Parents Informed and Educated

Current and Reliable Vaccine Information for Frum Families

A PROJECT OF THE EMES INITIATIVE

The information contained herein is provided for educational purposes only and is not intended to be a substitute for professional medical diagnosis or treatment by a qualified medical professional. Any questions you may have concerning the diagnosis or treatment of a medical condition should be directed to your doctor or other qualified health care provider.

The copyright and other intellectual property rights in all materials and content contained herein, including the organization and layout, is owned by EMES Initiative, Inc., and EMES Pro, LLC and/or its licensors. Any reproduction of content or layout with explicit permission from EMES is forbidden. Any rights not expressly granted in these terms are reserved. For permission, please email: Vaccinetaskforce@gmail.com.

© 2019 EMES Initiative, Inc. © 2019 EMES Pro, LLC.



3 Letter From the Vaccine Task Force 4 | P.I.E. Cheat Sheet 5 | The Immune System 7 | Pregnancy and the Immune System 9 | Immunocompromised Populations 11 | Pox Parties 12 Vaccinations 16 | Anti-Vaxx Myths and Vaccine Ingredients 22 | The Health Status of Unvaccinated Children 27 | Overall Vaccine Safety and Approval Systems 27 | Vaccine Development, Testing, Reporting, and Compensation **36** | Follow the Money 39 What Are Side Effects? 40 What Is a Titer? 41 Combination Vaccines and the CDC Schedule 46 | Shot by Shot 46 | Hepatitis B 51 | Rotavirus 53 | Diphtheria 55 | Tetanus 56 | Pertussis 58 | DTaP 63 | Polio (IPV) 67 | Haemophilus Influenzae/Hib 70 | Pneumococcal Conjugate 72 | Measles (Rubeola) 77 | Mumps 78 | Rubella (German Measles) 80 | MMR 81 | Varicella 85 | Meningococcal 87 | Hepatitis A 88 | HPV 93 | Influenza/Flu 100 Conditions Attributed to Vaccines 100 | Autism 101 108 | SIDS and the DTaP 115 | Febrile (Fever) Seizures

- 118 | Shedding
- 120 | Halacha and Vaccination
- 124 EMES Recommends
- 126 Acronyms
- 127 Appendix
- BACK | EMES Vaccine Task Force Leadership, Editors, and Contributors

ETTER FROM THE VACCINE TASK FORCE

Dear Readers,

With the recent measles outbreak, many nurses were approached by anxious parents with questions about vaccine safety. Physicians, including pediatricians, generally do not have the time for long conversations with parents on vaccine safety. The internet has a lot of information, but it can be hard to know who to rely on. Nurses are educators — we are the ones who talk to our patients about health, wellness, diseases, symptoms, and medication side effects. Nursing is also considered the most ethical and trustworthy of all professions, according to polls conducted *every* year (Brenan, 2018).

Furthermore, nursing is an evidence-based practice; we do not follow information that is proven to be false. We also do not follow information that has been proven to injure or harm patients. We do not provide care to patients using methods that are discredited. We question everything, from data to physicians.

When an outbreak of measles reached our Jewish community in late 2018, we discovered a locally distributed magazine, PEACH (Parents Educating and Advocating for Children's Health, also known as the "Vaccine Safety Handbook"), circulating in our communities. This magazine is inaccurate, highly biased, and full of misleading information. As the measles outbreak continued, we discovered the magazine was part of a much larger organized effort to spread misinformation to the public to discourage vaccinations. Parents cannot and should not make health choices for their children based on inaccurate information.

As nurse-scientists, we analyzed the entire PEACH magazine, as well as other common anti-vaccine (anti-vaxx) myths. In response to PEACH, vaccine hesitancy, and skepticism, the EMES (Engaging in Medical Education With Sensitivity) Initiative is providing accurate refutations and information about vaccines. We call the guidance **P.I.E.: Parents Informed and Educated**.

The EMES Initiative published "A Slice of P.I.E." in May of 2019 in direct response to the recent measles outbreak, focusing on measles, mumps, rubella, autism, and the MMR vaccine. Now this new publication you are reading is the "full" P.I.E., with lots of information on the immune system, vaccine development and components, the vaccines themselves, and conditions such as autism, seizure disorders, and sudden infant death syndrome (SIDS), among others, all referenced with hundreds of studies. Throughout much of this guide, we provide you with P.I.E **facts** after showing you a common anti-vaxx **myth**. We prove each myth wrong with evidence, giving you the scientific studies and references to back up the P.I.E facts.

Please note that this publication was completed prior to the recent authorization of the COVID-19 vaccines. Information from P.I.E. about the COVID-19 vaccines will be shared in a separate, future publication. For current information, you can visit the Centers for Disease Control and Prevention (CDC) website at **cdc.gov/ coronavirus/2019-ncov/vaccines**.

"Emes" means honesty in Hebrew. We chose this name to highlight our honest quest for the truth and to broadcast our hope that you will make good medical decisions based on this truth. Here is the result of our work. Please email us at vaccinetaskforce@gmail.com with any questions you have — we know you have many! We are ready for you, we have time for you, and we won't lie to you.

Sincerely, The Vaccine Task Force of the EMES Initiative

PIECHEAT SHEET

Too much information? Here is a short "cheat sheet" that summarizes what the EMES nurses found when studying anti-vaccination sources:

Outdated information

Research moves at a fast pace, yet to remain true to their biased stance, many anti-vaccination sources use decades-old research. In some areas of science, a study can be considered "old" in as little as five years. The date of the study is important. You may find studies we used with older dates. Since the invention of vaccines for certain diseases, many of these studies can no longer be replicated due to much lower infection rates. These studies may still be considered valid.

Biased sources

Many anti-vaccination sources claim to present studies by "independent researchers," although many of the authors they quote are affiliated with an anti-vaccination organization—and many of them are the founders and presidents of anti-vaccine websites. This demonstrates strong bias and will not give you any truly independent information. If a study was sponsored by a pharmaceutical company, it can be considered biased as well.

Discredited sources

Anti-vaxxers (people who oppose vaccination or laws that mandate vaccination) use dangerous practitioners as sources of information. Many of the doctors they cite have had their licenses revoked for injuries to others and malpractice. Other discredited sources include those who are known to believe purely unscientific claims.

Selective information

As you will see, anti-vaccination sources pull specific words and phrases out of studies, *while leaving out the rest of the sentence,* if it does not fit with their agenda! This is called cherry picking and is a common propaganda tactic.

False information

For reasons we cannot understand, anti-vaxxers use lies, in addition to their outdated, biased, and misleading information. You deserve honest information.

Anti-vaxxers act irresponsibly

During the course of our research, we had many dealings with those who promote "vaccine choice." Some of our experiences include calling the Akeres Habayis Hotline, where we were muted and not allowed to ask important questions. When we emailed PeachMoms about a piece of dangerous and false information ("fever reducers can cause measles complications") we were told to "look it up yourself." Subsequent emails were not answered.

EMES believes in providing the community with the most accurate, reliable, and up-to-date health care information. This effort is being made now because of the unprecedented level of communicable diseases, such as measles, as well as declining vaccination rates, in Jewish communities. While we strongly believe in parental choice, we also believe that educated parents make better choices for their families. We are always available to answer your questions and address your concerns. Email us at vaccinetaskforce@gmail.com.

THE INSUE SYSTEM

What is the immune system?

The immune system helps to protect us against diseases caused by viruses and bacteria, among other substances. It is made up of specialized organs, cells, and tissues that all work together to destroy the viruses or bacteria and protect the body by preventing harm they may cause. The immune system includes white blood cells, spleen, lymph nodes, thymus, and bone marrow.

Source: Zimmerman, 2018

The immune system develops different kinds of cells that help to destroy these diseases. Some of these cells are designed to fight a specific infection. All throughout the body, disease-fighting cells are stored, waiting for the signal to fight for the body. The immune system sends a message when there is an attack or invasion, then sends the correct immune cells to destroy the invading bacteria or virus. **Source:** Zimmerman, 2018

Antigens and Antibodies

An antigen is a substance that triggers a response in the immune system. The immune system produces a protein, called an antibody, to fight the antigen. Antibodies are created by white blood cells. Some white blood cells may also directly attack infected cells or bacteria.

Source: Zimmerman, 2018

How do the antibodies know which cells to attack?

The immune system must know which cells are good or bad. White blood cells and antibodies are very specific; they fight very specific antigens. They ignore good cells, such as those belonging to the body, and only attack bad cells such as bacteria or cells infected with a virus. **Source:** Zimmerman, 2018

How do we get immunity?

There are two types of immunity: active and passive.

• Active: Active immunity is when a person is exposed to an organism that causes disease and the immune system makes antibodies to that organism; this happens, for example, when a person gets sick (natural infection). It also happens when people are vaccinated (vaccine-induced immunity). Vaccines trick the immune system into thinking that it sees the disease-causing organism; this is because vaccines include killed or weakened forms of the organism or include instructions to the body to make proteins that look like proteins that the organism has and this causes the immune system to make antibodies to that organism without making a person sick. In both natural infection and vaccine-induced immunity, if an immune person later comes into contact with that disease in the future, their immune system will recognize it and immediately make the antibodies needed to fight it. Protection from active immunity is usually long-lasting.

• Passive: Passive immunity is when a person is *given* antibodies to a disease instead of making antibodies on their own; for example, when a newborn gets antibodies from their mother through the placenta, which may protect them from certain diseases for a short period of time after birth. **Source:** CDC, 2017

Immune System Facts

Some immunity eventually goes away, so people may need a booster dose of a vaccine after a period of time.

• Different people have different levels of immunity. Some people get sick more often than others.

• Sometimes the immune system can get confused and will attack good cells. This is called an autoimmune disease.

Source: Zimmerman, 2018

References:

Centers for Disease Control and Prevention CDC. (2017). Immunity Types. Retrieved from: https://www.cdc.gov/vaccines/vac-gen/immunity-types.htm Zimmerman, KA. (2018) Immune system: Diseases, disorders & function. Health. Retrieved from: https://www.livescience.com/26579-immune-system.html

Pregnancy and the IMMUNE SYSTEM

Being pregnant is a special time for the mother and the family. Every pregnant woman wants to have a healthy and happy baby.

Before Pregnancy

Before getting pregnant, it is important that a woman is up to date on her vaccines. Certain diseases, such as rubella, affect the baby early in the pregnancy. The best protection against rubella is having the MMR (measles, mumps, and rubella) vaccine, given prior to getting pregnant. A woman can get a blood test to see if she has immunity. If she does not have immunity, she should get the MMR vaccine before becoming pregnant. See the section on rubella and pregnancy (page 79) for more information.

Source: March of Dimes, 2018

During Pregnancy

There are a few blood tests suggested as a part of prenatal care. These tests look for conditions that can cause problems for the mother or the fetus. Some look at a woman's immune status for specific vaccine-preventable diseases. **Source:** American College of Obstetricians and Gynecologists (ACOG), 2017

There are certain serious bacteria, poisons, or viruses that can harm the fetus. These are called teratogens and they do the most serious damage between the 2nd and 8th week of pregnancy when the fetus's organs are forming but can be harmful at any time during the pregnancy. Some of the most common ones are:

- Rubella
- Varicella
- Viral hepatitis
- Herpes simplex
- Toxoplasmosis
- Cytomegalovirus infection

- Coxsackievirus infection
- Zika infection

Source: Marino, T., 2017

The pregnant mother shares everything with her baby. Any vaccines she had prior to, and while being pregnant, helps protect the baby against serious diseases before it is born and for a few weeks after birth.

It is important to get the Tdap to protect against whooping cough. Whooping cough is life-threatening to a newborn and young infant. Tdap is usually given in the third trimester between the 27th and 36th week of pregnancy. If the mother gets the vaccine during pregnancy, she passes along the antibodies, providing the baby with short-term protection after birth.

Source: ACOG, 2015

Pregnant or postpartum women are more likely to get pneumonia and be hospitalized as a result of influenza (the flu); and they are at increased risk of ICU admission and major complications for both them and their babies. During the 2009-2010 flu season, 12% of deaths in pregnant women were attributed to the flu, and many of these women were previously healthy. If a woman is pregnant during flu season, she can get the flu shot either before or during pregnancy. There are changes in the way a woman's heart, lungs and immune system work while she is carrying the baby. These changes make it easier to get severely ill from the flu, seriously affecting the baby, including premature labor. It is recommended to get a flu shot in early autumn.

Source: ACOG, 2018; Callaghan et al, 2015; ACOG, 2015

Mothers who get the flu shot in pregnancy provide passive immunity to their infants. One study showed that the vaccine was 91.5% effective in preventing hospitalization for influenza during an infant's first 6 months of life. This protection is so important because babies cannot be vaccinated until they are 6 months old, and infants have the highest mortality risk of any age group. Source: Benowitz et al, 2010; Bhat, N. 2005

Special Circumstances for Pregnant Women

 If travelling internationally, speak to a health care provider at least one month prior to traveling.

• If the mother is positive for hepatitis B, the baby is at high risk of being infected with hepatitis B at delivery. The baby should receive treatment immediately after birth with the hepatitis B vaccine and immune globulin. The mother is tested and receives treatment depending on her viral load.

• If living with chronic liver disease (including hepatitis B, hepatitis C, or other non-infectious chronic liver diseases), a hepatitis A vaccine is given.

 If working in a laboratory or traveling to a place where there is meningitis, meningococcal vaccines are given.
 Source: AAP, 2017; ACOG, 2018

References:

American Academy of Pediatrics AAP. (2017). AAP recommends that infants receive first hepatitis B dose within 24 hours of birth. Retrieved from: https://www.aap.org/en-us/about-the-aap/aap-press-room/Pages/AAP-Recommends-That-Infants-Receive-First-Hepatitis-B-Dose-Within-24-Hours-of-Birth.aspx

American College of Obstetricians and Gynecologists ACOG. (2017). Routine tests during pregnancy. Retrieved from: https://www.acog.org/Patients/FAQs/Routine-Tests-During-Pregnancy?IsMobileSet=false

American College of Obstetricians and Gynecologists ACOG. (2018). Maternal immunization. Retrieved from: https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Immunization-Infectious-Disease-and-Public-Health-Preparedness-Expert-Work-Group/Maternal-Immunization

American College of Obstetricians and Gynecologists ACOG. (2015). Immunization for women. Vaccine recommendations and safety information: Tetanus, diphtheria, and pertussis. Retrieved from: http://immunizationforwomen.org/patients/diseases-vaccines/tetanus-diphtheria-pertussis/vaccine-recommendations-safety.php

American College of Obstetricians and Gynecologists ACOG. (2018). Influenza vaccination during pregnancy. Retrieved from: https://www.acog.org/ Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Influenza-Vaccination-During-Pregnancy#11

American College of Obstetricians and Gynecologists ACOG. (2015). The flu vaccine and pregnancy. Retrieved from: https://www.acog.org/Patients/FAQs/The-Flu-Vaccine-and-Pregnancy?IsMobileSet=false

Benowitz, I., Esposito, DB, Gracey, KD, Shapiro, ED, Vazquez, M. (2010). Influenza vaccine given to pregnant women reduces hospitalization due to influenza in their infants. Clinical Infectious Diseases, 51:12, Pages 1355–1361, https://doi.org/10.1086/657309. Retrieved from: https://academic.oup. com/cid/article/51/12/1355/316344

Bhat, N, et al. (2005). Influenza-associated deaths among children in the United States, 2003-2004. New England Journal of Medicine.353:2559-2567. DOI: 10.1056/NEJMoa051721. Retrieved from: https://www.nejm.org/doi/full/10.1056/NEJMoa051721

Callaghan, W. M., Creanga, A. A., & Jamieson, D. J. (2015). Pregnancy-Related Mortality Resulting From Influenza in the United States During the 2009-2010 Pandemic. Obstetrics and gynecology, 126(3), 486–490. doi:10.1097/AOG.000000000000996. https://pubmed.ncbi.nlm.nih.gov/26244541/ March of Dimes. (2018). Vaccinations and pregnancy. Retrieved from: https://www.marchofdimes.org/pregnancy/vaccinations-and-pregnancy.aspx Marino, T, et al. (2017). Viral infections and pregnancy. Medscape. Retrieved from: https://emedicine.medscape.com/article/235213-overview

Immocompromised POPULATION

Immunocompromised people have problems with their immune systems and difficulty fighting off certain bacteria or viruses. There are four categories of immune disorders, and we will discuss three of them:

> **Immunodeficiency disorders** are either primary or acquired.

Autoimmune disorders in

which the body's own immune system attacks the body itself as if it were a foreign invader

> Allergic disorders in which the immune system overreacts in response to an antigen

Immunodeficiency Disorders

An immunodeficiency disorder is when part of the immune system is not working properly, or it is missing entirely. When a person is born this way, it is called a **primary immunodeficiency**. People born with these disorders typically have an abnormal amount of unusual infections during their infancy and childhood. Sometimes, the symptoms of this disorder won't show up until later in life. **Secondary immunodeficiency** can be caused by infection (such as HIV), poor nutrition, severe burns, or from medications such as chemotherapy, steroids, or other biologic agents.

Source: Carey, 2016

Autoimmune Disorders

Normally, the immune system protects the body from foreign invaders. An autoimmune disorder is where the immune system mistakes a healthy part of the body as an invader and attacks the healthy tissues. There are many different autoimmune diseases. The symptoms are different depending on what part of the body is affected.

Some autoimmune diseases occur in the:

- Blood cells (autoimmune hemolytic anemia)
- Blood vessels (vasculitis)
- Joints (rheumatoid arthritis)
- Skin, lungs and kidneys (lupus)
- Brain and spinal cord (multiple sclerosis)
- Thyroid (Graves disease or Hashimoto's thyroiditis)
- Pancreas (type 1 diabetes)

Source: Watson, 2019

References:

Boskey, E. (2019). Being immunocompromised or having an immune deficiency. VeryWell Health. Retrieved from: https://www.verywellhealth.com/what-it-means-to-beimmunocompromised-have-immune-deficiency-3132870 Carey, E. (2016). Immunodeficiency disorders. Retrieved from: https://www.healthline.com/health/immunodeficiency-disorders National Institute of Allergy and Infectious Diseases NIAID. (2015). Allergic diseases. Retrieved from: https://web.archive. org/web/20150617123632/. http://www.niaid.nih.gov/topics/ allergicdiseases/Pages/allergic-diseases-types.aspx

Watson, S. (2019). Autoimmune diseases: Types, symptoms, causes, and more. Retrieved from: https://www.healthline.com/health/autoimmune-disorders#symptoms

Allergic Disorders

Allergic disorders happen when the body's immune system overreacts to antigens. Allergens are the substances that cause an attack. The immune response to the allergen can include reactions such as sneezing, watery eyes, hives, and swelling, or in severe cases, a life-threatening allergic reaction called anaphylaxis. Antihistamines can relieve most allergic symptoms. Emergency medications such as epinephrine (also known as an EpiPen) may be needed in severe, life-threatening allergic reactions. **Source:** NIAID, 2015

Some allergic disorders include:

• Asthma, which causes breathing problems. If the lungs are over-sensitive to allergens (some of these include pollen, mold, or dust), the breathing tubes become swollen and narrowed, which makes it very hard to breathe.

• Eczema, which is an itchy rash also called atopic dermatitis. It is not always caused by an allergic reaction, but it happens most often in children who have allergies, asthma, hay fever or a family history.

- Allergies, which can be of several different types:
 - Seasonal allergies hay fever
- Environmental allergies dust or dust mites
- Drug allergies penicillin
- Food allergies peanuts, tree nuts, or milk
- Toxins bee stings
 Source: NIAID, 2015



POX PARTIES

Pox parties are social events where children are purposely exposed to chickenpox and measles. Before the varicella (chickenpox) or measles vaccine, people would make these parties to "get it over with." These diseases were seen as a part of life. Parents wanted to make sure their children became immune prior to adulthood, where infection would be more dangerous. It was also easier for all the children in the family to be sick at the same time. Today, some people organize these "parties" under the mistaken belief that vaccination is more dangerous than the disease. Source: Willingham, 2013; CDC,

Every health care provider today strongly advises against pox parties. The measles or chickenpox viruses have grave

complications far more likely to happen than any side effects of the vaccines. The chickenpox vaccine was introduced in 1995. Before that, about 4 million people were affected by chickenpox every year. Close to 15,000 infected people per year had to be hospitalized, and an average of 150 people died every year from this "childhood" disease. With the chickenpox vaccine, the total number of cases in the United States (U.S.) for 2017 was under 10,000 cases. Chickenpox can be dangerous for pregnant women and children under the age of 1 year. Complications of chickenpox include pneumonia, skin infection, infection of the nervous system, hospitalization, and death. There is evidence people who receive the chickenpox vaccine have a lower risk of getting herpes zoster

(shingles). Shingles is a reactivation of the chickenpox virus, caused by stress, immunosuppression, and getting older. It is a very painful condition that affects nerve roots. Shingles can be extremely severe in older adults. **Source:** CDC, 2018b; CDC, 2018c; CDC, 2017

As *frum* people, some might want to consider the halachic issues of purposely making their children sick. The majority of the world's health care providers believe in the safety of vaccines, support vaccinations, and warn against catching and sharing preventable illnesses. An observant Jew must consider whether it is halachically permissible to engage in deliberately infecting their children with diseases that may cause harm to them and others.

References:

- Centers for Disease Control and Prevention CDC. (2018a). Chicken Pox (Varicella): Transmission. Retrieved from: https://www.cdc.gov/chickenpox/about/transmission.html.
- Centers for Disease Control and Prevention CDC. (2018b). Chicken Pox (Varicella): Monitoring the Impact. Retrieved from: https://www.cdc.gov/chickenpox/surveillance/monitoring-varicella.html
- Centers for Disease Control and Prevention CDC. (2018c). Chicken Pox (Varicella): About. Retrieved from: https://www.cdc.gov/chickenpox/about/index.html

- Willingham, E. (2013). Chicken pox party: RSVP No. Forbes. Retrieved from:
- https://www.forbes.com/sites/emilywillingham/2013/11/22/chicken-pox-party/#43fb20004e8d

Centers for Disease Control and Prevention CDC. (2017). Shingles: Herpes Zoster. Retrieved from: https://www.cdc.gov/shingles/hcp/clinical-overview.html



Why Should We Vaccinate?

Vaccination produces an immune response in the body to a specific disease without the risk of getting the disease and any of its complications. This process creates antibodies and special white blood cells. These work to defend the body against the specific bacteria or virus a child may be exposed to in the future. Source: Denizer et al, 2018

Oxygen and water are both necessary for life; too much or too little of either can kill you. Keep this in mind. You are exposed to dangerous-sounding chemicals on a daily basis with no harm. The ingredients in vaccines have been tested for safety and effectiveness. The total antigens in vaccines today is about 150. You are exposed to thousands of antigens every single day from the air, surfaces, food, and other people. **Source:** Live Science, 2009

Types of Vaccines

Vaccines are made to get the immune system to respond. The type of vaccine depends on the virus or bacteria. The most common types are:

• Sub-unit vaccines: fragments of bacteria or viruses that are

non-infectious, or dead

• Live attenuated (weakened) organisms that generally do not cause any illness beyond rare, mild symptoms

• Killed (non-live) virus Source: Denizer et al, 2018

Sub-unit vaccines

Sub-unit vaccines only have selected fragments of the bacteria or virus instead of the whole cell. Because they only have fragments, the immune response may not be as strong. These types of vaccines may require boosters. **Source:** Denizer et al, 2018

Live attenuated vaccines

Live attenuated vaccines have a weakened or modified version of the bacteria or virus to make it **much** less harmful than the wild-type disease. These vaccines bring on a strong antibody response and can give long-term immunity after one or two doses only. Rarely, some people can get mild disease-like symptoms from the vaccine, such as a rash. However, these symptoms are not strong enough to produce full illness, nor strong enough to be contagious to others. People who are immunocompromised or pregnant need to be evaluated to find out if they can receive this type of vaccine by their health care provider. **Source:** Denizer et al, 2018

Non-live (inactivated) vaccines

Non-live vaccines do not have any infectious particles and cannot cause disease. Even an immunocompromised person can receive these vaccines. However, the immune response and length of protection is less than for live vaccines. These vaccines are given more times to induce long-term immunity. **Source:** Denizer et al, 2018

TYPE OF VACCINE:	EXAMPLES:	BENEFIIS:	LIMITATIONS:
Live Attenuated Vaccines	Measles, mumps, rubella, varicella, rotavirus (Rotarix, Rotavac), herpes zoster (shingles), influenza, yellow fever	 Mimic natural infection and immune response Life-long immunity possible after one to two doses Gives both antibodies and cell-mediated immunity 	 Please check with your health care provider if you are immunocompromised or pregnant
Sub-Unit and Split Sub-Unit Vaccines	Influenza, acellular pertussis, hepatitis B, human papillomavirus (HPV), meningococcal B, malaria, herpes zoster	 Non-infectious Very low chance of reactions 	• Doesn't give lifelong immunity
Toxoid	Tetanus, diphtheria, acellular pertussis (as part of DTaP combination vaccines)	 Proven safety for over 100 years Non-infectious 	 Vaccines target only the toxin No herd protection
Polysaccharide and Conjugate	Pneumococcal conjugate vaccine, meningococcal vaccine, Haemophilus influenzae type b	 Each additional dose gives better immune responses Protects against viruses for longer 	 Booster doses may be required to attain long-term protection
Reassortant Live Attenuated	Rotavirus (RotaTeq)	 Cannot cause the original disease, and a good safety profile Improved tolerability 	 Please check with your health care provider if you are immunocompromised

Source: Adapted from Vetter et al, 2018. Understanding modern-day vaccines: what you need to know, *Annals of Medicine*, 50:2, 110-120, doi: 10.1080/07853890.2017.1407035

How do vaccines work?



An inactive form of the disease is introduced to the body.

The body creates antibodies to defend itself.



These antibodies then work to destroy any occurrence of the live disease.

Source: Illustration provided with express permission of Hannah Henry.

WHAT IS IN VACCINES?

Source: US Department of Health and Human Services (HHS), 2017

Vaccines contain:

Antigens: dead or weak germ of the disease Adjuvants: ingredients to make the vaccine work better

Why do we need other ingredients in vaccines?

Every ingredient in a vaccine has a specific purpose. Ingredients:

- Keep the vaccine stable
- Prevent contamination by other unwanted bacteria or fungi
- Boost the immune response to the vaccine



What are the other ingredients in vaccines and are they safe?

Antibiotics: Antibiotics are used in some vaccines to prevent contamination by unwanted bacteria while they are making the vaccine. Certain antibiotics that can cause severe allergic reactions (penicillin, cephalosporins and sulfa) are **not** used. The only antibiotics that are used are neomycin, polymyxin B, streptomycin, and gentamicin. Only tiny amounts remain in vaccines. Ask your health care provider if you are allergic to any of these antibiotics. Source: CHOP, 2018

Aluminum salts: Aluminum salts have been used in vaccines for many years. Everyone is exposed to aluminum naturally because it is in the environment. It is in the air, food, and water naturally. It is present in baby formula AND breastmilk (the most natural food there is!). Aluminum is used in vaccines to improve the body's immune response to the vaccine. Source: Petrovsky, N., 2015

Formaldehyde: Vaccines made from live germs or toxins have to be killed so they don't cause the disease itself. Formaldehyde is used to kill the germ. It is completely removed from the vaccine, or if there is any left, the tiny amount will not cause harm. The human body creates small amounts of formaldehyde every day as a natural part of our metabolism. There is no difference in how the body processes naturally produced formaldehyde and the form found in vaccines.

Source: ACS, 2014; FDA, 2018

Other ingredients: Some vaccines contain other ingredients in very small amounts to keep the vaccine stable and safe while they are being made, shipped, and stored. These include sugars, amino acids, salts, and proteins, such as albumin and gelatin. Source: FDA, 2018

Do vaccines contain human or animal cells?

No. Vaccines do NOT contain human or animal cells. Viruses need to grow in a human or animal cell. Once grown, the virus is separated from those cells and used to make the vaccine. To use a comparison, fruits and vegetables that grow in the ground use fertilizer that may contain manure (animal waste). This does not mean that fruits and vegetables have waste inside them.

Do vaccines have egg protein?

The MMR vaccine has not had any egg protein in it for over 30 years and can safely be given to children with an egg allergy. Some flu vaccines are made by growing the influenza virus in chicken eggs. As a result, they may contain tiny amounts of egg protein. The American Academy of Allergy, Asthma and Immunology (AAAAI), the American Academy of Pediatrics (AAP), and Advisory Committee on Immunization Practices (ACIP) all say that the flu vaccine can be given safely to a person with an egg allergy. People who have hives after eating eggs may receive any recommended flu vaccine. People who have more serious reactions to eggs may be vaccinated, but they should be vaccinated in a medical setting where they can receive treatment, if needed. Source: FARE, 2019

Do vaccines have mercury (thimerosal)?

In 2000, the CDC determined the studies on mercury (thimerosal) and safety were inconclusive. Thimerosal is a mercury compound preservative that was used in multi-dose vials to keep the vaccine from being contaminated with outside bacteria or fungi. Thimerosal was removed from vaccines as a precaution. (Thimerosal is ethylmercury, which is rapidly metabolized, in contrast to methylmercury, which is known to be harmful.) Since then, no childhood vaccine has mercury (thimerosal). Today, all childhood vaccines in the U.S. are available in single-use dose only and don't need preservatives. The only exception are multi-dose vials of flu vaccine which may be given to children. However, there are many single-dose flu vaccines available that do not contain thimerosal. Since 2000, numerous studies have found no evidence that low doses of thimerosal are harmful. Source: NASEM, 2001

For more information on vaccine ingredients, please visit: www.fda.gov/vaccinesblood-biologics/safetyavailability-biologics/ common-ingredients-uslicensed-vaccines

222

Anti-Vaxx Myths and VACCINE VACCINE INGREDIENTS

Anti-Vaxx Myth: "By introducing disease entities combined with dangerous doses of toxic substances directly into the bloodstream, they have unnaturally bypassed the body's main defense systems, which

dangerous doses of toxic substances directly into the bloodstream, they have unnaturally bypassed the body's main defense systems, which probably could have eliminated most of the toxins from the body." **Source:** None given; seen in PEACH magazine.

P.I.E.: This is a classic tactic used by anti-vaxxers to create scarysounding messages about vaccines that are not only inaccurate but absolutely wrong. Let's deconstruct the terms anti-vaxxers use, and provide the facts:

Disease entities: Germs in vaccines cannot cause the actual disease.

Dangerous doses of toxic substances: Adjuvants in vaccines are not found in dangerous doses and are not toxic, as seen earlier in this chapter. Not a single study has linked vaccines to toxic conditions.

Directly into the bloodstream: Vaccines are **never** administered intravenously (IV), which means directly into the bloodstream. Vaccines are injected into the muscles or fat. Some vaccines are inhaled or swallowed.

Main defense system: The body's main defense system, the immune system, uses the vaccine safely and correctly. It doesn't matter how the immune system receives the bacteria or virus - it creates the same antibodies to protect you.

Eliminated most of the toxins from the body: The "main defense system" (the immune system) is not responsible for "eliminating toxins from the body." This is the job of the kidneys and liver. The kidneys can and do eliminate anything that the body does not need to keep, including leftover waste from medications, food, and the environment. Source: Goroll & Mulley, 2012

Mercury

Anti-vaccine activists focus on vaccine ingredients as the supposed culprits in many problems. They claim that "neurotoxins" and "heavy metals" such as mercury (thimerosal), and more recently, aluminum, cause brain damage. They insist this brain damage is the cause of autism and other neurodevelopmental disorders. This is wrong for several reasons:



Anti-vaxxers do not differentiate between the pure element of mercury

and the compound (ethylmercury, also known as thimerosal). For example, sodium chloride is made up of two toxic elements: sodium, which explodes when exposed to water, and chlorine, which is a poisonous gas. When it's compounded, it becomes NaCl, also known as table salt, which is safe to eat.

Anti-vaxxers do not differentiate between the dangerous forms of mercury compounds (methylmercury) and the safer form of mercury compounds (ethylmercury). They may sound similar, but they are vastly different. Ethylmercury is metabolized rapidly and excreted from the body. The Environmental Protection Agency (EPA) — which regulates toxic substances — has issued a recommendation of mercury doses for methylmercury, which is found in fish and in the environment. In high doses, this form of mercury is toxic and takes six weeks to clear from the human body. Vaccines used to contain the safe form.

Aluminum is not a heavy metal. Heavy metal refers to the weight, rather than toxicity. Gold, silver, and platinum are heavy metals, while aluminum is not. These metal compounds are only toxic in high doses. The amount found in vaccines is extraordinarily small.

No association between low-dose ethylmercury (the mercury compound found in vaccines) and autism has been found. Despite this, all thimerosal was removed from all vaccines in the late 1990s.

Source: EPA, 2007

Anti-Vaxx Myth: You can test the hair of a child. If the mercury levels are lower than normal, it means the child's body can't get rid of the mercury from a vaccine, which leads to autism.

Source: Holmes et al, 2003

P.I.E.: It is important to consider the source. This was not an independent study. The authors are all affiliated with SafeMinds, which is an anti-vaccination website. This is considered a conflict of interest because their work is prone to bias against vaccines. The results of this study were never replicated. The author never said which type of mercury they were testing. Please see previous column for an explanation of different mercury compounds. Ethylmercury (thimerosal) was removed from all childhood vaccines in the U.S. in 2000. Even with the removal, autism rates have not gone down. (See the Appendix for a detailed list of these studies).

Source: Stehr-Green et al, 2003; Fido & Al-Saad, 2005; El-Baz, 2010; Priya & Geetha, 2011; Tinkov et al, 2019

Anti-Vaxx Myth: Symptoms of mercury poisoning are the same as the symptoms of autism. Source: Bernard, 2000

P.I.E.: Misleading. Although both autism and mercury poisoning affect the central nervous system (brain and spine), they affect different parts, and the symptoms are different. Mercury damages the peripheral nervous system; autism does not. Depression and anxiety appear in both, but mercury poisoning does not appear physically or mentally like autism. There has never been a case where the doctor could not tell if it was mercury poisoning or autism. **Source:** Nelson & Bauman, 2003

Studies Investigating Thimerosal Exposure With Autism and Other Developmental Outcomes

	TYPE OF STUDY	OUTCOME MEASURE	ASSOCIATION WITH Thimerosal exposure
Andrews et al, 2004	Cohort	Autism	No
Croen et al, 2008	Case-Control	Autism	No
Geier and Geier, 2007	Case-Control	Autism	Yes
Heron et al, 2004	Cohort	Developmental Disorders	No
Hviid et al, 2003	Cohort	Autism	No
Madsen et al, 2003	Ecologic	Autism	No
Miles and Takahashi, 2007	Cross-Sectional	Autism	No
Thompson et al, 2007	Cohort	Neuropschological Functioning	No
Verstraeten et al, 2003	Cohort	Autism	No
Young, Geier, and Geier, 2008	Ecologic	Autism	Yes

The table shows multiple studies that examined thimerosal and autism. All but two found no association. The two studies that found an association are both by the same authors: Geier and Geier. Who are the infamous Geiers? Let's take a closer look.

Of all the researchers who studied thimerosal and autism, Mark and David Geier, a father-son duo, are the only researchers who found any associations between thimerosal and autism. However, this inconsistency requires a closer look at who these "researchers" are and what they did about their "findings."

Mark Geier is an obstetrician, yet he diagnosed neurological conditions and practiced as a geneticist, for which he was charged with a violation in court.



David Geier, his son, has a Bachelor of Arts from the University of Maryland.

David Geier was charged with practicing medicine without a license and was fined \$10,000. The duo ran a study under their own Institutional Review Board (IRB) created in their basement. IRBs must approve every study done on humans and must be composed of an independent panel of members. When the Geiers did not receive approval for their study, they created their own IRB panel to approve it. Members of the IRB included: Mark Geier, David Geier, Anne Geier (Mark Geier's wife), and a few people who claimed their children were damaged by vaccines.

The Geiers proposed (contrary to the findings of all autism experts and endocrinologists) that children with autism suffer from excess testosterone. They ran a clinic in which they administered Lupron, a drug used for prostate cancer and in sex offenders to reduce levels of testosterone, to children with autism.

Because he endangered children with autism, Mark Geier had his medical license revoked in Maryland and in nine other states in which he was licensed.

Source: Geier v. State Bd. of Physicians, 1095/14 (Md. Ct. Spec. App. 2015)

Aluminum

Anti-Vaxx Myth: "Aluminum is a known neurotoxin. Studies have found that high levels of aluminum are also associated with autism." Source: Neil Miller, 2010; Adams et al, 2009

P.I.E.: False. The FDA calculated that over its first year of life, an infant is exposed to a maximum of 4.25 milligrams (mg) of aluminum from vaccines. Based on minimal risk levels established by the Agency for Toxic Substances and Disease Registry, *aluminum exposure from vaccines in the first year of life is well below this threshold.* **Sources:** Agency for Toxic Substances and Disease Registry, 2008; Mitkus et al, 2011; Keith, Jones, & Chou, 2002

Anti-Vaxx Myth: The pathway from the bloodstream to the brain is direct, making it very likely that toxins, as well as vaccine-strain diseases, are finding their way into the brain." Source: None

P.I.E.: Misleading. The bloodbrain barrier (BBB) is a mechanism designed to protect the brain from harm. The blood vessels tightly regulate what can pass through to the brain. In fact, brain infections are hard to treat because most medications cannot get past the BBB.

Sources: Daneman & Prat, 2015

A proposed minimal risk level (MRL) is an estimated amount of a chemical a person can absorb daily, whether by eating, breathing, or drinking, without a detectable risk to their health. MRLs undergo a rigorous review process. They are reviewed by the Health Effects/MRL Workgroup within the Division of Toxicology and Human Health Sciences, an expert panel of external peer reviewers, the agencywide MRL Workgroup, and participation from other federal agencies, including the EPA. They are submitted for public comment through the toxicological profile public comment period. In short, deciding safe levels of chemicals is a complicated and thorough process.

Anti-Vaxx Myth: "Aluminum is not perceived...by the public as a dangerous metal. Therefore, we are comfortable in terms of defending its presence in vaccines."

"When SmithKline Beecham offered the CDC to supply mercury-free DTaP vaccines, the CDC rejected their offer. Why would they do this?" **Source:** Kennedy, 2005

P.I.E.: Misleading. Robert Kennedy, a fierce anti-vaxxer, claimed these statements came from a meeting called the Simpsonwood Conference, organized by the CDC to discuss the possible issues from adjuvants in vaccines. Kennedy received transcripts from the conference. He **selectively** published a false version of conversations that took place between CDC officials and vaccine companies. His version falsely stated that scientists "hushed up" findings that thimerosal is dangerous. The full transcript (200 pages) is publicly available at https://skeptico.blogs. com/Simpsonwood_Transcript.pdf. **Source:** Simpsonwood Conference, June 7-8, 2000

> For more details on the Simpsonwood Conference, scan the QR code.



Note: Do you have a hard time believing the anti-vaccine movement would mislead the public? We experienced this firsthand in December 2018. After a four-hour vaccine workshop delivered in Lakewood, NJ, the video of the lecture was edited by an anti-vaxxer who made it seem that the Vaccine Task Force is against vaccination.

Aluminum intake by 12 months

4.25 mg: The total amount of aluminum salts in all vaccines combined.

150 mg: The amount of aluminum an average infant ingests in the first year.*

3,000 mg: Considered a safe intake of aluminum during a healthy infant's first year.**

*exclusively breastfed for first 6 months **based on 1 mg/kg body weight per day

Source: Vaccine. 2011 Nov 28;29(51):9538-43. doi: 10.1016/j.vaccine.2011.09.124

References:

Agency for Toxic Substances and Disease Registry. (2008). Toxic Substances Portal - Aluminum. Retrieved from: https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=191&tid=34

American Cancer Society ACS. (2014). Formaldehyde. Retrieved from: https://www.cancer.org/cancer/cancer-causes/formaldehyde.html

Children's Hospital of Philadelphia CHOP. (2018). Vaccine ingredients: Antibiotics. Retrieved from: https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-ingredients/antibiotics

Daneman, R., & Prat, A. (2015). The blood-brain barrier. Cold Spring Harbor perspectives in biology, 7(1), a020412. doi: 10.1101/cshperspect.a020412. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5858162/

Denizer, G., Friedland, LR., Krishnan, J., Shapiro, M. (2018). Understanding modern-day vaccines: what you need to know. Annals of Medicine, 50:2, 110-120. https://doi.org/10.1080/07853890.2017.1407035

El-Baz, F., Elhossiny, R. M., Elsayed, A. B., & Gaber, G. M. (2010). Hair mercury measurement in Egyptian autistic children. Egyptian Journal of Medical Human Genetics, 11(2). https://doi.org/10.1016/j.ejmhg.2010.10.007.

Environmental Protection Agency EPA. (2007). Alkyl mercury (methyl and ethyl mercury). US EPA Archive. Retrieved from: https://archive.epa.gov/region5/teach/web/pdf/mercury_org_summary.pdf

Fido, A., & Al-Saad, S. (2005). Toxic trace elements in the hair of children with autism. Autism, 9(3), 290-298. https://doi.org/10.1177/1362361305053255 Food Allergy Research and Education FARE (2019). Egg allergy and vaccines. Retrieved from: https://www.foodallergy.org/life-with-food-allergies/ living-well-everyday/egg-allergy-and-vaccines

Geier v. State Board of Physicians. 1095/14. Court of Special Appeals of Maryland Filed: May 29th, 2015. Docket Number: 1095/14. Publicly available at https://www.courtlistener.com/opinion/2804508/geier-v-state-bd-of-physicians/

Goroll, AH, & Mulley, AG. (2012). Primary Care Medicine: Office Evaluation and Management of the Adult Patient. Lippincott, Williams, & Wilkins. LiveScience. (2009). Germs may be good for you. Retrieved from: https://www.livescience.com/10601-germs-good.html

Keith, L. S., Jones, D. E., & Chou, C. H. (2002). Aluminum toxicokinetics regarding infant diet and vaccinations. Vaccine, 20, S13-S17. https://doi.org/10.1016/S0264-410X(02)00165-2

Mitkus, R. J., King, D. B., Hess, M. A., Forshee, R. A., & Walderhaug, M. O. (2011). Updated aluminum pharmacokinetics following infant exposures through diet and vaccination. Vaccine, 29(51), 9538-9543. https://doi.org/10.1016/j.vaccine.2011.09.124

National Academies of Sciences, Engineering and Medicine (2001). Immunization Safety Review: Thimerosal - Containing Vaccines and Neurodevelopmental Disorders. Retrieved from: http://iom.nationalacademies.org/Reports/2001/Immunization-Safety-Review-Thimerosal---Containing-Vaccines-and-Neurodevelopmental-Disorders.aspx.

Nelson, KB, Bauman, ML. (2003) Thimerosal and Autism? Pediatrics 111(3) 674-679. DOI: 10.1542/peds.111.3.674 https://pediatrics.aappublications.org/ content/111/3/674.long

Petrovsky, N. (2015). Comparative safety of vaccine adjuvants: a summary of current evidence and future needs. Drug safety, 38(11), 1059-1074). doi: 10.1007/s40264-015-0350-4. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/26446142

Priya, M. D. L., & Geetha, A. (2011). Level of trace elements (copper, zinc, magnesium and selenium) and toxic elements (lead and mercury) in the hair and nail of children with autism. Biological trace element research, 142(2), 148-158. https://doi.org/10.1007/s12011-010-8766-2

Stehr-Green, P., Tull, P., Stellfeld, M., Mortenson, P. B., & Simpson, D. (2003). Autism and thimerosal-containing vaccines: lack of consistent evidence for an association. American journal of preventive medicine, 25(2), 101-106. https://doi.org/10.1016/S0749-3797(03)00113-2

Tinkov, A. A., Skalnaya, M. G., Simashkova, N. V., Klyushnik, T. P., Skalnaya, A. A., Bjørklund, G., ... & Skalny, A. V. (2019). Association between catatonia and levels of hair and serum trace elements and minerals in autism spectrum disorder. Biomedicine & Pharmacotherapy, 109, 174-180. https://doi.org/10.1016/j.biopha.2018.10.051

US Department of Health and Human Services (HHS) (2017). Vaccine ingredients. Retrieved from: https://www.vaccines.gov/basics/vaccine_ingredients US Food and Drug Administration FDA (2018). Common ingredients in US licensed vaccines. Retrieved from: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/common-ingredients-us-licensed-vaccines

The Health Status of UNVACCINATED CHILDREN

Anyone who is not immune to a disease is more likely to catch and spread it. Even among vaccinated people, a small percentage do not build immunity. These people are also susceptible to catching and spreading the disease. However, it is impossible for fully vaccinated individuals who do build immunity (which is the vast majority) to spread the disease. Many studies have clearly demonstrated that neighborhoods with high rates of vaccine exemptions (in other words, unvaccinated individuals) tend to have more disease outbreaks (see the Appendix). Source: CHOP, 2019

How does herd immunity work? Bacterial and viral diseases spread quickly and can easily make a lot of people sick. This in turn can lead to a widespread outbreak of the illness. However, when enough people are vaccinated against a particular disease, the bacteria or virus (which need a host to reproduce) dies out. Eventually, the disease becomes rare and, at times, eradicated altogether.

Source: Nazario, B., 2018

It appears that anti-vaccine parents do not understand that they don't see much preventable infectious diseases in their families because of herd immunity from those who do vaccinate. By not vaccinating their children, they put their children at a high risk of catching and suffering from preventable diseases.

Anti-Vaxx Myth: Unvaccinated children are far healthier than vaccinated children.

P.I.E.: FALSE. There are studies that look at health differences in children whose parents have chosen not to vaccinate. See the table on the next page for some of the studies.

STUDY	DETAILS	SUMMARY
Schmitz, R., Poethko-Müller, C., Reiter, S., & Schlaud, M. (2011). Vaccination status and health in children and adolescents: findings of the German Health Interview and Examination Survey for Children and Adolescents (KiGGS). <i>Deutsches</i> <i>Arzteblatt international</i> , 108(7), 99–104. doi: 10.3238/ arztebl.2011.0099	 Number of children: 17,641 Location: Germany Total time: 3 years Disease compared: allergic disease and non-specific infections 	Vaccinated children aged 0-17 were healthier than unvaccinated children, when comparing allergic disease and non-specific infections.
Grabenhenrich, LB, et al. (2014) Early-life determinants of asthma from birth to age 20 years: A German birth cohort study. Journal of Allergy and Clinical Immunology. 133:4, 979-988. doi: https://doi.org/10.1016/j. jaci.2013.11.035	 Number of children: 1,314 Location: Germany Total time: 20 years Disease compared: asthma 	Asthma incidence was lower in children who were vaccinated (MMR vaccine/tick- borne encephalitis vaccine/BCG vaccines were counted in this study). Asthma triggers for children included having a parent with asthma and nasal allergies. The researchers said avoiding tobacco smoke exposure during pregnancy, receiving vaccinations in early childhood, and starting daycare between 1.5 and 3 years of age might prevent or delay the development of asthma.
Timmerman, CA, et al. (2015) Asthma and allergy in children with and without prior measles. Pediatric Allergy and Immunology. (8):742-9. doi: 10.1111/pai. https://www.ncbi.nlm.nih.gov/ pubmed/25845848	 Number of children: 640 Location: Faroe Islands Total time: 13 years Disease compared: asthma and hypersensitivity/ allergies 	Children were followed from birth and examined at 5, 7, and 13 years old. Only 533 out of 640 children received the MMR. All received full physical examinations, blood work and allergy skin-prick tests. The study found that the children who received the MMR had a 66% risk reduction for asthma and hypersensitivity/allergy that lasted until the children were 13 years old. The researchers also found that the vaccinated children did not have eczema or other allergic reactions in higher instances than unvaccinated children.
Taylor LE, Swerdfeger AL, Eslick GD. (2014) Vaccines are not associated with autism: an evidence-based meta-analysis of case-control and cohort studies. Vaccine. 32(29):3623-9. doi: 10.1016/j. vaccine.2014.04.085.	 Number of children: 1,256,407 Location: U.K., U.S., Denmark, Poland, and Japan Total time: N/A Disease compared: Autism 	Vaccinations are not associated with the development of autism or autism spectrum disorder. Furthermore, the ingredients of vaccines (thimerosal or ethyl mercury) or the MMR are not associated with the development of autism or autism spectrum disorder.

Anti-Vaxx Myth: When they do a double-blind, randomized, saline placebo-controlled medical trial comparing vaccinated and unvaccinated children and we get the results, THEN we will see what the truth is!

P.I.E.: Unethical and almost impossible! Many anti-vaxxers claim a randomized, double-blind, placebo-controlled medical trial would be the only way to prove the benefit of vaccines. However, leaving children unvaccinated would leave them utterly unprotected against vaccine-preventable diseases. Besides being totally unethical, we can see the results of how many unvaccinated children have gotten sick with vaccine preventable diseases right now. But let's try to design such a study. This is what you would need to have a randomized, double-blind, placebo-controlled medical trial.

For a randomized study, we would need two very large groups of children. They would have to be divided equally to have the same number of percentages by age: newborns and children up to age 13. They would need to have similar numbers of children with issues: allergies, immune disorders, on chemotherapy, and other medical problems.

The children would have to be separated from everyone who has already been vaccinated to not take advantage of herd immunity. They may need to be moved to a location far away to keep the study as accurate as possible.

A double-blind study requires that neither the researchers nor the subjects know who is in which group. The first group, Group A, would follow the CDC's immunization exactly and on time. They would get these vaccines: diphtheria, tetanus, pertussis, Haemophilus influenzae type B (Hib), pneumococcus, polio, rotavirus, hepatitis A, hepatitis B, measles, mumps, rubella (MMR), chickenpox, human papillomavirus (HPV), meningococcus, and influenza. The second group, Group B, would also go to the doctor and also get injections but the injections would be a placebo. Why would they need to get stuck with a needle? This is to keep the study accurate and reliable. In a doubleblind study, no one knows who is getting the medicine or the placebo.



A common misconception about placebos is that they have to be saline only. This does not work for many reasons. For example, in a study for a new cancer drug, no one (researchers or patients) accepts the real risk of death by giving a cancer patient in the study a placebo made of sugar water or saline only. As a placebo, they use current cancer treatment compared to the new medication to test if the new medication is at least as good as current accepted treatments.

In the meantime, the children would all go to day care, school, and camp. They would go to amusement parks, shopping malls, and parks. They would travel by airplane. They would live their lives as normally as possible.

The children would be followed for several years. Why years? To do the study correctly, it takes time to see what develops. If the study is cut short, we will not have the correct data for long-term effects. We will look at side effects of everything because we will not know which group has been getting the vaccines and which have been getting the placebo. We will have to look at patterns with these side effects because a single report doesn't do us any good. If a side effect is really happening, it happens more than once.

After at least five years of the study, we can start to look back at the data we collected. The placebo group should not have had any side effects whatsoever. Maybe some of these kids will have allergies or autism — but we will know that it wasn't from the vaccines. We could compare all side effects and levels of disease between the vaccinated and placebo group. Then after 20 or 30 years we can finally examine the full data of how many children got sick, how many had serious complications, and how many died and try to guess which group got the placebo.

It is clear that such a study is impossible. No parent would want their child in such a double-blind study. An anti-vaxx parent would not risk their child receiving the vaccine and a pro-vaxx parent would not leave their child unprotected.

Anti-Vaxx Myth: Unvaccinated children do not have a unique ability to spread disease.

P.I.E.: Yes they do. Children who do not have immunity are at risk of catching and spreading disease. Among vaccinated children, 3% of those who get the MMR do not build immunity to the measles and 10% of children who get the DTaP don't build immunity to pertussis. Among unvaccinated children, the risk is 100%. Remember if you are immune, you cannot be a carrier of the disease.

Source: CDC, 2018

Anti-Vaxx Myth: "Why would an unvaccinated child pose a risk to children immune to the disease? Apparently, the vaccines are not as effective as hoped."

P.I.E.: False. The unvaccinated child poses a risk to children and adults who cannot be vaccinated

because of medical contraindications, and to the small percentage of people for whom the vaccines did not create immunity! People who may not be vaccinated include those with immunocompromised systems, going through chemotherapy, with severe allergies, or who are pregnant.

A person who is immune to a disease *cannot contract the disease and cannot spread it to others.* The more people vaccinated, the fewer opportunities a disease has to spread. **Source:** CDC, 2018

Anti-Vaxx Myth: "The FDA conducted a vaccine study on baboons to figure out what has gone wrong with the [pertussis] vaccine" ... "This research suggests that although individuals immunized with the acellular pertussis vaccine may be protected from disease, they may still become infected with the bacteria without always getting sick and are able to spread the infections to others."

P.I.E.: Misleading. The vaccine itself does not cause asymptomatic pertussis. A little over 80% of people gain immunity from the whooping cough vaccine. In the case of someone who had the vaccine but was still a carrier, the vaccine did not work for them. In some cases, vaccinated people may not have whooping cough symptoms (sometimes referred to as being "asymptomatic") but may still spread the disease. Researchers and scientists propose these reasons: a decrease in the protective immunity from the vaccination or natural infection over time, low vaccine coverage

in the community, a change in the *Bordetella pertussis* bacteria itself, or asymptomatic transmission from individuals.

Source: Althouse & Scarpino, (2015), FDA (2018)

Anti-Vaxx Myth: Vaccines are recognized by the U.S. Congress as being "unavoidably unsafe." Source: None given.

P.I.E.: Misleading. This is a legal phrase often used for any medication in which 100% safety is not guaranteed — which includes

nearly all medications. This term does not reflect on Congress' position on vaccine safety. Rigorous clinical trials and post-licensing studies continue to evaluate the safety of vaccines in conjunction with several safety databases and committees run by the CDC. These include VAERS (Vaccine Adverse Event Reporting System), VSD (Vaccine Safety Data Link), ACIP, and others. See "Vaccine Safety." **Source:** Schwartz, 1985; FDA, 2018

Anti-Vaxx Myth: The number of children with chronic illnesses has

quadrupled since the time when some of our parents were kids. **Source:** "A Harvard Study"

P.I.E.: This is a random statement which has no correlation with vaccines. The anti-vaccination groups attempt to connect chronic illnesses and vaccines, yet they bring no evidence to back up a connection, let alone to verify the accuracy of this blanket statement. **Source:** Van Cleave, Gortmaker, & Perrin, 2010

References:

Althouse, B. M., & Scarpino, S. V. (2015). Asymptomatic transmission and the resurgence of Bordetella pertussis. BMC medicine, 13, 146. doi:10.1186/ s12916-015-0382-8

Centers for Disease Control and Prevention (CDC) (2018). Vaccines and immunizations: Why immunize. Retrieved from: https://www.cdc.gov/vaccines/vac-gen/why.htm

College of Physicians at Philadelphia (CHOP) (2019). Herd immunity: History of vaccines. Retrieved from: https://www.historyofvaccines.org/content/ herd-immunity-0

Nazario, B. (2018) What is herd immunity and how does it protect us. Retrieved from: https://www.webmd.com/vaccines/news/20181130/what-herd-immunity-and-how-does-it-protect-us

Schwartz, V. (1985). Unavoidably unsafe products: Clarifying the meaning and policy behind Comment K, 42 Washington & Lee Law. Review 1139. Retrieved from: https://scholarlycommons.law.wlu.edu/wlulr/vol42/iss4/3

United States Food and Drug Administration (FDA) (2018). Vaccine safety questions and answers. Retrieved from: https://www.fda.gov/vaccinesblood-biologics/safety-availability-biologics/vaccine-safety-questions-and-answers

Van Cleave, J., Gortmaker, SL, Perrin, JM. (2010). Dynamics of obesity and chronic health conditions among children and youth. JAMA. 303(7):623-30. doi: 10.1001/jama.2010.104. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/20159870.

OVERALL VACCINE SAFETY AND APPROVAL SYSTEMS **VACCOUNT VACCINE SAFETY AND APPROVAL SYSTEMS DEVELOPMENT, TESTING, REPORTING, AND COMPENSATION**

How are vaccines developed?

Traditional vaccine development and approval is a lengthy process that can take decades. Vaccines are treated like any other biologic or drug. Vaccine development prior to testing in humans lasts five to six years. Basic laboratory research and pre-clinical studies must be performed. Many potential vaccines don't make it past the research phase due to a lack of immune response in laboratory testing.

To begin testing on humans:

1. An application for clinical trials must be submitted to the FDA. The application includes all available information, such as safety, results of animal testing, and the proposed method for clinical trial.

2. Pre-licensing testing is done in three stages (Phases 1-3), and each stage is closely monitored. In each stage, a larger group of people is tested. The final stage includes thousands of participants. The FDA may stop the trial at any point if there are potential safety concerns.

3. Once the three-step clinical trial is successfully completed, an application for licensing is submitted. The application is reviewed by a multidisciplinary team including biostatisticians, scientists, and physicians. This committee is separate from the FDA and makes a recommendation to the FDA on whether or not to allow licensing of the vaccine.

4. After the vaccine is licensed, the FDA continues to oversee every step of the production. Complete transparency is required, and any information must be turned over if requested. Each batch of the vaccine is tested to ensure that it is potent, pure, and sterile.

5. As long as the license is active, the vaccine continues to be monitored and studied. This is considered Phase 4 of clinical trials; post-market studies. **Source:** FDA, 2018a; History of Vaccines, 2018 any people who oppose vaccines will state there are no "real" safety studies on vaccines. This opinion is utterly false. Vaccines are studied and monitored from the very beginning. Pharmaceutical companies must prove repeatedly at every stage of development, testing, approval, and manufacturing that vaccines are safe, low risk, and beneficial. Once the vaccine is in use, multiple agencies continue to monitor its safety and provide additional checks.

There are several ways that vaccines are monitored for safety after licensing. There are multiple government agencies involved, including the CDC, FDA, National Institutes of Health, and Department of Defense.



1. Vaccine Adverse Event Reporting System (VAERS)

collects data of adverse events after vaccination from reports by health care professionals, vaccine manufacturers, vaccine recipients, and parents or family members of recipients. This system allows for patterns to be revealed and potential associations to be established by scientists at the FDA and CDC. Specific studies are conducted to follow up on reports of adverse events that are unexpected, happen more often than expected, or have unusual patterns. See examples of VAERS ID numbers in the text at the bottom of this page. For example, the RotaTeq vaccine was discontinued due to adverse events reported to VAERS.

2. Vaccine Safety Datalink (VSD) is a collaboration between the CDC and eight different health care organizations across the United States (CDC, 2018b). Scientists use the VSD to perform studies to determine if the side effects identified in VAERS are in fact related to vaccinations.

Anti-vaxxers like to pull data from VAERS. The issue with the information they pull is the data is self-reported. It is not proof that an injury or event was directly caused by the vaccine. Here are some examples taken directly from VAERS: ID 122363-1 (began craving bananas), 4482650-1 (cystic acne), 712613-1 (ingrown hair on lip).

3. Post-Licensure Rapid Immunization Safety Monitoring

(PRISM) is the largest vaccine safety surveillance system in the United States, accessing the health information of over 190 million people. This allows the FDA to monitor for rare events by linking data from health plans with state and city immunization records. PRISM is under the umbrella of the Sentinel Initiative, which is how the FDA monitors all medical products after they are licensed.

4. Clinical Immunization Safety Assessment (CISA) Project is a

network of vaccine experts from the CDC who work in collaboration with seven medical research centers and other partners. Together they study vaccine safety by conducting individual case reviews and clinical research studies. Their goal is more personal: "To improve understanding of AEFI [adverse events following immunization] at the *individual patient level.*" CISA serves as a consultant for providers to make case-by-case immunization decisions for patients with complex issues.

5. Advisory Council on Immunization Practices (ACIP)

is a group of medical and public health experts who make vaccine recommendations based on careful reviews of vaccine safety and effectiveness data. Recommendations are modified based on safety monitoring. Some of the factors considered include how safe and how effective the vaccine is at specific ages, how serious the disease we are preventing is, and how many people would get the disease if they weren't vaccinated. For example, although there are vaccines for yellow fever, typhoid, anthrax, dengue, and other illnesses, the CDC does not routinely recommend them for most people. According to the WHO (World Health Organization) and CDC, there are vaccines for 31 diseases, yet only 13 of them are on the routine childhood immunization schedule, protecting kids against 16 diseases.

6. Additional research and testing is done by DoD (Department of Defense), VA (Veterans Administration), NIH (National Institute of Health), and NVP (National Vaccine Plan).

For a more complete list, visit the US Department of Health and Human Services website: https://www.hhs.gov/nvpo/ national-vaccine-plan/vaccinesafety-scientific-agenda/index.html **Source:** CDC 2015a, CDC, 2018b; CDC, (N.D); HHS, 2017; FDA, 2018b

Anti-Vaxx Myth: "No reliable system is in place for tracking vaccine reactions since most doctors do not recognize and report them." Source: None given.

P.I.E.: False. The Vaccine Safety Datalink, together with VAERS, work together to monitor the safety of vaccines. Source: CDC, 2017

Anti-Vaxx Myth:

"The FDA estimates that VAERS numbers account for only 10% of actual [injury] cases... The true number of adverse vaccine reactions is anywhere between 120,000 and 1.2 million every year!" **Source:** None given.

P.I.E.: Misleading. The former FDA Commissioner, David Kessler, made a statement quoting a *study done in 1987* about under-reported side effects with regard to ALL drugs and medications, not just vaccines. It is important to keep in mind that VAERS uses an online reporting system, and this study was done before the internet was widely used. The data has *consistently* shown serious adverse effects occur at a rate of one per 1 million doses.

Source: Kessler et al, 1993; WHO, 2019

Anti-Vaxx Myth: "In response to the question of how the CDC could ethically promote vaccines whose safety has not been proven, they give the outrageous response that, 'Withholding new vaccines from children who would benefit from them while long-term studies were being done would be unethical.'

The Declaration of Helsinki is the foundational document on human research ethics, developed by the World Medical Association, and guides medical research involving humans. For more information, scan the QR code.



TYPE OF STUDY	EXPOSURE TO THE PROBLEM	FOLLOW-UP TO THE SOLUTION
Prospective	At the beginning when we decide to do the study	Outcome is seen in the future
Retrospective At some point in the past – looking back at history		Outcome is seen from what happened

If studies would prove that these vaccines are dangerous, wouldn't it be more unethical to administer them?"

Source: As seen in PEACH magazine.

P.I.E.: False. It is a big mistake to state the safety of vaccines has not been proven. The actual process of vaccine development is long and arduous (often 10-15 years!) and has many phases of clinical trials in which the vaccine is assessed for safety and effectiveness. Once the vaccine manufacturer has developed the vaccine and tested it repeatedly for safety, the FDA subjects it to a multi-step approval process that may include additional clinical trials. Only then will the vaccine be produced for widespread public use. Even after the vaccine has been developed and licensed, ongoing surveillance of the vaccine continues via the VAERS system, VSD, and occasionally, Phase 4 clinical trials.

Once studies have determined the safety of a new vaccine and benefits are recognized, it would be unethical under the terms of the Declaration of Helsinki (see callout on previous page) to withhold the vaccines while conducting "longterm" studies.

Source: FDA 2015; WMA 2013

Anti-Vaxx Myth: "As long as health authorities neglect to conduct long-term studies on individual vaccines, as well as the vaccine's schedule as a whole, their assertion that the benefits outweigh the risks is baseless. If they have not done a proper risk-benefit analysis..." Source: As seen in PEACH magazine.

P.I.E.: There are many clinical trials as well as retrospective short and long-term studies on vaccines that show the risk of vaccination is tiny (please see the Appendix).

Additionally, there is a tremendous amount of evidence that clearly shows vaccines provide enormous benefit. Long-term randomizedcontrolled prospective studies would require that large groups of children not be vaccinated for many years. It would be unethical under the Declaration of Helsinki (and see page 22 in "The Health Status of Unvaccinated Children" for more information) to conduct a study in which groups of individuals would be placed at extreme risk. There is plenty of evidence to support the fact that the benefits of vaccines outweigh the risks. The most important benefit is the dramatic decrease of illness and death from the nine main diseases targeted by vaccination in the United States. Sources: WMA 2013; Orenstein & Ahmed, 2017; Andre et al, 2008

Anti-Vaxx Myth: "When determining vaccine safety, longterm studies are never done... For example, a reaction is counted only if it occurs within an arbitrarily set time period, such as 48 hours... Two to three weeks is considered a normal trial period!" Source: None.



P.I.E.: False.

A. Dead vaccines produce arm redness, swelling or fever that usually happen within 48 hours. Most vaccine trials recognize this "reactogenicity" (the local reaction in the injection site such as redness and swelling) as common reactions. The trials look for adverse events such as other symptoms or outcomes. Therefore, many studies use information collected in the 72 hours following vaccination, and many collect information for far longer.

B. Live vaccines (for example, MMR, varicella) produce a *delayed* immune response, and fever can begin seven to 10 days after vaccination. All of these studies track adverse events for at least two weeks; most look through 42 days. Most clinical trials actively follow up with participants for at least one year. After this time, the CDC and FDA continue to evaluate possible adverse effects post-market through the VAERS and VSD reporting systems. Sources: Shimabukuro, Nguyen, Martin, & DeStefano, 2015; Sanofi Pasteur, 2005, GlaxoSmithKline, 2018; Merck & Co., 2018; History of Vaccines, 2018

Anti-Vaxx Myth: "It is rare for a vaccine to be removed from circulation, no matter how much damage it is causing."

P.I.E.: False. Although vaccines rarely cause long-term harm, there have been a few cases where a

specific vaccine was found to be unsafe. In these cases, the vaccine was immediately removed from circulation.

As with any drug, not all adverse effects will occur during clinical trials. Information is continually gathered to identify potential issues after a vaccine is available to the public. A well-known example is the rotavirus vaccine. Post-market reports, including VAERS reports, showed an increase in a condition called intussusception, or bowel obstruction. Thirteen months after licensing, the vaccine was removed from the market. **Source:** CDC, 2004

a. Cutter incident (1955)

In 1955, there were over 40,000 cases of abortive polio, a minor form of polio, seen in children who received the vaccine. In total, 164 people were permanently paralyzed, and 10 people died. Cutter Laboratories immediately recalled their vaccine and a close investigation by the government of the laboratory showed they did not follow proper protocol when developing the vaccine. The Cutter incident led to the creation of better vaccine regulations and oversight.

b. SV40 (1950s)

Several lots of polio vaccines were found to be contaminated with simian virus 40 (SV40). Following the discovery, all new lots of the vaccine were tested to ensure that they did not contain any SV40. Though there were initial concerns of its relationship to cancer, multiple studies were conducted and showed no causal relationship. Since 1963, SV40 is no longer used in the production of vaccine.

Examples of Removed Vaccinations

c. Swine flu vaccine (1976)

The 1976 swine flu vaccine was associated with a very small risk for developing Guillain-Barre syndrome (1 out of 100,000) (CDC, 2015a). Even though the risk was minimal, production of the vaccine was halted for that year (CDC, 2015b).

d. Rotavirus (1998)

Shortly after the RotaShield vaccine was licensed for use, there were cases of otherwise healthy babies who developed intussusception (bowel blockage) after vaccination. The manufacturer removed the vaccine from circulation in 1999 after two thorough government investigations showed a correlation between RotaShield and intussusception. The ACIP suspended its recommendation that babies be vaccinated with RotaShield.

Source: Offit, 2005; CDC, 2015b; CHOP, 2016

VACCINE INJURY COMPENSATION

accines save lives! They work by preventing serious disease. Vaccines, like all medications, can have side effects, but most are very mild. In very rare cases, a vaccine can cause a serious problem, such as a lifethreatening allergic reaction. For such cases, there is the National Vaccine Injury Compensation Program to which people can report their vaccine-related injury.

HHS created the program in 1988, as a no-fault alternative to the traditional U.S. legal system for vaccine injuries. This happened when lawsuits against doctors and vaccine companies threatened to cause vaccine shortages and a drop in vaccination rates in the United States. This is similar to programs started in the 1960s in Germany and France. The program is funded by a 75¢ tax on each vaccine dose that is collected from vaccine manufacturers by the US Department of the Treasury. Routine vaccines given to children and some adult vaccines are covered under this program.

Anyone who received a covered vaccine and believes that they were injured as a result can file a petition. Parents, legal guardians, and representatives can file for disabled adults or children.

Source: HRSA, 2019; WHO, 2011; Fine, 2003

What is the process?

An individual files a petition with the US Court of Federal Claims.

HHS medical staff reviews the petition, decides if it meets the medical criteria for payout, and makes an initial recommendation.

The US Department of Justice develops a report, including the medical recommendation and legal analysis, which is then submitted to the Court. The Court itself does not determine if the case meets medical criteria or if it is likely that the vaccine could have contributed to the injury.

The report is presented to a courtappointed special master who decides whether the petitioner should be paid, often after holding a hearing in which both petitioner and the government can present evidence. If compensation is awarded, the special master determines the amount and type. It is important to note that the special master does not determine IF the vaccine CAUSED the injury but whether it is possible that the injury could have been related to the vaccination based on a predetermined guideline.

The Court orders HHS to award compensation. Even if the petition is dismissed, in certain situations the Court may order HHS to pay attorneys' fees and costs.

VACCINE

The special master's decision may be appealed and petitioners who reject the decision of the court (or withdraw their petitions within certain timelines) may file a claim in civil court against the vaccine company and/or the health care provider who administered the vaccine. For more information, visit hrsa.gov/vaccinecompensation. **Source:** HRSA, 2018

Anti-Vaxx Myth: "Congress passed the National Childhood

Vaccine Injury Act...and established a disability and death tax on childhood vaccines.... Ironically, instead of protecting children, the act protects doctors and drug companies against legal action." **Source:** None given.

P.I.E.: Having a vaccine injury program is beneficial in the following ways:

1. Frequent lawsuits would be costly to companies that produce vaccines and would threaten vaccine supply. Because this would cause a public health issue, many countries decided to set aside money in a separate fund in order to ensure vaccine production would not be threatened.

2. The costs of filing a lawsuit can be prohibitive for people who struggle financially. An independent system of compensation removes most of these barriers. This system allows MORE people to receive payouts for disability or death. The US Department of Treasury collects the taxes, manages the fund's investments, and produces Vaccine Injury Compensation Trust Fund monthly reports.

Many developed countries, not just the United States, handle vaccine injuries this way, including Germany, Switzerland, Canada, Thailand, Finland, Sweden, Norway, Denmark, England, France, and more. See image below. Anti-Vaxx Myth: "Despite clear evidence that vaccines cause harm in at least hundreds of thousands of people yearly, the CDC has decided that they are nonetheless worthwhile."

P.I.E.: False. In the 10-year span from 2006-2016 over **3 billion doses of vaccines** were given in the U.S. In the same time period, there were **3,745** compensations through the Vaccine Injury Compensation Program for claims of vaccine injury, approximately *one per 1 million doses*, consistent with numerous studies indicating vaccine injuries happen to one in 1 million cases. **Source:** HRSA, 2018



Source: Looker, C. and Kelly, H. No-fault compensation following adverse events attributed to vaccination: A review of international programmes. Bulletin of the World Health Organization. 2011.

References:

Andre, F. E., Booy, R., Bock, H. L., Clemens, J., Datta, S. K., John, T. J., ... & Santosham, M. (2008). Vaccination greatly reduces disease, disability, death and inequity worldwide. *Bulletin of the World Health Organization*, *86*, 140-146. doi:10.2471/BLT.07.040089

Centers for Disease Control and Prevention (N.D.) The Vaccine Adverse Event Reporting System (VAERS) Request. Retrieved from: https://wonder.cdc.gov/controller/datarequest/D8; jsessionid=79C513B5C53B5BAFF429D2F4F7C7407E

Centers for Disease Control and Prevention (2004). Suspension of Rotavirus Vaccine After Reports of Intussusception ----United States, 1999. Retrieved from: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5334a3.htm

Centers for Disease Control and Prevention. (2015a). Clinical immunization safety assessment (CISA) project. Retrieved from: https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html

Centers for Disease Control and Prevention. (2015b). Historical Vaccine Safety Concerns. Retrieved from: https://www.cdc.gov/vaccinesafety/concerns/concerns-history.html

Centers for Disease Control and Prevention. (2017). Vaccine Safety Datalink. Retrieved from: https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html

Children's Hospital of Philadelphia. (2016). Vaccine Ingredients – SV40. Retrieved from: https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-ingredients/sv40

Fine, A. (2003). Diphtheria, tetanus and acellular pertussis vaccine (DTaP): a case study. Committee on the Evaluation of Vaccine Purchase Financing in the United States.

GlaxoSmithKline Biologicals. (2018). KINRIX (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine) [PDF]. Retrieved from: https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Kinrix/pdf/KINRIX.PDF Health Resources and Service Administration. (2018). National Vaccine Injury Compensation Program Data Report [PDF]. Retrieved from: https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/monthly-stats-december-2018.pdf

Health Resources and Service Administration. (2019). National Vaccine Injury Compensation Program. Retrieved from: https://www.hrsa.gov/vaccine-compensation/index.html

History of Vaccines (2018). Vaccine Development, Testing, and Regulation. Retrieved from: https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation

Kessler, D. A., Natanblut, S., Kennedy, D., Lazar, E., Rheinstein, P., Anello, C., ... & Couig, M. P. (1993). Introducing MEDWatch: a new approach to reporting medication and device adverse effects and product problems. Jama, 269(21), 2765-2768. doi:10.1001/jama.1993.03500210065033

Looker, C., & Kelly, H. (2011). No-fault compensation following adverse events attributed to vaccination: a review of international programmes. *Bulletin of the World Health Organization*, 89, 371-378.

Merck and Co., Inc. (2018). VARIVAX® Varicella Virus Vaccine Live. [PDF]. Retrieved from https://www.merck.com/product/usa/pi_circulars/v/varivax/varivax_pi.pdf

Offit, P. A. (2005). The Cutter incident, 50 years later. New England Journal of Medicine, 352(14), 1411-1412.

Orenstein, W. A., & Ahmed, R. (2017). Simply put: vaccination saves lives. Proceedings of the National Academy of Sciences of the United States of America 114(16); 4031-4033 https://doi.org/10.1073/pnas.1704507114

Sanofi Pasteur, Inc. (2005). Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed: Tripedia. [PDF]. Retrieved from: https://www.vaccineshoppe.com/assets/pdf/tripedia

Shimabukuro, T. T., Nguyen, M., Martin, D., DeStefano, F. (2015). Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). Vaccine 33(36), 4398-4405. doi: 10.1016/j.vaccine.2015.07.035

US Department of Justice (DOJ). (2018). Vaccine Injury Compensation Program. Retrieved from: https://www.justice.gov/civil/vicp.

US Food & Drug Administration FDA (2018a). Vaccine Product Approval Process. Retrieved from: https://www.fda.gov/vaccines-blood-biologics/ development-approval-process-cber/vaccine-product-approval-process

US Food and Drug Administration. (2018b). VAERS overview. Retrieved from: https://www.fda.gov/vaccines-blood-biologics/vaccine-adverse-events/vaers-overview

US Department of Health and Human Services. (2017). Vaccine safety. Retrieved from: https://www.vaccines.gov/basics/safety/index.html

World Health Organization (WHO) (2011). No-fault compensation following adverse events attributed to vaccination: a review of international programmes [PDF]. Retrieved from: https://www.who.int/bulletin/10-081901.pdf

World Health Organization (WHO). (2019). Vaccine Safety e-Training. Retrieved from: http://vaccine-safety-training.org/rates-of-adverse-vaccine-reactions.html

World Medical Association.(WMA) (2013). Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (10th Edition). Retrieved from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

FOLLOW THE MONEY

Big Pharma

The anti-vaccination movement claims there is a group of scientists, doctors, and medical experts who are paid to hide information from the public about the "dangers" of vaccines to protect the profits of drug companies. Some say "Big Pharma" (a term referring collectively to the global pharmaceutical industry) suppresses the research of brave scientists willing to tell the "truth" about vaccines.

Good studies carefully examine the effectiveness of drugs and therapies on large groups of people and use different methods to get the most accurate results. Before being published in the world's most prestigious journals, studies must be evaluated by multiple expert people (peer-reviewed). All reliable, accurate, and well-designed health care research is peer-reviewed. If there is any question about the outcome, or to test the results on different groups of people, the study is done again (replicated). There are many studies that actually cast doubt on popular drugs, devices, and therapies! **Source:** Blaskiewicz, 2013

For example, a study published by the *British Medical Journal* looked at the British version of acetaminophen (Tylenol) (manufactured by Johnson & Johnson) for treating back pain and osteoarthritis. The results said it is not an effective treatment. Another study in *Respirology* journal also looked at Tylenol and said that it doesn't work for influenza infection. These are just two examples of well-done studies, published within a year of each other, doubting the effectiveness of Tylenol, one of the most popular pain medications. Is it possible the scientists, researchers, hospitals, clinics, journal editors, peer-reviewers, and publishers all resisted the bribes to not publish this? The results of these studies caused a bit of a media frenzy. Johnson & Johnson was unable to suppress the truth. **Source:** Machado et al, 2015; Jeffries et al, 2016
Conspiracy theorists are wrong about the pharmaceutical companies, scientists, and researchers. Drug companies have a very hard time preventing studies from being done on their products by independent researchers or negative studies coming out.

Big Pharma *wants* to stay in business. It is a bad business practice for them to sell drugs that hurt and harm their customers.

Anti-Vaxx Myth: "It is in the pharmaceutical industry's best interest to make as many vaccines mandatory as possible." Source: None given.

P.I.E.: False. Each state government decides what is the best vaccine policy for its citizens, not pharmaceutical companies. The overall goal of the government, whether state or federal, is to guard the public health. Vaccines make this possible.

Source: NCSL, 2019

The global pharmaceutical industry's income from vaccines represent 2.4% of total revenue. The remaining 97.6% is generated from medications and medical devices. In comparison, if the total income of the pharmaceutical companies were \$1,000, vaccine sales would be equal to \$24. It would be far more profitable for the pharmaceutical industry to stop making vaccines and allow infectious diseases to become widespread again, as the treatments are significantly more profitable than vaccines. Note: After smallpox was eradicated, the smallpox vaccine was pulled off the vaccine schedule. The ACIP only

recommends vaccines that are truly necessary! **Source:** US Government Accountability Office, 2017; Vanderslott & Roser, 2018

Anti-Vaxx Myth: Health care providers *get paid* by "Big Pharma" to give vaccinations so they have a financial incentive to do so.

P.I.E.: Misleading. "Vaccine bonuses" (an incentive given to some pediatricians for fully vaccinating a percentage of their patients) are given by *health insurance companies*, not pharmaceutical companies. Health insurance companies don't want to pay out big money for every childhood illness. Vaccines not only reduce illness, hospitalizations, and death; they also reduce cost. Insurance companies would rather pay for the cost of the vaccine than the cost to treat the disease. As the saying goes, "an ounce of prevention is worth a pound of cure." **Sources:** Chien, Li, & Rosenthal (2010); Millett, Gray, Saxena, Netuveli, & Majeed (2007)



In March 2017, an unvaccinated boy in Oregon received a cut on his forehead, then contracted tetanus. This widely reported story stated the hospital costs alone were over \$800,000 for a 57-day hospital stay. This amount does not include the costs for the helicopter he needed to take him to the hospital, his rehabilitation, or any follow-up visits to his doctor. This child did not fully recover and has long-term effects from his tetanus infection. The cost of getting a tetanus shot at a local Walgreens is \$54.99 for a DT or \$63.99 for a DTaP without any insurance. Quite a cost difference.

Source: Mervosh, 2019; Walgreens, 2019

38 | Parents Informed and Educated

Anyone who has had any experience with insurance companies recognizes they do not like to pay out claims. Why would insurance companies want to reward doctors for giving vaccinations if they make children sick? Wouldn't they have to pay out **way** more money when these children have long-term chronic illnesses or get hospitalized?

FYI: "Pay for Performance" is a model where insurance companies give doctors bonuses for keeping their patients healthy. These bonuses are given for various reasons, such as a smoking reduction, weight management, increased vaccination, and diabetes management, among others. In some cases, there isn't a bonus. Doctors will not get paid all the money they are owed if they don't meet the specific patient health goals the insurance company demands.

Source: Blue Cross Blue Shield, 2014

Anti-Vaxx Myth: The CDC owns vaccine patents and has a financial incentive to make sure vaccines are given, whether or not they are actually safe. They cannot be considered a reliable source.

P.I.E.: Misleading. The CDC does own patents on vaccine technology. But here are several points to keep in mind. First, owning a patent means you own an idea, not the licensing or manufacturing. Second, vaccines are not composed of one giant patent per vaccine. Each step of the recipe for the vaccine has its own patent. The CDC does tons of research. During the hundreds of thousands of hours of research, CDC scientists will come across an idea and then patent it. In addition, the CDC does not directly receive money earned from the patents. The total amount earned from licensing the rights by high



estimation is about \$5 million, which equals less than one percent of the \$7 billion CDC budget. **Source:** CDC, 2019

References:

Blue Cross Blue Shield (2014). Blue Cross And Blue Shield Companies Continue To Lead Nation's Path To Value-Based Health care. Retrieved from: https://www.bcbs.com/news/press-releases/blue-cross-and-blue-shield-companies-continue-lead-nations-path-value-based

Centers for Disease Control and Prevention CDC (2019). CDC Budget Request Overview: FY 2020 President's Budget Request. Retrieved from: https://www.cdc.gov/budget/documents/fy2020/cdc-overview-factsheet.pdf

Chien, AT, Li, Z, Rosenthal, MB. (2010). Improving timely childhood immunizations through pay for performance in Medicaid-managed care. Health Services Research. 45(6 Pt 2):1934-47. doi: 10.1111/j.1475-6773.2010.01168.x. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/20849554# Jefferies, S. , Braithwaite, I. , Walker, S. , Weatherall, M. , Jennings, L. , Luck, M. , Barrett, K. , Siebers, R. , Blackmore, T. , Beasley, R. , Perrin, K. and , (2016), Paracetamol in influenza infection. Respirology, 21: 370-377. doi:10.1111/resp.12685. Retrieved from: https://onlinelibrary.wiley.com/doi/full/10.1111/ resp.12685

Machado, GC, Maher CG, Ferreira PH, Pinheiro MB, Lin Chung-Wei C, Day RO, et al. (2015). Efficacy and safety of paracetamol for spinal pain and osteoarthritis: systematic review and meta-analysis of randomised placebo controlled trials. BMJ. 350 :h1225. Retrieved from: https://www.bmj.com/ content/350/bmj.h1225

Mervosh, S. (2019) An Unvaccinated Boy Got Tetanus. His Oregon Hospital Stay: 57 Days and \$800,000. New York Times March 9, 2019. Retrieved from: https://www.nytimes.com/2019/03/09/well/oregon-child-tetanus-vaccine.html

Millet, C., Gray, J., Saxena, S., Netuveli, G., Majeed, A. (2007). Impact of a pay-for-performance incentive on support for smoking cessation and on smoking prevalence among people with diabetes. CMAJ.176(12):1705-10. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/17548383

National Conference of State Legislatures (NCSL) (2019). Immunization policy issues overview. Retrieved from: http://www.ncsl.org/research/health/ immunizations-policy-issues-overview.aspx

Vanderslott, S, Roser, M. (2018) Vaccinations. Our World in Data. Retrieved from: https://ourworldindata.org/vaccination Walgreens Price Menu (2019). Retrieved from: https://www.walgreens.com/topic/health care-clinic/price-menu.jsp#preventionFocus

Blaskiewicz, Robert (2013). "The Big Pharma conspiracy theory". Medical Writing. 22 (4): 259. doi:10.1179/2047480613Z.00000000142. Retrieved from: https://www.tandfonline.com/doi/full/10.1179/2047480613Z.00000000142

WHAT ARE SIDE EFFECTS?

"Adverse events" and "side effects" are terms to describe an undesired effect caused by a medicine. Each has a slightly different meaning. Any adverse events are generally unexpected events and can be influenced by individual patient factors such as allergies or drug intolerances. The effects can be stopped by either reducing or completely stopping the medication. A side effect is usually expected, and doctors will warn patients of these events. With time, most side effects resolve on their own.

Source: Leheny, 2017

Any medicine can have side effects. It does not matter if it is prescribed, over-the-counter (such as Tylenol), an herbal supplement, or a vitamin. There are many reasons why some people get side effects: age, gender, how the body absorbs the medication, if they have allergies, or interactions with other vitamins, supplements, or other medications that they are taking. **Source:** FDA, 2018 Any medicine, including vaccines, with approval from the US FDA, has to list all of its known adverse events and side effects. These are found in human clinical trials (see "Vaccine Development" on page 27) and must be reported and included in the vaccine insert or patient information leaflet.

Reading an insert and seeing all kinds of terrifying adverse events is enough to scare anyone. Not everything listed has a direct cause and effect from the vaccine. Good clinical practice in clinical trials requires every adverse event be recorded, reported, and submitted to the institutional review board (or IRB, consisting of the people who gave approval for the study). Even if the adverse event is not related at all to the study, it still must be reported as the participant of the study was in the clinical trial at the time. For example, if someone dies in a car accident while participating in the study, that death needs to

be reported, even if it is clearly not related to the trial. **Source:** Marten, 2017

In addition, some side effects from the vaccine have a much lower rate than the complications from the disease. For example, encephalitis from *measles disease* occurs in one to three out of every 1,000 children with measles, but from the *measles vaccine* it occurs in one in 1 million doses. **Source:** Encephalitis Society, 2017.

Suspected adverse events after administration of any vaccine can be reported to VAERS. Call 1-800-822-7967 or email

info@VAERS.org.



References:

Encephalitis Society. (2017) Measles and encephalitis. Retrieved from: https://www.encephalitis.info/measles-infection-and-encephalitis Leheny, S. (2017). Adverse effect not the same as side effect. Pharmacy Times. Retrieved from: https://www.pharmacytimes.com/contributor/shelbyleheny-pharmd-candidate-2017/2017/02/adverse-event-not-the-same-as-side-effect

Marten. (2017). Reporting side effects (adverse events) in clinical research. Clinical Research Associates Course. Retrieved from: http://www.clinicalresearchassociated.com/reporting-adverse-events-clinical-research/

United States Food and Drug Administration FDA (2018). Finding and learning about side effects (adverse reactions). Retrieved from: https://www.fda.gov/drugs/drug-information-consumers/finding-and-learning-about-side-effects-adverse-reactions



A titer is an amount of something found in a solution. A vaccine titer is the amount of antibody found in a person's blood. (Antibodies are part of the immune system produced by the body to find and remove dangerous bacteria and viruses).

Certain types of titers can help to tell if a person is immune to a disease (IgG) or if a person actually has the disease (IgM).

Titers let us know the immune status of a person. Some people have been exposed to a disease, never had any symptoms, and have immunity without knowing it! Some people can become immune from a single dose of a vaccine. Other people may require two doses. Some immunity is not permanent. Titers can help determine someone's immune status and whether or not a person needs a second dose of a particular vaccine. **Source:** Luo, EK, 2017

How do I test my titers?

Some vaccine titers test for IgG antibodies. Blood is drawn (about 1-2 milliliters) into a red top tube. It takes about two days to get an answer. A positive result means that a person has immunity to measles. **Source:** LabCorp, 2019

Some people have a negative result. In those cases, immune status can be considered positive with:

• Written documented evidence of at least two doses of the measles/

MMR vaccine given on or after a person's first birthday (the first vaccine is usually given at age 12 months and the second one between 4 and 6 years old)

- Birth before 1957
- Laboratory confirmation
 of measles

Source: CDC, 2018

Current CDC and New York City Health Department recommendations are that a person who tests negative or equivocal (unsure) who has documented proof of two valid doses of MMR or measles vaccine is considered immune and does **not** have to get another dose of MMR.

References:

Luo, EK. (2017). Antibody titer test. Retrieved from: https://www.healthline.com/health/antibody-titer

Centers for Disease Control and Prevention CDC. (2018). Measles (Rubeola): For Healthcare Professionals. https://www.cdc.gov/measles/hcp/index.html LabCorp. (2019). Measles, mumps, rubella (MMR) immunity profile. Retrieved from: https://www.labcorp.com/test-menu/30931/measles-mumpsrubella-mmr-immunity-profile#

COMBINATION VACCINES AND THE CDC SCHEDULE

Why do we give vaccines to children when they are so young?

Newborn babies get antibodies from their mothers, usually before they are born. The immunity they do get does not last very long. Because there is such a high risk of them catching diseases or dying when they are so young, children have to get their vaccines at a young age. Giving several vaccines at once is safe, but many people are concerned too many vaccines are given too soon. Source: CDC, 2018

Some vaccines are given together in a single shot. This is called a **combination vaccine**. Such vaccines have been used safely in the United States since the 1940s. Babies can safely receive more than one shot at the same doctor's visit. Source: CDC, 2018

COMMON Combination Vaccines:

- Pediarix: DTaP + Hep B + IPV
- ProQuad: MMR + varicella
- ☑ Kinrix: DTaP + IPV
- Pentacel: DTaP + IPV + Hib

Source: CDC, 2019

The minute a baby is born, they enter the environment we all live in, filled with potential infectious bacteria or viruses. Yet, babies remain protected because even their brand new immune system can tolerate so many infectious particles.

Children are exposed to all kinds of bacteria every day. Eating food or even breathing introduces bacteria into the body. A simple cold exposes a child to four to 10 new antigens. A case of strep throat introduces 25-50 different antigens. It doesn't matter if these antigens enter the body from the nose, mouth, skin, or an injection. The body detects something foreign and deploys the immune system to activate. **Source:** WHO, 2018 Babies are so vulnerable and need protection against diseases. They should get the shots on schedule as soon as possible. **Source:** CDC, 2018

Certain diseases can be overwhelming to the immune system. The purpose of a vaccine is to introduce a weakened version so a baby can create a response to protect against the real disease. The vaccines a baby gets in the first two years of life total to about 150 antigens. Even if a baby received every vaccine all at once, its immune system handles many more than 150 bacterial and viral threats every single day. Combination vaccines do not overwhelm the immune system. **Sources:** CDC, 2018; WHO, 2018 Vaxelis (DTaP-Hib-IPV-Hep B), a 6-in-1 vaccine, was approved by the FDA for children 6 weeks to 4 years old. This vaccine is given three times. This vaccine will be available in the U.S. in 2021. **Source:** WebMD, 2018

Combination vaccines contain fewer preservatives than if each vaccine were to be given individually. For example, if a combination vaccine was divided into individual vaccines, each would need its own preservatives. In total, the child would receive triple the amount of preservatives. Also, with combination vaccines, there are far less needle sticks. There are many proven benefits to giving combined vaccines and

Do vaccines overwhelm a child's immune system?

A newborn baby can mount an immune response to **billions** of antigens found in the environment.

Jumping in a puddle exposes a child to tens of thousands of antigens from microorganisms.

For most vaccines, there are fewer than **10 antigens** per dose.

NO. Childhood vaccines contain a tiny fraction of the antigens kids confront daily.

Source: Pediatrics 2002;109;124-129

the risks have been thoroughly evaluated. **Source:** CDC, 2018

Anti-Vaxx Myth: The current vaccine schedule was created for the benefit of the pharmaceutical industry and not for the benefit of the baby.

P.I.E.: The CDC schedule was created with the collaboration of scientists and specialists in public health, infectious disease, and pediatrics researching what would most benefit the child's health. The goal is to give just enough immunity to prevent disease at the age it would cause the most harm. The schedule is based on when the vaccines are the safest. best tolerated, and offers the most protection to the baby. If someone decides to alter the schedule, there may be less benefit for the vaccine or more side effects from the vaccine, or even both, and leave the baby unprotected. Source: CDC, 2018

Anti-Vaxx Myth: Giving so many vaccines at once overwhelms the baby's system! It is so dangerous!

P.I.E.: False! A number of studies look at the effects of giving various vaccine combinations. Every new vaccine goes through a rigorous

licensing process (see "Vaccine Development" on page 27) and is tested along with the vaccines that are already recommended for a particular-aged child. If a combination vaccine replaces individual vaccines, it is proven to work as effectively and safely as an individual vaccine. Studies further show that children who are fully vaccinated on schedule do not have an "overwhelmed" immune system and are not more likely to become ill. For example, a study which examined 800,000 vaccinated and unvaccinated children found that those who were vaccinated with multiple-antigen vaccines were at no higher risk of having infections, proving their immune systems were NOT "overloaded." Sources: Edwards et al, 2016; Glanz et al, 2018; Igbal, Barile, Thompson, & DeStefano 2013

Anti-Vaxx Myth. "The U.S. has the most jam-packed vaccine schedule in the world." Source: None given.

P.I.E.: False. A comparison of 194 countries' vaccine schedules shows that the United States compares well to other developed countries.

• Hepatitis B vaccine is given three times in 90 countries, four times in 90 countries, five times in 13 countries, and six times in one country. It is given three times in the United States.

• Polio vaccine is given three times in 20 countries, four times in 80 countries, five times in 59 countries, six times in 28 countries, and seven times in six countries. It is given four times in the United States.

• BCG vaccine (tuberculosis vaccine) is given once in 150 countries, and twice in six countries. It is not recommended at all in the United States.

 Japanese Encephalitis vaccine is given once in four countries, twice in four countries, three times in one country, four times in one country, six times in one country.
 It is not recommended at all in the United States.
 Source: WHO, 2019

2021 Recommended Immunizations for Children From Birth Through 6 Years Old



Shaded boxes indicate the vaccine can be given during shown age range.

NOTE:

- If your child misses a shot, you do not need to start over go back to your child's doctor for the next shot. Talk with
 your child's doctor if you have questions about vaccines.
- Is your family growing? To protect your new baby against whooping cough, get a Tdap vaccine. The recommended time is the 27th through 36th week of pregnancy. Talk to your doctor for more details.
- * Two doses given at least four weeks apart are recommended for children age 6 months through 8 years who are getting an influenza (flu) vaccine for the first time and for some other children in this age group.
- ⁺ Two doses of HepA vaccine are needed for lasting protection. The first dose of HepA vaccine should be given between 12 months and 23 months of age. The second dose should be given 6 months after the first dose. All children and adolescents over 24 months of age who have not been vaccinated should also receive two doses of HepA vaccine.

If your child has any medical conditions that put them at risk for infection or is traveling outside the United States, talk to your child's doctor about additional vaccines that they may need.

Source: CDC, American Academy of Family Physicians, and American Academy of Pediatrics

References:

Centers for Disease Control and Prevention CDC (2017). Combination vaccines. Retrieved from: https://www.cdc.gov/vaccines/hcp/conversations/ downloads/fs-combo-vac.pdf

Centers for Disease Control and Prevention CDC (2018). Multiple vaccines and the immune system. Retrieved from: https://www.cdc.gov/vaccinesafety/concerns/multiple-vaccines-immunity.html

Centers for Disease Control and Prevention CDC (2019). Combination Vaccines. Retrieved from: https://www.cdc.gov/vaccines/parents/why-vaccinate/combination-vaccines.html

Edwards, MK., Maldonado, Y., Byingon, CL., Jefferson, T., Demicheli, V. (2016). Is the timing of recommended childhood vaccines evidence based? BMJ.352:i867. doi: 10.1136/bmj.i867. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/26907183

Glanz JM, Newcomer SR, Daley MF, DeStefano F, Groom HC, Jackson ML, Lewin BJ, McCarthy NL, McClure DL, Narwaney KJ, Nordin JD, Zerbo O. (2018). Association Between Estimated Cumulative Vaccine Antigen Exposure Through the First 23 Months of Life and Non-Vaccine-Targeted Infections From 24 Through 47 Months of Age. JAMA. 319(9):906-913. doi: 10.1001/jama.2018.0708. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/29509866#

Iqbal S, Barile JP, Thompson WW, DeStefano F. (2013). Number of antigens in early childhood vaccines and neuropsychological outcomes at age 7-10 years. Pharmacoepidemiol Drug Saf.22(12):1263-70. doi: 10.1002/pds.3482. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/23847024 WebMD. (2018). FDA approves new children's vaccine. Retrieved from: https://www.webmd.com/children/news/20181228/fda-approves-new-

childrens-vaccine World Health Organization (WHO). (2018). Global Vaccine Safety: Six common misconceptions about immunization. Retrieved from: https://www.who.int/vaccine_safety/initiative/detection/immunization_misconceptions/en/index6.html

World Health Organization (WHO). (2019). Vaccine-preventable diseases and monitoring system: 2018 global summary. Retrieved from: http://apps.who.int/immunization_monitoring/globalsummary/countries?countrycriteria%5Bcountry%5D%5B%5D=CHN

2021 Recommended Immunizations for Children 7 Through 18 Years Old



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/.

More information:

Flu: Everyone 6 months and older should get a flu vaccine every year. **Tdap:** All 11- through 12-year-olds should get one shot of Tdap.

HPV: All 11- through 12-year-olds should get a 2-shots 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.

MenACWY: All 11- through 12-year-olds should get one shot of meningococcal conjugate (MenACWY). A booster shot is recommended at age 16.

MenB: Teens 16–18 years old **may** be vaccinated with a serogroup B meningococcal (MenB) vaccine.

NOTE:

• Talk to your child's doctor about the vaccines recommended for their age. As of April 2021, COVID-19 vaccination is recommended for some adolescents.

Source: CDC, American Academy of Family Physicians, and American Academy of Pediatrics

These shaded boxes indicate children not at increased risk may get the vaccine if they wish after speaking to a provider.

SHOT BY SHOT: Hepatitis B

The hepatitis B (hep B) vaccine is an example of a cancer-preventative vaccine. The American Cancer Society says one of the ways to lower your risk for liver cancer is to get the hepatitis B vaccine. Source: ACS, 2019

What is hepatitis **B** and how does it spread?

Hepatitis B is a viral infection that causes the liver to become inflamed and can hurt its function. It can be a mild illness lasting only a few weeks, but it can also become a lifelong disease, causing serious liver damage. The younger a person is, the greater the chance of progressing to chronic (lifelong) liver disease. Of all infants infected at birth with hepatitis B, 90% develop chronic hepatitis B. Healthy adults who contract hepatitis B fare better; only 5% go on to have it as a chronic infection. Source: CDC, 2019a It can be spread through:

- Infected mothers during childbirth

Bodily fluid exchange with an

infected partnerSharing needles or syringes

Toothbrushes

Razors

Poorly sterilized medical
 equipment

• Poorly sterilized beauty tools (manicure/pedicure)

Direct contact with blood

• Open sores of an infected person **Source:** CDC, 2018b

How do I know I have hepatitis B?

During different stages of hepatitis B infections, there are different signs and symptoms.

 Phase 1 – No real symptoms (asymptomatic), but blood tests will show hepatitis infection and elevated liver enzymes

• Phase 2 – Loss of appetite, nausea, vomiting, joint pain, tiredness, itchiness

• Phase 3 – Dark urine, palecolored stool; pain in the upper right part of the stomach with liver enlargement, yellowish skin and eyes (jaundice) Phase 4 – Symptoms and jaundice resolve, liver enzymes return to normal
 Source: Samji, NS, 2017

Complications of hepatitis B:

The most serious complications of hepatitis B are due to chronic infection. Fifty percent of liver cancers are caused by chronic hepatitis B. Chronic hepatitis B leads to long-term liver disease. This can include:

Cirrhosis

• Hepatic decompensation: liver failure, may require a liver transplant

- Liver cancer
- Death

Source: CDC, 2018; Fattovich, Bortolotti, & Donato, 2008

Effectiveness of the hepatitis B vaccine:

After three doses of the hepatitis B vaccine, more than 95% of children (from birth to 19 years old) and 90% of healthy adults have immunity to this disease. The percentage refers to how many people out of 100 would be immune, rather than an individual person's actual immunity rate. **Source:** CDC, 2018 HEPATITISB VACCINE HbV (Recombinant) Pediatric/Adolesc utto doses

For more specific information, scan the QR codes for the Hep B package insert.



Recombivax Merck



Engerix B GSK

HEPATITIS B FACTS



1.4 million people

in the United States are living with chronic HepB. Most were infected as infants or during early childhood.

Up to **two-thirds** of

Americans living with chronic HepB do not know they are infected.



HepB is transferred by bodily fluids, usually blood. It can be passed from an infected mother to her baby at birth, or from a family member in close household contact to young children.

HepB can survive over **7 days** on contaminated surfaces.





90% of infants and **50%** of children under age 5 who contract HepB will develop chronic disease, leading to liver cancer, cirrhosis, and premature death.

HepB infections have decreased **95%** in children and adolecents since 1990 when the Hepatitis B vaccine was recommended for all newborns.

Common side effects of hepatitis B vaccine:

- Injection site soreness
- Irritability
- Fever
- Diarrhea
- Fatigue/weakness
- Diminished appetite
- Source: Merck, 2018

Who cannot receive the hepatitis B vaccine:

People with yeast allergy

 People with previous severe allergic reaction to any hepatitis
 B-containing vaccine

 Infants weighing less than 2,000 grams (a little over 4 pounds)
 Source: Merck, 2018

The hepatitis B vaccine has been administered in the United States since 1982. There has been more than a 90% decrease of hepatitis B infections since then. Despite this advance in health, about 1,000 new cases of babies with hepatitis B infections are born every year, and this is incurable.

It is standard medical practice for all pregnant women in the U.S. to be tested for the hepatitis B infection. There is no evidence that simply treating the mother alone can prevent the transmission of hepatitis B. The first dose of the hepatitis B vaccine, given at birth, helps prevent the spread from mother to baby. In 2017, the American Pediatric Society recommended all newborns receive the hepatitis B vaccine within 24 hours of birth. **Source:** AAP, 2017

Source: CDC 2013 surveillance

Anti-Vaxx Myth: "The National Vaccine Information Center has received reports of many adverse reactions to this vaccine including chronic eczema, seizures, arthritis, autoimmune disorders, diabetes, and infant death." Source: None given.

P.I.E.: First, reports submitted to this website are not validated research. Second, the National Vaccine Information Center is an anti-vaccination organization, which makes them prone to bias. There are multiple studies proving there is **no** association with the hepatitis

B vaccine and eczema, arthritis, rheumatoid arthritis, Bell's palsy, autoimmune thyroid disease, or hearing loss.

Sources: Schlaud et al, 2017; Schillie, 2018; Stratton et al, 2002; Stratton et al, 2012; Halsey et al, 1999; DeStefano et al, 2007; DeStefano et al, 2001

Anti-Vaxx Myth: "The [hepatitis B] vaccine causes approximately 10,000 cases of diabetes each year in the U.S." Source: Attributed to a quote by Dr. Classen **P.I.E.: False.** Repeated studies on diabetes incidence following vaccination have found no correlation or causation at all. See "Childhood Vaccines and Type 1 Diabetes" table.

Source: DeStefano et al, 2001

Anti-Vaxx Myth: "[Hepatitis B] is rarely found in children." "Newborns are exposed to the risks of a vaccine for a disease irrelevant to them to protect IV drug users, and others with risky lifestyles." Source: None given.

CHILDHOOD VACCINES AND TYPE 1 DIABETES

How to read this table: The term "cases" is defined here as children with diabetes (252 total). The term "controls" is defined here as children without diabetes (768 total). The rows represent the number of children with (cases) or without diabetes (controls) who had received a particular vaccine. Note that the percentages (seen in parentheses) for each are virtually identical.

VACCINE	VACCINATED	
	Cases (Total=252) N(%)	Controls (Total=768) N(%)
Hepatitis B	111 (44.0)	356 (46.4)
Hib	241 (95.6)	729 (94.9)
Pertussis (whole cell)	242 (96.0) 748 (97.4)	
Pertussis (acellular)	58 (23.0) 177 (23.0)	
MMR	232 (92.1)	696 (90.6)
Varicella	40 (15.9)	112 (14.6)

Source: DeStefano et al. Childhood Vaccinations, Vaccination Timing, and Risk of Type 1 Diabetes Mellitus. *Pediatrics*. 2001. 108(6)e112. doi: 10.1542/peds.108.6.e112.

P.I.E.: False. Previously, the American Academy of Pediatrics stated the hepatitis B vaccine could be delayed to the first pediatric check-up. However, 1,000 babies are born with hepatitis B every year. Therefore, the updated recommendation changed in 2017, to recommend administering the hepatitis B vaccine within 24 hours of birth. There are several reasons for this recommendation. If infected at birth, the infant has a much higher risk of developing chronic hepatitis B, leading to terrible complications, as explained previously. Additionally, infants and young children don't show symptoms of the disease. Most children catch hepatitis B in their households, as it is easily transmitted by something as simple as sharing a toothbrush. The spread of hepatitis B has also been recognized in day care centers and schools. Source: AAP, 2017; NC Hepatitis B

Public Health Program, 2012

References:

American Academy of Pediatrics (AAP). (2017) Committee on Infectious Diseases and AAP Committee on Fetus and Newborn. Elimination of Perinatal Hepatitis B: Providing the First Vaccine Dose Within 24 Hours of Birth. Pediatrics.140(3):e20171870. Retrieved from: https://pediatrics. aappublications.org/content/pediatrics/140/3/e20171870.full.pdf and https://www.aap.org/en-us/about-the-aap/aap-press-room/Pages/AAP-Recommends-That-Infants-Receive-First-Hepatitis-B-Dose-Within-24-Hours-of-Birth.aspx

American Cancer Society (ACS). (2019). Liver cancer risk factors. Retrieved from: https://www.cancer.org/cancer/liver-cancer/causes-risks-prevention/risk-factors.html

Centers for Disease Control and Prevention (CDC).(2019). Hepatitis B questions and answers for the public. Retrieved from: https://www.cdc.gov/hepatitis/hbv/bfaq.htm

Centers for Disease Control and Prevention (CDC). (2018). Pinkbook: Hepatitis B. Retrieved from: https://www.cdc.gov/vaccines/pubs/pinkbook/ hepb.html#hepb

DeStefano, F., Mullooly, J. P., Okoro, C. A., Chen, R. T., Marcy, S. M., Ward, J. I., ... & Bohlke, K. (2001). Childhood vaccinations, vaccination timing, and risk of type 1 diabetes mellitus. *Pediatrics*, 108(6), e112-e112. Retrieved from: https://pediatrics.aappublications.org/content/108/6/e112.short

DeStefano F, Weintraub ES, Chen RT. (2007). Hepatitis B vaccine and risk of multiple sclerosis. Pharmacoepidemiol Drug Saf 16:705–7, author reply 707–8. 10.1002/pds.1408. Retrieved from: https://onlinelibrary.wiley.com/doi/abs/10.1002/pds.1408

Fattovich G, Bortolotti F, Donato F., (2008). Natural history of chronic hepatitis B: special emphasis on disease progression and prognostic factors. J Hepatol.48(2):335-52. PMID: 18096267. Retrieved from: https://www.sciencedirect.com/science/article/abs/pii/S016882780700637X

Halsey NA, Duclos P, Van Damme P, Margolis H. (1999).Viral Hepatitis Prevention Board. Hepatitis B vaccine and central nervous system demyelinating diseases. Pediatr Infect Dis J.18:23–4. 10.1097/00006454-199901000-00007. Retrieved from: https://journals.lww.com/pidj/Citation/1999/01000/Hepatitis_B_vaccine_and_central_nervous_system.7.aspx

Merck. Highlights of prescribing information: Recombivax HB. Retrieved from: https://www.merck.com/product/usa/pi_circulars/r/recombivax_hb/recombivax_pi.pdf

NC Hepatitis B Public Health Program Manual/Vaccination (2012). Hepatitis B vaccination. Retrieved from: https://epi.dph.ncdhhs.gov/cd/lhds/manuals/hepB/docs/hbv_vaccination.pdf

Samji, SN. (2017). Viral hepatitis clinical presentation. Medscape. Retrieved from: https://emedicine.medscape.com/article/775507-clinical

Schlaud, M., Schmitz, R., Poethko-Müller, C., & Kuhnert, R. (2017). Vaccinations in the first year of life and risk of atopic disease–Results from the KiGGS study. Vaccine, 35(38), 5156-5162. Retrieved from: https://www.sciencedirect.com/science/article/pii/S0264410X17310629

Schillie, S., Vellozzi, C., Reingold, A., Harris, A., Haber, P., Ward, J. W., & Nelson, N. P. (2018). Prevention of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices. *MMWR Recommendations and Reports, 67*(1), 1. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5837403/

Stratton K, Ford A, Rusch E, Clayton EW, eds. Adverse effects of vaccines: evidence and causality. Washington, DC: National Academy Press; 2012. Retrieved from: http://www.vaxchoicevt.com/wp-content/uploads/2015/02/673-748.pdf

Stratton K, Almario D, McCormick MC, editors. Immunization safety review: hepatitis B vaccine and demyelinating neurological disorders. Washington, DC: National Academies Press; 2002. Retrieved from: https://www.ncbi.nlm.nih.gov/books/NBK220661/

SHOT BY SHOT: ROTAVIRUS

Handwashing and cleanliness are very important to prevent the spread of infection, but they are unfortunately not enough to control the spread of rotavirus disease. Before a vaccine was available, many children who became ill with rotavirus were hospitalized. Source: CDC, 2018

What is rotavirus and how does it spread?

Rotavirus is a contagious virus that can cause gastroenteritis (inflammation of the stomach and intestines), with diarrhea, vomiting, and fever. The diarrhea can be severe and lead to dehydration. It mostly affects infants and young children but can affect older people as well. Rotavirus is the most common cause of gastroenteritis around the world. In 2013, rotavirus caused about 215,000 deaths worldwide in children under 5 years old. Due to vaccination, it is no longer the leading cause of gastroenteritis in the United States. Source: CDC, 2018

Rotavirus is spread via an infected person's stool. It is most contagious during the course of disease and for about three days after. The virus can be transmitted when a person places unwashed hands into their mouth after touching infected stool (such as eating food after a diaper change), or after eating contaminated foods. The virus can also be spread from a contaminated surface. Good hand hygiene helps prevent transmission. However, many people do not wash their hands properly and it takes only a tiny amount of the virus to spread the disease. Source: CDC, 2018

How do I know I have rotavirus?

A person infected with rotavirus will start feeling sick two days after exposure. Symptoms include:

- Severe watery diarrhea
- Vomiting
- Fever
- Abdominal pain
- Loss of appetite

Symptoms can last three to eight days and can often lead to emergency room visits or hospitalization. The symptoms can seem similar to other stomach viruses, and the only way to know definitively if you have rotavirus is with laboratory testing. **Source:** CDC, 2018

Common complications of rotavirus:

The most common complication of rotavirus is dehydration; this presents with:

- Decreased urination
- Dry mouth and throat
- Feeling dizzy when standing up
- Crying with few or no tears
- Unusual sleepiness or fussiness

• Sunken soft-spot on the top of the head (fontanelle) for children under 18 months

Source: CDC, 2018

Severe complications of rotavirus:

Dehydration, the most common complication, can lead to more severe issues, such as changes in heart rhythm, shock, seizures, coma, and death.

• Electrolyte imbalance: changes to the amount of elements that keep the body going (calcium, magnesium, chloride, potassium, sodium, and phosphorus).

For more specific information, scan the QR codes for the rotavirus vaccine package insert.



RotaTeq Merck



Rotarix GSK

• Metabolic acidosis: body produces too much acid, or the kidneys are not removing enough acid. Can lead to bone loss, seizures, and abnormal heart rhythms. **Source:** CDC, 2018

Long-term complications of rotavirus:

In immune-compromised children, prolonged rotavirus infections can cause abnormalities of the liver and kidney.

Source: CDC, 2018

Effectiveness of the rotavirus vaccine

The rotavirus vaccine is the best way to protect a child against this disease. The vaccine reduced doctor visits for diarrhea, and decreased emergency room visits and hospitalization for rotavirus. Currently, very few vaccinated children are hospitalized because of rotavirus illness (94% to 96% are protected from hospitalization). **Source:** CDC, 2018

Common side effects of the rotavirus vaccine

Irritability

 Diarrhea or vomiting: mild and temporary
 Source: GlaxoSmithKlein, 2019

Rare side effect of the rotavirus vaccine

• Intussusception: intestinal obstruction in which part of the intestine folds into itself. This happens to about 2,000 infants

References:

Centers for Disease Control and Prevention (CDC). (2018). Rotavirus Pinkbook. Retrieved from: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/rota.pdf

GlaxoSmithKline. (2019, March). Rotatrix Package Insert. Retrieved from: https://www.gsksource. com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Rotarix/pdf/ ROTARIX-PI-PIL.PDF

Lu, H. L., Ding, Y., Goyal, H., & Xu, H. G. (2019). Association Between Rotavirus Vaccination and Risk of Intussusception Among Neonates and Infants: A Systematic Review and Meta-analysis. JAMA network open, 2(10), e1912458-e1912458.

a year in the U.S.; 90% of intussusception has no cause. A 20-year investigative study looked at 25 clinical trials of 200,594 participants (104,647 receiving vaccine and 95,947 receiving placebo) in 33 countries from four continents, using all types of the rotavirus vaccine (monovalent, pentavalent, monovalent humanbovine, oral bovine pentavalent, and human neonatal). The finding showed that rotavirus vaccinations were not associated with an increased risk of intussusception compared with placebo for up to two years after vaccination in infants. Source: Lui et al, 2019

Who cannot receive the rotavirus vaccine?

• People with a history of intussusception

People with severe combined immunodeficiency

Source: GlaxoSmithKlein, 2019

Side note:

Based on several studies worldwide, there may be some shedding of rotavirus through the stool of vaccinated babies. This shedding is limited (one to 15 days). The amount shedded will decrease in the days following the vaccine as well as with repeat doses of the vaccine. Transmission from vaccine-related fecal shedding is low and can be avoided by good handwashing technique following diaper changes. **Source:** CDC, 2018

DPHTHERIA

What is diphtheria and how does it spread?

Diphtheria is an infection caused by a bacterium called *Corynebacterium diphtheriae.* Diphtheria spreads from person to person, through coughing and sneezing. A much less common form of transmission is from touching open sores of someone who has diphtheria, or an object contaminated with the bacteria.

Source: CDC, 2018a

Bacteria that cause diphtheria can get into and attach to the lining of the throat and airway (trachea). The bacteria then produces a toxin that destroys normal respiratory (breathing) tissues. Over two to three days, the dead tissue turns into a thick gray layer called a "pseudomembrane." This coating makes it difficult to swallow and difficult to breathe. The toxin can also enter the bloodstream and damage the kidneys, heart, or nerves. **Source:** CDC, 2018a

Diphtheria continues to be a dangerous disease. In children who get diphtheria, five to 10 out of 100 die, even in current times and with current treatment. Without treatment, death rates of diphtheria are as high as 40%. One study calculated diphtheria rates in the United States between 1980 and 1994 and found that 41 people acquired the disease. None of them were up to date with their vaccines (they were either unvaccinated or undervaccinated). Four of those cases (10%) resulted in death. Source: CDC, 2018a; WHO, 2017; Bisgard et al, 1998

How do I know I have diphtheria?

• Symptoms begin two to five days after infection. It can present

as a sore throat, hoarseness, swollen glands in the neck, difficulty breathing, nasal discharge, fever, and chills, with a thick gray coat covering the throat and tonsils.

• It is important to seek treatment immediately and not wait for laboratory confirmation. Even with treatment, one in 10 people can die.

• Some people have very mild symptoms. These people are carriers and can pass the infection to nonimmune people for up to six weeks even if they don't have symptoms.

 There is another type of diphtheria that only affects the skin: It is called cutaneous diphtheria. The symptoms include pain, redness, and swelling. Skin ulcers with the gray membrane can also develop. While this version of diphtheria usually occurs in tropical climates, cutaneous diphtheria can happen in the United States in people who live in crowded locations with poor hygiene, or when traveling to these areas.

• Doctors can usually diagnose diphtheria by looking for common signs and symptoms (as previously listed). They can confirm the diagnosis by testing a swab from the back of the throat or by testing a skin lesion. **Source:** Mayo Clinic, 2019;

CDC, 2018a

Severe complications of diphtheria:

• Blocking of the airway: caused by the thick coating that builds up in the nose and throat

• Severe damage to the heart muscle (myocarditis): leading to heart failure

• Nerve damage (polyneuropathy): can affect the nerves to vital muscles, such as the muscles needed for breathing

 Loss of the ability to move (paralysis)

- Lung infection (pneumonia)
- Respiratory failure
- Death

Source: CDC, 2018b



References:

Bisgard, KM, Hardy, IR, Popovic, T, Strebel, PM, Wharton, M, Chen, RT, Hadler, SC. (1998). Respiratory diphtheria in the United States, 1980 through 1995. American Journal of Public Health. 88(5):787-91. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/9585746#

Centers for Disease Control and Prevention (CDC). (2018a). Diphtheria. Retrieved from: https://www.cdc.gov/diphtheria/about/index.html Centers for Disease Control and Prevention (CDC). (2018b). Diphtheria: Complications. Retrieved from: https://www.cdc.gov/diphtheria/about/ complications.html

Mayo Clinic. (2019). Diphtheria: Symptoms and causes. Retrieved from: https://www.mayoclinic.org/diseases-conditions/diphtheria/symptoms-causes/syc-20351897



What is tetanus and how does it spread?

Tetanus, also called "lockjaw," is an infection caused by Clostridium tetani bacterium that causes painful and dangerous muscle contractions and spasms. "Spores of tetanus bacteria are everywhere in the environment," including in soil, dust, and manure (animal waste). The spores develop into bacteria when they enter the body, usually through an opening in the skin, such as a cut or wound. Tetanus can also enter the body through breaks in the skin caused by stepping on a nail, surgical procedures, insect bites, dental infections, a broken bone that is exposed through an opening in the skin, chronic sores and infections, and injections given

into a muscle if the skin isn't cleaned properly. Tetanus is different from other vaccine-preventable diseases because it does not spread from person to person. Tetanus cases in the U.S. are found in unvaccinated individuals or those who have not gotten a booster. Out of every 10 cases, one to two will be fatal. If someone survives tetanus, they still need to get the vaccine. Having tetanus disease *does not* result in tetanus immunity. **Source:** CDC, 2018

How do I know I have tetanus?

• Signs and symptoms of tetanus appear anytime from a few days to several weeks after tetanus bacteria enters the body through a wound.

• Eighty percent of tetanus cases are generalized. Symptoms come

in a descending pattern starting with lockjaw (trismus), followed by stiffness of the neck, difficulty in swallowing, and hardening of the stomach muscles. Other symptoms may include fever, sweating, high blood pressure, and high heart rate.

• Painful spasms occur frequently and last for a few minutes. They can be triggered by minor things such as a draft, loud noise, physical touch, or light. They continue for about three to four weeks.

 Complete recovery can take months.
 Source: CDC, 2018; Mayo Clinic, 2019

Severe complications of tetanus:

• Uncontrolled/involuntary tightening of the vocal cords (laryngospasm)

• Broken bones (fractures): caused by severe muscles spasms

• Blood clot in the lungs (pulmonary embolism)

Aspiration pneumonia

Abnormal heart rhythm

• Death: Severe tetanus-induced (tetanic) muscle spasms can

cause breathing to stop, which is the most common cause of death from tetanus. **Source:** CDC, 2018; Mayo Clinic, 2019

Long-term complications of tetanus:

Complete recovery from a tetanus infection can take up to several months. During this time, supportive care is required. Care can include assistive breathing devices such as a ventilator and intense rehabilitation. **Source:** CDC, 2018

References:

Centers for Disease Control and Prevention CDC.(2018). Pinkbook: Tetanus. Retrieved from: https://www.cdc.gov/vaccines/pubs/pinkbook/tetanus.html Mayo Clinic. (2019). Tetanus: Symptoms and causes. Retrieved from: https://www.mayoclinic.org/diseases-conditions/tetanus/symptoms-causes/syc-20351625

PERTUSSIS

What is pertussis and how does it spread?

Pertussis is a highly contagious illness caused by the bacterium *Bordetella pertussis*. The bacteria cause damage and swelling to the airway, causing coughing spasms which can be severe. The cough often ends with a sharp inhale of air that sounds like a "whoop," which is why it's also known as "whooping cough."

Pertussis spreads from person-to-person by the infected person coughing or sneezing, or by being in the same room as an infected person. Pertussis is usually mild in older children and adults but **can be severe and even deadly to babies**. Many babies who get pertussis are infected by older siblings, parents, or caregivers who might not even know they have the disease. There isn't any real treatment for pertussis in infants. It is all mainly supportive: giving IV fluids, antibiotics, and keeping the infected patient in isolation. There is nothing to relieve the cough, which is the part of the infection causing the most severe complications. **Source:** CDC, 2017

How do I know I have pertussis?

 In the early stages of illness, pertussis symptoms are similar to the common cold — runny nose, nasal congestion, fever, and cough. However, after a week or two, the cough worsens, and may become severe, particularly in babies.

• Severe coughing attacks may cause vomiting, extreme fatigue, and red or blue facial color, and typically end with a high-pitched "whoop" sound (although this may be absent in older children and adults). Infants may struggle to breathe, and even stop breathing.

• Pertussis can be diagnosed based on symptoms. A swab of the nose can also be done and sent to a lab to confirm the diagnosis. **Source:** Mayo Clinic, 2018



Common complications of pertussis:

Mild complications usually occur in older children or adults, who typically have a milder form of the illness. These can include:

- Loss of appetite (anorexia)
- Loss of bladder control
 (incontinence)
- Ear infection (otitis media)
- Dehydration

Severe complications of pertussis:

Severe complications usually occur in infants. About half of all infected children under 1 year of age end up hospitalized. Complications can be life-threatening for children under 6 months.

• Due to the pressure from the severe coughing spasms:

 Rib fractures (broken ribs): severely increases pain during uncontrolled coughing

 Lung collapse (pneumothorax): requires a drain in the chest

- Brain bleed (subdural hematoma)
 - Nose bleeds (epistaxis)
 - Hernia: may require surgery
 - Rectal prolapse: may

require surgery

Loss of consciousness

- Pneumonia (lung infection)
- Seizures
- Apnea (when breathing slows or stops)
 - Encephalopathy (brain disease
- or damage)
 - Death

Source: CDC, 2017



Long-term complications of pertussis:

• Long-lasting cough: in infants can last 10 weeks or longer, even with the proper treatment.

• Long-term immunosuppression, which increases the risk of contracting other infections.

• Brain damage: from the lack of oxygen due to severe coughing **Source:** Carbonetti, 2010

References:

Carbonetti, N. H. (2010). Pertussis toxin and adenylate cyclase toxin: key virulence factors of Bordetella pertussis and cell biology tools. *Future microbiology*, 5(3), 455-469.

Centers for Disease Control and Prevention CDC. (2017). Retrieved from: https://www.cdc.gov/pertussis/about/signs-symptoms.html Mayo Clinic. (2018). Pertussis. Retrieved from: https://www.mayoclinic.org/diseases-conditions/whooping-cough/diagnosis-treatment/drc-20378978



For more specific information, scan the QR codes for the DTaP vaccine package insert.



Infarix (GSK)



Daptacel (Sanofi)

DTaP The DTP vaccine was first introduced in the 1940s. This

vaccine (also known as DTwP) had diphtheria and tetanus toxoids and inactive whole-cell Bordetella pertussis. There were some reports of side effects to this vaccine. In 1996, the CDC recommended against using the DTwP and to use the DTaP only. The DTaP replaced the whole pertussis cell with individual antigens (or acellular) and has very few side effects. The DTaP vaccine can help protect your child from diphtheria, tetanus, and pertussis.

DTaP is only for children younger than 7 years old.

Current and Reliable Vaccine Information for Frum Families | 59

DTaP Vaccine Effectiveness

Nine out of 10 children who get all five doses on schedule will have full protection. By age 11, the protection drops to 70%. Therefore, boosters are recommended for children at about 11 years old. **Source:** CDC, 2019a

Common side effects of DTaP:

- Fever
- Drowsiness
- Irritability
- Redness at the injection site

Source: GSK, 2018

Who cannot get the DTaP vaccine?

• People with allergic reaction to a previous dose of DTaP, or with life-threatening allergies

 People with coma or long repeated seizures within seven days after DTaP vaccination not attributable to any other cause

 People with a progressive, neurological disorder that is not stable.

Source: CDC, 2019b

Anti-Vaxx Myth: "We get calls all the time that a child who got the DTaP started coughing right away. The infant caught [pertussis] from their vaccinated sibling."

P.I.E.: It is impossible to "catch" a disease from a vaccine made from an inactivated virus. The immune system is sensitive enough to respond to the inactivated virus and create antibodies, but it is absolutely impossible for them to cause the disease in the person receiving the vaccine, to be shed, or to be transmitted to anyone around them!

Source: Denizer et al, 2018

DTaP is only given to children up to age 7. Teenagers, adults and seniors still need to be protected. **A dose of the Tdap vaccine is recommended at about age 11.** Pregnant women should get a Tdap during every pregnancy to protect their babies from pertussis (see page 7 for more details). Health care workers or anyone having close contact with a baby that is younger than 12 months should also have the Tdap. Sometimes, this version of the vaccine is given to a person who is being treated for a severe burn or cut to prevent tetanus infection. **Some people get a modified version, called the Td which protects against tetanus and diphtheria only** (**not pertussis**) **and is recommended every 10 years.** Source: AAP, 2014

For more specific information, scan the QR codes.

NU







Adcel (Sanofi)

Anti-Vaxx Myth: "Countries that introduced the vaccine saw a dramatic increase in disease incidence."

Source: Neil Miller, 2010

P.I.E.: False. When the diphtheria vaccine was widely introduced and used in the 1940s, rates of the disease dropped dramatically. The current DTaP vaccine is highly effective at preventing diphtheria. The diphtheria toxoid vaccines are 97% effective at three doses; 99% effective at five doses.

Source: Bisgard et al, 2000; Chen et al, 2000; Galazka, Robertson, & Oblapenko, 1995

Anti-Vaxx Myth: "Before the vaccine was introduced, tetanus cases in wounded American soldiers had dropped 92% and continued to decline to 0.44 in 100,000 cases by World War II. Researchers attribute this to better wound care."

Source: Neil Miller, 2010

P.I.E.: Tetanus cases in U.S. troops dropped so dramatically during World War II because of *routine immunization of soldiers before the war.* In World War I, 70 out of 520,000 wounded U.S. soldiers died of tetanus (this is 13.4 per 100,000 soldiers). In World War II, there were only 12 deaths out of 2,730,000 U.S. troops (0.44 per 100,000 soldiers) and eight of those soldiers were not vaccinated.

Source: Long & Sartwell, 1947*

*The date of this study is important, as at times we must evaluate whether old research is still valuable. The reason we used this study is because tetanus rates have dropped so significantly **due to vaccination**; this study has not been and cannot be replicated.

Anti-Vaxx Myth: If I do a good job cleaning the wound, I won't get tetanus.

P.I.E.: Wound cleaning is always the right thing to do. **BUT:**

Wounds start healing within 20 minutes of an injury. C. tetani (the spore that causes tetanus) could be deep inside the wound while the outside is already closing up. Wound cleaning may not get that deep or reach every part of the injury inside.

Source: CDC, 2018

In addition, wound care can only go so far. If someone begins to show symptoms of tetanus, it is too late for vaccination. Treatment includes the following:

• Remove the source of infection. Clean the area, remove the unhealthy tissue with surgery, and give antibiotics to prevent further tetanus toxin release.

• Give tetanus immune globulin, which has tetanus antibodies from donated blood. This will help if the toxin is outside the central nervous system.

• If the tetanus toxin is already in the central nervous system, there is no way to remove it. The patient can only receive supportive care such as being placed on a respirator and medications because the ends of the nerve are damaged. It takes weeks for the nerve endings to regrow. Severe cases will need to be in the ICU for about three to five weeks. Recovery can take months.

• As soon as the patient is able to receive the tetanus vaccine after recovering, the patient should receive it.

Source: CDC, 2018

Anti-Vaxx Myth: You can't get tetanus from a wound that bleeds.

P.I.E.: Incorrect. A bleeding wound does not flush out tetanus spores that may have contaminated the wound. Source: CDC, 2018

Anti-Vaxx Myth: "Similar levels of severe adverse events are found with the current acellular pertussis vaccine [in comparison with the previous]."

Source: Noble et al, 1987

P.I.E.: False. This 1987 study found the acellular pertussis vaccine (DTaP) caused *fewer* mild reactions (such as fever and local swelling) than whole-cell vaccines (DTP). **Source:** Noble et al, 1987 Anti-Vaxx Myth: "In 2010, out of 227,500 cases of whooping cough reported in the U.S., there were 27 deaths, 25 of which occurred in children under 1 year old." Source: National Vaccine Information Center (NVIC), 2010

P.I.E.: Actually, the NVIC has since updated the 2017 statistics with newer information: "There were 15,808 reported cases of pertussis including 13 deaths, with 4 deaths occurring in infants under age 1 year."

The NVIC also goes on to include a CDC report which states, "In 1922, there were 107,473 pertussis cases reported in the U.S. with 5,099 deaths." The Anti-Vaxx Myth statement/quotation above actually proves how well vaccines have worked for pertussis. Infant death rates dropped from over 5,000 deaths in 1922 to 27 deaths in 2010, and then to 13 deaths in 2017. Sources: NVIC, 2018; CDC, 2018

Anti-Vaxx Myth: "[Death from pertussis] does not come close to the 10,000 annual cases of SIDS, 70% of which <u>may be caused</u> by the DTaP vaccine." Source: None given.

P.I.E.: First, the rates of SIDS are closer to 1,500 cases per year. Furthermore, not a single study has shown that SIDS is caused by vaccines. (See the upcoming section titled "SIDS and the DTaP" for more information.) **Source:** National Vital Statistics Reports, 2019

Anti-Vaxx Myth: "The British Medical Journal stated that out of 5,140 cases of pertussis in **1978**,



it was found that 84% had been vaccinated three times." **Source:** Trollfors & Rabo, 1981

P.I.E.: First, the recommendation is for five doses of the DTaP vaccine for young children, not three, for greater than 90% immunity. In addition, the 1978 study was quoted out of context. The study said the batch of Swedish-developed vaccines used in 1978 was considered ineffective. The vaccine was removed (pertussis rates subsequently soared), and that form is no longer used today. This vital point is conveniently omitted by anti-vaxx proponents. Source: CDC, 2019a; Trollfors & Rabo, 1981

Many scary statements about the DTP vaccine (almost 40 years ago) were taken from the book "A Shot in the Dark", written in 1985 by Fisher and Coulter, which suggests that the pertussis vaccine caused significant neurological damage. This has since been *completely disproven* by multiple studies that examined millions of children who received the DTP. Nevertheless, Fisher continues to promote her book and other disproven claims on her website, the National Vaccine Information Center.

Additionally, the DTP has not been used in the United States since 1998. It was replaced by the DTaP, which has milder local and systemic reactions. **Source:** Gale et al 1994; Ray et al 2006; Moro et al, 2018

Think about it... Would you want your doctor making decisions for your health based on data from 40 years ago? Anti-Vaxx Myth: Researchers found that most babies dying after DTP shots were not found dead in their cribs without any symptoms before they died. They were dying after suffering plenty of vaccine reaction symptoms within days of their DTP shot: high fever, sudden collapse, hours of persistent crying, or high-pitched screaming with arching of the back that can be a sign of brain inflammation, severe diarrhea, redness, swelling and pain at the injection site, and signs of seizures that too many pediatricians were dismissing as unimportant. **Source:** None.

P.I.E.: Scare tactic with no source provided. If these, in fact, were findings by "researchers," it would benefit the authors to provide their readership with a source for this frightening statement. *Any* of these symptoms would require an

Think about it...

The DTP vaccine has not been used in the U.S. in more than 20 years. For details, visit ncbi.nlm.nih.gov/pmc/articles/PMC4975064

> immediate visit to a doctor or emergency room, and are unlikely to be "blown off" by a pediatrician as "unimportant."

References:

American Academy of Pediatrics (AAP). (2014) DTaP vaccine: What you need to know. Retrieved from: https://www.healthychildren.org/English/ safety-prevention/immunizations/Pages/Diphtheria-Tetanus-Pertussis-Vaccines-What-You-Need-to-Know.aspx

Bisgard KM, Rhodes P, Hardy IR, Litkina IL, Filatov NN, Monisov AA, Wharton M. (2000). Diphtheria toxoid vaccine effectiveness: A case-control study in Russia. J Infect Dis. 181 Suppl 1:S184-7. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/10657211

Centers for Disease Control and Prevention CDC (2019a). Pertussis. Retrieved from: https://www.cdc.gov/pertussis/about/faqs.html

Centers for Disease Control and Prevention CDC (2019b). Vaccine Information Statement: DTaP. Retrieved from: https://www.cdc.gov/vaccines/hcp/vis/vis-statements/dtap.html#dtap-vacc

Centers for Disease Control and Prevention CDC (2018). Epidemiology and prevention of vaccine-preventable diseases. Pinkbook: Tetanus. Retrieved from: https://www.cdc.gov/vaccines/pubs/pinkbook/tetanus.html

Chen RT, Hardy IR, Rhodes PH, Tyshchenko DK, Moiseeva AV, Marievsky VF. (2000). Ukraine, 1992: first assessment of diphtheria vaccine effectiveness during the recent resurgence of diphtheria in the Former Soviet Union. *J Infect Dis*.181 Suppl 1:S178-83. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/10657210#

Denizer, G., Friedland, LR., Krishnan, J., Shapiro, M. (2018). Understanding modern-day vaccines: what you need to know. Annals of Medicine, 50:2, 110-120. https://doi.org/10.1080/07853890.2017.1407035

Fisher, BL & Coulter, HL. (1985). DPT: A shot in the dark. Published by Warner Home Medical Library.

Galazka AM, Robertson SE. (1995). Diphtheria: changing patterns in the developing world and the industrialized world. *Eur J Epidemiol*. 11(1):107-17. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/7489768

Gale JL, Thapa PB, Wassilak SGF, Bobo JK, Mendelman PM, Foy HM. (1994). Risk of serious acute neurological illness after immunization with diphtheria-tetanus-pertussis vaccine. *Journal of the American Medical Association*; 271:37-41. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/7903109

GlaxoSmithKline GSK. (2018). Infanrix. Retrieved from: https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_ Information/Infanrix/pdf/INFANRIX.PDF

Long A P, and Sartwell P E. (1947) Tetanus in the United States Army in World War II. Bulletin of the US Army Medical Department. United States. Army Medical Department 7.4: 371–385.

Moro, PL., Perez-Vilar, S., Lewis, P., Bryant-Genevier, M., Kamiya, H, Canos, M. (2018). Safety Surveillance of Diphtheria and Tetanus Toxoids and Acellular Pertussis (DTaP) Vaccines. *Pediatrics*. Retrieved from: https://doi.org/10.1542/peds.2017-4171.

National Vaccine Information Center. (2010). Retrieved from: https://www.nvic.org/

National Vaccine Information Center. (2018). Retrieved from: https://www.nvic.org/

National Vital Statistics Reports for 2017 (2019) Volume 68, Number 6. Retrieved from: https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_06-508.pdf Noble GR, Bernier RH, Esber EC, Hardegree MC, Hinman AR, Klein D, Saah AJ. Acellular and whole-cell pertussis vaccines in Japan. (1987) Report of a visit by US scientists. *JAMA*. 257(10):1351-6. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/3820444#

Ray P, Hayward J, Michelson D, Lewis E, Schwalbe J, et al. (2006). Encephalopathy after whole-cell pertussis or measles vaccination: Lack of evidence for a causal association in a retrospective case-control study. *Pediatr Infect Dis J.* 25(9):768-73. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/16940831

Sifris, D., Myhre, J., (2019). What you need to know about the DTaP vaccine. Retrieved from: https://www.verywellhealth.com/what-you-need-to-know-about-the-dtap-vaccine-4156747.

Trollfors, B., & Rabo, E. (1981). Whooping cough in adults. *BMJ* (Clinical research ed.), 283(6293), 696–697. doi:10.1136/bmj.283.6293.696. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1506984/

US Department of Health and Human Services (HHS). (2018).Vaccine Information

Statement: DTaP: What you need to know. Retrieved from:

http://www.immunize.org/vis/dtap.pdf



Polio

Vaccine

Exp:/Lot

20ml Rx Only SHOT BY S

Before the vaccine, polio was very common in the U.S. and killed thousands of people every year. Polio is a very contagious disease that spreads easily from person-to-person and can be very dangerous. In some people it can lead to permanent disabilities, paralysis, and death. Because of the effectiveness of this vaccine, there hasn't been a new case of polio in the United States in more than 35 years. **Source:** US Department of Health and Human Services, 2019

What is polio and how does it spread?

Polio is a crippling and potentially deadly infectious disease caused by poliovirus. Poliovirus infects the brain and spinal cord, causing temporary or permanent paralysis (loss of ability to move parts of the body). Poliovirus only infects humans. It enters through the mouth and spreads through contact with stool from an infected person. Less commonly, droplets from a sneeze or cough can spread polio from one person to another. A person is contagious immediately before and up to one to two weeks after symptoms appear. The virus can live in stool for several weeks and can contaminate food and water. Most people who catch the poliovirus don't have symptoms. Even if a person does not have symptoms, polio is still contagious.

How do I know I have polio?

Most people who contract polio will not have visible symptoms. One in four people with poliovirus will have flu-like symptoms such as sore throat, fever, fatigue, nausea, headache, and stomach pain. These symptoms usually last two to five days and go away on their own.

Source: CDC, 2017

A smaller percentage of people with polio will develop severe complications that affect the brain and spinal cord:

Mild complications of polio:

• Paresthesia: feeling pins and needles in the legs

Severe complications of polio:

• Meningitis: an infection of the outer cover of the spinal cord and brain; this develops in one in 25 people with poliovirus

For more specific information, scan the QR code for the polio vaccine package insert. Please note that most polio vaccines are part of combination vaccines. To find the specific vaccine, visit http://www.immunize.org/fda/





A picture of children in iron lungs prior to the development of the polio vaccine.

Long-term health problems caused by polio:

• Paralysis: Weakness or loss of ability to move arms, legs, or both that can lead to permanent disability; this happens in one in 200 people with poliovirus.

• Post-polio syndrome: Children who seem to fully recover from polio can develop new muscle pain, weakness, or paralysis 15-40 years later.

• Death: Between two and 10 out of 100 people who develop paralysis die due to the loss of the ability to use the muscles to breathe. **Source:** CDC, 2017

Effectiveness of the inactivated polio vaccine (IPV)

Two doses of this vaccine are 90% effective. Three doses are 99 to 100% effective for almost life-long protection.

Source: CDC, 2018a

Common side effects of polio vaccine

- Soreness at the injection site

Severe side effects of polio vaccine

• None. Note that the oral polio vaccine (OPV) caused polio in one out of 2.4 million recipients. The OPV is no longer administered in the United States since 2000, and the current vaccine, IPV, cannot cause polio.

Source: CDC, 2018b

Who cannot get the IPV?

• People with life-threatening allergies to the IPV vaccine

• People with moderate or severe illness on day of scheduled vaccination - can be given once recovered

Source: CDC, 2016

Polio Facts

Epidemics of polio paralysis throughout the 1900s led to the development of the polio vaccine in 1955. Rates of polio dropped immediately, however anti-vaccine proponents seek other explanations as to the cause of polio and reasons for its disappearance. One common myth is that polio was caused by pesticides. Another, that clean water resulted in its disappearance. Finally, they claim that other versions of childhood paralysis seen today are simply polio under a new name. These claims are inaccurate and an attempt to avoid giving credit to the IPV (polio vaccine) for nearly eradicating this debilitating disease. **Source:** Davis, 2018

Anti-Vaxx Myth: "The polio vaccine continues to cause paralysis to this very day." Source: None **P.I.E.:** Since 2000 in the United States, only the IPV has been given. There is *absolutely no risk* of the IPV vaccine causing polio or paralysis. **Source:** WHO, 2017; Global Polio Eradication Initiative (n.d.)

Anti-Vaxx Myth: "Polio was already declining before vaccination was introduced." "In fact, after the vaccine in the U.S., cases of polio nearly doubled!" Source: Alderson, 1981; Mendelsohn, 1984; US Government Statistics, 1955

P.I.E.: Both statements are **false**. The frequency of polio *disease*

was very high in the 1950s, but the development of the iron lung reduced *death rates* by reducing polio-related lung complications (see figure below). In 1952, the incidence of polio reached an alltime high, with 20,000 active cases documented. The polio vaccine was approved for public use in 1955. By the mid-1960s there were less than 100 reported cases of polio per year in the U.S. By 1979, polio was considered completely eliminated in the United States.

Sources: CDC, 2018c; Ochmann & Roser, 2017

Polio Paralysis Cases and Deaths in the United States 1910-2010

The reported figures include both wild- and vaccine-derived type polio infections that occurred indigenously and as imported cases.



Source: Our World In Data, based on US Public Health Service; US Center for Disease Control; and WHO. Retrieved from: https://ourworldindata.org/polio.

AFP DIFFERENTIAL

SYMPTOMS	POLIO	GUILLAIN-BARRE Syndrome	TRANSVERSE Myelitis
Paralysis	24 to 48 hours	Hours to 10 days	Hours to 4 days
Fever	High: always present with paralysis and then gone the following day	Not common	Rarely
Muscle Tone	Decreased in the affected area	Low muscle tone throughout the body	Low muscle tone in the lower body
Spinal Tap Fluid (CSF)	Inflammatory	Increased protein	Normal
Sensation	Severe muscle pain	Cramping, tingling, loss of feeling in palms and soles	Loss of feeling in the lower body
Flaccid Paralysis	Acute: usually asymmetrical (uneven)	Acute: symmetrical	Acute in the low body: symmetrical

Source: Schwartz et al. (2018). Enteroviruses Differential Diagnosis. 2018. Retrieved from: https://emedicine.medscape.com/article/217146-differential#

Anti-Vaxx Myth: "In 1954, the CDC changed the diagnostic criteria for polio, labeling most cases that would have previously been diagnosed as polio as "acute flaccid paralysis (AFP)". Source: None given or known.

P.I.E.: False. The definition of AFP is "sudden onset of paralysis/ weakness in any part of the body of a child under 15 years of age." AFP is a set of symptoms rather than a disease. It is currently used as a surveillance tool to detect rare cases of polio. According to WHO, between 2012-2014 a total of 166,240 cases of AFP in India were tested for polio and none were found to be positive for polio. Polio is easily diagnosed via stool tests that can detect the presence of poliovirus. Other forms of paralysis (Guillain-Barre syndrome, neuritis, transverse myelitis, spinal meningitis, etc.) have different symptoms and methods of diagnosis. For disease comparison, see the table at left.

Source: Gorson, KC, & Ropper, AH, 2001

References:

Centers for Disease Control and Prevention (2017). What is Polio? Retrieved from: https://www.cdc.gov/polio/about/index.htm. Centers for Disease Control and Prevention (2018a). Polio vaccine effectiveness and duration of protection. Retrieved from: https://www.cdc.gov/vaccines/vpd/polio/hcp/effectiveness-duration-protection.html

Centers for Disease Control and Prevention (2018b). Polio vaccination: What everyone should know. Retrieved from: https://www.cdc.gov/vaccines/vpd/polio/public/index.html

Centers for Disease Control and Prevention (2018c). Polio Elimination in the United States. Retrieved from: https://www.cdc.gov/polio/us/ Centers for Disease Control and Prevention (2016). Vaccine information statement: Polio. Retrieved from: https://www.cdc.gov/vaccines/hcp/vis/ vis-statements/ipv.html

Davis, CP., (2018) Polio. Retrieved from: https://www.medicinenet.com/polio_facts/article.htm#is_it_possible_to_prevent_polio_is_there_a_polio_vaccine Global Polio Eradication Initiative (n.d.) Vaccine-Derived Poliovirus. Retrieved from: http://polioeradication.org/polio-today/polio-prevention/the-virus/ vaccine-derived-polio-viruses/

Gorson, K. C., & Ropper, A. H. (2001). Nonpoliovirus poliomyelitis simulating Guillain-Barré syndrome. Archives of neurology, 58(9), 1460-1464. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/11559319

Ochmann & Roser (2017). Polio. Retrieved from https://ourworldindata.org/polio.

US Department of Health and Human Services (2019). Polio. Retrieved from: https://www.vaccines.gov/diseases/polio.

World Health Organization WHO (2017). What is Vaccine-Derived Polio? Retrieved from:https://www.who.int/features/qa/64/en/.

SHOT BY SHOT: HAEMOPHILUS INFLUENZAE/HIB

Haemophilus influenza type b (Hib) is a dangerous illness mostly affecting babies and young children. Hib infections can affect a child's lungs or brain. Infections caused by this bacteria can be severe, causing long-term disability and even death. **Source:** CDC, 2019a

What is Hib and how does it spread?

Haemophilus influenzae is a cause of bacterial infections that are often severe, particularly among infants. The symptoms of the infection depend on what part of the body is affected. Before vaccines, Hib was the most common cause of all cases of meningitis (an inflammation of the membrane surrounding the brain and spinal cord). **Source:** CDC, 2019b; Hamborsky, Kroger & Wolfe, 2015 Hib is transmitted from personto-person by coughing, sneezing, and direct contact with respiratory secretions. Newborns can become infected with Hib during delivery. Breastfeeding can give some protection against Hib in children under 6 months of age. Children who had a Hib infection when younger than 24 months of age may get Hib again. **Source:** CDC, 2019a

Complications of Hib:

In patients who survive Hib meningitis, 15-30% have hearing impairment or other neurological symptoms, such as dizziness, decreased intellectual function, memory loss, seizures, and problems walking. Three to six percent of patients diagnosed with meningitis will die, even when treated with the correct antibiotics. When Hib infection enters the bloodstream or bones, it may result in limb amputation. **Source:** CDC, 2019b; Hamborsky, Kroger & Wolfe, 2015; Roos & Tyler, 2007

Effectiveness of the Hib Vaccine:

Before the vaccine, one in 200 children under the age of 5 was affected by Hib infection. More than 95% of infants will be protected from the disease after receiving two to three primary doses. It even gives immunity to patients who are at higher risk for disease, such as children with leukemia. Currently, there is less than one case per 100,000 children under age 5. Today's Hib infections are seen more frequently in the elderly, under-vaccinated or unvaccinated children, and the immunocompromised.

Source: Hamborsky, Kroger & Wolfe, 2015

HOW DO I KNOW I HAVE HIB?

Hib presents differently depending on which parts of the body are affected: Hib infections frequently require hospitalization.

HIB PNEUMONIA

Lung infection: Fever, chills, cough, shortness of breath or difficulty breathing, sweating, chest pain, excessive tiredness, decreased appetite, nausea, and vomiting, especially in children **Source:** CDC, 2019b

HIB MENINGITIS

Infection of the tissue covering the brain and spinal cord: Fever, headache, stiff neck, nausea with or without vomiting, photophobia (eyes being more sensitive to light), altered mental status (confusion)

Babies with meningitis may be irritable, vomit, feed poorly, or appear to be slow or inactive. In young babies, doctors may also test the child's reflexes, which can be abnormal with meningitis. **Source:** CDC, 2019; Johansson et al, 2015

HIB EPIGLOTTITIS

Swelling of the back of the throat that protects the breathing tube (trachea) and voicebox (larynx) when swallowing. This can be life-threatening.

Source: CDC, 2019b

HIB SKIN, BLOOD, AND BONE INFECTIONS

Cellulitis: skin infection, on the neck and head
[can also be called a "roiz"]
Septic arthritis: joints are infected
Osteomyelitis: bone infection. May lead to amputation.
Pericarditis: infection of the sac around the heart
Bacteremia: blood infection

Source: CDC, 2019b

For more specific information, please scan the QR codes for the Hib package insert.



PedvaxHIB Merck



ActHIB Sanofi

Common side effects of the Hib vaccine:

Pain, swelling, and hardness

- at the injection site
 - Irritability
 - Drowsiness
 - Fever
 - Loss of appetite
 - Vomiting
 - Decreased activity
 - Inconsolable crying and fussiness

Source: Sanofi Pasteur, 2019

Incidence of Hib since the vaccine was introduced:



Who cannot get the Hib vaccine?

• A person who has ever had a severe allergic reaction (for example, anaphylaxis) after a previous dose of any *Haemophilus influenzae* type b or combination vaccine **Source:** Sanofi Pasteur, 2019

Anti-Vaxx Myth: Hib vaccination increases the risk of insulindependent diabetes mellitus.

P.I.E.: False. In a study of all children born in Denmark from

1990-2000 there was no increase in the incidence of insulindependent diabetes. This was evident when comparing vaccinated and unvaccinated children, even in children who are genetically predisposed to diabetes (those who have siblings with insulindependent diabetes). **Source:** Hviid, Stellfeld, Wohlfahrt, & Melbye, 2004

References:

Centers for Disease Control and Prevention CDC. (2019a) Haemophilus influenzae/HiB. Retrieved from: https://www.cdc.gov/vaccines/parents/ diseases/child/hib.html

Centers for Disease Control and Prevention CDC. (2019b) Haemophilus influenzae type B. Retrieved from: https://www.cdc.gov/vaccines/pubs/pinkbook/hib.html

Centers for Disease Control and Prevention (2017). Bacterial Meningitis. Retrieved from https://www.cdc.gov/meningitis/bacterial.html

Hamborsky J, Kroger A, Wolfe S (Eds.). (2015). Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. (13th ed.). Washington D.C.: Public Health Foundation, 2015.

Hviid, A., Stellfeld, M., Wohlfahrt, J., & Melbye, M. (2004). Childhood Vaccination and Type 1 Diabetes. New England Journal of Medicine. Retrieved from: doi: 10.1056/NEJMoa032665

Johansson Kostenniemi U, Norman D, Borgström M, Silfverdal SA (2015). The clinical presentation of acute bacterial meningitis varies with age, sex and duration of illness. Acta Paediatrica. 104(11), 1117-24. Retrieved from: doi: 10.1111/apa.13149.

Roos K.L., Tyler K.L., (Eds.). (2007). Meningitis, Encephalitis, Brain Abscess, and Empyema. 17th ed. New York: McGraw-Hill Co. Sanofi Pasteur. (2019). *ActHIB: Full Prescribing Information*. Marcy L'Etoile, France. Retrieved from https://www.fda.gov/media/74395/download.

SHOT BY SHOT: PNEUMOCOCCAL CONJUGATE

The pneumococcal vaccine is given to help protect against the 13 types of pneumococcal bacteria that most commonly cause serious infections such as meningitis, blood infections, ear infections, and pneumonia in young children and older adults.

Source: CDC, 2017

What is *Streptococcus pneumoniae* and how does it spread?

Streptococcus pneumoniae (also known as pneumococcus) is a bacterium that lives in the respiratory tract. It causes infections in the ear, sinus, lungs, blood, and the meninges (lining of the brain). The most common infection caused by *Streptococcus pneumoniae* is strep pneumonia, an infection in the lungs. It spreads via respiratory droplets. Diagnosis is made by isolating the bacteria from blood or body fluids. **Source:** CDC, 2018; CDC, 2017a; CDC, 2017c Pneumococcus is the most common cause of bacteremia (blood infection) in the U.S. in children younger than 2 years. It is also the most common cause of infection in children without a known site of infection. About 5% of people with less serious pneumococcal pneumonia will die from it. Twenty percent of patients with pneumococcal bacteremia will die; the number increases to 60% in elderly patients.

Source: CDC, 2018; CDC, 2017b

How do I know I have strep pneumonia?

Once infected, symptoms can show up one to three days later. The symptoms have a very fast onset, with fever, chills, and rigor. Other symptoms may include:

- Chest pain when breathing
- Productive cough
- Rusty sputum (mucus)

- Shortness of breath and rapid breathing
 - Rapid heart rate
- Weakness
- Source: CDC, 2017d

Complications of *Streptococcus pneumoniae* infection:

- Sinus infections
- Ear infections

 Some children may need ear tubes

Source: CDC, 2017d

Severe complications of *Streptococcus pneumoniae* infection:

 Infection and collection of pus surrounding the chest and lungs (empyema)

 Inflammation of the sac surrounding the heart (pericarditis)

 Airway blockage with collapsed lungs and pus in the lungs Source: CDC, 2017d

Pneumococcal Meningitis: How do I know I have pneumococcal meningitis? Symptoms include:

- Headache
- Lethargy
- Vomiting
- Fever
- Irritability
- Stiff neck
- Seizures
- Coma

Source: CDC, 2018

References:

Centers for Disease Control and Prevention CDC. (2017a). Pneumococcal vaccine: What everyone should know. Retrieved from: https://www.cdc.gov/vaccines/vpd/pneumo/ public/index.html

Centers for Disease Control and Prevention CDC. (2017b). Pneumococcal disease. Types of infection. Retrieved from: https://www.cdc.gov/pneumococcal/about/infectiontypes.html.

Centers for Disease Control and Prevention CDC. (2017c). Pneumococcal disease. Diagnosis and medical management. Retrieved from: https://www.cdc.gov/pneumococcal/clinicians/ diagnosis-medical-mgmt.html.

Centers for Disease Control and Prevention CDC. (2017d). Pneumococcal disease. Symptoms and complications. Retrieved from: https://www.cdc.gov/pneumococcal/about/symptoms-complications.html

Centers for Disease Control and Prevention CDC. (2018). Pneumococcal disease. Pinkbook. Retrieved from: https://www.cdc.gov/vaccines/pubs/pinkbook/pneumo.html#features;

United States Food and Drug Administration FDA. (2016). Prevnar 13 (PCV13). Retrieved from: https://www.fda.gov/files/vaccines%2C%20blood%20%26%20biologics/ published/Package-Insert-----Prevnar-13.pdf

Long-term complications of pneumococcal meningitis:

Meningitis can lead to hearing loss and brain damage. It results in death in one out of 15 children under age 5, and the number of deaths increases in elderly patients. **Source:** CDC, 2017d

Effectiveness of the pneumococcal vaccine:

The pneumococcal conjugate vaccine PCV13 is more than 90% effective against pneumococcus disease serotypes in children. It is 75% effective for vaccinetype invasive disease and 45% effective against non-bacteremic pneumococcal pneumonia in adults over 65.

Source: CDC, 2018

Pneumococcal Vaccine Side Effects:

• Pain, redness, or swelling at the injection site

- Fever
- Irritability
- Temporary loss of appetite
- Drowsiness

Source: FDA, 2016

Note: Young children who get a pneumococcal conjugate vaccine at the same time as the inactivated flu vaccine may be at increased risk for seizures caused by fever. **Source:** CDC, 2017a

Who cannot get the PCV13?

• Severe allergic reaction (for example, anaphylaxis) to any component of Prevnar 13 or any diphtheria toxoid-containing vaccine.

Source: FDA, 2016

Another version of the pneumococcal vaccine (PPSV23) is available for certain individuals under specific conditions. For more information, scan the QR codes for the pneumococcal vaccine package insert.



Prevar 13 Pfizer



Pneumovax 23 Merck

SHOT BY SHOT: MEASLES (RUBEOLA)

Anti-vaxx myths say that measles is harmless, a necessary part of childhood, and helps build immunity. This is utterly false.

What is measles and how does it spread?

Measles is an extremely contagious virus that spreads through the air from droplets beginning in an infected person's nose or throat, usually by coughing and sneezing. The virus can remain in the air for up to two hours and can spread just by breathing in the contaminated air or touching any infected surfaces and then touching one's eyes, nose, or mouth. It is so contagious that up to 90% of people who are exposed to the measles virus and are not immune become infected. Infected people can pass along the measles about four days before and four days after the rash appears. Measles is not spread by any other animal species; it is a disease that only affects humans. **Source:** CDC, 2018a

How do I know if I have measles?

• The disease starts with a rash seven to 21 days (average 14 days) after a person is exposed to the virus.

• Symptoms first include: high fever, cough, runny nose, and red, watery eyes. A few days after these symptoms begin, Koplik spots (tiny blue-white dots) can appear inside the affected person's mouth.

• About three to five days after symptoms begin, the characteristic measles rash starts to appear. It usually starts flat and red on the face near the hairline and spreads down towards the neck, the rest of the body, arms, legs, and feet. **Source:** CDC, 2018b

Common complications of measles: These occur in 30% of cases; more often in children under 5 years and adults over 20 years.

• Ear infections: one out of every 10 children with measles

Diarrhea: less than one out of 10
people with measles
Source: CDC, 2018a
MEASLES FACTS

Prior to the vaccine in 1963, there were approximately 500 deaths reported each year out of an estimated 3-4 million annual cases in the U.S. The key here is the word "reported," Health departments track measles with these three criteria: the patient must seek health care with a health care professional, the diagnosis must be recognized, and the case must be reported to the relevant health care department. This is called "completeness of reporting." The range of estimates in completeness of reporting from the 1980s and '90s is guite wide: between 3% and 58%. This means that anyone who had the measles and never visited a doctor or nurse, or never had the measles diagnosed, or the health care professional didn't report it, is not counted in the reported measles cases (Harpaz, 2004). Following the licensure of the vaccine, there was a 95% decline in reported cases. In 1989, a second measles vaccine was added to the schedule to prevent outbreaks in school-age children. By 2000, measles was considered eliminated from the United States, and all cases were either imported or related to an imported case. Source: CDC, 2018

In 2019, there were a total of **1,282 cases of measles** in the U.S. New York City experienced the largest measles outbreak in the U.S. since 1992. Most of the cases in New York have been in the *frum* community. Source: CDC, 2019



Source: CDC. PHIL Photo ID#1150. https://www.cdc.gov/measles/about/photos.html

Severe complications

of measles: (can lead to hospitalization and even death)

• Pneumonia (lung infection): one out of every 20 children with measles; the most common cause of death from measles in young children

• Swelling of the brain (encephalitis): one out of every 1,000 children with measles; can lead to convulsions, deafness, and intellectual disabilities



• **Death:** one or two out of every 1,000 children who get measles

 Measles during pregnancy can cause miscarriage, preterm labor, and low birth weight.
 Source: CDC 2018a; 2018b

Long-term complications:

In rare cases, seven to 10 years after seemingly recovering from the measles disease, one can develop signs of subacute sclerosing panencephalitis (SSPE), a progressively disabling and fatal central nervous system (brain and spine) disorder with only a 5% chance of survival.

Source: CDC, 2018b; NIH, 2019

Anti-Vaxx Myth: Having the measles will build my children's immune systems and make them stronger. Having a measles party is an excellent way to make sure my children become naturally immune to measles and a good way to avoid the MMR vaccine.

P.I.E.: FALSE and DANGEROUS! In children and adults who have

the measles, it can take *two to three full years for the immune system to fully recover*. During this time, children are at higher risk for other viruses, bacterial infections, and death at much higher rates than children who did not get the measles. In addition, even if the child had the measles, they will still require the MMR in order to be protected against mumps and rubella. **Source:** Mina et al, 2015

Anti-vaxx Myth: It is dangerous to take "fever reducers" with the measles.

P.I.E.: a. This is false and poor advice! If a child (or adult) develops a rash and fever due to the measles, they may take Tylenol, Advil, Motrin, or Aleve only as instructed by a doctor and the label dosage information. DO NOT take aspirin. **Source:** Mayo Clinic, 2018

b. Aspirin should NEVER be given to children or teenagers with measles symptoms, as it can cause a rare but potentially fatal condition, Reye's syndrome, in individuals recovering from chickenpox or flu-like symptoms. Source: Mayo Clinic, 2018

Anti-Vaxx Myth: If I vaccinate my child, they are more likely to get measles from the shot.

P.I.E.: FALSE! According to basic understanding of how germs are shared, this is a completely ridiculous claim (see "Shedding", page 118). According to the FDA, the majority of people who get measles are unvaccinated and often have had international travel. **Source:** FDA, 2019

Anti-Vaxx Myth: Measles is harmless to my child.

P.I.E.: In 2017 alone, there were 110,000 measles deaths worldwide (WHO 2018), an average of 300 deaths per day. Without vaccination, we would once again see a drastic rise in disease, similar to the numbers seen in the pre-vaccine era. **Source:** WHO, 2018

References:

Centers for Disease Control and Prevention. (2018a). Complications of measles. Retrieved from: https://www.cdc.gov/measles/about/complications.html Centers for Disease Control and Prevention. (2018b). Measles. Retrieved from: https://www.cdc.gov/vaccines/pubs/pinkbook/meas.html

Centers for Disease Control and Prevention. (2019). Measles Cases and Outbreaks. Retrieved from: https://www.cdc.gov/measles/cases-outbreaks.html Harpaz, R. (2004). Completeness of measles case reporting: review of estimates for the United States. The Journal of infectious diseases, 189(Supplement_1), S185-S190. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/15106109

Mayo Clinic. (2018) Measles: Diagnosis and Treatment. Retrieved from: https://www.mayoclinic.org/diseases-conditions/measles/diagnosis-treatment/drc-20374862

Mina, M. J., Metcalf, C. J. E., de Swart, R. L., Osterhaus, A. D. M. E., & Grenfell, B. T. (2015). Long-term measles-induced immunomodulation increases overall childhood infectious disease mortality. Science, 348(6235), 694-699.

National Institute of Health. (2019). Subacute sclerosing panencephalitis information page. Retrieved April 16, 2019 from: https://www.ninds.nih.gov/ Disorders/All-Disorders/Subacute-Sclerosing-Panencephalitis-Information-Page

US Food and Drug Administration. (2018). Finding and learning about side effects (adverse reactions). Retrieved from: https://www.fda.gov/drugs/ resourcesforyou/consumers/ucm196029.htm

US Food and Drug Administration. (2019). Vaccines for children - a guide for parents and caregivers. Retrieved from: https://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/Consumers/ucm345587.htm

World Health Organization (WHO). (2018). Measles. Retrieved from: https://www.who.int/news-room/fact-sheets/detail/measles

Measles infection essentially resets a child's developing immunity to that of a newborn.

MEASLES: The master childhood infection

- The immune system functions as a memory system: When a child is exposed to a germ, their body develops a way to memorize that bacteria or virus. The next time that same germ is around that child, they will not get sick because the body will immediately release protective cells to prevent illness.
- Our children's immune systems, as they grow, are a treasure chest of memorized illnesses that happened once and will not happen again.
- Many years of research and studies about children who had the measles have shown that the measles causes a strong, lifelong immunity to measles, BUT it wipes out immunity to other illnesses that the child has developed throughout their life.
- This happens because the measles memory cells REPLACE all of the memory cells to other diseases.
- When the measles virus ends, the cells that fought the illness leave the body, but they also wipe out the remaining memory cells from other diseases.

MEASLES VIRUS INFECTION CYCLE

Source: https://www.immunopaedia.org.za/ wp-content/uploads/2014/12/measles-virusinfection-cycle.jpg

Measles Local virus lymph node Alveolar macrophages Skin and dendritic rash cells • • • 0 Thymus Dissemination 0 • • 0 T and B 00 0 / cells 0 0 0 0 0 Lungs Liver Transmission Blood Lymphatic Skin tissue Spleen

The Proof

• Researchers found that measles outbreaks increased death rates for two to three years after their appearance.

• For up to five years after the measles, children who had previously had the measles experienced *more diagnosed infections* than children who hadn't.

• Children who had measles were **15% to 24% more likely to receive** *a prescription* for an infection than children who never had measles.

How long does this new phase of risk last?

Studies have found that it can take an average of 27 months for the child to regain their immune memory — and this can only occur after repeated exposure to the germs they were once immune to, or by revaccination.

There is a way for children to keep their immune systems intact, keep their immunity to other diseases, and STILL develop powerful immunity to the measles: the MMR vaccine.

References:

Johns Hopkins Bloomberg School of Public Health. (2003). The story of vitamin A. Retrieved from: https://www.jhsph.edu/news/stories/2003/sommer-vita.html

Mayo Clinic. (2019) Measles: Diagnosis and treatment. Retrieved from: https://www.mayoclinic. org/diseases-conditions/measles/diagnosis-treatment/drc-20374862

Mina, M. J., Kula, T., Leng, Y., Li, M., de Vries, R. D., Knip, M., ... & Larman, H. B. (2019). Measles virus infection diminishes preexisting antibodies that offer protection from other pathogens. *Science*, 366(6465), 599-606.

Mina, M. J. (2017). Measles, immune suppression and vaccination: direct and indirect nonspecific vaccine benefits. *Journal of Infection*, 74, S10-S17.

Mina, M. J., Metcalf, C. J. E., De Swart, R. L., Osterhaus, A. D. M. E., & Grenfell, B. T. (2015). Long-term measles-induced immunomodulation increases overall childhood infectious disease mortality. *Science*, 348(6235), 694-699.

Measles and Vitamin A

Dr. Alfred Sommer was working in Indonesia in the 1970s, treating children with vitamin A for vision problems. There was clear evidence this vitamin plays an important role in both day and night vision. As he and his group were caring for the children, they noticed something very interesting. Children who were either supplemented with vitamin A or had their own sufficient stores of vitamin A had better outcomes if they were ill with diarrhea or measles. The vitamin did not give them immunity; it just made the course of disease a bit easier. In fact, children who were vitamin A-deficient died in greater numbers. The results from his original work were so dramatic there were multiple large-scale clinical trials testing vitamin A. The result was proven: Vitamin A has a significant impact on children's health and ability to temper virulent disease and diarrhea. As a result, the World Health Organization made vitamin A supplementation a priority for children's health around the world. Source: Johns Hopkins, 2003

If a child has low levels of vitamin A, they are likely to have a more severe case of measles. A large dose of 200,000 international units (IU) can be given to hospitalized children over the age of 1 year to potentially lessen the severity. **This does not treat the measles.** The most effective prevention for measles is the measles vaccine. **Source:** Mayo Clinic, 2019

Current and Reliable Vaccine Information for Frum Families | 77

MUMPS

What is mumps and how does it spread?

Mumps is an acute viral infection that spreads either by breathing in infectious particles in the air, or from the saliva of an infected person. The virus will grow in the nose, throat, and lymph nodes, then spreads in the body to the membranes protecting the brain and spine (meninges), salivary glands, pancreas, testes, and ovaries, which causes complications. Mumps is contagious two days before through five days after the salivary glands swell. Symptoms start at about 16-18 days after exposure. Some people can have mumps and show no symptoms, but are still contagious. The most common symptom is inflammation of the salivary glands (parotid gland) or parotitis.

Source: CDC, 2019

How do I know if I have mumps?

• In the early stages of infection, there will be a general feeling of illness, generalized pain, lack of appetite, headache and/or low-grade fever. Inflammation and swelling in the salivary glands (parotitis) develops
 16-18 days after exposure. The swelling can occur on either one or both sides of the face and neck.
 The infected person will begin to complain of an earache or tenderness.

• Some infected people can have mumps with mild or no symptoms. Source: CDC, 2019

Common complications of mumps:

 Inflammation of the testicles (orchitis): Common in males who have reached puberty; this can lead to a decrease in testicular size and fertility.

Inflammation of the pancreas
(pancreatitis)

Source: CDC, 2019

Severe complications of mumps:

 Inflammation of the ovaries and/ or breast tissue: not associated with infertility in women

• Deafness: Generally one-sided occurs. General deafness, although rare, can happen.

 Inflammation of the membranes protecting the brain and spine (meningitis)

• Inflammation of the brain (encephalitis)

• Permanent and severe complications such as paralysis, seizures, and hydrocephalus (excess fluid on the brain), are extremely rare. **Source:** CDC, 2019



Source: CDC.PHIL Photo ID# 130. https://www.cdc.gov/mumps/about/photos.html

References:

Centers for Disease Control and Prevention (CDC). (2019). Mumps. Retrieved from: https://www.cdc.gov/mumps/index.html

RUBELLA (GERMAN MEASLES)

What is rubella and how does it spread?

Rubella is a moderately contagious virus spread by breathing in infectious particles from the air. The virus then grows in the nose, throat, and nearby lymph nodes. The virus is most contagious when the rash first appears but can infect others from seven days before and up to seven days after the rash becomes visible. About 50% of those who become infected have no symptoms but can still spread the virus. The rash is very similar to measles, which is why it is also known as "German measles." **Source:** CDC, 2017

How do I know if I have rubella?

 In children, there is usually no early symptoms where the child is feeling unwell, and the rash is the first symptom to appear. In older children and adults there is a general discomfort, mild fever, swollen lymph nodes, and coughing or runny nose. This usually lasts one to five days.

• The rash appears 14-17 days after exposure; it is red and flat with small bumps. It is similar to measles, but is lighter.

• The rash starts on the face and then moves to the entire body. It lasts three days and is occasionally itchy.

• Swollen lymph nodes can develop about a week before the rash and can last several weeks thereafter.

• Adults often develop joint pain and/or arthritis.

• Other symptoms include eye infection (conjunctivitis), testicular pain (testalgia), or inflammation of the testicles.

Source: CDC, 2107

Common complications of rubella:

Generally, rubella has no complications for children. Adults with rubella are more likely to have complications.

• Arthritis: up to 70% of adult women are affected and can last up to one month. Chronic arthritis is rare.

Source: CDC, 2017

Between 1964 and 1965 — when the last major rubella epidemic occurred — there were approximately 12.5 million cases of rubella in the United States. Of those cases, the complications were as follows: 2,000 cases of encephalitis, 11,250 miscarriages, 2,100 neonatal deaths, and **20,000 babies born with congenital rubella syndrome (CRS)**.

Between 1998 and 2015, there was **a total of 40 cases of CRS in the United States**. Thirty-five of the mothers in these cases were born outside of the United States, and it is unclear whether these women were vaccinated.

Source: CDC, 2017

Severe complications of rubella:

• Severe bleeding: conditions in the blood, such as low platelet counts, which can lead to severe bleeding occur in about one in 3,000 cases. Gastrointestinal, brain, and kidney hemorrhages may occur.

 Inflammation of the brain:
 Encephalitis occurs at a rate of about one in 6,000 cases, generally in adults.

• Inflammation of the testicles

• Inflammation of the nerves

• Late syndrome of progressive panencephalitis: Similar to SSPE (see the measles section for more information).

• Congenital Rubella Syndrome (CRS): Most severe if the mother is infected in the first 12 weeks of pregnancy. This syndrome will affect all body parts of the fetus. It can lead to fetal death, prematurity, deafness, eye and cardiac defects, mental retardation, liver and spleen damage, bone alterations, and microcephaly (abnormally small skull), among many other medical issues. Up to 85% of infants who were infected in the first trimester will have CRS. Additionally, infants with CRS can shed a lot of the virus and infect caretakers who are susceptible for up to one year. **Source:** CDC, 2017

What is congenital rubella syndrome (CRS)?

CRS, the most dangerous complication of rubella, affects the fetus of a pregnant woman who becomes infected with rubella. CRS can result in miscarriage, stillbirth, and severe birth defects. For some infants affected, damage from CRS won't appear until they are 2-4 years old. This damage includes diabetes, or higher rates of autism and SSPE. Since most women have been vaccinated, this is rarely seen and, if so, acquired overseas. **Source:** CDC, 2017

References:

Centers for Disease Control and Prevention (CDC). (2017). Rubella: German measles. Retrieved from: https://www.cdc.gov/rubella/index.html

MMR Vaccine Injection only 5 ml Store F

Effectiveness of the MMR (measles, mumps, and rubella) Vaccine:

The percentage refers to how many people out of 100 would be immune, rather than an individual person's actual immunity rate.

- Measles: 93% for one dose and 97% for two doses
- Mumps: 78% for one dose and 88% for two doses
- Rubella: 97% for one dose

Source: CDC, 2019

Common Side Effects:

Common side effects from MMR and MMRV vaccines that can occur seven to 10 days after vaccination include:

- Fever
- Faint red rash (not infectious)
- Head cold, runny nose, cough, or puffy eyes
- Tiredness
- Swelling of salivary glands
- · Pain, redness, and swelling at the injection site

Rare Side Effects

• Brain inflammation (encephalitis or subacute sclerosing panencephalitis): one out of every 3 million

SHOT BY SHOT: N NR

• Steven-Johnson syndrome: A rare and serious disorder of your skin and mucous membranes

• Guillain-Barre syndrome: A rare disorder in which your body's immune system attacks your nerves

• Anaphylactic allergic reaction: If someone has an allergy to the antibiotic neomycin or other components of the MMR, do not take the MMR vaccine. Discuss with your health care provider.

Source: Medscape, n.d.

Who cannot receive the MMR vaccine?

- Pregnant women
- People with certain cancers
- · People with some immunodeficiencies
- · People with respiratory illness with high fever
- People with severe allergy to neomycin
- People with severe allergy

to gelatin

People with a previous
history of severe allergic
reaction to the MMR

For more information, scan the QR code for the MMR insert.



References:

Centers for Disease Control and Prevention. (2019). Vaccine for measles. Retrieved from https://www.cdc.gov/measles/vaccination.html

Medscape. (n.d.). Measles mumps and rubella vaccine, live. Retrieved from https://reference.medscape.com/drug/mmrii-measles-mumps-and-rubella-vaccine-live-343159#4 Current and Reliable Vaccin

SHOT BY SHOT: VARICELLA

What is varicella and how does it spread?

Varicella, also known as chickenpox, is a very contagious disease caused by the varicella zoster virus. It is spread by direct contact with blisters, saliva, or mucus of an infected person, and transmission through droplets released into the air by coughing and sneezing. Chickenpox is usually mild, but can be serious in infants under 12 months of age, adolescents, adults, pregnant women, and people with weakened immune systems. Children and people with weakened immune systems are at highest risk of catching chickenpox.

Source: CDC, 2018a

Important: Neonatal varicella is common in pregnant women who get chickenpox for the first time in their lives during the last three weeks of pregnancy. If the pregnant woman gets maternal varicella from five days before to two days after delivery, the resultant chickenpox infection of the newborn can cause a death rate as high as 30%. **Source:** CDC, 2018b

How do I know I have varicella?

The classic sign of chickenpox is an itchy rash made up of fluidfilled blisters. Symptoms of fever, tiredness, loss of appetite, muscle aches, and headache can begin two to three days before the rash. The rash appears 10 to 21 days after exposure to a person with chickenpox. The rash begins on the face, scalp, and mouth and then spreads downward, causing itchy blisters all over the body. A person infected with chickenpox is contagious from one to two days before the rash appears, until all the blisters have turned into crusted scabs and no new blisters have appeared for 24 hours. Source: CDC, 2018c

Severe complications of varicella:

- Hospitalization
- Dehydration

• Bacterial infections of the skin and soft tissue (including bones, lungs, joints, and blood)

Pneumonia

• Encephalitis - an infection or inflammation of the brain

Hemorrhagic complications bleeding problems

• Sepsis - multiple organ system damage in response to infection

Death

Source: CDC, 2018d

Long-term complications of varicella:

Shingles-varicella zoster virus remains in the nerve cells of the body even after a person recovers from chickenpox. Shingles is common in people 50 years of age and older. Shingles is not contagious but can cause chickenpox infection in those who do not have immunity (either from vaccination or previous infection). The first symptoms of shingles are pain, numbness, or tingling on one side of the body that begins two to four days before the rash appears. Then, a painful, blistering rash appears at the site. The pain or numbness may last for as long as a year, or longer, even after the rash is gone.

Source: CDC, 2015

Varicella Vaccine Effectiveness

This vaccine is effective at almost 90%, even with a single dose with long-term protection. **Source:** Baxter et al, 2013

Varicella Vaccine Adverse Effects/Side Effects

 Soreness, redness, or swelling at the injection site

- Fever
- Mild rash

• Temporary pain and stiffness in the joints

Source: CDC, 2018e

Serious side effects:

- Bacterial infection of skin lesions
- Fever-associated seizures
- Infection of the lungs

Source: CDC, 2018e

You do not need to get the chickenpox vaccine if you have evidence you are immune to chickenpox.

Who cannot get the varicella vaccine:

• A person who has ever had a severe allergic reaction (for example, anaphylaxis) to a previous dose of chickenpox vaccine or any ingredient of the vaccine, including gelatin or the antibiotic neomycin

CHICKENPOX VACCINE SAVES LIVES AND PREVENTS SERIOUS ILLNESS

Chickenpox-related deaths in the U.S. have decreased dramatically



Two doses of vaccine are needed to protect against chickenpox.

Find out more about chickenpox at http://www.cdc.gov/chickenpox/.

• Pregnant women should wait until after they have given birth. Women should not get pregnant for one month after getting the chickenpox vaccine.

Check with your health care
provider if you have immune issues,
are on chemotherapy, or recently
had a blood transfusion.
Source: CDC, 2019

Anti-Vaxx Myth: "According to the FDA, serious reactions (including life-threatening events, disabilities and death) have occurred in anywhere from 4-14% of those vaccinated!"

Source: Wise, 2000

P.I.E.: False. This study actually said that "Most of the reported adverse events associated with varicella vaccine are minor, and

serious risks appear to be rare." A quote by the FDA in this study says that only 4% of adverse reactions were reported, and these reports include *rashes and pain at the injection site.*

A study of the safety of the second dose of varicella vaccine looked at data from July 1, 2006, to December 31, 2014. There were 14,641 reports from VAERS and 494 (3%) were considered serious. This percentage of serious reports was the same even if other vaccines were given at the same time and regardless of age when receiving the vaccine.

Compare this to pre-vaccine statistics, when approximately 11,000 individuals with varicella required hospitalization each year. Death occurred in approximately 1 in 60,000 cases. In addition, from 1990 through 1996, an average of 103 deaths from varicella were reported each year, with some of the deaths occurring in immunocompetent children and adults. **Sources:** Wise, 2000; Su et al, 2017; CDC, 2018b

Studies have found that when the vaccine was introduced, the incidence of chickenpox decreased by 90% due to "cocooning" or the simple effect of children not bringing home the infectious disease. Furthermore, children who died of chickenpox after vaccine introduction often had a cancer diagnosis and were unable to fight the infection. **Source:** Marin, Zhang, & Seward, 2011

Weigh the Risks: Chickenpox

The Disease

Rash (300-500 blisters) Pneumonia or encephalitis (1 of 1,000) Up to 479% higher risk of shingles if unvaccinated Bacterial infection of skin lesions Hospitalization (2-3 of 10,000) Birth defects (1 to 50 born to infected mothers) Death (1 of 60,000)

The Vaccine

Injection site pain and tenderness (19%) Low-grade fever (15% in children) Rash around injection site (4 of 100)



Sources: chop.edu; CDC; *The Journal of Infectious Diseases*, Volume 208, Issue 11, December 1, 2013, pages 1859-1868, doi.org/10.1093/infdis/jit405

Redrawn from an illustration by Hannah Henry; used with permission.

Chickenpox Deaths 1972-2013



Source: ProCon.org, vaccines.procon.org/vaccine-histories-and-impact/varicella-chickenpox

Anti-Vaxx Myth: "Additionally, the varicella vaccine has caused a huge increase in the once rare shingles disease, an infection significantly more painful and chronic than chickenpox." Source: Kohl et al, 1999

P.I.E.: False. This often-quoted study by the anti-vaxx movement has *no mention of this statement.* Instead, it states that "Zoster (shingles) in childhood is an unusual occurrence and *probably even less common after varicella-zoster virus immunization.*" The article also mentions that varicella immunization may play a role in increased protection against zoster. Source: Kohl et al, 1999

For more specific vaccine information, scan the QR code.



Chickenpox

References:

Baxter, R., Ray,P., Tran,TN., Black, S., Shinefield, HR., Coplan,MR, Lewis, E., Fireman, B., Saddier, P. (2013) Long-term Effectiveness of Varicella Vaccine: A 14-Year, Prospective Cohort Study. *Pediatrics*. 131 (5) e1389-e1396; DOI: 10.1542/peds.2012-3303. Retrieved from https:// pediatrics.aappublications.org/content/131/5/e1389

Centers for Disease Control and Prevention CDC. (2018a). Chickenpox (Varicella) Transmission. Retrieved from: https://www.cdc.gov/chickenpox/about/transmission.html

Centers for Disease Control and Prevention CDC. (2018b). Pinkbook: Chickenpox. Retrieved from: https://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html.

Centers for Disease Control and Prevention CDC. (2018c). Chickenpox Symptoms. Retrieved from: https://www.cdc.gov/chickenpox/about/symptoms.html.

Centers for Disease Control and Prevention CDC. (2018d). Chickenpox Complications. Retrieved from: https://www.cdc.gov/chickenpox/about/complications.html.

Centers for Disease Control and Prevention CDC. (2015). Shingles (Herpes Zoster) Vaccine Safety. Retrieved from: https://www.cdc.gov/vaccinesafety/vaccines/shingles-herpes-vaccine.html.

Centers for Disease Control and Prevention CDC. (2018e). Chickenpox VIS. Retrieved from: https://www.cdc.gov/vaccines/hcp/vis/vis-statements/varicella.html.

Centers for Disease Control and Prevention CDC. (2019). Chickenpox vaccination: What everyone should know. Retrieved from: https://www.cdc.gov/vaccines/vpd/varicella/public/index.html#not_vac

Kohl, S., Rapp, J., LaRussa,P., Gershon,AA. Steinberg, SP. (1999). Natural varicella-zoster virus reactivation shortly after varicella immunization in a child. *Pediatric Infectious Disease*. DOI:10.1097/00006454-199912000-00023. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/10608641

Marin, M, Zhang, JX, Seward, JF. (2011). Near elimination of varicella deaths in the US after implementation of the vaccination program. Pediatrics, 128 (2) 214-220; DOI: 10.1542/ peds.2010-3385 Retrieved from: https://pediatrics.aappublications.org/content/128/2/214

Su, JR., Leroy, Z., Lewis, PW., Haber, P., Marin, M., Leung, J., Woo, EJ., Shimabukuro, TT. (2017). Safety of second-dose single-antigen varicella vaccine. *Pediatrics*. 139(3) e20162536; DOI: 10.1542/peds.2016-2536. Retrieved from: https://pediatrics.aappublications.org/content/139/3/e20162536

arcent and Reliable Vaccine Information for Frum Families | 85

SHOT BY SHOT: MENNGOCOCCAL

Bacteria called *Neisseria meningitidis* cause meningococcal disease. This disease can be deadly in a matter of hours. Teens and young adults are at an increased risk for this disease. There are two types: meningococcal meningitis and meningococcal septicemia. **Source:** CDC, 2019a

How do I know it is meningococcal meningitis and how does it spread?

Meningococcal meningitis is when the bacteria infects the protective membranes (the meninges) covering the brain and spinal cord, and causes swelling. About one in 10 people have these bacteria in the back of their nose and throat with no signs or symptoms of disease; this is called being "a carrier." However, there are times bacteria enter the body and cause meningococcal disease. Both meningococcal meningitis and septicemia are spread by people sharing saliva or spit (for example, close or lengthy contact such as coughing or kissing, or sharing food and dishes/cups). It is not as contagious as a cold or the flu. It takes a lot of close contact to spread meningococcal disease. **Source:** CDC, 2019a

Common symptoms include:

- Fever
- Headache
- Stiff neck

Other symptoms:

- Nausea
- Vomiting

• Photophobia (eyes being more sensitive to light)

Altered mental status (confusion)

It might be hard to tell if newborns or babies have meningitis. They may act very slow, not move properly, cry a lot, throw up, or not eat. **Source:** CDC, 2019b

How do I know it is meningococcal septicemia?

Meningococcal septicemia is when the bacteria go into the bloodstream and break the walls of the blood vessels. This causes bleeding into the skin and organs. **Source:** CDC, 2019b

Common symptoms include:

- Fever
- Vomiting
- Cold hands and feet
- Chills

 Severe aches or pain in the muscles, joints, chest, or abdomen (belly)

- Very fast breathing
- Diarrhea

In the later stages, a dark

purple rash

Source: CDC, 2019b

How meningococcal disease is treated

Antibiotics

Breathing support

Medications to treat low blood
pressure

Treatment for the damaged skin
 Source: CDC, 2019c

Complications of Meningococcal Disease

Even with immediate antibiotic treatment, 10 to 15 in 100 people infected with meningococcal disease will die. About 10 to 20 in 100 survivors will have long-term disabilities, such as loss of limb(s), deafness, nervous system problems, or brain damage.

Source: CDC, 2019c

Effectiveness of the Meningococcal Vaccine

Vaccines help protect against serogroups of *Neisseria meningitidis* bacteria seen in the U.S. This vaccine is 85% effective. This means there is still a chance a person can develop meningococcal

For more specific vaccine information, scan the QR codes.



men-ACWY



men-B

disease even if they have been vaccinated. It is important to know the symptoms of meningococcal disease because immediate medical treatment can make the difference between life and death. **Source:** CDC, 2019d

There are certain people at high risk of this disease who definitely need this vaccination. These include people with:

- Sickle cell disease
- No spleen
- Certain immune disorders
- HIV

These people may need a shot every three to five years. **Source:** CDC, 2019d

People who are more likely to be exposed to the disease should also get the vaccine more frequently. These include:

• Teens (increased risk after age 16)

International travelers to

certain countries

- Laboratory workers
- Military

Source: CDC, 2019d

Adverse Effects/Side Effects of the Vaccines

There are two types of meningococcal vaccines. MenACWY vaccine common

side effects (which usually go away

in one to two days):

• Redness or pain where the vaccine was given

Fever

MenB vaccination common side effects (which usually get better in three to seven days, but serious reactions are possible):

 Soreness, redness, or swelling where the vaccine was given

- Tiredness (fatigue)
- Headache
- Muscle or joint pain
- Fever or chills
- Nausea or diarrhea
- Source: CDC, 2019d

Who cannot get the meningococcal vaccine?

MenACWY vaccine

• A person who has ever had a severe allergic reaction (for example, anaphylaxis) to a previous dose of meningococcal ACWY vaccine or any ingredient in the vaccine, or any severe, life-threatening allergies. **Source:** CDC, 2019e

MenB vaccine

• A person who has ever had a severe allergic reaction (for example, anaphylaxis) to a previous dose of meningococcal B vaccine or any ingredient in the vaccine, or any severe, life-threatening allergies. **Source:** CDC, 2019f

References:

Centers for Disease Control and Prevention CDC. (2019a). Meningococcal disease: Causes and spread to others. Retrieved from: https://www.cdc.gov/meningococcal/about/symptoms.html Centers for Disease Control and Prevention CDC. (2019b). Meningococcal disease: Signs and symptoms. Retrieved from: https://www.cdc.gov/meningococcal/about/symptoms.html Centers for Disease Control and Prevention CDC. (2019c). Meningococcal disease: Diagnosis, treatment, and complications. Retrieved from: https://www.cdc.gov/meningococcal/about/ diagnosis-treatment.html

Centers for Disease Control and Prevention CDC. (2019d). Meningococcal vaccination: What everyone should know. Retrieved from: https://www.cdc.gov/vaccines/vpd/mening/public/index.html

Centers for Disease Control and Prevention CDC. (2019e). Vaccine information statement. Meningococcal ACWY VIS. Retrieved from: https://www.cdc.gov/vaccines/hcp/vis/vis-statements/mening.html

Centers for Disease Control and Prevention CDC. (2019f). Vaccine information statement. Serogroup B Meningococcal (MenB) VIS. Retrieved from: https://www.cdc.gov/vaccines/hcp/vis/vis-statements/ mening-serogroup.html

SHOT BY SHOT: HEPATITS A

Hepatitis A (Hep A) is a contagious viral disease of the liver that can be prevented by vaccine. **Source:** CDC, 2019a

What is hepatitis A and how does it spread?

Hepatitis A is a very contagious viral infection of the liver and can be spread even before an infected person feels sick. It can be a shortterm, mild illness, or in rare cases, cause chronic liver failure or even death. The virus is usually spread through the "fecal-oral" route. This can happen due to poor hand washing after using the bathroom or changing a diaper. It can also be caused by eating or drinking food or water contaminated by tiny, undetectable amounts of infected stool. Source: CDC, 2019a

How do I know I have hepatitis A?

A person exposed to hepatitis A will have symptoms as early as two weeks and up to seven weeks after exposure.

Symptoms include fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, diarrhea, clay-colored stools, joint pain, and jaundice (yellowing of the skin and eyes).

Children under the age of 6 years may not have symptoms or jaundice, but they can still spread the infection to others. Adults and children over the age of 6 years usually have yellowing of the skin and eyes as one of the symptoms.

Hepatitis A is diagnosed by a health care professional by discussing symptoms and reviewing blood work.

Symptoms of the illness usually last less than two months but can persist for up to six months in some infected individuals. **Source:** CDC, 2019a; CDC, 2019b

Mild complications of hepatitis A:

Relapsing hepatitis can occur in approximately 10% of patients, in which the symptoms stop and start a few times for six months after the original infection. **Source:** CDC, 2019b

Severe complications of hepatitis A:

- Liver failure
- Death

• Fulminant hepatitis: Very rare. A large portion of the liver dies; it is the most severe rare complication. 80% of patients who experience this complication will die. **Source:** CDC, 2019b

Effectiveness of the hepatitis A vaccine

Almost 100% of adults who receive two doses will have protective antibodies; a single dose protects about 95%. For children and teenagers, 97% will have protective antibodies with a single dose. Studies at 10, 15, and 17 years showed continued protection against the virus from vaccination. **Source:** CDC, 2019b

Common side effects of the hepatitis A vaccine:

These common side effects usually begin shortly after receiving the vaccine, and last one or two days:

- Soreness or redness where the shot was given
 - Low-grade fever
 - Headache
 - Tiredness
 - Decreased appetite
 - Nausea

Source: GlaxoSmithKlein, 2018

Who cannot get the hepatitis A vaccine?:

 Severe allergic reaction (for example, anaphylaxis) after a previous dose of any hepatitis A-containing vaccine, or to neomycin.
 Source: GlaxoSmithKlein, 2018

For details, scan the QR code.



Hep A

References:

Centers for Disease Control and Prevention. (2019a). Hepatitis A. Retrieved from: https://www.cdc.gov/hepatitis/hav/index.htm Centers for Disease Control and Prevention. (2019b). Hepatitis A. Retrieved from: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hepa.pdf GlaxoSmithKlein. (2018) Havrix. Hepatitis A vaccine. Retrieved from: https://gsksource.com/pharma/content/gsk/source/us/en/brands/havrix.html

What is HPV and how does it spread?

Human papillomavirus (HPV) is a virus that only infects humans. HPV is a very common virus; nearly 70 million people are currently infected in the U.S. Every year, about 14 million people, including teens, become infected with HPV. HPV is transmitted through skin-to-skin contact with an infected individual, who may not have any symptoms and may not even know they have the virus. It is easily spread through a cut or abrasion in the skin, usually during intimacy. It can take only one encounter to be infected with the virus.

The HPV vaccine protects against cervical, anal, oropharyngeal, vulvar, vaginal, and penile cancers caused by HPV. Ninety percent of cervical cancers worldwide are caused by HPV and can be prevented by vaccination. **Source:** CDC, 2019

How do I know I have HPV?

• Most people who have the virus won't show any signs of the infection and unknowingly can pass the infection to others.

• Women ages 21 to 65 years should receive the Pap screening test every three years. This screening test can detect cell changes that are abnormal and often turn into cancerous cells. The HPV vaccine is not intended to replace the Pap screening test. **Source:** Mayo, 2019

Serious complications of HPV:

• Cancer: HPV will usually clear on its own but when it doesn't, lingering HPV infection can cause several cancers.

 Recurrent respiratory papillomatosis (RRP): Noncancerous tumors grow on the respiratory tract, usually on the larynx (voicebox). RRP may occur in adults as well as infants and small children who may have gotten the virus during childbirth. Symptoms are much more severe in children than adults. Management may require frequent surgeries as the growing tumors can restrict the breathing and become lifethreatening. The HPV vaccine can prevent the development of RRP. Source: CDC, 2019; HHS, 2017

Effectiveness of the HPV vaccine:

The vaccine is for both boys and girls. The HPV vaccine provides almost 100% protection from nine HPV types: 6, 11, 16, 18, 31, 33, 45, 52, and 58, when all doses are received on schedule and before there is any infection with these types of viruses. If a person is younger than age 15, they need two injections spaced at least six months apart. If a person is 15 years or older, they need three injections over six months. This is because younger people produce the best immune response to the vaccine. Protection against these nine HPV types remains at about 99% more than a decade after it was received and shows no sign of weakening. The vaccine was recently approved for women up until age 45.

Source: NCI, 2019

HPV Vaccine Adverse Effects/ Side Effects:

Side effects of the HPV vaccine are usually mild and include:

- Injection-site pain, swelling, and redness
 - Nausea
 - Fever
 - Headache
 - Fainting: Vaccinations in

adolescents can sometimes cause fainting, which is attributed to the fear of getting injections. Fainting isn't harmful, but falling can cause injury. These injuries can be prevented by sitting or lying down for 15 minutes after getting the vaccine.

Source: Merck, 2019

Who should not receive the HPV vaccine?

• Anyone who is severely allergic to yeast

Anyone who is allergic to any ingredients in the vaccine
Source: Merck, 2019

Anti-Vaxx Myth: "There were 17 deaths during the clinical

trials, but investigators dismissed these events, claiming they were unrelated to the shot!"

P.I.E.: Misleading; selective reporting. Clinical trials often last many years, and all deaths which occur for any reason must be reported in the study. There were a total of 40 deaths out of 30,000 people during clinical trials: 21 in the vaccine group and 19 in the placebo group. The study also must list the cause of death. In this clinical trial, the most common cause of death was from motor vehicle accidents, which are clearly not caused by vaccine injury. The other causes of death, such as cardiac events, suicide, cancer, and postoperative complications, were divided among placebo and vaccine groups. Source: Merck, 2015

Anti-Vaxx Myths: "This vaccine has caused huge numbers of severe reactions in young girls and women."

"Hundreds of young women required extended hospital care." "As of 2016, at least 317 young women have died after receiving the HPV shots."

"Since the vaccine has been released in 2006, according to VAERS there have been more than 50,000 adverse reactions reported." **Multiple Sources:** VAERS data, 2013; Neil Miller

P.I.E.: VAERS is intended to function as an alert system to notify the CDC about vaccine reactions. Reported reactions are not proven, and they need to be verified first by medical records and autopsy reports. Many of the deaths reported to VAERS, and later confirmed by autopsy, are shown to be caused by anything from undiagnosed cardiac issues to drug overdoses. Some also reflect multiple reports of the same death reported in multiple news stories. However, studies using verified information submitted through the VAERS system have found no new or unexpected safety concerns.

A study in July 2014 included patterns of adverse events reported in VAERS on the HPV vaccine.

Think about it...

Clinical studies must list all adverse events that occur during the time frame of the study, even if they are clearly not related to the vaccine, such as deaths due to motor vehicle accidents. Deaths were reported for the placebo group as well. This information can easily be misconstrued and used as a scare tactic. • More than 67 million doses of the HPV vaccine were administered in the U.S. from June 2006–March 2014.

• There were 25,176 reports to VAERS of adverse events.

• 92.4% of those adverse events were not serious. These included fainting, redness or pain at the site of the injection, dizziness, nausea, and headache.

A review of 600.558 doses found no statistically significant risk of any of the adverse effects studied. The review looked at Guillain-Barre syndrome (GBS), stroke, venous thromboembolism (VTE, or blood clots), appendicitis, seizures, syncope (sudden loss of consciousness), allergic reactions, and anaphylaxis (severe allergic reaction). Note: This study found a statistically insignificant difference in the case of VTE, and a 2016 follow-up study confirmed that there is no link to VTE. Sources: White, 2014; Gee, 2011; Yih, 2016; Siegrist et al, 2007; Arana et al, 2018

Anti-Vaxx Myth: "Some strains of HPV may, in rare instances, cause cervical cancer. However, there has been no study for a time period long enough to prove the vaccine has prevented even a single case of cancer."

Source: Cave, "What Your Doctor May Not Tell You About Children's Vaccinations," 2010.

P.I.E.: False. This book promotes the author's own unproven vaccine schedule and is filled with misinformation. HPV is a common virus that in most cases clears up



on its own. However, when it persists, it can lead to different types of cancer. The newest research shows the percentage of precancers caused by HPV 16 and 18 went *down* from 52.7% in 2008 to 44.1% in 2014. In women who were vaccinated, precancers caused by HPV 16 and 18 dropped from 55.2% to 33.3%. In unvaccinated women, the rate dropped from 51% to 47.3%. The study authors say this is because of herd immunity. **Sources:** McClung et al, 2019

Anti-Vaxx Myth: "In clinical trials, 93% of women who received the HPV vaccine reported adverse reactions within 15 days. Many women even withdrew from the study to avoid further reactions." **Source:** Merck & Co. product insert, 2006

P.I.E.: False; selective reporting; misconstrued data. See complete quote below:

"93% of those that received the vaccine **and 91% of the placebo group** (in other words, the group that received an injection which *did not* contain the vaccine) reported adverse effects, most commonly *mild pain at the injection site*. Few individuals (0.2%) discontinued due to adverse reactions, none due to severe adverse reactions." **Source:** Merck & Co., 2015 Women who are intermittently positive for HPV DNA over the course of several months to years are often enrolled in studies of HPV infection. We have learned that it is impossible to know when these intermittently HPV 16 DNA positive women were initially infected, in part because levels of anti-HPV antibodies due to naturally acquired infection tend to be low or undetectable.

> Anti-Vaxx Myth: "Incredibly, women who received the series of three shots and then tested positive for HPV16 were excluded from the study."

Source: Neil Miller, 2010

P.I.E.: Misleading. The Vaccine Task Force contacted the main author of this landmark study, Laura Koutsky, via email regarding this exclusion data. Laura's response follows:

In other words, it is impossible to know whether these women were infected before or after receiving the vaccine, so they could not be included in a study designed to determine if the vaccine prevents infection. **Source:** L. Koutsky, 2019

Anti-Vaxx Myth: "The vaccine only targets nine out of the over 100 strains of HPV that exist." Source: None given. **P.I.E.:** Selective reporting. These nine strains account for over 90% of cervical cancer cases worldwide. Two of these strains, HPV types 16 and 18, (the strains included in the first Gardasil vaccine) account for about 70% of all cases of cervical cancer. It would be illogical, and a waste of time and money, to create a vaccine that contained 140+ extremely rare strains of HPV. **Sources:** Huh, 2017; Castellsague, 2008

Anti-Vaxx Myth: "Many American parents only allow their children to receive this vaccine out of fear of promiscuous behavior." Source: None given.

P.I.E.: False. Some parents worry that vaccinating against HPV can be an indirect endorsement of risky behavior, or that it could lead to risky behaviors due to the perception of protection.

Sadly, a study found that 26% of married Orthodox Jewish women reported a history of molestation or abuse, with 16% of these incidents occurring before the age of 13 years. Rates were higher in the ultra-Orthodox community than in the modern-Orthodox community. Another study found that across the Jewish religious spectrum, the rates of childhood molestation or abuse were statistically equivalent to the national rates.

A study in the *Journal of the American Medical Association* showed that this is not the case. Those who received the vaccine did not show signs of increased promiscuity when compared to those who did not. **Sources:** Yehuda et al, 2007; Rosmarin et al, 2018; Jena et al, 2015

Anti-Vaxx Myth: "The vaccine is not for young girls, and not only may not protect them, but may cause the rates of cervical cancer to increase."

Source: Quote attributed to Dr. Harper, from Cave, "What Your Doctor May Not Tell You About Children's Vaccinations," 2010.

P.I.E.: False; speculation. This is referring to Dr. Harper's speculation that the vaccine is given too early. She believes it is not as effective in younger girls, leading to higher cervical cancer rates later on. However, the results are promising. A recent study has shown the cervical cancer rate for women ages 15 to 24 years dropped by 29% from 2011-2014. For women ages 25 to 34 years, the rates dropped by 13%. These decreases are not due to a drop in high-risk behavior, but rather from the vaccine.

Current studies show that the vaccine offers protection for at least 14 years post-vaccination. Antibody levels are predicted to remain higher than those acquired by natural infection for at least 20 years post-vaccination.

Sources: Guo, Cofie, & Berenson, 2018; Harper, 2017; Schwarz, 2014; Schwarz, 2017

For details, scan the QR code.



HPV

92 | Parents Informed and Educated

References:

Arana, J. E., Harrington, T., Cano, M., Lewis, P., Mba-Jonas, A., Rongxia, L., ... & Shimabukuro, T. T. (2018). Post-licensure safety monitoring of quadrivalent human papillomavirus vaccine in the Vaccine Adverse Event Reporting System (VAERS), 2009–2015. *Vaccine*, 36(13), 1781-1788. Retrieved from: doi: 10.1016/j.vaccine.2018.02.034

Castellsagué, X. (2008). Natural history and epidemiology of HPV infection and cervical cancer. *Gynecologic oncology*, 110(3), S4-S7. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/18760711

Centers for Disease Control and Prevention (CDC). (2019). Human papillomavirus vaccination: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. Retrieved from: https://www.cdc.gov/hpv/parents/vaccine.html

Gee J, Naleway A, Shui I, et al. (2011). Monitoring the safety of quadrivalent human papillomavirus vaccine: Findings from the Vaccine Safety Datalink. *Vaccine* 2011; 29(46):8279-8284. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/21907257

Guo, F., Cofie, L. E., & Berenson, A. B. (2018). Cervical cancer incidence in young US females after human papillomavirus vaccine introduction. *American journal of preventive medicine*, 55(2), 197-204. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/29859731

Harper, D. M., & DeMars, L. R. (2017). HPV vaccines–a review of the first decade. *Gynecologic oncology*, 146(1), 196-204. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/28442134

Huh WK, Joura EA, Giuliano AR, et al. (2017). Final efficacy, immunogenicity, and safety analyses of a nine-valent human papillomavirus vaccine in women aged 16-26 years: a randomised, double-blind trial. *Lancet*. 390(10108):2143-2159. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/28886907

Jena, A. B., Goldman, D. P., & Seabury, S. A. (2015). Incidence of sexually transmitted infections after human papillomavirus vaccination among adolescent females. *JAMA internal medicine*, 175(4), 617-623. Retrieved from: doi:10.1001/jamainternmed.2014.7886

Koutsky, Laura. Personal Interview. May, 2019.

Mayo Clinic (2019). HPV Infection Symptoms & Causes. Retrieved from Mayo Clinic: https://www.mayoclinic.org/diseases-conditions/hpv-infection/ symptoms-causes/syc-20351596

McClung, N. M., Gargano, J. W., Bennett, N. M., Niccolai, L. M., Abdullah, N., Griffin, M. R., ... & Markowitz, L. E. (2019). Trends in human papillomavirus vaccine types 16 and 18 in cervical precancers, 2008–2014. *Cancer Epidemiology and Prevention Biomarkers*, 28(3), 602-609. Retrieved from: https://cebp.aacrjournals.org/content/early/2019/02/18/1055-9965.EPI-18-0885

Merck & Co., (2019). *Information about Guardasil* 9. Retrieved from Guardasil 9: https://www.gardasil9.com/about-gardasil9/what-is-gardasil9/ Merck & Co. (2015). GARDASIL[®] [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant]. Retrieved from: https://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf

National Cancer Institute. National Institute of Health. (2019) Human Papillomavirus (HPV) vaccines. Retrieved from: https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-vaccine-fact-sheet#how-effective-are-hpv-vaccines

Rosmarin, D. H., Pirutinsky, S., Appel, M., Kaplan, T., & Pelcovitz, D. (2018). Childhood sexual abuse, mental health, and religion across the Jewish community. *Child abuse & neglect*, 81, 21-28. Retrieved from: https://touroscholar.touro.edu/gssw_pubs/33/

Schwarz, T. F., Huang, L. M., Lin, T. Y., Wittermann, C., Panzer, F., Valencia, A., ... & Descamps, D. (2014). Long-term immunogenicity and safety of the HPV-16/18 AS04-adjuvanted vaccine in 10-to 14-year-old girls: open 6-year follow-up of an initial observer-blinded, randomized trial. *The Pediatric infectious disease journal*, 33(12), 1255-1261. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5673947/

Schwarz, T. F., Galaj, A., Spaczynski, M., Wysocki, J., Kaufmann, A. M., Poncelet, S., ... & Struyf, F. (2017). Ten-year immune persistence and safety of the HPV-16/18 AS 04-adjuvanted vaccine in females vaccinated at 15–55 years of age. *Cancer medicine*, 6(11), 2723-2731. Retrieved from: https://doi.org/10.1002/cam4.1155

Siegrist, C. A., Lewis, E. M., Eskola, J., Evans, S. J., & Black, S. B. (2007). Human papilloma virus immunization in adolescent and young adults: a cohort study to illustrate what events might be mistaken for adverse reactions. *The Pediatric infectious disease journal*, 26(11), 979-984. Retrieved from: doi:10.1097/INF.0b013e318149dfea

US Department of Health and Human Services. National Institutes of Health: National Institute on Deafness and other Communication Disorders. (2017). Recurrent Respiratory Papillomatosis or Laryngeal Papillomatosis. Retrieved from: https://www.nidcd.nih.gov/health/recurrent-respiratory-papillomatosis

White M. D. (2014). Pros, cons, and ethics of HPV vaccine in teens-Why such controversy? *Translational andrology and urology*, 3(4), 429–434. Retrieved from: doi:10.3978/j.issn.2223-4683.2014.11.02

Yehuda, R., Friedman, M., Rosenbaum, T. Y., Labinsky, E., & Schmeidler, J. (2007). History of past sexual abuse in married observant Jewish women. *American journal of psychiatry*, 164(11), 1700-1706. Retrieved from: https://www.researchgate.net/profile/Talli_Rosenbaum/publication/5871332_ History_of_Past_Sexual_Abuse_in_Married_Observant_Jewish_Women/links/09e4150c8453255c44000000/History-of-Past-Sexual-Abuse-in-Married-Observant-Jewish-Women.pdf

Yih, W. K., Greene, S. K., Zichittella, L., Kulldorff, M., Baker, M. A., de Jong, J. L., ... & McMahill-Walraven, C. N. (2016). Evaluation of the risk of venous thromboembolism after quadrivalent human papillomavirus vaccination among US females. *Vaccine*, 34(1), 172-178. Retrieved from: https://doi.org/10.1016/j.vaccine.2015.09.087

SHOT BY SHOT: INFLUENZA/FLU

Flu vaccines cause antibodies to develop in the body about two weeks after vaccination to protect against infection. Influenza viruses evolve very quickly, so last year's vaccine may not offer protection for the current or future year's viruses. New flu vaccines are released every year to provide protection against these rapidly changing flu viruses. **Source:** Mayo Clinic, 2019

What is influenza and how does it spread?

Influenza, also known as the flu, is a contagious respiratory infection caused by the influenza virus. Severe infections can result in hospitalization and/or death. A person infected with the flu can spread it to others up to 3 feet away via respiratory droplets released in the air by coughing, sneezing, and even talking. These droplets can land into other people's mouths or noses. Droplets can also land on surfaces, and be transferred by touching the surface, and then touching the mouth, nose, or eyes. People who get the flu are most contagious in the first three to four days after the illness begins. Infection can spread even one day *before* symptoms develop, and up to five days *after* symptoms develop. Children or those with weakened immune systems can be contagious for even longer.

Sources: CDC, 2018a; CDC, 2018b

How do I know if I have influenza?

• Influenza is different than a cold because the onset of symptoms is sudden and fever is usually present with the flu.

• Symptoms usually develop within two days of exposure, but can range from one to four days.

People who are sick with flu

often feel some or all of these symptoms:

- Fever* or feeling feverish/chills
- Cough
- Sore throat
- Runny or stuffy nose
- Muscle or body aches
- Headaches
- Fatigue (tiredness)
- Some people may have

vomiting and diarrhea, though this is more common in children than adults.

*It's important to note that not everyone with flu will have a fever.

Recovery can take a few days or up to two weeks. **Source:** CDC, 2019a

Please seek immediate medical attention for these symptoms:

Children

• Fast breathing or trouble breathing

- Bluish lips or face
- Ribs pulling in with each breath
- Chest pain
- Muscle pain

• Dehydration (no urine for eight hours, dry mouth, no tears when crying)

• Not alert or interacting when awake

Seizures

• Fever above 104 degrees Fahrenheit

• In children less than 12 weeks, any fever

• Fever or cough that improve but then return or worsen

Worsening of chronic medical conditions

Adults

SIGNS AND SYMTOMS

Symptom onset

Fatigue, weakness

Chest discomfort, cough

Fever

Aches

Chills

Sneezing

Stuffy nose

Sore throat

• Difficulty breathing or shortness of breath

IS IT A

COLD

Rare

Slight

Uncommon

Sometimes

Common

Common

Common

Rare

Mild to moderate

Gradual

- Persistent pain or pressure in the chest or stomach
- Persistent dizziness, or difficult to wake up
- Seizures
- Not urinating
- Severe muscle pain
- Severe weakness
- Fever or cough that improve but then return or worsen
- Worsening of chronic medical conditions

FLU

Abrupt

Usual

Usual

Usual

Sometimes

Sometimes

Sometimes

Common

Common

Fairly common

Source: CDC, 2019a

Mild complications of influenza:

- Ear infections
- Sinus infections
- Bronchitis
- Source: CDC, 2019a

Severe complications of influenza:

• Pneumonia: a serious complication resulting from viral influenza alone or from a second bacterial infection caused by the flu making the immune system weak.

• Myocarditis: inflammation of the heart muscle

• Encephalitis: inflammation of the brain

• Rhabdomyolysis: Breakdown of the muscle, can lead to kidney failure and death

Multi-organ failure: Can be caused by sepsis or rhabdomyolysis.
Can affect the lungs and kidneys.
People hospitalized with the flu will often be placed on ECMO (Extracorporeal Membrane
Oxygenation). This is a machine that oxygenates the blood outside the body, to allow the lungs to heal.
It is similar to the machine used during heart bypass surgery.

• Sepsis: an extreme inflammatory response leading to sepsis, the body's life-threatening response to infection.

• Heart attack and stroke: Studies have shown that influenza is associated with an increase of heart attack and stroke.

Death

Sources: CDC, 2019a; CDC, 2019b

Long-term complications of influenza:

Flu can also trigger worsening of chronic medical problems, such as congestive heart failure, asthma, and diabetes. **Source:** CDC, 2019a

Headache



Who is at high risk of severe and long-term complications of the flu?

People with these conditions are more likely to be hospitalized or die. It is extremely important people in these groups receive the flu shot every year:

• Asthma, chronic lung disease, and cystic fibrosis

- Diabetes
- Heart disease
- Kidney disorders
- Liver disorders
- Morbidly obese: very overweight

• Children under 19 years on aspirin therapy

• Weak immune system: whether born with, from disease, or from medication

• 65 years or older; or who live in a nursing home

Children under 2 years

• Pregnant women up to two weeks after giving birth **Source:** CDC, 2018d

Effectiveness of the influenza vaccine

The CDC checks the effectiveness of the flu vaccine each year against the current year's flu. The vaccine works best when the flu vaccine is well-matched to the flu virus. The vaccines seem to be most effective against influenza B, influenza A(H1N1) and not as effective against influenza A(H3N2) viruses. In general, in any year, the flu vaccine reduces the risk of flu illness between 40% and 60%. **Source:** CDC, 2018c



Flu Vaccine Adverse Effects/Side Effects:

Common mild side effects:

 Soreness, redness, and/or swelling where the vaccine was injected

- Headache
- Fever
- Nausea
- Muscle aches

Rare side effects:

Guillain-Barré syndrome (GBS): less than one case per million doses. GBS is more common following flu illness than the flu vaccine (estimated at 17 per million). GBS is not associated with the nasal spray vaccine.

Source: CDC, 2017; Kawai et al, 2014; Vellozzi, Iqbal, & Broder, 2014

Who should not receive the flu vaccine?

Everyone over the age of 6 months should receive a yearly flu vaccine. Those who should not are: - Babies under the age of 6 months

Anyone with a severe allergy

to the flu vaccine or any of the ingredients in the vaccine

Speak to your doctor if you:

- Have a severe allergy to eggs
- Have a history of Guillain-Barré syndrome (GBS)
 - Are currently sick

Source: CDC, 2017

Anti-Vaxx Myth: "Influenza is a disease that is innocuous in more than 99% of the population." **Source:** None given.

P.I.E.: False. The World Health Organization states that 650,000 deaths per year are due to seasonal influenza. The 2017-2018 flu season in the U.S. had the highest reported flu-associated deaths for children with 186 children dying of the flu. About 80% of these children were not vaccinated against the flu. Flu deaths in children are nationally notifiable; they have to be reported to the CDC. Even so, some flu deaths in children may be



underreported because they were not tested for the flu.

The CDC does not know how many adults die from the seasonal flu each year. States are not required to report individual flu diagnosis or death for people over the age of 18 years. Flu is not always written on the death certificate even if people die of flu-related complications. Some deaths happen one to two weeks after the initial flu infection either because the patient caught a bacterial infection along with the flu, such as pneumonia, or the flu aggravated an already existing disease such as chronic heart disease. Most people who die from the flu are never tested for it or they go to the hospital when the flu cannot be detected from their respiratory samples. Flu tests can only detect the infection within a week of the onset of the symptoms. These are some of the reasons why the CDC and health departments use statistics and math models to estimate the number of flu deaths.

According to the estimates, there were more than 22.7 million medical visits, 959,000 hospitalizations, and 79,400 deaths in 2017-2018. The 2017-2018 flu season was considered a severe year with above-average hospitalizations and associated deaths. **Sources:** CDC, 2018e; CDC, 2019c; WHO, 2017.

Anti-Vaxx Myth: "Aside from the rarity of flu deaths, the vaccine is not usually capable of preventing the disease, since it rarely matches the circulating virus strain." Source: None given. P.I.E.: False. Depending on the person's age, prior flu vaccination history, and the year, the vaccine can range from 20-76% effective in preventing the flu. This prevention lessens the risk of severe illness, complications, and hospitalizations in certain populations. If a person does catch the flu, symptoms will be milder. Additionally, flu deaths are not rare; in 2017-2018 there were approximately 79,400 deaths in the U.S. due to the flu. Source: CDC, 2018e; Garten, 2018

Anti-Vaxx Myth: "The amount of people who get the flu from the flu vaccine is just too many to count!" "Many experience the flu shortly after vaccination." Source: Neil Miller

P.I.E.: The injected flu vaccine cannot cause the flu as it contains a dead virus. Mild flu-like symptoms after vaccination may be attributed to:

1) Other illnesses, such as the common cold (which is different from the flu)

2) Mismatched flu viruses

3) The immune system working to produce antibodies, which can cause body aches and a slight fever.

It takes about 14 days for the flu shot to take full effect. It is possible, although rare, to have caught the flu before the vaccine is fully effective (in other words, you were already infected with the flu virus when you were vaccinated).

Source: CDC, 2019c

Anti-Vaxx Myth: "In 2005 The Lancet published a review that concluded, 'the safety of influenza vaccines given to babies



and children is *unknown*...They found clear evidence of systemic suppression of data."" **Source:** Jefferson, 2005

P.I.E.: False. The review found no evidence of harm caused by vaccines. However the authors concluded more studies should be done in children under age 2 years. Of the 31 studies reviewed, one vaccine company declined to send the authors additional, unpublished information. This can hardly be considered "systemic suppression of data," and nowhere in the review did the authors make this claim.

In 2004, the influenza vaccine was recommended for children 6 months and older. Children under age 2 were identified as having hospitalization rates similar to or higher than the elderly, making them a high-risk population. In light of these recommendations, a review published in the *Journal of Clinical Infectious Diseases* examined the studies and concluded the vaccine was safe and effective for infants and children.



Influenza: . . . * . shown that the influenza virus can narrow the airway, cause mucus to

In 2011, The Lancet published a paper studying the flu vaccine in children ages 9 months to 3 years, and found it to be effective with no adverse events reported. The flu vaccine prevents pediatric deaths. Source: Jefferson, 2005; Ruben, 2004; Heinonen et al, 2011; Englund et al, 2010

Anti-Vaxx Myth: "... Influenza and pneumonia were the ninth leading cause of death in 2010 with 50,097 deaths...Further analysis of the data



reveals that out of all those deaths, 49,597 were from pneumonia, and only 500 were from the flu!" "This deceptive lumping of disease data convinces the public of the danger of influenza, making the flu shot seem like a lifesaving necessity." "Pneumonia commonly occurs in debilitated hospitalized patients; it may portend death, but it is rarely associated with the flu." Sources: J. Rappaport, Natural News, 2013,

P.I.E.: False, false, false. Post-viral (or secondary) bacterial pneumonia occurs because the flu virus damages the cells in the airway, which then allows bacteria to flourish. The virus also suppresses the body's immune system, which makes it easier for bacteria to overwhelm the body's natural defenses. Studies have

linger, and become infected, leading to pneumonia.

Approximately 30% of all pneumonia cases begin as respiratory viruses, including the influenza virus. This is by no means a "rare association." It is very likely people who ended up with secondary bacterial infections would not have gotten them without having the flu first.

Source: CDC, 2019b; Walker, & Ison, 2014; Jennings et al, 2008

Anti-Vaxx Myth: "The flu is of little concern compared to the damage the shot is capable of, including disability and death. The CDC admits that the flu vaccine can cause Guillain-Barré syndrome, a debilitating paralytic condition. They play down the seriousness of this condition while emphasizing the dangers of the flu..."

P.I.E.: False; selective information. Guillain-Barré syndrome is a rare immune response that causes paralysis. It usually develops after a bacterial or viral respiratory infection or diarrhea, and rarely from a vaccine. In a review looking at data from 1993-2011, with a population size of about 13 million, risk of GBS following influenza vaccination was 1.03 per 1 million, as opposed to following influenza infection, which was 17.2 per 1 million. The risk of developing GBS is still greater after having the flu itself than after receiving the flu vaccine. Source: Vellozzi, Iqbal, & Broder, 2014

Anti-Vaxx Myth: Flu vaccines have not been shown to be safe for pregnant women and can cause miscarriages.

P.I.E.: Misleading. The reason the flu vaccine is recommended during pregnancy is because the risk of not vaccinating is greater than the

risk associated with the vaccine. Pregnant or postpartum women are more likely to get pneumonia and be hospitalized as a result of the flu. They are at increased risk of ICU admission and negative outcomes for both them and their babies. This is especially noticeable during a pandemic. During the 2009-2010 flu season, 12% of deaths in pregnant women were attributed to the flu, and many of these women were previously healthy.

Women who are vaccinated during pregnancy also pass on immunity to their infants. One study showed the vaccine was 91.5% effective in preventing hospitalization for influenza during their infants' first 6 months of life. This protection is crucial because babies cannot be vaccinated until they are 6 months old, and infants have the highest mortality risk of any age group.

Numerous studies have found the flu vaccine to be safe and effective for both mother and fetus. (See the Appendix for a table of these studies.)

A single observational study found a small association between women who received the flu vaccine early in the first trimester and miscarriage. The same group of researchers just finished conducting a much larger follow-up study that did not find any link between the flu vaccine and miscarriage. **Source:** ACOG, 2018; Callaghan et al, 2015; Benowitz, 2010; Bhat et al, 2015; Nordin et al, 2013; Munoz et al, 2005; Brown, 2017; Branswell, 2019



References:

American College of Obstetricians and Gynecologists. (2018). Influenza vaccination during pregnancy: Committee opinion. Retrieved from: https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Influenza-Vaccination-During-Pregnancy#11

Benowitz, I., Esposito, DB., Gracey, KD., Shapiro, ED., Vazques, M. (2010). Influenza vaccine given to pregnant women reduces hospitalization due to influenza in their infants, *Clinical Infectious Diseases*, 51(12) 1355–1361. https://doi.org/10.1086/657309. Retrieved from: https://academic.oup.com/cid/article/51/12/1355/316344

Bhat, N., Wright, JG., Broder, KR., et al. (2015). Influenza-associated deaths among children in the United States, 2003–2004. N Engl J Med 2005; 353:2559-2567. DOI: 10.1056/NEJMoa051721. Retrieved from: https://www.nejm.org/doi/full/10.1056/NEJMoa051721

Branswell, H. (2019). New study finds no link between flu shots and miscarriages, allaying fears. Stat News. Retrieved from: https://www.statnews.com/2019/02/27/new-study-finds-no-link-between-flu-shots-and-miscarriages-allaying-fears/

Brown, HL. (2017) It is Safe to Receive Flu Shot During Pregnancy. American College of Obstetricians and Gynecologists. Retrieved from: https://www.acog.org/About-ACOG/News-Room/Statements/2017/It-is-Safe-to-Receive-Flu-Shot-During-Pregnancy

Callaghan, W. M., Creanga, A. A., & Jamieson, D. J. (2015). Pregnancy-related mortality resulting from influenza in the United States during the 2009-2010 Pandemic. *Obstetrics and gynecology*, 126(3), 486–490. doi:10.1097/AOG.000000000000996. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4557717/

Centers for Disease Control and Prevention (CDC). (2017). Flu vaccine safety information. Retrieved from: https://www.cdc.gov/flu/prevent/general.htm

Centers for Disease Control and Prevention (CDC). (2018a). Key facts about the flu. Retrieved from: https://www.cdc.gov/flu/about/keyfacts.htm;

Centers for Disease Control and Prevention (CDC). (2018b). How flu spreads. Retrieved from: https://www.cdc.gov/flu/about/disease/spread.htm

Centers for Disease Control and Prevention (CDC). (2018c). Flu vaccine effectiveness. Retrieved from: https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm

Centers for Disease Control and Prevention (CDC). (2018d). People at high risk of flu complications. Retrieved from: https://www.cdc.gov/flu/highrisk/index.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fflu%2Fabout%2Fdisease%2Fhigh_risk.htm

Centers for Disease Control and Prevention (CDC). (2018e). Estimated Influenza Illnesses, Medical visits, Hospitalizations, and Deaths in the United States — 2017–2018 influenza season. Retrieved from: https://www.cdc.gov/flu/about/burden/2017-2018.htm

Centers for Disease Control and Prevention (CDC). (2019a). Flu symptoms. Retrieved from: https://www.cdc.gov/flu/symptoms.htm Centers for Disease Control and Prevention (CDC). (2019b). Flu and heart disease and stroke. Retrieved from: https://www.cdc.gov/flu/highrisk/ heartdisease.htm

Centers for Disease Control and Prevention (CDC). (2019c). Seasonal flu shot. Retrieved from: https://www.cdc.gov/flu/prevent/flushot.htm

Englund, J. A., Walter, E., Black, S., Blatter, M., Nyberg, J., Ruben, F. L., ... & GRC28 Study Team. (2010). Safety and immunogenicity of trivalent inactivated influenza vaccine in infants: a randomized double-blind placebo-controlled study. *The Pediatric infectious disease journal*, 29(2), 105-110. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/19934787/

Garten R, Blanton L, Elal AI, et al. (2018). Update: Influenza Activity in the United States During the 2017–18 Season and Composition of the 2018–19 Influenza Vaccine. *MMWR Morb Mortal Wkly Rep* 2018;67:634–642. DOI: http://dx.doi.org/10.15585/mmwr.mm6722a4. Retrieved from: https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a4.htm?s_cid=mm6722a4_w

Heinonen, S., Silvennoinen, H., Lehtinen, P., Vainionpää, R., Ziegler, T., & Heikkinen, T. (2011). Effectiveness of inactivated influenza vaccine in children aged 9 months to 3 years: an observational cohort study. *The Lancet infectious diseases*, 11(1), 23-29. Retrieved from: https://doi.org/10.1016/S1473-3099(10)70255-3

Jefferson, T., Smith, S., Demicheli, V., Harnden, A., & Rivetti, A. (2005). Safety of influenza vaccines in children. *The Lancet*, 366(9488), 803-804. Retrieved from: https://doi.org/10.1016/S0140-6736(05)67204-2

Jennings, L. C., Anderson, T. P., Beynon, K. A., Chua, A., Laing, R. T., Werno, A. M., ... & Murdoch, D. R. (2008). Incidence and characteristics of viral community-acquired pneumonia in adults. *Thorax*, 63(1), 42-48. Retrieved from: http://dx.doi.org/10.1136/thx.2006.075077

Kawai, A. T., Li, L., Kulldorff, M., Vellozzi, C., Weintraub, E., Baxter, R., ... & Nordin, J. D. (2014). Absence of associations between influenza vaccines and increased risks of seizures, Guillain–Barré syndrome, encephalitis, or anaphylaxis in the 2012–2013 season. *Pharmacoepidemiology and drug safety*, 23(5), 548-553. Retrieved from: https://onlinelibrary.wiley.com/doi/abs/10.1002/pds.3575

Mayo Clinic. (2019) Flu shot: your best bet for avoiding influenza. Retrieved from: https://www.mayoclinic.org/diseases-conditions/flu/in-depth/flu-shots/art-20048000

Munoz, FM, et al. (2005). Safety of influenza vaccination during pregnancy. American Journal of Obstetrics and Gynecology. 192(4), 1098-1106. Retrieved from: https://www.ajog.org/article/S0002-9378(04)02102-7/fulltext.

Nordin, JD,. Kharbanda, EO., Benitez, GV., et al. (2013). Maternal safety of trivalent inactivated influenza vaccine in pregnant women.Obstet Gynecol.121(3):519-25. doi: 10.1097/AOG.0b013e3182831b83. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/23635613

Ruben, F. L. (2004). Inactivated influenza virus vaccines in children. *Clinical infectious diseases*, 38(5), 678-688.Retrieved from: https://doi.org/10.1086/382883

Vellozzi, C., Iqbal, S., & Broder, K. (2014). Guillain-Barre syndrome, influenza, and influenza vaccination: the epidemiologic evidence. *Clinical infectious diseases*, 58(8), 1149-1155. Retrieved from: https://doi.org/10.1093/cid/ciu005

Walker, E., & Ison, M. G. (2014). Respiratory viral infections among hospitalized adults: experience of a single tertiary health care hospital. *Influenza and other respiratory viruses*, 8(3), 282-292. Retrieved from: https://doi.org/10.1111/irv.12237

World Health Organization WHO (2017). Up to 650 000 people die of respiratory diseases linked to seasonal flu each year. Retrieved from: https://www.who.int/news-room/detail/14-12-2017-up-to-650-000-people-die-of-respiratory-diseases-linked-to-seasonal-flu-each-year

AUTISM 101

Why are there so many more autistic people today than ever before?

There are several reasons for the ever increasing numbers of autistic individuals. First, 30 years ago, a child had to meet eight out of 16 criteria to be diagnosed. Today, there are only two criteria: (1) impaired social communication/interaction, and (2) restricted and repetitive behaviors. Second, educators, in addition to doctors, can now diagnose autism. Third, autism screening has become routine since 2006. All of this adds up to more and more children being diagnosed. **Source:** Volkmar & McPartland, 2014

Is there any connection between autism and vaccines?

In 1998, a study by Andrew Wakefield, then a consultant gastroenterologist, was published in *The Lancet*, a British medical journal. He studied 12 children whose parents claimed they noticed behavioral regression and gastrointestinal symptoms after their children received the MMR vaccine. After publishing his study, Wakefield then held a press conference where he stated that the MMR vaccine was unsafe and advocated the use of single-antigen vaccines (in other words, separating the measles, mumps, and rubella into three separate vaccines). **Source:** Dyer 2010; Wakefield, 1998

Wakefield's study, however, never concluded that MMR caused either autism or gastrointestinal problems. To the contrary, Wakefield actually made the following statement in his study: "We did not prove an association between measles, mumps, and rubella vaccine and the syndrome described." He also concluded that, "A genetic predisposition to autistic-spectrum disorders is suggested by over-representation in boys and a greater concordance rate in monozygotic [identical] than in dizygotic [fraternal/non-identical] twins." Source: Dyer 2010; Wakefield, 1998 Anti-Vaxx Myth: "I can prove to you that autism is a new and growing problem with a very simple comparison: How many 50-year-olds are autistic? How many 5-year-olds?"

P.I.E.: MISLEADING. The above questions are by no means "proof" of anything. A lifelong condition, autism can be diagnosed at any age and at any stage. While today many children are diagnosed in their preschool years, people who were not evaluated or did not fit the criteria decades ago can now receive a diagnosis of autism at any age if they fit the current criteria. In fact, a study in 2012 examined old cases of diagnostic data on autism in Utah from the 1980s. When the subjects of the original study were re-evaluated with current diagnostic criteria, 59% of the adults, who as children were considered "not autistic," now qualified for the autism diagnosis. In short, if all of the adults with autism spectrum disorder (ASD) features came forward and were formally evaluated by current criteria, many would likely receive a diagnosis of autism today. Source: Miller et al, 2013

Anti-Vaxx Myth: "The autism population keeps rising as more vaccines are being mandated."

P.I.E.: Selective information; misleading association. Although autism rates seem to be rising (due to changes in diagnostic criteria), and it is true that we now give more vaccines than we did 50 years ago, these are nevertheless two unrelated phenomena. A simple look at the vaccine schedule shows

Think about it...

Andrew Wakefield himself, the "doctor" who many credit with establishing a link between the MMR vaccine and autism, admitted that he was never able to prove any association between the two!

Despite multiple studies performed, and millions of children studied, no connection was found. (For a detailed review of the studies mentioned above, see the Appendix.)

Several years later, researchers reviewed the study done by Wakefield and found evidence of fraud, as well as many ethical concerns, and his publication was retracted in 2010. Wakefield subsequently lost his license to practice medicine.

no radical changes since the 1990s, yet autism rates have continued to rise *in line with the current broader diagnostic criteria.* **Source:** Children's Hospital of Philadelphia, 2019

Anti-Vaxx Myth: "Studies proved that since 1991, the burgeoning vaccine schedule had caused autism rates to skyrocket." Source: Neil Miller, 2010; Robert Kennedy, 2005 **P.I.E.: False.** *Diagnosis* of autism has increased since the 1980s due to the changes in diagnostic criteria, state-offered services, and awareness of autism (see the Autism Timeline on page 106). Although multiple studies have examined vaccines and autism, no link has been found between the two. (See the Appendix.)

The cost of treating autism in the United States is \$126 billion a year!

(autismspeaks.org, 2012)

Think about it...

Much of these expenses are government-funded, such as special education services. Why would the government continue to recommend vaccines if they were secretly aware that vaccines cause autism, which comes along with such a hefty price tag? Source: Autism Speaks, 2012

Study Spotlight

In a study titled "No effect of MMR withdrawal on the incidence of autism: a total population study," published in the *Journal of Child Psychology and Psychiatry* in 2005, researchers Hideo Honda, Yasuo Shimizu, and Michael Rutter looked at the "cumulative incidence of autism spectrum disorders [ASD] up to age seven for children born from 1988 to 1996 in Kohoku Ward, Yokohama, Japan." They found that the MMR vaccination rate kept dropping from 1988 through 1992, and from 1993 onward not a single MMR vaccine was given. Even with the complete stopping of the MMR vaccine, the rate of autism kept climbing. In fact, it rose even higher from 1993 onward. Therefore, the MMR vaccine was "most unlikely to be a main cause of ASD."

Source: Honda et al. No effect of MMR withdrawal on the incidence of autism: a total population study, *Journal of Child Psychology and Psychiatry*, 2005, Volume 46, Issue 6, pages 572-579, doi.org/10.1111/j.1469-7610.2005.01425.x

Need more proof? Let's take a look at Japan.

In 1988, the Japanese MMR vaccine was withdrawn due to a contaminated mumps strain. MMR vaccination rates in Japan dropped to zero, while autism rates—with and without regression—continued to rise. This was the only time the MMR vaccine was completely discontinued in any country, allowing researchers to evaluate autism rates independent from the vaccine (see study above). **Source:** Honda, Shimizu, & Rutter, 2005

Anti-Vaxx Myth: "[Autistic children] usually lack a clear genetic abnormality that can account for their ... deficits."

P.I.E.: False. Genetics has been proven to account for many cases of autism. The rate of ASD is six to 15 times higher in boys than

in girls. Additionally, research shows that babies born to parents of older age are at higher risk of autism. Finally, when a child is diagnosed with autism, a younger sibling has a ten-fold increased risk of being diagnosed with autism as well. These all clearly point to a genetic factor. Furthermore, a very recent study has revealed that autism features are present on brain MRI as early as 6 months of age (prior to MMR vaccination, which is first given at one year). Based on MRI, whether or not a child will develop autism can now be predicted with 90% accuracy.

Sources: Johnson & Meyers, 2007; Bailey et al, 1995; Risch et al, 1999; Asherson & Curran, 2001; Muhle, Trentacoste, & Rapin, 2004; Reichenberg et al, 2006; Croen, Najjar, Fireman, & Grether, 2007; Emerson et al, 2017 Anti-Vaxx Myth: "Autism often appears as a sudden regression after a history of normal development." Source: National Autism Association (no date given).

P.I.E.: False. Regressive autism makes up only 20% of all autism diagnoses. 80% of children with autism do not have a sudden reversal of development; rather, signs of delayed milestone development are already seen in infancy, prior to their having ever received any vaccinations. **Source:** Dobbs, 2017; Tuchman & Rapin, 1997; Werner & Dawson 2005; Sigman, Dijamco, Gratier, & Rozga, 2004

Anti-Vaxx Myth: "The U.S. has one of the highest rates of autism in the world."

Source: RescuePost, a partner of the anti-vaccination group Generation Rescue.

P.I.E.: Selective information. The more developed a country is, the better equipped it is to evaluate and diagnose its children, and it will therefore have a higher rate of diagnosis of any disorder, autism included. Interestingly, Japan, which does **not** have mandatory vaccination, has the second highest rate of autism in the world.

Anti-Vaxx Myth: "Before 1999, autism was virtually nonexistent in China. By June 2005, over 1.8 million cases were reported." Source: Kennedy, 2005

P.I.E.: False. China has always had autism. However, due to different diagnostic tools, they

had under-reported cases of autism for many years. **Source:** Sun et al, 2013; Duan, Yao, Ma, & Zhang, 2014

Anti-Vaxx Myth: "The relationship between vaccines and autism is undeniable (unless you are working for the CDC, FDA, or WHO)."

P.I.E.: False. Despite numerous studies examining these two factors, a relationship between autism and vaccines has NEVER been found. In fact, it *has* been proven that vaccines do *not* cause autism. Unvaccinated children have autism at the same rates as vaccinated children. Consider the studies in the appendix.

Think about it...

Numerous studies, collectively including millions of children, have found that autism rates are no different in vaccinated versus unvaccinated kids. Was Dr. Eisenstein, a notorious anti-vaccine proponent, who was also sued multiple times for malpractice, somehow seeing a unique population that no one else in the world has come across?

Prevalence of autism spectrum disorder among children in select countries worldwide as of 2020 (per 10,000 children)



Source: World Population Review, Statista, 2020. Additional information: Worldwide, 2020.

Study Spotlight

In a study titled "Measles, Mumps, Rubella Vaccination and Autism," published in the Annals of Internal Medicine in 2019, researchers Anders Hviid, Jorgen Vinslov Hansen, Morten Frisch, and Mads Melbye looked at 657,461 Danish children born from 1999 through the end of December 2010, collecting information on the MMR, other childhood vaccinations, autism diagnoses, sibling history of autism, and other factors known to be related to a higher risk of autism in order to evaluate whether the MMR vaccine increases the risk for autism in children, subgroups of children, or time periods after vaccination. What they found was 6,517 children were diagnosed with autism and the chances of developing autism were the same for children who received the MMR vaccine and those who did not. There was no increased risk of autism even in those families in which children had a sibling with autism, other childhood vaccinations, or other autism risk factors.

Source: Hviid et al. Measles, Mumps, Rubella Vaccination and Autism: A Nationwide Cohort Study, *Annals of Internal Medicine*, 2019, Volume 170, Issue 8, pages 513-520, doi: 10.7326/M18-2101

Anti-Vaxx Myth: "Dr. Mayer Eisenstein has seen over 35,000 children, the majority of whom are unvaccinated. He and his colleagues reported that among their unvaccinated patients, they have not seen a single case of autism." Source: Olmsted, 2005

P.I.E.: Biased/unreliable source. Aside from the fact that this was reported by an anti-vaccine writer (a clear bias), there is no way to verify this statement. Furthermore, many studies, covering millions of children, researched vaccines and autism and no correlation was ever found.

Source: See the Appendix.

Who is Dr. Mayer Eisenstein? Consider this:

He was sued for damaging autistic children with Lupron injections—a service for which he charged \$6,000 per month!

He was sued \$30 million for malpractice. Dr. Eisenstein faced 15 lawsuits, and in 80% of them, the plaintiff won, or Eisenstein settled with them.

Dr. Peter Rosi, a colleague who practiced together with Eisenstein and was also named in some of the malpractice cases against Dr. Eisenstein's practice, is known to have stated that maternal psychological issues are the cause in 80% of cases where infants die during childbirth. Rosi was also criminally prosecuted for malpractice. Eisenstein's associations with people such as Peter Rosi should raise red flags about the kind of practice these doctors engaged in and the lack of legitimacy for the beliefs they hold. **Source:** Callahan & Tsouderos, 2009; Haugland vs. Einsenstein, 2013

References:

Asherson, P. J., & Curran, S. (2001). Approaches to gene mapping in complex disorders and their application in child psychiatry and psychology. *The British Journal of Psychiatry*, 179(2), 122-128. doi: 10.1192/bjp.179.2.122

Autism Speaks. (2012). New research finds annual cost of autism has more than tripled to \$126 billion in the U.S. and reached £34 billion in the U.K. Retrieved from: https://www.autismspeaks.org/press-release/new-research-finds-annual-cost-autism-has-more-tripled-126-billion-us-and-reached Bailey, A., Le Couteur, A., Gottesman, I., Bolton, P., Simonoff, E., Yuzda, E., & Rutter, M. (1995). Autism as a strongly genetic disorder: Evidence from a British twin study. *Psychological Medicine*, 25(1), 63-77. doi:10.1017/S0033291700028099

Callahan, P., Tsouderos, T. (2009). Autism doctor: Troubling record trails doctor treating autism. *Chicago Tribune*. Retrieved from: https://www.chicagotribune.com/

Children's Hospital of Philadelphia. (2019). Vaccine History: Developments by Year. Retrieved from: https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-history/developments-by-year

Croen, L. A., Najjar, D. V., Fireman, B., & Grether, J. K. (2007). Maternal and paternal age and risk of autism spectrum disorders. Archives of Pediatrics & Adolescent Medicine, 161(4), 334-340. doi:10.1001/archpedi.161.4.334

Dobbs, D. (2017). Rethinking regression in autism. Retrieved from: https://www.spectrumnews.org/features/deep-dive/rethinking-regression-autism/ Duan, G., Yao, M., Ma, Y., & Zhang, W. (2014). Perinatal and background risk factors for childhood autism in central China. *Psychiatry Research*, 220(1-2), 410-417. https://doi.org/10.1016/j.psychres.2014.05.057

Dyer, C. (2010). Lancet retracts Wakefield's MMR paper. BMJ https://doi.org/10.1136/bmj.c696

Haugland v. Eisenstein (In re Eisenstein), 525 B.R. 428 (Bankr. N.D. III. 2013)

Emerson, R. W., Adams, C., Nishino, T., Hazlett, H. C., Wolff, J. J., Zwaigenbaum, L., ... & Kandala, S. (2017). Functional neuroimaging of high-risk 6-monthold infants predicts a diagnosis of autism at 24 months of age. *Science Translational Medicine*, 9(393), eaag2882. doi: 10.1126/scitranslmed.aag2882 Honda, H., Shimizu, Y., & Rutter, M. (2005). No effect of MMR withdrawal on the incidence of autism: a total population study. Journal of Child Psychology and Psychiatry, 46(6), 572-579. https://doi.org/10.1111/j.1469-7610.2005.01425.x

Jain, A., Marshall, J., Buikema, A., Bancroft, T., Kelly, J. P., & Newschaffer, C. J. (2015). Autism occurrence by MMR vaccine status among U.S. children with older siblings with and without autism. *Jama*, 313(15), 1534-1540.

Johnson, C. P., & Myers, S. M. (2007). Identification and evaluation of children with autism spectrum disorders. *Pediatrics*, 120(5), 1183-1215. doi: 10.1542/ peds.2007-2361

Madsen, K. M., Hviid, A., Vestergaard, M., Schendel, D., Wohlfahrt, J., Thorsen, P., ... & Melbye, M. (2002). A population-based study of measles, mumps, and rubella vaccination and autism. *New England Journal of Medicine*, 347(19), 1477-1482. doi: 10.1056/NEJMoa021134

Miller, J. S., Bilder, D., Farley, M., Coon, H., Pinborough-Zimmerman, J., Jenson, W., ... & Ritvo, R. A. (2013). Autism spectrum disorder reclassified: A second look at the 1980s Utah/UCLA autism epidemiologic study. *Journal of Autism and Developmental Disorders*, 43(1), 200-210. https://doi. org/10.1007/s10803-012-1566-70

Muhle, R., Trentacoste, S. V., & Rapin, I. (2004). The genetics of autism. *Pediatrics*, 113(5), e472-e486. doi: 10.1542/peds.113.5.e472

Reichenberg, A., Gross, R., Weiser, M., Bresnahan, M., Silverman, J., Harlap, S., ... & Knobler, H. Y. (2006). Advancing paternal age and autism. *Archives of General Psychiatry*, 63(9), 1026-1032. doi:10.1001/archpsyc.63.9.1026

Risch, N., Spiker, D., Lotspeich, L., Nouri, N., Hinds, D., Hallmayer, J., ... & Nguyen, L. (1999). A genomic screen of autism: evidence for a multilocus etiology. *The American Journal of Human Genetics*, 65(2), 493-507. https://doi.org/10.1086/302497

Sigman, M., Dijamco, A., Gratier, M., & Rozga, A. (2004). Early detection of core deficits in autism. *Mental Retardation and Developmental Disabilities Research Reviews*, 10(4), 221-233. https://doi.org/10.1002/mrdd.20046

Statista. (2019). Prevalence of autism spectrum disorder among children in select countries worldwide as of 2018 (per 10,000 children). Retrieved April 15, 2019 from: https://www.statista.com/statistics/676354/autism-rate-among-children-select-countries-worldwide/

Sun, X., Allison, C., Matthews, F. E., Sharp, S. J., Auyeung, B., Baron-Cohen, S., & Brayne, C. (2013). Prevalence of autism in mainland China, Hong Kong and Taiwan: A systematic review and meta-analysis. *Molecular autism*, 4(1), 7. https://doi.org/10.1186/2040-2392-4-7

Taylor, L. E., Swerdfeger, A. L., & Eslick, G. D. (2014). Vaccines are not associated with autism: an evidence-based meta-analysis of case-control and cohort studies. *Vaccine*, 32(29), 3623-3629. https://doi.org/10.1016/j.vaccine.2014.04.085

Tuchman, R. F., & Rapin, I. (1997). Regression in pervasive developmental disorders: Seizures and epileptiform electroencephalogram correlates. *Pediatrics*, 99(4), 560-566. doi: 10.1542/peds.99.4.560

Volkmar, F. R., & McPartland, J. C. (2014). From Kanner to DSM-5: autism as an evolving diagnostic concept. *Annual review of clinical psychology*, 10, 193-212

Wakefield, A. J., Murch, S. H., Anthony, A., Linnell, J., Casson, D. M., Malik, M., ... & Valentine, A. (1998). RETRACTED: Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. https://doi.org/10.1016/S0140-6736(97)11096-0

Werner, E., & Dawson, G. (2005). Validation of the phenomenon of autistic regression using home videotapes. Archives of general psychiatry, 62(8), 889-895. doi:10.1001/archpsyc.62.8.889

AUTISM TIMELINE

MID-1800s	Interest in child development and psychiatry begins.
LATE 1800s	 Psychiatric diagnoses such as schizophrenia, bipolar disorder, etc., receive their official titles. Note that within the diagnosis of schizophrenia, a concept of "autistic thinking" existed. Children who exhibited any sign of withdrawal, rigidity, or repetitive movement were considered to have a psychiatric condition.
1943	 Leo Kanner first coined the term "infantile autism" to describe children who seemed socially isolated and withdrawn.
1940s-1960s	• Autism was thought to be the first stage of psychiatric disorders such as schizophrenia. <i>Rates of autism rise slightly.</i>
1967	Research by Bettleheim suggested that autism is caused by pathological parenting. This was disproven, but not before the blame on parents hurt thousands of men and women who were accused of causing their children's disorder.
1980	 "Infantile Autism" is accepted as a diagnosis in the American Psychiatric Association (APA) diagnostic manual. Infants or children had to meet EVERY criteria established by the APA in order to receive the diagnosis Because the diagnosis now exists, autism rates begin to rise.
1987	• A revision by the APA changes the diagnosis to "autistic disorder" and expands the criteria. To be diagnosed, a child now needs to meet eight of 16 new criteria, rather than all criteria, as previously required. <i>Autism rates rise again due to fewer inclusion criteria and ease of diagnosis.</i>
1991	The U.S. Department of Education rules an autism diagnosis qualifies a child for special education services. Furthermore, autism can now be diagnosed by educators, and not just physicians. Autism rates leap even higher now that services are available and there is more awareness via the Department of Education.
1994 -	• The definition of autism broadens even further to include children with Asperger syndrome. Many children who previously didn't qualify for the diagnosis of autism now do. <i>Autism rates skyrocket now that children on the milder end of the spectrum can also receive a diagnosis of autism.</i>
2006	The American Academy of Pediatrics recommends screening all children for autism during routine wellness visits at 18 and 24 months of age. Autism rates increase even more, now that screening becomes routine.
2013	 The APA changes the diagnostic criteria of autism in the DSM V (the primary diagnostic manual used for psychiatric disorders). Instead of three categories (social reciprocity, communicative intent, restricted and repetitive behaviors), there are now two categories: (1) social communication/interaction, and (2) restricted and repetitive behaviors. Autism rates climb even higher due to reduced diagnostic criteria.

References:

Hyman, S. (2013, June 4). New DSM-5 includes changes to autism criteria. American Academy of Pediatrics.

Retrieved from https://www.aappublications.org/content/early/2013/06/04/aapnews.20130604-1

- Zeldovich, L. (2018, May 9). The evolution of 'autism' as a diagnosis, explained. Spectrum News.
- Retrieved from https://www.spectrumnews.org/news/evolution-autism-diagnosis-explained/

University of Oregon. Diagnostic Criteria for Autistic Disorder through the years.

 $Retrieved \ from \ https://pages.uoregon.edu/eherman/teaching/texts/DSM-I\%20-\%20DSM-IV\%20diagnostic\%20criteria.pdf$

Volkmar, F. R., Bregman, J., Cohen, D. J., & Cicchetti, D. V. (1988). Dsm-Iii and Dsm-Iii-R diagnoses of autism. The American Journal of Psychiatry, 145(11), 1404.

THE WAKEFIELD TIMELINE

1994	 Wakefield files for a patent for a diagnostic tool to detect measles virus in bowel tissue and body fluids, claiming that Crohn's disease and ulcerative colitis could have their origins in the measles vaccine.
1996	• A lawyer named Richard Barr hires Wakefield to support a legal attack against the MMR vaccine. He pays Wakefield over £400,000.
1997	Wakefield files for a patent of his own version of the measles vaccine.
1998	 The Lancet publishes Wakefield's findings of 12 children with autism and colitis. Days after his study is published, Wakefield meets with managers at England's Royal Free Hospital to discuss the importance of using single-antigen measles vaccines.
1999	The head of Royal Free Hospital informs Wakefield that he must replicate his study to confirm or refute his findings. Wakefield refuses.
2001	• Wakefield still hadn't repeated his study and is asked to resign from Royal Free Hospital.
2003	Lawyers for the claimants (the 12 autistic children) say they no longer have the evidence to prove that the MMR vaccine caused the autism.
2004	An investigation by a reporter finds that Wakefield had filed for a patent for the single-antigen measles vaccine prior to conducting his study, which conveniently led him to make the recommendation of dividing up the MMR into three separate vaccines. The investigation also finds that although Wakefield claimed to find traces of measles virus in the colons of these children, molecular studies on these samples found no trace of measles in these children's colons. Additionally, medical records of the children are reviewed, and reveal that several of them had shown signs of behavioral and neurological regression <i>before receiving the MMR vaccine</i> .
2005	Japan withdraws the MMR vaccine due to contaminants, and rates of <i>autism continue to rise</i> .
2006	 Measles in England becomes rampant due to a decrease in vaccination, and for the first time in 14 years, a patient dies from the measles.
2007	 Investigations reveal that Wakefield was paid £435,643 by lawyers for his "research."

Source: Deer, 2010; Deer 2011a; Deer, 2011b

References:

Deer, B. (2010). Wakefield's "autistic enterocolitis" under the microscope. *Bmj*, 340, c1127. Deer, B. (2011a). How the case against the MMR vaccine was fixed. *Bmj*, 342, c5347. Deer, B. (2011b). How the vaccine crisis was meant to make money. *Bmj*, 342, c5258.

SIDS and the DTaP

Sudden infant death syndrome (SIDS) is the unexplained death of a healthy-looking baby less than 1 year old, usually during sleep. SIDS was previously called "crib death" because many of the infants died in their cribs. While the exact cause of SIDS is unknown, some scientists believe a possible cause is a defect in the infant's brain preventing them from repositioning their heads during sleep to breathe better. **Source:** Mayo Clinic, 2018

According to the most recent studies, there were 1,331 infant deaths due to SIDS in 2018. **Source:** National Vital Statistics Report, 2020

Common risk factors for SIDS

The most common risk factor is putting a baby to sleep on their stomach, which is why it's important for babies to sleep on their backs.

Physical factors

• **Brain defects.** Some babies are born with a problem in the part of the brain that controls breathing. This defect may prevent them from repositioning their heads during sleep to breathe better.

• Low birth weight. When a baby is born prematurely, their brain may not be fully mature and may not properly control breathing and heart rate.

• **Respiratory infection.** Many of the babies who died from SIDS had recently had a cold, which may have caused breathing problems during sleep.

Source: Mayo Clinic, 2018

Where and how the baby sleeps

• Put the baby to sleep on their back! Babies can have trouble breathing if they are put to sleep on their stomach or side. Stomach sleeping is a major known risk factor for SIDS. Don't put the baby to sleep on a soft surface. Soft surfaces like fluffy blankets, soft mattresses, or waterbeds, can block a baby's airway.

• Let the baby sleep in the parent's bedroom but not in the parent's bed. Sharing a bed with parents, siblings, or pets can increase the baby's risk for SIDS.

 Don't let the baby get too hot!
 Being too warm while sleeping is another risk factor.

Source: Mayo Clinic, 2018

Risk factors for the baby

There are several factors that can increase the risk of SIDS.

• **Gender:** The number of boys who died of SIDS is slightly higher than girls.

• Age: Most SIDS deaths occur between 2 and 4 months of age.

• **Race:** More non-White babies died of SIDS than White babies. The reason for this is not well-understood.
• Family history: Babies born into families that have had prior SIDS deaths are at higher risk.

 Secondhand smoke: Smoking around a baby exposes the baby's brain to chemicals in the secondhand smoke that can affect the baby's breathing.

• Being premature: The brains of babies born too early or with low birth weight may not have matured completely, so they have less control of their breathing or heart rate.

Source: Mayo Clinic, 2018; CDC, 2018

Risk factors for the mother

A baby can be at risk for SIDS if their mother had these risk factors during her pregnancy:

- Younger than 20 years old
- Cigarette smoking
- Drug or alcohol use
- Lack of prenatal care

Source: Mayo Clinic, 2018

Can you prevent SIDS?

Here are some tips to help your baby sleep more safely:

Back to sleep: Babies should sleep on their backs, rather than their stomachs or sides, every time they are put to sleep until they are 1 year old. If a babysitter or family member helps out, make sure they put the baby to sleep on their back as well.

Keep the crib as empty as possible. Use a firm mattress. Never put a baby on a thick or fluffy padding, such as lambskin or a thick quilt. Don't leave pillows, fluffy toys, or stuffed animals in a baby's crib. These items can block a baby's breathing.

Don't overheat the baby. Babies should not be too warm or hot when sleeping. Never cover a baby's head. Try a sleep sack to

What is **"Back** to Sleep"?

Safe sleep interventions work. The American Academy of Pediatrics released the "Back to Sleep" recommendations in 1994. SIDS rates dropped from 130.3 deaths per 100,000 live births in 1990 to 38.0 deaths per 100.000 live births in 2016 (Moon, 2016). Many countries, including Sweden, New Zealand, and the United States, have studied the effect of placing babies on their backs for sleep. All of the countries that implemented "Back to Sleep" campaigns have seen their SIDS rates drop dramatically. Source: Moon, 2016



Trends in Sudden Unexpected Infant Death by Cause, 1990–2018

Source: CDC, National Center for Health Statistics, National Vital Statistics System, Mortality Files. Rates calculated via wonder.cdc.gov.

SAFE SLEEP

Put Babies to Bed as if Their Life Depends on It, Because It Does.

At all sleep times — naps and at night — babies sleep safest on their backs. It makes it easier for them to breathe, and they are less likely to choke if they spit up.

Babies sleep safest alone, on their backs, in a bare crib or bassinet with a firm, flat sleep surface covered only by a fitted sheet — not in bed with you.

REMEMBER:

No pillows. No blankets. No toys. Not on their belly. Not in bed with you. keep the baby warm rather than using lots of blankets.

Put your baby to sleep with you in your bedroom. Babies should sleep in their own cribs or bassinets for at least the first six months of life, and ideally for the first full year in the same room as their parents. Babies can get trapped and potentially suffocate in any space in an adult bed, such as between the wall and the bed. Babies can also suffocate if a sleeping parent accidentally rolls over on to the baby.

Breastfeed (nurse) your baby. Breastfeeding or nursing for at least six months lowers the risk of SIDS.

Use a pacifier. When a baby sucks on a pacifier — using only an approved pacifier clip, **without** a strap or string — at naptime and bedtime, this may lower the risk of SIDS.

Immunize your baby. There is NO evidence that routine DTaP immunizations increase the risk of SIDS. There are multiple studies that show immunizations can help prevent SIDS. (See the Appendix for study details.) Source: Mayo Clinic, 2018

The evidence that SIDS rates have dropped significantly since the "Back to Sleep" campaign started speaks for itself!

Anti-Vaxx Myth: "Compared to other countries, America had fallen from 12th (1960) to 56th place (2014) in infant mortality, due to its high incidence of infant death." Source: Vaccine Epidemic, 2012; CIA World FactBook **P.I.E.: Selective information:** Infant mortality in the U.S. is high because of many factors that do not exist in other countries:

The U.S. counts **all** births as live births if a baby shows **any** signs of life, regardless of size or level of infant maturity. This differs from many other countries, where premature babies are reported as "non-viable births" and are therefore not counted.

Examples: The Czech Republic only lists a live birth if the baby weighs at least 500 grams. France requires the baby to be at least 22 weeks gestation. Other countries do not register babies who die within the first 24 hours of birth. However, all these would be considered live births in the U.S. These babies are usually very ill and many die within the first year of life. Therefore, the United States reports a far higher infant mortality rate than other countries. The United States has a very high level of preterm births (babies born between 22 and 37 weeks). This rate is 65% higher than that of England and Wales, and more than double that of Finland, Greece, and Ireland. Preterm birth is an increased risk factor for SIDS. **Source:** Gonzalez & Sawyer, 2017; MacDorman et al, 2009; MacDorman et al, 2014

Anti-Vaxx Myth: "SIDS is a new classification for infant death presented in 1969. The new diagnosis was meant to explain the rise in death rates in healthy full-term infants." Source: None

P.I.E.: Unfortunately, many babies didn't get to celebrate their first birthdays prior to the 1900s. Death rates for babies have been declining since the 1960s, and ever since immunizations for babies, these rates have dropped even more significantly. In 1960, the total number of infant deaths in the U.S. was 110,873. In 2018, the total number of infant deaths in the U.S. was 21,498 with only 1,331 of those deaths attributed to SIDS. SIDS accounts for a very small percentage of all infant deaths (see figure below). **Source:** US Dept. of Health, Education, and Welfare, 1960;

National Vital Statistics Report, 2020

Anti-Vaxx Myth: A study found "a high statistically significant correlation between increasing numbers of vaccine doses and increasing infant mortality rates." Source: Neil Miller & Gary Goldman

Think about it...

If vaccines cause SIDS, why is the number of SIDS deaths declining, while the number of vaccinations remains the same?



Infant mortality rate,* by year – United States, 1915–1997

*Per 1,000 live births.

Source: CDC MMWR Weekly, October 1, 1999, Volume 48, Number 38, page 849, cdc.gov/mmwr/PDF/wk/mm4838.pdf

SIDS cases have fallen since 1980. SIDS Deaths per 100,000 Live Births, 1980-2010



P.I.E.: False: Unreliable data, unreliable conclusions, and unreliable "researchers." First let's look at the research.

• In comparing vaccine numbers in the U.S. and Europe, the authors (Miller and Goldman) miscounted the amount of doses on Germany's vaccination schedule. Had they counted it correctly, their study would have reflected that Germany actually has the most vaccines on their schedule.

• In order to make a correlation between vaccinations and infant mortality, these "researchers" created a graph in which they plotted a line reflecting the amount of vaccinations, using inaccurate German vaccination rates, along with a line reflecting infant mortality numbers, without including the causes of infant death, thereby falsely creating what appeared to be a correlation between the two.

• The authors cited old research, while failing to discuss all the current and relevant research that refutes any association between vaccinations and SIDS.

Now let's look at the researchers:

Neil Miller has been
rejectedfrom all science-based
organizations. His work has
been published in journals
of poor quality, and he is a
world-famous anti-vaxxer
who is the director of the
anti-vaxx website ThinkTwice.

He published a book that discusses how his daughter communicates with aliens (a book titled *Ambassador Between Worlds*).

• Gary Goldman is a computer scientist and the president of a



journal called *Medical Veritas*, which denies the existence of HIV and AIDS. He has also written anti-vaxx books.

These unscientific stances have alienated these two "researchers" and their views from the rest of the scientific community. Both "researchers" failed to disclose bias; in other words, their associations with anti-vaccination organizations.

Anti-Vaxx Myth: While vaccine manufacturers deny the link, researchers have found a strong correlation between the DTP vaccine and infant death. One study found 70% of all SIDS cases occurred within three weeks of DTP vaccination, 26% of the deaths occurring within three

days of the shot. **Source:** Neil Miller & Gary Goldman

P.I.E.: False. DTP use was discontinued in 1999 and the DTaP has been used since then in the U.S.

This single study was written by Neil Miller and Gary Goldman in 2011. The authors must have known this vaccine had not been given in over a decade. In addition, the authors failed to disclose their bias and conflicts of interest (see previous column). The information showing this "link" has been proven to be cherrypicked and **no other** studies have been able to replicate these findings.

A majority of SIDS cases occur within the first four months of life, a time frame in which the DTaP vaccine is given twice (at 2 months and 4 months of age). It is therefore very likely that a SIDS death may occur within three weeks of an infant receiving the DTaP vaccine, *but it does not mean they are related!*

Source: Sifris & Myhre, 2019

Anti-Vaxx Myth: In the U.S., doctors give at least 26 doses of vaccines before age 1 year, which is twice as many vaccinations as babies get in Sweden and Japan. Source: Fisher, B.L.

P.I.E.: False. Here is an accurate breakdown of the vaccination schedules in each of these countries:

U.S.: 16 or 18 doses before age 1 year

3 doses each of:

Diphtheria/tetanus/pertussis
 (DTaP)

• Hepatitis B (HBV)

• Hib (or only two doses, depending on the brand of the vaccine used)

- Pneumococcal conjugate (PCV13)
- Polio

• Rotavirus (or only two doses, depending on the brand of the vaccine used).

Sweden: 12 vaccines before age 1 year

3 doses each of :

• Diphtheria/tetanus/pertussis (DTaP)

• Hib

Pneumococcal conjugate (PCV12)

Polio

Other vaccines are given, if needed, to medically fragile children.

Japan: 16 doses before age 1 year

3 doses each of:

Diphtheria/tetanus/pertussis
 (DTaP)

- Hepatitis B (HBV)
- Hib
- Pneumococcal conjugate (PCV13)
- Polio

1 dose of:

BCG (against tuberculosis)

Other vaccines such as Rotavirus are considered "voluntary."

Source: Public Health Agency of Sweden, 2018; Japan Pediatric Society, 2019; CDC, 2019

Anti-Vaxx Myth: Other mothers reported that their babies suffered progressive mental and physical deterioration that got worse after each shot before the baby was found dead in the crib. Source: None given

P.I.E.: Scare tactic with no legitimate source. This claim

and similar claims made by many anti-vaxxers do not have sources, and no evidence of this has been found in any medical literature.

References:

Centers for Disease Control and Prevention CDC. (2019). US Vaccination Schedule: Birth to 6 years. Retrieved from: https://www.cdc.gov/vaccines/schedules/easy-to-read/child-easyread.html#table-child

Centers for Disease Control and Prevention CDC. (2018). Health effects of secondhand smoke. Retrieved from: https://www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/health_effects/index.htm

Gonzalez, S. & Sawyer, B. (2017). Peterson Kaiser. Health System Tracker. How does infant mortality in the US compare to other countries? Retrieved from: https://www.healthsystemtracker.org/chart-collection/infant-mortality-u-s-compare-countries/#item-start

Institute of Medicine (US) Immunization Safety Review Committee. (2003). Immunization Safety Review: Vaccinations and Sudden Unexpected Death in Infancy. Washington, DC: National Academies Press. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/25057654

Japan Pediatric Society. (2019). Vaccination schedule. Retrieved from: https://www.jpeds.or.jp/uploads/files/20180801_JPS%20Schedule%20English.pdf

MacDorman MF, Mathews TJ. Behind international rankings of infant mortality: How the United States compares with Europe. NCHS data brief, no 23. Hyattsville, MD: National Center for Health Statistics. 2009. Available from: http://www.cdc.gov/nchs/data/databriefs/db23.pdf.

MacDormand, MF, Mathews TJ. Mohangoo, AD, Zeitlin, J. (2014). International Comparisons of Infant Mortality and Related Factors: United States and Europe, 2010. National Vital Statistics Reports. 63(5). Retrieved from: https://www.cdc.gov/nchs/data/nvsr/nvsr63/nvsr63_05.pdf

Mayo Clinic. (2018). Diseases and Conditions: SIDS. Retrieved from: https://www.mayoclinic.org/diseases-conditions/sudden-infant-death-syndrome/ symptoms-causes/syc-20352800

Miller, NZ. & Goldman, GS. (2011). Infant mortality rates regressed against number of vaccine doses routinely given: Is there a biochemical or synergistic toxicity? *Human and Experimental Toxicology*. Retrieved from: https://journals.sagepub.com/doi/full/10.1177/0960327111407644

Moon RY. (2016) Task Force on Sudden Infant Death Syndrome. SIDS and Other Sleep-Related Infant Deaths: Evidence Base for 2016 Updated Recommendations for a Safe Infant Sleeping Environment. Pediatrics.138(5). Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/27940805

Moro PL, Perez-Vilar S, Lewis P, Bryant-Genevier M, Kamiya H, Cano M. (2018) Safety Surveillance of Diphtheria and Tetanus Toxoids and Acellular Pertussis (DTaP) Vaccines. *Pediatrics*. 142(1). Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/29866795

National Vital Statistics Reports for 2018 (2020) Volume 69, Number 7. Retrieved from: https://www.cdc.gov/nchs/data/nvsr/nvsr69/NVSR-69-7-508.pdf Public Health Agency of Sweden. (2018) Vaccine programmes. Retrieved from: https://www.folkhalsomyndigheten.se/the-public-health-agency-ofsweden/communicable-disease-control/vaccinations/vaccination-programmes/

Sifris, D. & Myhre, J. (2019). What you need to know about the DTaP vaccine. Retrieved from: https://www.verywellhealth.com/what-you-need-to-know-about-the-dtap-vaccine-4156747

US Department of Health, Education and Welfare. Public Health Service. Vital Statistics of the United States, 1960. Retrieved from: https://www.cdc.gov/nchs/data/vsus/VSUS_1960_2A.pdf

FEBRILE (FEVER) SEIZURES

About 5% of children between the ages of 6 months and 5 years will experience at least one febrile seizure. They generally occur with temperatures over 102 degrees Fahrenheit, but can also occur with lower temperatures or with a drop in temperature. These seizures usually last one to two minutes, and while frightening, do not cause any lasting damage. The exact mechanism of febrile seizures is unknown, but it is thought that brain immaturity and genetics can play a part. Any illness or infection that causes a fever can cause febrile seizures, such as the common cold, ear infections, or the flu.

116 | Parents Informed and Educated

Febrile seizures run in families so if the child's parents, sisters, or brothers had one, the child is more likely to have a febrile seizure. Among babies who have their first febrile seizure before their first birthday, half will have another seizure. Among babies who are over one year old, only 25% will have another febrile seizure. Almost all children with febrile seizures do not have seizures with high fevers after age 5 years.

Source: CDC, 2015; Primiani et al, 2019

Febrile Seizures from Vaccination

With some vaccines or vaccine combinations, there is a small increased risk of a febrile seizure (up to 30 out of 100,000). There is a slight increased risk of febrile seizure with the MMR. If it is given in a combination dose with varicella (MMRV) for the first dose, the risk is slightly higher. There is also some evidence that the inactivated influenza vaccine can cause a slightly increased risk of seizures



We are always looking for reasons why something happened. The example I use is from my wife, who is a pediatrician. She was about to vaccinate a four-month-old baby, and while she was drawing the vaccine from the syringe, the baby had a seizure—and went on to have a permanent seizure disorder. Now, my wife hadn't given the vaccine yet. But if she had given that vaccine five minutes earlier, there would have been no amount of statistical data in the world that would have convinced that mother that the vaccine hadn't caused the baby's seizure. You can do studies that show no increased risk with vaccines and seizure disorders, but that mother might still say "well, that's true for the population but it's not true for my child."

-Paul A. Offit, MD, Director of the Vaccine Education Center at The Children's Hospital of Philadelphia

if given on the same day as the DTaP or pneumococcal vaccines. Other vaccines such as the hepatitis B vaccine, DTaP alone, HPV, or varicella, have not been shown to increase the likelihood of febrile seizures. It is important to note that vaccines can help prevent febrile seizures that would occur with natural infections. For example, the flu itself is much more likely to cause a febrile seizure than the flu shot. As with natural infections. febrile seizures from vaccinations do not cause lasting damage. Source: Johns Hopkins, 2018

Epilepsy/Vaccine Encephalopathy

There is no evidence that vaccines cause seizure disorders. Interestingly, there is a higher rate of epilepsy in those who have had pertussis, a vaccinepreventable illness. In the past, it was believed that some vaccines, such as DTP or MMR, could cause encephalopathy or seizure disorders, but this has been disproven. Certain seizure disorders, such as Dravet syndrome, develop during the first year of life in children who appear healthy. Vaccination may trigger a slightly earlier onset of the seizures, but not having vaccinations will not prevent the disease from developing. Source: Olsen et al, 2015; Ray et al, 2006; McIntosh, 2010; Verbeek et al, 2014

Anti-Vaxx Myth: "If seizures become epilepsy, they say the child had an underlying condition, rather than face the truth – that the vaccine caused epilepsy!" Source: None given **P.I.E.:** Epilepsy is the general name for a seizure disorder. Epilepsy does not have an identifiable cause in about 50% of the people who have it. In the other half of people who are diagnosed with epilepsy it can be traced to:

• **Genetics:** Epilepsy can run in families. Certain genes make a person more sensitive to seizure triggers.

• Head trauma: Being hit hard in the head from a car accident or other trauma can cause epilepsy.

• Brain conditions: Brain tumors or strokes can cause epilepsy.

• Infectious diseases: Meningitis, AIDS, and viral encephalitis can all cause epilepsy.

• **Prenatal injury:** Before birth, a baby is very sensitive and an

infection or poor nutrition in the mother, or not enough oxygen, can cause brain damage leading to epilepsy or cerebral palsy.

• Developmental disorders: Autism, neurofibromatosis, and other developmental disorders can cause epilepsy.

Risk factors for developing epilepsy after febrile seizures:

• If the child had developmental issues before the febrile seizure

Having febrile seizures lasting longer than 15 minutes

• Febrile seizures are only on one side of the body

• Having more than one seizure in 24 hours

• Seizures without fever in a parent or siblings

If a child has NONE of these risk factors, the chance of developing epilepsy is the same as anybody else (1% to 2% of the population). If a child has ONE of these risk factors, the risk of developing epilepsy increases to 2.5%. If a child has TWO or THREE risk factors, the chances that they will develop epilepsy later on in life grow to between 5% and 10%.

The bottom line is, vaccines DO NOT cause epilepsy. **Source:** Mayo Clinic, 2019; Primiani et al, 2019

References:

Centers for Disease Control and Prevention CDC. (2015). Childhood vaccines and febrile seizures. Retrieved from: https://www.cdc.gov/vaccinesafety/ concerns/febrile-seizures.html

Johns Hopkins Bloomberg School of Public Health. (2018). Do vaccines cause seizures? Retrieved from: http://www.vaccinesafety.edu/vs-seizure.ht) Mayo Clinic. (2019). Epilepsy. Retrieved from: https://www.mayoclinic.org/diseases-conditions/epilepsy/symptoms-causes/syc-20350093

McIntosh, A. M., McMahon, J., Dibbens, L. M., Iona, X., Mulley, J. C., Scheffer, I. E., & Berkovic, S. F. (2010). Effects of vaccination on onset and outcome of Dravet syndrome: a retrospective study. *The Lancet Neurology*, 9(6), 592-598. Retrieved from: https://www.sciencedirect.com/science/article/pii/S1474442210701071

Offit, P. (2011). Interview with Paul Offit. Thinking Person's Guide to Autism. Retrieved from: http://www.thinkingautismguide.com/2011/01/interview-dr-paul-offit.html

Olsen, M., Thygesen, S. K., Østergaard, J. R., Nielsen, H., Henderson, V. W., Ehrenstein, V., ... & Sørensen, H. T. (2015). Hospital-diagnosed pertussis infection in children and long-term risk of epilepsy. *Jama*, 314(17), 1844-1849. Retrieved from: https://jamanetwork.com/journals/jama/fullarticle/2467554?resultClick=3) Primiani, CT., Benbadis, S., Wirrell, E. (2019). Epilepsy. Febrile seizures. Retrieved from: https://www.epilepsy.com/learn/types-seizures/febrile-seizures Ray, P., Hayward, J., Michelson, D., Lewis, E., Schwalbe, J., Black, S., ... & Mullooly, J. (2006). Encephalopathy after whole-cell pertussis or measles

vaccination: lack of evidence for a causal association in a retrospective case-control study. *The Pediatric infectious disease journal*, 25(9), 768-773. Retrieved from: https://journals.lww.com/pidj/Abstract/2006/09000/Encephalopathy_After_Whole_Cell_Pertussis_or.3.aspx

Verbeek, N. E., Jansen, F. E., Vermeer-de Bondt, P. E., de Kovel, C. G., van Kempen, M. J., Lindhout, D., ... & Brilstra, E. H. (2014). Etiologies for seizures around the time of vaccination. *Pediatrics*, 134(4), 658-666. Doi: 10.1542/peds.2014.0690. Retrieved from: https://pediatrics.aappublications.org/content/134/4/658.long?trendmd-shared=0

SHEDDING

Anti-Vaxx Myth: Vaccines can shed, causing or spreading the disease the vaccine is supposed to protect us from!

P.I.E.: FALSE!

Shedding occurs when a germ is found in a person's bodily fluids. However, for the germ to spread and infect others, there are several steps which occur in the following order:

1. A person has to be infected with a germ.

2. The germ has to be shed from the infected person via bodily fluid.

3. The shedded germ must remain alive while transmitted to another person.

4. Lastly, the germ has to be strong enough to cause the disease in the second person. **Source:** Higuera, V. & Pietrangelo, A. 2016 Most vaccines are made with miniscule pieces of a bacteria or virus. They are so small, it cannot cause the disease in the person receiving the vaccine, let alone pass it on to someone else. **Source:** Denizer, 2018

Vaccines that **cannot cause the disease** itself (only stimulates the body's immune response) include:

- Pertussis
- Diphtheria
- Tetanus
- Hepatitis B
- Hib
- IPV*
- Pneumococcus
- Meningococcus
 Source: lanelli, 2019

*Note that the oral polio vaccine (OPV) was a live vaccine and it was found to shed. However, it has not been used in the U.S. since 2000. The inactivated polio vaccine (IPV) is given intramuscularly, and cannot shed. **Source:** CDC, 2019

Vaccines containing live material do have whole germs in them but are attenuated, which means weakened. It is possible to find live vaccine germs in the bodily fluids of someone who has been vaccinated. However, this is not enough to cause the full disease in the person who received the vaccine, let alone transmit the weakened germ to another person. **Source:** Ianelli, 2019

These vaccines include:

- Measles
- Mumps
- Rubella
- Varicella (Chickenpox)
- Rotavirus

Live attenuated influenza vaccine (LAIV)

Concerns about shedding and catching the disease from a vaccine are just that - concerns. The "natural" wild-type diseases are virulent, which means they can be deadly in otherwise young and healthy people. Vaccines protect against dangerous diseases. Vaccines do not cause diseases nor do they transmit them.

Source: lanelli, 2019

Shedding From the Measles Vaccine

Because the measles vaccine is a weakened virus and mimics natural measles infection, about 5% of vaccine recipients may develop a transient rash but they are not infectious. **Source:** Ianelli, 2019

Shedding From the Rubella Vaccine

The rubella virus and the antibodies were found in the noses of the babies who were being nursed and in the breast milk of mothers who were vaccinated after giving birth. There is no evidence that this caused rubella in the mother, the baby or anyone else. **Source:** Ianelli, 2019

Varicella/Chickenpox Vaccine Shedding

About 15% of the people who receive the varicella vaccine develop a very mild form of the chicken pox with a few small spots. While not as infectious as "natural" chickenpox, care must be taken to avoid contact with any open blisters. **Source:** lanelli, 2019

Rotavirus Vaccine Shedding

Rotavirus can be found in the stool of recently vaccinated babies. Proper handwashing with soap after diaper changes will prevent

Think about it...

The majority of people vaccinate. If shedding caused disease, wouldn't rates of diseases increase dramatically from all the vaccinated people "shedding"? Why did disease rates go down, as vaccination rates went up?

transmission. If someone in the house is immunocompromised, they should avoid diaper changes for a week after the baby was vaccinated. **Source:** Ianelli, 2019



Note that this hospital measles warning sign (photograph taken during the 2018 measles outbreak) does not contain statements about those who are recently vaccinated. The sign warns about those with measles symptoms or those who are unvaccinated.

References:

Centers for Disease Control and Prevention CDC (2018). Polio vaccination: What everyone should know. Retrieved from: https://www.cdc.gov/vaccines/vpd/polio/public/index.html

Denizer, G., Friedland, LR., Krishnan, J., Shapiro, M. (2018). Understanding modern-day vaccines: what you need to know. *Annals of Medicine*, 50:2, 110-120. https://doi.org/10.1080/07853890.2017.1407035. Retrieved from: https://www.tandfonline.com/doi/full/10.1080/07853890.2017.1407035 Higuera, V. & Pietrangelo, A. (2016). How are diseases transmitted? Healthline. Retrieved from: https://www.healthline.com/health/disease-transmission

Ianelli, V. (2019). Understanding live vaccines and vaccine shedding: How they are used and why they are not contagious. Accessed: https://www.verywellhealth.com/live-vaccines-and-vaccine-shedding-2633700

and VACCINATION

The following is a list of questions one may have about vaccines, answered according to *halachic* sources.

Are we permitted to vaccinate? Even if a disease carries risks, are we permitted to inject healthy people with vaccines that may cause them harm?

Answer:

The smallpox epidemic of the late 1700s gives precedent to several *halachic* rulings regarding vaccines. In 1796, Dr. Edward Jenner created the first vaccine to combat smallpox when he inoculated an individual with cowpox, thus creating immunity to the disease. Jenner's medical breakthrough, however, was not without risk. The method of vaccination involved obtaining infected fluid from an individual with a mild case of smallpox, and injecting the same fluid into the bloodstream of a healthy person. In the early years of this experimental vaccination, a number of individuals who were inoculated contracted smallpox and died. This raised concerns at the time about whether the small risk of contracting smallpox from the inoculation was worth the benefit of immunity.

Rabbi Abraham Nasich, who lost two children to smallpox, wrote a book devoted to the permissibility of inoculation. In Rabbi Nasich's work *Aleh Terufah*, published in 1785, he articulates a strong position to permit smallpox inoculations. A major authority of that era, Rabbi Yisrael Lipschitz writes in his commentary on the Mishnah, *Tiferet Yisrael:* "It appears to me, that inoculations are permissible... Even if one out of a thousand dies as a result of the inoculations, there is a far [greater and] more imminent danger should one naturally contract the disease than the remote danger of dying as a result of the inoculation."

Does the "majority rule" apply since most doctors believe that the benefits of vaccines outweigh the risks?

Answer:

The Shulchan Aruch rules that when it comes to medical treatment, the doctor's opinion rules. When there is a majority versus a minority of doctors' opinions, the majority opinion rules. The example given is that of a person eating on Yom Kippur — in other words, a person breaking one of the most serious *mitzvahs* (commandments) in the Torah. A physician has the ability to rule that the person can or even must eat on Yom Kippur. However, if two physicians state that the person should NOT eat on Yom Kippur, then the person may not eat.

The following four questions are answered below by the same *halachic* ruling, given by Rabbi Yosef Shalom Elyashiv.

Are we obligated to vaccinate? What are the halachic and hashkafic guidelines of "venishmartem me'od linafshoseichem — be very careful with your lives (Devarim [Deuteronomy] 4:15)" and how do they apply to preventing future contagious disease? What are the halachic parameters of hishtadlus (personal effort)?

Are we permitted to coerce parents to vaccinate their children? If the parents are advised or forced by others to vaccinate their children, who is responsible if the child is injured or killed by the vaccine?

Can "shomer pesayim Hashem – G-d watches over the simple ones (Tehillim [Psalms] 116:6)" be accurately applied to vaccines? Does the fact that the majority of society accepts vaccinations have any halachic bearing? If rabbinic authorities have already concluded that vaccines are permissible or required based on testimony from doctors, and that testimony is later proven incorrect, do those decisions still stand?

Answer:

Rabbi Yosef Shalom Elyashiv was asked the following question: Could parents refuse to vaccinate their children for fear of a remote chance of vaccine injury? (The particular vaccine in question was the pertussis vaccine that, at the time this question was asked, carried a one in 20,000 risk of injury.) Rabbi Elyashiv ruled that the parents should vaccinate despite their concerns. His reason was that since immunization of children is normal practice throughout the world today, and one should follow that normative course. In fact, Rabbi Elvashiv went so far as to assert that failure to immunize would amount to negligence.

Refusing childhood immunizations due to fears of vaccine side effects is irresponsible and against halacha. The danger of precipitating epidemics of measles, polio, and other diseases with potentially devastating complications is far more real than the dangers attributed to vaccines on the basis of anecdotal claims. When we have evidence, the *halachically* correct approach is to do what is the normal and accepted practice. This is the obligation of hishtadlus. In addition, when a legitimate government has laws concerning medical conduct, this adds weight to their halachic acceptability.

The "unsubstantiated fears of vaccine side effects," which Rabbi Elyashiv terms "irresponsible," (above) refers to the popular notion among some parents that the MMR vaccine is responsible for autism — a claim which has been thoroughly discredited by all reputable medical authorities.

Rabbi Elyashiv was further asked who would bear responsibility should the child of a parent who was coerced to vaccinate, does in fact have an adverse reaction to a vaccine? His response was that should a reaction occur, it was destined to occur regardless. One cannot avoid a "gezeira" (negative decree from Above) by doing something contrary to *halacha*.

Is an individual obligated to sacrifice his own health in order to protect others?

Answer:

Based on the answer to Question 1, we have established that the risk of vaccination is considered minimal, and therefore Rabbi Abraham Nasich and Rabbi Yisrael Lipschitz ruled strongly that vaccination is permissible, in addition to more contemporary rulings of Rabbi Yosef Shalom Elyashiv and Rabbi Shlomo Zalman Auerbach.

In terms of protecting others, individuals who refuse immunization not only place themselves at risk, but may possibly put others at risk by transmitting a contagious disease to their family, friends, and the community at large. The Torah mandate for one to be proactive in

122 | Parents Informed and Educated

protecting the health and welfare of others is found in *Devarim* (*Deuteronomy*) 22:8: "If you build a new house, you shall make a fence for your roof, so that you will not place blood in your house if one falls from it." This mandate goes far beyond preventing potential environmental hazards, and extends to avoiding and preventing transmission of life-threatening plagues and virulent diseases:

.... one should flee from a city afflicted by a plague, and one shall leave at the beginning of it, not at the end... it is forbidden to rely on a miracle or to endanger one's life in any similar way.

The imperative to "flee from a city afflicted by a plague..." was declared by Rabbi Jacob Moelin, the Maharil. Shortly before Rabbi Moelin's birth, the Black Death pandemic was rampant throughout Europe, killing an estimated 25-60% of its population. In hindsight, the wisdom of the Maharil's advice to evacuate a city suffering from an epidemic in order to prevent contagion and transmission of disease seems clear.

The question can be taken one step further. Does Jewish law require a healthy individual to be immunized when there is no threat of an epidemic or where he would not expose a very vulnerable population (such as school children, or patients in health care facilities who are clustered together in close quarters for extended periods of time)? In other words, would one be obligated to put himself at any risk when there is no apparent or immediate risk to others?

There is no doubt that the regular protocol of childhood immunizations prevents disease in the child and in the general



population. However, there are parents who are fearful of possible dangers about immunizing their children. Rabbi Yehoshua Neuwirth ruled that though, as a result of this fear, "we may not compel parents to have their children vaccinated [when they have concerns about any risks to their health], we are obligated to strongly urge them to vaccinate their children." This ruling leads to a catch-22 dilemma (in other words, a difficult situation from which there is no escape because of mutually conflicting or dependent conditions). If, for example, a statistically significant number of healthy children are not vaccinated, then diseases such as measles and mumps may very well re-emerge as serious public health threats, as we clearly see today

in the recent measles outbreak. Thus, the question remains: Are we collectively obligated to be vaccinated (where health risks of the vaccine itself are miniscule) to provide herd immunity to protect ourselves and others from future epidemics?

Jewish law has critical concerns about preventing or avoiding possible life-threatening risks, particularly those which affect the community, and they are not limited to clear and imminent dangers, but extend to those which may not be immediate. For example, Rambam rules that one may be mechalel Shabbos (break Shabbos) in order to trap a snake that MAY cause harm to someone, even if it is not definite that harm would be caused, due to the concern for Pikuach Nefesh (saving a life) to an individual or group.

Consequently, while an individual who refuses a vaccination may not present any clear and imminent danger to himself or others, he may still be obliged to be vaccinated for the sake of the greater good of the community. In *halachic* terms, even an extremely low level of risk, which might not present a life-threatening danger to an individual, is of far greater concern when applied to the community (*safek pikuach nefesh d'rabim*).

Halacha's profound concern about even the most remote life-threatening danger to the larger community was clearly demonstrated in a 1992 ruling by Rabbi Shlomo Zalman Auerbach. Rabbi Auerbach was asked whether an autopsy (which is not normally allowed according to Jewish law) should be performed on an infant who died within hours after receiving a routine vaccination against a viral liver infection. The Ministry of Health requested an autopsy of the baby to determine if the cause of sudden death was in any way related to the vaccine. Rabbi Auerbach maintained that although the public health threat was minimal, the autopsy must be conducted. He stressed that in such matters of life and death, we must be painstakingly careful, so that under no circumstances would our carelessness in taking precautions lead to the death of a single person.

Is there any problem with making medical use of tissue from aborted fetuses?

Answer:

Varicella (chickenpox), rubella, hepatitis A, one version of the shingles vaccine, and one preparation of the rabies vaccine are all made by growing the viruses in laboratory-grown fetal embryo fibroblast cells. Fibroblast cells are the cells needed to hold skin and other connective tissue together. The fetal fibroblast cells that are used to grow vaccines were first obtained from two elective abortions in the 1960s – one from a woman in Sweden, called the WI-38 cells, and one from a woman in the United Kingdom, called the MRC-5 cells.

Fetal cells are extremely valuable to medical research and are used in many ways, one of which is vaccine research and production. Viruses grow better in human cells than cells from animals, and scientists were able to grow the viruses necessary for these vaccines using fetal cells.

The use of fetal tissue for medical research is not new. When the concept was initially introduced, it was immediately addressed by rabbinic authorities. While *halacha* generally opposes abortion, there is no intrinsic *halachic* prohibition to use already aborted tissue if intended for a potentially life-saving purpose. Is there a Torah basis for considering unvaccinated children a threat to others? Is it reasonable to fear for one's life or health in the presence of these children?

Answer:

According to Rabbi Mordechai Halpern, those who refuse vaccination can be divided into two categories:

An individual who refuses to be vaccinated during a life-threatening epidemic could be considered a "*rotzeach b'grama*" (indirect homicide), and consequently would be held responsible by the heavenly court.

An individual who refuses to be inoculated and, consequently, could be transmitting a non-life-threatening disease which causes pain and suffering to the infected could be considered a "mazik" (one who damages), which, according to Rabbenu Yonah (Avos 1:1) is a subcategory of gezel (theft).

124 | Parents Informed and Educated

ERES RECOMMENDS

Recommendations for Providers

Pediatricians, Physician Assistants, Nurse Practitioners, and Registered Nurses

EMES recommends that health care providers listen to and respect concerned parents. Parents know their own children better than providers ever will. When a parent reports that their child appears unwell or is not acting like their usual self, providers need to take time to listen to them carefully. While most instances of presumed vaccine reactions are later found to not be caused by vaccines, parental concerns should never be dismissed. If a reaction does appear to be related to a vaccine, EMES urges all health care providers to report the reaction to VAERS. VAERS was established as an alert system. The more reports received

by VAERS, the more likely important information related to vaccine safety will be picked up. As believers in science, we always want more data!

Recommendations for Parents

EMES recommends that parents continue to ensure that they are well-informed, and seek opportunities for education on important topics related to the health and safety of their children and families. The nurses of EMES are available to help with health education by phone and email.

For parents who want to do their own research, EMES recommends several methods to do so:

The WHO maintains a list of verified evidence-based vaccine safety websites in many languages: vaccinesafetynet.org Use caution with YouTube, videos and social media. It is an easy way to spread information that cannot be fact-checked, which makes it a preferred method for anti-vaxxers. There ARE many good and informative videos on the immune system, how vaccines work, and other science topics. Some reliable sources:

a. Khan Academy: **khanacademy.org** (on biology and the immune system)

b. Children's Hospital of Philadelphia Vaccine Education Center: Visit **chop.edu** and search for **vaccine education center**.

c. CDC: cdc.org/vaccines

d. NOVA, produced by WGBH Boston: Visit **pbs.org/wgbh/nova/** video/vaccinescalling-the-shots Use websites that end in ".edu" or ".org," but carefully read their mission statement or "About Us" sections. This will help you understand whether they are biased. If you come across a website ending in ".com" use caution and be extra careful when reading their "About Us" section and checking if they're biased.

Use ScholarGoogle.com.

This version of Google filters out unreliable information and leaves mostly dependable, scientific information in the results. That said, it is not perfect, and the sources should still be double-checked for reliability and bias.



When reading a study, check for a few things:

a. **The date:** If the research is older than 20 years, it is generally not reliable. Good research is replicated often, and there should be updated information available. b. **The authors:** Look them up and ensure that they are truly "independent researchers." This means they are not affiliated with any institution which may lend bias to their results. This may include pharmaceutical companies or anti-vaccination organizations.

c. **The disclosure section:** Often located at the end of the study, this will tell you if the researchers have been paid for their research, which may skew the results. If the disclosure names or organizations are not familiar to you, look them up.

d. **Was the study repeated?** Were the same results found when the study was replicated? A study is worthless if it is not generalizable and reproducible. A one-time finding is insufficient to be considered strong scientific evidence. When multiple studies by different researchers result in the same results, these findings are then considered reliable. e. When being given information from anyone (physicians, friends, hotlines), ask for their source! Tell them to prove it to you or to show it to you. Do not believe anything without verification. It is very easy to spread misinformation.

If you or your child experiences a symptom that you believe is related to a vaccine, and your provider does not report it to VAERS, you can do it yourself! Call 1-800-822-7967, visit vaers.hhs.gov, or send an email to info@vaers.org to file a report.

Finally, if you're having trouble accessing or understanding information, email a nurse! EMES has many *frum* nurses available to talk to you: VaccineTaskForce@Gmail.com



ACRONYMS USED IN THIS GUIDE

Organizations

- **AAP** = American Academy of Pediatrics **ACIP** = Advisory Committee on Immunization Practices ACOG = American College of Obstetricians and **Gynecologists ACS** = American Cancer Society **APA** = American Psychiatric Association **ATSDR** = Agency for Toxic Substances and Disease Registry **CDC** = Centers for Disease Control and Prevention **CHOP** = Children's Hospital of Philadelphia **CISA** = Clinical Immunization Safety Assessment **DoD** = U.S. Department of Defense **DOE** = U.S. Department of Education **DOJ** = U.S. Department of Justice **DSM** = Diagnostic and Statistical Manual of Mental Disorders **EPA** = Environmental Protection Agency **FARE** = Food Allergy Research and Education **FDA** = U.S. Food and Drug Administration **GSK** = GlaxoSmithKline HHS = U.S. Department of Health and Human Services **HRSA** = Health Resources and Service Administration **IOM** = Institute of Medicine, now called the National Academies of Medicine (NAM) **NASEM** = National Academies of Sciences, Engineering and Medicine **NAM** = National Academies of Medicine **NCSL** = National Council of State Legislators **NIAID** = National Institute of Allergy and Infectious Disease **NIH** = National Institutes of Health **NVIC** = National Vaccine Information Center, an anti-vaccination website **NVICP** = National Vaccine Injury Compensation Program **NVPO** = National Vaccine Program Office **NVSR** = National Vital Statistics Reports **VA** = Veterans Affairs **VAERS** = Vaccine Adverse Event Reporting System **VSD** = Vaccine Safety Datalink
- WHO = World Health Organization
- WMA = World Medical Association

Vaccines

- **DTP, or DTawP** (whole-cell) = Diphtheria, tetanus, pertussis. This was associated with adverse effects and a newer vaccine, DTaP, was developed to replace it.
- **DTaP** = Diphtheria, tetanus, acellular pertussis (also TDaP/TD, showing components in different order)
- **Hib** = Haemophilus influenza type B
- **Hep A** = Hepatitis A
- Hep B = Hepatitis B
- **HPV** = Human papillomavirus
- **IPV** = Inactivated polio vaccine
- **MenACWY** = Meningococcal conjugate
- MenB = Meningococcal B
- **MMR** = Measles, mumps, rubella
- **MMRV** = Measles, mumps, rubella, varicella
- **OPV** = Oral polio vaccine
- **PCV** = Pneumococcal conjugate
- **PPSV** = Pneumococcal polysaccharide vaccine

Conditions

AFP = Acute Flaccid Paralysis **ASD** = Autism Spectrum Disorder **CRS** = Congenital Rubella Syndrome **GBS** = Guillain-Barré Syndrome **HPV** = Human Papillomavirus **RRP** = Recurrent Respiratory Papilloma **SIDS** = Sudden Infant Death Syndrome **VTE** = Venous Thromboembolism General

- **BBB** = Blood-Brain Barrier **BMJ** = British Medical Journal
- IgE = Immunoglobulin E allergy-related
- **IgG** = Immunoglobulin G type of antibody
- **IgM** = Immunoglobulin M type of antibody, first to appear in an infection
- **IRB** = Institutional Review Board
- **JAMA** = Journal of the American Medical Association
- **MRL** = Minimum Risk Levels

APPENDIX AUTISM SPECTRUM DISORDER (ASD) AND VACCINE STATUS

CITATION	PURPOSE/METHODS	PARTICIPANTS	OUTCOMES
Honda, H., Shimizu, Y., & Rutter, M. (2005). No effect of MMR withdrawal on the incidence of autism: a total population study. <i>Journal of</i> <i>Child Psychology</i> <i>and Psychiatry</i> , <i>46</i> (6), 572-579.	In 1988, Japan replaced the MMR vaccine with single-dose vaccines due to contaminated MMRs. Researchers examined the autism rates in Japan following the withdrawal of the MMR.	31,000 children who did not receive the MMR in Yokohama were tracked for six years to see if they developed autism.	The seven-year incidence of ASD rose from 47.6 per 10,000 for children born in 1988 to 117.2 for those born in 1996. This rise continued in cohorts of children born after MMR was withdrawn, and no decline in ASD incidence occurred in the five-year period from 1988 to 1992 during which MMR vaccine usage fell from 69.8% to zero population coverage.
Taylor, L. E., Swerdfeger, A. L., & Eslick, G. D. (2014). Vaccines are not associated with autism: an evidence-based meta-analysis of case- control and cohort studies. <i>Vaccine</i> , <i>32</i> (29), 3623-3629.	A meta-analysis, which examined several pooled studies to seek connections between MMR vaccination and autism.	Five cohort studies involving 1,256,407 children, and five case-control studies involving 9,920 children were included in this analysis.	Analyses looking specifically at MMR vaccinations, mercury dosage, and thimerosal exposure were negative, as were subgroup analyses looking specifically at development of autistic disorder versus other spectrum disorders.

AUTISM SPECTRUM DISORDER (ASD) AND VACCINE STATUS (CONTINUED)

CITATION	PURPOSE/METHODS	PARTICIPANTS	OUTCOMES
Jain, A., Marshall, J., Buikema, A., Bancroft, T., Kelly, J. P., & Newschaffer, C. J. (2015). Autism occurrence by MMR vaccine status among U.S. children with older siblings with and without autism. <i>Jama</i> , <i>313</i> (15), 1534-1540.	Researchers decided to study whether ASD is more common in vaccinated children than unvaccinated children. They also examined whether having a sibling with autism increased the chance that the MMR would cause autism.	Of 95,727 children with older siblings, 994 (1.04%) were diagnosed with ASD and 1,929 (2.02%) had an older sibling with ASD. Of those with older siblings with ASD, 134 (6.9%) had ASD versus 860 (0.9%) children with unaffected siblings	The authors found that the MMR vaccine was not associated with increased risk of autism, regardless of whether older siblings had ASD. Their findings indicated no association between the MMR vaccine and ASD even among children <i>already at</i> <i>higher risk for ASD.</i>
Madsen, K. M., Hviid, A., Vestergaard, M., Schendel, D., Wohlfahrt, J., Thorsen, P., & Melbye, M. (2002). A population- based study of measles, mumps, and rubella vaccination and autism. <i>New England</i> <i>Journal of Medicine</i> , <i>347</i> (19), 1477-1482. Note: See accompanying chart of data from this study in the section on Autism. Tip: Read percentages of autism in vaccinated versus unvaccinated children.	A retrospective cohort study of all children born in Denmark from January 1991 through December 1998. MMR status was obtained from the Danish National Board of Health. Information on the children's autism status was obtained from the Danish Psychiatric Central Register.	537,303 children were studied. 440,655 were vaccinated, while nearly 100,000 were unvaccinated.	There was no association between vaccination and the development of autism. The odds ratio for developing autism after receiving the MMR was 0.92 (which indicates no correlation at all). Autism rates were found equally in vaccinated and unvaccinated children.

HEAVY METALS AND SAFETY

CITATION	METHODS	PARTICIPANTS	OUTCOMES
Andrews, N., Miller, E., Grant, A., Stowe, J., Osborne, V., & Taylor, B. (2004). Thimerosal exposure in infants and developmental disorders: a retrospective cohort study in the United Kingdom does not support a causal association. <i>Pediatrics</i> , <i>114</i> (3), 584-591.	Scientists in England studied 14,000 children who were exposed to thimerosal (also known as ethylmercury) to see if this impaired cognitive development in children.	14,000 children who were exposed to thimerosal. Information on vaccination was collected from the government, and behavioral outcomes were examined.	The authors found "no convincing evidence that early exposure to thimerosal had any deleterious effect on neurologic or psychological outcome when given according to an accelerated schedule."
Hviid, A., Stellfeld, M., Wohlfahrt, J., & Melbye, M. (2003). Association between thimerosal- containing vaccine and autism. <i>Jama</i> , 290(13), 1763-1766.	Researchers in Denmark evaluated whether thimerosal- containing vaccines were associated with the development in autism.	All children born in Denmark between 1990 and 1996 - a total of 467,450 children. Some children received thimerosal-containing vaccines, and some did not.	The authors found no association between the vaccines given and the autism rate in Denmark.
Taylor, L. E., Swerdfeger, A. L., & Eslick, G. D. (2014). Vaccines are not associated with autism: an evidence- based meta-analysis of case-control and cohort studies. <i>Vaccine, 32</i> (29), 3623-3629.	A meta-analysis by researchers sought to analyze connections between mercury and thimerosal, and autism rates.	Five cohort studies involving 1,256,407 children, and five case-control studies involving 9,920 children were included in this analysis.	They found no association between components of the vaccines (thimerosal or mercury) or multiple vaccines (such as MMR) and the development of autism.
Uno, Y., Uchiyama, T., Kurosawa, M., Aleksic, B., & Ozaki, N. (2015). Early exposure to the combined measles- mumps-rubella vaccine and thimerosal- containing vaccines and risk of autism spectrum disorder. <i>Vaccine</i> , 33(21), 2511-2516.	Japanese researchers searched for a correlation between thimerosal-containing vaccines and ASD rates.	They compared 189 children with autism to 189 children without autism, and collected their vaccination history.	They found no association between the vaccines given and the autism diagnoses.

HEAVY METALS AND SAFETY (CONTINUED)

CITATION	METHODS	PARTICIPANTS	OUTCOMES
Burbacher, T. M., Shen, D. D., Liberato, N., Grant, K. S., Cernichiari, E., & Clarkson, T. (2005). Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing thimerosal. <i>Environmental health</i> <i>perspectives</i> , <i>113</i> (8), 1015.	To understand whether ethylmercury was toxic, monkeys were given injections of different mercuries.	Forty-one monkeys were given injections of either methyl mercury (which is neurotoxic) and ethyl mercury, which used to be in vaccines (which is NOT neurotoxic).	The authors found that methylmercury accumulated in the blood monkeys and remained detectable 28 days after the last dose. However, among the monkeys exposed to ethylmercury (which is used in vaccines), mercury in the blood dropped quickly between doses. Ethyl mercury cleared the body 5.4-fold faster than methylmercury. Furthermore, brain concentrations of total mercury were 3 to 4 times lower in the ethylmercury group than in the methylmercury group.
Karwowski, M. P., Stamoulis, C., Wenren, L. M., Faboyede, G. M., Quinn, N., Gura, K. M., & Woolf, A. D. (2018). Blood and hair aluminum levels, vaccine history, and early infant development: A cross-sectional study. <i>Academic</i> <i>pediatrics</i> ,18(2), 161-165.	To evaluate relationships between blood aluminum and hair aluminum levels in healthy infants and their immunization history and development.	Data was analyzed for 85 infants who met inclusion criteria and for whom information was obtained on aluminum levels as well as on neurodevelopment. Vaccine-related aluminum load for each subject was calculated using immunization histories collected from medical records, published data on vaccine aluminum content. and	Infant blood aluminum and hair aluminum varied considerably but did not correlate with their immunization history. Likewise, there was no correlation between blood aluminum and infant development or between hair aluminum and language or cognitive development.

assumptions of 100%

bioavailability.

HEAVY METALS AND SAFETY (CONTINUED)

CITATION	METHODS	PARTICIPANTS	OUTCOMES
Keith, L. S., Jones, D. E., & Chou, C. H. (2002). Aluminum toxicokinetics regarding infant diet and vaccinations. <i>Vaccine, 20</i> , S13-S17.	The pharmacokinetic properties and end-point toxicities of aluminum are presented. Researchers estimated infant body burdens during the first year of life for breast milk and formula diets and for a standard vaccination schedule.	Researchers compared those body burdens with that expected for intake at a level considered safe for intermediate-duration exposure.	The calculated body burden of aluminum from vaccinations is below the minimal risk level following injection. Aluminum was injected into a human volunteer and blood aluminum levels were found to decrease by more than 50% in 15 minutes and by more than 99% in two days.
Jefferson, T., Rudin, M., & Di Pietrantonj, C. (2004). Adverse events after immunisation with aluminium- containing DTP vaccines: systematic review of the evidence. <i>The Lancet infectious</i> <i>diseases, 4</i> (2), 84-90.	A systematic review of adverse events after exposure to aluminium- containing DTP vaccines, alone or in combination, compared with identical vaccines that either did not contain aluminium salts or contained them in different concentrations.	Reference lists of all relevant articles obtained and any published reviews were examined for additional studies. The Vaccine Adverse Event Reporting System website was accessed December 10, 2003.	In younger children, the addition of aluminum hydroxide caused more redness and swelling at the injection site. However, the children who received aluminum-containing vaccines experienced significantly fewer reactions of all types than vaccines without aluminum.

SIDS

CITATION	METHODS	PARTICIPANTS	OUTCOMES
Griffin, M. R., Ray, W. A., Livengood, J. R., & Schaffner, W. (1988). Risk of sudden infant death syndrome after immunization with the diphtheria-tetanus- pertussis vaccine. <i>New England Journal</i> <i>of Medicine, 319</i> (10), 618-623.	Retrospective review from 1974 and 1984. Computerized immunization records from these sources were linked with Tennessee birth and death certificates to establish the cohort, ascertain the timing of immunization, and identify cases of SIDS. 109 deaths were classified as SIDS.	129,834 children in Tennessee in four counties that had received the DTwP shot at least once.	A multivariate analysis in which they controlled for age, sex, race, year, birth weight, and Medicaid enrollment, produced similar results. Authors conclude that in this large population of children there was no increase in the risk of SIDS after immunization with the DTP vaccine.
Duszynski, K. M., Pratt, N. L., Lynch, J. W., Berry, J. G., Gold, M. S., & Vaccine Assessment Using Linked Data (VALiD) Working Group. (2019). Use of different combination diphtheria-tetanus- acellular pertussis vaccines does not increase risk of 30- day infant mortality. A population-based linkage cohort study using administrative data from the Australian Childhood Immunisation Register and the National Death Index. <i>Vaccine, 37</i> (2), 280-288.	Observational nationwide cohort study of the linked population data from the Australian Childhood Immunization Register and National Death Index to determine whether differences in combination DTaP vaccine types at 2, 4, and 6 months of age were associated with mortality within 30 days of vaccination.	Australian infants administered a combination trivalent, quadrivalent or hexavalent DTaP vaccine (DTaP types) between January 1999 and December 2010 at 2, 4, and 6 months of age as part of the primary vaccination series. The study population included 2.9, 2.6, and 2.3 million children in the 2, 4, and 6 months of age vaccine cohorts, respectively.	The rate of 30-day all-cause mortality was low and declined from 127.4 to 59.3 deaths. When compared with trivalent DTaP vaccines, no elevated risk was seen with any quadrivalent or hexavalent DTaP vaccines, for any cohort. Use of routine DTaP combination vaccines with differing disease antigens administered during the first 6 months of life is not associated with infant mortality.

SIDS (CONTINUED)

CITATION	METHODS	PARTICIPANTS	OUTCOMES
Eriksen, E. M., Perlman, J. A., Miller, A., Marcy, S. M., Lee, H., Vadheim, C., & Black, S. (2004). Lack of association between hepatitis B birth immunization and neonatal death: a population-based study from the vaccine safety datalink project. <i>The Pediatric infectious</i> <i>disease journal, 23</i> (7), 656-662.	Researchers compared the proportions of deaths among birth HBV-vaccinated and unvaccinated newborns and reviewed the causes and circumstances of their deaths.	Birth cohort at Southern and Northern California Kaiser Permanente Health Plans of more than 350,000 live births from 1993 to 1998 and ascertained all deaths occurring under 29 days of age.	There were 1,363 neonatal deaths during the study period. They found no significant difference in the proportion of HBV- vaccinated (31%) and unvaccinated (35%) neonates dying of unexpected causes. There was no causal relationship with the vaccine and infant death.
Müller-Nordhorn, J., Hettler-Chen, C. M., Keil, T., & Muckelbauer, R. (2015). Association between sudden infant death syndrome and diphtheria- tetanus-pertussis immunisation: an ecological study. <i>BMC</i> <i>pediatrics</i> , <i>15</i> (1), 1.	The CDC provided the number of cases of SIDS and live births per year (1968–2009), allowing the calculation of SIDS mortality rates. Immunization coverage was based on (1) the United States Immunization Survey (1968–1985), (2) the National Health Interview Survey (1991–1993), and (3) the National Immunization Survey (1994–2009). They used sleep position data from the National Infant Sleep Position Survey.	The entire infant populations in the U.S. from 1968-2009, with the cases of SIDS. Vaccine coverage of all U.S. infants from 1968-1985, with two surveys: National Health Interview Survey (1991-1993) and National Immunization Survey (1994-2009).	Increased DTP immunization coverage is associated with decreased SIDS mortality. Current recommendations on timely DTP immunization should be emphasized to prevent not only specific infectious diseases but also, potentially, SIDS.

SIDS (CONTINUED)

CITATION	METHODS	PARTICIPANTS	OUTCOMES
Fleming, P. J., Blair, P. S., Platt, M. W., Tripp, J., Smith, I. J., Golding, J., & CESDI SUDI research group. (2001). The UK accelerated immunisation programme and sudden unexpected death in infancy: case-control study. <i>BMJ</i> , 322(7290), 822.	Population-based case-control study, February 1993 to March 1996. Parental interviews were conducted for each death and for four controls matched for age, locality, and time of sleep. Immunization status was taken from records held by the parents.	Five regions in England with a combined population of over 17 million. Immunization details were available for 93% (303/325) of infants whose deaths were attributed to the Sudden Infant Death Syndrome (SIDS); 90% of infants with explained sudden deaths; and 95% of controls.	After all potential confounding factors were controlled for, immunization uptake was strongly associated with a lower risk of SIDS. In fact, immunization does not lead to sudden unexpected death in infancy, and the direction of the relation is toward protection rather than risk.
Zhou, W., Pool, V., Iskander, J. K., English-Bullard, R., Ball, R.,Wise, R. P., & Braun, M. M. (2003). Surveillance for safety after immunization: vaccine adverse event reporting system (VAERS)—United States, 1991–2001. <i>MMWR Surveill Summ</i> , 52(1), 1-24.	Population-based study on retrospective data on vaccination	307 SIDS cases and 971 controls	SIDS cases were vaccinated less frequently and far later than the controls; showing that vaccination actually prevented SIDS . They also found that there was no increased risk for SIDS for two weeks after vaccination.
Institute of Medicine (US) Immunization Safety Review Committee. Immunization Safety Review: Vaccinations and Sudden Unexpected Death in Infancy. Washington, DC: National Academies Press, 2003.	Retrospective study examining vaccination and SIDS for 15 years. Full literature review of all scholarly articles on vaccination and SIDS, and epidemiological studies.	U.S. National Health Data	The researchers looked at individual and combination doses of these vaccines: diphtheria, tetanus, both whole-cell and acellular pertussis (DTP or DPT), DTwP, DTap, Hep B, Hib, and polio and SIDS. There was no evidence that any of these vaccines were the cause of the infants' death

UNVACCINATED CHILDREN AND OUTBREAKS OF DISEASE

CITATION	PURPOSE/METHOD	PARTICIPANTS	OUTCOMES
Aloe, C. F. (2016). The Correlation of Nonmedical Vaccine Exemptions and Clusters of Pertussis Cases in the United States, 2012 (Doctoral dissertation).	The aim of this investigation was to determine if there was a correlation between nonmedical vaccine exemptions and clusters of pertussis cases in the United States during 2012.	Kindergarten immunization data and pertussis cases at the county level were examined.	The results of the investigation indicated that geographic clusters of nonmedical vaccine exemptions pose a risk to the surrounding communities.
Feikin, D. R., Lezotte, D. C., Hamman, R. F., Salmon, D. A., Chen, R. T., & Hoffman, R. E. (2000). Individual and community risks of measles and pertussis associated with personal exemptions to immunization. <i>Jama</i> , <i>284</i> (24), 3145-3150.	Population-based, retrospective cohort study using data collected on standardized forms regarding all reported measles and pertussis cases.	Children ages 3 to 18 years in Colorado during 1987-1998	Exemptors were 22.2 times more likely to acquire measles and 5.9 times more likely to acquire pertussis than vaccinated children.
Imdad, A., Tserenpuntsag, B., Blog, D. S., Halsey, N. A., Easton, D. E., & Shaw, J. (2013). Religious exemptions for immunization and risk of pertussis in New York State, 2000–2011. <i>Pediatrics</i> , peds-2012.	The objective of this study was to describe rates of religious vaccination exemptions over time and the association with pertussis in New York State (NYS).	Religious vaccination exemptions reported via school surveys of the NYS Department of Health from 2000 through 2011 were reviewed by county, and the changes were assessed against incidence rates of pertussis among children reported to the NYS Department of Health Communicable Disease Electronic Surveillance System.	The prevalence of religious exemptions varies among NYS counties increased during the past decade. Counties with higher exemption rates had higher rates of reported pertussis (33 per 100,000) among exempted and vaccinated children, when compared with the low-exemption counties (20 cases of pertussis per 100,000).

UNVACCINATED CHILDREN AND OUTBREAKS OF DISEASE (CONTINUED)

CITATION	PURPOSE/METHOD	PARTICIPANTS	OUTCOMES
Phadke, V. K., Bednarczyk, R. A., Salmon, D. A., & Omer, S. B. (2016). Association between vaccine refusal and vaccine-preventable diseases in the United States: a review of measles and pertussis. Jama, 315(11), 1149-1158.	To evaluate the association between vaccine delay, refusal, or exemption and the epidemiology of measles and pertussis	 a. Eighteen published measles studies which described 1,416 measles cases b. Thirty-two reports of pertussis outbreaks, which included 10,609 individuals for whom vaccination status was reported 	Of the 970 measles cases with detailed vaccination data, 70.6% of these had nonmedical exemptions Among eight outbreaks, from 59% through 93% of unvaccinated individuals were

intentionally unvaccinated.

THE HEALTH OF VACCINATED CHILDREN

CITATION	METHOD	PARTICIPANTS	OUTCOMES
Glanz, J. M., Newcomer, S. R., Daley, M. F., DeStefano, F., Groom, H. C., Jackson, M. L., & Nordin, J. D. (2018). Association between estimated cumulative vaccine antigen exposure through the first 23 months of life and non-vaccine- targeted infections from 24 through 47 months of age. <i>Jama</i> , <i>319</i> (9), 906-913	A case-control study conducted in six U.S. health care organizations participating in the Vaccine Safety Datalink. Cases were identified by ICD codes for infectious diseases in the emergency department (ED) and inpatient medical settings and then validated by medical record review.	944 participants (193 cases and 751 controls)	Among children from 24 to 47 months of age with ED and inpatient visits for infectious diseases, compared with children without such visits, there was no significant difference in estimated cumulative vaccine antigen exposure through the first 23 months of life.
Anderson, M. M., & Arvidson, C. (2017). Childhood vaccine status and correlation with common nonvaccine- preventable illnesses. <i>Journal of the American</i> <i>Association of Nurse</i> <i>Practitioners, 29</i> (7), 415-423.	To determine if there is a difference in incidence of common childhood illnesses dependent on vaccination status	Participants were separated into one of three groups: fully vaccinated, partially vaccinated, and unvaccinated. There were 111 total participants.	Fully vaccinated children were more likely to have ear infections, but less likely to have upper respiratory infections, than unvaccinated children.
Iqbal, S., Barile, J. P., Thompson, W. W., & DeStefano, F. (2013). Number of antigens in early childhood vaccines and neuropsychological outcomes at age 7–10 years. <i>Pharmacoepidemiogy</i> <i>and drug safety, 22</i> (12), 1263-1270	They examined whether cumulative vaccines have an effect on their neurocognitive development later in childhood. Vaccination histories up to 24 months of age were obtained from medical charts, electronic records, and parents' records.	10,000 children between the ages of 7 and 10 years were assessed for general intellectual function, speech and language, verbal memory, fine motor coordination, attention and executive function, tics, visual spatial ability, and behavior regulation.	No adverse association was found in any category.

THE HEALTH OF VACCINATED CHILDREN (CONTINUED)

CITATION	METHOD	PARTICIPANTS	OUTCOMES
Hviid, A., Wohlfahrt, J., Stellfeld, M., & Melbye, M. (2005). Childhood vaccination and nontargeted infectious disease hospitalization. <i>Jama, 294</i> (6), 699-705.	Researchers explored whether an "overload" of vaccines causes immune dysfunction, resulting in a greater number of non-vaccine illnesses.	They looked at 84,317 hospitalizations in Danish children for respiratory infections, viral pneumonia, bacterial pneumonia, septicemia, viral central nervous system infections, bacterial meningitis, and diarrhea.	Hospitalizations for infections were equally divided between vaccinated and unvaccinated children, showing that children receiving combination vaccines do not suffer from "immune overload."
Marom, T., Tan, A., Wilkinson, G. S., Pierson, K. S., Freeman, J. L., & Chonmaitree, T. (2014). Trends in otitis media-related health care use in the United States, 2001-2011. JAMA pediatrics, 168(1), 68-75.	An analysis of an insurance claims database of a large, nationwide managed health care plan was conducted. Researchers used the ICD-9 to identify children who had claims with a diagnosis of ear infections.	Seven million children 6 years or younger with ear infections	There was a downward trend in otitis media visit rates from 2004 to 2011, with a significant drop that coincided with the advent of the pneumonia vaccine (PCV-13) in 2010. Along with the decreased ear infection visit rates, mastoiditis diagnoses and myringotomy (ear tube) insertions decreased significantly (2009-2011).
DeStefano, F., Gu, D., Kramarz, P., Truman, B. I., Iademarco, M. F., Mullooly, J. P., & Marcy, S. M. (2002). Childhood vaccinations and risk of asthma. <i>The Pediatric infectious</i> <i>disease journal, 21</i> (6), 498-504.	Vaccinations were ascertained through computerized immunization tracking systems, and onset of asthma was identified through computerized data on medical care encounters and medication dispensed.	Cohort study involving 167,240 children who were enrolled in four large health maintenance organizations during 1991 to 1997, with follow-up from birth until at least 18 months to a maximum of 6 years of age.	18,407 children (11.0%) developed asthma, with a median age at onset of 11 months. The relative risks of asthma were: 0.92 for diphtheria, tetanus and whole cell pertussis vaccine; 1.09 for oral polio vaccine; 0.97 for MMR; 1.18 for (Hib);

and 1.20 for hepatitis B vaccine.

childhood leukemia (in comparison with exclusive breastfeeding).

Children who received the MMR: decreased risk of leukemia (50% risk reduction).

THE HEALTH OF VACCINATED CHILDREN (CONTINUED)

parents or guardians.

CITATION	METHOD	PARTICIPANTS	OUTCOMES
MacArthur, A. C., McBride, M. L., Spinelli, J. J., Tamaro, S., Gallagher, R. P., & Theriault, G. P. (2007). Risk of childhood leukemia associated with vaccination, infection, and medication use in childhood: the Cross- Canada Childhood Leukemia Study. <i>American journal of</i> <i>epidemiology</i> , <i>167</i> (5), 598-606.	The authors examined the effect of exposures predicted to affect early immune functioning, including childhood vaccinations, illness, medication use, and breastfeeding patterns. For each participating case, an age-, gender-, and area-matched control was randomly selected from government health insurance rolls. Risk factor information was obtained through personal interviews with each child's	Children 0 to 15 years of age diagnosed with leukemia from 1990 to 1994 and resident within principal cities across Canada were eligible for inclusion. Through pediatric oncology centers and population-based cancer registries, 399 cases were ascertained at the time of diagnosis.	Children who received MMR, DTP, poliomyelitis, or hepatitis vaccines: no association with leukemia. Children who took vitamin supplements: increased risk of leukemia (OR 1.66). Children who took immunosuppressant medication: decreased risk of leukemia (OR 0.37). Children who were fed breast milk with more than 50% milk supplementation: increased risk of

THE HEALTH OF VACCINATED CHILDREN (CONTINUED)

CITATION	METHOD	PARTICIPANTS	OUTCOMES
Pagaoa, M. A., Okcu, M. F., Bondy, M. L., & Scheurer, M. E. (2011). Associations between vaccination and childhood cancers in Texas regions. <i>The</i> <i>Journal of pediatrics</i> , <i>158</i> (6), 996-1002.	To determine whether children born in Texas regions with higher vaccination coverage had reduced risk of childhood cancer	The Texas Cancer Registry identified 2800 cases diagnosed from 1995 to 2006. The state birth certificate data were used to identify 11,200 control subjects. They compared vaccination rates among cases and control subjects at the public health region and county level.	Children born in counties with higher hep B vaccine coverage had lower odds of all cancers combined (OR 0.81). A decreased odds for leukemia was associated at the county level with higher rates of the inactivated poliovirus vaccine coverage (OR 0.67). Children born in regions with higher coverage levels of the Hib vaccine had lower odds of leukemia (OR 0.58).
Morra, M. E., Kien, N. D., Elmaraezy, A., Abdelaziz, O. A. M., Elsayed, A. L., Halhouli, O., & Phi, A. P. (2017). Early vaccination protects against childhood leukemia: A systematic review and meta-analysis. <i>Scientific reports, 7</i> (1), 15986.	Researchers aimed to systematically review and meta- analyze the current literature to provide evidence regarding the association between a range of vaccines and the risk of childhood leukemia.	Fourteen studies that examined any associations between vaccination and leukemia were identified and meta- analyzed. Vaccinations studied included BCG vaccine, Triple vaccine, hep B vaccine, polio, measles, rubella, mumps, trivalent MMR and Hib vaccine.	The authors found a protective association between any vaccination in the first year of life and risk of childhood leukemia (OR 0.58). Early vaccination appears to be associated with a reduced risk of childhood leukemia.

THE HEALTH OF VACCINATED CHILDREN (CONTINUED)

CITATION	METHOD	PARTICIPANTS	OUTCOMES
A. Nandi, A. Shet, J. R. Behrman et al, (2019) Anthropometric, cognitive, and schooling benefits of measles vaccination: Longitudinal cohort analysis in Ethiopia, India, and Vietnam, Vaccine. https://doi.org/ 10.1016/j.vaccine.2019. 06.025	Researchers examined more than 12,000 children over 15 years of age in four countries comparing measles vaccinated children's health to unvaccinated in specific cohorts.	Measles vaccination has proven benefits in health outcomes in longitudinal studies: this study looked at anthropometric, cognition and school/ studying benefits.	The measles vaccination prevents against measles-caused blindness, hearing loss, pneumonia, and diarrhea. These purely physical benefits gave children in these countries a cognitive, emotional and social edge in their educational and environmental milieu.
Schmitz, R., Poethko- Müller, C., Reiter, S., & Schlaud, M. (2011). Vaccination status and health in children and adolescents: findings of the German Health Interview and Examination Survey for Children and Adolescents (KiGGS). <i>Deutsches Arzteblatt</i> <i>international, 108</i> (7), 99–104. doi:10.3238/ arztebl.2011.0099 https://www.ncbi.nlm. nih.gov/pmc/articles/ PMC3057555/	Researchers examined data on vaccine- preventable diseases as well as infectious and atopic diseases in both vaccinated and unvaccinated children in Germany.	17,641 children ages 0 to 17 were studied over three years (2003-2006). 0.7% were not vaccinated. This is the largest study in children and adolescents (at this time) looking at vaccine-preventable disease, infectious and atopic diseases.	Vaccine-preventable disease was much higher in unvaccinated children. There was no difference in the number of allergies and infectious diseases between the two groups.

EMES LEADERSHIP

President: Blima Marcus, DNP, RN, ANP-BC, OCN Secretary: Tamar Y. Frenkel, BSN, RN Treasurer: Tobi Ash, MBA, BSN, RN

P.I.E.

EDITOR-IN-CHIEF Tobi Ash, MBA, BSN, RN

EDITORS

Denise Benkel, MD Tamar Y. Frenkel, BSN, RN Blima Marcus, DNP, RN, ANP-BC, OCN Jane Zucker, MD

CONTRIBUTORS

Tobi Ash, MBA, BSN, RN Minna Cohen, FNP Rebecca Feldman, MSN, RN, FNP-BC Tamar Y. Frenkel, BSN, RN Adena Friedman, BSN, RN Leah Honig, BSN, RN, CMSRN Miriam Lieberman, MD Esther Litenatsky, MSN, AGACNP-BC, RN, OCN Blima Marcus, DNP, RN, ANP-BC, OCN

CONTACT US:

EMES Initiative, Inc. 347.669.EMES vaccinetaskforce@gmail.com emesinitiative.org

EMES.initiative



@EMES_initiative

SCAN THE QR CODE TO JOIN US ON WHATSAPP

