

Vaccine Safety

by
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TABLE 1 Some of the Subjects on Which I Was Questioned by an Antivaccination Lawyer During a Deposition

Subject
Money I have received from vaccine companies
Have I done any consulting for the government despite having consulted for the industry?
Is the pertussis vaccine effective?
What royalties have I received for vaccine invention?
Do vaccines have nonspecific effects, such as increased mortality after DTP (shown by Dr Peter Aaby)?
Some package inserts seem to say subjects in vaccine trials were only managed for 4–5 d.
According to the package insert, Salk IPV reactions were only managed for 2 d.
How was MMR safety documented? Where are safety data? Was there an unvaccinated group managed at the same time?
A Gardasil safety study used the Alum adjuvant as a control, not a placebo, so how can you exclude reactions? Of the control group, 2%–3% had reactions said to be autoimmune; so did Gardasil.
The National Academy of Medicine published a book that says many reactions may have been caused by vaccines.

TABLE 1 Some of the Subjects on Which I Was Questioned by an Antivaccination Lawyer During a Deposition (Cont.)

Subject
What proof is there that DTaP doesn't cause autism?
Is there a study comparing vaccinated and unvaccinated children for health later in life?
Can Alum travel to the brain and cause autism?
IL-6 is induced by vaccination and can cause autism.
Package inserts mention encephalopathy as a possible reaction to influenza and pertussis vaccines.
Some vaccines were produced in monkey cells; therefore, monkey DNA and protein are in the vaccine.
Human diploid cell proteins are in vaccines made in MRC-5.
Can adjuvants increase responses to nonvaccine antigens in vaccines?
What about my work with the oral polio vaccine in the Belgian Congo in the 1950s? Did I vaccinate anyone without permission?
What's the evidence that receiving multiple vaccines at the same time is safe?

DTaP, diphtheria-tetanus-acellular pertussis; DTP, diphtheria-tetanus toxoids-pertussis vaccine; IL-6, interleukin-6; IPV, inactivated polio vaccine; MMR, measles-mumps-rubella vaccine; MRC-5, Medical Research Council cell strain 5.

Vaccine Safety Library Topics

May 2019

Heather Monk Bodenstab, PharmD, Paul Offit, MD, Frank DeStefano, MD

- **Adjuvants Other than Aluminum in Vaccines**
 - *Squalene (MF59, AS03, AF03)*
 - *Monophosphoryl lipid A (MPL), Saponin (QS21), and Related Adjuvant Systems (AS01, AS02, AS04)*
 - *CpG*
- **Aluminum in Vaccines**
- **Diabetes and Vaccines**
 - *Type-1 Diabetes*
 - *Gestational Diabetes*
- **DNA and Vaccines**
- **Egg Allergy and Vaccines**
 - *Influenza Vaccine*
 - *Measles-Containing Vaccine*
 - *Yellow Fever Vaccine*
- **Guillain-Barre Syndrome (GBS) and Vaccines**

Vaccine Safety Library Topics (cont.)

May 2019

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- **Human Papillomavirus (HPV) Vaccine Safety Concerns**
 - *HPV Vaccine and Chronic Fatigue Syndrome (CFS)/Systemic Exertion Intolerance Disease (SEID)*
 - *HPV Vaccine and Multiple Sclerosis/Central Demyelinating Disease*
 - *HPV Vaccine and Postural Orthostatic Tachycardia Syndrome (POTS)*
 - *HPV Vaccine and Primary Ovarian Insufficiency*
 - *HPV Vaccine and Promiscuity*
 - *HPV Vaccine and Venous Thromboembolism (VTE)*
- **MMR and Autism**
- **Multiple Sclerosis/Central Demyelinating Disease and Vaccines**
 - *Hepatitis B*
 - *Flu Vaccine*
- **Pertussis Vaccine and Neurologic Complications**
- **Pregnancy and Vaccines**
 - *HPV Vaccine and Pregnancy*
 - *Influenza Vaccine and Pregnancy*
 - *Pertussis-containing Vaccines and Pregnancy*
- **Sudden-infant death syndrome (SIDS) and Vaccines**
- **Thimerosal and Autism**
- **Too Many, Too Soon**
- **Vaccine Ingredients**
 - *Formaldehyde*
 - *Gelatin*
 - *Polysorbate 80*
- **Yeast and Vaccines**

Package Insert for MMR

Risks of a Vaccine Reaction

- Soreness, redness, or rash where the shot is given and rash all over the body can happen after MMR vaccine.
- More serious reactions happen rarely. These can include seizures (often associated fever), temporary pain and stiffness in the joints (mostly in teenage or adult women), pneumonia, swelling of the brain and/or spinal cord covering, or temporary low platelet count which can cause unusual bleeding or bruising.
- In people with serious immune system problems, this vaccine may cause an infection which may be life –threatening. People with serious immune system problems should not get MMR vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

There are few published studies that specifically explore and evaluate the methods or effectiveness of witness preparation. Research on verbal and non-verbal communication suggests witnesses should speak powerfully in a narrative style and avoid hypercorrect speech in addition to attending to their nonverbal cues. Nonverbally, witnesses should maintain eye contact, have a moderately relaxed posture, lean forward slightly, avoid frequent posture shifts, and avoid ending their sentences with a rise in pitch. Other research conducted with expert witnesses suggests assertiveness is appropriate, particularly when intrusive questions are asked. A series of studies has found empirical support for the assertion that credible expert testimony is characterized by knowledge, confidence, trustworthiness, and likeability on part of the witness.

Tess M.S. Neal, American Society of Trial Consultants 2009

The role of vaccine safety monitoring in maintaining vaccine confidence [DeStefano]

In the United States, several government agencies, vaccine manufacturers and other entities are involved in evaluating and monitoring the safety of vaccines. The core of the U.S. vaccine safety post-licensure monitoring enterprise consists of four systems operated by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA): 1) the Vaccine Adverse Event Reporting System (VAERS); 2) the Vaccine Safety Datalink (VSD); 3) the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) Program; and 4) the Clinical Immunization Safety Assessment (CISA) project.

Vaccine Safety Concerns in Europe [Larson]

The European Medicines Agency(EMA) conducted a study monitoring online and social media in all European Union (EU) member states, in order to listen for concerns related to the human papillomavirus(HPV) vaccine. In response to a series of adverse events following immunization, particularly in Denmark, the EMA was asked to conduct a review of the safety of the HPV vaccine[22], and the media monitoring preceded the launch of the EMA safety review and helped to prepare the EMA officials to anticipate questions around the launch of the final report, which confirmed the HPV vaccine's safety.[23-25]

Vaccine Hesitancy in Lower Middle-Income Countries [Arora]

Common concerns regarding vaccination in LMICs include fear of adverse events, lack of trust in medical community or public health program, health system related issues such as quality of service delivery, cost and access to vaccines and may even be politically motivated.[29]. The above reasons accounted for nearly 80% of the responses for missing vaccinations from care givers of under-vaccinated children during the Mission Indradhanush (MI) campaign in India. Ethnicity and faith based perceptions towards vaccination, reinforced by local social, economic and community connections have also been identified as factors driving hesitancy during the Pulse Polio (2006) and the MI campaigns (2018) in India. [30,31].

Vaccine Safety Concerns as Seen by the World Health Organization [Zuber]

Safety of vaccines utilized in global public health programs is a paramount concern for the World Health Organization (WHO). In the past 20 years, WHO has paid increasing attention to vaccine safety and developed a program dedicated to managing those issues. The Global Advisory Committee on Vaccine Safety (GACVS) was established in 1999 to respond promptly, efficiently and with scientific rigor to vaccine safety issues of potential global importance.[34] GACVS has examined the robustness of vaccine safety concerns to assist risk/benefits-based vaccine safety policies development.

Autism [Fombonne]

Controlled observational studies (case-control and cohort studies) equally failed to show that past exposure to MMR vaccination was higher in children with autism compared to controls[43]; similarly, infants and toddlers exposed to MMR or to thimerosal-containing vaccines in various doses, when followed up several years later, were not an increased risk of developing autism,

Neurologic Adverse Events Following Immunizations [Sejvar]

Although the 1976 formulation of the H1N1 swine-origin influenza vaccine was associated with a slightly increased risk of developing GBS – to the amount of approximately 1 excess case of GBS per 100,000 vaccinees – subsequent formulations of the seasonal influenza vaccine have demonstrated either no increased risk or a very mild increased risk, to the amount of 1-3 excess GBS cases per million vaccinees, and nothing like the magnitude of that seen with the 1976 formulation. These studies, however, may be underpowered, and the 2009 formulation of the H1N1 pandemic influenza vaccine was associated with a mild increased risk (1 excess case/million vaccinees).

Vaccination and Autoimmunity [Lambert]

There are an increasing number of allegations suggesting the occurrence of autoimmune manifestations following vaccination. The scientific basis of these allegations is usually lacking. This situation is largely the result of coincidental events linked with the increasing administration of vaccines in adolescents and young adults at an age known to be associated with autoimmune diseases. It is also reflecting a trend to call autoimmune a variety of vague clinical manifestations of unknown origin (e.g. the ASIA syndrome) (“Everything is autoimmune until proven otherwise”. [58] Serious epidemiological studies did not confirm an association of autoimmune diseases with HBV, HPV nor with seasonal influenza vaccination.

Thiomersal and Mercury [Hviid]

The majority of large observational studies of thiomersal exposure have focused on autism. There have been no support for an association in key analytical studies from Denmark, the United Kingdom and the United States comprising more than 690,000 children.[77-80] Similarly, studies looking at a wide range of neurodevelopmental outcomes including both diagnostic outcomes and questionnaire information on early life behavior, cognition and motor skills have been reassuring

Formaldehyde and Aluminum [Halsey]

The very small amounts of residual formaldehyde in vaccines following removal after inactivation of the target organisms are not additive to the amounts produced from the body's natural metabolism, are below the levels deemed acceptable by regulatory authorities, and are not harmful.

Formaldehyde and Aluminum [Halsey]

Although there have been allegations that aluminum adjuvants cause persistent myalgia, fatigue, autoimmune diseases, encephalopathy and other conditions based on poor science, expert reviews have concluded that the scientific evidence does not support these claims. The detection of aluminum at injection sites many months after vaccination “... represent(s) a simple marker of vaccination with long-term persistence of aluminum at the injection site and local inflammatory response to it, without other symptoms or consequences.”[93] Similarly, the U.S. FDA has concluded “...episodic exposures to vaccines that contain aluminum adjuvant continue to be extremely low risk to infants and that the benefits of using vaccines containing aluminum adjuvant outweigh any theoretical concerns.”[94]

New Adjuvants in Vaccines [Garçon]

As their mode of action is limited in space and time, no adjuvants currently present in vaccines have been shown to induce de novo rare events such as autoimmune diseases.

Non-specific Effects of Vaccines [Pollard]

While it seems that immunological non-specific effects occur, we don't know enough about them to predict when or for how long they might last and have no understanding of their clinical relevance. The animal studies show that there are intriguing effects, whether underpinned by the above immunological observations or not, which can be induced in these controlled settings and can have a profound impact on survival. The animal studies, provide a strong case for improved understanding of the biology that might one day be translated into benefits for humans. The human data, with clinical endpoints, indicate that there are intriguing signals which warrant investigation, but trials to provide a definitive answer will be challenging to realize as global childhood mortality continues to fall. Today we do not have definitive evidence of non-specific effects of vaccines that should lead to a change in immunization policy.

HPV Vaccines [Markowitz]

The World Health Organization's (WHO) Global Advisory Committee on Vaccine Safety (GACVS) reviewed safety of HPV vaccines seven times since 2007; in 2017 GACVS conducted a comprehensive assessment and systematic review focusing on serious events after 2vHPV and 4vHPV.[120] In this systematic review, 26 randomized controlled trials and six good quality post-licensure cohort studies were included.[120-122] Among the cohort studies: four looked at autoimmune diseases, two venous thromboembolic disease and one multiple sclerosis and other demyelinating conditions. Results from both clinical trial evidence and cohort studies were consistent in finding no relationship between serious adverse events and HPV vaccination.

Too Many Vaccines? [Glanz]

The VSD has developed analytic metrics for measuring adherence to the recommended schedule, including cumulative vaccine antigen exposure, cumulative vaccine aluminum exposure, and a summary measure called the average days under-vaccinated. Thus far, these metrics have been used to study all-cause mortality and non-targeted infection, both of which produced null results.[141,142] Studies examining asthma and type 1 diabetes mellitus are currently underway.

Summary

Vaccination is under attack all over the world.

It is not a good idea to ignore it.

We must prepare ourselves for attacks.

Vaccine safety should be approached using science.