

Vaccine Safety Project



"Autism, ADHD, epilepsy, autoimmune disorders, deadly allergies, SIDS, juvenile rheumatoid arthritis, diabetes, learning disabilities and more have been increasing for over 25 years. Over 50% of our children are chronically ill. A new NIH study found that 49.5% of adolescents ages 13 to 18 have a mental disorder. This is unacceptable."

Robert F. Kennedy, Jr.

The long-term health effects of our vaccine program are inadequately studied and our regulatory bodies are conflicted. Childhood health epidemics have mushroomed along with the childhood vaccine schedule. Vaccines contain many ingredients, some of which are known to be neurotoxic, carcinogenic and cause autoimmunity. **Vaccines injuries can and do happen. The National Vaccine Injury Compensation Program of Health and Human Services (HHS) has awarded almost \$4 billion for vaccine injuries since 1988.**

Common sense dictates that these Six Steps to Vaccine Safety must be taken:

1. **Subject vaccines to a scientifically rigorous approval process.**
2. **Require reporting of vaccine adverse events. Automate VAERS and VSD databases for research.**
3. **Ensure all parties involved with federal vaccine approvals and recommendations are free from conflicts of interest.**
4. **Reevaluate all vaccines recommended by ACIP prior to the adoption of evidence-based guidelines.**
5. **Study what makes some individuals more susceptible to vaccine injury.**
6. **Support fully-informed consent and individual rights to refuse vaccination.**



1 Subject vaccines to a scientifically rigorous approval process.

Vaccines are regulated by the FDA's CBER division as "biologics" and are not always put through the same level of safety testing as new pharmaceuticals, which are regulated under CDER.

Vaccines, which are given to healthy patients, should be tested more rigorously than drugs because they are not given to treat an existing disease.

Inadequate testing currently ensures that the **true risk/benefit assessments for the safety and cost of vaccines are impossible to calculate accurately.**

These vaccines are given to about 4 million American infants annually.

Typical Drug Approval Process	Typical Vaccine Approval Process
<p>Prelicensure follow-up for adverse events often takes years. For example:</p> <p>Lipitor – 4.8 years Enbrel – 6.6 years Botox – 4.25 years</p>	<p>Prelicensure follow-up for adverse events may take as little as 2-5 days. For example:</p> <p>HepB (Engerix - GSK) – 4 days HepB (Recombivax - Merck) – 5 days Polio (PVI – Sanofi Pasteur) – 2 days Hib (Pedvax – Merck) – 3 days Hib (Hiberix – GSK) – 4 days Hib (ActHib – Sanofi Pasteur) – 30 days</p>
<p>Requirement for trials to be done against an inactive placebo – with the exception of drugs for life-threatening diseases (cancer, etc.) where the placebo is typically the current standard of care.</p>	<p>Trials not done against an inactive placebo. Trials of vaccinated compared to unvaccinated children are not performed.</p>
<p>Placebo is often:</p> <ul style="list-style-type: none"> • Saline • A sugar pill designed to look like the active pill • Another inactive substance or base 	<p>Placebo is often:</p> <ul style="list-style-type: none"> • Another vaccine, but not always for the same disease • An adjuvant or preservative like aluminum or mercury that is not inactive • A group of vaccines
<p>Safety follow-up is incentivized by education and lawsuits. There are free market checks and balances to produce safer drugs.</p>	<p>Lack of any product liability for vaccine manufacturers provided by the National Childhood Vaccine Injury Act eliminates market incentives to produce safer vaccines.</p>

2 Require reporting of vaccine adverse events. Automate the VAERS and VSD databases for research.

Reporting and study of adverse events after receipt of vaccines is currently haphazard and antiquated. Since these two databases are the primary sources of U.S. post-licensure surveillance, serious side effects of vaccination that were unclear or not seen in clinical trials will be missed.

The Vaccine Adverse Events Reporting System (VAERS) is the online system into which doctors and patients report adverse events after vaccination. HHS admits that the system **likely records only about 1% of the actual adverse events** but even after a three-year HHS/ AHRQ study showed the feasibility of automating reports using electronic medical records, Centers for Disease Control (CDC) has been non-responsive to "multiple requests to proceed with testing and evaluation."

- Clinical trials for vaccines typically only enroll a few thousand patients in total. When vaccines are subsequently approved for use in populations of millions of healthy individuals, it is imperative that rates of known adverse events and any new or rare adverse events are monitored.
- Without adequate safety follow-up, serious side effects may be missed entirely putting the public at risk (examples of the past importance of safety follow-up include hormone replacement therapy, Vioxx and amphetamines).

- There has never been a comparative study of broad health outcomes in vaccinated vs. unvaccinated populations.

The National Childhood Vaccine Injury Act (NCVIA) requires healthcare providers to report:

- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine; or
- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccination.

But, in practice, this doesn't happen. There is no consequence for failing to report an injury. There is no mechanism for prosecution of non-compliance and, therefore, no incentive for a busy doctor to report vaccine safety problems.

The Vaccine Safety Datalink (VSD) is a collaborative project between CDC's Immunization Safety Office and eight private health care organizations. The VSD was started in 1990 to monitor safety of vaccines and conduct studies about rare and serious adverse events following immunization. **However, research is currently hampered by lack of broad access to this publicly-funded database, variability of reporting and the statistical structure of the database.**

3 Ensure all parties involved with federal vaccine approvals and recommendations are free from conflicts of interest.

FDA's Vaccine and Related Biological Products Advisory Committee (VRBPAC) is responsible for licensing of vaccines. CDC's Advisory Committee on Immunization Practices (ACIP) is responsible for adding vaccines to the recommended schedules.

- CDC or NIH Employees whose names appear on vaccine patents can receive **up to \$150k in licensing fees per year** (in perpetuity).

- Regarding VRBAC, a House OGR Committee Report found that the **“overwhelming majority of members, both voting members and consultants have substantial ties to the pharmaceutical industry,”** and “committee members with substantial ties to pharmaceutical companies have been given waivers to participate in committee proceedings.”
- A similar report on the ACIP found that, **“The CDC grants blanket waivers to the ACIP members each year that allow them to deliberate on any subject, regardless of their conflicts, for the entire year.”**

- A 2009 HHS Office of the Inspector General report found that:
 - “CDC had a systemic lack of oversight of the ethics program”
 - 97 percent of committee members’ conflict disclosures had omissions.
 - 58 percent had at least one unidentified potential conflict.
 - 32 percent had at least one conflict that remained unresolved.
 - CDC continued to grant broad waivers to members with conflicts.

All vaccine regulatory agencies must rigorously enforce their ethics policies to ensure that our vaccine program is free from financial conflicts of interest.

4 Reevaluate all vaccines recommended by ACIP prior to the adoption of evidence-based guidelines.

A vote by the Advisory Committee on Immunization Practices results in:

- Mandating the vaccine to millions of children
- Immunity from liability for the manufacturers
- Inclusion in the Vaccines for Children program

However, prior to 2012, ACIP did not use evidence-based guidelines to evaluate their vaccine recommendations. Evidence Based Practice is “the conscientious, explicit and

judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research.” The final ACIP guidelines published in November of 2013 outlined clearly, **for the first time**, a standardized plan to evaluate the quality and strength of the research behind each recommendation for a vaccine for each population. ACIP’s recommendations include the populations, timing, spacing,

number of doses, boosters and appropriate ages for each vaccine to be administered.

The CDC’s infant schedule, given to approximately 4 million babies a year, was largely adopted before these guidelines were in place. Vaccines recommended before the adoption of evidence-based guidelines should not have been “grandfathered” in. Earlier ACIP recommendations should be thoroughly reviewed in light of the new guidelines and current research.

5 Study what makes some individuals more susceptible to vaccine injury.

The Institute of Medicine (now National Academy of Medicine) has issued three disturbing reports on the evidence for suspected and/or reported vaccine adverse events.

For 80% of the suspected vaccine adverse conditions investigated, there wasn’t enough research evidence to accept or reject vaccine causation. Of the reviews with sufficient evidence, 72% found that the vaccine did likely cause the injury.

or other aspects of the immunization schedule have not been conducted.”

The Vaccine Injury Compensation Program has paid out over \$3.8 billion in compensation to victims of vaccine injury. The children and adults who have been compensated for injuries have never been studied to determine why they were injured, in an effort to make vaccines safer for everyone. Preventing vaccine injuries should be tackled as zealously as we tackle preventing infectious diseases.

In 2013, the IOM studied the entire Childhood Immunization schedule and stated:

“No studies have compared the differences in health outcomes... between entirely unimmunized populations of children and fully immunized children... Furthermore, studies designed to examine the long-term effects of the cumulative number of vaccines

Vaccine safety science, particularly long-term safety science, is inadequate to ensure children’s safety or to accurately assess risks for purposes of informed consent.

Year	Vaccine(s) Studied	# of Conditions Reviewed	Evidence Supports Vaccine Causation	Evidence Supports Rejection of Vaccine Causation	Evidence Inadequate to Accept or Reject Vaccine Causation
1991	DPT	22	6	4	12
1994	DT, MM, HepB, Hib	54	12	4	38
2011	Varicella, T, HepB, MMR	155	16	5	134
Totals		231	34	13	184

6 Support fully-informed consent and individual rights to refuse vaccination.

The American Academy of Pediatrics statement on the ethics of informed consent includes the following stipulation, “patients should have explanations, in understandable language, of ...; **the existence and nature of the risks involved**; and the existence, potential benefits, and risks of recommended alternative treatments (**including the choice of no treatment**).”

In the case of vaccination, informed consent is often ignored completely in real world settings. By law, “all health care providers in the United States who administer, to any child or adult, any of the following vaccines – diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) – shall, **prior**

to administration of each dose of the vaccine, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC) to the parent or legal representative¹ of any child to whom the provider intends to administer such vaccine, or to any adult² to whom the provider intends to administer such vaccine.”

In practice, particularly when multiple vaccines are administered on the same day, many parents report that they got the Vaccine Information Sheet (VIS) as they left and there was no explanation of information before a vaccine was given. It is also rare that medical history is thoroughly discussed to identify contraindications to a vaccine. For example, a patient with a family history of autoimmunity is likely at increased risk for an autoimmune reaction after vaccination.

The following are examples of the types of information that patients may learn after the fact from the Vaccine Information Sheets:

“Severe events have very rarely been reported following MMR vaccination, and might also happen after MMRV. These include: **Deafness, long-term seizures, coma, lowered consciousness, brain damage.**”

Or this from the Polio VIS and several others: “As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.”

Lack of informed consent encompasses vaccine advertising as well. While television drug ads disclose the side effect risks of that drug at length, vaccine advertising does not. The patient, again, is at a disadvantage.

Insistence on fully-informed consent and individual rights to refuse a vaccination become imperative given the lack of long-term follow-up and surveillance, only 1% adverse events are captured and reported, vaccine recommendations are tainted by financial conflicts of interest of regulators, the current childhood vaccine schedule was not approved using evidence-based science and policy, the childhood vaccine schedule has never been tested on fully vaccinated vs. unvaccinated, and there is sparse research into which patients are likely to have adverse events. America is in the midst of many childhood epidemics. Over 50% of our children are chronically ill. We owe it to our children to examine what is happening to their health and correct it as soon as possible.



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