

NEJM Commentary: Establishing Ongoing Funding for Post-Authorization Vaccine Safety Science

Frequently Asked Questions

1. If the NCVIA was passed in 1986, why wait almost 40 years to amend it?

While the law was clearly intended to include science to prevent adverse reactions, at the time the science had not sufficiently evolved to do so. However, over the past 40 years our capacity to use large healthcare databases to determine or rule out possible associations between vaccines and adverse events following immunization and to determine the biological mechanism for adverse reactions has grown tremendously. We now have the capacity to rapidly conduct these studies with adequate resources. The time is now to amend the tax law to be consistent with the initial legislation, leading to major improvements in vaccine safety science to detect and reduce vaccine injuries, improve vaccine communication and confidence, and equitably compensate persons, who are injured by vaccines.

2. There has been a lot of concern about inadequate compensation for vaccine injuries (in general and for COVID19 vaccines), shouldn't the trust fund surplus go to meet those needs instead?

COVID-19 compensation is through a separate program and not the vaccine injury compensation program (VICP). The VICP has run a substantial surplus every year.

3. Some members of the public and advocacy groups feel the surplus in the trust fund is because the injury compensation program is too stringent, and these funds should be used for more compensation of people who may have been injured by vaccines. Will these people and groups be opposed to your proposal?

The vaccine injury compensation program uses a very generous standard for compensation – either because the medical event is on the vaccine injury table, or a special master determines it is more likely than not that the vaccine caused the adverse event following immunization. This has resulted in billions of dollars of payments over the years. Undoubtedly, many of the people who have been compensated by the program suffered from the adverse health outcome, but it was not due to the vaccine. For example, the influenza vaccines double the risk of GBS in the 42 days after vaccination (1-3 persons per million vaccinated will get GBS from the vaccine). GBS is on the injury compensation table after influenza vaccine. This means that half the people eligible for compensation would have gotten GBS without the vaccine.

There may be improvements that could be made to the vaccine injury compensation program, and a review by the National Academy of Medicine we recommend could consider such improvements. Fundamentally, the public and consumer groups as well as all other stakeholders share a common desire to study the safety of vaccines, make vaccines as safe as possible, reduce adverse reactions when possible and compensate fairly when people experience serious adverse reactions.

4. Have you found congressional sponsors [or other supporters (e.g., government, industry, consumers) for your proposal?

We have not yet identified congressional or stakeholder support. This is an important next step.

5. Given how controversial and political polarizing immunizations and vaccine safety have become in the US post-COVID, how do you expect your proposal to gain enough support to pass, especially in an election year?

Vaccines have historically received strong bipartisan support given their tremendous impact of saving lives and money. However, COVID has led to politization around vaccines. Funding additional vaccine safety science affords the opportunity for political parties to come together on common ground and make an improvement important to Americans. Our approach is budget neutral – meaning that vaccine safety can be funded without impacting the deficit. This makes bipartisan support much more likely. Champions in Congress would be extremely helpful and serve as an opportunity for political leaders to show leadership by addressing a concern to Americans without costing the taxpayer more money.

6. All the adverse events of special interest (AESI) that you propose studying are rare, given the benefits of immunization vastly outweigh these rare risks, why should we invest in studying these rare risks?

Serious vaccine adverse reactions are rare. But when the vaccine is given to very large populations (as during the COVID19 pandemic for example), the total number affected is no longer negligible. It is important to find out which adverse events are causally related to vaccines, and which are coincidental. Careful studies of persons with vaccine-caused adverse reactions can lead to understanding the characteristics which are associated with the adverse reaction, and lead to development of safer vaccines or contraindicating the vaccine in those persons to prevent the occurrence of future adverse reactions.

Furthermore, when someone is vaccinated, they are usually not only trying to protect themselves, but they are also protecting their community, either voluntarily or under some kind of mandate. They reduce the chances that they will transmit the disease to someone who cannot be vaccinated (e.g., someone with a legitimate medical contraindication) or is too young to be vaccinated or was vaccinated and the vaccine didn't work for them (no vaccine is 100% effective). Given vaccination protects society and the government has such an active role in developing, purchasing and promoting vaccines, society and the government has an obligation to compensate people truly injured by vaccines. Thus, even if risks are rare, those persons who are injured should be compensated. Research is needed to inform who should be compensated.

Finally, preventing rare adverse reactions from vaccines will help improve public confidence in our vaccine program.

7. Given how rare these AESI's are (e.g., one to three excess cases of Guillain-Barre Syndrome (GBS) per million influenza vaccine recipients in some seasons), how do you realistically expect to study them affordably?

With current rates of influenza vaccination, we would expect a few hundred cases of GBS per year in the US and more globally. Large healthcare databases now afford the opportunity to study even such rare adverse reactions.

8. Since the benefits of a safer vaccine extend outside of the US, shouldn't the global community contribute their fair share?

It is important for vaccine safety efforts to be funded and conducted globally both to share the burden (costs) and take advantage of what can be learned in other and across countries. The Global Vaccine Data Network (GVDN) is doing these studies globally. The Institute for Vaccine Safety (IVS) and the National Institute of Health Foundation (FNIH) are forming a public-private partnership to leverage global resources.

9. Some vaccine companies (e.g., Moderna and Pfizer) made huge profits during the pandemic, why shouldn't they (vs. taxpayer) fund making their vaccines safer?

Vaccine companies already spend a lot of resources to study their vaccines and make them safer when possible. However, there are needs beyond single vaccines and it is the responsibility of the government to make sure the public's needs are fully met given the important role the government already plays in vaccines (funding vaccine research, recommending vaccines, purchasing vaccines, requiring vaccines for school entry, etc). The current excise tax on vaccines (75 cents per disease prevented) is already being collected. We propose the surplus from this tax be used to study vaccine safety and prevent adverse reactions. As this is budget neutral, it would not cost taxpayers more money.

10. If your proposal is successful,

- a. *How would the funds be allocated?*
- b. *Who would provide oversight over it?*
- c. *Would non-traditional researchers like Dr. Wakefield be eligible?*

We recommend that the National Academy of Medicine conduct an independent and comprehensive review to address these important and complex issues of structure and governance. The highest quality research should be funded.

11. Should vaccine critics, such as RFK Jr., be involved in determining how best to spend the money?

We recommend that the National Academy of Medicine conduct an independent and comprehensive review to address these important and complex issues of structure and governance.

12. Please explain the difference between the NCVIA and the tax code that funded it and what part you propose amending.

The [NCVIA \(PHL 99-660\)](#) created the vaccine injury compensation program, provided liability protection to vaccine manufacturers and healthcare providers, required healthcare providers to keep vaccine records, required CDC and FDA to create VAERS, required HHS to provide Congress annual vaccine safety reports, and created the National Vaccine Advisory Committee. But most importantly, Section 2127 of [NCVIA](#) (p. 1336) is titled “Mandate For Safer Childhood Vaccines” and calls for:

“In the administration of this subtitle and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall:

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on the effective date of this part 27 and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.”

The clear intent of the law’s intent was to study vaccine safety and prevent adverse reactions.

Unfortunately, the tax code ([26 U.S. Code § 9510](#)) created the funding for NCVIA restricted use of the funds only for compensation and running the compensation program. We are recommending this tax code be amended to use the funds for the full intent of NCVIA.

13. What will guarantee that enhancements to the present system will really improve vaccine safety monitoring?

There are tremendous opportunities in big data through large healthcare databases and advanced knowledge of disease pathology and genomics that can be realized with adequate funding. The science is ready.

14. What should be done with this additional funding? What science is needed?

There are a broad range of vaccine safety activities that would greatly benefit from additional funding:

- Domestic passive and active surveillance
- Standard case definitions
- Clinical Immunization Safety Assessment (CISA) services rolled out nationally
- Vaccine safety biobank
- Genomic and other – omic studies for pathogenesis studies
- Global active surveillance
- Investigator initiated research
- Academic Centers of Excellence
- Public and stakeholder engagement
- Special studies of emergent issues

- Communications
- Administrative technical expertise, management, oversight
- Advisory committee
- Training program

15. Given we are concerned that current vaccines have safety problems, not yet evaluated, should we stop vaccinating until more safety evaluations have been performed? In other terms, why should we continue vaccinating?

The science clearly shows that the benefits of vaccines far outweigh the risks as recommended by the CDC immunization schedule for the vast majority of vaccinees. However, we need to strive to reduce the incidence of all serious vaccine adverse reactions.

16. In addition to lack of resources, why has vaccine safety research been so challenging?

With any medicine (including vaccine), we are interested in its safety and efficacy. But safety, unlike efficacy or effectiveness, generally cannot be measured directly. It can only be inferred indirectly from the absence of multiple possible adverse events following immunizations (AEFI), given the number of persons vaccinated. But if there is not a standardized case definition available for the AEFI, and a monitoring system is not in place, then a case of AEFI can be easily missed, especially if it's rare. Even if both a case definition and monitoring are in place, if not enough persons who received the vaccine are monitored, then the AEFI can still be missed. This is the case when the sample size of the pre-authorization trials of a new vaccine is too small (e.g., ~10,000 persons) to detect a rarer risk.

Adequate funding of post-authorization monitoring of vaccine safety, once the vaccine is used in larger populations is therefore critical. The US uses [multiple complementary data systems](#), each with their respective strengths and weaknesses to do so.

Additional References:

1. Legislation

1.1. [NCVIA \(PHL 99-660\)](#)

1.2. [26 U.S. Code § 9510](#)

1.3. Lainie Rutkow, Brad Maggy, Joanna Zablotzky & Thomas R. Oliver, Balancing Consumer and Industry Interests in Public Health: The National Vaccine Injury Compensation Program and Its Influence During the Last Two Decades, 111 DICK. L. REV. 681 (2007).

Available at: <https://ideas.dickinsonlaw.psu.edu/dlra/vol111/iss3/5>

2. Vaccine Safety Papers

2.1. Faksova K, Walsh D, Jiang Y, et al. [COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network \(GVDN\) cohort study of 99 million vaccinated individuals](#). Vaccine 2024 Apr 2;42(9):2200-2211. doi: 10.1016/j.vaccine.2024.01.100. Epub 2024 Feb 12. PMID: 38350768.

2.2. Chen RT. [Vaccine risks: real, perceived and unknown](#). Vaccine 1999 Oct 29;17 Suppl 3:S41-6. doi: 10.1016/s0264-410x(99)00292-3. PMID: 10559533.

- 2.3 Salmon DA, Chen RT, Black S, Sharfstein J. [Lessons learned from COVID-19, H1N1, and routine vaccine pharmacovigilance in the United States: a path to a more robust vaccine safety program](#). *Expert Opinion on Drug Safety* 2024;23(2):161–175. <https://doi.org/10.1080/14740338.2024.2305707>.
- 2.4 Salmon DA, Orenstein WA, Plotkin SA, Chen RT. [Funding Postauthorization Vaccine-Safety Science](#). *N Engl J Med*. 2024 Jul 6. doi: 10.1056/NEJMp2402379. Epub ahead of print. PMID: 38973739.

3. Websites

- 3.1. [Institute for Vaccine Safety \(IVS\), Johns Hopkins University School of Public Health](#)
- 3.2. [The Brighton Collaboration, a program of the Task Force for Global Health](#)
- 3.3. [National Academy of Medicine. Vaccine Safety Reports](#) (as compiled by IVS)
- 3.4. [Global Vaccine Data Network \(GVDN\)](#)
- 3.5. [International Network of Special Immunization Services \(INSIS\)](#)