

School Vaccination Requirements in the Commonwealth

Joint Commission on Health Care
Healthy Living / Health Services Subcommittee Meeting
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Stephen Weiss
Senior Health Policy Analyst

Study Background

- HB 1342 (Delegates Filler-Corn and Stolle) was introduced during the 2016 General Assembly session. As written the bill amended § 32.1-46 by striking subsections D.1. and D.2. removing religious and medical exemptions and by adding “if the vaccine is medically contraindicated” as the only exemption.
- HB 1342 was stricken by the patron.
- Delegates Filler-Corn and Stolle requested that the JCHC study the requirements surrounding school vaccinations and make recommendations as to whether non-medical exemptions should be tightened for children attending public schools, private schools, child care centers, nursery schools and family day care home or developmental centers.
- The request asked the Commission include the following information in its study:
 - How the inoculation serum is discovered, developed and marketed – the science behind the making of a vaccine;
 - What is “vaccine efficacy” and how accurate is it in terms of effectiveness;
 - What childhood illnesses are making a comeback due to public attitudes toward immunization and where is this occurring in the country;
 - How do vaccinations get on the CDC recommended schedule lists;
 - What do the different states require, and their laws, related to vaccinations for children entering public schools and private schools;
 - What is required for passports in order to travel to other countries;
 - Is there a scientific reason why people oppose vaccinations;
 - Is there a medical reason why people oppose vaccinations;
 - What religions traditionally oppose vaccinations;
 - Do the risks scientifically outweigh the rewards of vaccination?

Additional Questions to Consider

- During the May 26, 2016 meeting of the Joint Commission on Health Care Delegate Bulova asked the Commission to consider 17 additional questions submitted to him by Barbara Caceres.
- The questions are included on the next two slides.

Additional Questions

Submitted May 26, 2016

How many children/families take exemptions in Virginia?
How do these numbers compare to exemptions in other states?

What does the Virginia Constitution say about conscience and religious freedom?

What does the US Constitution say about religious freedom?

What is the history and rationale of the principle of medically informed consent and what does it mean with regard to the mandated injection of pharmaceutical products into children and adults?

What is the “precautionary principle” and how does it relate to vaccines?

In cases of outbreaks of diseases for which people are vaccinated (mumps, for instance), what percentage of those people who contract the disease are vaccinated vs. not vaccinated?

Is the theory of herd immunity correctly applied to vaccine-induced temporary protection or was it developed to describe what happens when wild viruses give people lifelong natural immunity?

“Protecting the immune compromised” is often heard as the rationale for vaccinating all children. What does the CDC recommend with regard to vaccination of immune compromised children?

Is it reasonable to expect a zero occurrence of viral diseases when live virus vaccines (i.e. MMR, rotovirus, varicella, flumist) carry a risk of viral “shedding” and therefore recently vaccinated people can potentially spread the disease? What guidance do the manufacturer’s inserts give for dealing with the issue of viral shedding?

Additional Questions

Submitted May 26, 2016

“Sizeable outbreaks” of measles have been reported in other states. Exactly how many people were infected and what was the health outcome of those who were infected? In terms of relative numbers, how do those numbers compare to the incidence of other diseases that affect children such as asthma, autism, cancer, diabetes or epilepsy, or things like suicide or gun violence?

What is the pharmaceutical industry’s role in influencing vaccine policy at both the federal and state level and does their role raise any concerns about conflicts of interest with those making policy?

Are there any long-term clinical studies that have used true placebo controls (using saline, not adjuvants) to compare the health of vaccinated people to completely not vaccinated people?

Are there any benefits to children to getting acute inflammatory diseases in childhood and obtaining the immunity derived from those exposures?

Do any vaccines contain aborted fetal tissue, foreign DNA or genetically altered material that would pose a particular problem for the religious beliefs of people?

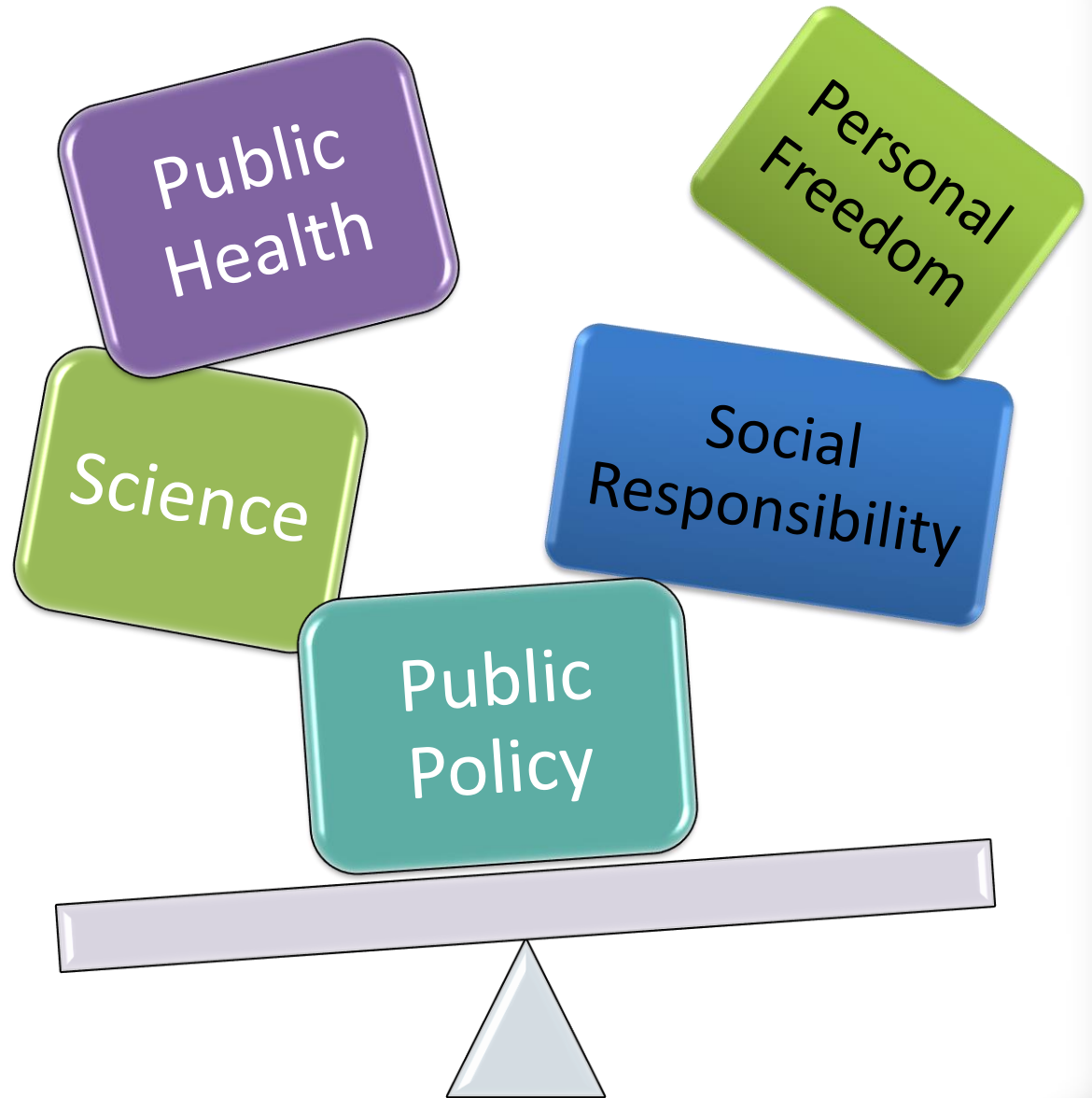
Do vaccines contain ingredients that are known neurotoxins, carcinogens, or that can cause infertility? Is “death” listed as a possible side effect on the manufacturer’s insert for any of the childhood vaccines mandated in Virginia?

What is the difference between efficacy and effectiveness?

Are physicians and nurses trained to detect vaccine adverse reactions/injury and are they required to report them to the VAERS (Vaccine Adverse Event Reporting System)? How many reactions are reported to VAERS each year? What percentage of vaccine reactions are estimated to be reported to VAERS?

The Balancing Act of Vaccination Policies

- Vaccination / Immunization policies are a balancing act between public health, science, personal freedoms, social responsibility, and public policy.
- Vaccination policy and requirements ask people to forgo their individual choice for the good of the whole, the general public.
- Disease science explains in detail why vaccination policies are important public policy and good for promoting public health.
- Success of the policy was originally defined by comparing death rates between those immunized to those not immunized.
- Over time it was observed and documented that even those who were immunized and still became ill with a disease suffered less with reduced long term side-effects.



Modern Day Vaccines - Introduction

- Smallpox is one of the first diseases recorded in history that was recognized as preventable through a form of “immunization.” Records dating as far back as 960 A.D. reveal that the Chinese inhaled dried powder of smallpox crusts through the nose in a manner similar to taking snuff to create an “immunization” from the disease. (1)
- The ingredient for the original smallpox “inoculation” was the disease itself taken from a sick person and mixed into a healthy person. The risks from using the disease to create immunity were obvious – the person receiving the inoculation got smallpox to create immunity.
- Making people sick to keep them healthy is counterintuitive, goes against our understanding of the purpose of medical treatment, and was difficult for most people to understand. As a result, smallpox inoculations were controversial from the beginning during the Colonial American period and then after the revolution; the controversy was also acute in Great Britain and Europe.
- The discovery of a safer alternative to the live disease occurred in the late 1700s. Using cowpox instead of smallpox meant that immunity from the disease could be achieved without making people sick first. But using something other than the disease itself made the issue of vaccination even more complex, difficult to explain, and hard to understand.
- In addition, the discovery of “Germ Theory” during the 1800s led to the development of more vaccines for different infectious diseases. Germ theory also contributed to the promotion of sanitation programs designed to prevent, end, and stop the spread of many other infectious diseases; cholera, typhoid fever, etc.
- While the development of vaccines and the sanitation movement occurred at the same time and were both designed to accomplish the same things neither one is a substitute for the other, in fact they work together. There are diseases that only vaccines can address and there are diseases that only good sanitation can address.

Attitudes About Vaccines

Survey of U.S. Adults and Members of the American Association for the Advancement of Science (AAAS) (2)

Childhood Vaccines

% of each group saying ...

	—Among AAAS members surveyed—			
	All AAAS members surveyed	Working Ph.D. Scientists	Active Research Scientists	U.S. adults
All children should be required to be vaccinated	86	87	87	68
Parents should be able to decide not to vaccinate their children	13	13	13	30
No answer	1	1	1	1
N	3,748	1,627	1,246	2,002

AAAS survey Sept. 11-Oct. 13, 2014. “Working Ph.D. Scientists” are those employed full time who have a doctorate degree in a medical, natural or physical science; “Active Research Scientists” are “Working Ph.D. Scientists” who also report having received a research grant within the past five years.

Changing Opinion On Vaccines 2001 Compared To 2015 (3)

How important is it that parents get their children vaccinated -- extremely important, very important, somewhat important, not very important, or not at all important?

	Extremely important	Very important	Somewhat important	Not very important	Not at all important
	%	%	%	%	%
Feb 28-Mar 1, 2015	54	30	11	2	2
Jun 28-Jul 1, 2001	64	30	4	*	1

* Less than 0.5%

Note: % No opinion not shown

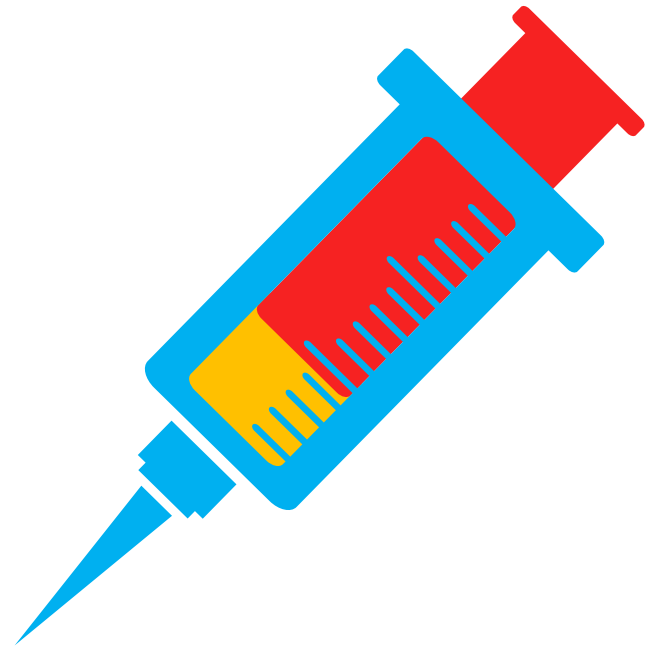
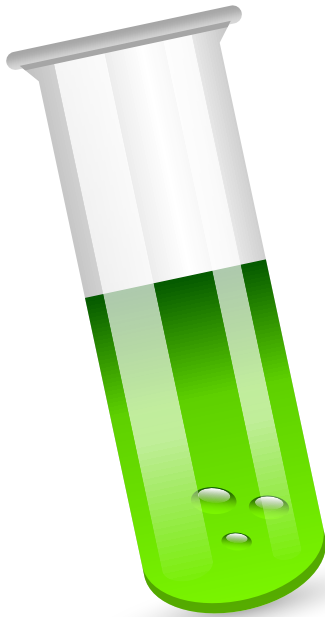
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How much have you, personally, heard about the advantages/disadvantages of vaccinations for children -- a great deal, fair amount, only a little, or nothing at all?

	A great deal	Fair amount	Only a little	Nothing at all
	%	%	%	%
ADVANTAGES				
Feb 28-Mar 1, 2015	49	34	13	4
Jun 28-Jul 1, 2001	37	36	17	9
DISADVANTAGES				
Feb 28-Mar 1, 2015	30	43	18	9
Jun 28-Jul 1, 2001	15	24	32	28

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The Making of Vaccines



Oversight and Regulations

- Two federal agencies have primary responsibility for overseeing, regulating and insuring vaccine safety in the United States.
- The Food and Drug Administration, Department of Health and Human Services
 - Reviews data and ingredients of vaccines for safety, efficacy and effectiveness;
 - Regulates the vaccine by insuring the ingredients are safe and the package inserts accurately reflect the content of the vaccine and any adverse effects pre- and post-licensure;
 - Monitors safety through cooperative systems with the CDC. (4)
- The Center for Disease Control, Department of Health and Human Services
 - Monitors and reports on vaccine preventable diseases in the US and world;
 - Monitors vaccines for safety and effectiveness through cooperative systems with the FDA;
 - Operates the Clinical Immunization Safety Assessment (CISA) Project, a national network of vaccine safety experts from the CDC's Immunization Safety Office (ISO), seven medical research centers;
 - Sets the immunization schedule for the United States based on recommendations from the Advisory Committee on Immunization Practices (ACIP). (5)

FEDERAL AGENCIES INVOLVED IN VACCINE SAFETY

Federal Agency	Description of Role	Outside Organizations
National Institutes of Health (NIH)	Researches/ develops new vaccines. Evaluates existing vaccines.	
Vaccine Injury Compensation Program (VICP)	Resolve vaccine injury claims; compensates those found injured as a result of vaccines.	The Advisory Commission on Childhood Vaccines (ACCV) makes recommendations on the operation of the VICP. A special master or the court, within the United States Court of Federal Claims, issues legal decision on claims.
National Vaccine Program Office (NVPO)	Coordinates vaccine-related activities between federal agencies, provides leadership to carry out the disease-prevention goals of the National Vaccine Plan.	National Vaccine Advisory Committee.
Countermeasures Injury Compensation Program (CICP)	Provides compensation for serious injuries that occur as the result of countermeasures taken during a public health emergency or a security threat. There have only been 6 public health emergencies since the program began in 2010.	

Creating Immunity from Disease

- There are two ways of acquiring immunity — by natural infection and by vaccination.
- Natural infections and vaccines produce a very similar end result — immunity — but the person who receives a vaccine does not endure the illness and its potential life-threatening complications and is not contagious. (6)
- The goal of all vaccines is to create a response from the body's immune system against an antigen. The antigen may be the disease or a part of the disease that causes a reaction depending on the science and research involved.
- Once the immune system responds it “remembers” the antigen and is able to respond when exposed again.
- In most cases the response to a vaccine prevents the disease from taking hold in the body, in some cases it reduces the effects of the disease and in a very small percentage of cases the immune system may not respond at all.

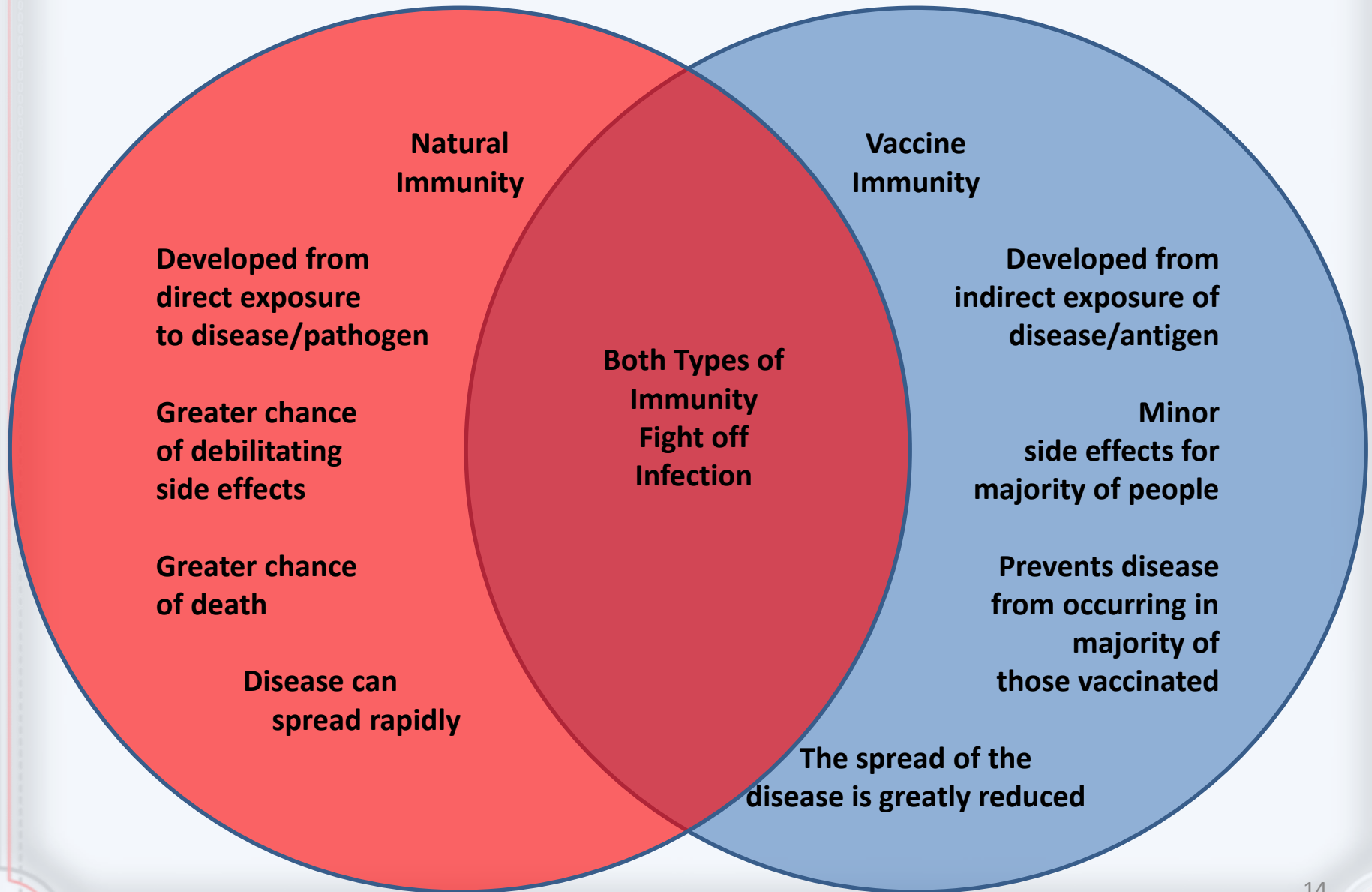
A weakened version of the pathogen is identified or genetically modified

This is given to the person to be vaccinated (normally by injection)

The person's immune system responds - their body notices antigens (foreign proteins) on the pathogens

White blood cells (lymphocytes) then produce antibodies which destroy the pathogens

Natural Immunity Compared To Vaccine Induced Immunity



Do Vaccines Work? (23)

Impact of Vaccines in the 20th & 21st Centuries

Comparison of 20th Century Annual Morbidity & Current Morbidity

Disease	20 th Century Annual Morbidity*	2013 Reported Cases [†]	% Decrease
Smallpox	29,005	0	100%
Diphtheria	21,053	0	100%
Pertussis	200,752	28,639	86%
Tetanus	580	26	96%
Polio (paralytic)	16,316	1	>99%
Measles	530,217	187	>99%
Mumps	162,344	584	>99%
Rubella	47,745	9	>99%
CRS	152	1	99%
<i>Haemophilus influenzae</i>	20,000 (est.)	31 [‡]	>99%

Sources:

* JAMA. 2007;298(18):2155-2163

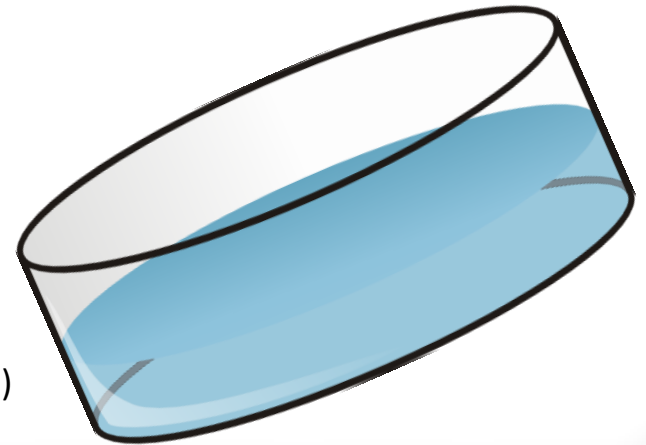
† CDC. MMWR August 15, 2014;63(32):702-715. (MMWR 2013 final data)

‡ *Haemophilus influenzae* type b (Hib) <5 years of age. An additional 10 cases of Hib are estimated to have occurred among the 185 reports of Hi (<5 years of age) with unknown serotype.

- A 2007 article appearing in the Journal of American Medicine reviewed historical records to establish prevaccine estimated annual averages per disease and determine the number of (reported or estimated) cases, deaths, and hospitalizations (when available) for vaccine-preventable diseases. For comparison purposes the CDC updated the reported cases for 2013. (7)

What is in a Vaccine?

- An Antigen – any substance that causes the immune system to produce antibodies against it. The production of antibodies means your immune system does not recognize the substance, and is trying to fight it off. Any part of an antigen can be used in a vaccine; the choice depends on information about the microbe, such as how it infects cells and how the immune system responds to it.
 - An adjuvant, such as aluminum salts, is added in some vaccines to create a stronger immune response. In the US, vaccines against measles, mumps, rubella, chickenpox, rotavirus, polio, and seasonal influenza vaccines do not contain added adjuvants.
 - Antibiotics help prevent bacterial contamination during manufacturing. Antibiotics that are most likely to cause severe allergic reactions (e.g., penicillin, cephalosporin and sulfa drugs) are not used.
 - Diluted formaldehyde is added to some vaccines to inactivate viruses so that they don't cause disease (e.g., polio virus used to make polio vaccine) and to detoxify bacterial toxins, such as the toxin used to make diphtheria vaccine.
 - Stabilizers, such as sugars, amino acids, and proteins may be added to help protect the vaccine from adverse conditions during manufacturing, i.e. for those vaccines that are freeze dried.
 - Preservatives are added to some vaccines to prevent the growth of bacteria or fungi that may be introduced during the vaccine's use.
 - Fetal calf/bovine serum may be used as a source of nutrition for viral cells during the manufacturing process. (Eggs are used in flu vaccines.)
- (9)



Antigens for Selected Vaccines

Live attenuated (LAV)

- Tuberculosis (BCG)
- Oral polio vaccine (OPV)
- Measles
- Rotavirus
- Yellow fever

- Live Attenuated Vaccines are prepared from living micro-organisms that have been weakened under laboratory conditions.

The antigen replicates and produces an immune response; it usually causes mild or no disease. Produces an excellent immunity.

Inactivated (killed antigen)

- Whole-cell pertussis (wP)
- Inactivated polio virus (IPV)

- Inactivated vaccines are made from microorganisms that have been killed through physical or chemical processes. These killed organisms cannot cause disease.

The immune response is less strong than that of the live attenuated vaccines and several doses may be required to achieve desired levels of immunity.

Subunit (purified antigen)

- Acellular pertussis (aP),
- *Haemophilus influenzae* type B (Hib),
- Pneumococcal (PCV-7, PCV-10, PCV-13)
- Hepatitis B (HepB)

- Subunit vaccines contain only the parts of the disease cell necessary to create an immune response.

The development of this type of vaccine can be costly due to the research needed to determine which parts of the disease cell create an immune response.

Toxoid (inactivated toxins)

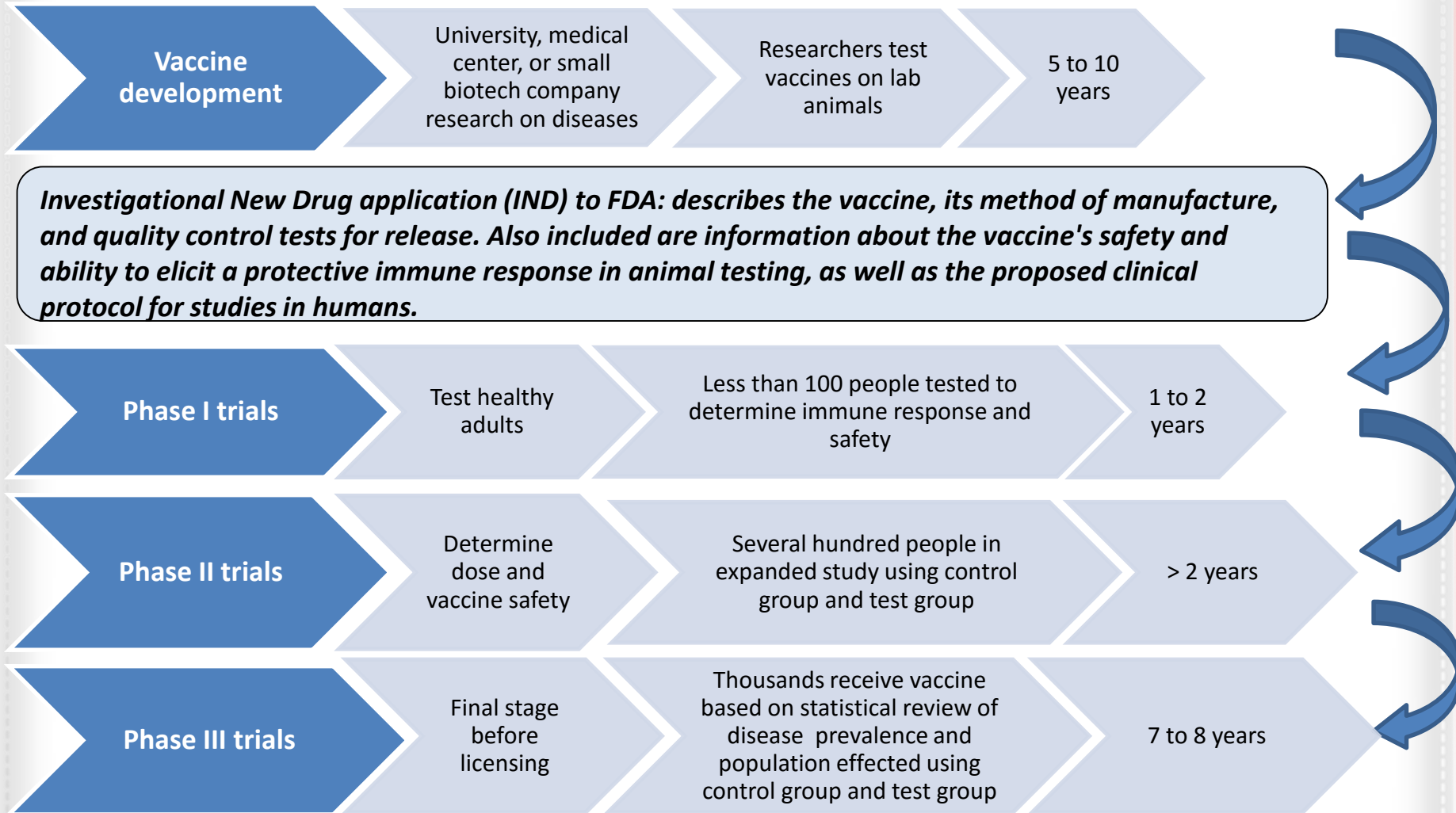
- Tetanus toxoid (TT),
- Diphtheria toxoid

- Toxoid vaccines are made from the toxin produced by certain bacteria. The toxin is made harmless during production.

To increase the immune response, the toxoid is adsorbed in aluminum or calcium salts, which serve as adjuvants. (8, 9)

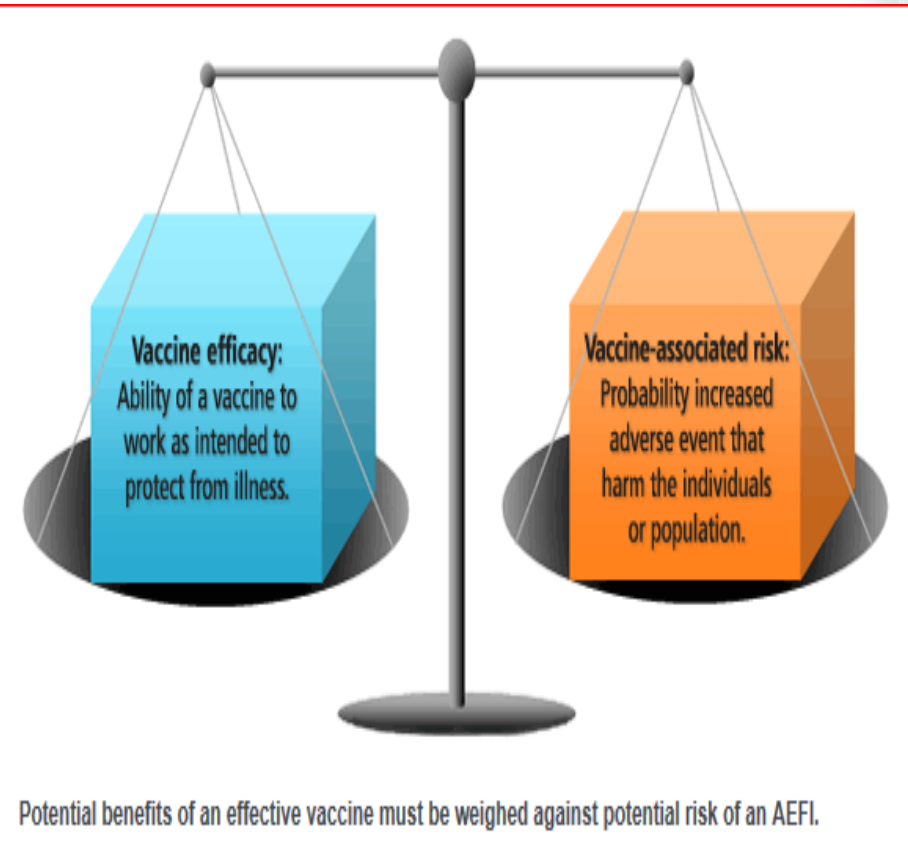
FDA: Process Of Creating A Vaccine And Getting It Licensed

Determining “Efficacy” (10)



Weighing The Risk Against The Benefit

- Vaccine **efficacy** is defined as the reduction in the incidence of a disease among individuals who have received a vaccine compared to the incidence in unvaccinated people;
 - efficacy is measured in phase 2 or phase 3 of clinical trials by giving one group a vaccine and comparing the incidence of disease in that group to another group who do not receive the vaccine;
 - group sizes vary depending on the disease and its impact on general populations.
- Vaccine **effectiveness** is the ongoing assessment of whether a vaccine is preventing the intended disease from occurring or spreading in the general population.
- Throughout the entire process the FDA and the manufacturer monitor and report on safety, side effects and any other abnormal responses a vaccine may cause in the test groups as well as the general population over time. (4)
 - The pre-licensure studies identify common and acute undesirable reactions that occur during the studies.
 - There is continuous post-licensure monitoring of vaccine safety worldwide.



<http://vaccine-safety-training.org/balancing-efficacy-and-safety.html>

Adverse Reactions & Adverse Events

- The FDA may request additional information through more studies or halt existing studies at any stage of development or post-marketing if data raise significant concerns about either safety or effectiveness.
- A vaccine has to pass through all three phases of clinical studies before the manufacturer can apply for a Biologics License.
- The pre-licensure studies often identify common and acute undesirable reactions that occur with a frequency greater than 1 in 10 000 vaccinations, depending on total sample size of the study. The sample size is determined mathematically based on the disease. (9)

Rotavirus - Adverse Events and the Re-making of a Vaccine

- The rotavirus is the most common cause of severe diarrhea in children and infants.
- Before the vaccine the disease caused over 400,000 doctor visits and 200,000 emergency room visits annually.
- Estimated number of deaths for children under 5 was 60 per year.
- A vaccine was introduced in 1998 and then withdrawn in 1999 after wide spread adverse events were reported and studied.
- Safer vaccine was introduced in 2006.
- Results from CDC monitoring between 2000 – 2006 showed that hospitalization rates for acute gastroenteritis dropped by 16% in 2007 and by 45% in 2008. (10)

Definitions:

Adverse reaction – “A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function'.” (WHO – 1972)

Adverse event - Medical occurrence temporarily associated with the use of a medicinal product, but not necessarily causally related (WHO)

- The sensitivity to detect uncommon or rare adverse events, or those with delayed onset, is low during the pre-licensing phases of development. As a result, continuous post-licensure monitoring of vaccine safety is done to identify and evaluate any reported adverse events. (9)

Vaccine Safety

General public has low tolerance to adverse events as vaccines are usually given to healthy persons.

Expectation to safety standard is higher with vaccines compared to medicines for sick people.

National regulatory authorities (NRAs) rigorously ensure the quality, safety, & effectiveness of vaccines and pharmaceutical products.

Once introduced, vaccines are thoroughly and continuously reviewed.

NRAs monitor and investigate AEFIs to ensure safety for population. *

Before being introduced, vaccines are assessed in clinical trials.

World Health Organization: Vaccine Safety Basics Course. <http://vaccine-safety-training.org/expectations-towards-safety-of-vaccines.html>

* AEFI – Adverse Events Following immunization.

Vaccine Related Adverse Reactions

- The Vaccine Adverse Event Reporting System (VAERS) was created in 1988 after passage of the National Childhood Vaccine Injury Act (NCVIA) of 1986.
- VAERS is a national vaccine safety surveillance program co-sponsored by the CDC and the FDA.
- VAERS collects information about adverse events (possible side effects) that occur after the administration of vaccines. Information is collected from parents/guardians, vaccine distributors, vaccine administrators, the person completing the form on behalf of the patient or the health professional who administered the vaccine.
- VAERS data does not determine cause-and-effect relationships between vaccines and adverse events. People are encouraged to report all adverse events. The forms require information on any other health issues or medicines the patient might be taking at the time of the vaccine.
- VAERS data is used by scientists and researchers to determine if there is a causal link between a vaccine and an adverse event through scientific research. (11)

Monitoring Vaccine Safety

VAERS Data	Vaccine Safety Datalink (VSD)	Clinical Immunization Safety Assessment (CISA) Project
<ul style="list-style-type: none"> • VAERS data is open to the public and can be downloaded through the VAERS website (https://vaers.hhs.gov/about/index) • For use by any person. Patient specific identifying information is kept confidential. • According to the VAERS website, VAERS receives 30,000 to 50,000 reports annually, with 13% classified as serious (e.g., associated with disability, hospitalization, life-threatening illness or death). • The 30,000 to 50,000 reports are .0095% to .016% of an average of 316.2 million doses of vaccines distributed. (HRSA) • Since 1990, VAERS has received over 200,000 reports, most of which (85%-90%) describe mild side effects such as fever. 	<ul style="list-style-type: none"> • A collaborative effort between CDC and a group of managed care organizations (MCOs). • VSD is a closed system. Researchers must get permission from the CDC to access the data. • VSD is a linked database used for monitoring immunization safety and studying potential rare and serious adverse events. The program includes Rapid Cycle Analysis of data that is reported in real time through electronic records. • Nine MCOs with approximately 9.5 million children and adults enrolled, or about 3 percent of the U.S. population participate. • Data in the database are not based on voluntary adverse event reporting. • Strategic priorities for research and surveillance are developed and updated regularly. 	<p>National network of vaccine safety experts from the CDC's Immunization Safety Office (ISO), seven medical research centers and other partners.</p> <p>Current CISA Project Sites</p> <ul style="list-style-type: none"> • Boston Medical Center • Cincinnati Children's Hospital Medical Center • Columbia University • Duke University • Johns Hopkins University • Kaiser Permanente Northern California • Vanderbilt University <p>Provides a comprehensive vaccine safety public health service to the nation – specifically providers.</p> <ul style="list-style-type: none"> • Clinical Case Reviews • Expert Evaluation of Vaccine Safety Issues • Research • Public Health Response

National Vaccine Injury Compensation Program

The National Childhood Vaccine Injury Act of 1986 created the National Vaccine Injury Compensation Program (VICP) as a no-fault alternative to the traditional lawsuits.

- VICP provides compensation to people found to be injured by certain vaccines.
- The program began accepting claims in 1988 and is administered by three different federal agencies:
 - Federal Department of Health and Human Services (HHS) conducts medical reviews and makes the court ordered payments;
 - The Department of Justice represents HHS in court;
 - The US Court of Federal Claims makes the final determination on a claim through a special master.
 - The program is funded by an excise tax on vaccines.
- Over 80% of the payments are awarded based on a negotiated settlement.
- Attorneys are paid whether the petitioner receives an award or not.
- From 2006 to 2015 over 2.8 billion doses of vaccines were distributed in the United States.
- Since 1988 over 17,095 petitions have been filed with the court
- 4,747 were determined to be compensable and 9,915 were dismissed.
- Total compensation paid out by the fund since 1988 is approximately \$3.58 billion. (12)

Modern Day Vaccine Controversy

Preservative – Thimerosal

Adjuvant - Aluminum

Controversy over the ingredients of vaccines began with the first smallpox vaccine and continues today. The concerns over a particular vaccine often get conflated to all vaccines and many childhood illnesses where science and medicine are still researching cause and effect.

The nature of science requires that there be active ongoing research projects on many topics and issues. The stage of the scientific process and the actual study methods used are critical in determining if the research is legitimate. The ability to draw conclusions from such research can only be made when the studies can be replicated by other scientists and proven to be more than just observational.

Thimerosal

During the 1990s many people theorized that Thimerosal, a mercury based ingredient used in vaccine production for 80 years, caused neurological disorders including Autism and Attention Deficit Disorder.

The science behind the ingredient did not support the theory. Reviews by the CDC, FDA and the Institute of Medicine could find no link between Thimerosal and the disorders it presumably caused.

Regardless of the science, Thimerosal was taken out of childhood vaccines in the United States in 2001 over concerns that parents would stop immunizing their children.

An extensive review of Thimerosal and the scientific studies conducted on the ingredient can be found on the FDA website titled “Thimerosal in Vaccines”. (13)

Aluminum

Aluminum salts have been used in vaccines as an adjuvant for more than 70 years to strengthen the body’s immune response to the vaccines. Like Thimerosal, aluminum in vaccines has been assumed to cause the rising rate of Autism among children.

In addition, there are ongoing studies of aluminum in vaccines and its relationship to food allergies. None of the studies have made any causal connection. The studies highlight the complex nature of food allergies.

Like Thimerosal, the body of science behind aluminum as an ingredient does not support the theories linking it to Autism or food allergies. (13, 14)

Modern Day Vaccine Controversy

Human Cell Strains Through Aborted Fetus And Religion

Two main human cell strains have been used to develop currently available vaccines, both were developed in the 1960s.

The WI-38 cell strain was developed in 1961 in the United States and the MRC-5 cell strain was developed in 1965 in the United Kingdom.

There have been no new or additional fetal cells used or required to be used to sustain the two cell strains.

The vaccines below were developed using either of the cell strains:

- Hepatitis A vaccines [VAQTA/Merck, Havrix/GlaxoSmithKline, and part of Twinrix/GlaxoSmithKline]
- Rubella vaccine [MERUVAX II/Merck, part of MMR II/Merck, and ProQuad/Merck]
- Varicella (chickenpox) vaccine [Varivax/Merck, and part of ProQuad/Merck]
- Zoster (shingles) vaccine [Zostavax/Merck]
- Adenovirus Type 4 and Type 7 oral vaccine [Barr Labs] (*not routinely given*)
- Rabies vaccine [IMOVAX/Sanofi Pasteur] (*not routinely given*) (15)

Concerns Based on Religious Belief

- Two of the largest Christian organizations in the United States, the Catholic Church and the Southern Baptist Convention, support and encourage their followers to vaccinate for the common good. However, both leave open an the option of an individual to oppose certain vaccines based on religious grounds.
- A review of other religious organizations (including Hinduism, Buddhism, Jainism, Judaism, Christianity, and Islam) found that opposition to vaccines reflected personal concerns among social networks of people organized around a faith community. (16, 17, 18)

Vaccine Controversy – Autism

Measles, Mumps, Rubella (MMR)

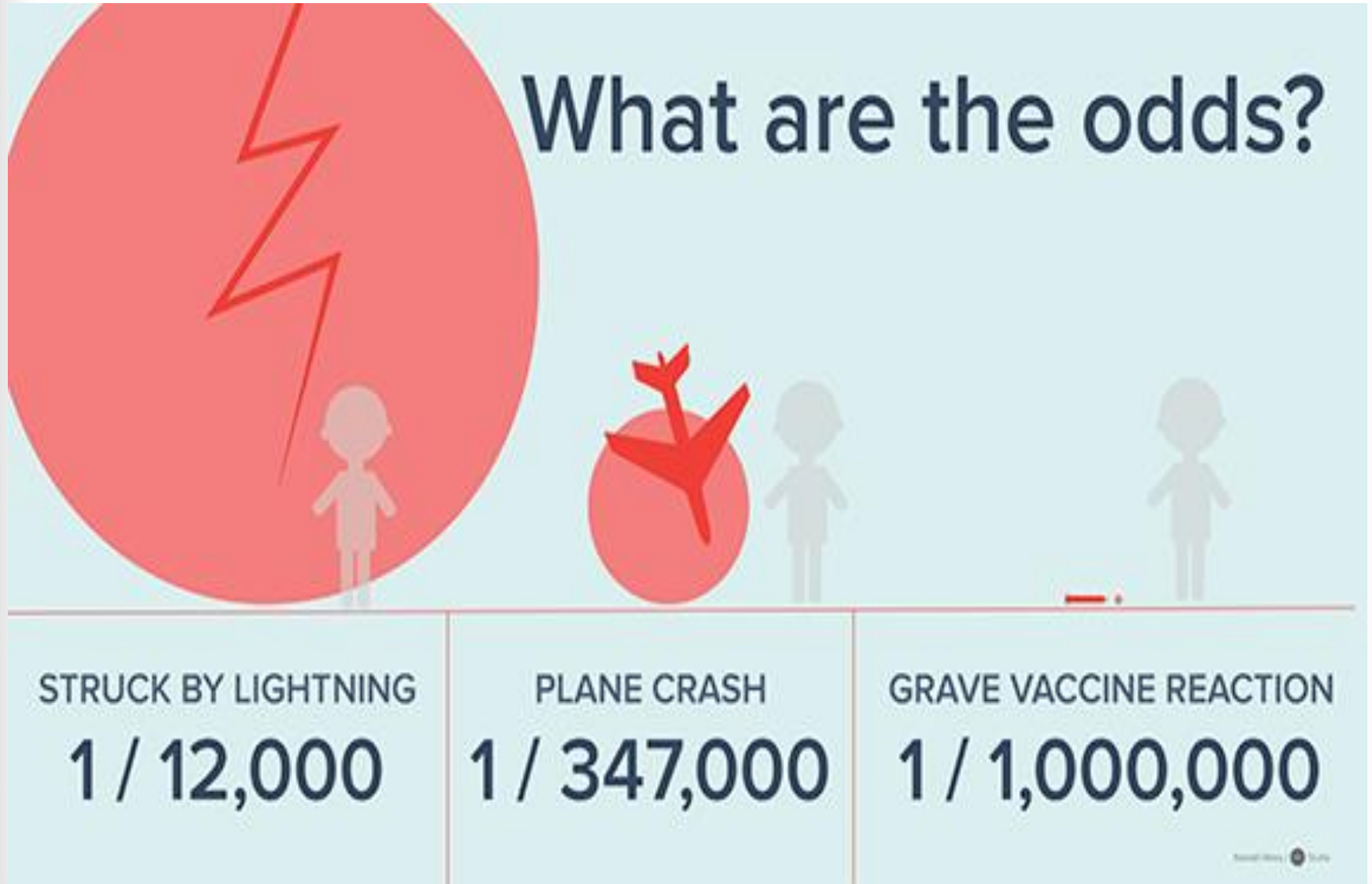
- In 1998 The Lancet, a British Medical journal, published a small study in its clinical case series. The study was printed as an "early report" from a group of 13 doctors at London Bowel Clinic. The lead author of the study was Andrew Wakefield. The purpose of the study was to examine the link between the MMR vaccine and parental reports of an association with Autism.
- Prior to release of the study a press conference was held by Wakefield and hospital administrators to announce the finding that the MMR vaccine may be “associated” with Autism based on parental reports of an association. The written study, however, concluded that further investigation was needed.
- In 2004 a series of newspaper articles uncovered significant ethical issues with the 1998 study. After the articles appeared 10 of the 12 co-authors withdrew their support of the study. A 2010 British General Medical Council review found that Wakefield committed serious professional misconduct that included ordering or performing medical experimentations on developmentally challenged children. Wakefield lost his license to practice medicine in Great Britain and 12 years after the study appeared in its publication The Lancet fully retracted it.
- Andrew Wakefield maintains he did nothing wrong. He believes his work was distorted and he was a target of a “ruthless pragmatic attempt to investigate valid vaccine safety concerns.” (CNN) Wakefield moved to Austin, Texas and has sued the British Medical Journal and the journalist who wrote the 2004 articles in Texas court for making false allegations against him and for defamation. By 2014 all of the lawsuits were dismissed. (19 - 24)

No Link Or Association Between Vaccines And Autism

- The original Wakefield study of 12 children from 1998 could not be replicated by anyone in the science or research community, not even by Wakefield himself. The retracted 1998 study never reported a scientific link between MMR vaccine and Autism. The original study reported “parental association” and concluded that there was a need for further study.
- The American Academy of Pediatricians provides a list of studies with links to the publications that have tried to determine an association or link between vaccines and Autism or Autism Spectrum Disorders. (https://www.aap.org/en-us/Documents/immunization_vaccine_studies.pdf).
- In 2013 the AAP list included approximately 43 different studies from around the world involving the examination of existing literature, birth records, case studies, and reports of adverse events for 9 million children and none of the studies found a link or association between vaccines and autism or autism spectrum disorder.

Vaccinations And Chance (25)

What are the odds?



Clustering Case Study: The Ohio Measles Outbreak - 2014

- In 2014 there were 23 measles outbreaks across the country involving 644 cases.
- Of that amount, 382 involved an Ohio Amish community.
- The outbreak was caused by two Amish missionaries returning home from a trip to the Philippines. Both men went to the hospital but were misdiagnosed as having dengue fever and sent home.
- The Amish community involved in the outbreak was largely unvaccinated but not because the Amish opposed vaccination on religious grounds. The low vaccination rate was due to a belief in the 1990s that an Ohio child became ill from the MMR vaccine.
- The rural location and lack of telephones delayed reaction time to the outbreak. The outbreak resulted in 9 hospitalizations. (26)
- According to a 2011 article in Pediatrics Online, Holmes County, Ohio, immunization data indicated that 45% of the county was fully immunized compared to a statewide average of 80%. (27)

What Is Herd Immunity

Herd immunity occurs when a high percentage of the population is protected through vaccination against a virus or bacteria.

Herd immunity varies for each disease. The immunity thresholds are calculated by using complex math formulas and public health surveillance data collected by epidemiologists, mathematicians, economists, statisticians and clinicians. (28)

Surveillance data across the world shows that herd immunity can effectively stop the spread of disease. (28)

The calculations begin with the number of people that one sick person can pass a disease into an unprotected population (the R_0) and the percent of the population that needs to be immunized to protect a community (HIT). The higher the R_0 the more contagious the disease. (29)


Herd immunity is particularly important for protecting people who cannot be vaccinated.

Herd immunity is considered a “public good”. Like all other public goods it is “non-excludable”; and yet it does not restrict someone else’s choice to be vaccinated or not. Ideally everyone in a community should be vaccinated but not everyone has to be vaccinated to achieve a herd immunity threshold. (30)


Disease	Basic Reproduction Number (R_0)	Herd Immunity Threshold (HIT)
Mumps	4–7	75–86%
Diphtheria	6–7	83–86%
Rubella	6–7	83–86%
Varicella (Chicken Pox)	8–9	90%
Pertussis (Whooping Cough)	12–17	92–94%
Measles	12–18	92–95%

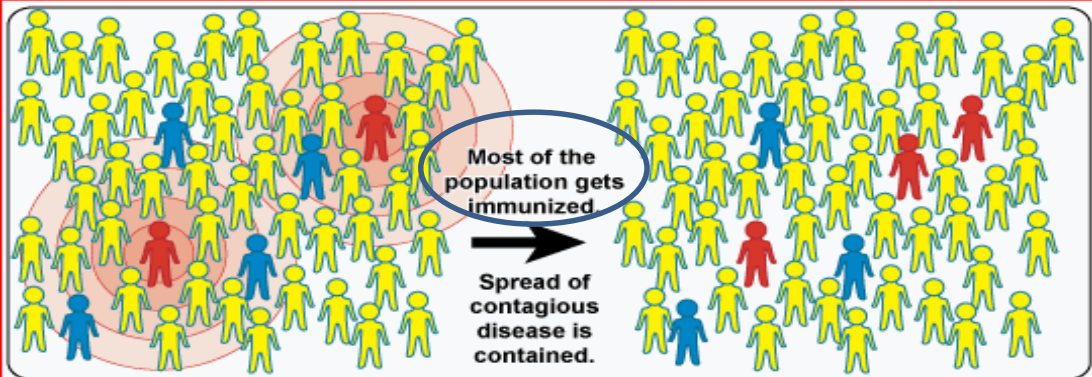
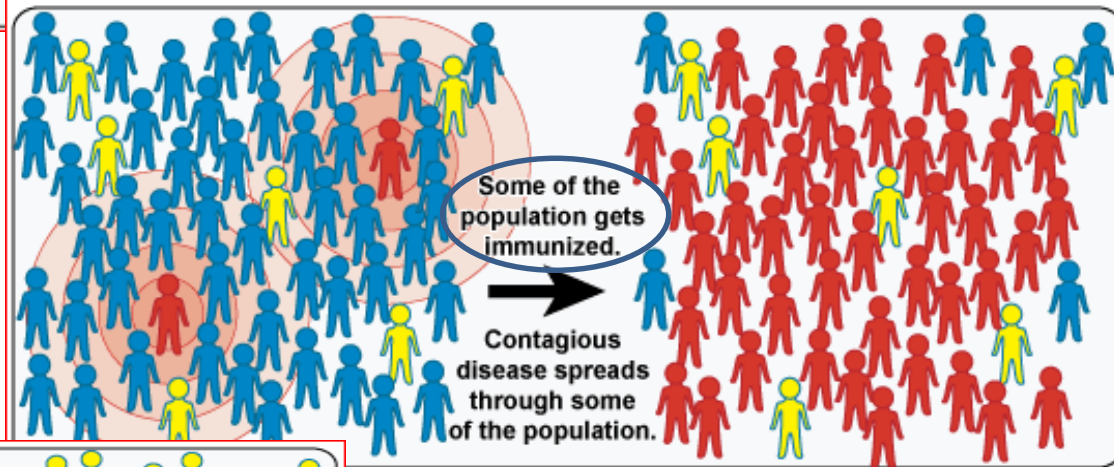
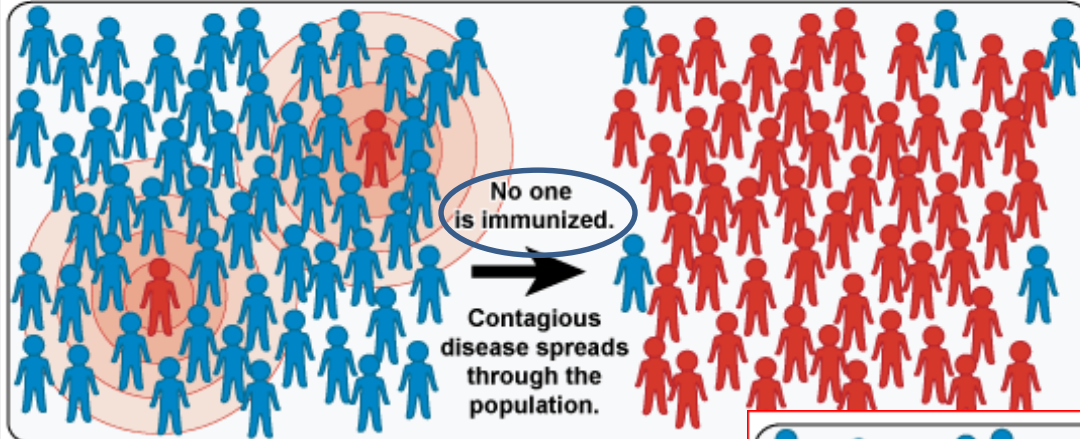
Children that can't be vaccinated?

In general children who are too young to be vaccinated, those with immune system problems and those who are too ill to receive vaccines (such as some cancer patients). (Vaccines Today)

 = not immunized but still healthy

 = immunized and healthy

 = not immunized, sick, and contagious



Measles and Herd Immunity

- 90% of unvaccinated people are likely to get measles if they come in contact with the disease.
- 3% to 7% of vaccinated people are likely to get measles if they come in contact with the disease (depending on 1 or 2 doses of the vaccine).

A Difference of Opinion...

Ongoing research to improve the effectiveness and safety of existing vaccines and to develop new vaccines for an ever changing world.



Science is not 100% and the ongoing research proves that vaccines are either not as effective as promoted or as safe.

Disney Theme Park Measles Outbreak

According to the CDC, 110 of the 125 cases of measles associated with the Disney Theme Parks were from California in 2015.

Average daily attendance to the two Disney Theme Parks combined is 66,000. That means that 0.17% of those in attendance from California were confirmed to have measles.

Of the 110, 42 were either unvaccinated or under-vaccinated; or 0.064% of those Californians in attendance.

Note that 47 of the 110 Californians associated with the Disney Theme Park measles outbreak had unknown or undocumented vaccine records. (32)



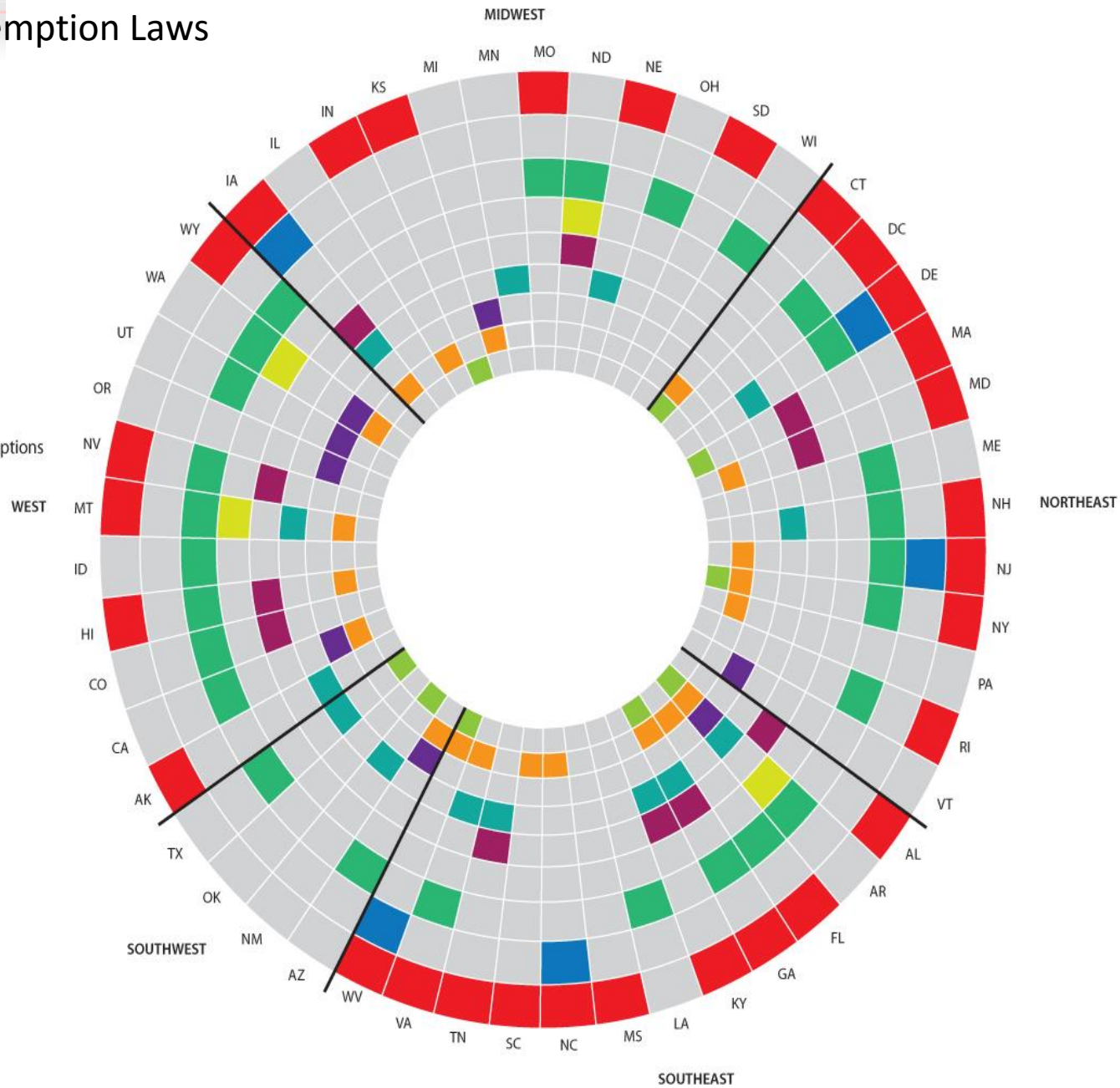
Measles is a highly contagious and preventable disease. Of the 110 Californians at the Disney Theme Parks that were confirmed to have measles, 38.18% were confirmed as un- or under-vaccinated while 7.27% were confirmed to be fully vaccinated, 11% were infants too young to be vaccinated and the remaining 43% were reported as unknown.

The success of the vaccination program, surveillance and monitoring prevented a national widespread outbreak of measles. (32)

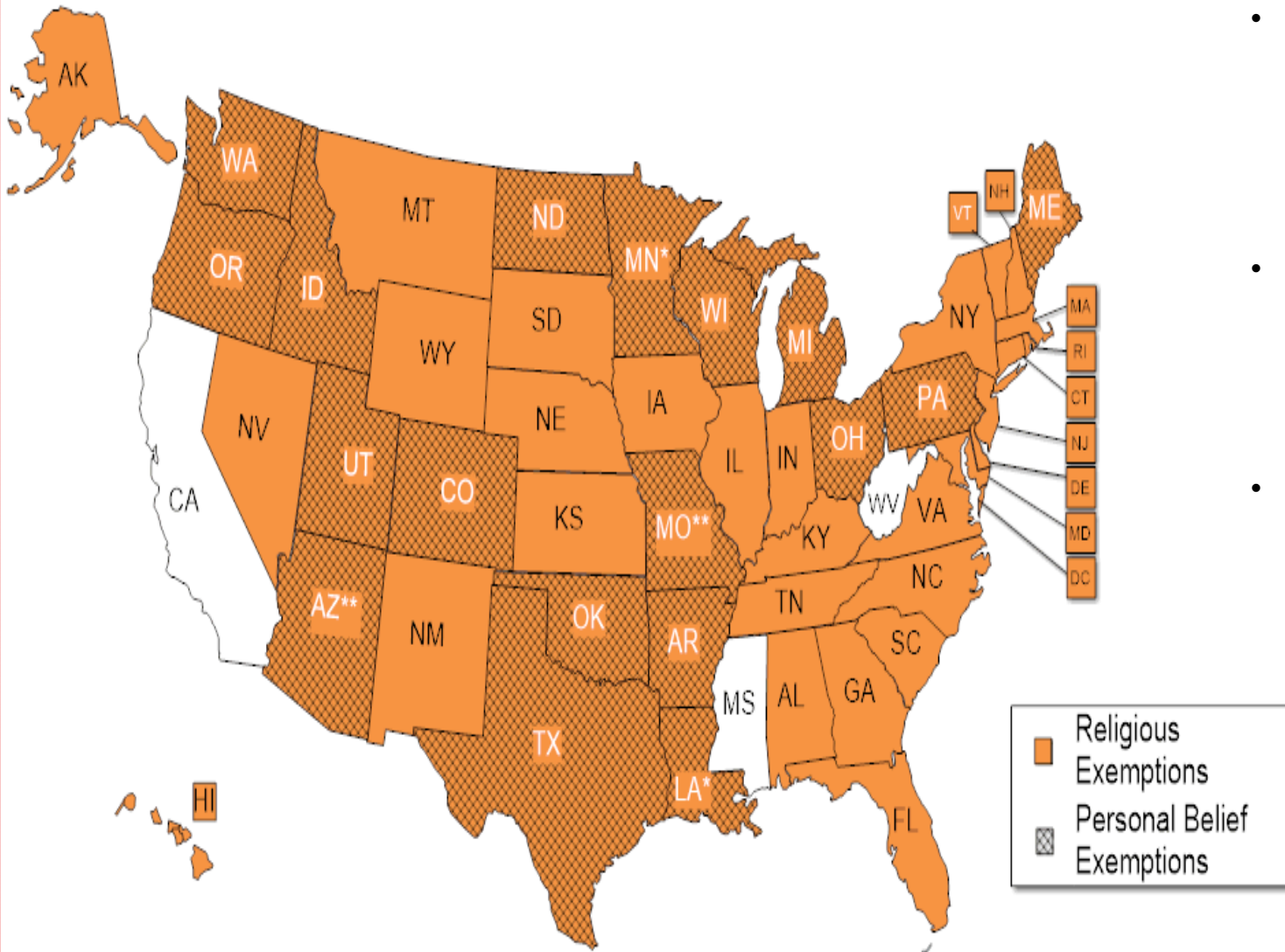
Other State And Virginia

9 Attributes Of School Exemption Laws

- Medical or religious exemptions only
- Philosophical exemptions expressly excluded
- Exempted student exclusion during outbreak
- Parental acknowledgment of student exclusion
- Exemptions not recognized during outbreak
- Parental notarization or affidavit required for exemptions
- Enhanced education for exemptions
- Medical exemptions expressly temporary or permanent
- Annual healthcare provider recertification for medical exemptions



State Non-medical Exemptions From School Immunization Requirements, 2015



- According to NCSL, all states and the District of Columbia have vaccination requirement statutes for students entering public school.
- Mississippi, West Virginia and now California are the only states that no longer have religious exemptions.
- Beginning in 2016 eighteen states will have personal belief exemptions. Both California and Vermont repealed theirs in 2015 effective July 1, 2016.

Source: National Conference of State Legislatures. Accessed 7-28-2016. <http://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx>

Recent State Law Changes

- According to the National Conference of State Legislatures several states, including California, Connecticut, Illinois, Vermont and West Virginia passed legislation in 2015 related to vaccine exemptions. The laws listed by NCSL are as follows:
- California passed Senate Bill 277 removing exemptions based on personal beliefs, which are defined in that state as also including religious objections.
- Connecticut House Bill 6949 requires an annual notarized statement from parents or guardians specifying religious objection to required vaccinations.
- Illinois Senate Bill 1410 requires each public school district to make exemption data available to the public. It also requires parents or guardians who claim a religious exemption to detail their objections for specific immunizations, obtain a health care provider's signature, and submit an exemption certificate for each child before kindergarten, sixth and ninth grade. Local school authorities would determine if the exemption request constitutes valid religious objection, as philosophical exemption is not permitted in Illinois.
- Vermont passed House Bill 98 which repealed the state's personal belief exemption. (The legislation does not change the existing exemption for parents who wish to opt out for religious reasons.). Vermont House Bill 98 also requires schools and child care facilities to provide school immunization rates to parents.
- West Virginia Senate Bill 286 requires certification by a licensed physician for medical exemption requests. It also authorizes the commissioner of the Bureau for Public Health to appoint an immunization officer to make determinations about requests for exemptions. (33)

California SB 277 - FAQ Changes To Immunization (34)

- The California legislation that changed immunization policy for the state after a measles outbreak in 2015 made the following changes for 2015 and future years beginning in 2016:
- In 2015 **but not** future years:
 - Parents or guardians of entering students may submit a personal beliefs exemption to fulfill an immunization requirement.
 - Students must fulfill immunization requirements if entering: a home-based private school or an independent study program and do not receive classroom-based instruction.
- Starting January 1, 2016:
 - Eliminates personal belief and religious belief exemptions to currently-required vaccines. Personal belief exemptions filed before January 1, 2016 will remain valid until the student enrolls in the next grade span (grade spans are K-6 and grades 7-12).
 - Once a child reaches the next grade span they are required to meet all age-appropriate immunizations.
 - Personal belief exemptions filed in 2015 are not valid for children entering school in the fall of 2016.
 - Students will no longer be required to have immunizations for entry if they attend:
 - A home-based private school or
 - An independent study program and do not receive classroom-based instruction
 - Students who have an individualized education program (IEP) should continue to receive all necessary services regardless of vaccination status. Parents or guardians must continue to provide immunization records for these students to their schools.
 - Medical exemptions can only be obtained from a licensed physician and must say what the physical condition of the child is, which vaccines are being exempted, whether the exemption is temporary or permanent and if temporary when the exemption will expire.

Virginia

Current Virginia Law

School Immunization Laws are found in the following sections of state law:

VA Code Annotated § 22.1-271.2. Immunization requirements

- Students cannot be admitted to school without proof of immunization.
- Students with incomplete records can be admitted conditionally for a period of 90 days or 180 days specifically for Hepatitis B vaccine .
- Students can be exempt if immunization agents conflict with the student or parent's religious tenets or practices; a notarized affidavit is required.
- Students can be exempt if physician certifies that one or more immunizations may be detrimental to the student's health.
- Students can be excluded from school if they do not provide immunization records or exemption documents.
- Excludes Haemophilus Influenzae Type b immunization from the requirements for admission to school.

VA Code Annotated § 32.1-46. Immunization of patients against certain diseases

- Parent or guardian must cause each child to be vaccinated in order to attend:
 - public or private elementary, middle or secondary school,
 - child care center, nursery school,
 - family day care home, or
 - developmental center
- The minimum required vaccinations for attendance shall not be required if immunization agents conflict with religious tenets or practices. (listed on the next slide)
- A physician states that immunizing the child will be detrimental to the child's health.
- Parent or guardian can object to HPV vaccine.

VA Code Annotated § 22.1-271.4. Health requirements for home-instructed, exempted, and excused children

- Parents or guardian must comply with VA Code Annotated § 32.1-46
- Proof of immunization or exemption documentation is made upon request from the division superintendent.

VA. CODE ANNOTATED § 32.1-46 - MINIMUM REQUIRED VACCINATIONS FOR SCHOOL ATTENDANCE

Requirement	Vac. Abbr.
A minimum of three properly spaced doses of hepatitis B vaccine	HepB
A minimum of three or more properly spaced doses of diphtheria toxoid. One dose shall be administered on or after the fourth birthday	DTaP
A minimum of three or more properly spaced doses of tetanus toxoid. One dose shall be administered on or after the fourth birthday	DTaP
A minimum of three or more properly spaced doses of acellular pertussis vaccine. One dose shall be administered on or after the fourth birthday. A booster dose shall be administered prior to entry into the sixth grade	DTaP
Two or three primary doses of Haemophilus influenzae type b vaccine, depending on the manufacturer, for children up to 60 months of age (not required for school attendance by Va. Code Annotated. § 22.1-271.2).	HIB
Two properly spaced doses of live attenuated measles (rubeola) vaccine. The first dose shall be administered at age 12 months or older	MMR
One dose of live attenuated rubella vaccine shall be administered at age 12 months or older	MMR
One dose of live attenuated mumps vaccine shall be administered at age 12 months or older	MMR
All children born on and after January 1, 1997 shall be required to have one dose of varicella vaccine on or after 12 months of age.	VAR
Three or more properly spaced doses of oral polio vaccine (OPV) or inactivated polio vaccine (IPV). One dose shall be administered on or after the fourth birthday. A fourth dose shall be required if the three dose primary series consisted of a combination of OPV and IPV.	IPV
One to four doses, dependent on age at first dose, of properly spaced pneumococcal conjugate (PCV) vaccine for children up to 60 months of age	PCV
Three doses of properly spaced human papillomavirus (HPV) vaccine for females. The first dose shall be administered before the child enters the sixth grade (parents can elect not to provide this vaccine)	HPV

Virginia Medical Exemption Form

COMMONWEALTH OF VIRGINIA
SCHOOL ENTRANCE HEALTH FORM

Health Information Form/Comprehensive Physical Examination Report/Certification of Immunization

Section II
Conditional Enrollment and Exemptions

Complete the medical exemption or conditional enrollment section as appropriate to include signature and date.

MEDICAL EXEMPTION: As specified in the *Code of Virginia* § 22.1-271.2, C (ii), I certify that administration of the vaccine(s) designated below would be detrimental to this student's health. The vaccine(s) is (are) specifically contraindicated because (please specify):

DTP/DTaP/Tdap: ; DT/Td: ; OPV/IPV: ; Hib: ; Polio: ; Measles: ; Rubella: ; Mumps: ; HBV: ; Varicella:

This contraindication is permanent: , or temporary and expected to preclude immunizations until: Date (Mo., Day, Yr.):

Signature of Medical Provider or Health Department Official: _____ Date (Mo., Day, Yr.):

- The Virginia medical exemption form is part of the state's comprehensive school health entrance form.
- The physician completes the required section by indicating what vaccine the child is being exempt from along with an explanation.

Virginia Vaccine Exemption Forms

COMMONWEALTH OF VIRGINIA CERTIFICATE OF RELIGIOUS EXEMPTION

Name _____ Birth Date _____

Student I.D. Number _____

The administration of immunizing agents conflicts with the above named student's/my religious tenets or practices. I understand, that in the occurrence of an outbreak, potential epidemic or epidemic of a vaccine-preventable disease in my/my child's school, the State Health Commissioner may order my/my child's exclusion from school, for my/my child's own protection, until the danger has passed.

Signature of parent/guardian/student _____ Date _____

I hereby affirm that this affidavit was signed in my presence on

This _____ Day of _____

Notary Public Seal

- The Virginia Religious Exemption form is a simple form to complete.
- The parent signs a document that says immunizing agents conflict with their personal religious tenets or practices; then they get the form notarized for submission.
- The form is essentially a personal philosophical objection form – no religion has to be listed and no objectionable vaccine has to be listed.
- During a meeting with parents I was informed that physicians no longer like to do medical exemption forms. According to the parents, physicians are directing them to the religious exemption form because they are easier to complete and less complicated.
- Many parents indicated during conversations that they only object to one vaccine or another but this form essentially exempts them from all vaccines. In the case of an outbreak of any kind the student has to be sent home by law.

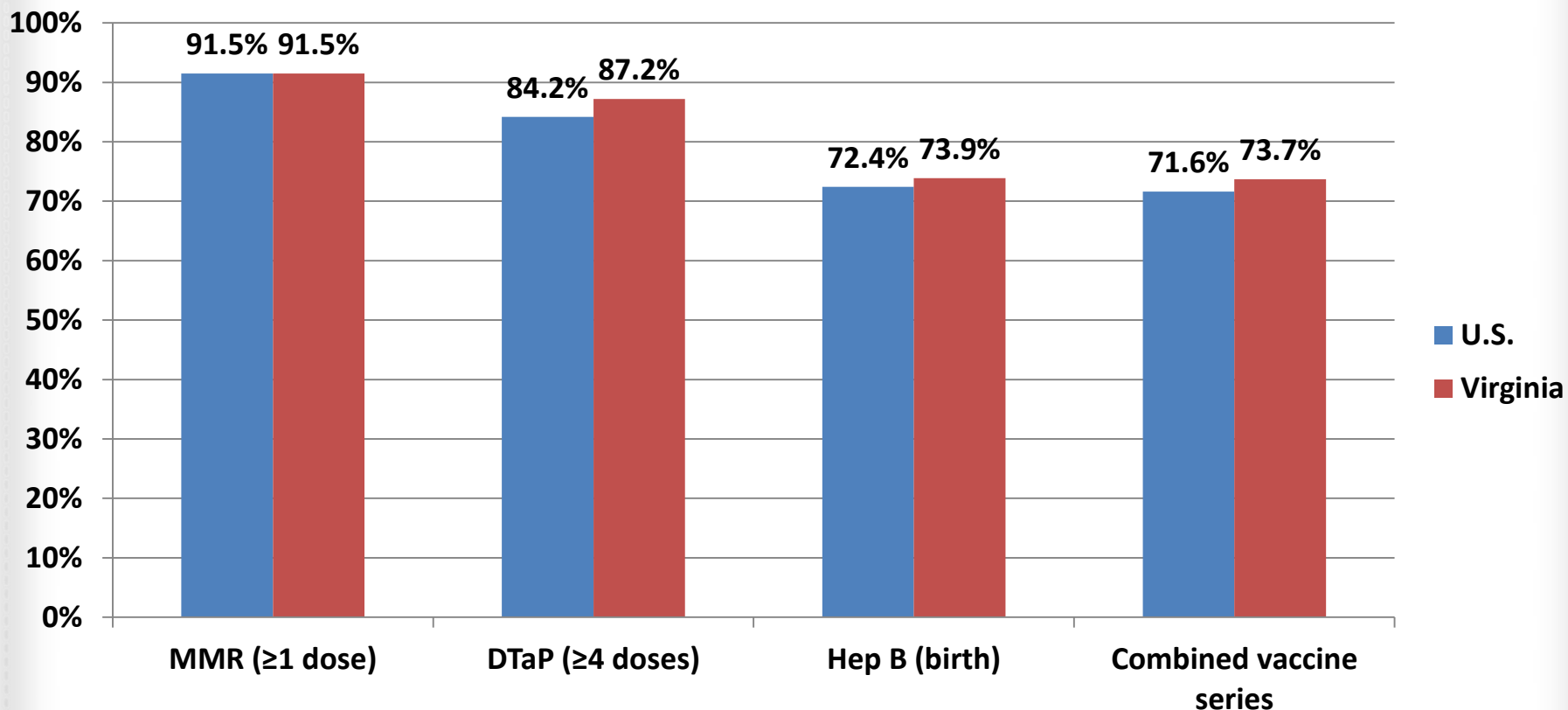
Home School and Private School Vaccination Information

- VA Code Annotated Code § 22.271.2 and VA Code Annotated § 32.1-46 require schools, both public and private, to submit student immunization data to the local health departments within 30 days after the beginning of the school year and must make their records available for inspection by the state and local health departments.
- Most public schools report but there are difficulties identifying private schools and ensuring that the reporting requirement is communicated annually to the appropriate personnel. Data are currently required only from schools with kindergarten and/or sixth grade students. No data are collected from other schools. According to the State Health Department, resources for monitoring compliance is also an issue.
- VA Code Annotated § 22.1-271.4 requires all home school students to be immunized but records are only transmitted to the superintendent of the local school division upon request. In separate conversations with the State Health Department and the State Department of Education each thought the other was collecting immunization data about home school children.
- State Department of Education records indicate that there are 32,314 home schooled children in the state broken down by the following grade levels:

Grade Level	Enrollment
K – 5	14,959
6 – 8	7,370
9 – 12	7,684
Other	2,311

- According to the State Department of Education, home instruction parents ask for permission to home school from the local school superintendent. While the children of those that do not make the request are considered truants the information is not tracked. Finally, there is no annual head count of children home schooled and there is no way to know precise information on vaccine rates among them. (35)

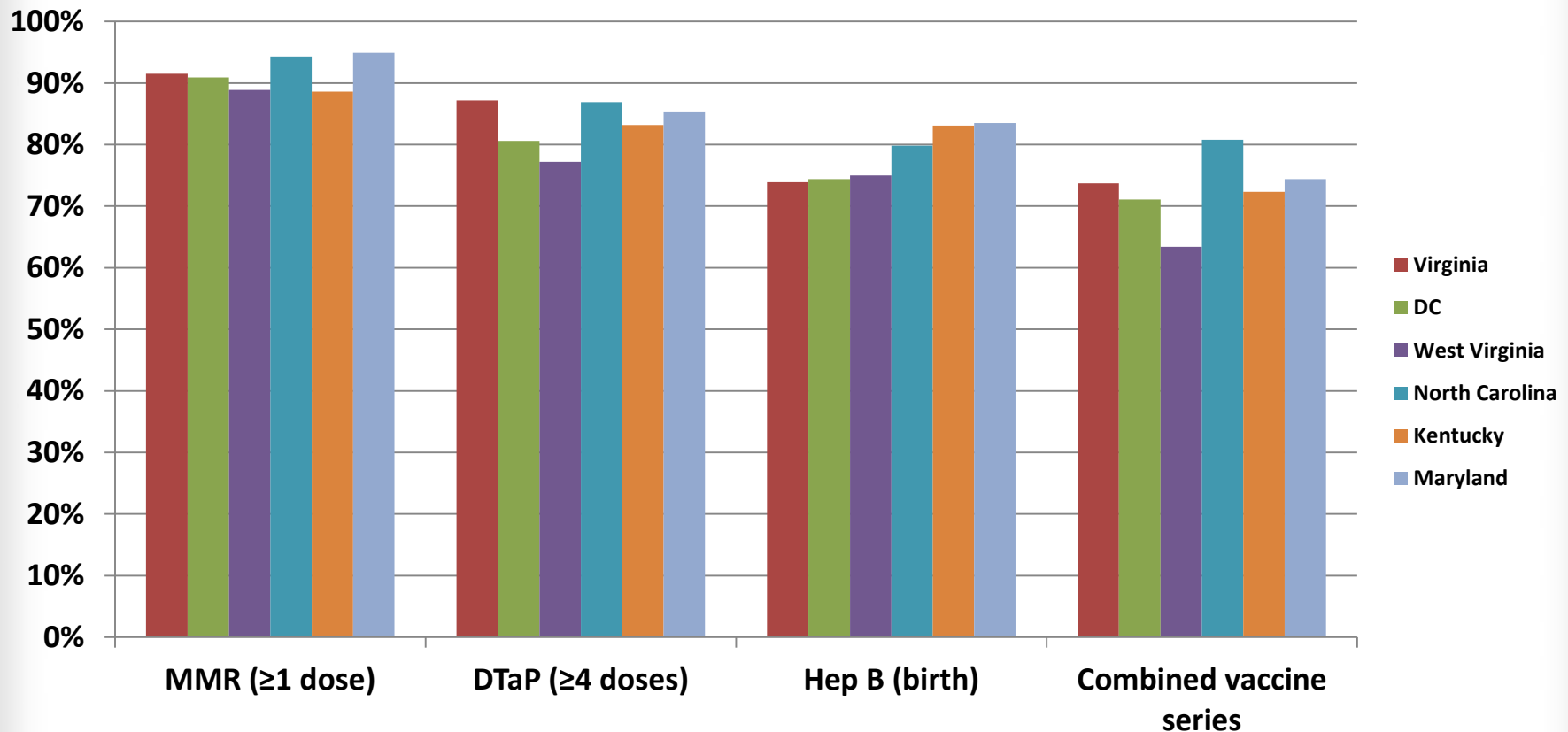
ESTIMATED VACCINATION COVERAGE AMONG CHILDREN AGED 19–35 MONTHS VIRGINIA COMPARED TO THE U.S. - 2014



Vaccine key: Tdap = tetanus, diphtheria, and pertussis; MMR = Measles, Mumps & Rubella; Hep B = Hepatitis B;
 * The combined (4:3:1:3*:3:1:4) vaccine series includes ≥4 doses of DTaP/diphtheria and tetanus toxoids vaccine/diphtheria, tetanus toxoids, and pertussis vaccine, ≥3 doses of poliovirus vaccine, ≥1 dose of measles-containing vaccine, ≥3 or ≥4 doses of Hib (depending on product type of vaccine), ≥3 doses of HepB, ≥1 dose of varicella vaccine, and ≥4 doses of PCV.

Source: National, State, and Selected Local Area Vaccination Coverage Among Children Aged 19–35 Months.
 Table 3. Weekly / Vol. 64 / No. 33. August 28, 2015 (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6433a1.htm>)

Estimated Vaccination Coverage Among Children Aged 19–35 Months Virginia Compared To Surrounding States - 2014



Vaccine key: Tdap = tetanus, diphtheria, and pertussis; MMR = Measles, Mumps & Rubella; Hep B = Hepatitis B;
 * The combined (4:3:1:3*:3:1:4) vaccine series includes ≥4 doses of DTaP/diphtheria and tetanus toxoids vaccine/diphtheria, tetanus toxoids, and pertussis vaccine, ≥3 doses of poliovirus vaccine, ≥1 dose of measles-containing vaccine, ≥3 or ≥4 doses of Hib (depending on product type of vaccine), ≥3 doses of HepB, ≥1 dose of varicella vaccine, and ≥4 doses of PCV.

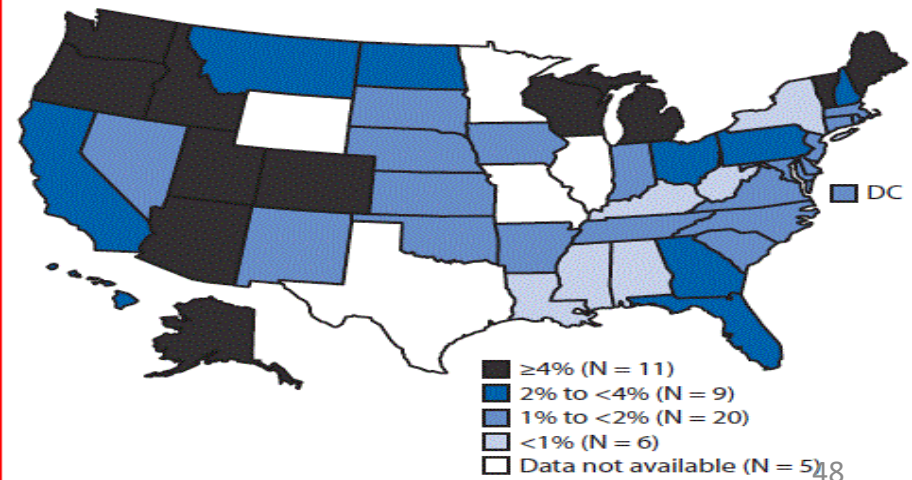
Vaccination Rates And Exemptions As Reported To The State Health Department By Virginia Schools

All Virginia Schools Self Reported Immunization Compliance Data for 2015-2016 School Year

Description	Kindergarten (T =96,474)	Sixth Grade (T = 101,198)
Number Adequately Immunized	94.40%	96.02%
Number With Medical Exemptions	0.26%	0.42%
Number With Religious Exemptions	0.86%	0.77%
Percent of Known Exempt	1.12%	1.19%
Unknown (conditional & n/a)	4.49%	2.78%

- State law requires all Virginia schools to report immunization data within 30 days of the beginning of school.
- The data is posted on the VDH website directly from the schools. According to VDH, the total number of exemptions are fairly accurate because of the way the data is collected and tabulated.
- A limitation of the exemption data, however, is that it does not necessarily reflect vaccination status – especially for those students receiving exemptions.
- In addition, state law allows schools to admit students with incomplete records conditionally for a period of 90 days; or 180 days specifically for Hepatitis B vaccine .

Estimated Percent of Kindergarten Children Exempt from Receiving 1 or more vaccines 2014 – 2015 (CDC)



- The map to the right is from the CDC and represents an estimated percentage range for children enrolled in kindergarten who have been exempted from receiving one or more vaccines for school year 2014 – 2015.
- The data used by the CDC to generate the map is incomplete and limited as follows:
 - Immunization programs used different school vaccination assessment methods
 - Exemption status does not always reflect vaccination status
 - Not all states collect data and some states report exemptions by vaccine which may result in double counting of children.
 - The data for some states is adjusted for non-responsiveness where surveys are used to collect information.

Vaccination Rates And Exemptions Public Compared To Private Schools

Virginia <u>Public</u> Schools Self Reported Immunization Compliance Data for 2015-2016 School Year		
Description	Kindergarten (T = 90,460)	Sixth Grade (T = 95,468)
Number Adequately Immunized	94.39%	96.05%
Number With Medical Exemptions	0.26%	0.44%
Number With Religious Exemptions	0.76%	0.73%
Percent of Known Exempt	1.02	1.17
Unknown (conditional & n/a)	4.59%	2.78%

Virginia <u>Private</u> Schools Self Reported Immunization Compliance Data for 2015-2016 School Year		
Description	Kindergarten (T = 6,014)	Sixth Grade (T = 5,730)
Number Adequately Immunized	94.51%	95.41%
Number With Medical Exemptions	0.17%	0.24%
Number With Religious Exemptions	2.33%	1.47%
Percent of Known Exempt	2.50%	1.71
Unknown (conditional & n/a)	2.99%	2.88%

Fourteen Virginia Public And Private Schools With >10 Enrollment Under 70% Of Kindergarteners Adequately Immunized For 2015 – 2016

School	Division	City	Public / Private	% Adequately Immunized	% Medical Exemptions	% Religious Exemptions
Fairview Elementary	Fairfax Co Pblc Schs	Fairfax Station	Public	5.7%	0.0%	0.0%
St. Mary's Catholic	Henrico	Richmond	Private	43.0%	0.0%	0.0%
E. S. H. Greene Elem.	Richmond City Pblc Schs	Richmond	Public	45.5%	0.0%	0.0%
Greenbrier Montessori	Chesapeake City	Chesapeake	Private	48.1%	0.0%	3.7%
G. A. Treakle Elem.	Chesapeake City Pblc Schs	Chesapeake	Public	49.7%	0.0%	0.6%
Siena Academy	Fairfax	Great Falls	Private	54.5%	0.0%	45.5%
Woodville Elem.	Richmond City Pblc Schs	Richmond	Public	57.4%	0.0%	0.0%
Overby-Sheppard Elem.	Richmond City Pblc Schs	Richmond	Public	58.1%	0.0%	0.0%
Fox Mill Elementary	Fairfax Co Pblc Schs	Herndon	Public	60.0%	0.0%	0.0%
P. B. Young Sr. Elem.	Norfolk City Pblc Schs	Norfolk	Public	62.4%	0.0%	0.0%
Woodley Hills Elementary	Fairfax Co Pblc Schs	Alexandria	Public	62.8%	0.9%	0.0%
Camp Allen Elem.	Norfolk City Pblc Schs	Norfolk	Public	63.2%	1.3%	0.0%
Belvedere Elementary	Fairfax Co Pblc Schs	Falls Church	Public	66.7%	0.0%	1.1%
Halley Elementary	Fairfax Co Pblc Schs	Fairfax Station	Public	69.6%	0.0%	0.0%

- The table above indicates that while the statewide school immunization rates are high there are schools that report well below the statewide percentage of Kindergartners being adequately immunized.
- Only three of the schools listed above are private schools.
- In all, there are 177 schools that report under 90.0% of their Kindergartners as adequately immunized. Of that amount, 32 are private schools and 145 are public schools.

Thirteen Virginia Public And Private Schools With >10 Enrollment Under 70% Of Sixth Graders Reported Adequately Immunized For 2015 – 2016

School	Division	City	Public / Private	% Adequately Immunized	% Medical Exemptions	% Religious Exemptions
Portsmouth Christian Schools	Portsmouth City	Portsmouth	Private	23.4%	0.0%	0.0%
Chelsea Academy	Warren	Front Royal	Private	27.3%	0.0%	54.5%
Grace Preparatory School	Stafford	Stafford	Private	27.3%	0.0%	0.0%
Legacy Christian Academy	Frederick	Stephens City	Private	36.4%	0.0%	27.3%
Daniel Morgan Middle	Winchester City Pblc Schs	Winchester	Public	48.5%	0.6%	0.5%
Pocahontas Middle	Powhatan Co Pblc Schs	Powhatan	Public	49.3%	0.5%	0.5%
Jack Jouett Middle	Albemarle Co Pblc Schs	Charlottesville	Public	49.4%	1.0%	0.3%
Temple Baptist School	Fairfax	Herndon	Private	50.0%	0.0%	0.0%
Mountaintop Montessori	Albemarle	Charlottesville	Private	57.1%	0.0%	14.3%
Forest Edge Elementary	Fairfax Co Pblc Schs	Reston	Public	61.6%	0.9%	0.0%
St. Mark School	Fairfax	Vienna	Private	66.7%	0.0%	2.1%
Linton Hall	Prince William	Bristow	Private	66.7%	0.0%	0.0%
Clearview Elementary	Fairfax Co Pblc Schs	Herndon	Public	67.3%	1.0%	0.0%

- The table above indicates that while the statewide school immunization rates are high there are schools that report well below the statewide percentage of sixth graders being adequately immunized.
- Eight of the schools listed above are private schools.
- In all, there are 87 schools that report under 90.0% of their sixth graders as adequately immunized. Of that amount, 21 are private schools and 66 are public schools.

Vaccine Preventable Illness	Number of Cases Considered an Outbreak	Incubation Period	Infection Period
Varicella	≥ 5	14–16 days, with a range of 10–21 days.	2 days before rash onset until all lesions are crusted over or until no new lesions appear within a 24-hour period (average range, 4-7 days)
Pertussis	≥ 2	About 7-10 days (range 4-21 days)	Beginning of cough onset; up to 21 days after the cough starts.
Measles	≥ 1	14 days, with a range of 7-21 days	4 days before until 4 days after onset of rash with the rash onset being considered as day zero
Mumps	≥ 3	12-25 days, but swelling typically develops 16 to 18 days after exposure	7 days before, through 11-14 days after

Source: CDC Manual for the Surveillance of Vaccine-Preventable Diseases
<https://www.cdc.gov/vaccines/pubs/surv-manual/index.html>

Statewide Reports Of Vaccine Preventable Outbreaks (*) By Year And Disease: 2010 - 2015

Year	Varicella	Pertussis	Measles	Mumps	Total
2010	57	116	3		176
2011	48	121	7	6	182
2012	59	101			160
2013	25	59		92	176
2014	6	89	2		97
2015	25	129	1	21	176
Grand Total	220	615	13	119	967

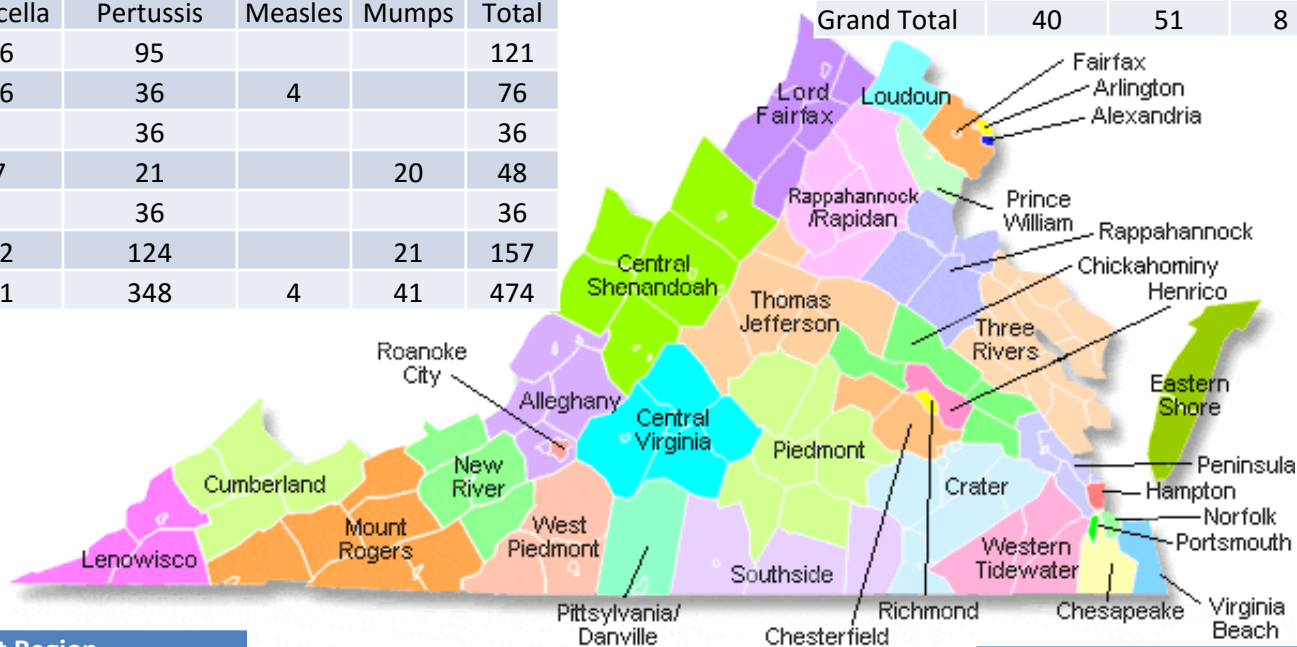
Source: Virginia Department of Health.

* *Outbreaks – represents the number of cases associated with outbreaks but not the number of cases reported. (36)*

Vaccine Preventable Outbreaks by Year, Disease and VDH Region 2010 – 2015 (37) *

Northwest Region					
Year	Varicella	Pertussis	Measles	Mumps	Total
2010	26	95			121
2011	36	36	4		76
2012		36			36
2013	7	21		20	48
2014		36			36
2015	12	124		21	157
Grand Total	81	348	4	41	474

Northern Region					
Year	Varicella	Pertussis	Measles	Mumps	Total
2010	23	10	3		36
2011		4	2	6	12
2012	17	2			19
2013		15			15
2014		17	2		19
2015		3	1		4
Grand Total	40	51	8	6	105



Southwest Region			
Year	Varicella	Pertussis	Total
2011	5	70	75
2012	17	18	35
2013	18	19	37
2014		12	12
2015	7		7
Grand Total	47	119	166

Central Region				
Year	Varicella	Pertussis	Mumps	Total
2010	8			8
2011	7	3		10
2012		18		18
2013		4	72	76
2014	6			6
Grand Total	21	25	72	118

Eastern Region				
Year	Varicella	Pertussis	Measles	Total
2010		11		11
2011		8	1	9
2012	25	27		52
2014		24		24
2015	6	2		8
Grand Total	31	72	1	104

Source: Virginia Department of Health

* Outbreaks – represents the number of cases associated with outbreaks but not the number of cases reported.

Travel

- Diseases can be transmitted in many ways – one way is through travel. Virginia is home to the busiest international airport in the Mid-Atlantic, receives visitors from all over the country and residents travel nationally and internationally.
- According to the CDC, the majority of measles cases brought into the United States come from U.S. residents who were traveling abroad. (38)
 - Over 870,000 Virginians travel overseas, while 350,000 people are expected to visit the state from other countries (39)
 - Over 41 million visitors from all over the United States in 2015. (40)
 - 7.2 million international travelers passed through Dulles airport in 2015. (41)
 - Over 370,000 passports were issued to Virginians in 2015 Bureau of Consular Affairs, US Department of State. (42)
- The only vaccine classified as "required" by International Health Regulations is the yellow fever vaccination for travel to certain countries in sub-Saharan Africa and tropical South America. Otherwise vaccination prior to international travel is recommended based on the countries you are visiting.
- Many of the vaccine preventable diseases were brought into communities through travelers and visitors.

Two Case Studies from Virginia

Measles in Charlottesville - 2011

The Charlottesville Health Department confirmed four residents of the Thomas Jefferson Health District contracted measles in May of 2011.

The initial case was confirmed on May 19, 2011. An adult female resident of Charlottesville was hospitalized after reportedly contracting the virus while traveling in India.

The vaccination status of the woman was reported as “unknown.”

One of the confirmed cases was a student at Waldorf School, a private school. More than 220 people were exposed, and of those, 40 were considered susceptible either because they were unvaccinated or they had only received one dose of the vaccine.

The school was closed for a day to offer vaccination clinics and 50 people who were exposed spent three weeks in quarantine.

The last case of the measles in the Thomas Jefferson Health District was in 1990. (43)

Pertussis in Floyd County – 2011

Blue Mountain School in Floyd County was closed for a week in an effort to stop the spread of pertussis among its students.

Thirty of the school’s students, faculty and others within the school were physician-confirmed to have whooping cough on April 4, 2011. School enrollment was 45 students.

According to the local health department the outbreak was caused by people not being properly vaccinated against the disease. (44)

Conclusions

- Vaccines target diseases that spread through society, some more rapidly than others.
- Arguments against mandatory immunization center around questions of how vaccines are made, safety of the vaccine, religious and/or philosophical objections, and the rights of parents to decide what is best for their children.
- In 1905 the United States Supreme Court weighed in on personal liberty, religious freedom and protecting society in the *Jacobson v. Massachusetts* decision. The court found that individual liberties and individual religious freedoms within the context of a society can be restrained for the good of the whole.
- In another court decision, *Troxel v. Granville* (2000), the United States Supreme Court stated that "the interest of parents in the care, custody and control of their children—is perhaps the oldest of the fundamental liberty interests recognized by this Court." But the Court also found in this decision that the Constitution permits a State to interfere with parental rights to prevent harm or potential harm to a child.
(45)
- Taken together these two Supreme Court decisions address the rights of an individual over the rights of the whole society.

Conclusions (continued)

- The questions to address are whether vaccines are more harmful than the diseases they are created to address. The statistics concerning the level of adverse reports indicate that of an average of 316.2 million doses of vaccines distributed each year (including flu vaccines), approximately 30,000 on average (or .0095%) resulted in a complaint to VAERS and approximately 314 on average resulted in a compensation (or 0.0001%) resulted in a complication severe enough to warrant compensation from the VICP. (12, 13)
- No publication or website says vaccines are 100% safe or effective. But, as the information in this presentation indicates, the preponderance of evidence is that vaccines are safer than the diseases they are intended to protect children from and the link between vaccines and the host of other illnesses they have been associated with are not supported by science.

POLICY OPTIONS AND DESCRIPTION

1. Take no action.
2. Reintroduce legislation to amend section 22.1-271.2 and section 32.1-46 of the Virginia Code, removing religious and medical exemptions and by adding an exemption for medical contraindication as the only exemption.
3. Introduce legislation to amend section 22.1-271.2 and section 32.1-46 of the Virginia Code, eliminating the religious exemption.
4. Introduce legislation to amend section 22.1-271.2 and section 32.1-46 of the Virginia Code, eliminating the religious exemption and providing that medical exemptions can only be obtained from a licensed physician and must say what the physical condition of the child is, which vaccines are being exempted, whether the exemption is temporary or permanent and if temporary when the exemption will expire.
5. Introduce legislation to amend section 22.1-271.2 and section 32.1-46 of the Virginia Code, splitting the religious exemption into two parts – a religious exemption and a philosophical exemption. Both the religious and philosophical exemptions would be required to include what vaccines the person objects to based on religion or philosophical beliefs.
6. Introduce legislation to amend section 22.1-271.2 and section 32.1-46 of the Virginia Code, adding a subsection allowing physicians to file alternative vaccination plans provided that the child receives all required vaccines before Kindergarten.

POLICY OPTIONS AND DESCRIPTION

7. Introduce legislation to amend Chapter 29 of Title 54.1 of the Virginia Code to improve the continuing medical education (CME) of physicians on childhood vaccinations.

8. Introduce budget amendment (language and funding) for the Virginia Department of Health to design more effective messages concerning vaccination programs for different communities and for the continuing education of physicians and other health care providers.

9. Request by letter of the JCHC Chair that the Health Department and the Department of Education work with local school divisions and private schools to improve reporting by schools and home schools to make certain that schools with low vaccination rates are filing reports properly and timely and the reports are reviewed for the reasons for low vaccination rates. A report to the Commission detailing the results of the agency efforts will be provided by October 1, 2017.

Public Comments

Written public comments on the proposed options may be submitted to JCHC by close of business on September 3, 2016.

Comments may be submitted via:

- ❖ E-mail: adymora@jchc.virginia.gov
- ❖ Fax: 804-786-5538
- ❖ Mail: Joint Commission on Health Care
P.O. Box 1322
Richmond, Virginia 23218

Comments will be provided to Commission members and summarized and presented during JCHC's September 7th meeting.

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APPENDIX

A Brief History of Vaccines – Small Pox

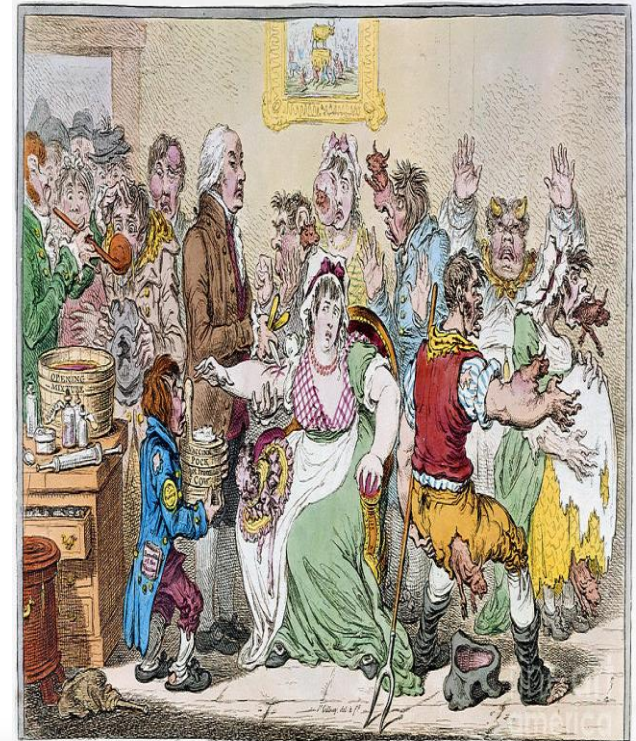
A Brief History of Vaccines: Immunization

- Smallpox is one of the first diseases recorded in history that was recognized as preventable through a form of “immunization.” Records dating as far back as 960 A.D. reveal that the Chinese inhaled dried powder of smallpox crusts through the nose in a manner similar to taking snuff to create an “immunization” from the disease. (1)
- When smallpox spread into Europe its impact on the population was severe. During the 18th century in Europe 400,000 people died each year from the disease, one-third of the survivors went blind and most others were left with disfiguring scars. In the late 1800s the case-fatality rate from smallpox varied from 20% to 60%, and was even higher among infants – approaching 80% in London and 98% in Berlin. (2) In fact, by all accounts, “no other disease of the past or present times has come close to smallpox in wreaking such havoc on the world population.” (1)
- The Latin term for smallpox was variola and the practice of immunizing people was called “Variolation”. The variola was inoculated, or mixed with the blood, into a healthy person through a variety of techniques. The person then got a mild case of smallpox, and once recovered from the illness developed an immunity. (2)
- Variolation was heavily criticized by many because it was believed that the practice ran counter to the will of God. Variolation was also risky. Obtaining smallpox through Variolation meant there was a risk that the person inoculated could spread the disease to the rest of the population. And because the person actually became mildly ill with smallpox they were contagious and had to be quarantined for at least two weeks. (2, 3, 4)
- In Colonial America success of Variolation was documented after a 1721 smallpox outbreak in Boston. Zabdiel Boylston, a prominent physician in the city, practiced Variolation at the urging of the Rev. Cotton Mather. In spite of criticism and arrest for the practice, Boylston recorded the results of his practice during the outbreak. Over half (55%) of the residents of Boston were infected with smallpox. Of the 282 that were inoculated, only 6 died, or 2.1% of those inoculated. Of the 5,759 that were not inoculated, 884 died of the disease, or 15.3%. (3)

Background-

A Brief History of Vaccines: Opposition to Vaccination

- In spite of the recorded success, the concerns about religion and the spread of illness from the inoculation resulted in a legal ban or restriction by every American Colony (except Pennsylvania) of the practice of Variolation. (3)
- The impact of the Colonial laws and limited exposure to smallpox by many colonists of the time was felt during the American Revolution. A smallpox epidemic among the northern Continental Army in 1775 led to the collapse of the army's Canadian campaign. George Washington wrote often of the impact smallpox was having on his troops, the battles, and recruitment of new enlistees. By 1777 Washington ordered compulsory inoculation for every new recruit. The success of this move was reflected in Washington's writings – by 1778 his concerns about smallpox were mentioned less frequently. (5)
- In 1798 a physician in England named Edward Jenner published a paper on a new type of inoculation. Jenner discovered that cowpox was similar to smallpox and once injected through inoculation into a person could create an immunity against the smallpox disease without actually causing a person to become ill from the inoculation. (1)
- Opposition and skepticism to Jenner's discovery came first from the medical community that characterized the innovation as unnatural and dangerous. As the new procedure caught on though opposition included personal attacks on Jenner, accusing him of withholding or excluding negative data; there were also newspaper cartoons – one famously showing people growing horns after being inoculated with cowpox vaccine; and rumors were spread that the cowpox was really modified syphilis (calling into question the content of the vaccine). A book published as late as 1977 even suggested that smallpox was on the decline before the vaccine was created and suggested that the disease would have been eliminated through Variolation, which the book described as "safe". (1)

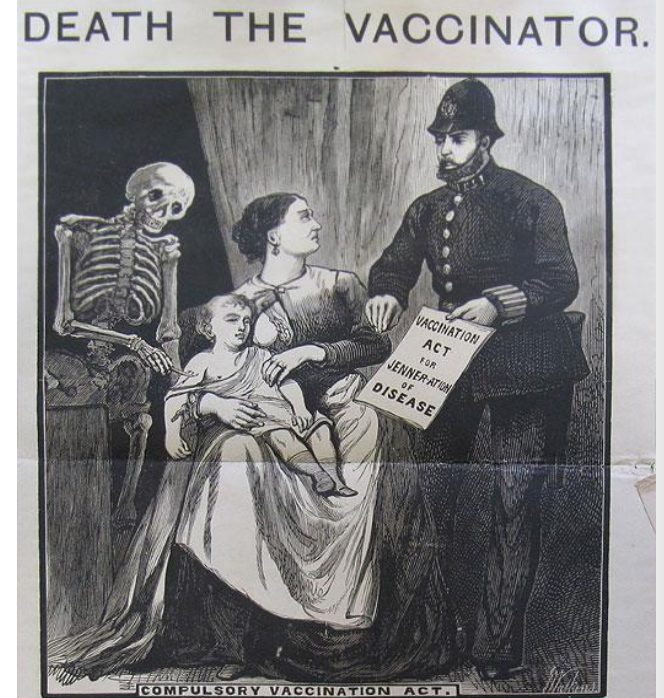


The Cow-Pock ... or ... the Wonderful Effects of the New Inoculation! ... the Publications of J. G. ...

Background-

A Brief History of Vaccines: British Vaccination Act

- In 1840 the British government outlawed the practice of Variolation and mandated the use of the safer cowpox inoculation in the Vaccination Act of 1840. In 1853 the law was amended making the vaccine mandatory for infants up to three months old and holding the parents legally responsible for non-compliance. The 1867 amendments increased the age requirement to fourteen. In 1871 amendments were added that required the poor to be vaccinated with severe penalties for noncompliance. (6)
- The British Vaccination Act and its amendments were innovative because they extended government powers into areas of traditional civil liberties in the name of public health. Amendments to the Act, however, led to violent protests and the formation of anti-vaccination leagues. (6)
- An 1885 anti-vaccination protest in Leicester, Great Britain, led to the creation of a Royal Commission to study anti-vaccination grievances and in response an 1898 law allowed parents who did not believe in the “safety or effectiveness” of vaccines to obtain a certificate of exemption based on “conscience”; the first use of “conscientious objector”. (8)
- One of the most prominent critics of vaccination was a scientist, Lord Alfred Russel Wallace, a co-discoverer of the principle of natural selection. In 1898 he wrote *Vaccination a Delusion, Its Penal Enforcement a Crime* (1898). In the book his first criticism of the smallpox vaccine was that there were no controlled scientific experiments to test its efficacy. He argued that comparing two groups of similar people – one group vaccinated and the other unvaccinated – would prove whether vaccines were effective. Wallace provided statistical evidence that smallpox was on a “well-marked steady decline” from 1760 to 1800 due to improvements in sanitation. He used the limited and unreliable data available at the time to make his point, the very same data used by vaccine proponents. (8)



Background-

A Brief History of Vaccines: The United States

- In the United States Massachusetts passed the first immunization law in 1809 granting local boards of health the authority to require smallpox vaccinations when necessary and in 1827 Boston became the first city to require public school students to be vaccinated for smallpox. (7)
- In 1813 Congress passed the National Vaccine Agency Act. The act promoted the use and administration of smallpox vaccines and made smallpox vaccine material available through the US Post Office. The Act was repealed in 1822 and the authority to promote vaccination policy was returned to the states after a smallpox outbreak in North Carolina occurred due to the inadvertent mailing of contaminated vaccine material by a federal official. During the mid-1800s there were smallpox outbreaks throughout the United States and North America. In each outbreak local areas, state governments and Congress responded by promoting vaccinations. (10, 11, 14)
- The widespread vaccination policies of the early 1800s contained and in some cases eliminated smallpox outbreaks. Vaccinations fell into disuse as new generations grew up without the disease. However, in the 1870s the smallpox became epidemic again. As states attempted to enforce existing vaccination laws or pass new ones, vigorous anti-vaccination movements arose across the country. In 1879, William Tebb, the leading British anti-vaccinationist, went to New York and inspired the founding of the Anti-Vaccination Society of America; the New England Anti-Compulsory Vaccination League was formed in 1882 and the Anti-Vaccination League of New York City in 1885. (6)
- Promoting vaccinations against smallpox became more complex after the discovery of germ theory. Opponents of vaccines used the new theory to argue that implementation of public sanitation was a more appropriate defense against smallpox.
- American physician and author of Spiritualist books, James Martin Peebles, published *Vaccination: A Curse and a Menace to Personal Liberty* in 1900. Peebles added a peculiarly American twist to the debate by declaring mandatory vaccinations an “outrage upon the personal liberty of the American citizen.” He added that the “vaccination syndicate” is “continually lobbying our legislatures for an extension of privileges on the pretense that the public welfare will thereby be enhanced.” (8)

Background-

A Brief History of Vaccines: The United States Supreme Court

- In 1902 the City of Cambridge Massachusetts mandated smallpox vaccinations to stop the spread of the disease during an outbreak. The penalty for not vaccinating was \$5 (\$135 today). Henning Jacobson, a Lutheran Pastor, refused to comply and was fined \$5. Jacobson appealed the fine up to the US Supreme Court.

“Jacobson argued that the Compulsion to introduce disease into a healthy system is a violation of liberty.” (10, 13, 16)

- In 1905 the United States Supreme Court voted 7-2 against Jacobson, writing in part, that:

“[T]he liberty secured by the Constitution . . . does not import an absolute right in each person to be . . . wholly freed from restraint. . . . On any other basis organized society could not exist with safety to its members. . . . [The Massachusetts Constitution] laid down as a fundamental . . . social compact that the whole people covenants with each citizen, and each citizen with the whole people, that all shall be governed by certain laws for the ‘common good,’ and that government is instituted ‘for the protection, safety, prosperity and happiness of the people, and not for the profit, honor or private interests of any one man...” (10, 13, 16)

- The court decision acknowledged in general that there were “extreme cases” where vaccination laws were not intended to apply to adults in certain conditions where the requirement of vaccination would be considered “cruel and inhuman.” The Court did not consider the Jacobson case to be one of those “extreme cases.” The language in the decision that discussed “extreme cases” became the impetus for creating a medical exemption for mandatory vaccinations of adults under the Massachusetts health law. The Massachusetts law already included an exemption for children. (13)
- The 1905 Supreme Court ruling is the cornerstone of public health law and vaccination policies. The decision set a precedent related to individual rights versus the common good (the social compact) and the police power regulations of the government. According to LexisNexis the case has been cited 669 times, including 80 times in the Supreme Court, 286 in federal court and 383 in state courts across the country.

Case Study: 1893 - Muncie Indiana Smallpox Outbreak

- From August 17, 1893 to December 1893 (4.5 months) there was a smallpox outbreak in Muncie, Indiana. The disease was traced to a young girl visiting the city from New Jersey.
- From the day the disease was first diagnosed until the last 150 people became ill and 22 died. Of the 150 cases, the first 102 were diagnosed in the first 32 days of the outbreak and 31 in the next 18 days.
- The disease had not been present in the city since 1876 and as a result a new unvaccinated and uninformed population grew up in the city.
- When the disease first appeared in August it was misdiagnosed as chicken pox.
- Citizens of Muncie, including the physician that misdiagnosed the disease, refused to believe smallpox was present and opposed early efforts by the City to stop the spread of the disease.
- The local Anti-vaccination Society, and its affiliated physicians, objected to government policies related to vaccination, including a new public school attendance requirement.
- The Society argued that medical compulsion of vaccines was as un-American as religious compulsion and cited the First Amendment to the U.S. Constitution as their principle reference.
- The debate over diagnosis, especially among the physicians, confused residents and delayed the response time to stop the spread of the disease.
- Eventually, the City overcame the opposition and implemented quarantines, a vaccination program and built smallpox hospitals.
- Several physicians wrote that vaccination, isolation, and disinfection were the three important factors in ending the epidemic; they noted that in some cases immunity was not acquired after one vaccination; vaccination, even though it did not always give absolute immunity, did lessen the liability of attack, the severity of the disease, and the possibility of death. (15)



SMALLPOX VICTIM
22 YEARS OLD

Reproduced from Indiana, *Twelfth Annual Report of the Indiana State Board of Health* (Indianapolis, 1893), 178.

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