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Vaccine Myths: Setting the Record Straight

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Introduction

Vaccines are one of the most important public health achievements of the 20th century and are responsible for the steep decline in vaccine-preventable diseases (VPDs) in the U.S. The incidence of most VPDs in the U.S. has declined by 90 to 100% (Centers for Disease Control and Prevention [CDC], 1999) (see Table 1).

Table 1. Vaccine-preventable diseases: post-vaccine percent decrease in morbidity.

Disease	Pre-Vaccine Estimated Annual Morbidity†	2016 Reported Cases*	Percentage Decrease
Smallpox	29,005	0	100%
Diphtheria	21,053	0	100%
Measles	530,162	85	99.98%
Mumps	155,760	6,369	95.91%
Pertussis	185,120	17,972	90.29%
Polio (paralytic)	16,316	0	100%
Rubella	47,734	1	100%
Congenital Rubella Syndrome	151	2	98.68%
Tetanus	539	34	93.69%

†Source: Roush, Murphy, and the Vaccine-Preventable Disease Table Working Group (2007).
* Source: CDC (2017a).

Despite the important role that vaccines have played in dramatically improving public health over the last century, myths that the risks of vaccines outweigh the benefits continue to persist. These myths date as far back as the 18th century, during a time of smallpox epidemics in England and colonial America. At the time, anti-vaccine activists claimed that the smallpox vaccine would turn a child into “a scrofulous, idiotic ape, a hideous foul-skinned cripple: a diseased burlesque on mankind” (as cited in Durbach, 2004, p. 114). Since it was derived from cowpox, parents also feared that the smallpox vaccine would turn their children into cows or cow-like creatures (Offit, 2011). In early American puritanical society, vaccine myths also took a religious bent, with parents believing that the smallpox vaccine was anti-Christian (Offit, 2011).

As more vaccines were added to the recommended childhood immunization schedule, more myths arose. The modern-day anti-vaccine movement is often traced to a documentary that first aired in 1982. This documentary, *DPT: Vaccine Roulette,* sparked concerns that the DPT vaccine caused brain damage, seizures, intellectual disability, and permanent disability in infants (DPT: Vaccine Roulette: WRC-TV, Washington, D.C., April 19, 1982). This sensationalist reporting started the modern-day trend of news sources widely publicizing case reports of "vaccine-injured" children, with little attention paid to the scientific research showing no association between the vaccine and injury. The culture of fear incited by this type of reporting plays into the widely held vaccine misconceptions of today: vaccines cause autism; too many vaccines are given too soon; vaccines are not safe; and the flu vaccine is not necessary.

Myth: Vaccines Cause Autism

One of the most common myths related to vaccines is the erroneous belief that vaccines cause autism. This myth originated in 1998 when Andrew Wakefield and colleagues at the Royal Free Hospital and School of Medicine in London published a small study of 12 children in *The Lancet,* a highly respected medical journal; the article proposed that the combination measles-mumps-rubella (MMR) vaccine was associated with autism (Wakefield et al., 1998). Following Wakefield's publication, parental vaccine concerns increased dramatically, resulting in a sudden decrease in rates of MMR vaccine uptake and the occurrence of measles outbreaks throughout the United Kingdom (Offit, 2011). Concerns regarding the MMR vaccine quickly spread to the U.S. While anti-vaccine sentiment existed in the U.S. prior to Wakefield's assertions about the MMR vaccine, it became notably more mainstream following the publication of his paper.

The emergence of actress Jenny McCarthy as a parent advocate against vaccines generated substantially more media exposure to the myth that vaccines cause autism. McCarthy blamed the MMR vaccine for her son Evan's autism and quickly launched into a media frenzy to advocate for parents of autistic children who blamed vaccines, often the MMR vaccine specifically, for their child's autism. In 2007, McCarthy appeared on *Oprah, Larry King Live*, *Good Morning America,* and numerous other television shows during which she passionately shared the story of how her son quickly descended into autism following his MMR vaccination. In her appearances, McCarthy criticized the public health and medical communities, questioned vaccine safety, and demanded additional research into the purported link between vaccines and autism (Bratton, 2011). McCarthy summarized her experiences and opinions in her 2007

book*, Louder than Words: A Mother's Journey in Healing Autism* (McCarthy, 2007). Initially, McCarthy's message focused on the theory put forth by Wakefield regarding the MMR vaccine; however, gradually she turned her focus to all vaccines, asserting that they contained toxic ingredients and caused autism and suggesting that the recommended vaccine schedule was unsafe (Offit, 2011). Wakefield's and McCarthy's highly publicized criticism of vaccines launched a period of significant parental concerns about vaccines, particularly the belief that vaccines may cause autism. Sadly, the effects of Wakefield and McCarthy's efforts continue to be felt today.

Following the publication of Wakefield's paper suggesting an MMR vaccine-autism link, the scientific community immediately began to evaluate the theory that the MMR vaccine caused autism. To date, nearly two dozen studies have been conducted in multiple countries examining hundreds of thousands of both vaccinated and unvaccinated children, some of whom were followed for several years. All of the studies demonstrated that there is no causal association between the MMR vaccine and autism (Dales, Hammer, & Smith, 2001; Farrington, Miller, & Taylor, 2001; Fombonne & Chakrabarti, 2001; Kaye, del Mar Melero-Montes, & Jick, 2001; Madsen et al., 2002; Peltola et al., 1998; Smeeth et al., 2004; Taylor et al., 1999; Taylor et al., 2002). Importantly, Wakefield's findings were unable to be confirmed by other researchers worldwide. One of the most compelling studies to provide evidence against the MMR vaccine-autism theory was conducted in Denmark among more than 500,000 children, of whom 100,000 were not vaccinated with the MMR vaccine. Researchers compared the relative risk of autism among children vaccinated with the MMR vaccine to those who were not vaccinated with the MMR vaccine. They demonstrated no association between the age at time of vaccination, time since vaccination, or the date of vaccination and development of autism (Madsen et al., 2002). In 2000, the Institute of Medicine (recently renamed the National Academy of Medicine), a nonprofit nongovernmental organization that works to provide evidence-based research and recommendations for public health and science policy, convened the Committee on Immunization Safety Review to conduct an independent review of the evidence examining the link between the MMR vaccine and autism (National Academy of Medicine, 2018). The Institute of Medicine determined that the "evidence favors rejection of a causal relationship between the MMR vaccine and autism" (Immunization Safety Review Committee. Institute of Medicine, 2004, p. 126). Furthermore, investigative journalist Brian Deer conducted an extensive inquiry into Wakefield's study and found Wakefield's findings to be fraudulent. In 2004, as a result of Deer's incriminating evidence, 10 of

the 13 authors withdrew their names from the study. In 2010, *The Lancet* formally retracted the paper, and Wakefield lost his license to practice medicine in the United Kingdom (Deer, n.d.; Offit, 2011; Wakefield, 1998). In 2011, Deer published a series of articles in the *British Medical Journal* outlining his findings. Deer discovered that no institutional review board approved the study, study subjects were recruited by an anti-vaccine group, all of the subjects' medical histories were misreported, and the study itself was funded by a personal injury lawyer who was suing vaccine manufacturers on behalf of several families who believed the MMR vaccine caused their child's autism. Additionally, Deer discovered fraudulent behavior by Wakefield himself: eight months prior to *The Lancet* publication, Wakefield submitted a patent for his own single-antigen measles vaccine (Deer, 2011a; Deer, 2011b; Deer, 2011c).

After the purported MMR vaccine-autism association was widely discredited, this myth continued to persist with anti-vaccine advocates, including McCarthy, who subsequently focused on vaccine ingredients, specifically thimerosal. Thimerosal is a mercury derivative, ethyl mercury, previously used in vaccines as a preservative. Because thimerosal is a form of mercury, misconceptions regarding its safety and composition were prevalent; however, many parents failed to understand that thimerosal, or ethyl mercury, differs significantly from the toxic form of mercury, methyl mercury. Ethyl mercury does not cross the blood-brain barrier and is structurally different from methyl mercury, rendering it safe for use in vaccines. In 1999, as a precautionary measure and to appease public demand, the U.S. Public Health Service and the American Academy of Pediatrics (AAP) recommended the removal of thimerosal from nearly all vaccines (AAP, 1999). Currently, thimerosal is only used as a preservative in the multi-dose influenza vaccine. Nearly a dozen peer-reviewed studies were conducted which examined the possibility of a causal relationship between thimerosal-containing vaccines and autism. Several of these studies compared the risk of autism in children who received thimerosal-containing vaccines to those who received thimerosal-free vaccines. Each study produced the same result—the incidence of autism in both sets of children was the same (Andrews et al., 2004; Fombonne, Zakarian, Bennett, Meng, & McLean-Heywood, 2006; Heron, Golding, & ALSPAC Study Team, 2004; Hviid, Stellfield, Wohlfarht, & Melbye, 2003; Madsen et al., 2003; Stehr-Green, Tull, Stellfeld, Mortenson, & Simpson, 2003; Verstraeten et al., 2003). Also of note, thimerosal was removed as a preservative in Denmark in 1991, yet the country continued to see an increase in rates of autism (Gerber & Offit, 2009). In 2004, the Institute of Medicine reviewed the cumulative evidence examining thimerosal-

containing vaccines and autism and found that the "evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism" (Institute of Medicine, 2014, p. 65).

The body of evidence exonerating vaccines from a causal association with autism is overwhelming, yet this unfounded myth continues to persist. Parents with concerns regarding a link between vaccines and autism may choose to decline the MMR vaccine—or even all vaccines—for their children. Children who are unvaccinated against measles are significantly more likely to contract and spread measles to unvaccinated or under-vaccinated individuals in their community (Feikin et al., 2000). Several notable measles outbreaks have occurred throughout the last few years as a result of parents refusing measles vaccination for their children (Clemmons, Wallace, & Patel, 2017). For example, the highly publicized Disneyland multistate outbreak in 2014-2015 resulted in 147 measles cases across seven U.S. states as well as Mexico and Canada. Among the reported measles cases, 45% were unvaccinated and 38% were of unknown vaccination status. Among the unvaccinated, 43% cited philosophical or religious objections to vaccines (Clemmons, Gastanaduy, Fiebelkorn, Redd, & Wallace, 2015). Overall, between 2001 and 2015, 70% of measles cases were in unvaccinated individuals (Clemmons, Wallace, & Patel, 2017). It is critical for providers to educate parents with concerns related to the vaccine-autism myth to ensure these children are vaccinated, reducing their individual risk for vaccine-preventable diseases as well as the community's risk for outbreaks.

Myth: Vaccines Are Not Safe

One myth that has always been present but that has increased in popularity recently is the belief that vaccines are not safe. More specifically, some people believe that vaccines are not adequately tested and monitored for safety. Unfounded anecdotal stories of vaccine adverse events are pervasive; however, the general public fails to understand the vaccine safety monitoring systems that examine those anecdotes to determine whether adverse events are caused by vaccines or if the adverse event is merely coincidental. This myth plays into conspiracy theories related to the trustworthiness of the federal government and pharmaceutical companies. Unfortunately, these conspiracy theories have gained traction in the Internet age. One element of this myth is that parents are reporting adverse vaccine side effects that government health agencies and pharmaceutical companies are either hiding or willfully ignoring. Websites that discourage vaccination and emphasize vaccine risk are more likely to use language framed around institutional distrust and skepticism toward government

organizations such as the CDC (Kang et al., 2017). Parents who use the Internet as a source of vaccine information are more likely to hold misconceptions related to vaccine science, vaccine benefits, and vaccine safety. They are also more likely to have obtained nonmedical vaccine exemptions for their children (Jones et al., 2012).

One vaccine particularly impacted by this myth is the human papillomavirus or HPV vaccine. Anecdotes of adolescent girls who suffered chronic illness after receiving the HPV vaccine spread worldwide on both mainstream and social media after introduction of the vaccine, despite a lack of evidence of a causal relationship between the HPV vaccine and any chronic disease (Chao et al., 2012; Grimaldi-Bensouda et al., 2014; Moreira et al., 2016; Vichnin et al., 2015). On December 4, 2013, Katie Couric's television show, *Katie*, discussed the "HPV vaccine controversy" and featured two mothers who claimed their daughters were harmed by the vaccine (Herper, 2013; Jaslow, 2013). The underlying message was that the HPV vaccine harmed adolescents and that medical professionals did not acknowledge adverse effects. The episode failed to provide any evidence supporting these false medical claims. Couric's show was one of many mass media outlets to use these tactics. An analysis of 13 peer-reviewed papers examining the mass media response to the HPV vaccine found an increased use of themes that made the vaccine seem politically controversial when it was not medically controversial (Gollust, LoRusso, Nagler, & Fowler, 2016). Moreover, social media has also played a meaningful role in perpetuating HPV safety concerns. One study examined the relationship between HPV vaccine content on the social media platform Twitter and statewide immunization rates. States with higher levels of exposure to negative tweets about HPV vaccine had lower statewide HPV vaccination rates (Dunn et al., 2017). Unfortunately, these types of safety myths persist despite robust systems in the U.S. and globally that extensively test vaccines pre-licensure and monitor for safety post-licensure.

All pharmaceutical products, including vaccines, are required to undergo three phases of clinical testing prior to applying for approval from the Food and Drug Administration (FDA). In the initial application to the FDA for a proposed new vaccine, the pharmaceutical company must outline the complete manufacturing process and the proposed mechanisms for vaccine evaluation. As part of the Investigational New Drug Application, the pharmaceutical company must also ensure vaccine safety in animal models before human testing can begin. After approval, the vaccine undergoes Phase 1 through Phase 3 clinical trials. Phase 1 studies are the first studies in human subjects, which are conducted using smaller sample sizes to

assess vaccine safety. Phase 2 studies assess vaccine effectiveness, using hundreds of volunteers in populations at risk for the targeted vaccine-preventable disease. Phase 3 studies examine both vaccine safety and effectiveness and are conducted in thousands to tens of thousands of subjects (Edwards, Hackell, the Committee on Infectious Diseases, and the Committee on Practice and Ambulatory Medicine, 2016; FDA, 2018). Once the vaccine is demonstrated to be safe and effective, it can be considered for licensure by the FDA.

After the vaccine is licensed by the FDA, it undergoes a rigorous review process by the Advisory Committee for Immunization Practices (ACIP) before the committee votes to incorporate the vaccine into the recommended vaccine schedule. ACIP is comprised of medical and public health experts who hold no financial or ethical conflicts of interest with pharmaceutical companies or government agencies. The entire process from an investigational new drug application to inclusion on the U.S. Recommended Immunization Schedule often takes 10 or more years, during which the vaccine is continuously monitored for safety and emergence of adverse effects. For example, Merck® submitted Gardasil™, an HPV vaccine, as an investigational new drug in 1997, and it was not recommended by the ACIP until 2006 (CDC, 2007; FDA, 2006).

Monitoring vaccine safety does not end once the vaccine is licensed. In the U.S., multiple surveillance systems continue to assess risk and ensure ongoing vaccine safety. Key among these efforts is the Vaccine Adverse Events Reporting System (VAERS), a passive surveillance system to which any individual (including patients, parents, and medical professionals) can report a suspected adverse event. Investigators from the CDC, FDA, and scientific community then investigate the reports at both individual and population levels to determine if there is a potential causal relationship between the vaccine and any reported adverse event. In addition to VAERS, vaccine safety is also actively monitored through the Vaccine Safety Datalink (VSD), the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) system, and the Clinical Immunization Safety Assessment Project (CISA Project). Through the VSD, the CDC uses electronic health records from eight healthcare organizations across eight states to monitor adverse events and conduct research on vaccine safety questions (CDC, 2016). Similar to the VSD, the PRISM system utilized by the FDA analyzes insurance claims data from large insurers such as AETNA, HealthCore, and Humana. The FDA is then able to quickly and securely access this extensive database of over 100 million individuals to detect patterns which could trigger further investigation (Baker, Nguyen, Cole, Lee, & Lieu, 2013; Shoaibi, 2017). Similarly, the CISA Project is a

network of seven academic medical research centers that actively monitor and research vaccine safety (CDC, 2016; Edwards et al., 2016). Along with the aforementioned safety monitoring systems specific to the U.S., there are worldwide and European safety monitoring systems. The World Health Organization uses the Global Advisory Committee on Vaccine Safety to monitor vaccine safety globally, and the European Centre for Disease Prevention and Control funds the Vaccine Adverse Event Surveillance and Communication research network to monitor adverse events following immunization throughout Europe (Bonanni et al., 2017). Moreover, following vaccine licensure, both private and public institutions across the U.S. continue to monitor vaccine safety and effectiveness independently.

The effectiveness of safety monitoring in the U.S. was clearly demonstrated in the case of the RotaShield® vaccine. This vaccine was first approved for use in the U.S. in August 1998 to protect against rotavirus disease. After initial use in the general population, cases of a rare gastrointestinal blockage called intussusception were reported. The previously discussed surveillance systems flagged these cases as potentially concerning. As a result, the CDC initiated two investigations into vaccinated populations and quickly suspended its recommendation for the vaccine. Intussusception usually occurs at a baseline rate of 1 to 2,000-3,000 infants under the age of one. The CDC investigations revealed the RotaShield® vaccine could cause an additional one to two cases of intussusception per 10,000 infants. As a result, in October 1999, the CDC permanently withdrew its recommendation and the vaccine manufacturer voluntarily withdrew RotaShield® from the market (CDC, 2011). As demonstrated in this example, the vaccine safety monitoring systems in the U.S. are effective in detecting serious adverse events, including those considered rare such as intussusception related to the RotaShield® vaccine.

In summary, vaccines are extensively monitored for safety in the United States and worldwide. If evidence-based safety concerns are discovered post-licensure, the vaccine is withdrawn from the market. It is important that medical providers are knowledgeable about these monitoring systems and are able to use this safety data to mitigate patients' safety concerns. It is also helpful for providers to be engaged with social media so they know which misconceptions are common and can help debunk myths quickly when they arise. This active approach on social media has been demonstrated to increase vaccination rates (Glanz et al., 2017).

Myth: Too Many Vaccines Are Given Too Soon

In more recent history, the myth that too many vaccines are given too soon in a child's life has arisen. This myth began to develop as the number of

vaccines given to children increased throughout the 1980s up until the early 2000s. For example, in 1980, children received a maximum of 5 injections by age 2, which protected against 7 vaccine-preventable diseases. By 2000, children received a maximum of 20 injections by age 2, which protected against 11 vaccine-preventable diseases (Offit et al., 2002). Due to the increase in vaccine coverage, the incidence of vaccine-preventable diseases has dramatically decreased, and many parents today have never witnessed the diseases from which their children are protected. The seemingly rapid increase in the number of vaccines added to the recommended immunization schedule coupled with a dramatic decrease in VPD rates has led many parents to question whether children receive too many vaccines too soon (Offit, 2011). One study demonstrated that nearly 25% of parents believe children receive too many vaccines. Approximately 25% also believe giving too many vaccines could weaken their child's immune system (Gellin, Maibach, & Marcuse, 2000). As a result of this pervasive myth, some parents are intentionally deviating from the CDC's Recommended Immunization Schedule. The use of alternative vaccination schedules has substantially increased in the last several years with more parents choosing to either limit the number of shots given in one visit, delay one or more vaccines, or refuse one or more vaccines (Robison, Groom, & Young, 2012). It is estimated between 10% and 34% of parents are intentionally using an alternative vaccination schedule (Dempsey et al., 2011; Glanz et al., 2013b; Nadeau et al., 2015; Robison, Groom, & Young, 2012; Smith, Humiston, Parnell, Vannice, & Salmon, 2010). For example, a recent study assessing the use of alternative vaccination schedules in New York State found an estimated 34% of infants up to 9 months of age followed an alternative vaccine schedule (Nadeau et al., 2015).

One individual who has greatly contributed to the perpetuation of this particular myth is Dr. Robert Sears, a pediatrician from southern California. Sears authored a best-selling book that erroneously validated many vaccine myths, including the idea that infants were given too many vaccines too soon (Offit, 2011). Moreover, in his book--*The Vaccine Book: Making the Right Decision for Your Child*—Sears offers vaccine-concerned parents alternative approaches to vaccination. Sears supports the parental practice of delaying or refusing vaccines and even puts forth his own vaccination schedules—an alternative vaccination schedule and a selective vaccination schedule. The alternative vaccination schedule delays certain vaccines until the child is older while the selective vaccination schedule excludes certain vaccines entirely (Sears, 2011).

While children receive more vaccines today than 30 years ago, many parents are unaware that the immunological challenge from the vaccines

given today is actually much lower than it was previously. For example, in 1980, children received vaccines that protected against 8 VPDs for which the total number of immunogenic proteins was more than 3,000. Today, children are recommended to receive vaccines that protect against 14 VPDs and for which the total number of immunogenic proteins and polysaccharides is approximately 150 (Children's Hospital of Philadelphia, 2018). In short, while the total number of vaccines has increased, the number of immunological components contained in the vaccines has significantly decrease while still providing protection against more potentially devastating VPDs (Offit et al., 2002). Parents who utilize alternative vaccination schedules fail to understand that they are increasing the amount of time during which their infants and children are at risk for VPDs. The current immunization schedule is designed to protect infants when they are most vulnerable; intentionally delaying vaccination only leaves children susceptible to serious vaccine-preventable diseases during a time when they need the protection most. Moreover, under-vaccinated or unvaccinated children are at risk of contributing to the outbreak of VPDs in their communities and across the U.S., which could subsequently impact individuals who are too young or unable to be vaccinated for medical reasons (Aloe, Kulldorff, & Bloom, 2017; Atwell et al., 2013; CDC, 2013; Feikin et al., 2000; Omer et al., 2008; Salmon et al., 1999).

Infants are more than capable of handling the immunological challenge from the vaccines they receive. From birth, infants encounter numerous immunologic challenges in their natural environment on a daily basis, and their immune systems are able to effectively respond. In fact, the immunological challenge infants face from vaccines is substantially less than what they encounter in their everyday life (Offit et al., 2002).

Of note, the safety and effectiveness of the vaccination schedules put forth by Sears remain unstudied as compared to the rigorous safety review that the CDC's Recommended Immunization Schedule has undergone. Renowned pediatric infectious disease physician and vaccine expert Dr. Paul Offit articulates it best in his statement, "It's . . . amazing when one considers that Robert Sears has never published a paper on vaccine science; never reviewed a vaccine license application; never participated in the creation, testing, or monitoring of a vaccine; and never developed an expertise in any field that intersects with vaccines—specifically, virology, immunology, epidemiology, toxicology, microbiology, molecular biology, or statistics. Yet he believes he can sit down at this desk and come up with a better schedule" (Offit, 2011, p. 187).

Myth: The Flu Vaccine Isn't Necessary

Influenza vaccine has been plagued by a plethora of myths. This vaccine is recommended by the ACIP annually for individuals 6 months of age and older. Despite this recommendation, many children and adults do not receive their annual influenza vaccine. In 2015-16, influenza vaccine coverage among children age 6 months through 4 years was 70%, while coverage for children 5 through 17 years was a dismal 55.9% (CDC, 2018a). Surveys reveal that the most common reasons among parents for poor influenza vaccine compliance include the following misconceptions: the vaccine doesn't work, the vaccine could be harmful or dangerous, or the vaccine has unacceptable side effects (Flood et al., 2010; Imburgia, Hendrix, Donahue, Sturn, Zimet, 2017; Paterson, Chantler, & Larson, 2017). Unfortunately, providers may also hold misconceptions about the influenza vaccine. In one survey, 5% of pediatric providers held misconceptions regarding the importance and safety of influenza vaccine and failed to routinely recommend influenza vaccination (Suryadevara, Handel, Bonville, Cibula, & Domachowske, 2015).

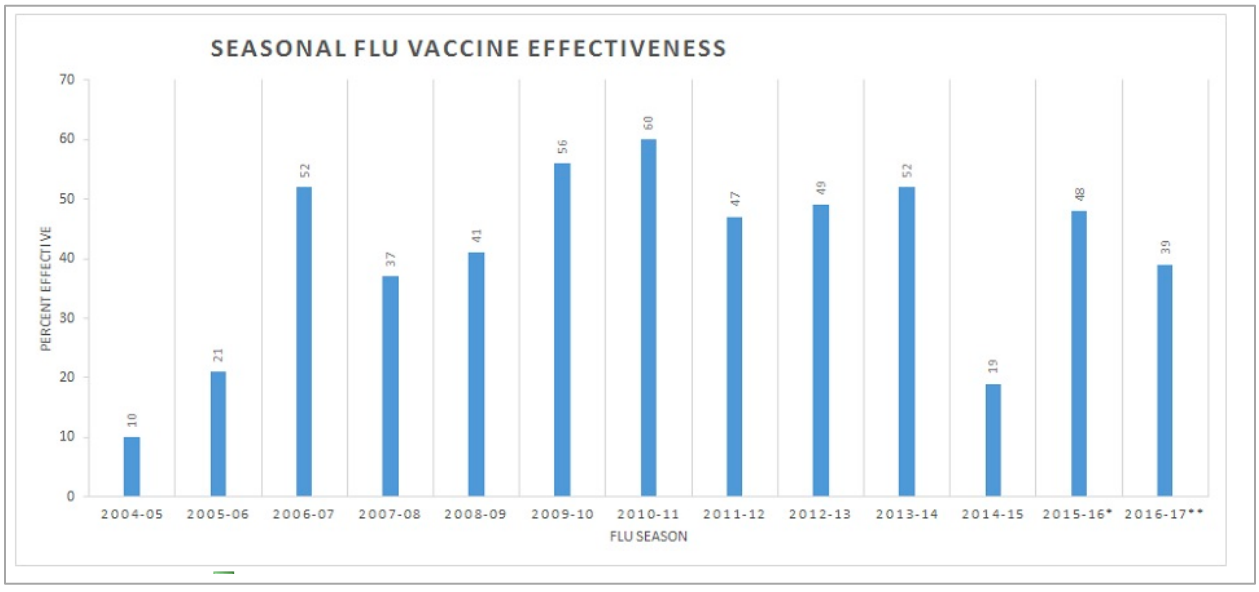
Furthermore, some parents believe the influenza vaccine doesn't work. In fact, the effectiveness of the influenza vaccine varies year to year. Due to antigenic changes in influenza virus, the match between the viruses circulating in the community and those contained in the vaccine may vary. Over the past decade, influenza vaccine effectiveness ranged between 19 and 60% (CDC, 2018a).

Table 1

Reasons for Not Getting the Influenza Vaccine

Reasons	Frequency (n = 180)	Percent
I don't believe the flu vaccine works	50	27.8
I think the flu vaccine could be dangerous for my child	42	23.3
I believe the flu vaccine will have side effects	33	18.3
I believe that getting the flu vaccine every year is too frequent and may be harmful for my child	24	13.3
My child did not see a doctor or healthcare provider during the most recent flu season	15	8.3
I didn't have the insurance or money to pay for the flu vaccine	6	3.3
My child's doctor or healthcare provider did not recommend that my child receive the flu vaccine	5	2.8
My child decided he/she did not want the flu vaccine	5	2.8

Source: Imburgia et al. (2017)



Source: CDC (2018a)

Figure 2. Effectiveness of seasonal flu vaccines from the 2004-2017 flu seasons

Although the vaccine may not be fully protective against influenza in any given year, vaccinated children still experience direct benefits from vaccination. Studies demonstrate that children vaccinated against influenza are less likely to experience an influenza-like illness, develop pneumonia, require hospitalization, or die compared to unvaccinated children (Flannery et al., 2017; Smith & Huber, 2018). In addition, the community experiences indirect benefits of influenza vaccination in children, including preventing disease in household contacts, decreased missed school days, and fewer missed work days for parents (Jordan et al., 2006; Smith & Huber, 2018). Some parents erroneously believe the influenza vaccine will protect against all winter viral infections. If their child becomes ill with a non-influenza viral infection following influenza vaccination, parents often claim the vaccine does not work. It is important for providers to educate parents on the difference between the influenza virus and other seasonal viral infections so that parents understand the influenza vaccine can only protect against the flu. Therefore, their children will still be susceptible to other seasonal viruses. In addition, some individuals may be exposed to the influenza virus just prior to vaccination or within one to two weeks following vaccination. These individuals may still become ill with influenza as their vaccine has not yet induced immunity. This distinction is important especially when the vaccine is obtained after the influenza virus is widely circulating in the community (CDC, 2017b).

In addition to concerns regarding influenza vaccine effectiveness, some parents believe the influenza vaccine may be harmful or could cause the flu. The two types of influenza vaccines currently available are inactivated and recombinant. The inactivated influenza vaccine contains inactive influenza virus which is no longer infectious. Recombinant influenza vaccines do not contain the influenza virus at all. Therefore, following vaccination, the influenza virus cannot replicate and cause disease. Providers should emphasize to parents that it is scientifically impossible for the influenza vaccine to cause the flu. Following vaccination, local reactions such as redness and soreness at the site of injection are common. Less commonly, some individuals will also report systemic symptoms such as low-grade fever, myalgia, fatigue, malaise, or headache and subsequently assume the influenza vaccine caused the flu. In actuality, the systemic symptoms are a result of the immune response to the influenza vaccine. Moreover, true influenza infection is much more severe and long-lasting than the systemic reaction the vaccine may cause (CDC, 2017b). It is helpful to warn patients of the possibility of local and systemic symptoms

so children and parents understand the cause of these symptoms and have a plan to mitigate them.

Some parents will decline influenza vaccination based on the belief that it is unnecessary because their child is healthy and has never had the flu. Although these children may have avoided disease exposure and subsequent illness to date, most children will eventually contract influenza virus given the annual prevalence and contagiousness of influenza. According to the CDC (2018b), since 2010, influenza caused an estimated 9.2 million to 35.6 million illnesses, 140,000 to 710,000 hospitalizations, and 12,000 to 56,000 deaths annually in the U.S. Considering these morbidity and mortality estimates, parents should be warned against erroneously assuming their child is not at risk for influenza each year. Moreover, some children may contract influenza, manifest no symptoms, and yet still shed influenza virus. These seemingly healthy children then may put other children and adults at risk, particularly those who are either medically unable to be vaccinated or infants too young to be vaccinated. Parents should be reminded that children are important vectors for influenza virus and should not only be vaccinated to protect themselves but also to protect others.

Implications

Undoubtedly, belief in vaccine myths has led parents to decline vaccines, resulting in serious consequences in the U.S. Currently, all states permit medical exemptions and all but three states (California, Mississippi, and West Virginia) permit religious exemptions from school-required vaccines. Moreover, 18 states allow parents to exempt their child from school-required vaccines for personal belief or philosophical reasons. (National Conference of State Legislatures, 2017). Both religious and philosophical exemptions are considered nonmedical exemptions. Unfortunately, an increasing number of parents have chosen to exempt their child from one or more vaccines (Glanz et al., 2013b; Omer, Richards, Ward, & Bednarczyk, 2012; Thompson et al., 2007). A systematic review of studies published between 1997 and 2013 found 42 publications that suggest immunization exemption rates have increased and unvaccinated and under-vaccinated children cluster geographically (Guadino & Robison, 2012; Imdad et al., 2013; Lieu, Ray, Klein, Chung, & Kulldorff, 2015; Safi et al., 2012; Smith et al., 2017; Sugerman et al., 2010; Wang, Clymer, Davis-Hayes, & Buttenheim, 2014). Moreover, states that allow personal belief exemptions have higher rates of VPDs such as pertussis. The ease with which vaccine exemptions can be acquired is also associated with a higher rate of pertussis (Omer et al., 2006). Fortunately, recent data suggest that nonmedical exemption rates

plateaued during the 2015-2016 school year (Omer et al., 2017). Continued examination of vaccine exemption trends is critical.

Children who have claimed nonmedical vaccine exemptions and are missing some or all immunization are at increased risk for contracting and transmitting vaccine-preventable diseases (Aloe, Kulldorff, & Bloom, 2017; Atwell et al., 2013; CDC, 2013; Feikin et al., 2000; Omer et al., 2008; Salmon et al., 1999). Studies of these children demonstrate that they are 6 to 23 times more likely to contract pertussis compared to vaccinated children (Feikin et al., 2000; Glanz et al., 2009). Children who were under-vaccinated with 1, 2, 3, or 4 doses of DTaP (Diphtheria-Tetanus-Pertussis-containing vaccine) were 2.25, 3.41, 18.56, and 28.38 times more likely, respectively, to be diagnosed with pertussis (Glanz et al., 2013a). From 1996 to 2007, 11% of pertussis cases were attributed to parental vaccine refusal (Glanz et al., 2009).

In addition to placing unvaccinated and under-vaccinated children at risk for pertussis, nonmedical exemptions also place children at increased risk for measles (Feikin et al., 2000; Salmon et al., 1999). Children with nonmedical exemptions are 22 to 35 times more likely to contract measles (Feikin et al., 2000; Salmon et al., 1999). A systematic literature review examining measles outbreaks occurring between 2000 and 2015 revealed 1,416 measles cases, among which 56.8% of individuals affected were unvaccinated (Phadke, Bednarczyk, Salmon, & Omer, 2016). Importantly, as previously discussed, vaccine refusal also was implicated in the 2014-2015 Disneyland measles outbreak (Zipprich et al., 2015).

Finally, vaccine refusal has been associated with outbreaks of other vaccine-preventable diseases such as *H. influenzae* type b, varicella, and pneumococcal disease (CDC, 2009; Glanz et al., 2010; Glanz et al., 2011). Prior research demonstrated that intentionally unvaccinated children were 8.6 times more likely to contract varicella and 6.5 times more likely to contract pneumococcal disease than vaccinated children (Glanz et al., 2010; Glanz et al., 2011).

In addition to contributing to outbreaks of disease, vaccine refusal has an important impact on vaccine providers. A 2012 survey of pediatricians and family physicians revealed that 83% of providers encountered a parent who refused one or more vaccines, while 20% of pediatricians and family practitioners reported that more than 5% of families refused vaccines (O'Leary et al., 2015). Furthermore, discussions with vaccine-concerned parents are time-consuming. In one survey, 53% of physicians spent 10 to 19 minutes discussing vaccine concerns with parents while 8% of physicians reported spending ≥20 minutes with these families (Kempe et al., 2011). As a result, some physicians have chosen to

schedule more time for these discussions while others have chosen to avoid lengthy discussions and simply follow the parents' wishes to either delay or omit certain vaccines. As a final resort, some physicians are opting to dismiss vaccine-refusing patients from their practices: 14% of physicians reported that they often or always dismiss families who refuse ≥1 childhood vaccines (O'Leary et al., 2015). Pediatricians who dismiss patients from their practice are more likely to be those in private practice, live in the southern part of the United States, and live in a state with nonmedical exemptions. Given the complexities of vaccine refusal and the variety of approaches chosen by pediatricians, AAP has modified its prior statement regarding the care of patients who refuse vaccines. This statement encourages pediatricians to address parents' vaccine concerns on an individual basis and use clear messaging regarding vaccine safety, vaccine-preventable disease severity, and the importance of on-time vaccination; in addition, it recognizes patient dismissal as a consideration for pediatricians who have exhausted other options (Edwards et al., 2016).

Conclusion

Despite the mountain of evidence demonstrating the safety and effectiveness of vaccines, myths regarding vaccines continue to persist. Belief in such myths can lead parents to delay or refuse vaccines for their children. As a result, unvaccinated or under-vaccinated children contribute to the spread of vaccine-preventable diseases in the U.S. To maintain adequate vaccine coverage and preserve public health, providers must continue to educate parents on the importance of vaccines, mitigate vaccine concerns, and dispel any vaccine-related myths.

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