An Overview of Vaccines In The US

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Abstract

Ever since the early 1800s, vaccines have been created, manufactured, and administered to people through medical professionals. Vaccines are made of biological substances that expose the immune system to parts of bacteria or viruses and provide protection from infection by different disease-inducing agents. Vaccines are cornerstones of public health, by preventing the spread of sometimes deadly diseases. Because of the recent COVID-19 pandemic, vaccine awareness has become an important discussion amongst the global population. This report includes a robust literature review of existing vaccine studies, including a deep dive into what a vaccine is, the immune reactions along with the side effects, and a risk-benefit analysis of getting vaccinated. This report will provide a factual basis for vaccines to inform individuals in deciding whether or not to receive a vaccine.

Keywords

Vaccine, Immunity, Infant, Antibody, Pathogen, Autism

Introduction

As of today, vaccines are a staple in the medical field. Children going to school are required to show proof of vaccination against diseases such as polio or chickenpox. Since more people received these two vaccines, severe illness resulting from polio and chickenpox infections are not as prevalent today as they were many years ago. For example, before the vaccine for polio was approved, there were around 58,000 cases across the United States and after five years after vaccinations, cases dropped to less than 5,000 cases nationwide. Influenza shots are offered and encouraged every fall season of the year, and with the recent pandemic, the COVID-19 vaccine has been required in many regions. Vaccines have proven to be an effective solution to prevent disease and save lives.

However, despite this longstanding history of vaccines, globally, there are many strong opinions on the topic of vaccines and choosing to get vaccinated. Despite medical professionals briefing patients on all vaccines taken, vaccines remain a subject that many patients are still hesitant about. This research paper will present data-driven findings and a thorough analysis of vaccine research so that readers can make more informed decisions in place of misguided beliefs or fear.

How Do Vaccines Work?

Modern Vaccines

Today, vaccines are given every day by medical professionals to patients all around the world. These are powerful tools that have been developed and revised over the course of

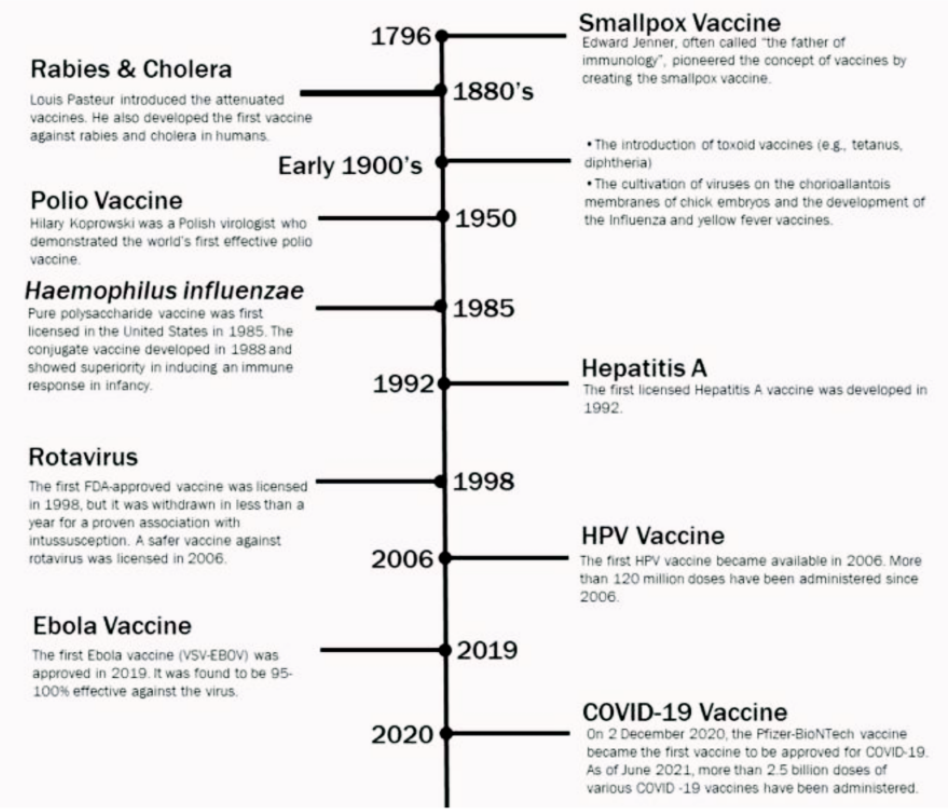

Figure One: Timeline of Vaccines

decades. In the early 1800s, the first vaccine was approved and prescribed to patients to protect against smallpox (Saleh et al., 2021). At birth, infants are also mandated by states to take numerous vaccines in order to prepare for participation in activities such as school or sports in the near future. Before the age of two, children are recommended to take a total of seventeen vaccinations. (Figure One) These range from vaccination for Hepatitis B at birth to vaccination for Measles, Mumps, and Rubella at the age of fifteen months (Centers for Disease Control and Prevention, 2019).

By law in all states across the United States, students must submit their proof of vaccination for diseases such as chickenpox, measles, mumps, polio, and many more (Centers for Disease Control and Prevention, 2019). Parents may file for medical or religious exemption; however, vaccine requirements are put in place for the children's safety. An exemption is filed through a form that is administered by the state government. A religious exemption is permitted if a patient's religion disagrees with taking a vaccine. A medical exemption may be given for a multitude of reasons, including allergies to vaccine ingredients or a history of medical conditions that interfere with the reactions of a vaccine.

When a disease is declared eradicated, vaccination does not need to be administered anymore. An example of this is smallpox, where vaccines are not routinely given anymore. Until a disease or virus has been

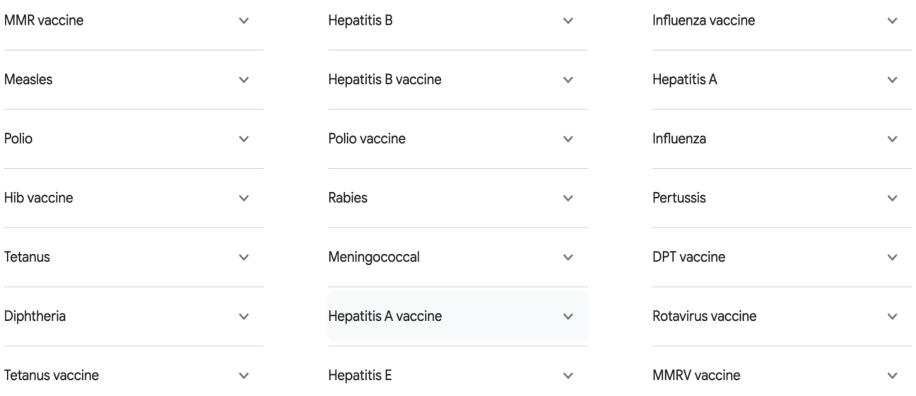

Figure Two: List of Vaccines

declared eradicated, it is still imperative that patients continue to take vaccinations against these diseases. The disease still exists in the environment around patients but the continued vaccination of a patient will increase protection if an outbreak suddenly happens, potentially deadly for patients that do not have prior vaccination or immunocompromised patients. This is especially dangerous for infants who have not received proper vaccination or older patients who have weaker immune systems. In modern healthcare, there are many vaccines that are recommended to be taken by patients across the nation. (See Figure two). Every fall influenza season patients are encouraged to be vaccinated for protection against the common flu. Tetanus is prescribed every ten years to patients, two to four vaccinations for Hepatitis A, two to three doses of HPV, and many more. (Centers for Disease Control and Prevention, 2019).

Types of Vaccines

There are six main types of vaccines. All of these different types of vaccine platforms have similar effects on the immune system. They expose our bodies to infectious pathogenic components (pathogens cause diseases and trigger an immune reaction), thus training our immune system to fight particular pathogens. Live attenuated vaccines inject a live version of a pathogen into a human body; this germ injected is a less harmful version of the disease. Most vaccines taken are live attenuated, some of the most common side effects for live attenuated vaccines include fevers, headaches, runny noses, rashes, and fatigue. The inactivated vaccines comprise dead pathogens and are created by taking a live pathogen and exposing it to extreme conditions, essentially killing it in the process. The immune responses triggered by the inactivated vaccine are weaker than that of the activated vaccines because a weakened pathogen requires less effort than an activated pathogen. This also implies that the activated vaccine can last longer than the inactivated, which requires more frequent injection of the inactivated compared to the activated. Conjugate vaccines are composed of various parts of a pathogen. This vaccine can cause very strong immune responses because it is only a part of a virus. Toxoid vaccines are vaccines that create protection for the toxins of a pathogen instead of the whole pathogen. The next vaccine is an mRNA vaccine. This vaccine triggers an immune response from proteins they synthesize. The first mRNA vaccine approved was the COVID-19 vaccine. Viral vectors are the last major type of vaccine where viruses, such as influenza or adenoviruses, are modified to serve as vehicles to generate protection against another virus. (Zoppi, 2020).

FDA Approval of Vaccines

Every vaccine that is developed and introduced to the industry is put through the diligent hands of the Food and Drug Administration (FDA). The FDA is administered by the United States Government. Their work is verified by not only the scientists in the FDA but scientists worldwide and other well-established organizations such as the United States Center for Disease Control and Prevention. The FDA has carefully thought-out processes that each vaccine seeking approval will undergo. (Figure Three). When a company requests approval for their vaccine, the FDA will evaluate many different areas of the vaccine. The company manufacturing the vaccine will submit a Biologics License Application (BLA), which includes preclinical and clinical data (phases of tests focused on vaccine safety and dosage amount), information on the manufacturing process, vaccine ingredients, and facilities at which the

vaccine was produced. After this comprehensive application is submitted, the FDA checks that the company's ingredients are safe and that facilities follow FDA regulations. Ingredient verification is tested during preclinical and clinical trials, conducted by the manufacturing company before the BLA is submitted to the FDA. Vaccines are under a three-phase trial to determine the safety of all ingredients and the vaccine itself. However, even after preclinical and clinical trials, the FDA's professionals will evaluate all ingredients as well. The FDA evaluates each company with a team of experts: physicians, chemists, statisticians, pharmacologists or toxicologists, microbiologists, experts in postmarketing safety, clinical study site inspectors, manufacturing and facility inspectors, and labeling communications. If a company is approved, the vaccine is permitted to be marketed. When placed in the market, the FDA will oversee the prescription process which is included in the BLA detailing: usage, dosing, and administration. Each company is required to list all factors, side effects, recommendations, and details of manufacturing a vaccine before anyone in the general public can be vaccinated. After approval, the FDA continues to rigorously watch the vaccine as people begin to receive the vaccine. This is accomplished by using protocols, results, and samples that are all agreed on by the company. The FDA maintains the safety of patients in the United States. (FDA, 2020)

Figure Three: FDA Approval of Vaccines

What is Happening in The Body?

The Immune System

Vaccines co-opt the functioning of a healthy immune system to generate immunity against pathogens and maintains the body's health. From a small cut to the flu, the immune system is taking care of the body. When a vaccine is injected, the body's first reaction is to initiate the immune response to eliminate the foreign substance from the body. The body will respond to something being injected into it. A vaccine can trigger an inflammatory response localized at the injection site. These responses can be seen through swelling, redness, fever, or pain at the injection site. These are common side effects of vaccines. Although some people may experience side effects, others will not experience any side effects at all. It depends on the person and varies from patient to patient. Side effects may also be more extreme for some patients compared to others. A study done by a group of notable medical research professionals in China explored the effects of the HPV-16 vaccine (Gardasil 9 vaccine) on Inflammation-Related Adverse Reactions (ISAR) among recipients of vaccinations. ISAR in this study was defined as injection-site pain, redness, swelling, or induration, as well as systemic symptoms such as fever. The group found that despite not all subjects experiencing a form of

ISAR, it still played an important part in the subject's response to the vaccine. It was later concluded that ISAR cannot be a precise indicator of vaccine efficacy and further experimentation would be needed to either prove or disprove the claim that experiencing inflammatory responses lowers vaccine efficacy. (Zhuang et al., 2021).

ISAR also triggers antibody production. Antibodies are proteins produced by the immune system in response to an infection or in this case, a vaccination. When a vaccine enters the body, B-cells (a white blood cell that creates antibodies) are released and then create antibodies to fight the virus injected from the vaccination. Antibodies are evolved to bind to each specific virus and can subsequently neutralize the virus by preventing the virus from infecting host cells. After vaccination, the immune system will make memory B and memory T cells so that the next time the same virus appears, the body already has prior knowledge on how to safely eliminate it from the body. (Hickman, 2023).

Vaccine Ingredients

Because patients do not usually see firsthand what the making of a vaccine looks like, it is easy to not comprehend. A vaccine includes three primary components, one of the most important is the active ingredient, termed antigen, which triggers the immune system to produce antibodies. An antigen is a marker that indicates potential danger to the immune system This sometimes triggers a response from the immune system. An adjuvant makes sure the immune system knows a virus is in the body. Live attenuated vaccines contain adjuvants which are chemicals containing aluminum that help the immune system to respond stronger to said pathogen. This process increases protection against the virus. (Policy (OIDP), 2021).

There are two types of ingredients that ensure the quality of the vaccine. A preservative, such as Thimerosal, in a vaccine ensures that once manufactured, it maintains a stable condition. This protects the vaccine from becoming contaminated with microbes. Today, preservatives are only used in vaccines that are in vials that contain more than one dose due to the increased exposure a larger stock vial experiences with the external environment. Another ingredient that supports the vaccine's quality is a stabilizer, such as gelatin, which serves to delay the degradation of the vaccine to ensure its quality. This will keep the vaccine safe and secure during storage, transportation, and moving. Temperature changes can affect vaccines and stabilizers will ensure that they will be in the best shape when the time comes to be injected into a patient. These ingredients are examples of some of the most discussed ingredients and components that patients may have the most concern about. (CDC, 2019b).

What Are The Risks and Benefits of Taking a Vaccine?

When taking a vaccine, there are many different factors that determine the risks and benefits of taking vaccines. Like most over-the-counter drugs and prescriptions, there are common side effects and rare side effects. Some common side effects include pain at the injection site, redness of the injection site, fever, chills, fatigue, headache, and muscle soreness. The majority of these effects could be caused by any medicine or drug. Some of the rarer side effects include difficulty breathing, swelling of face and throat areas, rapid heartbeat, severe rashes on the skin, dizziness, and weakness. Although these are rare side effects, the majority of over-the-counter prescriptions will also describe the same side effects. Pain at the injection

site was only seen in 34.8% of patients and fevers were seen in only 35.2% of patients. Not all patients will experience the same degree of ISAR or side effects.

Risks of Taking a Vaccine

The most infamous accusation surrounding the danger of vaccines is the MMR (Measles, Mumps, and Rubella) vaccine linked to increased incidence of ASD (Autism Spectrum Disorder) in young children. (DeStefano & Shimabukuro, 2019). ASD is defined as a developmental disorder that may be seen in a child's disability to communicate, make eye contact, and more neurodivergent traits. The exact origin of autism is still unknown to scientists but it is believed to mainly be caused by genetics. In most cases, ASD is developed in a child well before birth and is shown around twelve months of age. This suspicion was first brought to the public eye in 1998 when then-British physician, Andrew Wakefield, observed that as children were receiving more MMR vaccines, the cases of autism started to increase. This was only observed in a group of 12 children and designed with no control group, a poorly designed study. The study was later revoked by the lab, The Lancet located in the United Kingdom, which published Wakefield's study in 2010 for insufficient data, as well as the retraction of Wakefield's medical license for misconduct. Although this study was declared as not credible, because of the study's presence in the media, more patients grew cautious of the MMR vaccine.

Data shows that following 1963 (the year the MMR vaccine was approved) the cases of measles in the United States alone diminished from 500,000 to around 25,000 in just five years, and fourteen years after that, cases were close to zero. In the year 2000, measles was declared eliminated. An author and activist, David Kirby, published a book named "*Evidence of Harm*," discussing the findings of Wakefield's original study just seven years prior. Kirby brought attention to the popular vaccine preservative ingredient, Thimerosal (the preservative ingredient discussed earlier), and blamed increased ASD cases on Thimerosal. This ingredient was added to certain vaccines in order to protect it from microbial contamination as described previously. As of today, the vaccines that children of ages six and under do not have Thimerosal listed as an ingredient by the FDA or CDC. (CDC, 2020). Furthermore, the only vaccines that include Thimerosal are the influenza vaccines and tetanus (DTaP) vaccines, which also have a version for children that do not contain thimerosal. However, as vaccination numbers slowed after this book was published in 2005, parents did not want to vaccinate their children against a disease that was already eradicated. It was seen as unnecessary to feel the pain of a shot when the disease is no longer prevalent. Throughout 2008 and 2009, small but fatal outbreaks of measles started in America, Canada, and the United Kingdom. Although some people are still skeptical of the MMR vaccine, it has a proven high vaccine efficacy against the disease it was made to fight off. A large study evaluating vaccination and the risk of autism revealed that in pooled data of 1,256,407 children, the odds of developing autism after vaccination was 0.99, with a 95% confidence interval meaning that out of 100 trials, 95 of them would be accurate. The causes of autism are still under question to many medical professionals and its connection to the MMR vaccine and the preservative ingredient of thimerosal is still debated.

Another ingredient that has proven highly controversial is aluminum. This metal is an adjuvant in many vaccines. It triggers a stronger immune response from the human body as an adjuvant as discussed previously. (Policy (OIDP), 2021). It has been suspected to cause many of the side effects, namely asthma or long-term effects on a child's brain. (Corkins, 2019). In addition to this, many people believe that an infant's immune system cannot handle all vaccines

on the vaccine schedule but infants in fact are born with all the antibodies needed to fight viruses. All vaccines prescribed to infants should not take up more than 0.1% of the infant's general immune systems ability. This is because the cells are constantly being replenished in the system to make sure that the viruses that do enter the body are taken care of. In addition, infants encounter a number of viruses and bacteria already. There have been numerous studies done by scientists at the CDC, the World Health Organization, and many other well-known foundations, on the link between aluminum, autism, and asthma, or even possible neurotoxicity in infants. Many medical professionals have countered the possibility but still remain cautious and are still investigating. Aluminum is a common ingredient in many foods consumed by humans and infants through breast milk. Studies have shown that when rats are injected with high doses of aluminum, causing aluminum overload or aluminum toxicosis, it results in neurotoxicity. Although this proves too much aluminum can be fatal, vaccines that contain aluminum are regulated by how much can be injected into an infant. The levels of aluminum in these trials were significantly higher than in vaccines prescribed to infants. As of today, there is no evidence of neurotoxicity in humans caused by aluminum after episodic injections in infants. The FDA regulates the amount of aluminum that can be injected per dose and has reported that the number of patients, let alone infants, who reported any sort of neurological side effects after taking a vaccine is little to none. Medical professionals recommend that with the current regulations in place, aluminum can be effective in vaccines and remain safe for infants.

During the COVID-19 pandemic, when the vaccine was developed for the disease, a common concern of mRNA vaccines was infertility. This concern became particularly popular as the vaccine was being implemented into the medical field and patients were being vaccinated. Countless sources and studies conducted by medical professionals from institutes such as the FDA, CDC, and many university laboratories, have concluded that mRNA vaccines cannot result in infertility. In a US particular study, around four thousand females were closely monitored. Of these women 2,403 were vaccinated and 1,556 were unvaccinated. All women being observed tracked cycles on an app (Natural Cycles) for medical professionals to interpret. However, menstruation was observed to be longer in women who were vaccinated. On average, the first dose of the vaccine resulted in a 0.71-day increase in cycle length, and the second dose resulted in a 0.91-day increase in cycle length. After receiving the vaccine, there was an average increase of about one day in cycles. There were no changes observed in the cycles of women who were unvaccinated. The International Federation of Gynecology and Obstetrics claims that a change or variation in cycle length is normal if the cycle remains under eight days. As a result, this study concluded there was a slight increase in cycle length for vaccinated women but did not impair the fertility of any subjects. (*COVID-19 Vaccination Associated with a Small, Temporary Increase in Menstrual Cycle Length, Suggests NIH-Funded Study*, 2022). The study states that the vaccine could also cause a change in the intensity of pain, mood changes, etc, but additional research would be necessary to come to a conclusion. In a different study that observed both men and women, it was found that there was a short-term temporary decrease in fertility in some men that is believed to be caused by the inflammatory responses from vaccination but fertility recovered in time. The vaccine in conclusion did not permanently impair either partner's fertility. (*COVID-19 Vaccination Associated with a Small, Temporary Increase in Menstrual Cycle Length, Suggests NIH-Funded Study*, 2022).

Benefits of Receiving a Vaccine

Although vaccines have side effects, there are critical benefits to taking a vaccine. Vaccines were manufactured to protect patients all around the world. A virus is injected into a patient to assist the immune system in learning to eliminate the virus and prepare for the next time that it infects the body again. A vaccine was made to build strength in a human's immune system and prevent the spread of sometimes fatal diseases. As more people receive a vaccine, population immunity is slowly being gained as more human bodies learn to effectively attack and eliminate the virus. Vaccines have grown tremendously but their purpose has never wavered.

The easiest way to see the effects of being vaccinated is in a concept referred to as "Herd Immunity." This is when within a region, enough patients have been vaccinated for a disease to the point where the population has developed protective antibodies against the disease. Although herd immunity is possible, there still might be gaps in vaccinated patients. This is due to religious beliefs, concerns about the vaccine and its safety, or uneven access to the vaccine. The more people that receive a vaccine, the more patients that are able to fight off disease, and the easier it will be to achieve herd immunity by protecting the people around patients.

Another way to see the effect of vaccines is vaccine efficacy. Many diseases are now deemed eliminated by the CDC and it was only possible with the help of vaccines. An example of this is poliomyelitis or polio. The first case of polio in America was reported to be in the year of 1940. The vaccine against this disease was approved and implemented in the year of 1955 which had around 30,000 reported cases in America. Just six years later, in 1961, the number of cases of polio plummeted to little to none. As years passed, polio did not reappear in the nation. In 1979, America declared polio to be eliminated with no new reported cases in over decades. Although polio is eliminated from America, it still stands as a disease in other areas of the world. Therefore as cases become less popular with time, patients still are recommended to be vaccinated against polio for longer immunity, making sure that if an outbreak were to happen, the patient would be protected and equipped to handle the disease. This is the case with many diseases that have been declared eliminated in the United States. Without vaccination, humans would lack the ability to correctly fight some of the most fatal diseases and viruses.

Vaccines not only protect the patient but everyone around the patient. The spread of diseases can be exponential and, when not protected, lead to outbreaks and the possibility of a pandemic. The first outbreak of the COVID-19 pandemic was reported to have been in Wuhan, China on December 31st of 2019. Within less than a month on January 20th of 2020, the first confirmed case in America was reported to be in Washington state. The 35-year-old man had visited family in Wuhan, China, and just returned home to America. The virus spread to numerous states across America in a matter of weeks. Cases grew exponentially, the human immune system had not encountered a disease like this before. This led to outbreaks and widespread growth in the number of cases around America. This shows that if a human body does not have prior experience in eliminating disease, it will be far more dangerous for the immune system. If a vaccine is taken, it not only mitigates the risk of endangering the patient themself but also the risk of endangering the people around a patient.

Conclusion

A vaccine is a very powerful tool in the medical field that is used worldwide by medical professionals. It was made to support the immune systems of all patients by injecting a virus into the immune system triggering the body to eliminate the virus or disease. Once the body has learned and memorized how to fight the virus the first time, when the immune system is attacked again with the same virus or disease, the body will remember how to fight it and keep the patient safer. The more doses of a vaccine are taken by a patient, the stronger the immunity to the virus or disease. Vaccines are made of many different types of ingredients but the three main ingredients are adjuvants, preservatives, and stabilizers. Each ingredient plays a role. A lot of specific ingredients have received skepticism in vaccines but medical professionals have published many studies to counter the false accusations. The most popular theories include thimerosal causing autism, aluminum causing asthma and long-term neurotoxicity, and mRNA vaccines causing infertility in men and women. Although these claims were made, medical professionals are still cautious of results. The FDA and other governing bodies work with scientists to regulate components in vaccines to ensure that vaccines remain safe for patients all around the world. This research paper was conducted on pre-existing data and scholarly articles. When making an educated decision in the context of medicine and health, it's important to understand the facts presented both by medical professionals, as well as existing data and research. When deciding whether or not to take a vaccine, one should take into consideration the facts presented in this paper and make a sound decision based on evidence and not solely based on rumors.

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