Evidence-Based Responses to Common Vaccine Arguments in Court Proceedings

The following fact sheet provides evidence-based responses to common vaccine arguments that are raised in legal disputes. This resource is meant as an overview of possible responses to these arguments and should be adapted based on your own reading of the science, available through a collaboration housed at the Vaccine Education Center at the Children's Hospital of Philadelphia.

Key Arguments

VACCINE SAFETY CONCERNS

Q. Has there ever been a study which looked at the total health outcomes of children following the CDC's vaccination schedule and those that are completely unvaccinated?

A. Federal researchers have not conducted a study comparing these populations due to ethical concerns. A study comparing the health outcomes of vaccinated children with their unvaccinated counterparts would "intentionally leave unvaccinated people and the communities they live in subject to increased risk of death and illness."[1] Plus they could not be matched for other factors. In other words, it could not be a randomized study between vaccinees and non-vaccinated balanced for other factors.

Q. Are vaccine trials done with placebos?

A. According to the U.S. Department of Health and Human Services (HHS), "placebo controls are not required to understand the safety profile of a new vaccine, and are thus not required. In some cases, inclusion of placebo control groups is considered unethical. Even in the absence of a placebo, control groups can be useful in evaluating whether the incidence of a specific observed adverse event exceeds that which would be expected without administration of the new vaccine. Serious adverse events are always carefully evaluated by the Food and Drug Administration (FDA) to determine potential association with vaccination regardless of the control group."[2]

Q. Are rates of developmental delays and chronic illnesses in children increasing due to vaccinations?

A. No. Scientists have not found a causal link between vaccines and developmental delays or chronic illnesses. Researchers have attributed increases to broadened diagnostic criteria and increased awareness of these conditions, which has resulted in better, more frequent identification.

Q. Are vaccines more deadly than the diseases they were created to prevent?

A. No, vaccines are much safer than the diseases they were created to prevent. Vaccines given to children born between 1994-2016 will prevent an estimated 381 million illnesses, 24.5 million hospitalizations and 855,000 deaths.[3] Serious side effects from vaccines, however, are extremely rare.[4]

Q. Do vaccines contain potentially harmful ingredients?

A. No. Vaccine ingredients are selected for many reasons, including their ability to "enhance the immune response to the vaccine, decrease the quantity of vaccine needed to gain protective immunity, or lower the number of doses required."[5] Certain ingredients also "protect the integrity of the active ingredients during manufacturing, storage and transport, and others are used to in some vaccines to prevent bacterial or fungal contamination."[6]

Dosage is key when considering vaccine ingredient safety, as many of the ingredients "contained in vaccines are not at quantities that could possibly do harm."[7] Trace amounts of proteins and DNA have no effect.

Q. What is included in package inserts about side effects and why?

A. Manufacturers are required by the FDA to report all events during a clinical trial. For example, if a child is involved in a car accident during the clinical trial and reports to the hospital with a broken arm, the manufacturer must report a broken arm as an adverse event even though it is not likely linked to the vaccination. Many other events may occur after vaccination by chance and only controlled studies can demonstrate causation.

Q. Are recommendations from the U.S. Centers for Disease Control and Prevention (CDC) and rates of vaccine-preventable disease deaths sufficient proof of vaccine safety and efficacy?

A: Yes. According to the CDC, "the U.S. is a regulatory state and vaccines are no exception. The vaccine licensing process goes through multiple stages of vaccine testing and approval."[8] Development and licensure of a vaccine is a process that usually takes at least 15 years of study.

Before vaccines are licensed by the FDA, they must pass three phases of clinical trials. FDA licenses a vaccine only if it's proven to be safe and effective, and its benefits outweigh its risks. After vaccines are licensed, the Advisory Committee on Immunization Practices (ACIP) deliberates on whether to add it to the vaccine schedule. Vaccines that are recommended by ACIP aren't officially added until the CDC director reviews and approves them. After vaccines are added to the schedule, they are monitored for safety concerns by four separate federal surveillance programs as well as ongoing market research.[9]

DISEASE INCIDENCE & VACCINE EFFICACY

Q. Doesn't low disease incidence domestically indicate we no longer need vaccination?

A. No. Although the United States has achieved low rates of vaccine-preventable diseases through mass vaccination, these diseases are often just a plane ride away. Globalization has enabled travel to even the most remote corners of the world, where vaccine-preventable disease outbreaks are commonplace. For example, in 2011, 350,000 cases of measles were reported around the globe, with outbreaks in the Pacific, Asia, Africa, and Europe.[10] 90 percent of measles cases in the U.S. that year were associated with cases imported from another country.[11] Vaccination alone prevented a measles epidemic that year.

However, it's important to consider that some diseases will never be eradicated. Take tetanus: tetanus spores are present in environments around the globe in soil and animal intestinal tracts. The disease will never be eliminated due to the ubiquitous nature of the bacteria. Tetanus impacts people of all ages and typically requires hospitalization, but the disease is particularly life-threatening for newborn babies and their mothers. Vaccination provides effective lifelong protection against the condition.[12]

Q. Why have vaccines failed to eradicate the diseases they were created to prevent?

A. Eradication is a complex, costly process – as evidenced by the ongoing efforts to eradicate polio. Nearly 2.5 billion children have been vaccinated against polio at a cost of $15 billion, yet the disease has not been eradicated in the 40 years since campaigns launched. Reasons for this include vaccine costs and the nature of the disease. Vaccines are scarce in some parts of the world, such as war-torn countries, and they are quite costly when accounting for the costs of field workers and delivery chains. Additionally, the disease is highly contagious – for every child paralyzed by polio, 200 more carry the virus without symptoms. People from endemic countries can still spread the disease.[13]

Polio cases have dwindled over the last four decades through immunization – if we stopped using the polio vaccine today, cases would number 200,000 annually within a decade.

Despite the many barriers to achieving eradication, it is indeed possible. Smallpox was declared officially eradicated in 1979, after "a collaborative global vaccination programme led by the World Health Organization."

Q. Can you explain why pertussis is resurging despite the availability of a vaccine?

A: Prior to the 90's, the pediatric whole cell pertussis vaccine (DTP) was administered for pertussis prevention. However, parents and consumer groups "raised concerns about the safety of whole-cell pertussis vaccines, prompting the development of a more purified (acellular) pertussis vaccine (DTaP) that was first licensed in the early 90's. By the year 1997, the ACIP recommended DTaP be used routinely in place of DTP for the full 5-dose pediatric schedule. The good news was that it appeared less likely to provoke adverse events because these newer vaccines contain purified antigenic components of Bordetella pertussis. The bad news is that the newer acellular pertussis vaccine is just not as effective in providing lasting immunity as the whole cell version" – the duration of protective immunity wanes by as much as 60% four years after vaccination, depending on the vaccine brand.[14] Therefore, boosters are needed in adolescents and pregnant women are boosted to protect their offspring during the first months of life.

Q. Can you explain why mumps is resurging despite the availability of a vaccine?
A: The mumps vaccine is highly effective, resulting in a dramatic drop in mumps cases from about 200,000 prior to the introduction of the vaccine to a few thousand today. Unfortunately, immunity from the vaccine wanes about 10 years after the first dose and 10 years after the second dose. Because we did such a good job reaching so many kids with that second dose of the vaccine when it was

recommended by CDC, the cases had dropped dramatically once again. So now that the second dose is fading, mumps outbreaks are once again unusual and noteworthy.

Q. Has the CDC overstated the burden of vaccine-preventable diseases?

A. No. Extensive data suggests that vaccines prevent many deaths, hospitalizations and illnesses in the United States. The economic burden of vaccine-preventable disease outbreaks also underscores the importance of vaccination. Each case of a vaccine-preventable disease can cost communities thousands of dollars for care and containment. The recent measles outbreak in Minnesota, which lasted three months, cost state and local health departments $1.3 million for treatments and containment.[15] These costs can cause financial strain in local communities, as many states lack funding for outbreaks.

VACCINE INJURY

Q. Do you think anyone knows the true amount or burden of vaccine injuries?

A. Yes. Three systems – the Vaccine Safety Datalink (VSD), the Clinical Immunization Safety Assessment (CISA), and the Post-licensure Rapid Immunization Safety Monitoring System (PRISM) Project – offer useful, and properly controlled, methods for assessing possible vaccine adverse events by proactively collecting and analyzing data after vaccine licensure. A fourth, the Vaccine Adverse Event Reporting System or VAERS, serves as a broad access, early warning system that allows reporting by anyone. In this way, VAERS reports inform questions that the other three systems can explore more thoroughly.

Q. Shouldn't physicians, not the government, retain the authority to determine whether children should be vaccinated if patients have adverse reactions (or the potential for them), not the courts?

A. The initial determination of whether a child should be vaccinated is completed between physician and parents. States with school immunization entry requirements may have mechanisms to oversee exemptions, which aim to balance physician discretion with the health of their schools' populations. Every state has medical exemptions with guidelines for physicians and other health care providers to understand when an exemption is medically necessary. However, the system should not be abused by seeking "philosophical objections" unfounded in science and leaving the child susceptible to disease.

Q. How frequent is VAERS fraud?

A. According to the CDC, "the Vaccine Adverse Events Reporting System (VAERS) allows independent parties to report an event or injury that happened after vaccination that is believed to be caused by the vaccine. The system doesn't limit submissions to patients or to specific symptoms, so anyone can report anything, whether it was actually caused by vaccines or not.[16] Therefore, VAERS cannot be used to accurately report the frequency of vaccine injuries, but it is helpful in identifying patterns of injury.[17] The CDC states that "approximately 30,000 VAERS reports are filed each year. About 85-90% of the reports describe mild side effects."[18]

However, it's important to note that a 2006 study published in the journal *Pediatrics* found that between 1990 and 2003, there was a steep increase in the number of VAERS reports related to litigation and that attorneys comprised a sizeable portion of VAERS system reporters during that time period.[19]

RELIGIOUS OBJECTIONS TO VACCINES

Q. Do vaccines contain aborted fetal cells and human DNA?

A. Some do. Fetal cells are used to make five vaccines: rubella, chickenpox, hepatitis A, shingles and rabies. Fetal cells used to grow the vaccine viruses were isolated from two elective abortions performed in Sweden and England in the early 1960s. The cells themselves are not in the vaccine. Further abortions are not necessary as the cells isolated in the 1960s continue to be maintained in laboratory cultures.[20,21]

Q: Is the use of aborted fetal cells and human DNA a problem for organized religions?

A. No major organized religion objects to vaccinations.[22] In the case of Catholicism, the Vatican has specifically addressed this issue. An official statement declared that while alternative vaccines would be preferable, it is important to use these vaccines to protect the health of others, particularly pregnant women.[23]

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