VACCINATE TEXAS

THE SCIENCE OF VACCINES AND WHY THEY SHOULD BE A PRIORITY—2017 LEGISLATIVE SESSION

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VACCINATE IN TEXAS

About the Center for Child Health Policy and Advocacy

The Center for Child Health Policy and Advocacy at Texas Children's Hospital, a collaboration between the Baylor College of Medicine Department of Pediatrics and Texas Children's Hospital, delivers an innovative, multi-disciplinary, and solutions oriented approach to child health in a vastly evolving health care system and market place. The Center for Child Health Policy and Advocacy is focused on serving as a catalyst to impact legislative and regulatory action on behalf of vulnerable children at local, state, and national levels. This policy brief is written to address the public health implications of vaccines and provide evidence-based recommendations to advance the vaccine climate in Texas.

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EXECUTIVE SUMMARY

The Science of Vaccines and Why They Should be a Priority—2017 Legislative Session

As a result of widespread immunizations, the majority of Americans have never witnessed the devastating effects of diseases such as polio, smallpox, pertussis, and measles. These achievements have led public health experts to commend vaccines as the greatest public health victory of our generation. However, despite the historical success of vaccines and the overwhelming body of scientific evidence supporting them, myths and misinformation regarding immunizations persist in Texas and throughout the United States.

Public health experts around the state have begun to issue warnings about the dangers posed by rising vaccine exemption rates.[25,27,76] Since non-medical exemptions were first allowed in Texas in 2003, the number of exemptions on file has increased 19-fold. Recently, vaccine coverage in Texas has fallen well below national averages and this failure to immunize has come at great cost. From 2005-2015, 100,000 Texans suffered from vaccine-preventable disease, resulting in over 1,100 deaths.[77]

To prevent more death and disease, state representatives should act quickly to improve immunization rates across the state. In support of evidence-based decision making with regards to immunizations, we have compiled the following policy brief. The first half of this brief explains the science and economics of vaccines. We also examine the safety and efficacy of vaccines in relation to common vaccine misconceptions. The latter half discusses the mounting dangers of falling vaccination rates in Texas and details policy proposals for the upcoming legislative session.

We believe that the following proposals, modeled off of successful legislation enacted by other states, would advance the vaccine climate in Texas and protect the health and safety of its citizens:

1. Change the Texas Immunization Registry (ImmTrac) to an Opt-Out System
2. Empower families to make the best choices for their child by releasing school-specific data on vaccine exemption rates
3. Require online education modules for parents or guardians seeking non-medical vaccine exemptions for their children
4. Invest in teaching health care providers how to counter vaccine misinformation
5. Require the Texas Department of Health to publish an annual report on HPV immunization rates
6. Neutralize the legal language surrounding vaccine exemptions

HEALTH POLICY BRIEF

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Vaccines: The Most Successful Public Health Intervention

Vaccines prevent an estimated six million deaths per year globally.[1] They protect our bodies from infection by training the immune system to recognize harmful germs more quickly. Essentially, vaccines work by mimicking an infection. However, unlike the immunity acquired from an actual infection, vaccines do not cause illness.[2,3] Vaccines introduce a substance into the body that activates the immune system, producing disease-fighting blood cells and antibodies that last for years.

While not all vaccine-preventable diseases seem serious, common infections can lead to health complications and even death. For example, many Americans perceive seasonal influenza or "the flu" as a mundane infection.[4] However young children, older adults, and other individuals with weak immune systems can suffer devastating illness from the flu virus. This became a reality for two families who lost their children to the flu.

In 2004, the annual influenza vaccine was only recommended for children aged 6-23 months or for children with underlying chronic medical conditions.[5] Not fitting either of those categories, three-year-old Emily Lastinger did not receive the flu shot that year. In January, Emily fell ill with the flu. After several days of antiviral medication and fluids, Emily's parents found her lifeless and not breathing. Despite CPR and intensive medical intervention, Emily passed away. Autopsy reports indicated that Emily had died from pus filling her lungs—a complication seen with severe influenza virus infections.[6,7] Like the Lastingers, many families experienced losses under these previous immunization guidelines.[7] Consequently, these guidelines were changed to advise that every child six months and older receive an annual flu vaccine.[9]

Breanne Palmer Family (left), Emily Lastinger Family (right) 2010. Photograph. Vaccine-Preventable Disease: The Forgotten Story. Houston: Texas Children's Hospital Center for Vaccine Awareness and Research, 2010. 26-27, 34-35, 40-41. PHOTO CREDIT: Kuntz, Paul Vincent., Kramer, Allen S., Sinoris, George.

Between 2007 and 2015, 136 Texas children died from flu-related causes.[8]

Similarly, in 2003 Breanne Palmer's parents took her to the pediatrician for her annual flu shot. However, Breanne's doctor found an infection in her ear and told the family to return for the vaccine later. Shortly thereafter, just days before Christmas, 15-month-old Breanne fell ill. When her temperature rose to 101.5, her parents returned to the pediatrician. She was diagnosed with the flu and given antibiotics. That night, Breanne's fever persisted, rising to 107°F. By the time she was transported to an intensive care center, the virus had already attacked Breanne's heart and brain. Unable to survive the extensive organ damage, Breanne succumbed to the flu shortly thereafter.[6] After this tragedy, Breanne's parents learned that ear infections are not contraindications to receiving the flu vaccine. Breanne's parents believe that if their daughter had received the vaccine, she would alive today.[6]

"Vaccines are simple and inexpensive tools to protect kids. It's the right thing to do, like putting them in car seats."

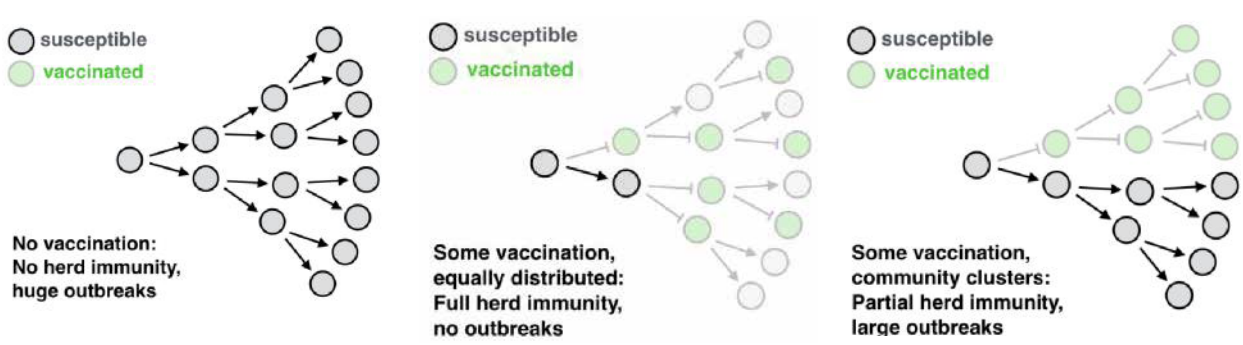
Importantly, these tragic examples show how commonplace diseases can result in severe illness and even death, leaving no doubt that failing to immunize puts children at increased risk of harm. Following their losses, the Palmer and Lastinger families became vocal advocates for flu vaccine awareness.[7,10]

THE IMPORTANCE OF HERD IMMUNITY

In addition to protecting the individual, vaccines protect communities from outbreaks of disease by creating herd immunity. Herd immunity occurs when a large majority of the community (the herd) is immunized, shielding the unvaccinated minority from disease. This phenomenon occurs because it is impossible for the disease to take hold when only few vulnerable individuals remain.[11,12]

The vaccine rate required to maintain herd immunity depends on the transmissibility of a particular disease. Most infections require immunization rates of 80-90% to maintain herd immunity. Highly contagious illnesses such as measles require 90-95% coverage.[13,14] This means that when less than 90-95% of the population is immunized, diseases like measles have the potential to cause serious disease outbreaks.

Furthermore, herd immunity protects individuals who cannot receive vaccines or be fully vaccinated. This group includes pregnant women, the elderly, newborns, and the immuno-compromised. These individuals only remain safe through high vaccination rates in their communities. Individuals with suppressed immune systems form a particularly vulnerable population.[15] This includes persons with inherited immunodeficiencies, immune suppressing infections, and individuals such as organ transplant recipients on immune-suppressing therapies.



Salanthe, Michael. "Herd immunity and measles: Why We Should Aim For 100% Vaccination Coverage." The Conversation, 2 Feb. 2015. Accessed 3 January 2017.

In 2014, an estimated 235 per 100,000 Texas adults were hospitalized for bacterial pneumonia. These hospitalizations cost an estimated $1.7 billion.[16]

VACCINES AS A COST-EFFECTIVE INTERVENTION

In Texas, vaccine-preventable diseases also constitute a significant economic burden. Data from the Texas Potentially Preventable Hospitalizations Program provides some insight into the cost burden of vaccine-preventable disease in our state. In 2014, an estimated 235 per 100,000 Texas adults were hospitalized for bacterial pneumonia. These hospitalizations incurred charges of an estimated $1.7 billion.[16] Many of these infections could have been prevented by immunization against pneumococcus, for which two vaccines exist.[17]

Vaccine-preventable diseases are costly in children as well. The DTaP vaccine protects children from diphtheria, tetanus and pertussis for a mere $30 per dose.[18] Children are routinely administered the DTaP vaccine at 2 months, 4 months, 6 months and 15 months.[19] The cost of this immunization series stands in stark contrast to the cost of care for these three vaccine-preventable diseases. A child with diphtheria must receive inpatient care. The CDC estimates that diphtheria requires an average of 6.1 days of hospitalization, which amounts to $16,982. Even higher costs accrue for a child with tetanus, another disease requiring intensive inpatient treatment. The CDC estimates the average tetanus case requires 16.7 days of inpatient care, costing an estimated $102,584 per hospitalization.[20,21]

Every $1 invested in immunization saves $3 in direct medical costs and more than $10 in societal costs, such as lost wages or productivity due to illness.[25]

While diphtheria and tetanus are exceedingly rare in Texas as a result of immunization, pertussis continues to affect Texans every year. Severe cases of pertussis necessitating in-patient treatment typically require an average 5.5–15 days in the hospital, costing between $10,765–$22,410.[20,21] From 2013–2015, there were 8,065 cases of pertussis in Texas and seven pertussis-related deaths. Of those cases, 1,762 occurred in children under the age of one, the age group at the greatest risk for pertussis-related complications and death.[22,23] Importantly, two of the 2013 Texas pertussis deaths occurred in infants under two months of age.[24] These infants were too young to be vaccinated, instead relying on the adequate immunization of their surrounding community. These cases highlight the importance of maintaining high rates of tetanus, diphtheria, and pertussis vaccination across the state and throughout all age groups.

VACCINES: A VICTIM OF THEIR OWN SUCCESS

In 1900 every one in ten U.S. infants died of infection.[26] Today, most Americans will never see a friend or family member lose their life to a vaccine-preventable disease. Ironically, immunizations have become a victim of their own success. In counseling parents, pediatricians commonly encounter the misbelief that vaccines are no longer necessary.[25]

As shown in the infographic below, there have been dramatic decreases in preventable disease with the advent of vaccines.

Reduction in Disease Morbidity Since the Introduction of Vaccines

99%
REDUCTION IN MEASLES

89%
REDUCTION IN PERTUSSIS

100%
REDUCTION IN POLIO

83%
REDUCTION IN HEPATITIS B VIRUS

100%
REDUCTION IN HEPATITIS A VIRUS

91%
REDUCTION IN SMALLPOX

Adopted from: Leon Farrant. "Impact of Vaccines in the 20th and 21st Centuries." Adapted from "CDC Pink Book Appendix E Data." Centers for Disease Control, Jan. 2011, https://www.behance.net/ gallery/2878481/ Vaccine-Infographic. Accessed 2 Jan. 2017.

Because the U.S. no longer suffers biennial outbreaks of the measles, an estimated 4,000 cases of neurological debilitation are averted in school-aged children each year.[27]

DEBUNKING VACCINE MYTHS

Despite the overwhelming body of research demonstrating the safety and efficacy of today's vaccine schedule,[26] not all Texans recognize the benefits of immunization. For example, in a 2016 survey of Texas health care providers, 81% of respondents replied that misinformation or poor knowledge about vaccination forms a "very important" barrier to maintaining high immunization rates in the state.[25] Much of this misinformation comes from vaccine skeptics who perpetuate myths about the recommended childhood vaccine schedule.

These skeptics express concern regarding three major themes:

1) vaccination side effects and safety

2) the effect of the current vaccine schedule on the young immune system, and

3) the purported link between the MMR vaccine and autism.

This section summarizes the scientific evidence addressing these concerns.

Vaccine Safety and Monitoring

Vaccine safety and monitoring begins long before vaccines are tested in human subjects. The initial step in ensuring safety begins with an application for New Drug Investigation to the U.S. Food and Drug Administration (FDA).

This application requires that the sponsor "describe the manufacturing and testing process, summarize the laboratory reports, and describe the proposed studies to evaluate the vaccine."[28] Each submission must pass a rigorous review before undergoing three phases of clinical trials, which are described in the graphic below.[28] Additionally, the FDA mandates concomitant use studies on all new vaccines to ensure that they do not affect the safety and efficacy of existing vaccines.

Once a new vaccine has passed the three phases of clinical trials, it must undergo further scrutiny before addition to the U.S. Recommended Immunization Schedule. The Advisory Committee on Immunization Practices (ACIP), made up of medical experts from a wide variety of fields, meticulously reviews the clinical trial data.[30] They examine the severity of the disease prevented, the number of Americans affected by the disease, and the optimal age to administer the vaccine. The ACIP then submits a recommendation to the director of the Centers for Disease Control (CDC). If approved by the director, the new vaccine is added to the official immunization schedule.[30]

Each vaccine submitted to the FDA must undergo three phases of clinical trials[29]

PHASE 1 CLINICAL TRIAL	PHASE 2 CLINICAL TRIAL	PHASE 3 CLINICAL TRIAL
20-100 HEALTHY VOLUNTEERS	**SEVERAL HUNDRED VOLUNTEERS**	**HUNDREDS TO THOUSANDS OF VOLUNTEERS**
• Is this vaccine safe? • Does this vaccine work? • Are there any serious side effects? • How do side effects change with size of the dose?	• What are the most common short-term side effects? • How do volunteers' immune systems respond to the vaccine?	• How do people who get the vaccine and people who do not get the vaccine compare? • Is the vaccine effective? • What are the most common side effects?

Rigorous monitoring does not end after addition of the vaccine to the recommended schedule. Four major regulatory bodies continue to scrutinize vaccine safety and efficacy after FDA approval:

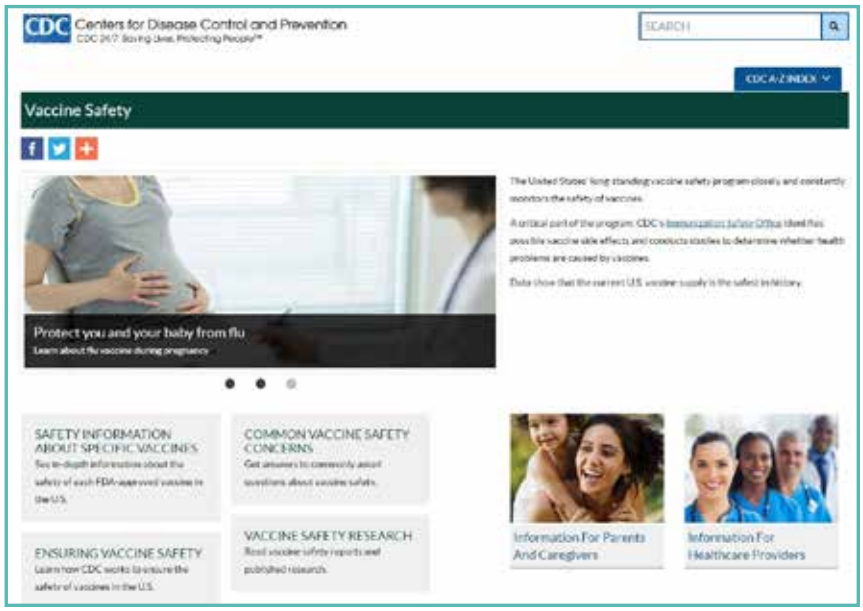
1. **Vaccine Adverse Event Reporting System (VAERS):**[31] Allows the CDC and FDA to monitor reports of adverse events that occur after vaccination. Anyone, including parents, patients, and healthcare professionals, can submit reports.

2. **Vaccine Safety Datalink (VSD):**[32] In collaboration with nine healthcare organizations across the U.S., the CDC maintains an extensive database on reported vaccine side effects. Scientists use this data to evaluate whether the reported side effects have an actual association with vaccination.

3. **Clinical Immunization Safety Assessment (CISA) Project**:[33] A national network of vaccine safety experts from the CDC's Immunization Safety Office have joined with seven medical research centers to form the CISA Project. This group conducts high quality clinical research and provides consultation to US clinicians who have questions regarding vaccine safety issues.

4. **Poslicensure Rapid Immunization Safety Monitoring (PRISM):**[34] In addition to conducting retrospective vaccine safety evaluations, PRISM is now in the process of establishing prospective, active surveillance of FDA-licensed vaccines in the United States.

The CDC makes all information on vaccine safety and the prevalence of reported side effects widely available to the public, accessible at **www.cdc.gov/vaccinesafety**



In addition to safety monitoring, skeptics voice concerns regarding the safety of certain ingredients contained in vaccines. However, pharmaceutical manufacturers and governing agencies meticulously review the ingredients in vaccines. The adjuvants and preservatives used in today's vaccines are safe.[26,28] While vaccine ingredients—such as formaldehyde and aluminum—can sound dangerous and unnecessary when examined out of context, the ingredients found in vaccines have been examined extensively and rigorously to ensure their safety.[35-39] Furthermore, these components are only included because they play an essential role in the creation or efficacy of the final product. For example, adjuvants are critical ingredients added to vaccines to bolster their efficacy by causing the body's immune response to be more robust. Nevertheless, vaccine skeptics continue to single out several specific compounds as dangerous and unnecessary:

MERCURY

Currently, only multi-dose vial flu vaccines contain thimerosal, a mercury derivative necessary to prevent bacterial growth.[36] It is not included in any of the vaccines administered to children. The form of mercury found in thimerosal is ethylmercury, which is rapidly eliminated by the body. This form of mercury is different from methylmercury (the form of mercury found in fish), which stays in the body for years and is toxic to humans at high doses. Nine major studies have shown no link between thimerosal and autism.[36]

ALUMINUM

Small amounts of aluminum form an important component of many vaccines. Aluminum has been found to improve the body's immune response to vaccination, improving the agent's efficacy.[37] Furthermore, aluminum is a common metal found in trace quantities in our drinking water, foods, breast milk, and infant formula. Today, the FDA regulates the amounts of aluminum present in vaccines to ensure they fall well below toxicity cutoffs.[38]

ANTIBIOTICS

Antibiotics form an important component of the vaccine production process because they help protect the products from contamination. The antibiotics most likely to cause severe allergic reactions in children (e.g. penicillins, cephalosporins, and sulfa drugs) are never used in vaccines. During the purification process, the amount of antibiotic present is reduced to almost undetectable amounts.[38]

FORMALDEHYDE

An organic chemical, formaldehyde is created naturally by the human body during energy production processes and protein synthesis. It is also found in building materials and many household products. The amount of formaldehyde found in vaccines is negligible compared to the amount naturally produced by the human body; vaccines include this small amount only because it is essential to inactivate viruses and bacterial toxins.[38,39]

TABLE 1

VACCINE FACTS
A large body of research demonstrates that vaccines are very safe.[26]
While children receive more vaccines now than in the past, advances in biochemistry mean that children are exposed to significantly fewer antigens using the modern vaccine schedule.[41, 42]
The immune system is not transiently weakened by vaccination. Studies have shown no increase in the risk of infection following vaccination. In fact, vaccinated children experience less overall illness.[41]
Delaying vaccines increases the time that children are susceptible to disease. All evidence shows that the current immunization schedule is safe.[26]
The components of vaccines are carefully considered. The adjuvants and preservatives used in vaccines are needed to keep them safe and effective during storage and use.[35-39]
Many large, well-designed studies have found no link between the MMR vaccine and autism.[50-72, 74]
Texans still suffer from vaccine-preventable disease. More than 1,100 Texas died from vaccine-preventable diseases from 2005-2015.[25] Additionally, Texas experienced a major mumps outbreak in 2016-2017 and a major measles outbreak in 2013.[75]
A large body of evidence debunks the belief that vaccines contribute to the development of chronic disease later in life.[43]

THE CURRENT VACCINATION SCHEDULE AND EFFECTS ON THE CHILD'S IMMUNE SYSTEM

Concerned that the recommended immunization schedule overburdens the child's immune system, some parents seek "alternative" schedules.

The current CDC immunization schedule aims to protect children from 10 vaccine-preventable diseases by age two.[40] While this may seem like a lot for a small child to handle, advances in protein chemistry allow us to expose our children to fewer immunogenic proteins than in the past.[41] In the early 1980s, the number of immunogenic proteins in the vaccine regimen exceeded 3,000. In contrast, today's regimen exposes a child to only 315 immunogenic proteins.[41,42]

To put these numbers into perspective, the number of antigens a child is exposed to in a single day from germs encountered in their normal environment far exceeds the amount of antigen exposure resulting from vaccination.[43]

The number of antigens a child is exposed to in a single day from germs encountered in their normal environment far exceed the amount of antigen exposure resulting from vaccination.[43]

Similarly, studies indicate that childhood immunizations do not overload a young child's immune system. Specialists in pediatric immunology have estimated the capacity of the child immune system. According to these estimates, if a child were administered 11 vaccines at one visit, only 0.1% of his or her total immune system would be utilized in responding to those vaccines. In other words, an infant's immune system can handle to up to 10,000 vaccines at once.[41]

Multiple studies demonstrate that children are not more susceptible to infection following vaccination. In fact, studies have shown that vaccinated children experience fewer overall infections compared to unvaccinated children.[41] For example, a study comparing children vaccinated against diphtheria, pertussis, *Haemophilus* influenza type B, and polio in the first three months of life to similar unvaccinated children showed that the immunized children experienced 50% fewer infectious symptoms such as cough, runny nose, and vomiting.[44]

Additionally, some people believe that the immunity acquired from natural infection is somehow "better." However, vaccine-preventable diseases actually weaken the immune system, leaving children more vulnerable to subsequent infection. For example, evidence suggests that chickenpox weakens a child's immune system, increasing their risk of developing subsequent infections like strep throat.[45] Similarly, unvaccinated children infected with measles experience a remarkable decline in their immunologic functions, leading to increased infection rates for 2-3 years following the infection.[46] Not only do vaccines protect against the disease they were intended to, they also bolster the immune capacity of young children.

Lastly, when creating the recommended immunization schedule, great care goes into ensuring that multiple vaccines can be administered together. When requesting a truncated immunization schedule, some parents worry that co-administration of multiple vaccines will produce harmful interactions. Each time a new vaccine is recommended at an age when other vaccines are already given, the FDA requires companies to conduct "concomitant use studies."

These studies must show that the new vaccines do not interact with or interfere with the safety and efficacy of existing vaccines.[47]

MMR AND AUTISM: A FALSIFIED ASSOCIATION

The autism-MMR link was originally conceived by Andrew Wakefield, a former British gastroenterologist and researcher. In 1998, under private funding from lawyers involved in lawsuits against vaccine manufacturers, Dr. Wakefield studied a group of twelve children who had received the measles, mumps, and rubella vaccination. Based on this statistically insignificant study size and what scientists later critiqued as an "uncontrolled design," Dr. Wakefield published an article in The Lancet speculating that the MMR vaccine may cause autism in children.[48] Shortly after the publication, ten of the twelve scientists working with Dr Wakefield issued a statement requesting to have any association with the study rescinded. In February 2010, The Lancet retracted the paper and held the authors guilty of scientific misrepresentation of data and ethical violations for conducting invasive investigations on children without obtaining ethical clearance. Today, the Wakefield publication is known as "one of the most serious frauds in medical history."[48]

VACCINE COVERAGE AMONG CHILDREN AGES 19-35 MONTHS UNITED STATES, 2014

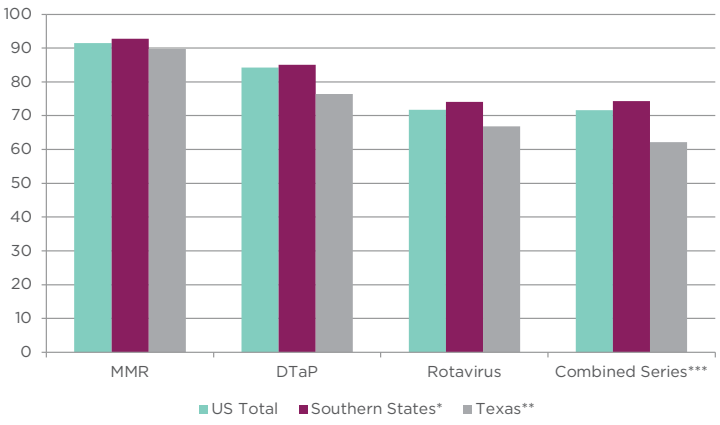


Figure 1. Source: Centers for Disease Control and Prevention, National Immunization Survey, 2014

**Southern States include Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee*

***Texas data excludes Bexar County, The City of Houston, and El Paso County*

****The combined (4:3:1:3*:3:1:4) vaccine series includes ≥4 doses of DTaP, ≥3 doses of poliovirus vaccine, ≥1 dose of measles-containing vaccine, full series of Hib vaccine (≥3 or ≥4 doses, depending on type), ≥3 doses of HepB, ≥1 dose of varicella vaccine, and ≥4 doses of PCV.*

RATES OF NON-MEDICAL VACCINE EXEMPTION IN TEXAS K-12 FROM 2003-2016

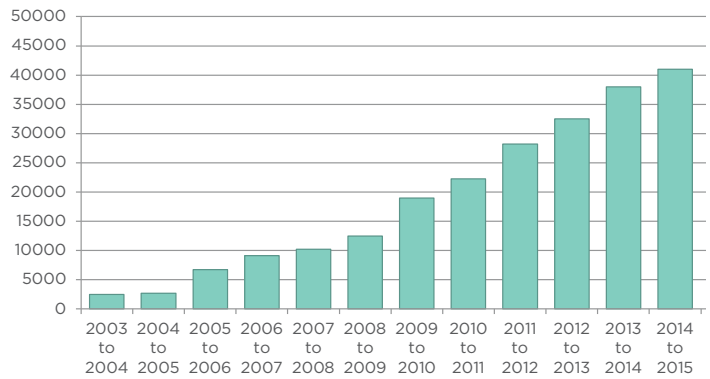


Figure 2. Original figure courtesy of the Immunization Partnership, "A Time for Action: Recommendations for Improving Texas Immunization Rates: Report on the State of the State"[25]

Today, the Wakefield publication is known as "one of the most serious frauds in medical history."[43]

As a result of this falsified report, people began to associate the MMR vaccine with autism. The spread of this misinformation has had dire repercussions. In a 2009 survey of several thousand U.S. parents, 11.5% of parents reported that they had refused at least one recommended vaccine for their child, with many citing the fear that vaccines cause autism.[49]

In response to parental concerns, a large number of research institutions have examined the purported link between the MMR vaccine and Autism Spectrum Disorders. Every single one of these studies has determined through statistically validated scientific trials that the MMR vaccine does not increase a child's risk for developing autism.[50-72]

Like many parents, the medical community is concerned about the prevalence of autism in our country. A significant amount of research has examined the origins of autism spectrum disorders. At present, evidence suggests that early dysfunction of brain neurons in the regions responsible for social, emotional, communication, and language function contribute to the development of autism.[73] These developmental changes occur during the second trimester of pregnancy, indicating that a child is likely destined to have autism before he or she leaves the womb.[73] With the vast amounts of evidence demonstrating that the MMR vaccine does not cause autism, we should dedicate our resources to better understand the causes and treatment of autism instead of generating redundant vaccine safety studies.

FALLING VACCINE RATES IN TEXAS: A TIME BOMB

Public health experts around the state have begun to issue warnings about the dangers posed by rising vaccine exemption rates. 25,27,76 Since non-medical exemptions were first allowed in the state in 2003, the number of exemptions on file has increased 19-fold (see Figure 1). Recently, vaccine coverage in Texas has fallen well below national averages (see Figure 2). This failure to immunize more Texans has come with great cost.

From 2005-2015, 100,000 Texans suffered from vaccine-preventable disease, resulting in over 1,100 deaths.[77]

Furthermore, vaccine refusal rates across Texas vary significantly from community to community, leaving some groups particularly vulnerable. For example, the Austin Waldorf School in Travis County reports vaccine exemptions for over 40% of students while the Regents Academy in Nacogdoches reports exemptions for over 37% of students.[78] These percentages stand in stark contrast to the immunization rates required to provide herd immunity. For example, epidemiological data has shown that at least 95% of a community must be vaccinated in order to prevent a measles outbreak.[27]

Importantly, evidence shows that rising vaccine refusal rates are not without consequence. Individuals with vaccine exemptions are significantly more likely to suffer from vaccine-preventable diseases,[75] with one study showing vaccine exempt individuals were 35 times more likely to contract the measles than vaccinated individuals.[79] Furthermore, communities with high rates of vaccine refusal tend to have higher rates of vaccine-preventable disease in both exempt and nonexempt community members.[75] This finding highlights the public health risk that vaccine exemptions confer to other vaccine-compliant community members.

Furthermore, gaps in herd immunity are already beginning to have concrete consequences in Texas. In December 2016, the Dallas area experienced Texas' worse mumps outbreak in years with at least 48 cases identified as of December 13, 2016.[80] The majority of those infected were school-aged children. Dallas area health authorities believe the outbreak spread rapidly through several local cheerleading competitions.[81] Similarly, a 2013 measles outbreak was sparked by the return of a North Texas man with an unknown vaccine history from a trip to Indonesia. The man acquired the infection abroad before returning home to his vaccine-hesitant church community. At least 21 additional individuals were infected with the measles at the Eagle Mountain International Church of Newark, Texas before the outbreak was contained.[27,82,83] While many vaccine-preventable diseases are no longer endemic to the United States, this narrative illustrates how travelers abroad can reintroduce these diseases upon their return home, triggering dangerous outbreaks.[27,84] Vaccine-preventable diseases are only a plane ride away. These cases highlight the need for policymakers to act promptly to ensure the safety and health of all Texans.

POLICY RECOMMENDATIONS

Given the steady rise in vaccine exemptions across the state, policy makers must act to ensure that all Texans remain healthy and safe. Evidence has shown that states with lenient non-medical vaccine exemption policies—such as Texas—experience higher rates of vaccine-preventable disease.[85] In order to improve vaccination rates in the state, we recommend the following policies.

1. Change the Texas Immunization Registry to an Opt-Out System

Currently, anyone who wishes for their child's vaccination records to be entered into the Texas Immunization Registry (ImmTrac) must sign paperwork to enroll—i.e., "opt into"—the system. In contrast, an opt out system would entail automatic enrollment unless parents signed paperwork to opt out. We propose that the State of Texas changes from an opt-in to an opt-out vaccine registry system. Today Texas is one of only four states (along with Vermont, Montana, and Kansas) that uses an opt-in system. This decision holds serious financial repercussions. A multi-institutional study approved by the Texas Department of State Health Services found that the state spends an annual total of $1,389,800 on obtaining and processing ImmTrac consents.[86] Under the current system an ImmTrac consent completed at birth costs an average of $2.00 per child, while a consent completed at a physician's office costs an average of $2.64 per child.[86] In contrast, an opt-out system would only cost on average $0.29 per child with an annual total cost of $110,710.[86]

In addition to the financial benefits, there are also numerous medical and practical benefits of automatic enrollment in the ImmTrac system. These include:

- Reduction of unnecessary revaccination when parents cannot find immunization records
- Seamless transition of care when families move or change medical providers
- Efficient location of records by public health agencies during emergencies that require large populations to move (e.g. Hurricane Katrina)

In order to protect decisional rights, health care providers can provide families with clear instructions on how to opt their children out of the registry if so desired.

2. Release School-Specific Data on Vaccine Exemption Rates to Empower Families to Make the Best Choices for Their Child

The State of Texas must protect the right of families to choose a safe school environment for their children. We believe that parents have the right to know about the dangers that their children face in school. Due to the state's failure to disclose immunization rates in by school, parents are currently unable to make informed decisions about where to send their children to school safely. Parents of children with weakened immune systems face particular uncertainty and anxiety. Importantly, many types of health conditions exist that can result in a weakened immune system. In medicine, we call these patients "immunosuppressed." These immunosuppressed children have either diseases that weaken the immune system or chronic health conditions that require them to take medications that impair their ability to fight infection. This population includes children born with immune deficiency syndromes, children diagnosed with cancer receiving chemotherapy, children with organ transplants on lifelong immunosuppressive drugs, and countless others.[87] These children rely on high rates of immunization uptake in their surrounding communities because they often cannot receive vaccines. They are particularly vulnerable to vaccine-preventable disease and face serious risk in schools where immunization rates fall short of the percentages required for herd immunity.

We support legislation to create a public listing of the annual immunization exemption rates for each state-funded school. Such legislation would give families the information they need to decide where their children can attend school safely. Importantly, schools across Texas already provide data to the Texas Department of State Health Services every year about the number of immunized and unimmunized students in attendance.[88] The department then publishes immunization rates by school district. Consequently, this legislation would not require more data to be collected; it simply introduces additional transparency into immunization reporting across the state.

Several states have already taken such measures. Table 2 explores existing legislation across the country.

TABLE 2

State Law	What does the policy require?	What party is responsible for implementing the policy?	When was this policy implemented?
Illinois SB 1410 HB 2560	Publish school specific immunization exemption rates on the State Board of Education website.	Illinois State Board of Education	August 2015
Washington RCW28A. 210-110 WAC 246-105-060	Private and public schools are required to submit grades K-12 immunization data. The Washington Department of Health must create publicly available reports on the immunization rates of private and public students.	Washington State Department of Health: Immunization and Child Profile office	March 2014
Vermont H98	Requires schools and child care facilities to provide immunization rates and types of exemptions (religious or medical) at the start of each academic year.	Vermont Department of Health, Agency of Education for Schools, Department for Children and Families	May 2015
Colorado HB 14-1288	All schools including charter, private and child care facilities are required to make vaccination rates and personal belief exemptions publicly available upon request	Colorado Board of Health, Colorado Department of Public Health and Environment	May 2014

In Illinois, SB 1410/HB2560 requires the State Board of Education to publish immunization exemption rates on its website based on data provided by schools. This bill, passed in 2015, attempts to curb rising vaccine refusal rates in other ways. Specifically, SB 1410/HB2560 requires parents seeking non-medical vaccine exemptions to undergo counseling by a licensed healthcare provider.[89,90,91]

Beginning in 2014, Washington state law RCW28A 210-110 and WAC 246-105-060 require all Washington public and private schools to submit immunization data for grades K-12.[92] The schools must send their data annually to the Immunization and Child

Profile Office, a division of the Washington State Department of Health, by November 1st. The ICPO then produces publicly available reports on the immunization rates of private and public students.[93]

Vermont and Colorado have also passed laws requiring publicly available exemption rates. Vermont H98 requires schools and child care facilities to provide aggregate student immunization rates along with medical and religious exemption rates to the Vermont Department of Health at the start of each academic year.[91,94] In Colorado, HB 14-1288 requires all charter, private and child care facilities to make vaccination rates and percentage of children who claimed a personal belief exemption publicly available upon request. The Colorado Board of Health and the Department of Public Health and Environment are responsible for the collection and publication of these rates. Additionally, this act requires immunization data sharing between state agencies.[95,96]

In a 2016 survey of Texas health care professionals, 95% agreed that families seeking non-medical exemptions should first undergo instruction regarding the risks and benefits of vaccination.[25]

Texas should follow other states in the creation of a public database listing annual immunization exemption rates for each state-funded Texas school. This database would provide parents and guardians with the information that they need to make important decisions regarding the safety of their children in school.

3. Require Online Education Modules for Non-Medical Vaccine Exemptions

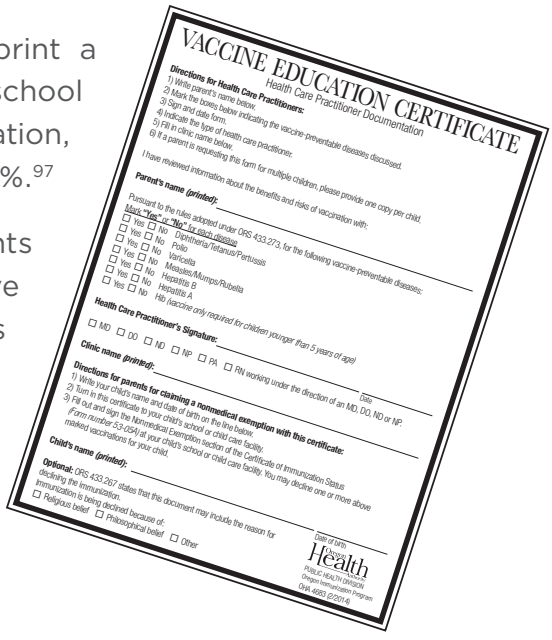
Under the current system, Texas families seeking non-medical vaccine exemptions simply sign and submit a notarized affidavit to their child's school. Given the significant amount of misinformation circulating on the internet and social media, policy makers should ensure that all families have access to accurate facts regarding immunizations. Furthermore, some families opt for vaccine exemptions simply because filling out a form presents a more convenient alternative to making a trip to the doctor's office. Requiring parents to first take part in an educational module before opting out of immunizations for their children would empower parents to make thoughtful, informed decisions while still giving them freedom of choice.

In a 2016 survey of Texas health care professionals, 95% agreed that families seeking non-medical vaccine exemptions should first undergo instruction regarding the risks and benefits of vaccination.[25]

Evidence shows that this type of policy can significantly increase the number of children protected by vaccines. For example, in 2013 Oregon passed a law requiring that parents seeking non-medical exemptions provide documentation of participation in an interactive, online educational module or in a discussion with a licensed physician.[97] The law requires the Oregon Health Authority (OHA) to develop an educational module based on information published by the CDC concerning epidemiology, "the safety and efficacy of vaccines" and "the prevention of disease through the use of vaccinations."98 As a result of the legislation, the OHA has developed an online module that takes parents 15-60 minutes to complete, depending on the number of vaccines from which the parent desires exemption.

After completion of the module, the parents print a certificate of completion to submit to their child's school administration.[99] Following the law's implementation, vaccine exemption rates in the state declined by 17%.[97]

There are several ways to ensure that parents seeking non-medical vaccine exemptions have access to accurate information regarding the risks and benefits of immunization. Table 3 examines policies implemented by other U.S. states.



VACCINE EDUCATION CERTIFICATE

Health Care Practitioner Documentation

Directions for Health Care Practitioners:

1) Write parent's name below.
2) Mark the boxes below indicating the vaccine-preventable diseases discussed.
3) Sign and date form.
4) Indicate the type of health care practitioner.
5) Fill in clinic name below.
6) If a parent is requesting this form for multiple children, please provide one copy per child.

I have reviewed information about the benefits and risks of vaccination with:

Parent's name (printed): _____

Pursuant to the rules adopted under ORS 433.273, for the following vaccine-preventable diseases:

Mark "Yes" or "No" for each disease

- ☐ Yes ☐ No Diphtheria/Tetanus/Pertussis
- ☐ Yes ☐ No Polio
- ☐ Yes ☐ No Varicella
- ☐ Yes ☐ No Measles/Mumps/Rubella
- ☐ Yes ☐ No Hepatitis B
- ☐ Yes ☐ No Hepatitis A
- Hib (vaccine only required for children younger than 5 years of age)

Health Care Practitioner's Signature: _____

☐ MD ☐ DO ☐ ND ☐ NP ☐ PA ☐ RN working under the direction of an MD, DO, ND or NP.

Clinic name (printed): _____ Date _____

Directions for parents for claiming a nonmedical exemption with this certificate:

1) Write your child's name and date of birth on the line below.
2) Turn in this certificate to your child's school or child care facility.
3) Fill out and sign the Nonmedical Exemption section of the Certificate of Immunization Status (Form number 53-054) at your child's school or child care facility. You may decline one or more above marked vaccinations for your child.

Child's name (printed): _____ Date of birth _____

Optional: ORS 433.267 states that this document may include the reason for declining the immunization.

immunization is being declined because of:

☐ Religious belief ☐ Philosophical belief ☐ Other

Oregon Health

PUBLIC HEALTH DIVISION

Oregon Immunization Program

OHA 4685 (12/01-I)

TABLE 3

State Law	Entity Responsible for Providing Accurate Vaccine Information	Policy Specifics
Arizona Revised Statutes § 15-873	Department of Health	The parent or guardian must submit a signed statement to the school administrator stating that they have "received information about immunizations provided by the department of health services and understand the risks and benefits of immunizations and the potential risks of nonimmunization."[100]
Utah Code § 53A-11-302.5(1)	Department of Health	Since 1992, Utah has required the Department of Health to provide local health departments with a form for parents or guardians claiming non-medical vaccine exemptions for their children. The form must "include a statement printed on the form and drafted by the Department of Health stating the department's position regarding the benefits of immunization."[101]
Vermont Statutes 18 V.S.A. § 1122	Department of Health	Requires parents or guardians claiming non-medical vaccine exemptions for their children to provide the school with a signed form created by the Department of Health stating that they have "reviewed evidence-based educational material provided by the Department regarding immunizations, including: (i) information about the risks of adverse reactions to immunization; (ii) information that failure to complete the required vaccination schedule increases risk to the person and others of contracting or carrying a vaccine-preventable infection; and (iii) information that there are persons with special health needs attending schools and child care facilities who are unable to be vaccinated or who are at heightened risk of contracting a vaccine-preventable communicable disease and for whom such a disease could be life-threatening."[102]
Oregon Statutes §433.267	Department of Health or Healthcare Provider	Passed in 2013, the law requires parents or guardians seeking non-medical vaccine exemptions for their children to submit to the school administration either (1) a "certificate verifying that the parent has completed a vaccine educational module" developed by the Oregon Health Authority or (2) a signature from a health care provider verifying that the provider "reviewed with the parent information about the risks and benefits of immunization that is consistent with information published by the Centers for Disease Control and Prevention and the contents of the vaccine educational module" approved by the Oregon Health Authority.[103]
Revised Code of Washing-ton 28A. 210.090	Healthcare Provider	Passed in 2011, the law requires parents or guardians seeking non-medical vaccine exemptions for their children to present a form created by the state health department with the signature of a healthcare provider "stating that he or she provided the signatory with information about the benefits and risks of immunization to the child."[104]
Illinois School Code 105 ILCS 5/27-8.1 on Statutes §433.267	Healthcare Provider	Passed in 2015, the law requires parents seeking non-medical vaccine exemptions for their children to present to the school administration a "signed Certificate of Religious Exemption detailing the grounds for objection" that includes the signature of a health care provider confirming that he or she "provided education to the parent or legal guardian on the benefits of immunization and the health risks to the student and to the community of the communicable diseases for which immunization is required in this State."[105,106]

In 2015, California passed Senate Bill 277, eliminating non-medical vaccine exemptions for students receiving classroom-based instruction. 107 California joined West Virginia and Mississippi as the only 3 states in the nation to ban non-medical vaccine exemptions. However, prior to the implementation of S.B. 277, California legislators sought other routes to combat rising vaccine exemption rates in the state. In 2012, California passed a law requiring parents or guardians seeking non-medical vaccine exemptions for their children to submit a letter from their healthcare provider to their school. In order for the exemption to be approved, the letter had to attest that the provider had given the parent "information regarding the benefits and risks of the immunization and the health risks of the communicable diseases [...] to the person and to the community." The law also required the parent or guardian to submit a written statement confirming that the parent or guardian received the information given by the healthcare provider. It applied to both public and private institutions and went into effect on January 1, 2014.[108] Following the implementation of the law, non-medical vaccine exemption rates fell among kindergarteners in the state. In the 2013-2014 school year, an average 3.15% of kindergarteners had non-medical vaccine exemptions, falling to 2.54% for the 2014-2015 school year.[109]

Texas should follow other states in ensuring that families have access to accurate facts regarding immunizations. Evidence suggests that these types of policies can significantly improve immunization rates.

4. Invest in Teaching Healthcare Providers to Counter Vaccine Misinformation

Primary care providers have a strong influence on the vaccination dialogue. For example, pediatricians have been cited as having the greatest impact on a family's choice to vaccinate.[28,110] When parents come to the office with vaccination concerns, health care professionals should be adequately prepared to correct misinformation and have meaningful dialogues about the benefits of vaccines. However, currently there are no official guidelines on vaccine education for healthcare professionals, which leads to varying degrees of knowledge on vaccines. As a result, parents may turn to less reputable sources for vaccine information. Therefore, the state of Texas should invest in training health care providers to utilize effective communication strategies that address vaccine concerns and correct misinformation.

A number of educational resources are already available, making this approach feasible. The Teaching Immunization for Medical Education (TIME) modules are ready-to-use course materials created by the Association For Prevention Teaching and Research.

These modules, comprised of free guides, booklets, and Powerpoints, give future healthcare professionals an in-depth course on immunizations, schedules, and

indications. In a study of 20 medical schools and primary residency programs across the United States, the TIME program has been shown to increase overall medical student and physician knowledge about vaccines.[111] Likewise, the CDC and AAP have put forth resources that can be incorporated into continuing medical education. CDC's "You Call the Shots" is a free, up-to-date web-based training course with the latest guidelines and recommendations about vaccine practice.[114]

For established physicians, vaccine educational modules have been shown to have a positive effect on vaccination rates. From 2009-2013, the quality improvement of 1,216 healthcare professionals were analyzed before and after the use of AAP clinical education modules. After completion of the immunization counseling module, immunization rates within the practices of the 1,216 healthcare professionals improved in adolescents and toddlers by 21% and 20%, respectively.[113]

The state of Texas must set guidelines to incorporate vaccine modules into medical education. Doing so will benefit families by training future and present physicians to facilitate productive dialogues about vaccines.

5. Require that the Texas Department of Health Publish an Annual Report on HPV Immunization Rates

The human papillomavirus (HPV) is the most common sexually transmitted infection in the United States. Each year HPV infects 14 million people, with over half of the U.S. population acquiring the virus in his or her lifetime.[114] While the majority of individuals with HPV have no symptoms of infection, HPV infection is the primary cause of both genital warts and cervical cancer. As a result of HPV infection, an estimated 10,000 American women are diagnosed with cervical cancer every year with an associated 3,700 deaths annually.[115] Furthermore, HPV causes significant death and disease in men as well. Nearly 5,700 American men are diagnosed with HPV-associated cancers of the head and neck annually.[115]

During the six years following the introduction of the HPV vaccine, surveillance studies found a 64% decrease in the prevalence of HPV strains covered by the vaccine among girls ages fourteen through nineteen.[116]

While no treatment or cure currently exists for HPV, the HPV vaccine protects against the most common cancer-causing strains of the virus. During the six years following the introduction of the HPV vaccine, surveillance studies found a 64% decrease in the prevalence of HPV strains covered by the vaccine among girls ages fourteen through nineteen.[116]

Given the clear life-saving benefits of this vaccine, we support legislation that requires the Texas Department of Health to publish an annual report detailing statewide immunization rates for HPV. As seen in Figure 3, Texas falls below the national average for HPV vaccination rates.[117] Health professionals and public health officials currently possess limited means to understand the reasons for Texas' failure to achieve widespread HPV vaccine administration. Widely available data on HPV vaccination rates will enable state officials and health professionals to identify specific barriers to HPV vaccination—such as lack of information or limited access to primary care providers—that affect each region. This data will be used to better allocate funds towards increasing HPV vaccine uptake in lagging regions of our state. Furthermore, such a measure would enable the state health authorities to accomplish the goals outlined by HB 1282, which was passed by the House in 2015. This bill mandated that the Department of State Health Services develop a strategic plan to significantly reduce morbidity and mortality from HPV-associated cancer.

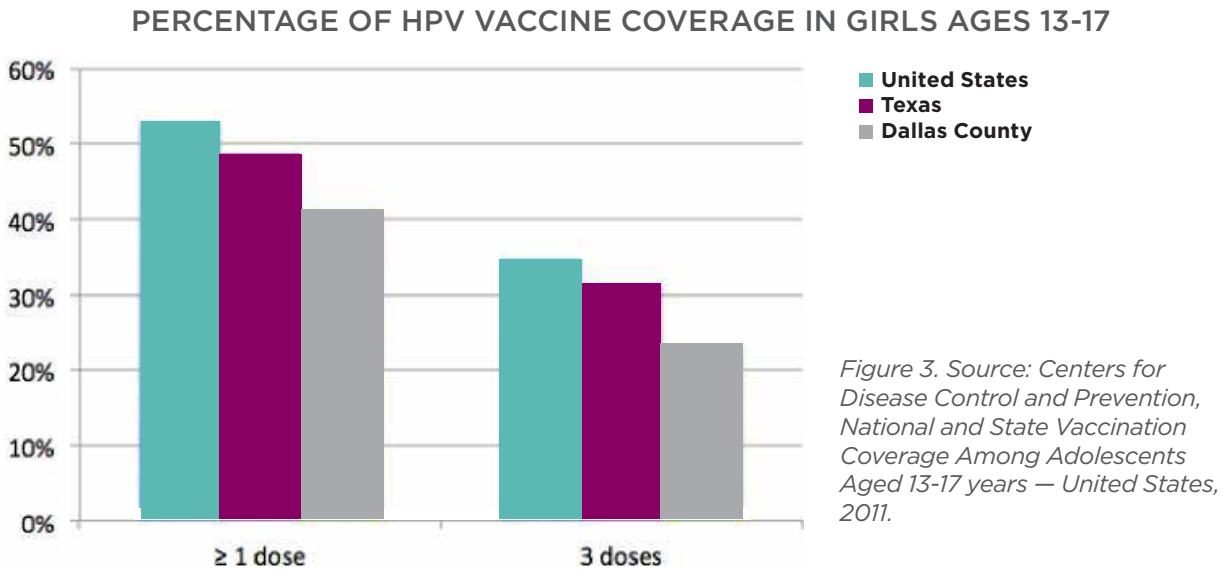


Figure 3. Source: Centers for Disease Control and Prevention, National and State Vaccination Coverage Among Adolescents Aged 13-17 years — United States, 2011.

6. Neutralize the Legal Language Surrounding Vaccine Exemptions by Changing the Wording from "Reasons of Conscience" to "Non-Medical Exemption"

Texas Education Code Section 38.001 allows parents or guardians to refuse the recommended immunization requirements for entry of their child into school based on "reasons of conscious."118 We believe the language of this legislation should be changed to accurately describe vaccine objection. Describing "conscience" as the reason for objecting to immunization implies that parents or guardians refusing vaccination for their children have done so as a result of superior moral judgement.[25] This wording leaves the impression that refusing vaccinations for one's child forms a better choice. The language should read "non-medical reasons" instead of "reasons of conscious."

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