# A GUIDE TO MICHIGAN IMMUNIZATION

Michigan Association for Local Public Health

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### Immunization and Disease Control Laws in Michigan

### <u>Control of Vaccine-Preventable</u> <u>Diseases (VPD)</u>

- The goals of disease control are to limit the spread of communicable disease throughout the community.
- This is usually achieved by:-
  - ♦ isolating the infectious person.
  - ♦ assuring a barrier between the infectious person and non-ill people.
- Immunity, usually after immunization, is the most effective barrier to disease, which is why it is so important.
- Some people however are not immune and are therefore at risk of infection.
- In schools and day care centers this has substantial implications.
- The legislature therefore recognized that when an outbreak of VPD occurs, the most effective way to protect those at risk is to place a spatial barrier, that is to exclude these at-risk students until the risk is substantially reduced.
- The local health officer can exclude "any individuals lacking documentation of immunity or otherwise considered susceptible to the disease until such time as the health officer deems there to be no likely further risk of disease spread."

- School immunization laws have been an important tool in the control of infectious disease in the US for almost 200 years <sup>1</sup>.
- School and day care immunization laws protect a vulnerable segment of our population and also target an environment where transmission of infectious disease is facilitated by the close contact that children have in enclosed spaces <sup>2</sup>,<sup>3</sup>.
- The Michigan laws include assessment of day care and school immunization<sup>4,5, 11</sup> as well as exclusion from day care or school in the event of an outbreak of vaccine preventable disease.
- Michigan law requires that children attending day care and similar children's group activities as well as children attending school are protected against certain infectious disease through immunization or demonstration of immunity <sup>4,11</sup>. LHDs assist schools and day care centers by offering immunization clinics, interpretation of immunization records, immunization educational materials and other activities.
- Unlike the majority of states, Michigan law permits parents to exempt their child from the immunization requirements for non-medical, non-religious reasons (Mich. 333.9215). While the cost-savings for vaccinations is substantial<sup>1</sup>, it has been calculated that there is a significant cost to a state which employs a personal/philosophical (as opposed to a medical or religious) exemption to immunization <sup>6</sup>.

### Mandatory roles of Local Health Departments

- Under Michigan law, local health departments (LHDs) are required to implement and monitor state laws covering immunization and disease control within their jurisdictions<sup>8,9,10</sup>.
- LHDs in Michigan are required by law to offer immunizations and to control infectious/communicable disease.
- Among measures that LHDs employ to control communicable diseases are
  - LHDs provide accurate and up-to-date information about vaccines to their communities, often through local collaborations, web and social media pages and seminars.
  - LHDs work with their local health care and education providers to assist in getting immunization data into the state immunization registry, the MCIR.
  - LHD work with local immunization providers to assure that publiclyfunded vaccines are stored correctly and are used only for children who are eligible for the vaccines.
  - LHDs are also responsible for disease surveillance and implementing measures to control infectious diseases, including those that are preventable by vaccines.

### To calculate when the risk has diminished

- A person can become infected when exposed to another person who is infectious. Once infected, it can take days or weeks before the symptoms show. The time between when a person is infected and when they show symptoms is called the incubation period.
- Different diseases have difference incubation periods. Measles has an incubation period of between 7 and 21 days, pertussis can be up to 20 days and hepatitis A is 15-50 days<sup>7</sup>.
- Depending upon the situation, the local health officer may determine that unvaccinated children should be excluded for a full incubation period since their last exposure to an infectious person.



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## WHY IMMUNIZATION IS IMPORTANT

### Economic Impact of Vaccines

- Local and state health departments incur costs in investigating and controlling these disease.
- In 2017, Minnesota estimated that it cost the tax-payer more than \$1 million to address a single outbreak of measles<sup>4</sup>
- Measles is a very expensive disease. Not only are there treatment costs, time and productivity lost from work by parents, but also the cost to local and state health departments to investigate and control these diseases.
- A recent study from the University of North Carolina calculated that the overall cost of 10 adult vaccine-preventable diseases was \$8.95 billion in 2015<sup>5</sup>.
- Unvaccinated people accounted for \$7.1 billion (about 80%) of this cost.
- The flu alone accounted for \$5.8 billion.
- A study in Colorado in 2015, showed that hospital and Emergency Department visits to treat vaccine preventable disease in children totaled more than \$35 million<sup>6</sup>.
- The actual costs, taking into account costs of office visits, medication, lost wages and decreased productivity, are much higher.

- Vaccine Preventable Disease (VPDs) can cause deaths and longterm disabilities and have a substantial cost to the community. So Immunization has many benefits to both the individual and the community by preventing these diseases.
- 1 out of every 20 children with measles gets pneumonia, which is the most common cause of death for young children<sup>2</sup>.
- 1 out of every 1,000 children with measles develops a swelling of the brain, leaving the child with deafness or intellectual disability<sup>2</sup>.
- Deaths and long-term disabilities due to VPDs are very expensive, costing millions of tax-payer and personal dollars, due to hospitalizations, long term care and lost productivity for parents as a result of time off work. (see Economic Impact of Vaccines sidebar)..
- Children with VPDs or who are unimmunized may miss school for many days or even weeks during an outbreak.
- Vaccines are not just for children. Vaccines can protect first responders (police and paramedics as well as health care staff during an influenza pandemic) and assure communities that their health and safety and not jeopardized.
- It is the right thing to do. As society we should protect our communities, including the very young, the very old and the vulnerable.



#### Vaccines fight Antimicrobial Resistance

- Resistance of bacteria to antibiotics is a major public health crisis.
- By 2050, it is projected that 10 million people worldwide could die from untreatable infections.
- Strep. pneumoniae causes diseases such as meningitis which are treated with antimicrobial drugs. A vaccine against this disease reduces the need for antimicrobial use.

### Measles

- Measles is a highly contagious disease spread from person-to-person through sputum.
- ♦ One person typically transmits the infection to 12-18 others<sup>3</sup>.
- Before 1963, the CDC estimates<sup>1</sup> that there were over 10,000 cases for every 100,000 people in the US (see graph to left).
- 1 out of 4 cases are hospitalized<sup>2</sup> and 1 per 1,000 cases results in encephalitis (inflammation of the brain).
- In 2013, hospital costs for a person with measles was anywhere from \$4,032 to \$46,060.
- The decline in measles cases is not related to hygiene, safer food handling or improvements in water treatment.
- No other factor, besides vaccination, can account for the substantial decline in the number of cases of measles following the introduction of the measles vaccine.



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## MICHIGAN IMMUNIZATION DATA

### Why is it important to know and understand Michigan's Immunization Rates ?

- •Allows parents to decide if they want to send their children to day care centers where many children have not been vaccinated.
- •Allows local health departments and their partners to identify where most children might be vulnerable to vaccine-preventable diseases and then design and implement plans to increase levels of immunization among specific populations
- By tracking immunization rates, communities can evaluate if their plans to increase immunization uptake have been effective.
- Emergency health planners can prepare more effectively for a flu pandemic if they know how many people have received vaccine in recent years.

### Highlights for 2017

- 663 of Michigan's children (251 of kindergarteners, 188 of 7th graders and 224 new students) are vulnerable to serious vaccine-preventable disease because, for medical reasons, they cannot receive a vaccine<sup>1</sup>. This does not include students in other grades who have a medical waiver, but were not in grades that were assessed
- 27% of children receiving vaccine waivers did so because of medical (4.6%) or religious (22.2%) reasons<sup>1</sup>.

Most data on immunization levels in Michigan are about children because of the legal requirement for immunizations in schools and day care centers.

By the age of 3 years, children are recommended by the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatricians to have a complete series of the following vaccines: Diphtheria, tetanus, pertussis (whooping cough), polio, measles, mumps, rubella (German measles) *Haemophilus* meningitis, hepatitis B, varicella (chickenpox), pneumococcal (the so-called 4:3:1:3:3:1:4 vaccine series) and hepatitis A (2 doses).

### In March of 2018

- \* 57.1% of Michigan's 19-35 month old children had been immunized with all recommended vaccines.
- \* By the time these children reach kindergarten and encounter the school immunization rules, the rates have risen by more than 63%. Health policy worked to protect more young children.
- \* 93.3% of kindergarteners were up-to-date for their vaccines.
- \* 93.9% of 7th graders were up-to-date.
- \* 23.9% of children aged between 6 months and 8 years had completed flu vaccination.4.2% of kindergarteners' parents decided to seek immunization waivers.
- \* 42.0% of adolescent girls and 37.2% of adolescent boys had received the full series of vaccines against the human papilloma virus vaccine (HPV).

#### In Michigan during 2017

\* 761 cases of whooping cough (pertussis) were reported from 20 counties.

- \* 542 cases of chickenpox were reported
- \* 959 cases of shingles were reported

\* Over 25,000 cases of flu were reported and another 394,652 flu-like illnesses were reported

#### Source of Data:

Michigan Department of Health and Human Services https://www.michigan.gov/mdhhs/0,5885,7-339-73971 4911 4914 68361-321114--,00.html

https://www.michigan.gov/documents/mdch/ Current\_WSR\_272689\_7.pdf

#### How does Michigan rank?

- \* Among the 50 US states, Michigan ranks 29th for the required childhood vaccine series with only 70.2% of children age 19-35 months being complete.
- \* For the mumps-measles and rubella vaccine (MMR), Michigan ranks 46th in the country with only 86.4% of 2-year olds having received the 1st dose of the MMR vaccine. To prevent outbreaks, at least 83%-94% of the population should be immune<sup>5</sup>. Michigan is therefore particularly vulnerable to outbreaks of this very serious disease.
- \*As the map below shows, Michigan more than 50% of its population were not vaccinated against the flu in 2016-2017 flu season.

### Influenza vaccine coverage, by state, $2016-7^2$



 Only 60.3% of Michigan's population that is over 65 years of age received a flu shot in 2017. This group is very vulnerable to complications of influenza.



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## WHAT IS A VACCINE?

### Adjuvants

- Not all vaccines elicit a strong immune response. Typically these are vaccines made from dead or weakened bacteria.
- To boost the response, sometimes an inert chemical called an adjuvant, is added to the vaccine. The adjuvant works to make the vaccine more visible to the immune response<sup>1</sup>.
- In the US, there are two adjuvants, aluminum and Lipid A in use<sup>2</sup>.
- Both are present in very small amounts and have been shown to be safe, even in very small babies.
- As adjuvants boost the vaccine, smaller amounts of the microbe can be used.

### Vaccines and Cancer

- $\Rightarrow$  Some cancers are now known to be caused by viruses.
- $\Rightarrow$  Therefore the use of a vaccine against a cancer-causing virus will protect against those cancers.
- $\Rightarrow$  Hepatitis B virus attacks the liver and can lead to liver cancer<sup>4.</sup>
- ⇒ Some strains of Human Papilloma Virus cause cervical cancer<sup>5,6</sup>.
- ⇒ Public Health England has reported an 86% decrease in HPV strains that cause cervical cancer since introduction of the vaccine.
- ⇒ It is reported that universal vaccination has wiped out hepatitis B infection and liver cancer among Alaska's young people<sup>7</sup>.

- A vaccine is a substance that is very similar to a diseasecausing microbe, but does not cause that disease. But it is similar enough for the immune system to start an immune response and to produce antibodies and store the information in its immunological memory, providing us with protection should we be infected with that microbe in the future.
- Vaccines can be made of the whole microbe that has been either killed or modified so that it cannot cause disease<sup>3</sup>.
- There are four basic types of vaccine.
- A *live vaccine* is sometimes called an attenuated vaccine.
- Examples of live, attenuated vaccines are the chickenpox vaccine and the measles vaccine.
- The advantage of a live, vaccine is that the immune system responds better to a live vaccine than to a killed one. Also a live vaccine is also able to reproduce itself in the body giving added stimulation to the immune system.
- *Killed vaccines* do not stimulate the immune system as strongly as live vaccines and so they usually have to be given in a number of doses in order to induce protection.
- Examples of killed vaccines include polio vaccine and the rabies vaccine. Because the microbe is killed it cannot cause the disease.
- Another type of vaccine is not made from the microbe, but from a toxin that the microbe produces and it is this that causes the disease. Examples of toxin derived vaccines are the diphtheria vaccine and the tetanus vaccine.
- The toxin, which is a protein, is inactivated by either heating it or treating it with a chemical. Once it has been inactivated it is known as a *toxoid vaccine* and can no longer cause disease
- Toxoids can be recognized by the immune system but they do not produce a strong response, so they are combined with an adjuvant (see sidebar Adjuvants).
- *Sub-unit, conjugate or recombinant vaccines* use a part of the microbe that produces a strong immune response.
- Examples of these vaccines are hepatitis B vaccine,
  whooping cough (pertussis) vaccine, HiB vaccine which
  prevents meningitis in infants, the Human Papilloma
  Virus (HPV) vaccine which can prevent some types of
  cancer and the pneumococcal vaccine which prevents
  pneumonia in the elderly.

### Preservatives

- Some vaccines, especially those that are given to many people at about the same time, such as flu vaccine during an epidemic, are sold in vials that contain many doses.
- This is good for the speed at which the vaccine can be administered, but it does increase the risk that contamination of the vial may occur.
- To prevent this, small amounts of anti-bacterial chemicals, called preservatives are added to each vial.
- An example of a preservative that has been used for many years is thimerosal, contains ethyl mercury.
- Mercury is ubiquitous in our environment as is methyl mercury. Methyl mercury can be damaging to the nervous system.
- Ethyl mercury from thimerosal behaves very differently than methyl mercury and its only known side effect is redness and swelling at the injection site.
- All vaccines routinely recommended for children are available in thimerosal free formulations.



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### DISEASES THAT CAN BE PREVENTED BY VACCINES

### <u>Influenza</u>

- Influenza virus changes frequently, requiring a new vaccine almost every year.
- Respiratory disease, spread by infectious droplets ending up on the inner surface of the nose or mouth of another, where it can enter the body, multiply and a few days or so later, cause illness.
- Usually sudden onset, fever, headache and muscle aches.
- Most people recover, but serious complications, including death can occur.
- The flu virus does not always grow well in the lab and so some years the vaccine is not as effective.
- Two pediatric death occurred in Michigan during the 2017-8 influenza season. Nationally, 180 children lost their lives to influenza between October 1, 2017 and 1 September 2018.

### **Chickenpox**

- Chickenpox (varicella) can be a dangerous disease.
- Chickenpox is easily transmitted by inhaling respiratory secretions or by contact with fluid from the blisters.
- Infected lesions can affect bones, the brain, soft tissues.
- Chickenpox in pregnant women can lead to birth defects in the baby.
- Chickenpox virus can become dormant in the body and many years later reactivate and attack nerves causing shingles. There are now vaccines to protect adults, 60 years and older, from shingles.
- In 2016, there were 8,953 cases of chickenpox reported to CDC, with 3 deaths;
   531 of the cases were from Michigan, but no deaths.

### Hepatitis B disease

- Caused by the Hepatitis B virus (HBV).
- HBV can cause inflammation of the liver, leading to liver failure, liver cancer and death.
- The virus is found in blood, serum and semen.
- Spread by unprotected sex, sharing injection needles or syringes or vaginal birth,
- Most infections do not last long and when recovered, people have lifelong immunity.
- Some people continue to produce virus becoming carriers and can infect others.
- The hepatitis B vaccine was the first vaccine able to prevent a cancer (liver cancer).
- In 2016, there were 3,218 cases of acute hepatitis B reported to CDC and 45 of these cases were from Michigan. Nationally, 32 newborn cases were reported with no Michigan cases.

### Human Papilloma Virus infections

- There are more than 120 types of Human Papilloma Viruses (HPV) and most cause skin warts.
- Some types can cause cancer.
- Most are cancers of the genital tract but some are cancers of the mouth and throat.
- HPV is transmitted by direct contact, usually sexual, with an infected person. Unfortunately most infectious people do not know that they are infected.
- Transmission can also occur during the birth process from mother to newborn.
- Human papilloma virus infections are not reportable to the CDC, so we do not have data on the number of cases that occur each year.

### Pertussis

- Pertussis, (whooping cough) is a bacterial, respiratory infection.
- Pertussis is highly contagious and produces an uncontrollable violent cough and a deep throaty intake of air the "whoop".
- It is most serious for babies before they complete the full vaccine series.
- Recently it has been found that in some people the immunity from vaccines against pertussis fades over time. Adults are therefore recommended to get one additional dose of Tdap vaccine.
- In 2016, there were 17.972 cases of pertussis reported to CDC, of which 416 were from Michigan.

### Meningococcal disease

- This bacterial disease results in inflammation of the brain (meningitis) and blood-borne septicemia.
- Meningococcal disease is a medical emergency with high mortality.
- Typical symptoms include fever, bad headache and a stiff neck.
- Transmission occurs when saliva and respiratory droplets are transferred such as by drinking out of the same glass or can.
- Close contacts should be treated right away to prevent disease developing.
- In 2016, 375 cases of meningococcal disease were reported to the CDC, of which 6 were from Michigan.



### Tetanus

- Disease results from a toxin produced by the tetanus bacteria.
- Tetanus is uncontrolled muscle spasms and is often fatal.
- Spores of the tetanus bacteria reside in the soil and other contaminated places and get into the body through cuts and other wounds.
- Not contagious from person to person.
- In 2016, there were 34 cases of tetanus reported to CDC and 1 of these was from Michigan.

### Mumps

- Mumps virus is transmitted through infected respiratory droplets or saliva.
- Symptoms can include swollen salivary glands around the neck and swelling of the testes in post-pubertal boys. Other tissues that can be affected include the brain, the pancreas and the ovaries.
- Death from mumps is rare in the US.
- In 2016, there were 6.369 cases of mumps reported to CDC, of which 20 were from Michigan.

### Hepatitis A

- Hepatitis A is not related to Hepatitis B, although they are both infections of the liver.
- The hepatitis A virus (HAV) is transmitted through water and food that has been contaminated by HAV-containing feces.
- The virus makes it way to the liver where it multiplies and then is shed into the intestines and out through feces.
- Transmission can be prevented by good handwashing after using the bathroom and before preparing food.
- Symptoms are fever, feeling of unwell, loss of appetite, nausea, abdominal discomfort, dark urine and jaundice (yellowing of the skin and whites of the eyes).
- Michigan has been experiencing an outbreak of hepatitis A since August 2016. Other states have experienced similar outbreaks.
- In 2016, there were 2,007 cases of hepatitis A reported to CDC, of which 112 were from Michigan.

### Diphtheria

- Diphtheria is also caused by a toxin
- The diphtheria toxin usually acts by destroying tissue in the tonsil and pharynx area of the throat.
- The toxin can also affect the heart muscle and nerves and if these are severely affected can result in death.
- Up to 20% of people under 5 years and older than 40 years will die from the disease

### Rubella

- Rubella, also known as German measles, is characterized by a rash with fever, swollen lymph glands and upper respiratory symptoms.
- Complications are rare, and when they do occur are likely to be joint pain or encephalitis.
- The major complication of rubella is congenital rubella syndrome, which can occur when pregnant women are infected, primarily in the 1st trimester.
- Virtually all organs may be affected—eyes, heart, neurological system.
- In 2016, there was 1 case of rubella and 2 cases of rubella congenital syndrome reported to CDC, but none of these were from Michigan.

### <u>Rotavirus</u>

- Rotavirus causes an acute diarrhea in babies and young children, resulting in dehydration, sometimes severe.
- In some cases, hospitalization and death occurs, especially with children with other medical problems.
- Transmission occurs through contaminated food or drink.

### Poliomyelitis

- Polio is a disease caused by a virus which preferentially multiplies in nerves, particularly those of the spinal cord.
- This damages the spinal nerves leading to paralysis.
- Children are most vulnerable and the disease used to be known as infantile paralysis.
- The virus enters the body through contaminated water. Most children have few or no symptoms.
- The eradication of polio from the western hemisphere, and from most of the rest of the world is a clear example of the power of vaccines.

### Measles

- Measles virus is transmitted through respiratory droplets
- Disease results in a fever, cough, runny nose, eye inflammation and then a dense skin rash.
- 30% of people get complications including pneumonia, ear infections, inflammation of the brain and death.
- A late developing complication is subacute sclerosing panencephalitis.
- In 2016, there were 85 cases of measles reported to CDC; 1 was from Michigan

### Hib

- Haemophilus influenzae B is a bacterium that causes invasive diseases such as meningitis, pneumonia, arthritis and inflammation of the throat.
- It is most severe in children under the age of 12 months.
- 3% 6% of patients die from the infection, even when appropriate antibiotics are administered.
- In 2016, there were 4,895 cases of Hib disease reported to CDC, of which 185 were from Michigan.

### Pneumococcal disease

- Pneumococcal diseases are acute bacterial infections which result in pneumonia, septicemia and meningitis.
- All age groups are susceptible, although the impact is highest upon children, those with certain medial conditions and the very elderly.
- Pneumococcal disease is particularly serious when it follows influenza.
- In 2016, there were 17,626 cases of pneumococcal disease reported to CDC, of which 908 were from Michigan.

### Other Vaccine-Preventable Diseases

- Rabies
- Yellow fever
- Anthrax
- Typhoid
  - Japanese encephalitis
- Smallpox



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## VACCINE SAFETY

### Post Licensure Monitoring of Vaccines

- Once FDA approval has been granted, there are a number of databases<sup>3</sup> that collect information on any vaccine side effects.
- Some side effects are not related to the vaccines, but occur at around the same time, but others may be related to the vaccine.
- Each report is therefore carefully reviewed by a health care professional. A more extensive follow-up is conducted on reports which suggest a new side effect.
- The Vaccine Adverse Events Reporting System (VAERS)<sup>4</sup> is the national vaccine safety surveillance system.
- Other vaccine safety surveillance systems include the Vaccine Safety Datalink (VSD)<sup>5</sup> which involves health care organizations and the Clinical Immunization Safety Assessment Project (CISA)<sup>6</sup> which involves medical centers around the country.
- Many other countries also have similar systems such as Canada<sup>7</sup> and England<sup>8</sup>.

### National Vaccine Injury Compensation Program

- ⇒ In very rare cases, a vaccine can cause a serious problem, such as a severe allergic reaction.
- ⇒ In these instances, the National Vaccine Injury Compensation Program (VICP)<sup>9</sup> may provide financial compensation to individuals who file a petition and are found to have been injured by a VICP-covered vaccine.

- It is very important that vaccines are as safe as we can make them. Indeed, because we are putting them into healthy people, vaccines are held to a higher standard than medicines used to treat illness, when side effects may be more acceptable.
- Historically vaccines were crude preparations of bacteria or viruses that would often lead to considerable pain at the injection site and fever. In spite of this, vaccines provided protection against even more serious infections, and so people continued to use them. But vaccine purification methods have improved and today's vaccines are purer and safer than they have ever been.
- Before a vaccine is licensed by the US Food and Drug Administration (FDA) it must undergo extensive safety and efficacy trials <sup>1,2</sup>. A new vaccine or a new formulation of a vaccine must pass all the clinical trials before the vaccine can be licensed and used by the public.
- The basic questions that the trials must answer are:
  - Is the vaccine safe?
  - Is the vaccine effective—does it lead to protection from the disease?
  - What are the side effects and are they serious?
- Only after these questions have been answered and the vaccine found to be safe and effective will the vaccine be licensed.
- Even after the vaccine has been licensed, the safety of the vaccine is monitored, because there may be rare side effects that occur, even after testing in thousands of people (see side bar on Post-licensure monitoring)
- Manufacturers make their vaccine in large batches called lots. Each lot must be thoroughly tested for safety, purity and potency before the FDA will approve it for distribution.
- Some side effects are very rare, only occurring a few times after millions of people have received the vaccine. As vaccine trials involve thousands, but not millions of people, these rare events are unlikely to have been recognized before licensure. For this reason, monitoring for serious side effects continues even after licensure.

### Vaccine Information Statements

- \* It is important for vaccine recipients to understand the vaccine they are being given.
- \* Vaccine Information Statements (VIS)<sup>10</sup> are information sheets explaining the vaccine and its benefits and risks.
- \* A VIS must be given to each vaccine recipient (or their parent) before the vaccine is administered and for them to keep.

### When a Safety Issue is Suspected

- ⇒ A good example of how post-licensing monitoring of vaccines can pick up rare, but possibly serious side effects of a vaccine can be seen with the 1st rotavirus vaccine licensed in the US.
- ⇒ Rotavirus infections can be a very serious, gastrointestinal infection, usually seen in newborns and infants.
- ⇒ RotaShield, a vaccine against rotavirus infection was introduced in the US in 1999 and soon after cases of a bowel obstruction, called intussusception, following vaccination began to be reported.
- ⇒ A very extensive investigation was conducted by public health . They found that the risk of this condition was higher in infants who received the vaccine than in children who had not received it.
- $\Rightarrow$  After weighing the risks and benefits of the vaccine, the vaccine was then taken off the market<sup>11</sup>.



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Additional Information:

Institute for Vaccine Safety, Bloomberg School of Public Health, Johns Hopkins University: <u>http://www.vaccinesafety.edu/</u>

American Academy of pediatrics: <u>https://www.healthychildren.org/English/safety-prevention/immunizations/Pages/Vaccine-Studies-Examine-the-Evidence.aspx</u>

iVaccinate: https://ivaccinate.org/about-vaccines/vaccines-are-safe/

Children's Hospital of Philadelphia. https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-safety

## HOW VACCINES PROTECT AGAINST DISEASE

### Glossary

<u>Immune system:</u> a complex , biological defense system consisting of many types of cells and chemicals, whose function is to protect the body from attack.

<u>Antibody:</u> a chemical produced by the immune system which can attach and help destroy a microbe.

<u>Microbe:</u> very small organism, such as a bacterium or virus. While many microbes are important for our health, some can cause disease

### When vaccines may not work

Vaccines rely on a good immune response, so if a person does not have a well-functioning immune system, they may not be protected by vaccines.

For instance, if a person has had an organ transplant, such as a kidney or liver, their immune system may have been suppressed to reduce organ rejection. So these people are advised to be vaccinated before the transplant to establish immunological memory.

Vaccines that are made from live, but weakened microbes, such as measles vaccine, are generally not advised for people with severe suppression of their immune system

- Just as the military is designed to protect a country, so our immune system protects our body.
- When we first encounter a microbe, our immune system works out how to destroy it using microbe-specific proteins, called antibodies..
- But it takes time to work out which is the correct antibody and while the immune system is working this out, the microbe may be causing disease. [time "A" on the diagram below.] This process is rather like having a large bunch of keys and trying each one in the lock to find out which one works.
- Once the immune system has worked out the correct antibody, it goes into high gear and usually overcomes the microbes, then the illness starts to get better.
- But the immune system also "remembers" which was the correct antibody to destroy that particular microbe. So the next time that we encounter that bacteria or virus, (time "B" in the diagram below) the immune response can be swift and effective. No illness results and the person is immune.
- Vaccination uses this "immunological memory", by administering a vaccine, a harmless form of the microbe (see the page on "What is a vaccine"). The immune system cannot tell the difference between the vaccine and a dangerous microbe and so starts to work out how to destroy it and put this information into its immunological memory, even though the vaccine did not cause disease.

#### Immunological memory



After 1st exposure, it takes a few days before sufficient antibodies are formed to suppress the infection and so microbes cause illness.

After 2nd exposure , antibody is produced quickly and the microbe is stopped from causing illness

### Injection Site Pain

When a vaccine is injected (or a cut of any kind is sustained), the body's immune system quickly senses that there has been an "invasion".

In addition to working out the right antibodies to kill the "invader", the body also sends many frontline defenses to the location. These includes attack cells and chemicals that can inhibit microbes.

This is why an injection site can feel warm to the touch and sometimes feels painful. It is all those immune cells gathering at the injection site.

Sometimes, the immune system response can be felt all over the body - muscle aches, a slight fever and generally not feeling good are all parts of the immune response to the breach in the skin—it's the good guys getting their defenses going!

This why some people who get a flu shot think that they have the flu symptoms, when in fact it is the immune system these symptoms only last a day or two, the flu symptoms last many days.



Further Reading

National Institute of Health <u>https://www.niaid.nih.gov/research/how-vaccines-work</u>

PBS NOVA https://www.youtube.com/watch?v=lXMc15dA-vw

Vaccines 101: How Vaccines Work <a href="https://www.youtube.com/watch?v=p8OOqnLJs2Q">https://www.youtube.com/watch?v=p8OOqnLJs2Q</a>

## HOW DO WE KNOW THAT VACCINES WORK?

## Vaccines are working around the world

- Reductions in infectious diseases due to vaccines have occurred in every country.
- ♦ Polio once affected about 350,000 people around the world each year<sup>1.</sup> With intensive immunization campaigns, there were only 22 cases of wild-type polio disease reported worldwide in 2017<sup>1</sup>.
- ◊ In the 1970s and earlier, an estimated 20,000 children, most under 5 years, suffered each year from meningitis, pneumonia and epiglottitis caused by the bacterium *H. influenza*<sup>2</sup>. After introduction of the *H. flu* vaccine, there was a reduction of these diseases by more than 99%
- ♦ The impact of vaccines is shown in the table below.

- The function of vaccines is to protect people from diseases which can kill or cause serious illness.
- So we can look at the impact that vaccination has had on the number of people who become sick from the disease before and after the introduction of vaccine.
- One of the most dramatic impacts was on smallpox, which historically killed thousands annually.
- Typically 1 out of every 3 people with smallpox died and those that survived usually had lifelong scars across their body.
- Smallpox vaccination was introduced widely in the late 18th century and 2 centuries later the disease was completely eradicated from the world, with the last naturally occurring case occurring in 1977.
- Measles is another disease that has historically killed many, primarily children as well as causing lifelong nerve damage to some. It was so common that it was deemed as inevitable as "death and taxes." <sup>4</sup>
- Around 500,000 cases were reported each year in the US before 1963<sup>5</sup>. However, it has been estimated that as many as 3–4 million persons each year became infected<sup>5</sup>. With the introduction of vaccination in the 1960s, cases of this highly infectious disease have plummeted, and the disease was officially determined to have been eradicated from the western hemisphere in 2016<sup>6</sup>.
- Before the introduction of the polio vaccines in the mid-1950s, many children used to die from polio and many of those who survived were left crippled or disabled for the rest of their lives.

- Before a vaccine was available, there were approximately 117.55 case of pertussis reported each year for every 100,000 people in the US. After the introduction of the vaccine, there were 1.9 cases for every 100,000 people occurring each year<sup>7</sup>.
- Before the mumps vaccine was introduced, there were 89.53 cases annually for every 100,000 people in the US, but after the introduction of the vaccine, this number dropped to 2.09 new cases each year<sup>7</sup>.
- ♦ As these diseases are transmitted vie respiratory droplets from person to person, it is unlikely that these substantial decreases can be attributed to improvements in sanitation.



#### Annual measles cases reported in the US, 1950 to 2016

### Impact of vaccines upon serious infectious diseases in the US<sup>3</sup>

Disease	Cases each year in 20th century	2017 cases	% decrease
Smallpox	29,005	0	100%
Diphtheria	21,053	0	100%
Pertussis	200,752	15,808	<b>92</b> %
Polio	16,316	0	100%
Measles	530,217	122	> <b>99</b> %
Chickenpox	4,085,120	126,639	<b>97</b> %
Measles Chickenpox	530,217 4,085,120	122 126,639	>99% 97%



Michigan Association for Local Public Health

#### 15

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### HOW VACCINES WORK TO PROTECT A COMMUNITY

The minimum proportion of people in a community who have to be immune to prevent transmission of a particular disease is called the threshold. Different diseases have different thresholds:

> Mumps ...... 75–86 % Pertussis ...... 92–94 % Measles ...... 83 -94 %

### Community/Herd Immunity Works !

Although the chickenpox vaccine is not recommended for infants under 1 year of age, after the introduction of the vaccines in 1995, the number of infants who died from chickenpox in the US dropped dramatically from an average of 8.8 deaths each year to 1 per year<sup>5</sup>.

- Communicable diseases spread from an infected person to susceptible persons. When a person gets vaccinated, they become protected (no longer susceptible) from that disease and do not spread the disease to anyone else.
- If everybody in a town gets vaccinated and so becomes immune, then if one person comes into the community who is infectious, they cannot transmit the disease to the townspeople, because no-one is susceptible.
- But not everyone can be protected by vaccines—some are too young, some too ill (they may have cancer or a transplant where the immune system does not function well). But because everyone else is protected, the unvaccinated person is protected by their neighbors' immunity. This is called community immunity (sometimes herd immunity)
- However, if lot of people do not get vaccinated, then there are a lot more susceptible people in the community who can become ill and infectious. The chances of an infant or transplant patient coming into contact with an infectious person and becoming infected are therefore much higher.

The graphic below illustrates the principle of community or herd immunity

It shows three communities. In Community A, no-one is vaccinated against an infectious disease, in Community B, some are vaccinated and Community C, most are vaccinated, but some are too ill or too young to be vaccinated. The impact of a couple of infectious people coming into the communities, has very different impacts on the three communities.



<u>Community A:</u> In this community, everyone is healthy, but not immune to measles because they were not vaccinated (blue figures). Into that community come 2 people who have just returned from abroad, and have become infected with measles (red figures). Measles is very infectious and almost everyone that they come into contact with becomes sick, and those contacts pass on the infection to others, and so on, until almost everyone became sick. Maybe some, babies or very elderly, will die; some sustain life-long neurological damage.<sup>1,2,3</sup>

<u>Community B:</u> In this community, some of the people have been immunized (yellow figures) and so do not get sick, but because most of the population are un-immunized, the majority of people get the measles

<u>Community C</u>: In this community, almost all of the people have been immunized (yellow figures) and so do not get sick,. There are a few people who are un-immunized. Because the majority of people are protected through vaccination, they provide a barrier around those that are unprotected, and so most vulnerable people do not get the measles.



Image credit: The National Institute of Allergy and Infectious Diseases

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### Myths and misconceptions about vaccines

### Modern Day Old Wives Tales

An old wives tale is a supposed truth that is actually false and makes unsubstantiated claims with exaggerated and/or inaccurate details. The concept of "old-wives" tales has a long history, and many, such as "butter on a burn" and "starve a fever, feed a cold" have not only been shown to be useless, but often damaging to health. With the growth of the internet and social media, many of these "old wives tales" have been updated, and many of these stories about vaccines are simply incorrect. However, just as spreading butter on a burn can make the burn worse, so these modern day "old wives tales" can result in increased risk from serious diseases.

When it comes to the health of our children and our communities, we should not be relying on old wives tales to determine what responsible policies and actions should be taken to keep our families healthy.

There is no doubt that to parents the media stories and celebrity "experts" talking about the harmful effects of vaccines can be frightening. But their child's physician or nurse is a trusted and better source of considerable scientific information about vaccines and their importance. In spite of considerable science-based evidence to the contrary, a number of myths about vaccines are still circulating. For many people, especially parents of young children, these are a cause for concern. The scientific evidence debunking these myths comes from many different sources and scientists in a number of different countries (the USA, Canada, Europe, the UK, Australia).

<u>Vaccines cause autism</u>: this myth arose from a paper that was published by a researcher who had an undisclosed financial conflict of interest in the outcome of his study and which was subsequently retracted by some of the authors. Researchers in the US and Europe tried to repeat his study and found that there was no association between a child developing autism and having received the MMR vaccine <sup>1,2,3,4,5</sup>. Recent studies indicate that autism develops during fetal development and although the cause is still unclear, exposure to environmental toxins may be implicated <sup>6,7,8</sup>.

Infant immune systems cannot handle all these vaccines: infant immune systems are exposed to hundreds of "foreign" substances every day, in what they breath, drink and put in their mouths (think dirty fingers). A small scratch, almost too small to see, can let into the baby's body many hundreds of bacteria or viruses. The immune system of a healthy baby easily handles this work—that what it was designed for. The immune system can, in fact, handle many more substances that would be injected in all of the vaccines recommended for babies <sup>9,10,11,12</sup>. The other thing to remember is that advances in technology and purification methods, means that vaccines today contain far fewer components that vaccines in the 1960s.

Natural immunity is better than immunity from vaccines. With some infections, the natural immunity following infection and illness is much stronger than immunity following vaccination. The problem is that natural immunity frequently entails getting sick with a disease that can kill or cause long-term damage. The risk of natural infection therefore outweighs the benefits and the alternative, that is vaccine-produced immunity, is very safe and very effective in almost all cases.

Vaccines contain chemicals that are harmful: First of all, chemical are what our bodies are made of, and many of these have long, complicated names. But they are essential to our existence. Vaccines, as all medicines, whether they be manufactured or "natural" contain many chemicals. Some vaccine contain very small amounts of chemicals which can stabilize, preserve and enhance the functions of the vaccine. However, the levels of these types of chemicals are very, very low and many of which, such as formaldehyde, can be found naturally in our bodies anyway. Other chemicals called adjuvants such as aluminum compounds, are added to vaccines to make it easier for the immune system to respond to the vaccine.

It is better to space out vaccines and delay some of them: A number of parents, not sure about some of the myths/misconceptions that they hear about vaccines decide to compromise and space out the vaccines given to their children by greater intervals than are recommended by pediatricians and vaccine experts. This is sometimes known as the alternative schedule. It is not however recommended for a number of reasons. Delaying vaccination lengthens the time that a child may be vulnerable to the disease. With the recent increases in measles and pertussis seen in Michigan and in around the country, this could have tragic consequences for under-immunized infants.

Spreading out vaccine doses beyond the recommended schedule requires additional vaccination visits, which could increase the stress on children. Lastly, there is no evidence that this practice decreases the risks of unwanted effects.



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## IMMUNIZATION WAIVERS



- ⇒ A study of immunization and pertussis data in Michigan has shown that in addition to the risk to individuals, the risk of community outbreaks of pertussis is increased where there are geographic clusters of children with immunization exemptions<sup>4</sup>.
- ⇒ Studies in other states have shown that where there are areas of high vaccine exemption rates there are much greater risks of outbreaks of diseases such as measles and pertussis <sup>5,6</sup>.

Under the Administrative Rules of the Michigan Public Health Code children can be exempted from school immunization laws in three circumstances (R 325.176)<sup>1</sup>.

"Medical exemption" means a written statement from a physician that a vaccination is medically contraindicated for a particular child for a specified period of time.

"Religious or other exemption" means a written statement which is signed by the parent, guardian of a child, which certifies that immunization is in conflict with religious or other convictions of the signer, and which includes the name and date of birth of the child. The non-religious exemption is also known as the philosophical exemption.

Children are assessed for immunizations if they are attending group programs, such as day care centers or camps, or entering school. For schools, this assessment is made when children are entering kindergarten, when they are entering into the 7th grade and if they are new students to the school district.

Michigan is one of just19 states to permit philosophical exemptions from immunization. The other 31 do not permit them. 2 states only permit medical exemptions<sup>3</sup>.

The increased risk of disease when many children have vaccine exemptions has substantial implications for public policy, health care costs for the state and for the health of children and adults who for medical reasons are particularly vulnerable to infectious disease, but cannot, because of those medical reasons, be vaccinated and thus protected <sup>7,8,9.</sup>

Among a review of 970 measles cases reported to CDC since 2000, that occurred in unvaccinated people who were old enough to receive MMR vaccine, **70.6**% had non-medical exemptions<sup>10</sup>.

Higher rates of vaccine exemption in a community are associated with greater measles incidence in that community<sup>10</sup>.

### **Medical Exemptions**

- A medical exemption is granted when a specific vaccine may be harmful to a child because of a medical condition.
- There are a number of medical conditions which would make receiving a vaccine inadvisable.
- ◊ If a child has a weakened immune system, for example if they have leukemia or other cancer, they should not receive a live vaccine such as chickenpox or the mumps, measles and rubella vaccine.
- If a child has a true allergy to any component of the vaccine or had a severe allergic reaction to that vaccine previously, they should not receive it.

Immunization Waivers among School Children, Michigan 2017<sup>2</sup>

Waiver type	Kinder- garten	7th grades	New Students
Total Waiver	5,005	3,882	5,478
Medical	251	188	224
Religious	1,095	793	1,299
Philosophical	3,659	2,901	3.955
Total No. students assessed	119,029	113,569	167,341

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### Parents' Voices Personal reports from parents

### Amanda Kanowitz<sup>1</sup>

Amanda was 4 1/2 years old when she developed a fever and cough. After talking with their pediatrician, her parents were told to keep giving her sips of water and make sure that she was urinating. Amanda woke in the middle of the night complaining of a stomachache. Four hours later, she was found, lifeless in her bed. Amanda died of influenza.

### Peggy Archer<sup>3</sup>

Peggy has a message for all vaccine-hesitant parents. She is a Michigan nurse, but as she had a busy schedule and the Hib vaccine was relatively new, had not had her 2-year old daughter, Sarah, vaccinated against this very serious disease that can cause meningitis and other deadly illnesses. One day however, her daughter developed a cough which got progressively worse, with fever and difficulty breathing. It became so bad they Peggy and her husband took Sarah to the ER, where she was diagnosed with epiglottitis, a manifestation of Hib disease. A small tube was inserted into Sarah's windpipe and she was readied for surgery to open up her windpipe surgically and insert a larger tube to help her breathing. She was given a drug to paralyze her to prevent her dislodging the tube, but she could still feel everything. The doctor who treated remarked that this could have been prevented by vaccination against Hib. Fortunately, Sarah recovered. Peggy says that if vaccine-hesitant parents are aware of children like Sarah, who nearly lost their lives to vaccine-preventable disease, they will reconsider their decision.

### Carla Newby<sup>5</sup>

Six-year old Jacob was a healthy boy who got along well with everyone. He awoke one morning not feeling well and during the day his fever climbed to 104.5°F. The family took him to the ER where he was treated and sent home. The next evening he complained of a terrible headache, so he went back to the ER. The doctors tested his spinal fluid and put him on oxygen. The tests showed that he had pneumococcal meningitis. He was transferred to another hospital, where he was on a respirator and became comatose. His parents were told that he would not make it, and 14 hours later he died. Jacob became infected with the pneumococcal bacteria before there was a vaccine. Today, his mother urges parents to get their children vaccinated against this disease. She believes that if the vaccine had been available, "they would not have lost him. Vaccination is very important. It is life and death."

### Lynne and Phil Baker<sup>2</sup>

Lynne Baker is a member of a large family of Polish immigrants from the Detroit suburbs. When she was in the 3rd trimester of pregnancy with her third child, she developed a cough. All through labor and delivery, Lynne coughed. The baby was born and the happy couple took Nelyn home. About 2 weeks later, Nelyn began to cough, then his fingers and toes turned blue. Two days later he died, just 18 days old, An autopsy determined that the cause was pertussis (whooping cough). They could not understand this as Lynne had been vaccinated as child. But protection against pertussis is not lifelong. To protect babies, women should receive the whooping cough vaccine during the 3rd trimester of each pregnancy and others who live in the home, or have regular contact with a newborn should also be vaccinated. Then make sure that the baby receives their vaccines on schedule.

### Thomas Morris<sup>4</sup>

"parents would never hesitate to immunize their children if they understood what whooping cough puts a child through" said Nick's father Thomas. Thomas and his wife decided not to get the 2nd dose of the pertussis vaccine because of all the stories in the media and on the internet about adverse reactions to the vaccine. They did not want to take the risk. When he was 4 years old, Nick developed a violent cough, causing him to vomit and turn blue. They feared for his life. Fortunately, with good medical care, Nick survived and is now fully vaccinated. About all the media blitz, Nick's father said that he thinks the media did a disservice by frightening parents about the vaccine without noting the risks of pertussis.

### Cyrstie<sup>6</sup>

Cyrstie's 16-month old daughter, Cambree, has not been vaccinated. When she was 2-months old, she was found to have non-functioning liver and bile ducts, and had to have a liver transplant. The first two transplant were not successful, but the third one was. But Cambree has to remain on heavy doses of drugs which suppress the immune system so that it will not reject her new liver. But it also means that she cannot be vaccinated against diseases such as measles and chickenpox. Cyrstie is scared to think that there are parents whose decision not to vaccinate their children could put her child at risk. "Please vaccinate your children" she pleads "Please protect my child who cannot be vaccinated. And please protect your own."



### Rebecca Cole<sup>7</sup>

"I have faced the worst nightmare any parent can possibly face. There is no experience on earth that compares to the horror and devastation of losing a child. It is shattered dreams, crushed wishes, and a future that suddenly vanishes before our eyes. It cannot be wished away, slept away, prayed away, or screamed away. It is darkness, agony, and shock. It leaves our hearts broken, bleeding, and bursting with pain, and it changes us forever. "

These are the words of Rebecca Cole, whose son, Christopher Chinnes, died aged 12 from chickenpox. He had been on corticosteroids for asthma, but these drugs also impaired his immune system so that it could not protect him against the chickenpox virus. Christopher died in 1988, before the varicella (chickenpox) had been licensed by the FDA. "Please don't get the impression" she says "that only those who are immunosuppressed can have problems with chickenpox. Anyone can. In fact about half of those who suffer complications or die each year (from chickenpox) are normal, healthy people".

### Frankie Milley<sup>8</sup>

Frankie Milley's only son Ryan, die whn he was 18 years old from meningococcal meningitis. Ryan had just graduated from high school and was a golf pro, when he started to show symptoms of a fever, aching ears, but no stiff neck, nausea or sore throat, which are typical symptoms of meningitis. Within 24 hours though he had developed red spots under his skin and was in the ER. Despite the medical team's efforts, Ryan died from meningococcal disease. At that time, the meningococcal vaccine was not recommended for health young adults such as Ryan. Ryan's mother has become a vocal advocate for vaccines. Frankie's mission has been to fight for children who need vaccines. She writes "As of today, I have helped to write, advocate for and pass over 18 laws across the US. My heart screams kids are still dying today in spite of all of the work. As more and more parents opt out of vaccines, this number will increase. The loss of life will be immeasurable". She goes on to say "One simply has to walk around an old cemetery to understand the value of vaccines. I have to simply look within the pain and memories of my heart to know. I believe if children had a voice and could choose between vaccine preventable diseases and a vaccine, they would choose vaccine. But they don't have a voice. We have to stand up and be that voice for children, proven science and reason, and one of life over death and debilitation. Disease kills, vaccines save lives".

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