine adverse events tracking systems upon which they are basing their confidence about society's ability to detect and track vaccine adverse events are alleged to be unable to be used to infer causal links between health outcomes and vaccination exposure, or (b) participating in a disinformation campaign to end scrutiny over the absence of properly controlled long-term randomized clinical trials to assess long-term vaccine safety. Neither of these is sufficient empirical basis for the knowledge claim of long-term safety.

Either way, the authors of the latest paper in *Science, Public Health Policy, & the Law* (Walach et al.) have been caught, like grist in the mill, in a nonsensical, convoluted torture session in which their detractors have broken all logic and reason on the question of how society renders causal inference between vaccine exposure and serious illness or death.

These authors studied publicly available data and reported a unique and potentially useful risk/benefit analysis that is routinely used in the assessment of the value that a drug will add to the treatment of a clinical disease. They attempted to calculate the number needed to vaccinate, inspired by the number needed to treat. The purported *raison d'être* of the data resource they used is pharmacovigilance: it exists to provide data for post-market, long-term vaccine safety studies.

As a result of the first publication of their results, a number of scientists on the editorial board of the publishing journal resigned in protest because the authors of the study had determined, in their interpretation of their analysis of the data collected to detect vaccine risk signals, that the vaccine caused specific health outcomes. The scientists on the board who disagreed with the authors claimed that the reason why they resigned was that vaccines did not cause the deaths that were reported to the vaccine adverse event tracking system.

The resigning editorial board members' knowledge claim is that no deaths have occurred due to the vaccination program. As helpful as that claim might be to a prescribed narrative, it is not based on empirical evidence, and it is, therefore, unwarranted.

From a Popperian view of science, one can see the fatal flaw in the editorial board members' knowledge claim: if, as they insist, passive vaccine adverse events tracking systems cannot test the hypothesis of causality, then how can editorial board members, resigning or otherwise, know that the events were NOT caused by the vaccine?

Reports that I've read tell me that the resigning editorial board members were epidemiologists and virologists. It is worth noting that neither category of scientist is clinically trained to determine the cause of death in any patient. Epidemiological correlation — and the absence of such correlation or association — is a weak test of causality. It requires forensic pathologists to determine cause of death. The amount of time it takes for victims of vaccines to acquire a ruling on causality in the United States National Vaccine Injury Compensation Program, based on debates over highly granular details of evidence in support of or countering the hypothesis of causality, is befuddling. In some cases, the debates between experts, mediated by special masters, can last over 10 years.

This pace stands in stark contrast to the lightning — perhaps miraculous, perhaps magical — speed with which physicians involved in short-term randomized COVID-19 vaccine trials determined the non-causality of the deaths that occurred following exposure to the first-in-human experimental mRNA vaccines.

I cannot tell other journals how to run their operations; however, I can report that it is the policy of *Science, Public Health Policy and the Law* not to retract papers on the basis of mere differences in the interpretation of studies that are adequately designed, adequately executed and appropriately presented. We also do not bias our contents to fit a prescribed narrative.

Authors' points in the discussion and conclusions made in scientific studies are suitably placed in those sections for a reason: they are challenges to other scientists to prove or disprove — i.e. test and potentially falsify or corroborate — such knowledge claims. There must be room for disagreement in science; otherwise, science does not exist.

It is sad to bear witness to the fact that science has degenerated into a war against unwanted and inconvenient results, conclusions and interpretations via the process of post-publication retraction for issues other than fraud, grave error in execution, and plagiarism. The weaponization of the process of retraction of scientific studies is well underway, and it induces a bias that could be called "retraction bias", or, in the case in which a few persons haunt journals in search of studies that cast doubt on their commercial products, a "ghouling bias", which leads to biased systematic reviews and warped meta-analyses.

It has become altogether too common for studies that find evidence of risk of vaccination of any kind to end up retracted from journals that one can only presume had already used the peer-review process to put the studies through proper jeopardy (Easy et al, 2021).

Post-publication retraction for mere differences of opinion expressed as interpretation is a form of weak double jeopardy with strong (negative) consequences to knowledge: when journals retract studies that have been conducted and have survived peer review due to prescribed conclusions, knowledge suffers. In the face of new results that challenge our existing background knowledge, Popper would have us update our background knowledge, not destroy new findings and the careers of objective scientists. Viewed on the basis of a reader's difference of interpretation, journals that retract to maintain a prescribed narrative are participating in the etiological equivalent of book-burning.

Rage-quitting is not Science.

In the absence of reliable and credible contrary evidence, journals, journal editors and journal editorial boards must remain relatively agnostic as to their opinion on how authors have interpreted a study's results. If they have truly credible evidence that is inconsistent with the interpretation of the data at hand, they should proceed in a manner that leads to advocacy for a position of interpretation that they themselves hold via peer-reviewed correspondence. The very best vehicle for this interchange is in editorials or in letters to the editor via rational discourse. When readers and other participants in the journal find points of sincere disagreement, the editor should entertain rational, open discourse on matters of interpretation. This rational discourse is how science has classically been moved forward, not through anonymous letters leading to retraction — and neither through emotion-driven resignations of editorial board members. If vaccine safety science is to advance, methodological advances such as the use of "number needed to vaccinate" and non-standard methods of analysis are needed to break the stronghold of the "vaccines are safe" bias that has hobbled scientists from detecting and reporting risk issues with vaccines. This is a stoutly pro-science view.

Since 2015, as I embarked on a journey into the science of public health, I have been disappointed to find that corporations who develop vaccines and have a vested interests in the profitability of vaccines, and regulatory agency members who, it turns out, also have financial vested interests in vaccines, routinely partake in science-like activities. In doing so, they eschew the products of the Enlightenment: science and reason, and they are causing a steady decay in the public's trust in Science as a process. The public should not confuse their mistrust of corrupted and captured institutions with a mistrust of Science. The offending individuals in these institutions can hardly be said to be doing science: They repeatedly bias interpretations to minimize the public's perception of risk; they cherry-pick results to include and exclude in vaccine studies; and they have not been forthright with key information, including the risk of fetal death from vaccination during pregnancy, the risk of infection following influenza vaccination, the risk of autoimmunity following vaccination, and the risk of neurodevelopmental disorders following vaccination.

In stark contrast to those who use these practiced and codified corrupting exercises in tobacco and glyphosate science, an informed public that examines how post-market vaccine safety studies have been conducted actually rally and protest for objective, rational science. For all of the ill that the year brought us, the events of 2020 also ushered in a new school of thought, which I have christened ``Popular Rationalism''. It is from the perspective of continued and powerful calls for objectivity in vaccine safety science that we now proceed.

Our decision to publish the Walach et al. study was made after thorough independent, blind review by three professionals who are more than adequately trained and skilled to appropriately execute the analysis and interpretation of data in retrospective clinical studies.

This decision was not undertaken lightly, nor was it undertaken without due consultation on the processes and policies that led to the retraction from the previous journal.

The issue of determining causality from passive vaccine adverse events tracking systems is not an easy one; even in our review of this study for publication in this journal, there was not a consensus among the reviewers on agreement or disagreement with the authors' interpretation.

There was, however, consensus among the reviewers on an elementary but critically important point: It is logical to conclude that since passive vaccine adverse event tracking systems do not lend themselves well to testing hypotheses of causality, they do not provide the opportunity to design and conduct sufficiently critical tests of causality, and therefore a replacement system is needed.

Vaccinologists act as if the process of collecting the data using a passive system destroys the causal link between vaccine exposure and poor health outcomes and death. In reality, the causal link exists, or it does not. If it does, the act of collating the data using a passive system that then only satisfies temporal association and statistical association or correlation does not destroy the causal link; it merely makes it difficult to ascertain causality. The lack of association thereby does not indemnify the vaccine exposure. A positive association, however, should be heeded; every single gene discovery made in the decades of gene association studies started with a mere association link between genetic variation in people and specific conditions or traits. Follow-up functional analyses studies then further tested causality in some but not all cases. Every time you read "Scientists Discover a Gene That Causes…" you were most likely reading association studies. The associations that were found were reported and acted upon; they were not ignored.

Imagine an Automobile Accident Adverse Events Reporting System in which victims of car accidents could report the effects of their personal, first-hand experience in a car accident. We could then download and analyze the data using association analyses. Would the act of collecting the data destroy the causal link? No. It would obfuscate the discovery of causality, but it would not prevent it.

US FDA recently approved Pfizer's COVID-19 vaccine for people sixteen years of age and older. They did so without holding the required advisory committee meeting. Acting Director Janet Woodcock must be held responsible for removing that particular safeguard. The purpose of the approval was to satisfy the requirements of the policy needs of allowing mandates (in the US, mandates for vaccines only approved for emergency use are not allowed). The realization that companies imposing mandates were sitting ducks for lawsuits for coercing individuals into human subjects research was an oversight by Dr. Anthony Fauci, who decreed unilaterally that companies could mandate or dismiss. The fact that FDA skipped the step has led to intense scrutiny, with many questions opening up about disconnect between earlier claims of "safe and effective" and the fact that ongoing studies had not been completed. It looks as if FDA's approval was designed to satisfy what was considered to be a required policy (mandates) instead of evidence-based rendering of a policy position. This, of course, is not new; last month, FDA approved of an Alzheimer's drug after ignoring input from an advisory board. Three of the board members resigned in protest. We can expect that FDA's approval of Pfizer's commercially branded COVID-19 vaccine will not stand.

It is not Walach et al.'s fault that a system capable of providing data that can be used to reliably render an inference of causality is not easily available to the public or the scientific community. The scientific community, however, must now stand up and call for the development of one that is suitable to detect risk.

What would such a system look like? In my view, such a system would have to require mandatory reporting by physicians, with penalties for non-reporting. Physicians should be required to report health events that follow vaccination whether they themselves suspect causality or not. Such a system would allow specific submitted records to be checked at random and verified against medical records to allow assessment of reporting reliability. Such a system would also, of course, allow the participation of non-vaccinating patients to provide a control or comparison group. Such a system would collect critical demographic and clinical data elements from all reportees. It would collect potential covariates which could be tested as confounders not as variables that explain away causality (they don't), but instead as vaccine adverse events risk factors, and an ideal system would allow onboard machine learning objective prediction models to be optimized and tested for generalizability.

A universal flaw with vaccine safety studies conducted by people with a vested interest in vaccines is the gross oversimplification assumption that all covariates are confounders. An ideal system would allow the use of such covariates as co-risk predictors along with vaccination status.

A machine learning–based prediction model optimizer analysis module would allow the refinement of model parameter selection, model selection, and allow for tests of the generalizability of the performance evaluation of models that would predict who is at most risk of vaccine injury or death.

While causality matters in determination of liability, the beauty of machine learning–based prediction modeling is that the question of causality becomes moot. In the quest to reduce human pain and suffering, causality is not even the correct hypothesis to test. Even if only correlated variables

that are non-causal are useful in predicting adverse outcomes of the application of a medical procedure that may be intolerable to some people, the models can be made immediately clinically actionable, systemically and reliably removing people from harm's way, ending the social discord between those who promote universal vaccines and those who report that they have experienced personal injury, or injury or death in a loved one, following vaccination.

This system would also, of course, allow a more reasonable analysis to be undertaken on the question of causality. However, such a system would still be vastly inferior to the requirement of the use of long-term prospective randomized inert placebo–controlled clinical trials to monitor vaccine safety and risk.

It is with these concepts and hopes in mind that I founded and launched this journal. To date, articles that appear are all present by invitation and are rigorously reviewed by our blind review process. This is also true of the Walach et al. analysis.

We seek ethical, non-governmental, non-corporate underwriters who have no vested interest in the outcome of public debates involving vaccines so we can better explore the application of popular rationalism to questions of *Science, Public Health Policy and the Law*. By definition, journal underwriters will have no say in the publication policies or direction of this journal into perpetuity. They will, however, have our and humanity's eternal gratitude for empowering objective science.

It is via this mechanism that Popular Rationalism will help society return objectivity to science and inject rational discourse into public health, leading to evidence-based policies and, only when absolutely necessary, evidence-based laws that respect personal experience with vaccine risk.

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Addendum

As this was going into production, we learned that the US FDA has approved the marketed version of the Pfizer COVID-19 vaccine for people over 16 years of age. These individuals did this without the required advisory committee meeting — a month after they were skewered in the media for approval of a drug for Alzheimer's disease that has limited, if any, efficacy.

The stunning move by FDA decision on approval of the Pfizer vaccine was made by ignoring the massive number of post-market safety events reported to VAERS. Many physicians see this as FDA acting on <1% of the safety information available, and they note that Americans are being injured and killed by the vaccines. This is intolerable — and the entire HHS should undergo Congressional review.

We need a viable public health system that does not engage in profit incentive but instead uses science, logic and reason in the studies of what is causing poor health and killing people. A decentralized plan exists to replace the CDC (Plan B); perhaps now we need a similar plan to replace the FDA.

Citations

Elisha E, Guetzkow J, Shir-Raz Y & Ronel N (2021). Retraction of scientific papers: The case of vaccine research, *Critical Public Health*, DOI: 10.1080/09581596.2021.1878109

Malone R, Nass M, et al., 2021. FDA Covid Vaccine "Approval" – Dr. Robert Malone has compiled a laundry list of concerns from multiple sources regarding the validity of the so-called approval. (Accessed 8/26/2021.) https://anthraxvaccine.blogspot.com/2021/08/fda-covid-vaccine-approval-dr-robert.html