Aluminum in Childhood Vaccines Is Unsafe

Neil Z. Miller

ABSTRACT

Aluminum is a neurotoxin, yet infants and young children are repeatedly injected with aluminum adjuvants from multiple vaccines during critical periods of brain development. Numerous studies provide credible evidence that aluminum adversely affects important biological functions and may contribute to neurodegenerative and autoimmune disorders. It is impossible to predetermine which vaccinated babies will succumb to aluminum poisoning. Aluminum-free health options are needed.

Introduction

From 1999 through 2002, several vaccines containing mercury were phased out of the childhood immunization schedule. Manufacturing of childhood vaccines with thimerosal ceased in 2001, but those that were not past their expiration date remained on the market for sale until January 2003.[1] They were replaced with low-mercury or "thimerosal-free" vaccines. In the years that followed, autism rates continued to rise, prompting health authorities to assert that autism is not linked to mercury in vaccines and that vaccination policies are safe and appropriate.[2-4] (If mercury in vaccines contributed to autism, then rates should have dropped after mercury was removed.) However, in 2002, during this so-called phase-out period, the Centers for Disease Control and Prevention (CDC) actually added two doses of mercury-containing influenza vaccines to the list of inoculations urged for all babies 6 to 23 months of age.[5] Two years later, the CDC also added *pregnant women in their first trimester* to the list of people officially recommended and actively encouraged to receive influenza vaccines, even though a majority of available doses contained mercury.[6]

In addition to these questionable actions during this highly publicized "phase-out" of mercury, four doses of a new vaccine with high *aluminum* content were added to the childhood immunization schedule in February 2000 (for pneumococcus) and two doses of another aluminum-containing vaccine (for hepatitis A) were added in 2005.[7,8] These changes to the vaccine schedule resulted in a substantial increase of aluminum-containing vaccine doses—from 10 to 16 injections—that babies are still mandated to receive by 18 months of age.

Prior to the mercury phase-out (pre-2000), babies received 3,925 micrograms (mcg) of aluminum in their first year-and-a-half of life. After pneumococcal and hepatitis A vaccines were added to the immunization schedule, babies began receiving 4,925 mcg of aluminum during the same age period—a 25% increase (Figure 1).[9,10] In 2011, CDC recommended that pregnant women receive a pertussis vaccine (Tdap), which also contains aluminum.[11] Studies show that aluminum crosses the placenta and accumulates in fetal tissue.[12] Thus, millions of babies in utero, infants, and young children were injected with, and continue to receive, unnaturally high doses of neurotoxic substances—mercury and aluminum—long after unsuspecting parents were led to believe that vaccines were purified and made safe.

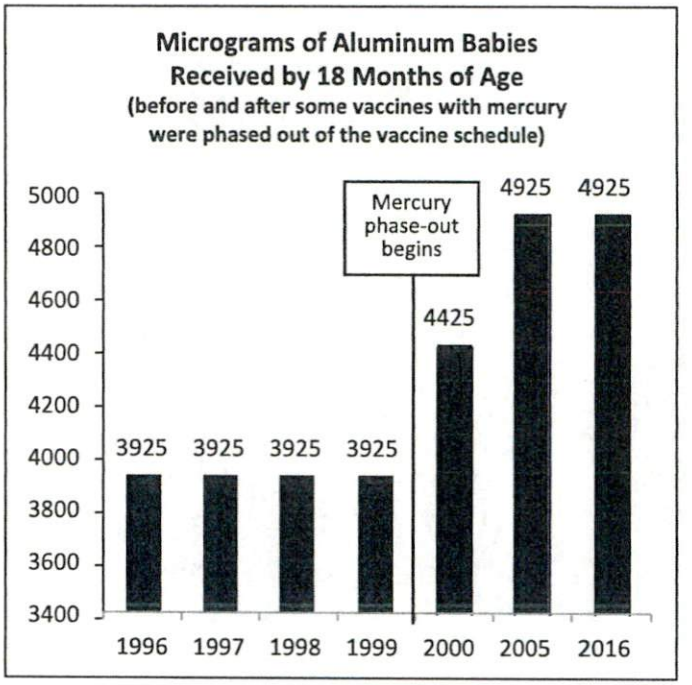


Figure 1. Aluminum Content from Childhood Vaccines

Vaccines containing aluminum were added to the childhood immunization schedule when some vaccines containing mercury were removed. Prior to the mercury phase-out (pre-2000), babies received 3,925 mcg of aluminum by 18 months of age. After pneumococcal and hepatitis A vaccines were added to the schedule, babies began receiving 4,925 mcg of aluminum during the same age period—a 25% increase.

Source: The vaccine manufacturers' product inserts and the CDC's annual childhood vaccination schedules.

Aluminum

Aluminum adjuvants are added to several vaccines to elicit a more robust immune response and increase vaccine efficacy. In the United States, Canada, Europe, Australia, and many other parts of the world, infants and young children receive high quantities of aluminum from multiple inoculations. For example, in the U.S. the hepatitis B, DTaP (for diphtheria, tetanus and pertussis), pneumococcal (PCV), *Haemophilus influenzae* type b (Hib), and hepatitis A vaccines are all administered during early childhood. Each of these

vaccines contains aluminum, and multiple doses (booster shots) are required (Table 1). Babies are injected with 1,225 mcg of aluminum instantaneously at age 2 months, and 4,925 mcg of accumulated aluminum by age 18 months (Figure 2).[9,10]

Table 1. Aluminum Exposures in Early Childhood from Recommended Vaccines

Vaccine	Aluminum Content	Vaccine Schedule
Hep B	250 mcg x 3 doses	Birth, 2, 6 months
DTaP	625 mcg x 4 doses	2, 4, 6, 15 months
PCV	125 mcg x 4 doses	2, 4, 6, 12 months
Hib	225 mcg x 3 doses	2, 4, 12 months
Hep A	250 mcg x 2 doses	12, 18 months

Source: The vaccine manufacturers' product inserts and the CDC's 2016 childhood vaccination schedule.

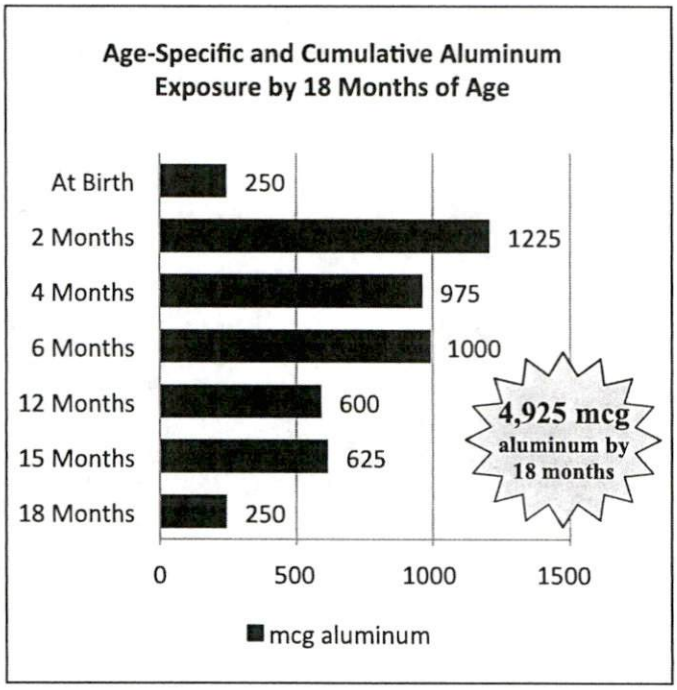


Figure 2. Cumulative Aluminum Exposure from Recommended Childhood Vaccines

Source: The vaccine manufacturers' product inserts and the CDC's 2016 childhood vaccination schedule.

Babies are not the only age group exposed to high quantities of aluminum from vaccines. The HPV vaccine (indicated for the prevention of cervical cancer and genital warts associated with some strains of human papillomavirus) is marketed to pre-teens and adolescents. Each dose in the three-dose series contains 500 mcg of aluminum. The Tdap vaccine (for tetanus, diphtheria, and pertussis) is given to pre-teens as well, and contains 390 mcg of aluminum.[13] Several adult vaccines also contain aluminum.

Aluminum is neurotoxic and has a long history of well-documented hazards.[14] For example, as early as 1921 The *Lancet* described a 46-year-old metal worker in whom "aluminium produced a rather slow intoxication. In this case it caused memory loss, tremor, jerky movements and incontinence of urine."[15] In 1927, Dr. Victor Vaughn, a toxicologist with the University of Michigan, testified before the Federal Trade Commission that "all salts of aluminum are poisonous when injected subcutaneously or intravenously."[16] By 1951, Chusid et al. showed that chronic epilepsy could be induced in monkeys through intra-cerebral administration of aluminum hydroxide cream.[17] In 1968, Driver et al. performed a similar experiment by placing aluminum hydroxide cream unilaterally on the posterior parietal cortex of six monkeys.[18] From 3 to 8 weeks after surgery, electrical abnormalities could be seen on an electroencephalogram and the monkeys exhibited "episodic twitching of the limbs and face." The animals were also impaired at learning new tasks and at re-learning tasks first learned prior to the intervention.

According to the American Academy of Pediatrics (AAP), "Aluminum is now being implicated as interfering with a variety of cellular and metabolic processes in the nervous system and in other tissues."[19] Bishop et al. published data showing that "aluminum accumulates in the body when protective gastrointestinal mechanisms are bypassed, renal function is impaired, and exposure is high."[20] For example, in premature infants, "prolonged intravenous feeding with solutions containing aluminum is associated with impaired neurologic development" by 18 months of age. More recently, Kawahara et al. published research confirming that "aluminum can cause severe health problems in particular populations, including infants."[21] The authors of this paper also declared that "whilst being environmentally abundant, aluminum is not essential for life. On the contrary, aluminum is a widely recognized neurotoxin that inhibits more than 200 biologically important functions and causes various adverse effects in plants, animals, and humans."

Neurologic and Autoimmune Disorders

Numerous studies provide compelling evidence that injected aluminum is detrimental to health. For example, a recent paper by Tomljenovic and Shaw affirmed that aluminum is a neurotoxin and may be a co-factor in several neurodegenerative disorders and diseases, including Alzheimer's, Parkinson's, multiple sclerosis, amyotrophic lateral sclerosis (ALS), autism, and epilepsy.[22] According to the authors, "The continued use of aluminum adjuvants in various vaccines for children as well as the general public may be of significant concern. In particular, aluminum presented in this form carries a risk for autoimmunity, long-term brain inflammation and associated neurological complications and may thus have profound and widespread adverse health consequences."

Recent data by Perricone et al. showed that aluminum adjuvants in vaccines have been linked to multiple sclerosis, systemic lupus erythematosus, chronic fatigue syndrome, Gulf War syndrome, macrophagic myofasciitis, arthritis, and autoimmune/inflammatory syndrome induced by adjuvants (ASIA syndrome), an autoimmune disease with neurological and cognitive manifestations.[23] Clinical symptoms associated with vaccine-induced autoimmunity can take months or years to manifest, much longer than the time intervals utilized in most vaccine safety studies.

Although aluminum is a neurotoxin, pre-school children are repeatedly injected with aluminum adjuvants from multiple vaccines during critical periods of brain development. A recent paper published in the journal *Lupus* found that this may lead to neuro-developmental and autoimmune disorders.[24] During early development, the child's blood-brain barrier is more permeable to toxins, and the kidneys are less able to eliminate them. Thus, children have a greater risk than adults of adverse reactions to aluminum adjuvants in vaccines. The authors of this paper issued the following warning: "Because children may be most at risk of vaccine-induced complications, a rigorous evaluation of the vaccine-related adverse health impacts in the pediatric population is urgently needed."

Macrophagic Myofasciitis (MMF)

Some people develop macrophagic myofasciitis (MMF) after receiving an aluminum-containing vaccine.[25-39] MMF is characterized by an aluminum-filled lesion (wound) at the site of an earlier vaccination. MMF lesions occur when the aluminum adjuvant from a vaccine remains embedded in the muscle tissue and causes a continuous immune reaction. The lesions are persistent, long-term granulomas (or inflammatory tumors) found in the quadriceps in children and deltoid muscles of adults, common vaccination sites. Several vaccines contain aluminum hydroxide, which has been identified as the causal factor of MMF lesions.[25]

Although MMF is associated with a macrophagic lesion at the site of vaccination, it is a systemic ailment. Symptoms include chronic fatigue, chronic diffuse myalgia (muscle weakness), arthralgia (joint pain), and disabling headaches. Aluminum's toxic effects can also manifest as impaired psychomotor control, repetitive behavior, speech disorders, sleep disturbances, seizures, confusion, and anxiety, as well as deficits of concentration, learning, and memory. Nearly 20% of patients with MMF develop an autoimmune disease, including neuromuscular and multiple sclerosis-like demyelinating disorders.[26-28]

Several descriptive studies document MMF in pediatric populations. For example, Spanish scientists presented data on seven children younger than 3 years of age with lesions of macrophages on muscle biopsies at the site of vaccination.[29] In three of four cases tested, elevated levels of aluminum in muscle were detected (indicative of a reaction to aluminum adjuvants in vaccines). All of the children developed hypotonia (a lack of normal muscle tone) and motor or psychomotor delay. Six of the children also had abnormal neuro-imaging, associated with neurological anomalies, including atrophy and abnormal myelination.

In the U.S., Gruis et al. evaluated four cases of MMF in young children with hypotonia, motor delay and failure to thrive, likely due to intramuscular injections of aluminum-containing vaccines.[30] Another team of American physicians evaluated MMF in two fully vaccinated children. Both showed typical aluminum-filled macrophages at muscle biopsies.[31] One child had abnormal pupillary reflexes and urinary retention suggesting dysautonomia while the other child had developmental delay and hypotonia.

Israeli researchers documented MMF in six Arab children.[32] Reactions included hypotonia, seizures, motor delay, and developmental delay. The authors of this paper believe that genetic predisposition is a factor in determining the prevalence of MMF in different populations.

German researchers documented MMF in a 3-month-old East Indian child following his hepatitis B vaccine at birth, "after which he developed generalized hypotonia, and central nervous system and peripheral nervous system manifestations at one month of age."[33] The child also had respiratory failure, decreased spontaneous movements, apnea spells, and generalized seizures. Aluminum was detected in the muscle biopsy macrophages. The authors recommend that "after vaccination, children should be closely followed to detect these complications at early stages."

Italian researchers believe that MMF in children "is probably more common than reported. Diagnosis requires a high index of suspicion and can be missed if biopsy is performed outside the vaccination site."[34] According to Canadian MMF researchers, "aluminum has been demonstrated to impact the central nervous system at every level, including by changing gene expression. These outcomes should raise concerns about the increasing use of aluminum salts as vaccine adjuvants." Moreover, "based on the current and emerging literature, it seems unlikely that in the future aluminum will be considered safe for human use in any of the current medicinal applications."[28]

Animal Studies

A recent paper by Luján et al. found that sheep developed a new type of autoimmune and inflammatory disorder—ovine autoimmune/inflammatory syndrome induced by adjuvants (ASIA)—after receiving vaccines containing aluminum adjuvants.[40] The condition appears in some sheep two to six days after they are vaccinated. Symptoms of the acute phase include poor response to external stimuli and acute meningoencephalitis. The chronic phase causes muscular atrophy, neurodegeneration of the gray matter of the spinal cord, and death.

Khan et al. conducted several mouse experiments to determine the long-term biological distribution of vaccine-related aluminum nanoparticles.[41] They discovered that aluminum travels from the injection site to distant organs such as the spleen and brain, where aluminum deposits could still be detected one year later. Aluminum remains in monocyte-lineage cells long after vaccination and may cause neurologic and autoimmune disorders. According to these scientists, "Alum has high neurotoxic potential, and administration of continuously escalating doses of this poorly biodegradable adjuvant in the population should be carefully evaluated by regulatory agencies since the compound may be insidiously unsafe."

Scientists also looked at whether Gulf War Syndrome, which afflicted many veterans of Western militaries with cognitive and behavioral deficits similar to ALS (a progressive neurodegenerative disease that destroys nerve cells), could be related to the aluminum-containing anthrax vaccines they received. In a series of studies, mice were injected with adjuvants at doses equivalent to those given to vaccinated U.S. Gulf War veterans.[42,43] The aluminum-injected mice exhibited significant deficits in memory and motor functions. Testing showed motor neuron loss and progressive deficiencies in strength. The mice also had pathological abnormalities that are characteristic of neurological diseases such as Alzheimer's and dementia. According to the authors of these studies, "The demonstrated neurotoxicity of aluminum hydroxide and its relative ubiquity as an adjuvant suggest that greater scrutiny by the scientific community is warranted."[43]

Israeli scientists recently evaluated an aluminum adjuvant and the HPV vaccine Gardasil to determine behavioral and inflammatory effects.[44] Female mice were injected with either aluminum or Gardasil in amounts equivalent to human exposure, or they received a true placebo. (Vaccine safety trials for the HPV vaccine did not provide the control group with an inert substance or true placebo; the "control" group was injected with aluminum.) The Gardasil and aluminum-injected mice spent significantly more time exhibiting depressive behavior when compared to the placebo-injected mice. In addition, anti-HPV antibodies from the sera of Gardasil-injected mice showed cross-reactivity with the mouse brain protein extract. Analysis revealed microglial activation in the hippocampi of Gardasil-injected mice. According to the authors, "It appears that Gardasil via its aluminum adjuvant and HPV antigens has the ability to trigger neuroinflammation and autoimmune reactions, further leading to behavioral changes."

Autism

There is evidence that aluminum in vaccines may be linked to autism. For example, the *Journal of Inorganic Biochemistry* published data showing a highly significant positive linear correlation between the amount of aluminum infants receive from their vaccines and the rates of autism in several developed nations (Pearson r = 0.89-0.94).[45] The authors of this ecological study commented on their findings: "Our results...suggest that a causal relationship may exist between the amount of aluminum administered to preschool children at various ages through vaccination and the rising prevalence of autism spectrum disorders."

In another recently published paper, Shaw et al. found that genetic predispositions may sensitize some children to central nervous system damage induced by aluminum-containing pediatric vaccines.[46] Moreover, vaccines with aluminum adjuvants are *injected* into the body, bypassing protective barriers of the gastrointestinal tract and skin. Absorption of aluminum by this mode is more efficient than through ingestion, increasing the likelihood of a toxic outcome. The authors summarized their findings: "Evidence has now emerged showing that autism may in part result from early-life immune insults induced by environmental xenobiotics. One of the most common xenobiotic with immuno-stimulating as well as neurotoxic properties to which infants under two years of age are routinely exposed worldwide is the aluminum vaccine adjuvant."

Recent research published in the *Journal of Toxicology* found that aluminum exposure produces adverse effects in living organisms and is especially damaging to the central nervous system.[47] Aluminum from vaccine adjuvants crosses the blood-brain and blood-cerebrospinal fluid barriers, provoking harmful immuno-inflammatory responses in neural tissues. Yet, clinical studies on vaccine safety often give aluminum-containing injections to a "control" group as a harmless "placebo" despite evidence that aluminum is toxic to humans and animals. The use of aluminum as a placebo cannot be justified. According to the authors of this paper, "Studies on animal models and humans have shown that aluminum adjuvants by themselves cause autoimmune and inflammatory conditions. These findings plausibly implicate aluminum adjuvants in pediatric vaccines as causal factors contributing to increased rates of autism spectrum disorders in countries where multiple doses are almost universally administered."

In another recent animal study, young mice were injected with either high or low levels of aluminum adjuvants (designed to correlate with U.S. or Scandinavian childhood vaccine schedules).[48] Significant changes in the mice were observed, affirming the role of aluminum adjuvants in adversely altering the central nervous system. The authors commented on their findings: "These current data implicate aluminum injected in early postnatal life in some central nervous system alterations that may be relevant for a better understanding of the etiology of autism spectrum disorders."

Vaccine Industry Conferences and Concerns

In May 2000—3 months *after* the CDC added the aluminum-containing pneumococcal vaccine to the recommended immunization schedule for children—the U.S.

Department of Health and Human Services (HHS) sponsored a Workshop on Aluminum in Vaccines.[49,50] The workshop, given in San Juan, Puerto Rico, was attended by members of the vaccine industry, including government officials, immunologists, pathologists, vaccine manufacturers, metal ion specialists, and other interested people. It was organized to increase knowledge about aluminum as an adjuvant in vaccines, investigate potential adverse reactions associated with aluminum in vaccines, and develop a research agenda on the effect of aluminum in the human body. Experts from around the world were invited to give their presentations on vaccines and aluminum.

Dr. Romain Gherardi, a specialist in neuromuscular disease and professor at the Mondor Institute of Biomedical Research, showed that MMF without vaccination does not occur. In fact, it often begins after receiving a hepatitis B vaccine. Myalgia was present in 94% of patients with MMF, and 85% of these people were disabled. Although 30% of patients had their first myalgias within 3 months after their last vaccination, 20% of patients' symptoms took longer than 2 years to manifest. These myalgias begin in the calves and legs, then progress to diffuse myalgia. Fatigue was present in 93% of patients with MMF, and 87% of these people were disabled. In addition, 34% of MMF patients had autoimmune disease, including multiple sclerosis and arthritis.[50, pp 48-74]

In June 2000, the CDC sponsored a conference on thimerosal (mercury) in vaccines, although aluminum was discussed as well.[51] CDC scientists analyzed the agency's Vaccine Safety Datalink (VSD) database containing thousands of medical records of vaccinated children and found statistically significant relationships between mercury in vaccines and developmental delay, tics, and attention deficit disorder.[51, pp 40-41] However, Dr. Tom Verstraeten, CDC epidemiologist, analyzed the data and determined that the injuries could have been caused by aluminum in the vaccines.[51, p 77] It is also possible that the neurological damage was due to the synergistic effects of both aluminum and mercury in the vaccines given to the affected children.

Although millions of children every year are required to receive vaccines containing aluminum and mercury, evidence supporting the safety of this practice is lacking. For example, according to Dr. Richard Johnston, immunologist and professor of pediatrics at the University of Colorado School of Medicine, "Aluminum and mercury are often simultaneously administered to infants, both at the same site and at different sites. However...there is absolutely no data, including animal data, about the potential for synergy, additivity or antagonism, all of which can occur in binary metal mixtures."[51, p 20] Dr. Alison Maule, who attended the Workshop on Aluminum in Vaccines, voiced similar concerns: "We need to bear in mind that we are not only putting aluminum in here, we are putting in mercury.... Often these effects are additive but there is always the possibility of synergy. We know nothing about that."[50, p 106] Dr. Vito Caserta, chief medical officer for the Vaccine Injury Compensation Program, had this to say: "One of the things I learned at the aluminum conference in Puerto Rico...that I never really understood before, is the interactive effect of different metals when they are together in the same organism. It is not the same as when they are alone, and I think it would be foolish for us not to include aluminum as part of our thinking with this."[51, p 234] Dr. William Weil, pediatrician, former member of the National Institutes of Health, and representative for the AAP Committee on Environmental Health, was also present at the CDC conference and made his concerns known: "In relationship to aluminum, being a nephrologist for a long time, the potential for aluminum and central nervous system toxicity was well established by dialysis data. To think there isn't some possible problem here is unreal."[51, pp 24-25]

Some health authorities who oversee federal vaccine initiatives candidly acknowledge their limited understanding of metals—aluminum and mercury—that are added to several vaccines. For example, Dr. Martin Myers, director of the National Vaccine Program Office and host of the HHS-sponsored Workshop on Aluminum in Vaccines, made a frank admission: "Perhaps the most important thing that I took away from the last meeting was that those of us who deal with vaccines have really very little applicable background with metals and toxicological research."[49, pp 1-2] Dr. Neal Halsey, director of the Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health, and former member of the CDC's Advisory Committee on Immunization Practices (ACIP), was also present at the workshop on aluminum. He had concerns regarding missing data: "We do not seem to have information on the age-related toxicity of aluminum, especially when we are dealing with very young infants.... We do not know whether or not there is a difference in susceptibility by age, as there [is] with other metals."[50, pp 83-84]

Some health authorities seemed to admit that even if aluminum is dangerous, it would be burdensome to remove it. For example, according to Dr. John Clements with the World Health Organization's Expanded Programme on Immunization, "There are not easy and obvious substitutes to aluminum adjuvants.... The existing vaccines, if they change the adjuvant for any reason, would need to be resubmitted for clinical trials for safety and efficacy and it would take a great deal of time to do that."[50, p 75] Furthermore, "Aluminum is not perceived, I believe, by the public as a dangerous metal. Therefore, we are in a much more comfortable wicket in terms of defending its presence in vaccines."[49, p 64]

Note: In 2005, 5 years after conference attendees spoke out about a lack of data on the effects of mixing different metals in childhood vaccines, Dr. Boyd Haley, former professor of medicinal chemistry and chairman of the chemistry department at the University of Kentucky, published a study in which he investigated the effect of combining aluminum hydroxide with thimerosal.[52] In this study, cultured neurons showed no significant cell death six hours after they were exposed to just aluminum; more than 90% survived. Thimerosal alone also caused few neurons

to die after six hours of exposure. Again, more than 90% survived. However, when cultured neurons were exposed to aluminum and thimerosal, only about 40% survived after six hours, clearly demonstrating synergistic toxicity (Figure 3).

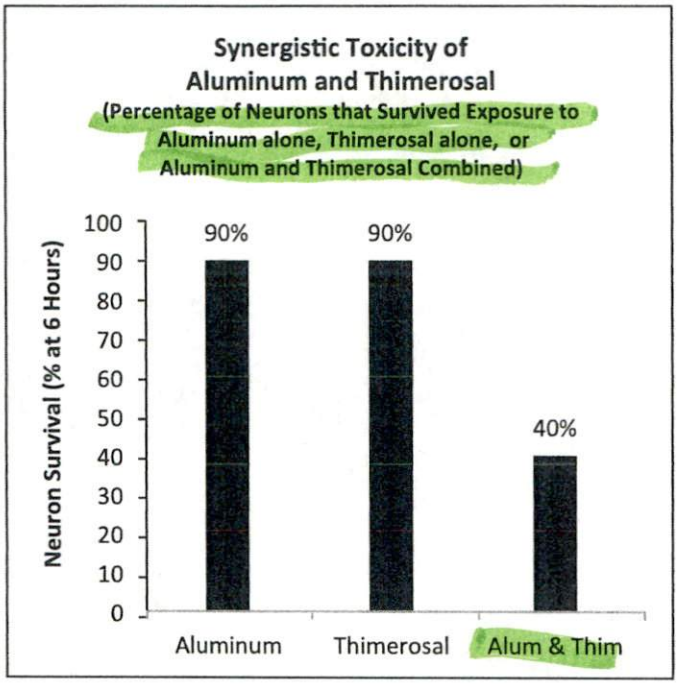


Figure 3. Survival of Neurons Exposed to Aluminum, Thimerosal, or Both

Unconvincing Evidence of Adjuvant Safety

Although several high-level representatives of the CDC, World Health Organization (WHO), American Academy of Pediatrics, Institute for Vaccine Safety, National Vaccine Program Office, and Vaccine Injury Compensation Program who attended the conferences on aluminum and thimerosal had serious concerns about the potential hazards associated with aluminum in vaccines, a conference report and workshop summary published in the journal *Vaccine* 2 years later declared that "the message from this conference for the global public should stress the safety of both these adjuvants and these vaccines," despite acknowledging that "we don't know" how aluminum adjuvants interact with the immune system and how it is processed by infants and children.[53] The conference report minimized risks by claiming that aluminum has been used as a vaccine adjuvant for more than 70 years and "has an established safety record with low incidence of reported adverse events." However, no one is warning vaccine recipients to consider the possibility that their adverse event could be related to aluminum in their vaccines nor encouraging them to report it to health authorities. Furthermore, research indicates that many people who have adverse reactions to aluminum-containing vaccines won't exhibit symptoms for several weeks, months, or years, so it's very difficult for vaccine recipients to recognize that the vaccines they received some time ago may be related to their current disabling autoimmune ailments.

A few years later, the FDA published a study, Mitkus et al., in which the authors concluded that "the benefits of using vaccines containing aluminum adjuvant outweigh any theoretical concerns."[54] This study is often cited as a confirmation that injecting babies with multiple doses of aluminum-containing vaccines is safe. However, there are major flaws in the FDA's analysis:

1. To determine an aluminum intake "minimal risk level" (MRL) for humans, a single animal study was used.[55] This study found that mice could receive up to 26 milligrams of aluminum per kilogram of body weight per day (26 mg/kg/day) with no adverse effects. After considering differences between mice and humans (and other factors), this number was reduced to create a margin of safety, and an MRL of 1 mg/kg/day was established for humans, including infants.[56] But there is a problem: 26 mg/kg/day is not a safe amount of aluminum for animals. Several studies confirm that animals are harmed by much lower quantities of aluminum—3.4 to 6.1 mg/kg/day—and at least three of these studies were published before the FDA paper in 2011, so the FDA study was fallacious at its inception.[57-60] Rats that were given just 6.1 mg/kg/day aluminum (30 mg/kg/day $AlCl_3$) needed significantly more repetitions to learn a maze when compared to a control group.[57] Rats that were given just 5.6 mg/kg/day aluminum (50 mg/kg/day $AlCl_3$-$6H_2O$) had significantly impaired spatial learning and memory abilities when compared to a control group. They also had cellular shrinking, plus behavioral, biochemical, and histological alterations.[58] Rats that were given just 3.4 mg/kg/day aluminum (17 mg/kg/day $AlCl_3$) "showed behavioral, biochemical, and histological changes similar to those associated with Alzheimer's disease."[60]

2. The MRL for humans is derived from dietary aluminum *fed* to mice. But infants are *injected* with aluminum. Injected aluminum bypasses the gastrointestinal tract and has unique toxic properties compared to aluminum that is ingested. To determine the safety of injected aluminum, scientists must conduct experiments with injected—not ingested—aluminum.

3. After vaccines containing aluminum adjuvants are injected into the body, aluminum nanoparticles can be transported by monocyte-lineage cells to draining lymph nodes, blood and spleen—and may also penetrate the brain.[41] Aluminum is unsafe even in trace quantities. For example, just 50 nanomolars of aluminum are sufficient to generate reactive oxygen species (ROS), or oxidative stress, in human primary neuronal-glial cell cultures and induce inflammatory gene expression.[61] In another study, just 10 nanomolars of aluminum increased C-reactive protein (CRP) levels four-fold, causing inflammation in human brain microvessel endothelial cells.[62] But the FDA assumes, without evidence, that these poorly biodegradable aluminum nanoparticles,

which have been detected in body organs up to a year after vaccination, are harmless, and they are not calculated by the FDA as part of the aluminum "body burden" until they dissolve.

4. The "retention function for aluminum," a mathematical equation that the FDA used to help estimate levels of aluminum in infants, was derived from data on only one person, an adult (rather than from numerous infants), and an estimate on the rate of absorption of aluminum hydroxide following injection was based on data from just two rabbits.

The FDA paper also falsely claimed that "occasional irritation (dermal) at the site of injection is the only adverse effect that has been reported in the published literature" following injections of aluminum-containing vaccines. And the clinical symptoms in patients diagnosed with MMF "are considered to be due to separate, coincidental immune or neurological disorders that are unrelated to the presence of aluminum in vaccines."[54] The Global Advisory Committee on Vaccine Safety, established by WHO, welcomed the FDA's analysis endorsing the safety of aluminum in vaccines.[63] The CDC vigorously defends the presence of aluminum in vaccines as well.[64] Clearly, FDA, CDC, and WHO agree on continuing indefinitely with their current policies of injecting babies with multiple doses of aluminum-containing vaccines.

Aluminum Toxicity Acknowledged for Parenteral Nutrition

Although the FDA's recent paper advocates the continued use of aluminum in childhood vaccines, FDA has known for many years that aluminum can be dangerous. For example, some infants require parenteral nourishment (administered by intravenous injection). All parenteral nutritional formulas contain aluminum. According to the FDA, "when medication and nutrition are administered orally, the gastrointestinal tract acts as an efficient barrier to the absorption of aluminum, and relatively little ingested aluminum actually reaches body tissues. However, parenterally administered drug products containing aluminum bypass the protective mechanism of the gastrointestinal tract and aluminum circulates and is deposited in human tissues."[65]

In a 1997 study published in the *New England Journal of Medicine*, scientists assessed 182 infants who received intravenous injections of nutritional formula that contained differing quantities of aluminum.[20] They calculated that infants who received aluminum at greater than 4 to 5 mcg/kg/day would lose 1 point per day on the Bayley Mental Development Index ($p = 0.03$). Babies who score low on this test are at risk for subsequent developmental and educational problems. This study contributed to FDA's decision to set limits on aluminum content in parenteral drug products and require warning labels on the package inserts—safety measures that were never required with aluminum-containing vaccines. In the Code of Federal Regulations, Title 21, published in the Federal Register, aluminum toxicity levels are revealed:

> WARNING: This product contains aluminum that may be toxic.... Research indicates that patients with impaired kidney function, including premature neonates, who receive [injections] of aluminum at greater than 4 to 5 mcg per kilogram of body weight per day, accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates.[66]

This means that for a 6-pound baby with impaired kidney function, 11-14 mcg of injected aluminum would be toxic. The hepatitis B vaccine given at birth contains 250 mcg of aluminum—20 times higher than safety levels indicated for preemies. Babies weigh about 12 pounds at two months of age when they are injected with 1,225 mcg of aluminum from their CDC-recommended vaccines—50 times higher than safety levels for preemies.

Healthy babies may be able to handle quantities of aluminum above FDA toxicity levels indicated for patients with impaired kidney function. However, no one knows how much more aluminum is safe because adequate studies were never conducted. In addition, babies are not screened for renal function prior to vaccination. Therefore, it is impossible to know ahead of time which babies will succumb to aluminum poisoning. Instead, parents are expected to play Russian roulette with their children.

Summary

Aluminum adjuvants are added to several vaccines to elicit a more robust immune response and increase vaccine efficacy. Infants and young children throughout the world receive high quantities of aluminum from multiple inoculations. Incremental changes to the vaccination schedule during the past several years significantly increased the quantity of aluminum in childhood shots. Numerous studies provide compelling evidence that injected aluminum can be detrimental to health. Aluminum is capable of remaining in cells long after vaccination and may cause neurologic and autoimmune disorders. During early development, the child's brain is more susceptible to toxins and the kidneys are less able to eliminate them. Thus, children have a greater risk than adults of adverse reactions to aluminum in vaccines.

Millions of children every year are injected with vaccines containing mercury and aluminum despite well-established experimental evidence of the potential for additive or synergistic toxicity when an organism is exposed to two or more toxic metals. Dr. Haley's study in which cultured neurons died at an accelerated rate following concurrent exposure to aluminum and thimerosal provides evidence of an enhanced detrimental effect. In addition, aluminum toxicity levels published by FDA indicate that two-month-old babies who are vaccinated according to CDC guidelines may

be receiving quantities of aluminum that are significantly higher than safety levels.

Conclusion

Toxic metals such as aluminum do not belong in prophylactic medications administered to children, teenagers, or adults. Vaccines are normally recommended for healthy people, so safety (and efficacy) standards must be impeccable. Parents, especially, should not be compelled to permit their loved ones to receive multiple injections of toxic metals that could increase their risk of neurodevelopmental and autoimmune ailments. Safe alternatives to current disease prevention technologies are urgently needed.

Neil Z. Miller is a medical research journalist. Contact: neilzmiller@gmail.com.

Disclosures: No conflicts of interest were disclosed.

REFERENCES

1. CDC. Timeline: thimerosal in vaccines, 1999-2010; Aug 28, 2015. Available at: http://www.cdc.gov/vaccinesafety/concerns/thimerosal/timeline.html. Accessed Aug 22, 2016.
2. Schechter R, Grether JK. Continuing increases in autism reported to California's developmental services system: mercury in retrograde. *Arch Gen Psychiatry* 2008;65(1):19-24.
3. CNN. Autism rates up despite removal of mercury from vaccines; Dec 22, 2008. Available at: http://www.cnn.com/2008/HEALTH/dailydose/12/04/autism.mercury/index.html?iref. Accessed Aug 22, 2016.
4. CDC. Thimerosal in vaccines; Oct 27, 2015. Available at: http://www.cdc.gov/vaccinesafety/concerns/thimerosal. Accessed Aug 22, 2016.
5. Bridges CB, Fukuda D, Uyeki TM, et al. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* 2002;51(RR03):1-31.
6. Harper SA, Fukuda K, Uyeki TM, Cox NJ, Bridges CB. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* 2004;53(RR06):1-40.
7. Advisory Committee on Immunization Practices. Preventing pneumococcal disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* 2000;49(RR09):1-38.
8. CDC. CDC's Advisory Committee on Immunization Practices expands hepatitis A vaccination for children. Press Release, Oct 28, 2005. Available at: http://www.cdc.gov/media/pressrel/r051028.htm. Accessed Aug 22, 2016.
9. CDC. Recommended immunization schedule for persons aged 0 through 18 years—United States; 2016.
10. Manufacturers' product inserts for hepatitis B (Engerix-B), DTaP (Infanrix), Hib (Pedvax), pneumoccocus (PCV13), and hepatitis A (Havrix). Accessed Aug 22, 2016.
11. CDC. Updated recommendations for use of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) in pregnant women—Advisory Committee on Immunization Practices (ACIP), 2012. *MMWR* 2013;62(7):131-135.
12. U.S. Department of Health and Human Services. *Toxicological Profile for Aluminum*. Atlanta, Ga.: Syracuse Research Corporation; 1999:94.
13. Manufacturers' product inserts for Gardasil 9, Cervarix, and Boostrix. Accessed Aug 22, 2016.
14. Miller NZ. Aluminum. *Miller's Review of Critical Vaccine Studies: 400 Important Scientific Papers Summarized for Parents and Researchers*. Santa Fe, NM: New Atlantean Press; 2016:44-63.
15. Spofforth J. Case of aluminium poisoning. *Lancet* 1921;197(5103):1301.
16. Ayoub D. Aluminum, vaccines and autism: déjà vu! National Autism Association Annual Conference, Atlanta, Ga.; Nov 11, 2007.
17. Chusid JG, Pacella BL, Kopeloff LM, Kopeloff N. Chronic epilepsy in the monkey following multiple intracerebral injections of alumina cream. *Proc Soc Exp Biol Med* 1951;78(1):53-54.
18. Driver M, Ettlinger G, Moffett AM, St John-Loe P. Epileptogenic lesions in the monkey. *J Physiol* 1968;May;196(2):93P-94P.
19. Committee on Nutrition. Aluminum toxicity in infants and children. *Pediatrics* 1996;97(3):413-416.
20. Bishop NJ, Morley R, Day JP, Lucas A. Aluminum neurotoxicity in preterm infants receiving intravenous-feeding solutions. *N Engl J Med* 1997;336:1557-1561.
21. Kawahara M, Kato-Negishi M. Link between aluminum and the pathogenesis of Alzheimer's disease: the integration of the aluminum and amyloid cascade hypotheses. *Int J Alzheimers Dis* 2011;2011:276393.
22. Tomljenovic L, Shaw CA. Aluminum vaccine adjuvants: are they safe? *Curr Med Chem* 2011;18(17):2630-2637.
23. Perricone C, Colafrancesco S, Mazor RD, et al. Autoimmune/inflammatory syndrome induced by adjuvants (ASIA) 2013: Unveiling the pathogenic, clinical and diagnostic aspects. *J Autoimmun* 2013;47(Dec):1-16.
24. Tomljenovic L, Shaw CA. Mechanisms of aluminum adjuvant toxicity and autoimmunity in pediatric populations. *Lupus* 2012;21(2):223-230.
25. Rigolet M, Aouizerate J, Couette M, et al. Clinical features in patients with long-lasting macrophagic myofasciitis. *Front Neurol* 2014;28;5(Nov):230.
26. Gherardi RK, Authier F. Macrophagic myofasciitis: characterization and pathophysiology. *Lupus* 2012;21(2):184-189.
27. Authier FJ, Cherin P, Creange A, et al. Central nervous system disease in patients with macrophagic myofasciitis. *Brain* 2001;124(May, Pt 5):974-983.
28. Shaw CA, Li D, Tomljenovic L. Are there negative CNS impacts of aluminum adjuvants used in vaccines and immunotherapy? *Immunotherapy* 2014;6(10):1055-1071.
29. Rivas E, Gómez-Arnáiz M, Ricoy JR, et al. Macrophagic myofasciitis in childhood: a controversial entity. *Pediatr Neurol* 2005;33(5):350-356.
30. Gruis KL, Teener JW, Blaivas M. Pediatric macrophagic myofasciitis associated with motor delay. *Clin Neuropathol* 2006;25(4):172-179.
31. Lacson AG, D'Cruz CA, Gilbert-Barness E, et al. Aluminum phagocytosis in quadriceps muscle following vaccination in children: relationship to macrophagic myofasciitis. *Pediatr Dev Pathol* 2002;5(2):151-158.
32. Nevo Y, Kutai M, Jossiphov J, et al. Childhood macrophagic myofasciitis—consanguinity and clinicopathological features. *Neuromuscul Disord* 2004;14(4):246-252.
33. Sharma MC, Prentice A, Schmidt PF, Sharma N, Goebel HH. Macrophagic myofasciitis in a 3-month-old child. *Journal of Pediatr Neurol* 2004;2(4):225-229.
34. Di Muzio A, Capasso M, Verrotti A, et al. Macrophagic myofasciitis: an infantile Italian case. *Neuromuscul Disord* 2004;14(2):175-177.
35. Israeli E, Agmon-Levin N, Blank M, Schoenfeld Y. Macrophagic myofaciitis a vaccine (alum) autoimmune-related disease. *Clin Rev Allergy Immu* 2011;41(2):163-168.
36. Exley C, Swarbrick L, Gherardi RK, Authier FJ. A role for the body burden of aluminium in vaccine-associated macrophagic myofasciitis and chronic fatigue syndrome. *Med Hypotheses* 2009;72(2):135-139.
37. Couette M, Boisse MF, Maison P, et al. Long-term persistence of vaccine-derived aluminum hydroxide is associated with chronic cognitive dysfunction. *J Inorg Biochem* 2009 ;103(11):1571-1578.
38. Gherardi RK, Coquet M, Cherin P, et al. Macrophagic myofasciitis lesions assess long-term persistence of vaccine-derived aluminium hydroxide in muscle. *Brain* 2001;124(Sep, Pt 9):1821-1831.
39. Gherardi RK. Lessons from macrophagic myofasciitis: towards definition of a vaccine adjuvant-related syndrome. *Rev Neurol (Paris)* 2003;159(2):162-164.
40. Luján L, Pérez M, Salazar E, et al. Autoimmune/autoinflammatory syndrome induced by adjuvants (ASIA syndrome) in commercial sheep. *Immunol Res* 2013;56(2-3):317-324.
41. Khan Z, Combadière C, Authier FJ, et al. Slow CCL2-dependent translocation of biopersistent particles from muscle to brain. *BMC Med* 2013;11:99.
42. Petrik MS, Wong MC, Tabata RC, Garry RF, Shaw CA. Aluminum adjuvant linked to Gulf War illness induces motor neuron death in mice. *Neuromolecular Med* 2007;9(1):83-100.
43. Shaw CA, Petrik MS. Aluminum hydroxide injections lead to motor deficits and motor neuron degeneration. *J Inorg Biochem* 2009;103(11):1555.
44. Inbar R, Weiss R, Tomljenovic L, et al. Behavioral abnormalities in female mice following administration of aluminum adjuvants and the human papillomavirus (HPV) vaccine Gardasil. *Immunol Res* 2016; Jul 16 [Epub ahead of print].

45. Tomljenovic L, Shaw CA. Do aluminum vaccine adjuvants contribute to the rising prevalence of autism? *J Inorg Biochem* 2011;105(11):1489-1499.
46. Shaw CA, Sheth S, Li D, Tomljenovic L. Etiology of autism spectrum disorders: genes, environment, or both? *OA Autism* 2014;2(2):11.
47. Shaw CA, Seneff S, Kette SD, et al. Aluminum-induced entropy in biological systems: implications for neurological disease. *J Toxicol* 2014;2014:491316.
48. Shaw CA, Li Y, Tomljenovic L. Administration of aluminium to neonatal mice in vaccine-relevant amounts is associated with adverse long term neurological outcomes. *J Inorg Biochem* 2013;128:237-244.
49. Department of Health and Human Services, National Vaccine Program Office, and Task Force for Child Survival and Development). Transcript of presentations at: Workshop on Aluminum in Vaccines; San Juan, Puerto Rico; May 11, 2000:1-263.
50. Department of Health and Human Services, National Vaccine Program Office, and Task Force for Child Survival and Development. Transcript of presentations at: Workshop on Aluminum in Vaccines. San Juan, Puerto Rico; May 12, 2000:1-160.
51. CDC. Transcript: Scientific review of vaccine safety datalink information. Norcross, Ga.; June 7-8, 2000.
52. Haley BE. Mercury toxicity: genetic susceptibility and synergistic effects. *Medical Veritas* 2005;2(2):535-542. Available at: http://www.1796kotok.com/pdfs/haley.pdf. Accessed Aug 23, 2016.
53. Eickhoff TC, Myers M. Workshop summary. Aluminum in vaccines. *Vaccine* 2002;20(Suppl 3):S1-S4.
54. Mitkus RJ, King DB, Hess MA, Forshee RA, Walderhaug MO. Updated aluminum pharmacokinetics following infant exposures through diet and vaccination. *Vaccine* 2011;29(51):9538-9543.
55. Golub MS, Germann SL. Long-term consequences of developmental exposure to aluminum in a suboptimal diet for growth and behavior of Swiss Webster mice. *Neurotoxicol Teratol* 2001;23(4):365-372.
56. ATSDR (Agency for Toxic Substances and Disease Registry). Toxicological profile for aluminum. Atlanta, Ga: U.S. Department of Health and Human Services; Sep 24, 2008.
57. Bilkei-Gorzó A. Neurotoxic effect of enteral aluminium. *Food Chem Toxicol* 1993;31(5):357-361.
58. Sethi P, Jyoti A, Singh R, Hussain E, Sharma D. Aluminium-induced electrophysiological, biochemical and cognitive modifications in the hippocampus of aging rats. *Neurotoxicol* 2008;29(6):1069-1079.
59. Sethi P, Jyoti A, Hussain E, Sharma D. Curcumin attenuates aluminium-induced functional neurotoxicity in rats. *Pharmacol Biochem Behav* 2009;93(1):31-39.
60. Alawdi SH, El-Denshary ES, Safar MM, et al. Neuroprotective effect of nanodiamond in Alzheimer's disease rat model: a pivotal role for modulating NF-κB and STAT3 signaling. *Mol Neurobiol* 2016; Feb 20. [Epub ahead of print.]
61. Lukiw WJ, Bjattacharjee S, Zhao Y, Pogue AI, Percy ME. Generation of reactive oxygen species (ROS) and pro-inflammatory signaling in human brain cells in primary culture. *J Alzheimers Dis Parkinsonism* 2012; Jan 25; Suppl 2:001. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3947825/. Accessed Nov 21, 2016.
62. Alexandrov PN, Kruck TP, Lukiw WJ. Nanomolar aluminum induces expression of the inflammatory systemic biomarker C-reactive protein (CRP) in human brain microvessel endothelial cells (hBMECs). *J Inorg Biochem* 2015; 152:210-213.
63. WHO. Global Advisory Committee on Vaccine Safety; Jun 6-7, 2012. *Weekly Epidemiology Record* 2012;87(30):281-288.
64. Keith LS, Jones DE, Chou CH. Aluminum toxicokinetics regarding infant diet and vaccinations. *Vaccine* 2002;20(Suppl 3):S13-S17.
65. FDA. Aluminum in large and small volume parenterals used in total parenteral nutrition; agency information collection activities, proposed collection, comment request. Federal Register 2006;71(38):9829-9830. DOCID: fr27fe06-65. Available at: http://www.fda.gov/ohrms/dockets/98fr/E6-2727.htm. Accessed Aug 22, 2016.
66. FDA. Aluminum in large and small volume parenterals used in total parenteral nutrition. Code of Federal Regulations—Title 21, Apr 1, 2015 (revised): 21CFR201.323(e). Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=201.323. Accessed Aug 22, 2016.

LIMITED TIME OFFER *Common Sense Medicine*

Bulk discounts on powerful new book to empower patients.

Hot off the press, is a powerful, easy-to-read, and entertaining exposé of the root problems plaguing American medicine and the simple solutions!

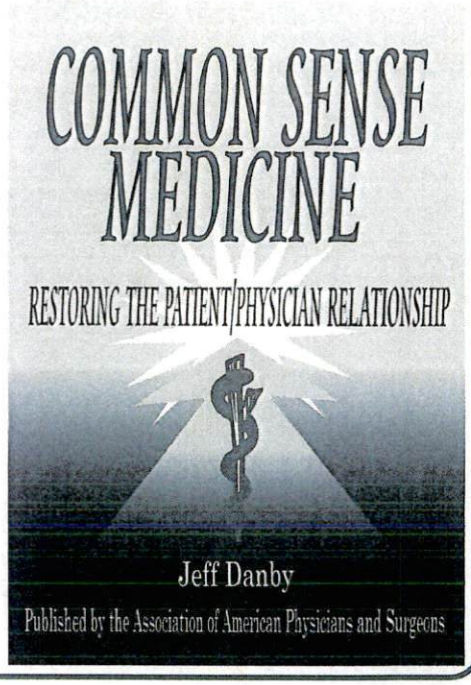
Buy copies to put in your waiting room!

1 to 24 copies: $3/book

BEST DEAL:

buy 25 or more for $1 each.

order online at http://aapsonline.org/bookdeal



Common Sense Medicine is written by award-winning author, Jeff Danby.

I trust that the depth and breadth of the carefully researched testimonies presented today will help you make a truly informed decision about this important legislation.

We have grave problems with corruption within **HHS** and the captured agencies under it's umbrella: The **CDC** and **FDA** and their committees like **ACIP**.

This is not the appropriate time to be promoting the type of legislation proposed in HB-1312 which serves to benefit the liability free pharmaceutical companies

https://www.usatoday.com/in-depth/news/investigations/2019/04/03/abortion-gun-laws-stand-your-ground-model-bills-conservatives-liberal-corporate-influence-lobbyists/3162173002/

and provides the personal data of a minority of children to the State.

This data can be used by pharmaceutical companies to promote their liability free products as happened recently in Indiana and Michigan. https://hslda.org/content/hs/state/mi/20151110.asp

This bill aims to adopt by rule the medical exemption recommendations as described by the **ACIP** p.8 lines 9-15.

It also aims to adopt the **ACIP** schedule which would double the required shots for school. p. 9 lines 7-27.

The ACIP is rife with conflicts of interest.

It is an unelected committee proven to be in a revolving door with Pharma.

The ACIP did not adopt evidence based guidelines to approve vaccines until 2010.

A Congressional investigation into ACIP found that among other things:

1- ACIP members have been found to have significant conflicts of interest, yet are given blanket waivers by the CDC that allow them to deliberate on any subject, regardless of their conflicts, for the entire year.

2- ACIP members are allowed to vote on vaccine recommendations, even when they have financial ties to drug companies developing related or similar vaccines

3- Members who are not allowed to vote on a recommendation due to financial conflicts are allowed to fully participate in the discussion leading up to a vote

The **CDC** owns over 50 vaccine patents, yet oversees the ACIP.

The right thing to do would be to create legislation to fix this corruption, not legislation which ignores it and harasses parents using exemptions. Vote NO on HB19-1312.

https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a4.htm

https://childrenshealthdefense.org/VSP/

https://www.bmj.com/content/350/bmj.h2362.full

https://childrenshealthdefense.org/wp-content/uploads/rfk-hhs-stipulated-order-july-2018.pdf

https://www.nvic.org/nvic-archives/conflicts-of-interest.aspx

https://childrenshealthdefense.org/news/the-u-s-needs-an-independent-vaccine-safety-organization/

ACIP

The Advisory Committee of Immunization Practices (ACIP) is the CDC committee that adds vaccines to the schedule. A year 2000 Congressional US Government Reform Committee investigation into Vaccine Policy Making found several troubling conflicts of interest with the ACIP.

HB 19-1312 seeks to require CDPHE to adopt the immunization recommendations from ACIP. **Page 9 lines 10-25.** This would force the health department to adopt the full ACIP Schedule and mandate those vaccinations in Colorado. As it is now, Colorado requires 8 different immunizations, which translates to 24 shots by the time a child leaves high school. The ACIP recommended schedule consists of 53 shots by the time a child leaves high school. Adopting all of the ACIP recommendations and making them required would more than double the required shots for school entry.

HB 19-1312 also seeks to force doctors to use only the ACIP guidelines for contraindications to vaccine administration when writing a medical exemption, instead of allowing doctors to use their professional judgment. **p. 8 lines 9-15.**

The conflicts of interest found in the Congressional investigation show that the ACIP is in a revolving door with Pharma:

- "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."

- ACIP routinely used working groups where Pharma insiders would effectively craft vaccine policy.

- ACIP reflects "a system where government officials make crucial decisions affecting American children without the advice and consent of the governed."

<u>The majority of the eight ACIP members were conflicted in their most recent vote:</u>

The chairman served on Merck's Immunization Advisory Board.

Another member shared the patent on a vaccine under development for the very same disease, had a $350,000 grant from Merck to develop this vaccine, and was a consultant for Merck.

Another member was under contract with the Merck Vaccine Division, received funds from various vaccine manufacturers including Pasteur, and was under contract as a principal investigator for SmithKline.

Another member received a salary from Merck as well as other payments from Merck.

Another member was participating in vaccine studies with Merck, Wyeth, and SmithKline.

Another member received grants from Merck and SmithKline.

Not only were there these glaring conflicts of interest within the ACIP, but the **ACIP admitted that until 2011 they weren't even using evidence based guidelines to add vaccines to the schedule.**

<u>Colorado should not be relying on a corrupt agency to inform our vaccination policy.</u>

HHS

Since we don't have adequate safety testing of vaccines the only way to see if they are causing harm is through post licensing surveillance. This is done through a voluntary system called the Vaccine Adverse Events Reporting System (**VAERS)** run by the **HHS**. In 2010 HHS commissioned a study of VAERS to determine if they were capturing accurate data by monitoring medical records and comparing them to the VAERS data base. They found that **only one percent of injuries were reported.** Last year alone VAERS reported 59,117 injuries in America. If this is only 1% of injuries then we can extrapolate that number to over 5 million actual injuries. Has HHS fixed the problem? **NO.**

The **Institute of Medicine (IOM)**, are top scientists in the country that review vaccine safety science at **HHS.** The IOM reports that they do not have the ability to assess the safety of vaccines because the science does not exist.

The 1986 NCVIA stipulated that every two years the **HHS would submit a report to Congress on the state of vaccine safety.** Through a 2017 lawsuit by Robert F. Kennedy Jr. and Del Bigtree of the Informed Consent Action Network (ICAN) it was revealed that the **HHS has not once submitted the required reports. They have neglected their duty for over 30 years.**

CDC

The CDC has an $11.5 billion dollar budget and almost $5 **billion is allocated to purchase and promotions of vaccines** and a mere **$20 million is allocated to vaccine safety.**

Owns 56 vaccine patents.

CDC or NIH employees whose names appear on vaccine patents can receive up to $150,000 in licensing fees per year (in perpetuity).

The CDC website claims it does not accept commercial support, but a 2015 article in the British Medical Journal reports that the "despite the agency's disclaimer, the CDC does receive millions of dollars in industry gifts and funding, both directly and indirectly, and several recent CDC actions and recommendations have raised questions about the science it cites, the clinical guidelines it promotes, and the money it is taking."

Former CDC Director, Julie Gerberding, 2002-2009, oversaw numerous vaccine studies while at the CDC, many have been recently deemed unreliable by the IOM.

In 2010 Gerberding became President of Merck Vaccines with an estimated $2.5 million annual salary and lucrative stock options.

FDA - VRBPAC

The **FDA is in charge with licensing vaccines**. The year 2000 Congressional US Governmental Reform Committee investigation into Vaccine Policy making found conflicts of interest in two Committees. One was the FDA committee in charge of the **initial licensing** phase, the Vaccine and Related Biological Products Advisory Committee **(VRBPAC).** This committee has 15 voting members. **Findings Included:**

"The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industries."

"Conflict of interest rules employed by the FDA ..... have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have given waivers to participate in committee proceedings.....In many cases, significant conflicts of interest are not deemed to be conflicts at all."

Three of the five FDA committee members who voted to approve the rotavirus vaccine in 1997 had financial ties to the pharmaceutical companies that were developing different versions of the vaccine.

One of the members was the principle investigator for a Merck grant to develop a rotavirus vaccine.

One of the five members had a $9 million contract for a rotavirus vaccine.

One of the five members received approximately $1million towards vaccine development.

https://www.nvic.org/nvic-archives/conflicts-of-interest.aspx

https://childrenshealthdefense.org/VSP/

https://www.bmj.com/content/350/bmj.h2362.full

https://childrenshealthdefense.org/wp-content/uploads/rfk-hhs-stipulated-order-july-2018.pdf

https://childrenshealthdefense.org/news/the-u-s-needs-an-independent-vaccine-safety-organization/

April 15, 2019

Dear Honorable Members of the House Health & Insurance Committee:

Please OPPOSE HB19-1312.

My name is Dr. Jason Miller. I am a Colorado native, I'm a licensed Chiropractic Physician and I am a Board Certified Fellow in BioPhysics. I am also an educator and serve as adjunct faculty at several colleges and universities, regularly lecturing at Chiropractic, Medical and Pharmacy schools across the country. Additionally I am a pubmed indexed author and researcher serving on the board of directors of a non profit research organization which has published over 220 articles in the index medicus to date. I am neither pro nor anti vax. I am pro objective unbiased science, risk vs benefit analysis and transparency in government and in health care.

Prior to reading may hundreds of peer reviewed papers on the subject of vaccination, I would have supported this bill. Now that I am more educated about certain risks, confirmed scientific fraud and many blatant conflicts of interest I can only oppose this bill in good conscience.

Specific problems with this bill include:

The language on Page 5 lines 4-7 would literally mandate that the CDPHE develop biased educational materials as the bill calls for the CDPHE to "develop educational material regarding the benefits of immunization" and by matter of exclusion would ignore the inherent risks involved with vaccination. Educational materials should include an unbiased risk vs benefit analysis and any research conducted by any organization which generates revenue through the sale of vaccines should be excluded from any and all educational materials due to the inherent bias accompanying what would commonly be referred to as "tobacco science". A one sided viewpoint would be propaganda not educational material

The language on Page 6 lines 24-27 attempt to create an impossible outcome as the language would mandate that a standardized form be developed by which a person would claim a personal belief exemption. Personal beliefs by nature are not standard. They are by definition inherent to the individual's unique beliefs and therefore impossible to standardize.

The language on Page 8 lines 9-15 constitute what I as a doctor see as a direct attack on the integrity of the doctor patient relationship. This bill literally strikes through language supporting a doctor's ability to make clinical decisions based upon sound medical practice and instead mandates that medical exemptions shall only be granted based upon the limited description of contraindications provided by ACIP, which is committee largely made up by individuals who personally hold vaccine ingredient patents, stock in vaccine manufacturing companies and who hold other personal financial motivations which creates an inherent bias of which the public should be warned NOT held subject to.

The language on Page 4 Lines 21 - 24 contains language which would require that ALL children receive ALL vaccines recommended by the ACIP. You don't have to be a doctor to know that NOT all medications are equally efficacious nor are ALL medications equally safe for ALL individuals. Furthermore we all know that as drugs are administered in combination their risks compound exponentially. An individual's unique genetics AND their personal body burden, a measure of pre existing toxic load, dictate different levels of efficacy and risk for individuals exposed to various drugs to which vaccines are no different. It is illogical and unscientific to blindly give all children all vaccines and pretend they each have the same risk vs benefit.

This bill constitutes playing a dangerous game of russian roulette with our children's lives. I fear that the authors and sponsors of this bill are woefully under educated regarding the documented risks of vaccination. Such is the nature of allowing the same agencies which are charged with studying, recommending and educating the public and it's servants regarding these invasive interventions to hold patents and generate multi billion dollar profits by the sale of the very compounds we blindly trust them to recommend and monitor for safety and efficacy.

We all have the same goal. We want to keep our children safe. For that reason I urge the committee to reject this bill in its entirety and focus its efforts on creating a state and then nationwide effort demanding that the ACIP and CDC be composed of individuals restricted from having any financial incentive to sell the very products they are charged with monitoring and recommending.

Thank you for your consideration and please feel free to contact me with any questions or concerns.

Sincerely-

Dr. Jason Miller, DC
Co-Founder and Owner
Posture Works Denver and San Francisco
110 16th Street, Suite 1300
Denver, CO 80202
Mobile 970-227-8340

2017 Colorado Statistics/Misrepresented Numbers

9,424 hospitalizations/ED visits due to "vaccine-preventable" diseases

9,116 were for **Flu**

(# tested for flu? # previously vaccinated for flu? # that had vaccine strains of flu? # that did NOT have vaccine strains flu? Lots of missing information here)

Flu shot **40%** effective in 2017

That leaves only **308** hospitalizations/ED visits for "vaccine-preventable" diseases (121 of those for chicken pox)

308 out of 1.2 million children under age 18 in Colorado =

.026%

Do not take these numbers at face value. Do not assume that 9,424 **unvaccinated** children were treated for "vaccine-preventable"diseases.

Children's Hospital Colorado

CONTAGIOUS COMMENTS

The Vaccine-Preventable Diseases Report

Jessica R. Cataldi MD, Carl Armon PhD, Marlee Barton MPH, Stephanie Wasserman MSPH, Elizabeth Abbott MPH, James K. Todd MD, Edwin J. Asturias MD

February 2019

- **In the News**: A case of measles in Denver
- **Statewide Summary:** The latest data on VPDs in Colorado and comparing our vaccination rates with other states
- **Mapping:** See where we have opportunities to improve immunization rates and Medicaid enrollment
- **Policy Perspective:** Why some Colorado parents continue to face barriers to accessing immunizations

In the News: What you need to know about measles in Denver

An adult living in Denver tested positive for measles on January 15 after returning from international travel. S/he visited several retail locations and an urgent care center in Stapleton before being hospitalized in Denver. It is unclear whether this person was vaccinated. State and local public health officials have contacted people who were directly exposed to this person and are monitoring for additional cases.

Symptoms of measles include fever, cough, runny nose and rash. Complications include pneumonia and encephalitis, or inflammation of the brain. One in four people sick with measles needs to be hospitalized and one in a thousand will die.[1] Young children, pregnant women and people with weakened immune systems are at higher risk of complications.

Measles is very contagious and even one case can lead to an outbreak, especially in places where vaccination rates are low. Because measles is so contagious, at least 95% of a community needs to be immunized to prevent the disease from spreading.[2,3] Across Colorado, 87-89%[4,5] of children 19-35 months of age have received at least one dose of MMR (the vaccine that protects against measles), which is below the threshold needed to reliably prevent an outbreak.

What can you do about measles?

Parents

- Call your doctor if you think you or your child have symptoms: fever, rash, cough and runny nose
- Make sure you and your family are vaccinated- the MMR vaccine is 97% effective in preventing measles
- Check your childcare and school vaccination rates. Call or look online: https://www.cohealthdata.dphe.state.co.us/Data/Details/21

Health Care Providers

- Be sure patients traveling internationally are fully vaccinated, including MMR
- Contact CDPHE if you think a patient may have measles or have been exposed to someone with measles

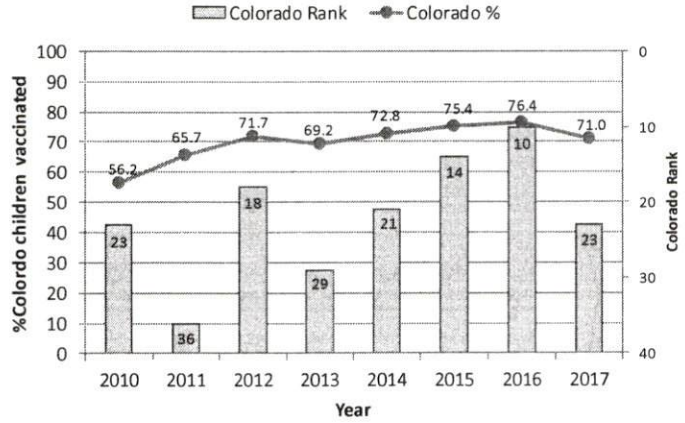
Between 2013 and 2017, Colorado had 1-2 reported cases of measles per year.[6] Public health teams respond to any case of measles by identifying people who may have been exposed and ensuring those people are protected against infection. Tri-County Health Department officials estimated the costs of responding to two separate measles cases in 2016 and 2017 at $18,000 and $49,000 respectively.[7]

Starting the new year with a measles case in Denver is concerning but not surprising based on increasing numbers of measles outbreaks across the country and around the world. The CDC reported 349 cases of measles in the US in 2018. At the beginning of 2019, an outbreak in the counties around New York City has grown to more than 200 cases and a newer outbreak of more than 40 people is ongoing in Oregon and southern Washington, an area with low vaccination rates. Many cases of measles in the US occur after someone returns from travel. In 2018, the World Health Organization (WHO) reported 60 million cases of measles in Europe and 17 million cases in the Americas. Most of the cases in Europe occurred in places with low immunization rates and the majority of cases in the Americas occurred in Brazil and Venezuela, in part due to weakening public health infrastructure.[8]

Statewide Summary: *Vaccination coverage had improved from 2013-2016, but NIS 2017 shows too many Colorado children are still incompletely protected.*

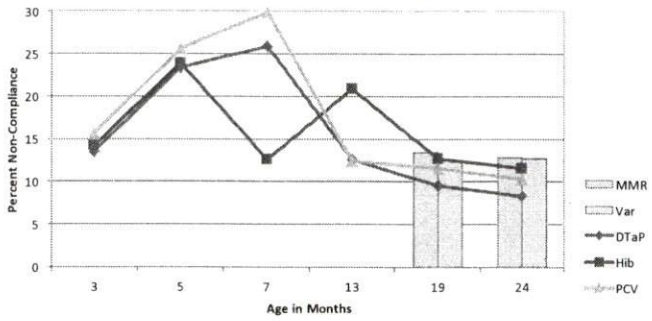
In the 2017 Centers for Disease Control and Prevention (CDC) National Immunization Survey (NIS), Colorado ranked 23rd among US States in vaccination rates for children 19-35 months of age (**Figure 1**, below).[4] This is a drop from being ranked 10th in 2016. More importantly, 29% of children in this age group had received fewer than the recommended number of doses of at least one of the vaccines required for enrolling in child care, leaving them vulnerable to many infectious diseases including measles, varicella, pertussis, and pneumococcal infection. Colorado's overall vaccination rate dropped to 71% in 2017 after having improved from 2013 through 2016. We still fall short of the Healthy People 2020 goal of 95% coverage for each of these vaccines in children 19-35 months of age.

Figure 1: NIS Vaccination Rates (4313314): US and Colorado (Source: NIS), 2010-2017



4313314: 4 doses of DTaP, 3 polio [IPV], 1 measles/mumps/rubella [MMR], 3 hepatitis-B, 3 *Haemophilus influenzae* type B [HiB], 1 varicella and 4 pneumococcal conjugate vaccine[PCV])

Figure 2: Colorado Vaccination Non-Compliance from 3 to 24 Months of Age, 2017



Number of vaccines required:

DTaP	1	2	3	3	4	4
Hib	1	2	2	3	3	3
PCV	1	2	3	3	4	4
MMR					1	1
Var					1	1

http://pediatrics.aappublications.org/content/133/2/357

NIS data show that rates of non-compliance (not being up to date on recommended vaccinations) were highest among children 3-19 months (**Figure 2**, above). Like we have seen in years past, much of the gap in coverage for early childhood immunizations is seen in the same age group that experiences the highest burden of vaccine-preventable illness. In 2017, more than quarter of all infants in Colorado were behind on DTaP and PCV vaccinations at 7 months- an age when young children remain vulnerable to pertussis and pneumococcal disease. Coverage with MMR vaccine at 24 months of age was similar to 2016, but at 87% was still below the level required to protect a population against outbreaks of measles (~95%).[2,3]

Vaccine-preventable diseases caused over 9,000 hospitalizations and emergency department visits for Colorado children in 2017 and resulted in over $56 million in health care charges

Table 1 shows 2017 Colorado Hospital Association data for the number of cases of hospitalizations or emergency department (ED) visits associated with a vaccine-preventable disease (VPD) as well as the hospital-associated charges for these cases. Diagnoses of VPDs were identified using ICD-10 codes. Population estimates from the American Community Population Survey and the Colorado Health Institute were used to calculate incidence rates.

Influenza, pneumococcal disease and pertussis were the three most common reasons for hospitalization due to vaccine-preventable disease in Colorado children in 2017. Additionally, there were three deaths among Colorado children hospitalized for VPD- two with influenza (an infant and a toddler) and one with *H. influenzae* (a toddler).

As we have seen in recent years, the most common vaccine-preventable cause of hospitalization and ED visits was influenza, with 460 hospitalizations and 8,656 ED visits in Colorado children in 2017. Total hospital charges and ED charges for vaccine-preventable diseases were over $55 million, with over $42 million due to influenza alone. The second most common vaccine-preventable cause of hospitalization was pneumococcal disease, with 61 hospitalizations and total hospital/ED charges of almost $10 million. The next most common vaccine preventable cause of ED visits was varicella, with 120 ED visits and total hospital/ED charges of close to $1 million.

Table 1: Cases, rates, and charges for Colorado children 0-19 years of age with vaccine-preventable diseases, 2017.

Vaccine	Hospitalized Cases	Rate per 100,000	Hospital Charges	ED Cases	Rate per 100,000	ED Charges	Total Charges
Diphtheria	0	--	--	--	--	--	--
H. influenzae	8	0.56	$974,904	--	--	--	$974,904
Hepatitis A	3	0.21	$215,047	3	0.21	$33,850	$248,897
Hepatitis B	3	0.21	$92,473	3	0.21	$49,416	$141,889
Influenza	460	32.48	$20,107,457	8,656	611.12	$22,632,148	$42,739,605
Measles	0			3	0.21	$14,320	$14,320
Mumps	1	0.07	$15,743	11	0.78	$24,321	$40,064
Pertussis	12	0.85	$426,771	58	4.09	$132,862	$559,633
Pneumococcal disease	61	4.31	$9,673,258	6	0.42	$41,057	$9,714,315
Polio	0	--	--	--	--	--	--
Rubella	0	--	--	2	0.14	$3,968	$3,968
Tetanus	0	--	--	4	0.28	$65,847	$65,847
Varicella	10	0.71	$812,241	120	8.47	$185,187	$997,428
Total	558	39.40	$32,317,894	8,866	625.95	$23,182,976	$55,500,870

Most hospitalizations related to vaccine-preventable diseases occurred among infants and children under 5 (**Figure 3a**), while most ED visits occurred in children 5-19 years of age (**Figure 3b**).

Figure 3a: VPD hospitalizations of Colorado children in 2017 by age, including influenza (N = 555)

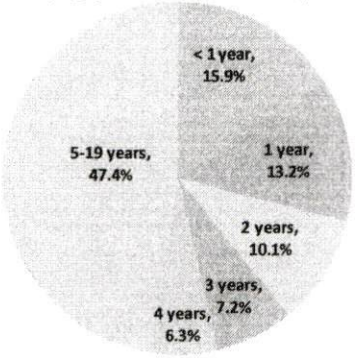
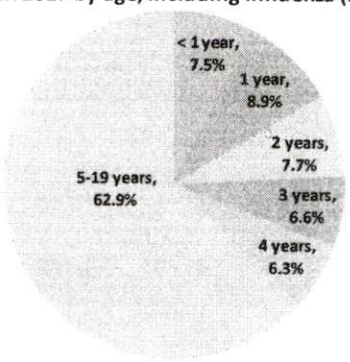


Figure 3b: VPD emergency department visits of Colorado children in 2017 by age, including influenza (N = 8,865)



Mapping Colorado Immunizations: *School District Immunization Rates and Health Care Access*

Marlee Barton, MPH, Colorado School of Public Health, University of Colorado

Comprehensive school district immunization data provides the opportunity to examine school immunization rates and health care access indicators at a local level. This data is available thanks to 2014 legislation (Colorado HB 14-1288) that requires schools and childcares to make immunization information publically available.

The 2016-2017 school immunization data collected by the Colorado Department of Public Health and Environment (CDPHE) was combined with 2015 insurance data from the Colorado Health Institute (CHI), clinic location data from the Vaccines for Children program (VFC, which provides vaccines for children with Medicaid), CDPHE health facilities data, and school demographic data from the Colorado Department of Education.

Indicators of High Immunization Rates

- Prevalence of Free-or-Reduced Lunch (PR 1.25, CI 1.09-1.43)
- Prevalence of Medicaid (PR 1.29, CI 0.09-1.75)

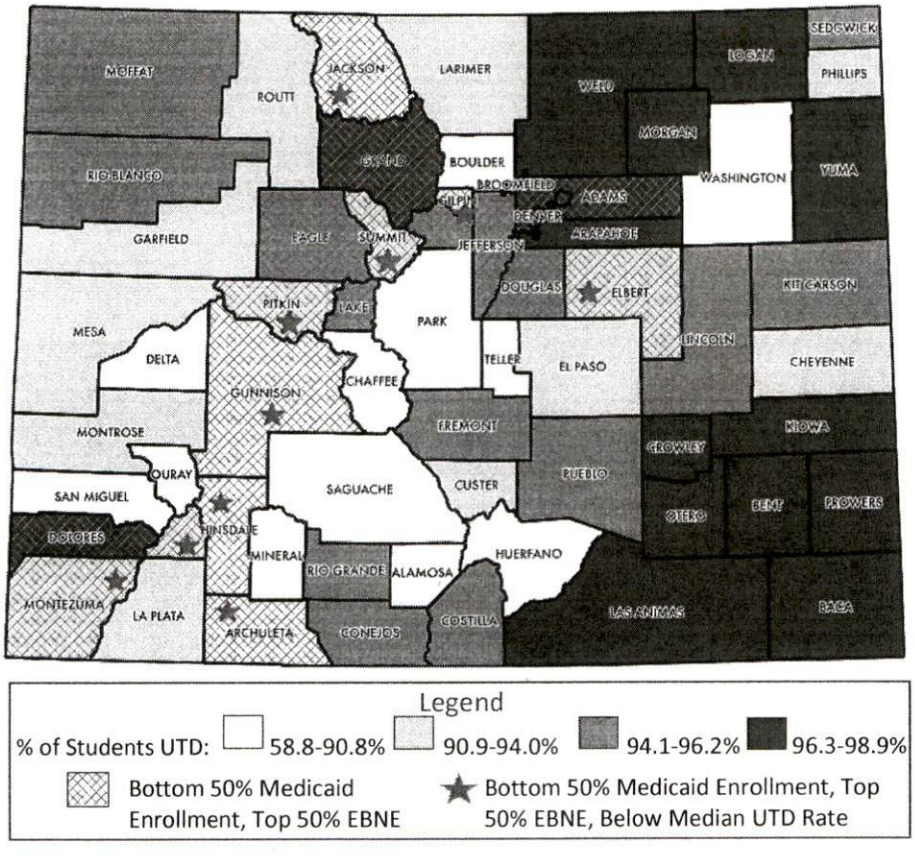
Indicators of Low Immunization Rates

- Prevalence of Student Mobility (PR 0.51, CI 0.33-0.80)
- Prevalence of Private Insurance (PR 0.88, CI 0.77-1.04)

Adjusted prevalence ratios showed that districts with more students enrolled in Medicaid or with more students eligible for free-or-reduced lunch were more likely to have ≥95% of their K-12 students up-to-date (UTD) with the school-required immunizations. This analysis also showed that districts with more students enrolled in private insurance or with more mobile students (those who begin and finish the school year in different districts) were less likely to have ≥95% of students UTD. Neither presence of VFC providers nor public health facilities within a district impacted the UTD status of students.

After seeing the link between Medicaid enrollment and school district immunization rates, we looked at county-level CDPHE immunization data for the 2017-2018 school year and 2015 insurance data from CHI. Every county in Colorado has children who are eligible for Medicaid but not currently enrolled (eligible but not enrolled or EBNE). There is a cluster of counties in the southwest corner of Colorado where there are more children who are EBNE and a similar cluster of counties in the same location with low Medicaid enrollment.

Map 1: Counties with High EBNE & Low Medicaid Prevalence (2015) Shown with UTD Immunization status (2017-2018)



Map 1 includes county immunization rates and highlights counties that fall above the median prevalence of EBNE children (2.7%) and below the median prevalence of Medicaid enrollment as places where there may be the greatest opportunity to increase Medicaid enrollment.

Again, several of these counties cluster in southwest Colorado and many also have lower immunization rates. Across Colorado, 19 counties fit the highlighted profile (high EBNE with low Medicaid enrollment). Of those counties, 10 fall below the median immunization rate for Colorado (94%) and are marked with stars on **Map 1**. The initial analysis demonstrated that Medicaid enrollment is associated with higher immunization rates.

There may be opportunities to increase immunization rates in certain counties by increasing Medicaid enrollment where there are more children who are eligible but not enrolled; especially in the southwest corner of the state.

Communities across Colorado have unique patterns of immunization coverage and require diverse approaches to strengthen vaccine uptake. These findings highlight the power of local data to identify immunization and health access trends at the county and school-district level.

References

1. Hamborsky J, Kroger A, Wolfe C. *Epidemiology and Prevention of Vaccine-preventable Diseases: The Pink Book: Course Textbook.* Public Health Foundation; 2015.
2. De Serres G, Gay NJ, Farrington CP. Epidemiology of transmissible diseases after elimination. *Am J Epidemiol.* 2000;151(11):1039-1048; discussion 1049-1052.
3. Thompson KM. Evolution and Use of Dynamic Transmission Models for Measles and Rubella Risk and Policy Analysis. *Risk Anal.* 2016;36(7):1383-1403.
4. CDC National Center for Immunization and Respiratory Diseases ISD. National Immmunization Survey 2017. 2018; https://www.cdc.gov/vaccines/imz-managers/nis/datasets.html. Accessed December 30, 2018.
5. CDPHE. CIIS county level rates. https://www.colorado.gov/pacific/cdphe/ciiscountylevel. Accessed January 24, 2019.
6. CDPHE. Colorado reportable disease data. https://www.colorado.gov/pacific/cdphe/colorado-reportable-disease-data. Accessed January 23, 2019.
7. Marx GE, Chase J, Jasperse J, et al. Public Health Economic Burden Associated with Two Single Measles Case Investigations - Colorado, 2016-2017. *MMWR Morb Mortal Wkly Rep.* 2017;66(46):1272-1275.
8. WHO. Regional summary of reported measles cases. Measles and Rubella Surveillance Data. https://www.who.int/immunization/monitoring_surveillance/burden/vpd/surveillance_type/active/measles_monthlydata/en/. Accessed January 26, 2019.

Policy Perspective: *Addressing the barriers to vaccination that some Colorado families face*

Stephanie Wasserman, MSPH, Colorado Children's Immunization Coalition

Colorado parents who refuse or delay vaccinating their children are a growing concern for our state because this trend leaves pockets of under- and unvaccinated kids in our schools, childcares and communities, making us all vulnerable to outbreaks of vaccine-preventable diseases. However, many families in Colorado want to vaccinate but continue to face barriers to accessing services. For these Coloradans, low immunization rates reflect ongoing challenges in insurance coverage, geography and other issues. While the Affordable Care Act (ACA) has increased the number of insured Coloradans covered on private health insurance or through Medicaid, many are still not able to easily and conveniently access immunization services and are missing out on the public health benefits and protections of vaccines. For example, fewer than 600 Colorado health care sites (including community health centers, pediatric and family practices, hospitals, Indian Health Service, local public health agencies, rural health centers, school-based health centers and youth services) participate in the Vaccines for Children (VFC) program, the federal program that allows healthcare providers to administer free vaccines to uninsured, Medicaid-eligible, and Alaska Native or American Indian children. One Colorado county (Gilpin) lacks a single healthcare provider site that participates in the VFC program. Another seven rural counties (Custer, Dolores, Elbert, Jackson, Mineral, Pitkin and San Juan), offer only a single location where VFC vaccine is available. Of these seven sites, more than half are small, rural local public health agencies, many staffed with a single public health nurse providing immunizations at limited times, or by appointment only. This means that some families are expected to travel many miles to get vaccinated at times that may not be feasible or convenient for them. Transportation challenges, inability to take time off of work, childcare issues and other barriers result in missed opportunities to vaccinate and lower immunization rates. Colorado must do more to provide funding, capacity and resources to support core public health infrastructure, especially in rural communities, and to encourage increased participation among health care providers in the VFC program.

If you wish to receive this publication, please provide us with your E-mail address below.

Name: _____
(Print clearly please)

E-mail Address: _____
(Print clearly please)

The Vaccine Preventable Diseases Report publications are always posted on Children's Hospital Colorado website at:
https://www.childrenscolorado.org/health-professionals/stay-informed/

Please return your E-mail address to: Emily Falco, Children's Hospital Colorado, Epidemiology – Box B276, 13123 E. 16th Avenue, Aurora, CO 80045
or E-mail address: emily.falco@childrenscolorado.org

Thank you for your interest in our publication.

The Vaccine Preventable Diseases Report
Department of Epidemiology©
Children's Hospital Colorado, Dept. of Epidemiology, B-276
13123 E. 16th Avenue, Aurora, CO 80045
Phone: (720) 777-6412; FAX: (720) 777-7295
emily.falco@childrenscolorado.org
www.ChildrensColorado.org

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Seasonal Influenza Vaccine Effectiveness, 2004-2018

CDC conducts studies to measure the benefits of seasonal flu vaccination each flu season to help determine how well flu vaccines are working. These vaccine effectiveness (VE) studies regularly assess and confirm the value of flu vaccination as a public health intervention. Study results of vaccine effectiveness can vary based on study design, outcome(s) measured, population studied and the season in which the flu vaccine was studied.

CDC has been working with researchers at universities and hospitals since the 2003-2004 flu season to estimate how well flu vaccine works through observational studies using medically attended laboratory-confirmed flu as the outcome. This is the U.S. Flu Vaccine Effectiveness (VE) Network. The U.S. Flu VE Network currently consists of five study sites across the United States that measure the flu vaccine's effectiveness at preventing outpatient medical visits due to laboratory-confirmed influenza. CDC's observational studies at U.S. Flu VE Network sites measure outpatient visits* for laboratory-confirmed influenza infections using a highly accurate lab test called rRT-PCR to verify the outcome. These studies compare the odds of vaccination among outpatients with acute respiratory illness and laboratory-confirmed influenza infection to the odds of vaccination among outpatients with acute respiratory illness who test negative for influenza infection.

The overall, adjusted vaccine effectiveness estimates for influenza seasons from 2004-2018 are noted in the chart below. (Estimates are typically adjusted for study site, age, sex, underlying medical conditions, and days from illness onset to enrollment.)

On This Page

Info on Flu Vaccine Effectiveness

CDC conducts studies to measure the benefits of seasonal flu vaccination each flu season to help determine how well flu vaccines are working.

More ›

Table. Adjusted vaccine effectiveness estimates for influenza seasons from 2004-2018

Influenza Season†	Reference	Study Site(s)	No. of Patients‡	Adjusted Overall VE (%)	95% CI
2004-05	Belongia 2009 (http://www.ncbi.nlm.nih.gov/pubmed/19086915)	WI	762	10	-36, 40
2005-06	Belongia 2009 (http://www.ncbi.nlm.nih.gov/pubmed/19086915)	WI	346	21	-52, 59
2006-07	Belongia 2009 (http://www.ncbi.nlm.nih.gov/pubmed/19086915)	WI	871	52	22 ,70
2007-08	Belongia 2011 (https://www.ncbi.nlm.nih.gov/pubmed/21767593)	WI	1914	37	22, 49
2008-09	Unpublished	WI, MI, NY, TN	6713	41	30, 50
2009-10	Griffin 2011 (https://www.ncbi.nlm.nih.gov/pubmed/21857999)	WI, MI, NY, TN	6757	56	23, 75

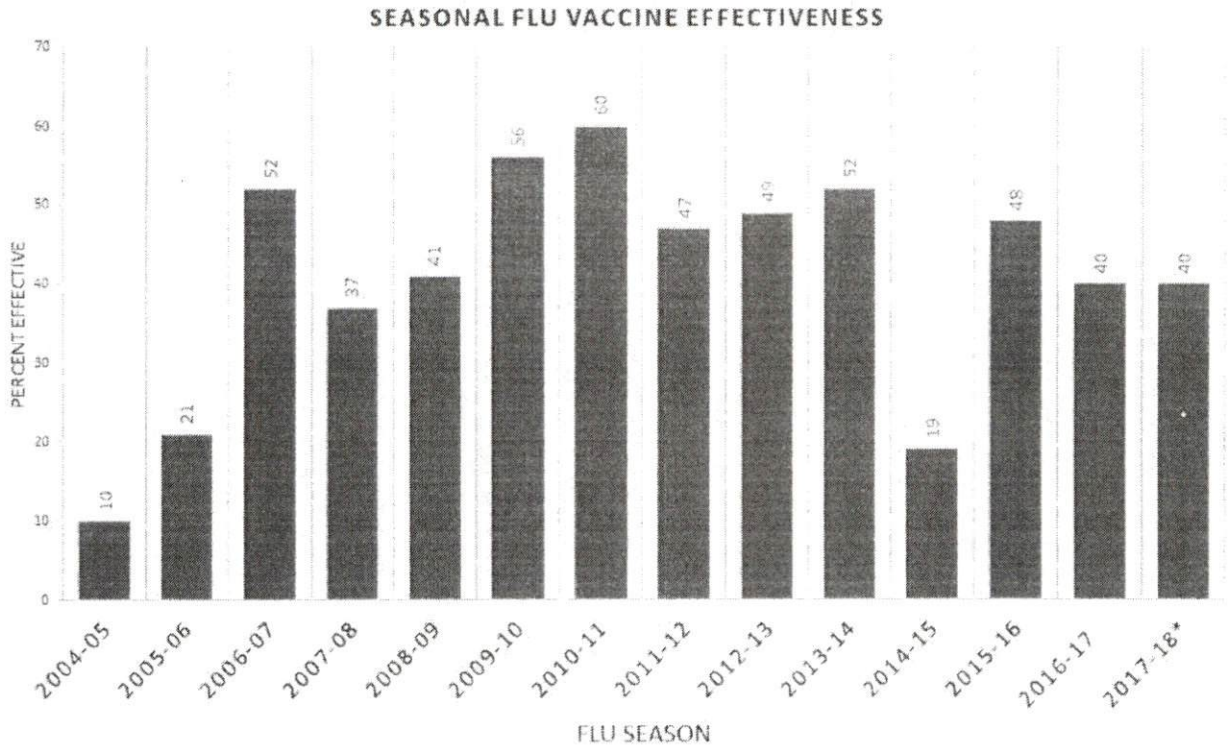
2010-11	Treanor 2011 (https://www.ncbi.nlm.nih.gov/pubmed/22843783)	WI, MI, NY, TN	4757	60	53, 66
2011-12	Ohmit 2014 (https://www.ncbi.nlm.nih.gov/pubmed/24235265)	WI, MI, PA, TX, WA	4771	47	36, 56
2012-13	McLean 2014 (https://www.ncbi.nlm.nih.gov/pubmed/25406334)	WI, MI, PA, TX, WA	6452	49	43, 55
2013-14	Gaglani 2016 (https://www.ncbi.nlm.nih.gov/pubmed/26743842)	WI, MI, PA, TX, WA	5999	52	44, 59
2014-15	Zimmerman 2016 (https://academic.oup.com/cid/article/63/12/1564/2282808/2014-2015-Influenza-Vaccine-Effectiveness-in-the)	WI, MI, PA, TX, WA	9311	19	10, 27
2015-16	Jackson 2017 (https://www.ncbi.nlm.nih.gov/pubmed/28792867)	WI, MI, PA, TX, WA	6879	48	41, 55
2016-17	Unpublished final estimates.	WI, MI, PA, TX, WA	7410	40	32, 46
2017-18	Rolfes 2019 (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciz075/5305915)	WI, MI, PA, TX, WA	8,436	38	31, 43
2018-19*	Doyle 2019	WI, MI, PA, TX, WA	3,254	47*	34, 57

* Vaccine effectiveness estimates for 2018-2019 are preliminary estimates and will be updated with final estimates at the end of the 2018-2019 U.S. influenza season.

^ Top of Page

Figure. Effectiveness of Seasonal Flu Vaccines from the 2004-2018 Flu Seasons

Download Excel Version [15 KB]



Text Version +

Download Vaccine Effectiveness PowerPoint Presentation Slides [PPT - 971 KB]

^ Top of Page

Belongia EA, Kieke BA, Donahue JG, et al. Effectiveness of inactivated influenza vaccines varied substantially with antigenic match from the 2004-2005 season to the 2006-2007 season. J Infect Dis. 2009 Jan 15;199(2):159-67. doi:10.1086/595861. PubMed PMID: 19086915. (http://www.ncbi.nlm.nih.gov/pubmed/19086915)

Belongia EA, Kieke BA, Donahue JG,et al. Influenza vaccine effectiveness in Wisconsin during the 2007-08 season: comparison of interim and final results. Vaccine. 2011 Sep 2;29(38):6558-63. doi: 10.1016/j.vaccine.2011.07.002. Epub 2011 Jul 19. PubMed PMID: 21767593. (http://www.ncbi.nlm.nih.gov/pubmed/21767593)

Flannery B, Clippard J, Zimmerman RK, Norwalk MP, Jackson ML, Jackson LA, Monto AS, Petrie JG, McLean HQ, Belongia EA, Gaglani M, Berman L, Foust A, Sessions W, Thaker SN, Spencer S, Fry AM. Early Estimates of Seasonal Influenza Vaccine Effectiveness – United States, January 2015. MMWR Morb Mortal Wkly Rep. 2015 Jan 13;64(1):10-15. (https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6401a4.htm)

Griffin MR, Monto AS, Belongia EA, et al. Effectiveness of non-adjuvanted pandemic influenza A vaccines for preventing pandemic influenza acute respiratory illness visits in 4 U.S. communities. PLoS One. 2011;6(8):e23085. doi: 10.1371/journal.pone.0023085. Epub 2011 Aug 12. PubMed PMID: 21857999. (http://www.ncbi.nlm.nih.gov/pubmed/21857999)

McLean HQ, Thompson MG, Sundaram ME, Kieke BA, Gaglani M, Murthy K, Piedra PA, Zimmerman RK, Nowalk MP, Raviotta JM, Jackson ML, Jackson L, Ohmit SE, Petrie JG, Monto AS, Meece JK, Thaker SN, Clippard JR, Spencer SM, Fry AM, Belongia EA. Influenza Vaccine Effectiveness in the United States During 2012-2013: Variable Protection by Age and Virus Type. J Infect Dis. 2014 Nov 18. pii: jiu647. [Epub ahead of print] PubMed PMID: 25406334. (http://jid.oxfordjournals.org/content/early/2014/12/16/infdis.jiu647.long)

Ohmit SE, Thompson MG, Petrie JG, et al. Influenza vaccine effectiveness in the 2011-2012 season: protection against each circulating virus and the effect of prior vaccination on estimates. Clin Infect Dis. 2014 Feb;58(3):319-27. doi: 10.1093/cid/cit736. Epub 2013 Nov 13. (http://www.ncbi.nlm.nih.gov/pubmed/24235265)

Treanor JJ, Talbot HK, Ohmit SE, et al. Effectiveness of seasonal influenza vaccines in the United States during a season with circulation of all three vaccine strains. CID 2012; 55(7):951-959. Epub 2012 Jul 25. PubMed PMID: 22843783. (http://www.ncbi.nlm.nih.gov/pubmed/22843783)

Jackson ML, Chung JR, Jackson LA, Phillips CH, Benoit J, Monto AS, Martin ET, Belongia EA, McLean HQ, Gaglani M, Murthy K, Zimmerman R, Nowalk MP, Fry AM, Flannery B. N Engl J Med. 2017 Aug 10;377(6):534-543. doi: 10.1056/NEJMoa1700153. PMID: 2879286 (https://www.ncbi.nlm.nih.gov/pubmed/28792867)

* From 2004-05 through 2010-11, the Network also enrolled inpatients.

† Vaccine effectiveness (VE) estimates for the 2008-2009 flu season have not yet been published.

‡ Number of patients used in VE calculation.

^ Top of Page

File Formats Help:

How do I view different file formats (PDF, DOC, PPT, MPEG) on this site? (https://www.cdc.gov/Other/plugins/)

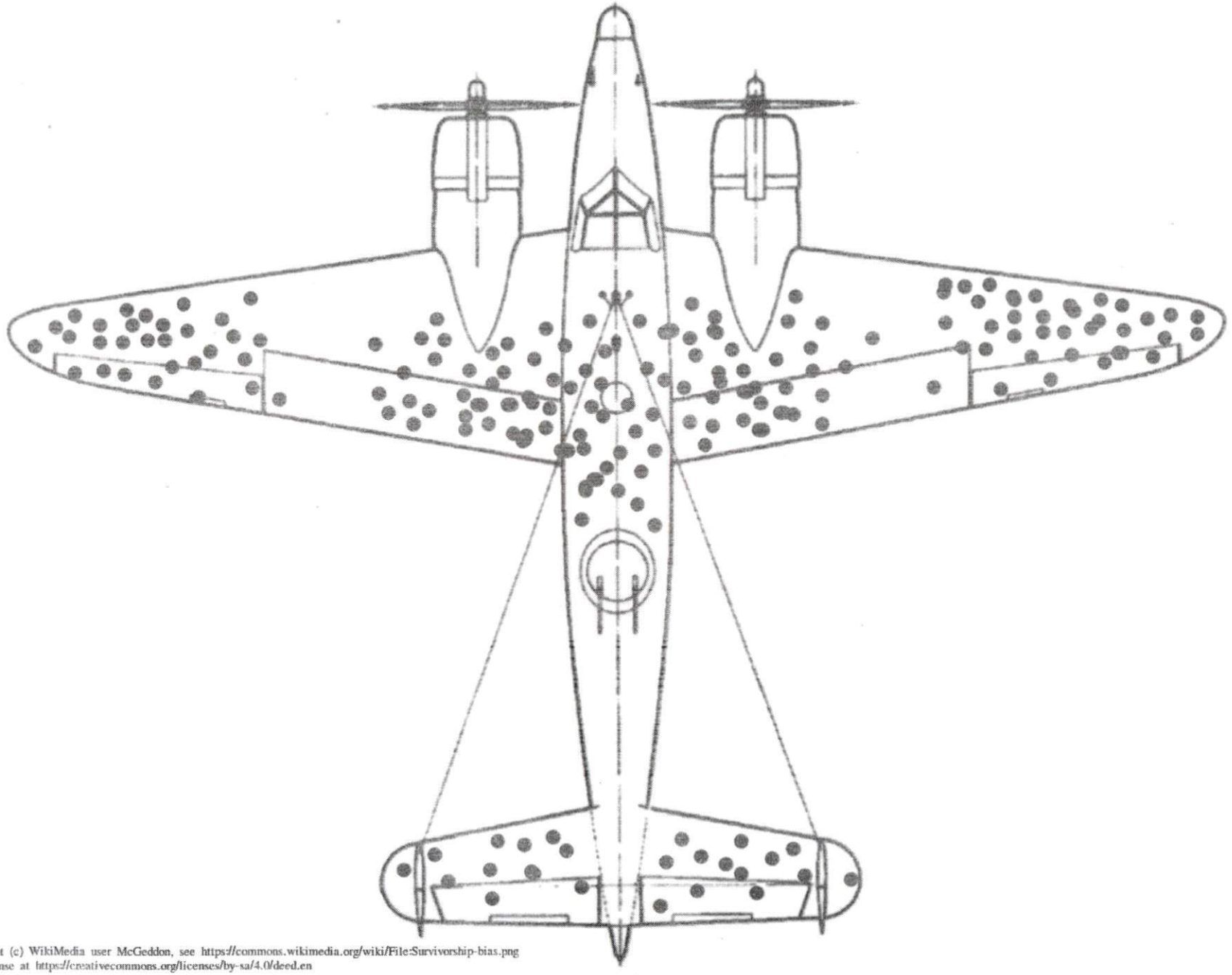
(https://www.cdc.gov/Other/plugins/#ppt) (https://www.cdc.gov/Other/plugins/#xls)

Page last reviewed: February 22, 2019

Page last updated: March 8, 2019

Content source: Centers for Disease Control and Prevention (https://www.cdc.gov/), National Center for Immunization and Respiratory Diseases (NCIRD) (https://www.cdc.gov/ncird/inde

Page maintained by: Office of the Associate Director for Communication, Digital Media Branch, Division of Public Affairs



Copyright (c) WikiMedia user McGeddon, see https://commons.wikimedia.org/wiki/File:Survivorship-bias.png
and license at https://creativecommons.org/licenses/by-sa/4.0/deed.en

April 2019
Colorado HB 19-1312
Jessica Cataldi MD, MSCS

Good afternoon Madam Chair and members of the committee. My name is Jessica Cataldi, and I am a pediatrician and specialist in infectious diseases at Children's Hospital Colorado. I am here today on behalf of the hospital to speak in support of House Bill 1312.

As a pediatrician, I have a duty to look out for the health of children. As a society, we all share this responsibility to keep children safe and healthy. Vaccination is the safest and most effective way to protect our children from many dangerous infectious diseases. This bill will help to increase vaccination rates in Colorado, allowing children in our state to learn and grow in healthy and safe schools and communities.

Parents value knowing that their child will attend a school or child care with high vaccination rates. In a 2016 survey of close to 400 Colorado parents, over 75% of parents described vaccination rate as 'moderately or very important' in choosing a school or child care.[1] These parents were willing to endure longer commute times to have their children attend schools with higher vaccination rates. Even those parents who were vaccine hesitant or chose not to vaccinate their children according to the recommended schedule were still willing to trade commute time for a school with higher vaccination rates. Colorado parents want their children to learn and grow in places where they are protected from vaccine preventable diseases.

Improving the process for non-medical vaccine exemptions will make sure that the safe and healthy choice for children is also the easy choice for parents to make. With this bill, those who choose not to vaccinate will follow a standardized process in making that choice - a choice that exposes both their child and their community to risks.

Across the country we are currently seeing outbreaks of several vaccine preventable diseases including measles, mumps, and hepatitis A. These diseases have disrupted the lives of hundreds of families, causing illness and suffering among sick children and adults and keeping many other people away from school and work. The cost of these outbreaks is high for the families affected and for the state and local public health officials tasked with stopping the spread of disease. In 2017, Tri-county Health Department estimated the cost of responding to a single measles case at $49,000. At the end of the day, those are tax-payer dollars.[2] With current vaccination rates, many communities in Colorado are highly vulnerable to an outbreak like those we see going on in New York, Washington, and Michigan. This bill offers the opportunity to protect Colorado children before we become the next state making national news for the outbreak of a dangerous and preventable disease.

Thank you for the opportunity to testify in support of this critical measure for kids' health. I am happy to answer any questions you may have.

References

1. Cataldi JR, Dempsey AF, Allison MA, O'Leary ST. Impact of publicly available vaccination rates on parental school and child care choice. *Vaccine*. 2018;36(30):4525-4531.
2. Marx GE, Chase J, Jasperse J, et al. Public Health Economic Burden Associated with Two Single Measles Case Investigations - Colorado, 2016-2017. *MMWR Morbidity and mortality weekly report*. 2017;66(46):1272-1275.

Hello,

My name is Joyce Regier. I developed Irritable Bowel Disease from my childhood shots and suffered a major flare-up for many years after my pre-college shots. My family has a history of autoimmune disease. Because of my family history, I intend to use one of the exemptions to protect my children from auto-immune disorders often caused by the adjuvants. (Schoenfeld)

This bill will cause exemption rates to rise because it will add HPV and the flu shot to the required school schedule in addition to several others. These 2 shots are the ones most avoided by the general public because of their side effects. Please do not promulgate the CDC schedule. (Pg 9, Line 16)

Governor Polis has stated in news reports that he does not want to encourage mis-trust of the government through this type of legislation. This bill will encourage mistrust of government by tracking a fraction of the population who choose to protect their children in alternative ways. By the wording in this bill, there is no way to fully opt out of the Dept of Health tracking system. This is very concerning to me, as a government database was the foundation for corralling all American-Japanese into the internment camps during WWII. Please provide a way to completely opt partially or non vaccinated children out of the database if we so choose. (Pg8, Lines1-8)

If you really want to lower exemption rates, then look at the bill just introduced in Texas. It places a moratorium on vaccines until they are proven to be safe, including:

- "True saline placebo testing
- studies to identify potential of causing autoimmune, neurological or chronic health conditions up to a year after administration
- evaluated for ability to
    - cause cancer
    - mutate genes
    - affect fertility or cause infertility
    - cause autism spectrum disorder"

If vaccines are truly proven to be safe by those guidelines, then force and pressure would not need to be used to improve exemption rates and we would be more than willing to consider them a viable option.

We all have the same goal, healthy kids and a healthy community.

86R13084 JG-F

By: Hall S.B. No. 2350

A BILL TO BE ENTITLED
AN ACT

relating to the prohibited administration of certain vaccinations.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter A, Chapter 161, Health and Safety Code, is amended by adding Section 161.0045 to read as follows:

Sec. 161.0045. ADMINISTRATION OF CERTAIN VACCINES PROHIBITED. A health care provider may administer a vaccine only if:

(1) the study relied on by the United States Food and Drug Administration for approval of the vaccine evaluated the safety of the vaccine against a control group that received:

(A) a placebo; or

(B) another vaccine or other substance approved by the United States Food and Drug Administration based on a study that evaluated the safety of that vaccine or substance against a control group that received a placebo for that study;

(2) the study relied on by the United States Food and Drug Administration for approval of the vaccine evaluated the safety of the vaccine for a sufficient time to identify potential autoimmune, neurological, or chronic health conditions that may arise on or after the first anniversary of the date the vaccine is administered;

(3) the vaccine has been evaluated for the vaccine's potential to:

(A) cause cancer;

(B) mutate genes;

(C) affect fertility or cause infertility; and

(D) cause autism spectrum disorder;

(4) the department has posted on the department's Internet website a disclosure of any known injuries or diseases caused by the vaccine and the rate at which the injuries or diseases have occurred; and

(5) the chemical, pharmacological, therapeutic, and adverse effects of the vaccine and the rate of injury of the vaccine when administered with other vaccines have been studied and verified.

SECTION 2. This Act takes effect September 1, 2019.

PubMed ▾

Format: Abstract

Full text links

OXFORD ACADEMIC

J Pediatric Infect Dis Soc. 2019 Feb 22. pii: piz005. doi: 10.1093/jpids/piz005. [Epub ahead of print]

The 112-Year Odyssey of Pertussis and Pertussis Vaccines-Mistakes Made and Implications for the Future.

Cherry JD[1].

Author information

Abstract

Effective diphtheria, tetanus toxoids, whole-cell pertussis (DTwP) vaccines became available in the 1930s, and they were put into routine use in the United States in the 1940s. Their use reduced the average rate of reported pertussis cases from 157 in 100 000 in the prevaccine era to <1 in 100 000 in the 1970s. Because of alleged reactions (encephalopathy and death), several countries discontinued (Sweden) or markedly decreased (United Kingdom, Germany, Japan) use of the vaccine. During the 20th century, Bordetella pertussis was studied extensively in animal model systems, and many "toxins" and protective antigens were described. A leader in B pertussis research was Margaret Pittman of the National Institutes of Health/US Food and Drug Administration. She published 2 articles suggesting that pertussis was a pertussis toxin (PT)-mediated disease. Dr Pittman's views led to the idea that less-reactogenic acellular vaccines could be produced. The first diphtheria, tetanus, pertussis (DTaP) vaccines were developed in Japan and put into routine use there. Afterward, DTaP vaccines were developed in the Western world, and definitive efficacy trials were carried out in the 1990s. These vaccines were all less reactogenic than DTwP vaccines, and despite the fact that their efficacy was less than that of DTwP vaccines, they were approved in the United States and many other countries. DTaP vaccines replaced DTwP vaccines in the United States in 1997. In the last 13 years, major pertussis epidemics have occurred in the United States, and numerous studies have shown the deficiencies of DTaP vaccines, including the small number of antigens that the vaccines contain and the type of cellular immune response that they elicit. The type of cellular response a predominantly, T2 response results in less efficacy and shorter duration of protection. Because of the small number of antigens (3-5 in DTaP vaccines vs >3000 in DTwP vaccines), linked-epitope suppression occurs. Because of linked-epitope suppression, all children who were primed by DTaP vaccines will be more susceptible to pertussis throughout their lifetimes, and there is no easy way to decrease this increased lifetime susceptibility.

© The Author(s) 2019. Published by Oxford University Press on behalf of The Journal of the Pediatric Infectious Diseases Society. All rights reserved. For permissions, please e-mail: journals.permissions@oup.com.

KEYWORDS: DTaP; DTwP; cellular response; linked-epitope suppression

PMID: 30793754 DOI: 10.1093/jpids/piz005

Madame Chair and Committee,

My name is Shanna Mossberger and this bill affects my family. My daughter has severe anaphylactic food allergies and has an immune system prone to allergic responses. Based on current ACIP recommendations, my daughter would not be eligible for a Medical Exemption because it would require her to have an anaphylactic reaction to a vaccine in order to receive a Medical Exemption. Protecting informed consent allows our family to make our own informed decisions about vaccines.

Section 2(c)(6) requires the Department of Public Health and Environment to develop "educational" materials regarding the benefits of vaccines which can then be made available to health care providers. Education by definition would need to include both the benefits as well as the risks of vaccines for three reasons:

1) If only the benefits are discussed, that would not be education. Education should include benefits and risks. Otherwise it would be indoctrination.
2) Doctors take a Hippocratic oath to "do no harm." It would be impossible for them to uphold that oath if they are only taught of the benefits of a medical procedure and none of the risks as they could unwillingly do a lot of harm.
3) Patients have a right to informed consent. This means knowledge of the benefits and risks in order to make an informed choice about their own bodies. If a health care provider is only providing the patient with benefits of vaccines and no risks, there is no informed consent. This would be a gross violation of legal and medical ethics.

If the department of public health is to make materials to distribute to the public or practitioners, the law should require that the materials also include the following:

Vaccine inserts themselves, citing known and acknowledged risks of each and every vaccine a patient chooses.

A statement that no vaccine has undergone true placebo controlled safety studies.

That the patient has no legal recourse in the event of harm due to a 1986 law giving vaccine manufacturers immunity from lawsuit.

I ask that you include those as requirements for the "educational" piece that the department must create. The science is never settled. The science used to be settled that the world was flat or that the atom was the smallest molecule. Science is often proven wrong by more science. Please present both sides of the science and let people decide what is best for their family. We all want the same things. Healthy kids and a healthy community.

Madame Chair and Committee,

My name is Jessie Schall and I am a lawyer and also have a masters in psychology, both from Duke. I am also a mother of a 5 year old who was vaccinated until 9 months of age, and 1 year old who has never had a vaccine. Both of my kids currently have medical exemptions based on a close family history of ALS, Lupus, Lyme, and celiac disease. Doctors feel that vaccines could trigger those conditions yet we would not be eligible for a medical exemption if this bill passes. I have looked deeply into the science for and against vaccines as well as the legal implications of having no one held accountable for vaccine failures or side effects. I refuse to risk my children's health on a product that has no placebo controlled safety testing and no legal recourse. I also refuse to sign a legal document with incriminating language that I do not agree with and have my child tracked in order to get a religious or personal exemption. I do not believe I should be faced with that choice.

Within the Bill of Rights of our Constitution are rights to privacy and protection of one's own bodily autonomy. The forcing of a medical procedure on another's person is considered an assault. Section 3 on page 8 of the bill seems to eliminate nearly every medical exemptions per ACIP guidelines. Section 3(b) on page 6 requires personal and religious exemptions to use a standardized form which in the past has included language that the parent is endangering the life of their child by refusing a vaccine. Parents who feel their child is susceptible to harm from a vaccine are held hostage under this bill, faced with either signing incriminating language under duress or vaccinating under duress. In addition, under Section 5, those signing an exemption will be entered into a tracking system. Considering what is happening in New York right now, being tracked for a socially unpopular decision is frightening. This is a direct violation of the Constitutional right to privacy.

And for what are we eradicating the basic human rights? There has been a lot of fear propagated about measles as a "deadly" disease yet measles is an infection for which we used to host parties just like used to for chickenpox. An infection that has virtually a zero death rate in the US. According to the CDC, even before the vaccine came into the market, the US death rate from Measles was 1 in 10,000 cases or .01%. Also according to the CDC, the chances of the MMR vaccine failing to protect you is 3%. So 300 out of every 10,000 MMR vaccines fail versus 1 out of every 10,000 measles cases ends in death. The media and the pharmaceutical industry have done a good job of making everyone fearful but the numbers don't lie. We cannot assume that we know what is best for another person's family or genetics. The makers of the Constitution KNEW we would come upon times when people fear each other and they wrote a document to guide us through it. Our Constitutional rights are meant to ground us and force us to make decisions that may go against our gut thinking when our guts are biased by fear. We all have the same goal. Healthy kids and a healthy community. Please oppose this bill.

frontiers in Endocrinology

Front Endocrinol (Lausanne). 2016; 7: 150.
Published online 2017 Jan 24. doi: 10.3389/fendo.2016.00150

PMCID: PMC5256113
PMID: 28167927

Autoimmune/Inflammatory Syndrome Induced by Adjuvants and Thyroid Autoimmunity

Abdulla Watad,[1,2,3] Paula David,[2,4] Stav Brown,[3] and Yehuda Shoenfeld[2,3,5,*]

[1]Department of Medicine "B", Sheba Medical Center, Tel-Aviv, Israel
[2]Zabludowicz Center for Autoimmune Diseases, Sheba Medical Center, Tel-Aviv, Israel
[3]Sackler Faculty of Medicine, Tel-Aviv University, Tel-Aviv, Israel
[4]Faculdade de Ciências Médicas, Universidade do Estado do Rio de Janeiro, Rio de Janeiro, Brazil
[5]Laura Schwarz-Kipp Chair for Research of Autoimmune Diseases, Tel-Aviv University, Tel-Aviv, Israel

Edited by: Alessandro Antonelli, University of Pisa, Italy
Reviewed by: Silvia Martina Ferrari, University of Pisa, Italy; Ilaria Ruffilli, University of Pisa, Italy; Carlo Perricone, Sapienza University, Italy
*Correspondence: Yehuda Shoenfeld, shoenfel@post.tau.ac.il
Specialty section: This article was submitted to Thyroid Endocrinology, a section of the journal Frontiers in Endocrinology

Received 2016 Oct 12; Accepted 2016 Nov 21.

Copyright © 2017 Watad, David, Brown and Shoenfeld.

This is an open-access article distributed under the terms of the Creative Commons Attribution License (CC BY). The use, distribution or reproduction in other forums is permitted, provided the original author(s) or licensor are credited and that the original publication in this journal is cited, in accordance with accepted academic practice. No use, distribution or reproduction is permitted which does not comply with these terms.

Abstract

The autoimmune/inflammatory syndrome induced by adjuvants (ASIA), presented by Shoenfeld and Agmon-Levin in 2011, is an entity that incorporates diverse autoimmune conditions induced by the exposure to various adjuvants. Adjuvants are agents that entail the capability to induce immune reactions. Adjuvants are found in many vaccines and used mainly to increase the response to vaccination in the general population. Silicone has also been reported to be able to induce diverse immune reactions. Clinical cases and series of heterogeneous autoimmune conditions including systemic sclerosis, systemic lupus erythematosus, and rheumatoid arthritis have been reported to be induced by several adjuvants. However, only a small number of cases of autoimmune thyroid disorder have been included under the umbrella of ASIA syndrome. Indeed, clinical cases of Hashimoto's thyroiditis and/or subacute thyroiditis were observed after the exposure to vaccines as well as silicone implantation. In our review, we aimed to summarize the current knowledge on ASIA syndrome presented as endocrinopathies, focusing on autoimmune thyroid disorders associated with the various adjuvants.

Keywords: autoimmune/inflammatory syndrome induced by adjuvants, thyroid, endocrinopathy, adjuvants, vaccines, silicone, Hashimoto's thyroiditis, Graves disease

Introduction

Adjuvants are substances that are able to trigger autoimmunity *via* a variety of mechanisms, such as alteration of the host's immune system, polyclonal activation of B cells, effects on cellular immunity, immunoregulatory cells, viral-induced antibodies, and acceleration of molecular mimicry (1). Exposure to adjuvants can occur in a variety of methods due to their wide range of uses in vaccines, mineral oils, silicone implants, and many other products and devices. The association between adjuvant exposure and autoimmunity manifests itself in five autoimmune conditions sharing similar autoimmunity manifestations (2, 3), such as the postvaccination phenomena, the macrophagic myofasciitis syndrome (MMF), the Gulf war syndrome (GWS), siliconosis, and the sick building syndrome (SBS) (4, 5). The autoimmune/inflammatory syndrome induced by adjuvants (ASIA), presented by Shoenfeld and Agmon-Levin (6) in 2011, is a single entity that incorporates all five conditions. Extensive research has identified the genetic background, contributing to the development of ASIA syndrome in predisposed individuals following adjuvant exposure. A large number of autoimmune diseases share several alleles of the HLA class II such as DRB1 locus. The development of specific autoantibodies is determined by DRB1 alleles leading to an abnormal response and development of full-blown autoimmune diseases (7, 8).

When used in vaccines, adjuvants are purposely used as immunogenicity enhancing agents that are essential for directing the adaptive immunoresponse (9). However, they might also trigger undesired autoimmune reactions that question the use of adjuvants and their safety in the context of DRB1*01 genetic background (10).

A systematic review by Jara et al. (4) reported that 4479 ASIA cases have been identified since its presentation in 2011. Among them, 305 were considered severe, with the majority of these cases being developed following vaccines mainly directed to HPV, HBV, and seasonal influenza. Despite vaccines' proven record of safety and efficiency, aluminum hydroxide was used in these vaccines along with the viral antigens as an adjuvant. Due to aluminum's capability to enhance the immunoresponse, it enables the usage of smaller amount of antigens. However, enhanced immunogenicity might lead to enhanced reactogenicity in a process not always benign involving pathological stimulation (11).

The other adjuvants containing products yielding severe clinical manifestations are silicone implants and mineral oil fillers (4, 12).

Silicone has been considered as an inert material, which is unable to induce immune reactions in the human body. Therefore, it has been used in many medical devices for the last 60 years, including both silicone and saline breast implants. However, a possible association between silicone exposure and autoimmune diseases has been reported in many studies demonstrating the development of autoimmune diseases and autoantibodies in patients following exposure to silicone implants (13, 14). Improved clinical manifestations after the extraction of implants (15) support the relationship between silicone and autoimmunity.

Mineral oil injections, which are prevalent in Mexico and Latin America for cosmetic uses, have been identified as a leading cause of ASIA syndrome as well *via* the proposed mechanism of chronic inflammation induction leading to granuloma formation and thickening of the dermis (4, 10).

The risk for autoimmune diseases, determined by the patient's genetic background, is increased in patients with autoimmune diseases history such as type 1 diabetes mellitus (T1DM). Thyroid antibodies can be identified in approximately 20–25% of patients with type 1 diabetes, and up to 50% of them progress to clinical autoimmune thyroid disease (AITD) (16). Thyroid autoimmune diseases have been described in many case reports and case series, presenting thyroid autoimmune manifestations along with other autoimmune conditions.

In genetically predisposed individuals, under particular conditions, molecular mimicry between microbial and human antigens has been shown to be able to turn a defensive immunoresponse into autoimmune response. This mechanism has yet to be explored in the field of thyroid autoimmune diseases (17). In our review, we aimed to summarize the current knowledge about ASIA syndrome and the relationship between adjuvants and autoimmune diseases, focusing on its association with autoimmune endocrinopathies and thyroid autoimmunity.

Endocrinopathy and ASIA Syndrome

Pathological processes of the endocrine glands result in abnormal levels of circulating hormones, which lead to endocrinopathies. Some endocrine disorders are immune mediated, such as Hashimoto's thyroiditis (HT), Graves' disease, and T1DM (18–20). Thus, it is possible that endocrine autoimmune diseases can be triggered by adjuvants, configuring cases of ASIA syndrome. Case reports, cohort and case–control studies on ASIA syndrome, and the majority of the endocrinopathies are still scarce. Lately, primary ovarian failure (POF) has been linked to ASIA, especially after vaccination (21–25).

Primary ovarian failure or premature ovarian insufficiency is defined as a combination of amenorrhea, for a minimum of 4 months, decline in sex steroids, and follicle-stimulating hormone (FSH) above 40 IU/l at two measurements with an interval of at least 1 month in women younger than 40 years (26). POF is a disorder with multiple etiologic mechanisms. The presence of lymphocytic invasion in the oophorus and the identification of autoantibodies against ovarium antigens on the theca, granulose, corpus luteum, and zona pellucida (27–29) support the idea that part of its etiology, estimated in 20–30% (30), is immune mediated. Furthermore, POF is commonly associated with other autoimmune diseases, including Addison's disease, thyroiditis, autoimmune polyglandular syndrome, systemic lupus erythematosus (SLE), hemolytic anemia, idiopathic thrombocytopenic purpura (ITP), and Sjogren's syndrome (31). The pathogenesis of POF also involves genetic mutations, metabolic disorders, and environmental factors, such as virus infection, chemo and radiotherapy, and surgeries (30).

HPV vaccine has been reported as an important issue in ASIA syndrome, already being related, for instance, to Guillain-Barré syndrome and other neuropathies, such as SLE, vasculitis, ITP, and autoimmune hepatitis (32–36). Developing autoimmune diseases as an adverse effect of the vaccine can be both due to its HPV virus-like particles, which have potent immuno-stimulatory properties (and can induce autoimmunity by molecular mimicry, epitope spreading, bystander activation, and polyclonal activation) (37), and due to the presence of aluminum as an adjuvant in the vaccine (38). Adjuvants are capable of increasing, intensifying, and prolonging antigen-specific immunoresponse of the vaccines without holding its own specific antigenic effect (38). Autoimmune well-defined diseases, as well as the non-specific immune disorders, following vaccination can present as a subacute vaccination side effect or appear months or years after the boosters (39–43). Genetically predisposed patients are more likely to exhibit late manifestations and are in a higher risk of developing ASIA syndrome (36, 44).

Colafrancesco et al. (21) recently reported three cases of POF following immunization with HPV vaccine. The three patients fulfilled the criteria for ASIA syndrome suggested by Shoenfeld and Agmon-Levin (6). They described three young women, previously healthy and with normal sexual development, who received three administrations of the quadrivalent HPV vaccine. The patients experienced general symptoms, including nausea, stomachaches, heavy and burning sensations in the injected arm, headaches, insomnia, arthralgia, depression, anxiety, and difficulty in concentrating, and then presented amenorrhea within approximately 10 months, 2 years, and 10 years after the first dose. Two of them were positive for previously negative antibodies (anti-TPO and antiovarian). Hormonal screening was performed, showing increased FSH and luteinizing hormone (LH) plus

extremely low levels of estradiol. Pregnancy was excluded, as well as no abnormalities were revealed in the transvaginal and pelvic ultrasound. After a karyotype evaluation and search for Fragile X syndrome with no aberrations, they were diagnosed with POF. Moreover, two of the three patients were siblings leading to the hypothesis that may exist as a rare risk factor for this adverse effect.

Little and Ward (22) also reported a case of POF succeeding HPV vaccination, in a 16-year-old patient, who presented irregular menses after taking the quadrivalent vaccine, followed by oligomenorrhea and amenorrhea. Her hormone profile also showed high levels of FSH and LH and low levels of estradiol and anti-mullerian hormone (AMH), and after excluding pregnancy and genetic, endocrinal, and other causes, she was diagnosed with POF.

Problems of quadrivalent HPV vaccine introduction in the market were wisely pointed by Little and Ward (25). They reported three other cases of young women who develop POF after having quadrivalent HPV vaccine and questioned some issues about its safety. First, despite the fact that the vaccine protocol suggests three doses, in the preclinical studies for toxicity, only two boosters were given to the rats. Still, the animals' reproductive system was not analyzed in a long-term period. Moreover, the phase II and III clinical studies on safety of the vaccine regarding the fertility were not complete: half of the subjects studied were lost to follow-up at 1 year; some of the subjects were on hormone contraception methods, which could mask the ovarian insufficiency; they have not considered medical conditions that flourished more than 7 months after the vaccination as associated with the vaccine; and adverse effects were only reported 2 weeks after the boosters. Furthermore, the placebo used as control in the phase III safety studies of the quadrivalent HPV vaccine was aluminum, also present in the vaccine solution, which was already shown to play as an adjuvant in ASIA syndrome.

Thus, HPV vaccine is likely to be an important trigger in ASIA syndrome, including immuno-mediated endocrine disorders, such as POF. Due to long periods of intervals between the vaccine injections and the development of the ovarian insufficiency, it is questionable if there is indeed a causal relationship between them. However, as previously mentioned, the safety preclinical and clinical studies of HPV vaccine are lacking some information regarding fertility safety, and the side effects were shown to be able to appear even after months or years.

Other vaccines and adjuvants may also trigger POF, as well as other immuno-mediated endocrinopathies, like for instance, type 1-diabetes may be induced by the same adjuvants. Indeed, in a cohort study with 211 young female patients with autoimmune diseases and 857 matched controls, they showed that patients exposed to quadrivalent HPV vaccine were in a higher risk of developing type 1-diabetes mellitus (OR = 1.2) (45). Additionally, it was shown in a prospective cohort study (46) that some vaccines are related to increased levels of diabetes autoantibodies, such as antibody against glutamic acid decarboxylase (GADA) and tyrosine phosphatase (IA-2A). These autoantibodies, which are considered reliable markers for the disease process (47, 48), were more frequently found in the subjects who received hemophilus influenza B (HIB) vaccination (OR = 5.9 and 3.4 in IA-2A and GADA, respectively). Especially, the IA-2A serum concentrations were significantly higher in patients exposed to HIB. Also, BCG was correlated to an enhanced prevalence of IA-2A ($p < 0.01$). The previously mentioned studies suggest that ASIA syndrome, particularly post vaccination, and endocrinopathies might be linked.

Autoimmune Thyroid Disease and ASIA Syndrome

During the last years, abundant case reports and series were published supporting that various autoimmune disorders may be induced by adjuvants and be enclosed under ASIA syndrome (4, 12). Despite the fact of being the most common autoimmune disorder, unexpectedly, we have revealed very few articles and case reports in the literature describing the induction of AITD by various adjuvants. In this section, we report that the relevant case descriptions of AITD were reported to be correlated to immunization and silicone implants.

Hernàn Martinez et al. (49) described a case of a 55-year-old man with a family history of autoimmune diseases and medical history of diabetes and psoriasis, who developed subacute thyroiditis shortly after the administration of an influenza vaccine. Subacute thyroiditis is a very rare disease, and the authors of the mentioned case concluded that the induction of the disease was a result of an interaction between the genetic predisposition and vaccination. Another similar case of subacute thyroiditis was reported in a 25-year-old female (50). The patient was admitted due to fever, swelling, and tender mass in the neck. Two days before her presentation, she received influenza vaccine (Vaxigrip). Biopsy of the thyroid has revealed multinuclear giant cell granulomas.

A previously healthy 36-year-old female presented with clinical symptoms of thyrotoxicosis including tachycardia, anxiety, and tenderness in her neck (51). One month before her presentation, she received H1N1 vaccine. Thyroid function tests confirmed remarkable thyrotoxicosis. Thyroid scintigraphy was performed and showed significant diffuse reduction in the technetium uptake. Therefore, a diagnosis of subacute thyroiditis was made. Moving to another type of adjuvant, cases of granulomatous inflammation of the thyroid have been reported with silicone breast implants (52). Vayssairat et al. (53) described two cases of HT after receiving a silicone gel-filled breast implants. Both cases were induced after a long period of incubation, the first case is a 45-year-old women who had bilateral silicone implant of the breast in 1976 and developed HT in 1991. In addition, the patient complained of other non-specific symptoms including fatigue, morning stiffness, and sicca syndrome. Thyroid ultrasonography showed an enlarged thyroid gland with a diffusely hypoechogenic pattern. The implants were painful and removed, showing extremely dense connective tissue with fibrosis. The second case of HT presented with hyperthyroidism clinical manifestation, 10 years after the silicon implantation, reporting positive anti-TPO. The implants were again painful, and the patient developed positive antinuclear

antibodies (ANA). An animal experiment aimed to evaluate the immunological adjuvancy potential of silicone gel taken from breast implants (54). The study has found that silicone gel is able to stimulate the production of autoantibodies to rat thyroglobulin and bovine collagen II. However, this immune reaction was not associated with any histological evidence of thyroiditis or arthritis.

A cohort study was performed to assess the risk of new onset autoimmune disease in young women exposed to human papillomavirus-16/18 AS04-adjuvanted vaccine in the United Kingdom (55). The study reported an incidence rate ratio (95% CI) of 3.75 (1.25–11.31) for autoimmune thyroiditis among females.

An animal study has reported that immunization of BALB/c mice with the extracellular domain of the human TSH receptor led to the production of TSH binding-inhibiting and thyroid-blocking antibodies accompanied by lymphocytic infiltration of the thyroid (56).

In summary, ASIA syndrome is being more recognized by physicians, and therefore, more studies and cases have reported the correlation of the exposure to various adjuvants with diverse autoimmune diseases. Still, very few clinical reports and animal models studies were published to show the relationship between endocrinopathies in general and AITD in particular with adjuvants. However, the clinical cases of HT and/or subacute thyroiditis were observed after the exposure to vaccines as well as silicone implantation. Therefore, we believe that the minority of cases is not owing to rarity of association between adjuvants and AITD rather than the lack of awareness among physicians of such association. Consequently, physicians must be mindful that thyroiditis and other thyroid disorders can be induced by diverse adjuvants and therefore to reconsider non-essential vaccination in genetically predisposed individuals for autoimmune diseases.

Author Contributions

AW, PD, SB, and YS designed the study and reviewed the literature on ASIA syndrome and thyroid autoimmunity. AW, PD, and SB wrote the manuscript. AW and YS edited the manuscript. All the authors have revised the paper and approved the final edition.

Conflict of Interest Statement

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. The reviewers IR and SF and handling Editor declared their shared affiliation, and the handling Editor states that the process nevertheless met the standards of a fair and objective review.

References

1. Perricone C, Colafrancesco S, Mazor RD, Soriano A, Agmon-Levin N, Shoenfeld Y. Autoimmune/inflammatory syndrome induced by adjuvants (ASIA) 2013: unveiling the pathogenic, clinical and diagnostic aspects. J Autoimmun (2013) 47:1–16.10.1016/j.jaut.2013.10.004 [PubMed] [CrossRef] [Google Scholar]

2. Vera-Lastra O, Medina G, Cruz-Dominguez MDP, Ramirez P, Gayosso-Rivera JA, Anduaga-Dominguez H, et al. Human adjuvant disease induced by foreign substances: a new model of ASIA (Shoenfeld's syndrome). Lupus (2012) 21:128–35.10.1177/0961203311429317 [PubMed] [CrossRef] [Google Scholar]

3. Meroni PL. Autoimmune or auto-inflammatory syndrome induced by adjuvants (ASIA): old truths and a new syndrome? J Autoimmun (2011) 36:1–3.10.1016/j.jaut.2010.10.004 [PubMed] [CrossRef] [Google Scholar]

4. Jara LJ, García-Collinot G, Medina G, Cruz-Dominguez MD, Vera-Lastra O, Carranza-Muleiro RA, et al. Severe manifestations of autoimmune syndrome induced by adjuvants (Shoenfeld's syndrome). Immunol Res (2016).10.1007/s12026-016-8811-0 [PubMed] [CrossRef] [Google Scholar]

5. Israeli E, Pardo A. The sick building syndrome as a part of the autoimmune (auto-inflammatory) syndrome induced by adjuvants. Mod Rheumatol (2011) 21:235–9.10.1007/s10165-010-0380-9 [PubMed] [CrossRef] [Google Scholar]

6. Shoenfeld Y, Agmon-Levin N. "ASIA" – autoimmune/inflammatory syndrome induced by adjuvants. J Autoimmun (2011) 36:4–8.10.1016/j.jaut.2010.07.003 [PubMed] [CrossRef] [Google Scholar]

7. Israeli E, Agmon-Levin N, Blank M, Shoenfeld Y. Macrophagic myofaciitis a vaccine (alum) autoimmune-related disease. Clin Rev Allergy Immunol (2011) 41:163–8.10.1007/s12016-010-8212-4 [PubMed] [CrossRef] [Google Scholar]

8. Arango M-T, Perricone C, Kivity S, Cipriano E, Ceccarelli F, Valesini G, et al. HLA-DRB1 the notorious gene in the mosaic of autoimmunity. Immunol Res (2016):1–17.10.1007/s12026-016-8817-7 [PubMed] [CrossRef] [Google Scholar]

9. Agmon-Levin N, Hughes GR, Shoenfeld Y. The spectrum of ASIA: "autoimmune (auto-inflammatory) Syndrome induced by adjuvants". Lupus (2012) 21:118–20.10.1177/0961203311429316 [PubMed] [CrossRef] [Google Scholar]

10. Vera-Lastra O, Medina G, Cruz-Dominguez MDP, Jara LJ, Shoenfeld Y. Autoimmune/inflammatory syndrome induced by adjuvants (Shoenfeld's syndrome): clinical and immunological spectrum. Expert Rev Clin Immunol (2013) 9:361–73.10.1586/eci.13.2 [PubMed] [CrossRef] [Google Scholar]

11. Inbar R, Weiss R, Tomljenovic L, Arango MT, Deri Y, Shaw CA, et al. Behavioral abnormalities in young female mice following administration of aluminum adjuvants and the human papillomavirus (HPV) vaccine Gardasil. Vaccine (2016) pii:S0264-410X(16)00016-5.10.1016/j.vaccine.2015.12.067 [PubMed] [CrossRef] [Google Scholar]

12. Colaris MJL, de Boer M, van der Hulst RR, Cohen Tervaert JW. Two hundreds cases of ASIA syndrome following silicone implants: a comparative study of 30 years and a review of current literature. Immunol Res (2016).10.1007/s12026-016-8821-y [PubMed] [CrossRef] [Google Scholar]

13. Muzaffar AR, Rohrich RJ. The silicone gel-filled breast implant controversy: an update. Plast Reconstr Surg (2002) 109:742–7; quiz 748.10.1097/00006534-200202000-00049 [PubMed] [CrossRef] [Google Scholar]

14. Bar-Meir E, Teuber SS, Lin HC, Alosacie I, Goddard G, Terybery J, et al. Multiple autoantibodies in patients with silicone breast implants. J Autoimmun (1995) 8:267–77.10.1006/jaut.1995.0020 [PubMed] [CrossRef] [Google Scholar]

15. Maijers MC, de Blok CJM, Niessen FB, van der Veldt AAM, Ritt MJPF, Winters HAH, et al. Women with silicone breast implants and unexplained systemic symptoms: a descriptive cohort study. Neth J Med (2013) 71:534–40. [PubMed] [Google Scholar]

16. Kahaly GJ, Hansen MP. Type 1 diabetes associated autoimmunity. Autoimmun Rev (2016) 15:644–8.10.1016/j.autrev.2016.02.017 [PubMed] [CrossRef] [Google Scholar]

17. Oldstone MBA. Molecular mimicry and autoimmune disease. Cell (1987) 50:819–20.10.1016/0092-8674(87)90507-1 [PubMed] [CrossRef] [Google Scholar]

18. Prabhakar BS, Bahn RS, Smith TJ. Current perspective on the pathogenesis of Graves' disease and ophthalmopathy. Endocr Rev (2003) 24:802–35.10.1210/er.2002-0020 [PubMed] [CrossRef] [Google Scholar]

19. Hollowell JG, Staehling NW, Flanders WD, Hannon WH, Gunter EW, Spencer CA, et al. Serum TSH, T(4), and thyroid antibodies in the United States population (1988 to 1994): National Health and Nutrition Examination Survey (NHANES III). J Clin Endocrinol Metab (2002) 87:489–99.10.1210/jcem.87.2.8182 [PubMed] [CrossRef] [Google Scholar]

20. Atkinson MA, Maclaren NK. The pathogenesis of insulin-dependent diabetes mellitus. N Engl J Med (1994) 331:1428–36.10.1056/NEJM199411243312107 [PubMed] [CrossRef] [Google Scholar]

21. Colafrancesco S, Perricone C, Tomljenovic L, Shoenfeld Y. Human papilloma virus vaccine and primary ovarian failure: another facet of the autoimmune/inflammatory syndrome induced by adjuvants. Am J Reprod Immunol (2013) 70:309–16.10.1111/aji.12151 [PubMed] [CrossRef] [Google Scholar]

22. Little DT, Ward HRG. Premature ovarian failure 3 years after menarche in a 16-year-old girl following human papillomavirus vaccination. BMJ Case Rep (2012) 2012:2–4.10.1136/bcr-2012-006879 [PMC free article] [PubMed] [CrossRef] [Google Scholar]

23. Gruber N, Shoenfeld Y. A link between human papilloma virus vaccination and primary ovarian insufficiency: current analysis. Curr Opin Obstet Gynecol (2015) 27:265–70.10.1097/GCO.0000000000000183 [PubMed] [CrossRef] [Google Scholar]

24. Hawkes D, Buttery JP. Human papillomavirus vaccination and primary ovarian insufficiency: an association based on ideology rather than evidence. Curr Opin Obstet Gynecol (2016) 28:70–2.10.1097/GCO.0000000000000240 [PubMed] [CrossRef] [Google Scholar]

25. Little DT, Ward HRG. Adolescent premature ovarian insufficiency following human papillomavirus vaccination: a case series seen in general practice. J Investig Med High Impact Case Rep (2014) 2:2324709614556129.10.1177/2324709614556129 [PMC free article] [PubMed] [CrossRef] [Google Scholar]

26. Nelson LM. Clinical practice. Primary ovarian insufficiency. N Engl J Med (2009) 360:606–14.10.1056/NEJMcp0808697 [PMC free article] [PubMed] [CrossRef] [Google Scholar]

27. Kelkar RL, Meherji PK, Kadam SS, Gupta SK, Nandedkar TD. Circulating auto-antibodies against the zona pellucida and thyroid microsomal antigen in women with premature ovarian failure. J Reprod Immunol (2005) 66:53–67.10.1016/j.jri.2005.02.003 [PubMed] [CrossRef] [Google Scholar]

28. Chattopadhyay D, Sen MR, Katiyar P, Pandey LK. Antiovarian antibody in premature ovarian failure. Indian J Med Sci (1999) 53:254–8. [PubMed] [Google Scholar]

29. Mande PV, Parikh FR, Hinduja I, Zaveri K, Vaidya R, Gajbhiye R, et al. Identification and validation of candidate biomarkers involved in human ovarian autoimmunity. Reprod Biomed Online (2011) 23:471–83.10.1016/j.rbmo.2011.06.013 [PubMed] [CrossRef] [Google Scholar]

30. Petrikova J, Lazurova I. Ovarian failure and polycystic ovary syndrome. Autoimmun Rev (2012) 11:A471–8.10.1016/j.autrev.2011.11.010 [PubMed] [CrossRef] [Google Scholar]

31. Hoek A, Schoemaker J, Drexhage HA. Premature ovarian failure and ovarian autoimmunity. Endocr Rev (1997) 18:107–34.10.1210/er.18.1.107 [PubMed] [CrossRef] [Google Scholar]

32. Pugnet G, Ysebaert L, Bagheri H, Montastruc J-L, Laurent G. Immune thrombocytopenic purpura following human papillomavirus vaccination. Vaccine (2009) 27:3690.10.1016/j.vaccine.2009.04.004 [PubMed] [CrossRef] [Google Scholar]

33. Souayah N, Michas-Martin PA, Nasar A, Krivitskaya N, Yacoub HA, Khan H, et al. Guillain-Barré syndrome after Gardasil vaccination: data from Vaccine Adverse Event Reporting System 2006-2009. Vaccine (2011) 29:886–9.10.1016/j.vaccine.2010.09.020 [PubMed] [CrossRef] [Google Scholar]

34. Alvarez-Soria MJ, Hernandez-Gonzalez A, Carrasco-Garcia de Leon S, del Real-Francia MA, Gallardo-Alcaniz MJ, Lopez-Gomez JL. [Demyelinating disease and vaccination of the human papillomavirus]. Rev Neurol (2011) 52:472–6. [PubMed] [Google Scholar]

35. Gomes SM, Glover M, Malone M, Brogan P. Vasculitis following HPV immunization. Rheumatology (Oxford) (2013) 52:581–2.10.1093/rheumatology/kes168 [PubMed] [CrossRef] [Google Scholar]

36. Gatto M, Agmon-Levin N, Soriano A, Manna R, Maoz-Segal R, Kivity S, et al. Human papillomavirus vaccine and systemic lupus erythematosus. Clin Rheumatol (2013) 32:1301–7.10.1007/s10067-013-2266-7 [PubMed] [CrossRef] [Google Scholar]

37. Sutton I, Lahoria R, Tan I, Clouston P, Barnett M. CNS demyelination and quadrivalent HPV vaccination. Mult Scler (2009) 15:116–9.10.1177/1352458508096868 [PubMed] [CrossRef] [Google Scholar]

38. Israeli E, Agmon-Levin N, Blank M, Shoenfeld Y. Adjuvants and autoimmunity. Lupus (2009) 18:1217–25.10.1177/0961203309345724 [PubMed] [CrossRef] [Google Scholar]

39. Couette M, Boisse MF, Maison P, Brugieres P, Cesaro P, Chevalier X, et al. Long-term persistence of vaccine-derived aluminum hydroxide is associated with chronic cognitive dysfunction. J Inorg Biochem (2009) 103:1571–8.10.1016/j.jinorgbio.2009.08.005 [PubMed] [CrossRef] [Google Scholar]

40. Mikaeloff Y, Caridade G, Suissa S, Tardieu M. Hepatitis B vaccine and the risk of CNS inflammatory demyelination in childhood. Neurology (2009) 72:873–80.10.1212/01.wnl.0000335762.42177.07 [PubMed] [CrossRef] [Google Scholar]

41. Shivane A, Hilton DA, Moate RM, Bond PR, Endean A. Macrophagic myofasciitis: a report of second case from UK. Neuropathol Appl Neurobiol (2012) 38:734–6.10.1111/j.1365-2990.2012.01293.x [PubMed] [CrossRef] [Google Scholar]

42. Poser CM, Behan PO. Late onset of Guillain-Barré syndrome. J Neuroimmunol (1982) 3:27–41.10.1016/0165-5728(82)90016-9 [PubMed] [CrossRef] [Google Scholar]

43. Gherardi RK, Authier F-J. Macrophagic myofasciitis: characterization and pathophysiology. Lupus (2012) 21:184–9.10.1177/0961203311429557 [PMC free article] [PubMed] [CrossRef] [Google Scholar]

44. Zafrir Y, Agmon-Levin N, Paz Z, Shilton T, Shoenfeld Y. Autoimmunity following hepatitis B vaccine as part of the spectrum of "autoimmune (auto-inflammatory) syndrome induced by adjuvants" (ASIA): analysis of 93 cases. Lupus (2012) 21:146–52.10.1177/0961203311429318 [PubMed] [CrossRef] [Google Scholar]

45. Grimaldi-Bensouda L, Guillemot D, Godeau B, Bénichou J, Lebrun-Frenay C, Papeix C, et al. Autoimmune disorders and quadrivalent human papillomavirus vaccination of young female subjects. J Intern Med (2014) 275:398–408.10.1111/joim.12155 [PubMed] [CrossRef] [Google Scholar]

46. Wahlberg J, Fredriksson J, Vaarala O, Ludvigsson J, Abis Study Group . Vaccinations may induce diabetes-related autoantibodies in one-year-old children. Ann N Y Acad Sci (2003) 1005:404–8.10.1196/annals.1288.068 [PubMed] [CrossRef] [Google Scholar]

47. Bingley PJ, Bonifacio E, Williams AJK, Genovese S, Bottazzo GF, Gale EA. Prediction of IDDM in the general population: strategies based on combinations of autoantibody markers. Diabetes (1997) 46:1701–10.10.2337/diab.46.11.1701 [PubMed] [CrossRef] [Google Scholar]

48. Samuelsson UU, Sundkvist GG, Borg HH, Fernlund PP, Ludvigsson JJ. Islet autoantibodies in the prediction of diabetes in school children. Diabetes Res Clin Pract (2001) 51:51–7.10.1016/S0168-8227(00)00199-6 [PubMed] [CrossRef] [Google Scholar]

49. Hernán Martinez J, Corder E, Uzcategui M, Garcia M, Sostre S, Garcia A. Subacute thyroiditis and dyserythropoesis after influenza vaccination suggesting immune dysregulation. Bol Asoc Med P R (2011) 103:48–52. [PubMed] [Google Scholar]

50. Hsiao J-Y, Hsin S-C, Hsieh M-C, Hsia P-J, Shin S-J. Subacute thyroiditis following influenza vaccine (Vaxigrip) in a young female. Kaohsiung J Med Sci (2006) 22:297–300.10.1016/S1607-551X(09)70315-8 [PubMed] [CrossRef] [Google Scholar]

51. Girgis CM, Russo RR, Benson K. Subacute thyroiditis following the H1N1 vaccine. J Endocrinol Invest (2010) 33:506.10.1007/BF03346633 [PubMed] [CrossRef] [Google Scholar]

52. Prebtani APH, Asa SL, Ezzat S. Is granulomatous thyroiditis a complication of breast implants? Endocr Pathol (2002) 13:239–44.10.1385/EP:13:3:239 [PubMed] [CrossRef] [Google Scholar]

53. Vayssairat M, Mimoun M, Houot B, Abuaf N, Rouquette AM, Chaouat M. [Hashimoto's thyroiditis and silicone breast implants: 2 cases]. J Mal Vasc (1997) 22:198–9. [PubMed] [Google Scholar]

54. Naim JO, Lanzafame RJ, van Oss CJ. The effect of silicone-gel on the immune response. J Biomater Sci Polym Ed (1995) 7:123–32.10.1163/156856295X00643 [PubMed] [CrossRef] [Google Scholar]

55. Willame C, Rosillon D, Zima J, Angelo M-G, Stuurman AL, Vroling H, et al. Risk of new onset autoimmune disease in 9- to 25-year-old women exposed to human papillomavirus-16/18 AS04-adjuvanted vaccine in the United Kingdom. Hum Vaccin Immunother (2016) 18:1–10.10.1080/21645515.2016.1199308 [PMC free article] [PubMed] [CrossRef] [Google Scholar]

56. Costagliola S, Alcalde L, Tonacchera M, Ruf J, Vassart G, Ludgate M. Induction of thyrotropin receptor (TSH-R) autoantibodies and thyroiditis in mice immunised with the recombinant TSH-R. Biochem Biophys Res Commun (1994) 199:1027–34.10.1006/bbrc.1994.1332 [PubMed] [CrossRef] [Google Scholar]

Articles from Frontiers in Endocrinology are provided here courtesy of **Frontiers Media SA**

1210. [PMC free article] [PubMed] [Google Scholar]

21. Kerr PJ, Perkins HD, Inglis B, et al. Expression of rabbit IL-4 by recombinant myxoma viruses enhances virulence and overcomes genetic resistance to myxomatosis. Virology. 2004;324:117–128. [PubMed] [Google Scholar]

22. Daly MJ, Rioux JD, Schaffner SF, Hudson TJ, Lander ES. High-resolution haplotype structure in the human genome. Nat Genet. 2001;29:229–232. [PubMed] [Google Scholar]

23. Martin YN, Salavaggione OE, Eckloff BW, Wieben ED, Schaid DJ, Weinshilboum RM. Human methylenetetrahydrofolate reductase pharmacogenomics: gene resequencing and functional genomics. Pharmacogenet Genomics. 2006;16:265–277. [PubMed] [Google Scholar]

24. Friso S, Girelli D, Trabetti E, et al. The MTHFR 1298A>C polymorphism and genomic DNA methylation in human lymphocytes. Cancer Epidemiol Biomarkers Prev. 2005;14:938–943. [PubMed] [Google Scholar]

25. Dedoussis GV, Panagiotakos DB, Pitsavos C, et al. An association between the methylenetetrahydrofolate reductase (MTHFR) C677T mutation and inflammation markers related to cardiovascular disease. Int J Cardiol. 2005;100:409–414. [PubMed] [Google Scholar]

26. Lim U, Peng K, Shane B, et al. Polymorphisms in cytoplasmic serine hydroxymethyltransferase and methylenetetrahydrofolate reductase affect the risk of cardiovascular disease in men. J Nutr. 2005;135:1989–1994. [PubMed] [Google Scholar]

27. Murphy N, Diviney M, Szer J, et al. Donor methylenetetrahydrofolate reductase genotype is associated with graft-versus-host disease in hematopoietic stem cell transplant patients treated with methotrexate. Bone Marrow Transplant. 2006;37:773–779. [PubMed] [Google Scholar]

28. Urano W, Taniguchi A, Yamanaka H, et al. Polymorphisms in the methylenetetrahydrofolate reductase gene were associated with both the efficacy and the toxicity of methotrexate used for the treatment of rheumatoid arthritis, as evidenced by single locus and haplotype analyses. Pharmacogenetics. 2002;12:183–190. [PubMed] [Google Scholar]

29. Harada H, Fujita T, Miyamoto M, et al. Structurally similar but functionally distinct factors, IRF-1 and IRF-2, bind to the same regulatory elements of IFN and IFN-inducible genes. Cell. 1989;58:729–739. [PubMed] [Google Scholar]

30. Goodbourn S, Didcock L, Randall RE. Interferons: cell signalling, immune modulation, antiviral response and virus countermeasures. J Gen Virol. 2000;81:2341–2364. [PubMed] [Google Scholar]

31. van den Broek MF, Muller U, Huang S, Aguet M, Zinkernagel RM. Antiviral defense in mice lacking both alpha/beta and gamma interferon receptors. J Virol. 1995;69:4792–4796.[PMC free article] [PubMed] [Google Scholar]

32. Symons JA, Alcami A, Smith GL. Vaccinia virus encodes a soluble type I interferon receptor of novel structure and broad species specificity. Cell. 1995;81:551–560. [PubMed] [Google Scholar]

33. Alcami A, Symons JA, Smith GL. The vaccinia virus soluble alpha/beta interferon (IFN) receptor binds to the cell surface and protects cells from the antiviral effects of IFN. J Virol. 2000;74:11230–11239. [PMC free article] [PubMed] [Google Scholar]

34. Crawford DC, Nickerson DA. Definition and clinical importance of haplotypes. Annu Rev Med. 2005;56:303–320. [PubMed] [Google Scholar]

35. Duan J, Wainwright MS, Comeron JM, et al. Synonymous mutations in the human dopamine receptor D2 (DRD2) affect mRNA stability and synthesis of the receptor. Hum Mol Genet. 2003;12:205–216. [PubMed] [Google Scholar]

36. Jackson RJ, Ramsay AJ, Christensen CD, Beaton S, Hall DF, Ramshaw IA. Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox. J Virol. 2001;75:1205–1210. [PMC free article] [PubMed] [Google Scholar]

37. Howell MD, Gallo RL, Boguniewicz M, Jones JF, Wong C, Streib JE, Leung DYM. Cytokine milieu of atopic dermatitis skin subverts the innate immune response to vaccinia virus. Immunity. 2006;24:341–348. [PubMed] [Google Scholar]

38. Fong TA, Mosmann TR. The role of IFN-gamma in delayed-type hypersensitivity mediated by Th1 clones. J Immunol. 1989;143:2887–2893. [PubMed] [Google Scholar]

39. Grom AA, Passo M. Macrophage activation syndrome in systemic juvenile rheumatoid arthritis. J Pediatr. 1996;129:630–632. [PubMed] [Google Scholar]

40. Stanley SL, Jr, Frey SL, Taillon-Miller P, et al. Immunogenetics of smallpox vaccination. J Infect Dis. 2007 in press. [PubMed] [Google Scholar]

6. Rock MT, Yoder SM, Talbot TR, Edwards KM, Crowe JE., Jr Cellular immune responses to diluted and undiluted aventis pasteur smallpox vaccine. J Infect Dis. 2006;194:435–443. [PubMed] [Google Scholar]

7. Shaklee JF, Talbot TR, Muldowney JA, III, et al. Smallpox vaccination does not elevate systemic levels of prothrombotic proteins associated with ischemic cardiac events. J Infect Dis. 2005;191:724–730. [PubMed] [Google Scholar]

8. Talbot TR, Stapleton JT, Brady RC, et al. Vaccination success rate and reaction profile with diluted and undiluted smallpox vaccine: a randomized controlled trial. JAMA. 2004;292:1205–1212. [PubMed] [Google Scholar]

9. Hirschhorn JN, Lohmueller K, Byrne E, Hirschhorn K. A comprehensive review of genetic association studies. Genet Med. 2002;4:45–61. [PubMed] [Google Scholar]

10. Lohmueller KE, Pearce CL, Pike M, Lander ES, Hirschhorn JN. Meta-analysis of genetic association studies supports a contribution of common variants to susceptibility to common disease. Nat Genet. 2003;33:177–182. [PubMed] [Google Scholar]

11. Talbot TR, Bredenberg HK, Smith M, LaFleur BJ, Boyd A, Edwards KM. Focal and generalized folliculitis following smallpox vaccination among vaccinia-naive recipients. JAMA. 2003;289:3290–3294. [PubMed] [Google Scholar]

12. Garcia-Closas M, Malats N, Real FX, et al. Large-scale evaluation of candidate genes identifies associations between VEGF polymorphisms and bladder cancer risk. PLoS Genet. 2007;3:e29.[PMC free article] [PubMed] [Google Scholar]

13. Packer BR, Yeager M, Burdett L, et al. SNP500Cancer: a public resource for sequence validation, assay development, and frequency analysis for genetic variation in candidate genes. Nucleic Acids Res. 2006;34:D617–D621. [PMC free article] [PubMed] [Google Scholar]

14. Wigginton JE, Cutler DJ, Abecasis GR. A note on exact tests of Hardy-Weinberg equilibrium. Am J Hum Genet. 2005;76:887–893. [PMC free article] [PubMed] [Google Scholar]

15. Barrett JC, Fry B, Maller J, Daly MJ. Haploview: analysis and visualization of LD and haplotype maps. Bioinformatics. 2005;21:263–265. [PubMed] [Google Scholar]

16. Lake SL, Lyon H, Tantisira K, et al. Estimation and tests of haplotype-environment interaction when linkage phase is ambiguous. Hum Hered. 2003;55:56–65. [PubMed] [Google Scholar]

17. Ihaka R, Gentleman R. R: A Language for Data Analysis and Graphics. Journal of Computational and Graphical Statistics. 1996;5:299–314. [Google Scholar]

18. R Development Core Team. R: A Language and Environment for Statistical Computing. R Foundation for Statistical Computing. [Accessed 31 August 2007]. http://www.R-project.org.

19. Howell MD, Gallo RL, Boguniewicz M, et al. Cytokine milieu of atopic dermatitis skin subverts the innate immune response to vaccinia virus. Immunity. 2006;24:341–348. [PubMed] [Google Scholar]

20. Jackson RJ, Ramsay AJ, Christensen CD, Beaton S, Hall DF, Ramshaw IA. Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox. J Virol. 2001;75:1205–

Testimonial, Monday the 15th of April at the Capitol to the Health and Insurance Committee:
Dear Madam Chair, Dear Representatives,

I am Dr. Katia Meier; I have been a MD for 20 years.

It is a fact that some children have complex medical and genetic vulnerabilities to vaccine injury.

I strongly oppose this bill, because it would endanger the medically and genetically vulnerable by eliminating the Doctor/Patient relationship and ignoring a Doctors' particular experience. I refer specifically to section 3 part (a) (II), where this bill would ELIMINATE all medical exemptions that could PREVENT a serious life threatening and permanently damaging vaccine reaction and would instead throw the genetically and medically vulnerable minority of children under the bus.

A parent would be forced to play Russian roulette with their child and risk an anaphylactic reaction, or permanent lifelong serious brain damage before a medical exemption can be written, if the child survives at all. And how can it be determined, which vaccine has caused the reaction if given with multiple other vaccines at the same time.
To save their children from harm, a Parent would have to seek other exemptions, therefore this bill would obscure the REAL reason a child is exempt.

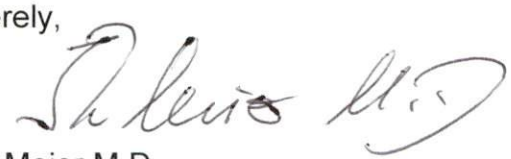
This bill would block doctors from abiding to their Oath of First Do No Harm because children would have to be put into harm's way before a medical exemption can be written for each one out of 53 different vaccines and 72 doses by the time a child is 18 years old.

This bill would make Colorado be the FIRST and ONLY state that allows someone without a medical degree, without a medical license, who has never seen the child, to override the medical judgement of a Colorado licensed Physician who is taking care of the child.

The medically and genetically vulnerable deserve to be PROTECTED, not put in harm's way by ill-conceived state regulations.

I urge you to vote against this dangerous bill.

Sincerely,



Katia Meier M.D.
Clear Sky Medical P.C., 9085 E Mineral circle #260, Centennial, CO 80126
Drmeier@clearskymedical.com Office: 303-790-7860

Please try the new PubMed mobile website.

Search term

↓ Full text

Association between MTHFR gene polymorphisms and the risk of autism spectrum disorders: a meta-analysis.

Pu D, et al. Autism Res. 2013.
Show full citation

Abstract

Methylenetetrahydrofolate reductase (MTHFR) is essential for DNA biosynthesis and the epigenetic process of DNA methylation, and its gene polymorphisms have been implicated as risk factors for birth defects, neurological disorders, and cancers. However, reports on the association of MTHFR polymorphisms with autism spectrum disorders (ASD) are inconclusive. Therefore, we investigated the relationship of the MTHFR polymorphisms (C677T and A1298C) and the risk of ASD by meta-analysis. Up to December 2012, eight case-control studies involving 1672 patients with ASD and 6760 controls were included for meta-analysis. The results showed that the C677T polymorphism was associated with significantly increased ASD risk in all the comparison models [T vs. C allele (frequency of allele): odds ratio (OR) = 1.42, 95% confidence interval (CI): 1.09-1.85; CT vs. CC (heterozygote): OR = 1.48, 95% CI: 1.09-2.00; TT vs. CC (homozygote): OR = 1.86, 95% CI: 1.08-3.20; CT+TT vs. CC (dominant model): OR = 1.56, 95% CI: 1.12-2.18; and TT vs. CC+CT (recessive model): OR = 1.51, 95% CI: 1.02-2.22], whereas the A1298C polymorphism was found to be significantly associated with reduced ASD risk but only in a recessive model (CC vs. AA+AC: OR = 0.73, 95% CI: 0.56-0.97). In addition, we stratified the patient population based on whether they were from a country with food fortification of folic acid or not. The meta-analysis showed that the C677T polymorphism was found to be associated with ASD only in children from countries without food fortification. Our study indicated that the MTHFR C677T polymorphism contributes to increased ASD risk, and periconceptional folic acid may reduce ASD risk in those with MTHFR 677C>T polymorphism.

© 2013 International Society for Autism Research, Wiley Periodicals, Inc.

PMID: 23653228 [Indexed for MEDLINE]

Full text

Full text at journal site

Similar articles

MTHFR C677T polymorphism associated with breast cancer susceptibility: a meta-analysis involving 15,260 cases and 20,411 controls.
Zhang J, et al. Breast Cancer Res Treat. 2010.

Methylenetetrahydrofolate reductase polymorphisms and breast cancer risk: a meta-analysis from 41 studies with 16,480 cases and 22,388 controls.
Qi X, et al. Breast Cancer Res Treat. 2010.

Methylenetetrahydrofolate reductase (MTHFR) C677T/A1298C polymorphisms and susceptibility to Parkinson's disease: a meta-analysis.
Review article
Wu YL, et al. J Neurol Sci. 2013.

Meta-analysis of MTHFR C677T and A1298C gene polymorphisms: association with the risk of hepatocellular carcinoma.
Review article
Qi YH, et al. Clin Res Hepatol Gastroenterol. 2014.

Association between methylenetetrahydrofolate reductase C677T polymorphism and epilepsy susceptibility: a meta-analysis.
Wu YL, et al. Seizure. 2014.

See all

Hello Madam Chair and Committee members, my name is Audrey Herman, and I am representing myself and my children. In section 25-4-903 section 2 and 2A states that we must complete a standardized form for exemptions. How can a bill be voted on before one of the most crucial elements is complete? Do we as citizens not have a right to view this standardized form prior to a vote?

What about my children's right to medical privacy? On page 7 line 5 states that our forms must be signed by a representative from the government. That directly violates HIPAA. It goes on to say that we will be provided with a copy to give to our children's schools, which means the original document will stay with the department of public health, they do NOT have a right to medical documentation in this manner. The bill says we can "opt out" of the immunization tracking system, BUT, according to page 7 lines 3 and 4 our information will be stored at these agencies. This is a tracking system in and of itself!

Furthermore, this bill violates FERPA by stating on page 9 lines 25-27 that schools may be required to report statistical information and names of noncompliers (the unvaccinated kids). The only time I see this being lawful is in the event of a health emergency which is in section 99.31(a)(10) and 99.36 of The Family Educational Rights and Privacy Act.

Do we as lawful citizens have the right to not be tracked by the government, especially when it comes to a matter of medical privacy? In the event of an outbreak our children's forms will be pulled and they will be tracked down, discriminated against, and potentially force vaccinated. We don't want to be in ANY tracking system based on vaccine status.

This bill will also impact homeschoolers according to Colorado state law, under "record keeping" it states that "... the records must include (and it lists) immunization records required by CRS section 25-4-901-903".

Homeschoolers have the right to be excluded from the proposed bill entirely. Please remove the standardized form from this bill, exclude homeschoolers from this bill, and change this bill so it doesn't violate our rights to privacy! We all want the same goal, healthy children. But, health looks different to everyone. For me, health looks like being a part time wheelchair user, for you

COLORADO DEPARTMENT *of* EDUCATION

201 East Colfax Avenue • Denver, Colorado 80203-1799
303-866-6600 • www.cde.state.co.us

Robert K. Hammond
Commissioner of Education

Keith Owen, Ph.D.
Deputy Commissioner

Model Notification of Privacy Rights under FERPA, PPRA and Colorado State Law

The Family Educational Rights and Privacy Act (FERPA) requires that schools and districts issue an annual notification to parents and eligible students explaining their rights under FERPA (34 CFR §99.7) to inspect and amend student records and to consent to the disclosure of student records in particular instances. FERPA also requires that schools and districts provide annual notice of their directory information policies (34 CFR §99.37). Additionally, the federal Protection of Pupil Rights Amendment (PPRA), requires schools and districts to provide notice to parents of students who are scheduled to participate in activities involving the collection, disclosure or use of personal information collected from students for marketing purposes and to allow parents the opportunity to opt out of these activities (20 U.S.C. §1232h(c)(2)(C)(i)). Finally, Colorado state law (§22-1-123, C.R.S.) requires that districts provide an annual notice to a parent or legal guardian of each student enrolled in the school district with written notice of the rights contained in that section. The template language below provides a model for meeting all four of these notification requirements.

FERPA Protections:

FERPA affords parents and students who are 18 years of age or older ("eligible students") certain rights with respect to the student's education records. These rights are:

1. The right to inspect and review the student's education records within 45 days after the day the **[Name of school ("School")]** receives a request for access.

   Parents or eligible students should submit a written request to the school **principal [or appropriate school official]** that identifies the records they wish to inspect. The school official will make arrangements for access and notify the parent or eligible student of the time and place where the records may be inspected.

2. The right to request the amendment of a student education records that the parent or eligible student believes are inaccurate, misleading or otherwise in violation of the student's privacy rights under FERPA.

   Parents or eligible students who wish to ask the **[School]** to amend a record should write the school principal **[or appropriate school official]**, clearly identify the part of the record they want changed and specify why it should be changed. If the school decides not to amend the record as requested by the parent or eligible student, the school will notify the parent or eligible student of the decision and of their right to a hearing regarding the request for amendment. Additional information regarding the hearing procedures will be provided to the parent or eligible student when notified of the right to a hearing.

3. The right to provide written consent before the school discloses personally identifiable information (PII) from the student's education records, except to the extent that FERPA authorizes disclosure without consent.

   One exception, which permits disclosure without consent, is disclosure to school officials with legitimate educational interests. A school official is a person employed by the school as an administrator, supervisor, instructor or support staff member (including health or medical staff and law enforcement unit personnel) or a person serving on the school board. A school official may also include a volunteer or contractor outside of the school who performs an institutional service of function for which the school would otherwise use its own employees and who is under the direct control of the school with respect to the use and maintenance of PII from education records, such as an attorney, auditor, medical consultant, or therapist; a

parent or student volunteering to serve on an official committee, such as a disciplinary or grievance committee; or a parent, student, or other volunteer assisting another school official in performing his or her tasks. A school official has a legitimate educational interest if the official needs to review an education record in order to fulfill his or her professional responsibility.

4. The right to file a complaint with the U.S. Department of Education concerning alleged failures by the **[School]** to comply with the requirements of FERPA. The address of the Family Policy Compliance Office that administers FERPA is:

Family Policy Compliance Office
U.S. Department of Education
400 Maryland Avenue, SW
Washington, DC 20202

[Optional] See the list below of the disclosures that elementary and secondary schools may make without consent.

FERPA permits the disclosure of PII from students' education records, without consent of the parent or eligible student, if the disclosure meets certain conditions found in §99.31 of the FERPA regulations. Except for disclosures to school officials, disclosures related to some judicial orders or lawfully issued subpoenas, disclosures of directory information, and disclosures to the parent or eligible student, §99.32 of the FERPA regulations requires the school to record the disclosure. Parents and eligible students have a right to inspect and review the record of disclosures. A school may disclose PII from the education records of a student without obtaining prior written consent of the parents or the eligible student under the following circumstances:

- To other school officials, including teachers, within the educational agency or institution whom the school has determined to have legitimate educational interests. This includes contractors, consultants, volunteers, or other parties to whom the school has outsourced institutional services or functions, provided that the conditions listed in §99.31(a)(1)(i)(B)(*1*) - (a)(1)(i)(B)(*2*) are met. (§99.31(a)(1))

- To officials of another school, school system, or institution of postsecondary education where the student seeks or intends to enroll, or where the student is already enrolled if the disclosure is for purposes related to the student's enrollment or transfer, subject to the requirements of §99.34. (§99.31(a)(2)) **[NOTE: FERPA requires a school district to make a reasonable attempt to notify the parent or student of the records request unless it states in its annual notification that it intends to forward records on request.]**

- To authorized representatives of the U. S. Comptroller General, the U. S. Attorney General, the U.S. Secretary of Education, or State and local educational authorities, such as the Colorado Department of Education. Disclosures under this provision may be made, subject to the requirements of §99.35, in connection with an audit or evaluation of Federal- or State-supported education programs, or for the enforcement of or compliance with Federal legal requirements that relate to those programs. These entities may make further disclosures of PII to outside entities that are designated by them as their authorized representatives to conduct any audit, evaluation, or enforcement or compliance activity on their behalf. (§§99.31(a)(3) and 99.35). Please note that the district does not provide any information to the Colorado Department of Education other than what is required by federal or state law or required to receive a benefit, such as competitive grant funding. This information is provided in order for the state to monitor the effectiveness of educational programs, diagnose areas of need, and inform improvement efforts.

- In connection with financial aid for which the student has applied or which the student has received, if the information is necessary to determine eligibility for the aid, determine the amount of the aid, determine the conditions of the aid, or enforce the terms and conditions of the aid. (§99.31(a)(4))

- To State and local officials or authorities to whom information is specifically allowed to be reported or disclosed by a State statute that concerns the juvenile justice system and the system's ability to effectively serve, prior to adjudication, the student whose records were released, subject to §99.38. (§99.31(a)(5))

- To organizations conducting studies for, or on behalf of, the school, in order to: (a) develop, validate, or administer predictive tests; (b) administer student aid programs; or (c) improve instruction. (§99.31(a)(6))

- To accrediting organizations to carry out their accrediting functions. (§99.31(a)(7))
- To parents of an eligible student if the student is a dependent for IRS tax purposes. (§99.31(a)(8))
- To comply with a judicial order or lawfully issued subpoena. (§99.31(a)(9))
- To appropriate officials in connection with a health or safety emergency, subject to §99.36. (§99.31(a)(10)
- Information the school has designated as "directory information" under §99.37. (§99.31(a)(11))

[NOTE: In addition, a school may want to include its directory information public notice, as required by FERPA §99.37, with its annual notification of privacy rights. Please see the Model Directory Information Public Notice below.]

While FERPA requires that **[School District]**, with certain exceptions, obtain your written consent prior to the disclosure of personally identifiable information from your child's education records, **[School District]** may disclose appropriately designated "directory information" without written consent, unless you have advised the district to the contrary in accordance with district procedures. The primary purpose of directory information is to allow the **[School District]** to include this type of information from your child's education records in certain school publications. Examples include:

- A playbill, showing your student's role in a drama production;
- The annual yearbook;
- Honor roll or other recognition lists;
- Graduation programs; and
- Sports activity sheets, such as for wrestling, showing weight and height of team members.

Directory information, which is information that is generally not considered harmful or an invasion of privacy if released, can also be disclosed to outside organizations without a parent's prior written consent. Outside organizations include, but are not limited to, companies that manufacture class rings or publish yearbooks. In addition, two federal laws require local educational agencies (LEAs) receiving assistance under the *Elementary and Secondary Education Act of 1965* (ESEA) to provide military recruiters, upon request, with the following information – names, addresses and telephone listings – unless parents have advised the LEA that they do not want their student's information disclosed without their prior written consent.

If you do not want **[School District]** to disclose directory information from your child's education records without your prior written consent, you must notify the District in writing by **[insert date]**. **[School District]** has designated the following information as directory information: **[Note: an LEA may, but does not have to, include all the information listed below.]**

-Student's name -Address -Telephone listing -Electronic mail address - Photograph -Date and place of birth -Major field of study -Dates of attendance -Grade level	-Participation in officially recognized activities and sports -Weight and height of members of athletic teams -Degrees, honors and awards received -The most recent educational agency or institution attended -Student ID number, user ID, or other unique identifier used to communicate in electronic systems that cannot be used to access education records without a PIN, password, etc. (A student's SSN, in whole or in part, cannot be used for this purpose)

PPRA Protections:

The federal Protection of Pupil Rights Amendment (PPRA) affords parents certain rights regarding our

conduct of surveys, collection and use of information for marketing purposes, and certain physical exams. These include the right to:

* *Consent* before students are required to submit to a survey that concerns one or more of the following protected areas ("protected information survey") if the survey is funded in whole or in part by a program of the U.S. Department of Education (ED)–
    1. Political affiliations or beliefs of the student or student's parent;
    2. Mental or psychological problems of the student or student's family;
    3. Sex behavior or attitudes;
    4. Illegal, anti-social, self-incriminating or demeaning behavior;
    5. Critical appraisals of others with whom respondents have close family relationships;
    6. Legally recognized privileged relationships, such as with lawyers, doctors or ministers;
    7. Religious practices, affiliations or beliefs of the student or parents; or
    8. Income, other than as required by law to determine program eligibility.

* *Receive notice and an opportunity to opt a student out of*–
    1. Any other protected information survey, regardless of funding;
    2. Any non-emergency, invasive physical exam or screening required as a condition of attendance, administered by the school or its agent, and not necessary to protect the immediate health and safety of a student, except for hearing, vision, or scoliosis screenings, or any physical exam or screening permitted or required under State law; and
    3. Activities involving collection, disclosure, or use of personal information obtained from students for marketing or to sell or otherwise distribute the information to others.

* *Inspect*, upon request and before administration or use –
    1. Protected information surveys of students;
    2. Instruments used to collect personal information from students for any of the above marketing, sales or other distribution purposes; and
    3. Instructional material used as part of the educational curriculum.

These rights transfer from the parents to a student who is 18 years old or an emancipated minor under State law.

[School District will/has develop[ed] and adopt[ed]] policies, in consultation with parents, regarding these rights, as well as arrangements to protect student privacy in the administration of protected information surveys and the collection, disclosure, or use of personal information for marketing, sales, or other distribution purposes. **[School District]** will directly notify parents of these policies at least annually at the start of each school year and after any substantive changes. **[School District]** will also directly notify, such as through U.S. Mail or email, parents of students who are scheduled to participate in the specific activities or surveys noted below and will provide an opportunity for the parent to opt his or her child out of participation of the specific activity or survey. **[School District]** will make this notification to parents at the beginning of the school year if the District has identified the specific or approximate dates of the activities or surveys at that time. For surveys and activities scheduled after the school year starts, parents will be provided reasonable notification of the planned activities and surveys listed below and provided an opportunity to opt their child out of such activities and surveys. Parents will also be provided an opportunity to review any pertinent surveys. Following is a list of the specific activities and surveys covered under this requirement:

* Collection, disclosure, or use of personal information for marketing, sales, or other distribution;
* Administration of any protected information survey not funded in whole or in part by ED; and
* Any non-emergency, invasive physical examination or screening as described above.

Parents who believe their rights have been violated may file a complaint with:

Family Policy Compliance Office

U.S. Department of Education

400 Maryland Avenue, SW

Washington, D.C. 20202

State Law Protections:

Colorado's state law also provides additional rights with respect to the collection of student information in any public school, regardless of whether or not the public school receives federal funding. Pursuant to §22-1-123, C.R.S., a school or district employee who requires participation in a survey, assessment, analysis or evaluation in a public school's curriculum or other official school activity must obtain the written consent of a student's parent or legal guardian before giving the student any survey, assessment, analysis or evaluation intended to reveal information, whether the information is personally identifiable or not, concerning the student or the student's or legal guardian's:

- Political affiliations;
- Mental and psychological conditions potentially embarrassing to the student or the student's family;
- Sexual behavior and attitudes;
- Illegal, anti-social, self-incriminating or demeaning behavior;
- Critical appraisals of individuals with whom a student has close family relationships;
- Legally recognized privileged or analogous relationships, such as those of lawyers, physicians and members of the clergy;
- Income, except as required by law;
- Social security number; or
- Religious practices, affiliations, or beliefs.

Please note that the requirement of written consent does not apply to a student's participation in statewide assessments. For gathering the type of information listed above, written consent will be valid only if the school district has given a parent or legal guardian written notice of the survey, assessment, analysis or evaluation, has made a copy of the document available for viewing at convenient locations and times, and has given the parent or legal guardian at least two weeks, after receipt of the written notice, to obtain written information concerning the collection.

Home School in Colorado

Nonpublic Home School Programs

Getting Started-Letter of Intent to Home School

Pursuant to Colorado law, parents who wish to begin home schooling must provide written notification of the establishment of the home school program **14 days** before beginning the home school program to a Colorado school district. The written notification must include the name, age, place of residence, and number of attendance hours for each child that will be participating in the home school program. Written notification must be re-submitted to a Colorado school district each year.

Subjects to Teach

Colorado law states that home school programs must include, but are not limited to, the subjects of communication skills of reading, writing, and speaking, mathematics, history, civics, literature, science, and regular courses of instruction in the constitution of the United States. The selection of curriculum is at the discretion of the parent who is overseeing the home schooling program. The state cannot offer any guidance in this area, and encourages contacting the district that received the written notification if there are further questions.

Attendance Requirements

Home school programs must have no less than 172 days of instruction, averaging 4 contact hours per day.

Record Keeping

Records for each child participating in a home school program must be kept on a permanent basis by the parent who is overseeing the home school program. The records must include, but are not limited to, attendance, test and evaluation results, and immunization records as required by C.R.S sections 25-4-901, 25-4-902, and 25-4-903. The records must be produced and provided to the school district that received the written notification, not the state of Colorado, at the school district's request.

Assessment/Evaluation

Students that are participating in a home school program must have academic progress evaluated in grades 3, 5, 7, 9, and 11. Students can take a nationally standardized achievement test or a qualified person, as described in C.R.S. 22-33-104.5(3)(f), can be selected by the parent to evaluate the student's academic progress. The results of the evaluation, whether by assessment or qualified person, must be submitted to the school district that received the written notification.

The state cannot provide guidance regarding assessments or evaluation. Please contact your local school district for resources or specific deadlines for submitting evaluation results.

Other Things to Know About Home School

Home school is considered nonpublic and is not regulated by the state of Colorado. The parent who oversees the home school program is taking on the responsibility of obtaining books, supplies, tests, and is responsible for any costs associated. Because home schooling is considered nonpublic education, home school is not accredited by the Colorado Department of Education or by a local school district.

Additional Resources

The links below include a copy of Colorado Home School Law, how to get started home schooling your child, and a resources link to home school organizations that provide information on networking, support groups, curricula, and testing.

- FAQs Regarding Home School
- Laws Pertaining to Home School
- Home School Resources

Home school inquires:
303-866-2818
Home_School@cde.state.co.us

Like 34

Good Afternoon,

Madam Chair Lontine and members of the committee, thank you for this opportunity. My name is Matt Baylor, I am here representing myself and my family and I oppose HB19-1312. As a Colorado parent I am concerned about student privacy. In order to have healthy kids and a healthy community we must protect our kids' privacy.

Our expectation of privacy has been codified in two different laws: FERPA and HIPAA. The Family Educational Rights and Privacy Act (FERPA) was enacted to protect students' personally identifiable information. The Health Insurance Portability and Accountability Act (HIPAA) defines and protects personal health information.

HB19-1312 causes great concern with both of these privacy protections. I will address them in the order they appear in the bill.

On page 6, line 10, this bill suggests medical providers offer information about opting-out of the immunization tracking system. In order to guard the spirit of HIPAA, participation in the immunization tracking system should be opt-in, not opt-out. I urge you to amend HB19-1312 to make the tracking system opt-in or oppose this legislation.

Simultaneously, on page 6, lines 12-13, it directs the provider to submit the medical exemption to the immunization tracking system. I ask that you clarify the language of HB19-1312 so that it is clear that parent and students control their data.

HB19-1312 on page 6, line 24 through page 7, line 19, requires students and their parents to disclose FERPA protected information in order to apply for the religious or personal belief exemption. FERPA already provides for the release of personally identifiable information in the event of a significant threat to the health and safety of our students. There is no need to disclose this information to any other agency since, according to FERPA, it is already readily available. I ask you to remove this requirement from HB19-1312 in order to continue the privacy protections afforded by FERPA.

Additionally, students and parents seeking a religious or personal belief exemption must opt-out of the immunization tracking system. To honor the privacy of health information as defined by HIPAA, HB19-1312's tracking system should be opt-in rather than opt-out.

HB19-1312 causes serious concerns for information protected by both HIPAA and FERPA. I urge you to either amend this bill so that it conforms to the privacy expectations codified in FERPA and HIPAA or oppose this bill in committee so that we ensure Colorado families have the assurance of privacy. We all have the same goal: healthy kids and a healthy community. Thank you for your time today.

I am a mum of four children living in Douglas County. I oppose this bill because it is fueled by fabricated data and false statements, Not only will it not prevent infectious disease outbreaks, but this bill will put an increasing number of vaccine vulnerable children at risk due to removal of the right of the medical practitioner to make an autonomous assessment of a child's need for a medical exemption (Pg 8 section 3).

There's been one death in the US from measles in the last 15 years. However, in 2018, the Vaers reporting system shows 443 deaths from vaccinations, 619 life threatening conditions, 1,267 permanent disabilities and 4,414 individuals hospitalized. The CDC's own internal review on Vaers identified that the Vaers system was capturing less than 1% of vaccine injuries.

I would also like to address statement in 1(a)

It is not possible to state the number of lives saved by vaccines! This statement assumes that everyone who is vaccinated does not contract an infectious disease, which we know is not the case.

Studies of measles outbreaks in Quebec, Canada, and China attest that **outbreaks of measles still happen, even when vaccination compliance is in the highest bracket** (95- 99%) (Appendix 1.) This is due to primary vaccine failure (Low Vaccine responders) (Appendix 3.) and secondary vaccine failure, where vaccine antibodies wane over time.

An experiment with deliberate pertussis infection in primates revealed that the Pertussis vaccine (DTAP) is not capable of preventing colonization and transmission of B. pertussis. The FDA has issued a warning regarding this crucial finding. (Appendix 2.)

As we know there is currently a Navel ship in quarantine due to a mumps outbreak in its fully vaccinated sailors and Marines.

With regards to costs; A study carried out by Mawson et al (2017) found that vaccinated children were 4 times more likely than the unvaccinated to be diagnosed with neuro - developmental disorders, 30 times more likely to be diagnosed with an immune-related disorder such as allergies, eczema and asthma, and 6 times more likely to get inner ear infections and pneumonia.

In 2017/18 it cost the taxpayer $508,725,204 to compensate for vaccine injury claims in the US (HRSA data). This does not include the ongoing healthcare costs of vaccine injury.

When you consider that our school age immunization rate is currently at 94%, the highest it's been for over 15 years, and that increasing vaccination rates above this will not prevent disease outbreaks, there IS NO NEED for this bill.

PLEASE VOTE NO TO THIS BILL

Appendix

1. http://webarchive.nationalarchives.gov.uk/20140714084352/http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1242198450982

2. http://www.ncbi.nlm.nih.gov/pubmed/24277828

3. http://www.cdc.gov/maso/facm/pdfs/BSCOID/ 2013121112_BSCOID_Minutes.pdf

4. Mawson et al 2017
Pilot comparative study on the health of ... - Open Access Texthttps://www.oatext.com/pdf/JTS-3-186.pdf

KINDERGARTEN THROUGH 12TH GRADE IMMUNIZATION CHART
REQUIRED VACCINES FOR SCHOOL ATTENDANCE 2018-19

VACCINE	Number of Doses	Grades K-12 (4-18 Years of Age)
	Vaccines must follow MINIMUM INTERVALS & AGES to be valid. A 4 day grace period applies in most situations.	
Diphtheria/Tetanus/ Pertussis (DTaP) *Only licensed through 6 yrs of age.*	4 to 5	5 DTaP unless dose 4 given is given on or after the 4th b-day. Final dose of DTaP given no sooner than 4 years of age.
Tetanus/Diphtheria/ Pertussis *For students 7 years of age or older who did not have a full series of DTaP.*	3 or 4	3 doses tetanus/diphtheria containing vaccines (DTaP, DT,Td, Tdap) is required, or 4 doses required if 1st dose of DTaP is given before 1 year of age. 1 dose of Tdap given if DTaP series not completed and student is at least 7 yrs of age. **Tdap is required at 6th grade entry through 12th grade.**
Polio (IPV) *With combination of OPV & IPV, need series of 4 doses*	3 to 4	4 IPV unless 3rd dose is given on or after 4th birthday. Students who were compliant with 3 or 4 doses (4 weeks minimum intervals between doses) prior to August 7, 2009 have met the requirement.
Measles/Mumps/Rubella (MMR) *There must be at least a 28 day interval between 2 live vaccines.*	2	The 1st dose is not valid if administered more that 4 days before the 1st birthday. 2 doses are required for students entering Kindergarten & through 12th grade.
Varicella (Chickenpox) *There must be at least a 28 day interval between 2 live vaccines.*	2	The 1st dose is not valid if administered more that 4 days before the 1st birthday. 2 doses are required for students entering Kindergarten & through 12th grade. ***Note:*** *no vaccine required if there is laboratory documentation of chickenpox disease or a disease screening performed by a health care provider.*
Hepatitis B *Dosing must follow minimum intervals between doses and last dose must be administered at or over 24 wks of age.*	3	The 2nd dose administered at least 4 weeks after the first dose. The 3rd dose must be administered at least 16 weeks after the 1st dose, at least 8 weeks after the 2nd dose, and the final dose must be administered no sooner than 24 weeks of age. *Note: there is a specific 2-dose series is for ages 11-15 years only using adult vaccine.*

RECOMMENDED VACCINES FOR THE BEST PROTECTION AGAINST VACCINE-PREVENTABLE DISEASE

VACCINE	Number of Doses	Grades K-12 (4-18 Years of Age) *Vaccines administered ≤ 4 days before the minimum age are valid*
Influenza (Flu)	1 to 2	2 doses initially if under 9 yrs of age with a minimum interval of 28 days between doses, then 1 dose annually, thereafter. (Recommended for all children 6 months of age and older).
Meningococcal Meningitis		
MenACWY	2 doses	Adolescents 11-18 years of age (11-12, 16-18)
MenB	Series	Adolescents 16-18 years of age
Human Papillomavirus (9vHPV)	2 to 3	Adolescents 11-18 years of age Series initiation age 9-14 - two doses 6-12 mo apart Series initiation 15+ - three doses 0, 1-2 and 6 mo
Hepatitis A (Hep A)	2	All children 1 year of age and older

Immunization requirements are strictly enforced for all students. Students who do not meet the requirements will be denied attendance according to Section 25-4-902, C.R.S. There are three ways to be in compliance with the school immunization law:

1. Student's immunization record shows they are fully immunized with required vaccines. A laboratory report for some vaccines or diseases showing immunity is also acceptable.

2. For the student who is not up to date on required vaccines, the school will notify the parent/guardian that the student has 14 days to receive the required vaccine(s) or to make an appointment to receive the required vaccine(s). Parents are to provide a written plan for the remaining vaccines following the minimum intervals of the Advisory Committee on Immunization Practices (ACIP) schedule. If the plan is not followed, the student shall be excluded from school for non-compliance.

3. Submission of a Medical Exemption form signed by a health care provider or a Non-Medical exemption (religious or personal) submitted by a parent/guardian or emancipated student go to www.colorado.gov/vaccinexemption.

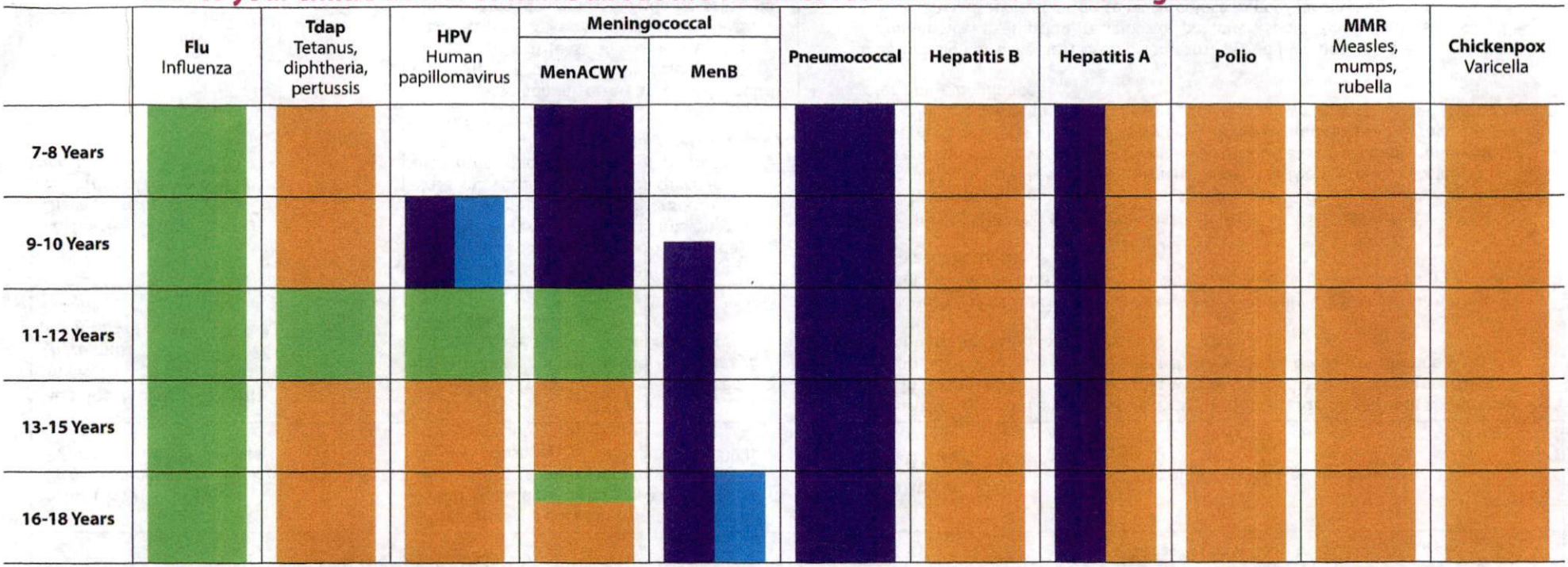
Last Reviewed January 2018

COLORADO
Department of Public Health & Environment

INFORMATION FOR PARENTS

2019 Recommended Immunizations for Children 7–18 Years Old

Talk to your child's doctor or nurse about the vaccines recommended for their age.



More information:	Everyone 6 months and older should get a flu vaccine every year.	All 11- through 12-year olds should get one shot of Tdap.	All 11- through 12-year olds should get a 2-shot series of HPV vaccine. A 3-shot series is needed for those with weakened immune systems and those who start the series at 15 years or older.	All 11- through 12-year olds should get one shot of meningococcal conjugate (MenACWY). A booster shot is recommended at age 16.	Teens 16–18 years old **may** be vaccinated with a serogroup B meningococcal (MenB) vaccine.

These shaded boxes indicate when the vaccine is recommended for all children unless your doctor tells you that your child cannot safely receive the vaccine.

These shaded boxes indicate the vaccine should be given if a child is catching up on missed vaccines.

These shaded boxes indicate the vaccine is recommended for children with certain health or lifestyle conditions that put them at an increased risk for serious diseases. See vaccine-specific recommendations at www.cdc.gov/vaccines/hcp/acip-recs/.

This shaded box indicates children not at increased risk may get the vaccine if they wish after speaking to a provider.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

AAFP
AMERICAN ACADEMY OF FAMILY PHYSICIANS

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

CHILDREN'S HOSPITAL ASSOCIATION

Colorado Medicaid Highlights

- **Number of children covered:** Medicaid provides health insurance for 406,000 low-income children in Colorado. Children make up 58.8 percent of Colorado's Medicaid population.[iv]
- **Cost of Medicaid-eligible children:** Each Medicaid-eligible child costs Colorado just $2,558 per year, on average, compared to average costs per adult Medicaid enrollee of $4,823.[iv]
- **Number of eligible but unenrolled children:** An estimated 52,000 – or 4.2 percent – of Colorado's children under 18 are uninsured.[v] Nationally, 89.8 percent of uninsured children are eligible for Medicaid or CHIP but not enrolled.[vi]
- **Federal funding for Colorado:** Colorado will lose $1.00 in federal matching funds for every $1.00 in state money it cuts from its Medicaid budget.[vii]
- **Medicaid family income levels:** For families of four in Colorado, children are eligible for Medicaid with family income up to $35,721.[viii]

Why are pediatricians important to children on Medicaid?

Nationally, pediatricians provide a majority of all office visits for children 0-5 (80 percent) and for children 0-18 (69 percent) enrolled in Medicaid.[ix] They provide the care children need, including routine check-ups, immunizations and treatment for problems found during health screenings.

Children depend on Medicaid to work well and pediatricians depend on Medicaid so that they can continue to ensure that every child has access to the care they need, regardless of income.

Unfortunately, low Medicaid payment rates place an unfair burden on children's providers, which can threaten children's access to quality health care. As an historical average, a pediatrician treating a child enrolled in Medicaid receives only 66 percent of what is paid to see a Medicare enrollee.[x] For many services and in many states, payment can be even lower. Without appropriate payments that cover the cost of care, fewer physicians may be able to participate in Medicaid, limiting the number of pediatricians who can treat children, increasing wait times for appointments or forcing families to travel long distances to seek care.

Why are children's hospitals important to children on Medicaid?

Children's hospitals save lives every day, regardless of a child's family income or health insurance coverage. Children's hospitals are major Medicaid providers, and the nation must ensure a strong Medicaid program so children are able to receive timely, quality health care. Medicaid reforms that lead to better care and lower costs while maintaining standards children rely upon are possible; children's hospitals are working with their states to advance these innovative solutions.

- Comprising less than 5 percent of the nation's hospitals, children's hospitals account for about 35 percent of all hospital days for children on Medicaid and 53 percent for children with medically complex conditions.[xi, xii]
- On average, each children's hospital devotes more than half its inpatient care (59 percent of inpatient days) to children assisted by Medicaid.[xiii]
- On average, Medicaid reimburses children's hospitals only 80 percent of the cost of care provided, including Disproportionate Share Hospital payments. If cuts or caps are adopted at the federal or state level, payment rates could decrease further.[xiii]

Why do children on Medicaid need your help?

- Preserving a strong Medicaid program is essential to ensuring all children have coverage and access to care, but Medicaid faces serious financial threats that endanger the health of Colorado's children.
- Appropriate provider payment for care is essential to ensuring that Medicaid patients have access to the providers they need. Already, Medicaid pays providers on average only 66 percent of what the Medicare program pays for those same services.[x] Cuts to the Medicaid program could further decrease provider payments, making it harder for beneficiaries to access care.
- If Medicaid funding is cut or capped, it could mean a loss of federal funds for states and an increase in the number of uninsured children since the federal government pays at least 50 percent of the total cost of Colorado's Medicaid program.[xiv] States would be left to pay more for health care services.

Sources

i Congressional Budget Office, "Detail of Spending and Enrollment for Medicaid for CBO's March 2016 Baseline," March 2016.
ii National Survey of Children with Special Health Care Needs, 2011/12.
iii SHADAC analysis of the 2015 American Community Survey (ACS) Public Use Microdata Sample (PUMS) files. Retrieved 2016.
iv Medicaid and CHIP Payment and Access Commission, "MACStats: Medicaid and CHIP Data Book," Dec. 2015.
v United States Census Bureau, "Health Insurance Status and Coverage by State – Children Under 18," 2008-2015 American Community Survey. Retrieved 2016.
vi American Academy of Pediatrics Analysis of United States Census Bureau, "Health Insurance Status and Coverage by State – Children Under 18," 2008-2015 American Community Survey.
vii American Academy of Pediatrics Analysis of Office of the Assistant Secretary for Planning and Evaluation, "ASPE FMAP 2017 Report," Jan. 2016.
viii American Academy of Pediatrics Analysis of the Henry J. Kaiser Family Foundation, "Medicaid Income Eligibility Limits for Children Ages 0-18, 2000-2016," Retrieved 2016.
ix National Ambulatory Medical Care Survey, 2012/13.
x Zuckerman, Skopec, and McCormack, "Reversing the Medicaid Fee Bump: How Much Could Medicaid Physician Fees for Primary Care Fall in 2015?" Dec. 2014.
xi Children's Hospital Association Analysis of American Hospital Association Database, 2014.
xii Children's Hospital Association Analysis of Kids' Inpatient Database (KID), Healthcare Cost and Utilization Project (HCUP). Agency for Healthcare Research and Quality, 2009.
xiii Children's Hospital Association Annual Benchmark Report, 2015.
xiv Office of the Assistant Secretary for Planning and Evaluation, "ASPE FMAP 2017 Report," Jan. 2016.

Unless otherwise noted, data referenced in this document refer to Medicaid only and non-disabled children younger than age 19.

WHAT YOU NEED TO KNOW

COLORADO BILL HB19-1312

WHERE THERE'S RISK THERE MUST BE

CHOICE

LIMITS MEDICAL EXEMPTIONS

PROPOSED: COLORADO WOULD ADOPT CDC/ACIP MEDICAL EXEMPTION GUIDELINES

- This would eliminate a doctor's authority to exercise judgement in **preventing** serious adverse events in the case that red flags raise concern **prior** to vaccination.
- Medical exemption would only be available **following** a serious adverse event, and the exemption given, would only be valid for the vaccination that **caused** initial reaction

REMOVES STATE BOARD AUTHORITY

PROPOSED: COLORADO WOULD ADOPT CDC/ACIP VACCINE SCHEDULE

- Colorado would forfeit authority over it's residents and adopt the CDC schedule with no room to contest it's schedule.
- **Upon passage of this bill, more mandatory vaccines would be added; including the HPV and flu vaccine.**
- As the CDC expands the vaccine schedule, Colorado would follow suit.

THREATENS HIPAA & FERPA RIGHTS

PROPOSED: COLORADO WOULD ADOPT STANDARDIZED FORMS, FORCED "EDUCATION" AND A TRACKING SYSTEM

- A form (not yet released) would be required for exemption, possibly implicating parents of endangering a child by refusing a vaccination hypothesized as "safe".
- The mandatory vaccine "education" proposal is biased and does **not** include addressing the possible serious adverse events a child may experience.
- HB19-1312 allows the health department to track exemptions instead of the school, allowing them to circumvent FERPA. This gives access to a child's health record that would otherwise be protected.

ONLY ALLOWED CONTRAINDICATIONS WITH PROPOSAL

DTAP	MMR	HEP B
• SEVERE ANAPHYLAXIS • ENCEPHALOPATHY (ONLY IF OCCURRENCE WITHIN 7 DAYS OF PREVIOUS DTAP DOSE)	• SEVERE ANAPHYLAXIS • SEVERE IMMUNODEFICIENCY	• SEVERE ANAPHYLAXIS

(SOME OF THE) POSSIBLE INELIGIBLE SERIOUS ADVERSE EVENTS

- PANNICULITIS
- ATYPICAL MEASLES
- MEASLES-LIKE RASH
- FEVER
- SYNCOPE
- DIZZINESS
- VASCULITIS
- PANCREATITIS
- POLYNEURITIS
- POLYNEUROPATHY
- OCULAR PALSIES
- DIARRHEA
- VOMITING
- PAROTITIS
- DIABETES MELLITUS
- ASEPTIC MENINGITIS
- PNEUMONIA
- RETROBULBAR NEURITIS
- OTITIS MEDIA
- ORCHITIS
- PARESTHESIA
- EPIDIDYMITIS
- THROMBOCYTOPENIA
- PURPURA
- LEUKOCYTOSIS
- CHRONIC ARTHRITIS
- ARTHRALGIA
- MYALGIA
- ENCEPHALITIS
- RETINITIS
- NERVE DEAFNESS
- CONJUNCTIVITIS
- ACUTE DISSEMINATED ENCEPHALOMYELITIS (ADEM)
- MEASLES INCLUSION BODY ENCEPHALITIS (MIBE)
- STEVENS-JOHNSON SYNDROME
- TRANSVERSE MYELITIS FEBRILE CONVULSIONS ATAXIA
- SUBACUTE SCLEROSING PANENCEPHALITIS (SSPE)
- GUILLAIN-BARRÉ SYNDROME (GBS)
- REGIONAL LYMPHADENOPATHY
- OPTIC NEURITIS
- PAPILLITIS
- DEATH

HTTPS://WWW.MERCK.COM/PRODUCT/USA/PI_CIRCULARS/M/MMR_II/MMR_II_PI.PDF

THIS MEANS THAT EVEN IF YOUR CHILD EXPERIENCES SERIOUS ADVERSE REACTIONS, UNLESS IT'S "ALLOWED" THEY WILL BE REQUIRED TO CONTINUE RECEIVING THE SAME SHOT.

86R13084 JG-F

By: Hall S.B. No. 2350

A BILL TO BE ENTITLED
AN ACT

relating to the prohibited administration of certain vaccinations.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter A, Chapter 161, Health and Safety Code, is amended by adding Section 161.0045 to read as follows:

Sec. 161.0045. ADMINISTRATION OF CERTAIN VACCINES PROHIBITED. A health care provider may administer a vaccine only if:

(1) the study relied on by the United States Food and Drug Administration for approval of the vaccine evaluated the safety of the vaccine against a control group that received:

(A) a placebo; or

(B) another vaccine or other substance approved by the United States Food and Drug Administration based on a study that evaluated the safety of that vaccine or substance against a control group that received a placebo for that study;

(2) the study relied on by the United States Food and Drug Administration for approval of the vaccine evaluated the safety of the vaccine for a sufficient time to identify potential autoimmune, neurological, or chronic health conditions that may arise on or after the first anniversary of the date the vaccine is administered;

(3) the vaccine has been evaluated for the vaccine's potential to:

(A) cause cancer;

(B) mutate genes;

(C) affect fertility or cause infertility; and

(D) cause autism spectrum disorder;

(4) the department has posted on the department's Internet website a disclosure of any known injuries or diseases caused by the vaccine and the rate at which the injuries or diseases have occurred; and

(5) the chemical, pharmacological, therapeutic, and adverse effects of the vaccine and the rate of injury of the vaccine when administered with other vaccines have been studied and verified.

SECTION 2. This Act takes effect September 1, 2019.

A BILL TO BE ENTITLED

AN ACT

relating to the prohibited administration of certain vaccinations.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter A, Chapter 161, Health and Safety Code, is amended by adding Section 161.0045 to read as follows:

Sec. 161.0045. ADMINISTRATION OF CERTAIN VACCINES PROHIBITED. A health care provider may administer a vaccine only if:

(1) the study relied on by the United States Food and Drug Administration for approval of the vaccine evaluated the safety of the vaccine against a control group that received:

(A) a placebo; or

(B) another vaccine or other substance approved by the United States Food and Drug Administration based on a study that evaluated the safety of that vaccine or substance against a control group that received a placebo for that study;

(2) the study relied on by the United States Food and Drug Administration for approval of the vaccine evaluated the safety of the vaccine for a sufficient time to identify potential autoimmune, neurological, or chronic health conditions that may arise in or after the first anniversary of the date the vaccine is administered;

(3) the vaccine has been evaluated for the vaccine's potential to:

(A) cause cancer;

(B) mutate genes;

(C) affect fertility or cause infertility; and

(D) cause amniotic aneurysm disorders;

(4) the department has posted on the department's Internet website a disclosure of any known injuries or diseases caused by the vaccine and the rate at which the injuries or diseases have occurred; and

(5) the chemical, pharmacological, therapeutic, and adverse effects of the vaccine and the rate of injury of the vaccine when administered with other vaccines have been studied and verified.

SECTION 2. This Act takes effect September 1, 2019.

U.S. Department of Education

Print ✖ Close Window

Family Educational Rights and Privacy Act (FERPA)

Get the Latest on FERPA at https://studentprivacy.ed.gov/ (https://studentprivacy.ed.gov/?src=fpco)

- **Frequently Asked Questions (https://studentprivacy.ed.gov/frequently-asked-questions)**
- FERPA for **parents and students (https://studentprivacy.ed.gov/audience/parents-and-students)**, **K12 school officials (https://studentprivacy.ed.gov/audience/school-officials-k-12)** and **Postsecondary school officials (https://studentprivacy.ed.gov/audience/school-officials-post-secondary)**
- Protection of Pupil Rights Amendment (**PPRA**) (https://studentprivacy.ed.gov/search/node/ppra)
- **Guidance and Notices** (https://studentprivacy.ed.gov/resources)

Family Policy Compliance Office (FPCO) Home (/policy/gen/guid/fpco/index.html)

The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when he or she reaches the age of 18 or attends a school beyond the high school level. Students to whom the rights have transferred are "eligible students."

- Parents or eligible students have the right to inspect and review the student's education records maintained by the school. Schools are not required to provide copies of records unless, for reasons such as great distance, it is impossible for parents or eligible students to review the records. Schools may charge a fee for copies.
- Parents or eligible students have the right to request that a school correct records which they believe to be inaccurate or misleading. If the school decides not to amend the record, the parent or eligible student then has the right to a formal hearing. After the hearing, if the school still decides not to amend the record, the parent or eligible student has the right to place a statement with the record setting forth his or her view about the contested information.
- Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 99.31):
  - School officials with legitimate educational interest;
  - Other schools to which a student is transferring;
  - Specified officials for audit or evaluation purposes;
  - Appropriate parties in connection with financial aid to a student;
  - Organizations conducting certain studies for or on behalf of the school;
  - Accrediting organizations;
  - To comply with a judicial order or lawfully issued subpoena;
  - Appropriate officials in cases of health and safety emergencies; and
  - State and local authorities, within a juvenile justice system, pursuant to specific State law.

Schools may disclose, without consent, "directory" information such as a student's name, address, telephone number, date and place of birth, honors and awards, and dates of attendance. However, schools must tell parents and eligible students about directory information and allow parents and eligible students a reasonable amount of time to request that the school not disclose directory information about them. Schools must notify parents and eligible students annually of their rights under FERPA. The actual means of notification (special letter, inclusion in a PTA bulletin, student handbook, or newspaper article) is left to the discretion of each school.

For additional information, you may call 1-800-USA-LEARN (1-800-872-5327) (voice). Individuals who use TDD may use the Federal Relay Service (/about/contacts/gen/index.html#frs).

Or you may contact us at the following address:

Family Policy Compliance Office
U.S. Department of Education
400 Maryland Avenue, SW
Washington, D.C. 20202-8520

Print ✖ Close Window

Last Modified: 03/01/2018

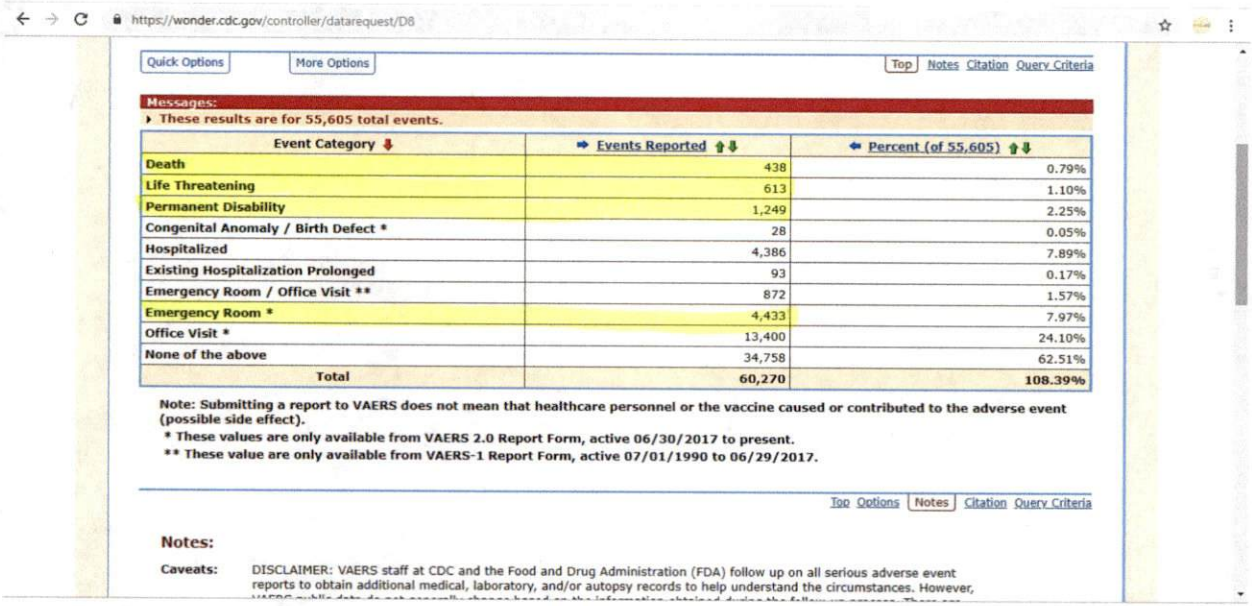
HB19 – 1312 Testimony

Thank you, Madame Chair and Representatives. My name is Katy LeVasseur and I'm representing myself, my two kids, and my husband. I oppose and ask that you vote no to HB19 – 1312. I have been one of many who have been emailing and calling you all. What is being heard over and over is that this bill is very benign, it doesn't take any of the exemptions away, it won't come between the doctor/patient relationship, and that all the bill is trying to do is formalize the exemption process with the goal of increasing vaccination rates in Colorado. Ultimately, those who oppose this bill and those who support this bill actually have the same goal in mind: The health and safety of Colorado children.

However, for my family, being fully vaccinated does not equal health and safety. My kids had all their vaccines by kindergarten. Not too long after that, my daughter was diagnosed with Type 1 diabetes, a life-threatening autoimmune disease that she will have for the rest of her life. Type 1 is listed as an adverse effect on the insert of the MMR. Maybe this is the reason my daughter developed Type 1, maybe not. Regardless, she is immunocompromised, and her brother is obviously a sibling of someone with 'immune system problems' as the CDC mentions in a list of those who shouldn't receive certain vaccines. The availability of a medical exemption moving forward is extremely important to my family.

The bill summary on page two states that the state board of health is required to adopt the medical exemption and immunization recommendations of the CDC and ACIP, AND the state board of health may add to the immunization schedule as they see fit. So I ask this.....if with this bill there is no threat to medical exemptions staying between doctor and patient, then why are these restrictive and scary state board of health medical exemption statements in the bill? The strangers at this government agency should have NOTHING to do with what is or is NOT injected into my kids' bodies! That decision should remain between myself and my husband and my kids' physician.

For those who support this bill, I realize that you believe that higher vaccine rates mean better health and wellness for our children. Higher vaccine rates do not equal healthier children. You'll see that in much of the testimony you hear today, but to add to that, here are the US stats from the Vaccine Adverse Event Reporting System (VAERS) for 2018:



https://wonder.cdc.gov/controller/datarequest/D8

Quick Options | More Options | Top | Notes | Citation | Query Criteria

Messages:

▸ These results are for 55,605 total events.

Event Category	Events Reported	Percent (of 55,605)
Death	438	0.79%
Life Threatening	613	1.10%
Permanent Disability	1,249	2.25%
Congenital Anomaly / Birth Defect *	28	0.05%
Hospitalized	4,386	7.89%
Existing Hospitalization Prolonged	93	0.17%
Emergency Room / Office Visit **	872	1.57%
Emergency Room *	4,433	7.97%
Office Visit *	13,400	24.10%
None of the above	34,758	62.51%
Total	60,270	108.39%

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

* These values are only available from VAERS 2.0 Report Form, active 06/30/2017 to present.

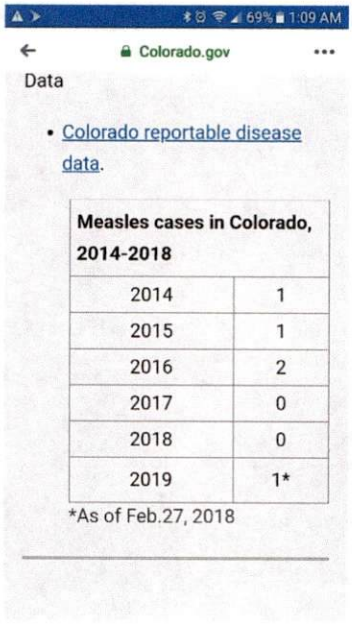
** These value are only available from VAERS-1 Report Form, active 07/01/1990 to 06/29/2017.

Top | Options | Notes | Citation | Query Criteria

Notes:

Caveats: DISCLAIMER: VAERS staff at CDC and the Food and Drug Administration (FDA) follow up on all serious adverse event reports to obtain additional medical, laboratory, and/or autopsy records to help understand the circumstances. However,

And to shed a little light on measles rates here in Colorado:



69% 1:09 AM

Colorado.gov

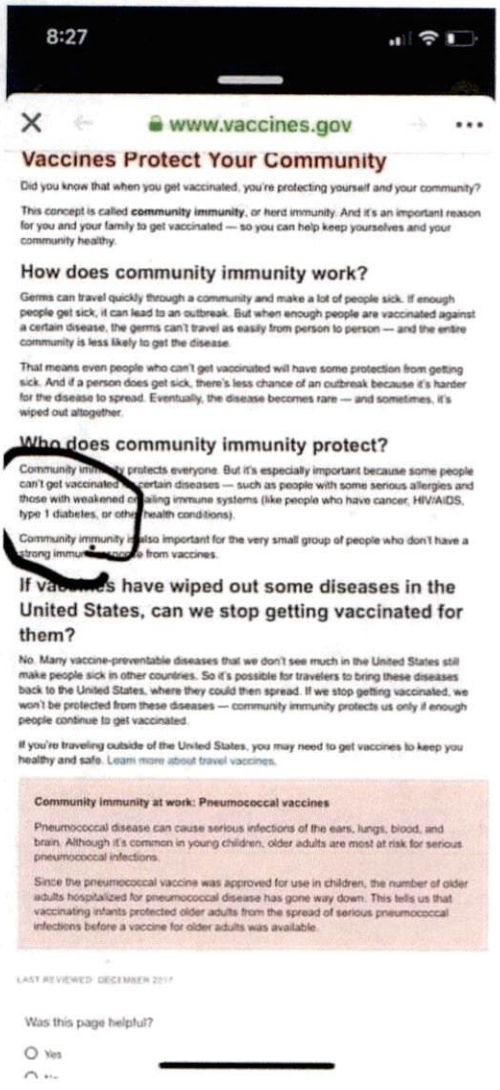
Data

- Colorado reportable disease data.

Measles cases in Colorado, 2014-2018	
2014	1
2015	1
2016	2
2017	0
2018	0
2019	1*

*As of Feb.27, 2018

Please vote NO on HB19-1312. Thank you.



8:27

www.vaccines.gov

Vaccines Protect Your Community

Did you know that when you get vaccinated, you're protecting yourself and your community?

This concept is called **community immunity**, or herd immunity. And it's an important reason for you and your family to get vaccinated — so you can help keep yourselves and your community healthy.

How does community immunity work?

Germs can travel quickly through a community and make a lot of people sick. If enough people get sick, it can lead to an outbreak. But when enough people are vaccinated against a certain disease, the germs can't travel as easily from person to person — and the entire community is less likely to get the disease.

That means even people who can't get vaccinated will have some protection from getting sick. And if a person does get sick, there's less chance of an outbreak because it's harder for the disease to spread. Eventually, the disease becomes rare — and sometimes, it's wiped out altogether.

Who does community immunity protect?

Community immunity protects everyone. But it's especially important because some people can't get vaccinated for certain diseases — such as people with some serious allergies and those with weakened or failing immune systems (like people who have cancer, HIV/AIDS, type 1 diabetes, or other health conditions).

Community immunity is also important for the very small group of people who don't have a strong immune response from vaccines.

If vaccines have wiped out some diseases in the United States, can we stop getting vaccinated for them?

No. Many vaccine-preventable diseases that we don't see much in the United States still make people sick in other countries. So it's possible for travelers to bring these diseases back to the United States, where they could then spread. If we stop getting vaccinated, we won't be protected from these diseases — community immunity protects us only if enough people continue to get vaccinated.

If you're traveling outside of the United States, you may need to get vaccines to keep you healthy and safe. Learn more about travel vaccines.

Community immunity at work: Pneumococcal vaccines

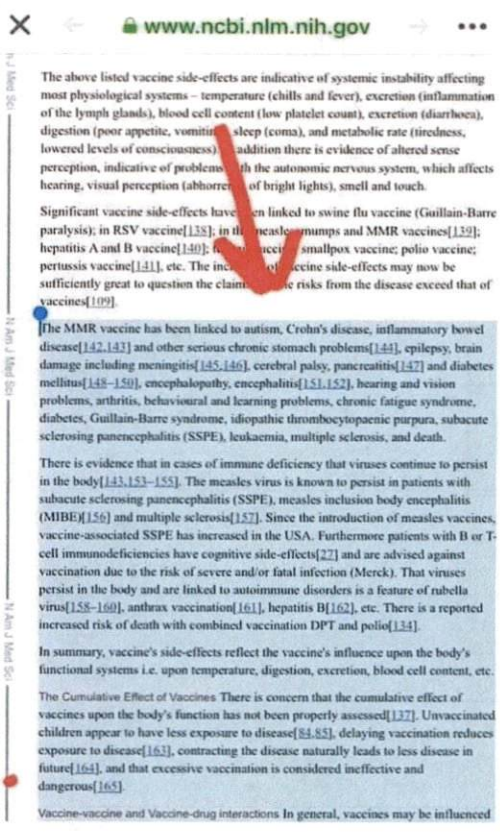
Pneumococcal disease can cause serious infections of the ears, lungs, blood, and brain. Although it's common in young children, older adults are most at risk for serious pneumococcal infections.

Since the pneumococcal vaccine was approved for use in children, the number of older adults hospitalized for pneumococcal disease has gone way down. This tells us that vaccinating infants protected older adults from the spread of serious pneumococcal infections before a vaccine for older adults was available.

LAST REVIEWED: DECEMBER 2017

Was this page helpful?

○ Yes



www.ncbi.nlm.nih.gov

The above listed vaccine side-effects are indicative of systemic instability affecting most physiological systems – temperature (chills and fever), excretion (inflammation of the lymph glands), blood cell content (low platelet count), excretion (diarrhoea), digestion (poor appetite, vomiting), sleep (coma), and metabolic rate (tiredness, lowered levels of consciousness). In addition there is evidence of altered sense perception, indicative of problems with the autonomic nervous system, which affects hearing, visual perception (abhorrence of bright lights), smell and touch.

Significant vaccine side-effects have been linked to swine flu vaccine (Guillain-Barre paralysis); in RSV vaccine[138]; in the measles, mumps and MMR vaccines[139]; hepatitis A and B vaccine[140]; [illegible] smallpox vaccine; polio vaccine; pertussis vaccine[141], etc. The incidence of vaccine side-effects may now be sufficiently great to question the claim that the risks from the disease exceed that of vaccines[109].

The MMR vaccine has been linked to autism, Crohn's disease, inflammatory bowel disease[142,143] and other serious chronic stomach problems[144], epilepsy, brain damage including meningitis[145,146], cerebral palsy, pancreatitis[147] and diabetes mellitus[148–150], encephalopathy, encephalitis[151,152], hearing and vision problems, arthritis, behavioural and learning problems, chronic fatigue syndrome, diabetes, Guillain-Barre syndrome, idiopathic thrombocytopaenic purpura, subacute sclerosing panencephalitis (SSPE), leukaemia, multiple sclerosis, and death.

There is evidence that in cases of immune deficiency that viruses continue to persist in the body[143,153–155]. The measles virus is known to persist in patients with subacute sclerosing panencephalitis (SSPE), measles inclusion body encephalitis (MIBE)[156] and multiple sclerosis[157]. Since the introduction of measles vaccines, vaccine-associated SSPE has increased in the USA. Furthermore patients with B or T-cell immunodeficiencies have cognitive side-effects[27] and are advised against vaccination due to the risk of severe and/or fatal infection (Merck). That viruses persist in the body and are linked to autoimmune disorders is a feature of rubella virus[158–160], anthrax vaccination[161], hepatitis B[162], etc. There is a reported increased risk of death with combined vaccination DPT and polio[134].

In summary, vaccine's side-effects reflect the vaccine's influence upon the body's functional systems i.e. upon temperature, digestion, excretion, blood cell content, etc.

The Cumulative Effect of Vaccines There is concern that the cumulative effect of vaccines upon the body's function has not been properly assessed[137]. Unvaccinated children appear to have less exposure to disease[84,85], delaying vaccination reduces exposure to disease[163], contracting the disease naturally leads to less disease in future[164], and that excessive vaccination is considered ineffective and dangerous[165].

Vaccine-vaccine and Vaccine-drug interactions In general, vaccines may be influenced

25% 12:14 AM
UCM126618.p...

less.

6.1.1.5.4 Secondary Safety Endpoints

- Incidence of solicited local (pain, redness, and swelling) and general (fever, drowsiness, and loss of appetite) symptoms within 4 days (Day 0 through Day 3) after vaccination
- Increase in the mid-upper arm circumference at the DTaP-containing vaccine injection site within 4 days (Day 0 through Day 3) after vaccination

[redacted]

- Incidence of general symptoms that may be associated with MMR vaccination (fever, rash/exanthem, parotid/salivary gland swelling, and any suspected signs of meningism including febrile convulsions) within 15 days (Day 0 through Day 14) after vaccination
- Incidence of unsolicited symptoms within 31 days (Day 0 through Day 30) after vaccination
- Occurrence during the entire study period (from Visit 1 through 6 months [minimum 182 days] post-vaccination) of serious adverse events
- Occurrence during the extended safety follow-up phase (from Day 31 through 6 months [minimum 182 days] post-vaccination) of:
  - onset of chronic illness(es) (e.g., type 1 diabetes, autoimmune diseases, asthma, and allergies)
  - adverse events leading to emergency room visits or to physician office visits that are not related to well-child care, vaccination, injury or common acute illnesses such as upper respiratory tract infection, otitis media, pharyngitis, and gastroenteritis

6.1.1.6 Surveillance/Monitoring

6.1.1.6.1 Immunogenicity Monitoring

A subset of subjects, equally distributed between the four treatment groups (i.e., three KINRIX lots and Control group), provided blood samples for serological analysis prior to vaccination and 31-48 days post-vaccination. This subset was referred to as the safety and immunogenicity subset and was planned to consist of the first 1,340 vaccinated subjects who agreed to be part of the subset. In case of insufficient blood sample volume to perform all assays, the assays for KINRIX antigens were prioritized as follows: polio type 1, polio type 2, polio type 3, PT, FHA, PRN, diphtheria, tetanus.

Serological assays performed for this study are listed in Table 7.

Table 7. Study 213503/048 Serological assays for KINRIX antigens

Marker	Assay method	Assay unit	Assay cut-off	Laboratory
anti-diphtheria toxoid	ELISA	IU/mL	0.1	GSK Rixensart
anti-tetanus toxoid	ELISA	IU/mL	0.1	GSK Rixensart
anti-PT	ELISA	EU/mL	5	GSK Rixensart
anti-FHA	ELISA	EU/mL	5	GSK Rixensart
anti-PRN	ELISA	EU/mL	5	GSK Rixensart
anti-poliovirus types 1, 2, 3	Neutralization	ED50	1:8	GSK Rixensart

6.1.1.6.2 Safety Surveillance/Monitoring

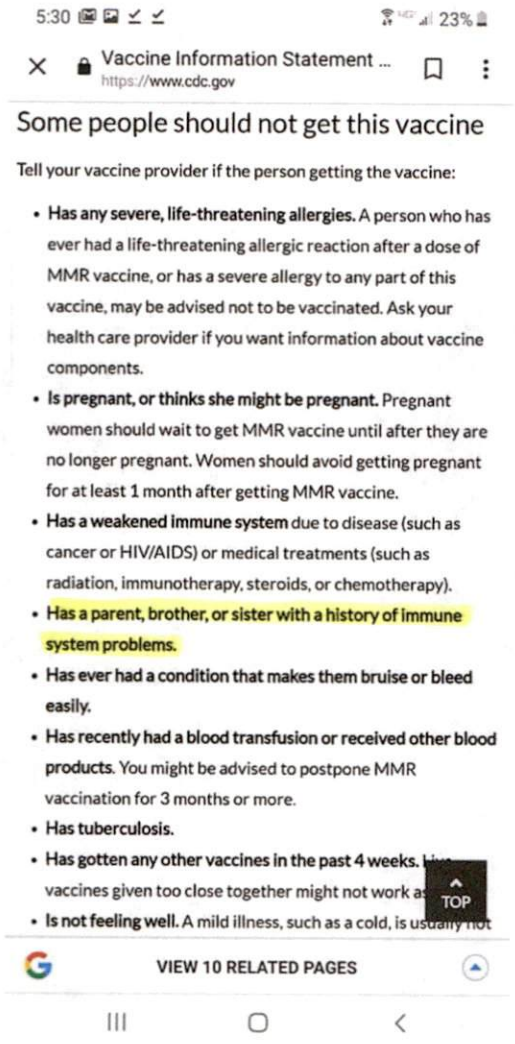
- Prior to vaccination at the first study visit, study personnel measured and recorded the length of subjects' both upper arms (from acromion to tip of elbow) and the mid-upper arm circumference (at mid-distance between the acromion and the tip of the elbow, while the arm

[redacted]

...axia, gastroenteritis, and culture negative clinical sepsis and 4 cases of bronchiolitis) and 5 serious adverse ...bjects (1% [4/335]) who received INFANRIX, ENGERIX-B, and IPV (uteropelvic junction obstruction and reflux- ...f 3 cases of bronchiolitis).

...trials, 5 deaths were reported among 8,088 (0.06%) recipients of PEDIARIX and 1 death was reported among ...omparator vaccines. Causes of death in the group that received PEDIARIX included 2 cases of Sudden Infant ...ne case of each of the following: convulsive disorder, congenital immunodeficiency with sepsis, and pneumo- ...as reported in the comparator group. The rate of SIDS among all recipients of PEDIARIX across the 14 trials ...IDS observed for recipients of PEDIARIX in the German safety study was 0.2/1,000 infants (reported rate ...r part of the 1990s was 0.7/1,000 newborns). The reported rate of SIDS in the United States from 1990 to ...t. By chance alone, some cases of SIDS can be expected to follow receipt of pertussis-containing vaccines. ...ses: In the US safety study in which all subjects received concomitant Hib and pneumococcal conjugate ...) received PEDIARIX and 14 subjects (4%) who received INFANRIX, ENGERIX-B, and IPV reported new onset ...eriod from 1 to 6 months following the last dose of study vaccines. Among the chronic illnesses reported ...EDIARIX, there were 4 cases of asthma and 1 case each of diabetes mellitus and chronic neutropenia. ...n subjects who received INFANRIX, ENGERIX-B, and IPV.

...safety study over the entire study period, 6 subjects in the group that received PEDIARIX (N = 4,666) ...subjects had a febrile seizure, 1 of whom also developed afebrile seizures. The remaining 4 subjects had ...h infantile spasms. Two subjects reported seizures within 7 days following vaccination (1 subject had ..., and 1 subject had afebrile seizures), corresponding to a rate of 0.22 seizures per 1,000 doses (febrile ...ebrile seizures 0.14 per 1,000 doses). No subject who received concomitant INFANRIX, Hib vaccine, ...[redacted] infants who received


5:30
23%
Vaccine Information Statement ...
https://www.cdc.gov
Some people should not get this vaccine
Tell your vaccine provider if the person getting the vaccine:
• Has any severe, life-threatening allergies. A person who has ever had a life-threatening allergic reaction after a dose of MMR vaccine, or has a severe allergy to any part of this vaccine, may be advised not to be vaccinated. Ask your health care provider if you want information about vaccine components.
• Is pregnant, or thinks she might be pregnant. Pregnant women should wait to get MMR vaccine until after they are no longer pregnant. Women should avoid getting pregnant for at least 1 month after getting MMR vaccine.
• Has a weakened immune system due to disease (such as cancer or HIV/AIDS) or medical treatments (such as radiation, immunotherapy, steroids, or chemotherapy).
• Has a parent, brother, or sister with a history of immune system problems.
• Has ever had a condition that makes them bruise or bleed easily.
• Has recently had a blood transfusion or received other blood products. You might be advised to postpone MMR vaccination for 3 months or more.
• Has tuberculosis.
• Has gotten any other vaccines in the past 4 weeks.
vaccines given too close together might not work a
TOP
• Is not feeling well. A mild illness, such as a cold, is
VIEW 10 RELATED PAGES