

DOCUMENT RESUME

ED 417 134

SP 037 777

TITLE Plain Talk about Childhood Immunizations.
 INSTITUTION Alaska State Dept. of Health and Social Services, Juneau.
 Div. of Family and Youth Services.
 PUB DATE 1997-00-00
 NOTE 32p.
 AVAILABLE FROM State of Alaska, Division of Public Health, Section of
 Epidemiology, Immunization Program, 3601 C Street, Suite
 540, Box 240249 Anchorage, AK 99503; phone: 907-269-8000.
 PUB TYPE Guides - Non-Classroom (055)
 EDRS PRICE MF01/PC02 Plus Postage.
 DESCRIPTORS *Child Health; Disease Control; Elementary School Students;
 Elementary Secondary Education; *Health Promoti^on;
 *Immunization Programs; Parent Responsibility; Preventive
 Medicine; Public Health; Secondary School Students
 IDENTIFIERS Alaska; *Vaccination

ABSTRACT

This booklet provides parents with information about immunizations and vaccine-preventable diseases, balances the benefits and risk of vaccination, and responds to inaccuracies or misinformation about immunizations and vaccine-preventable diseases. Section 1 presents a message to parents about vaccination. Section 2 offers facts about vaccine-preventable diseases (measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, haemophilus influenzae type b, hepatitis A and B, and varicella). This section explains that proper immunization saves lives, prevents the spread of disease, and saves money. Section 3 describes how the immune system and vaccines work. Section 4 helps parents understand the importance of vaccinating early rather than waiting to receive any recommended vaccinations. Section 5 answers questions about specific vaccines. Section 6 explains that proper adolescent health care includes immunizations. Section 7 discusses legal requirements and considerations related to vaccinations. Section 8 highlights the safety of vaccines, discussing vaccine approval and monitoring by the U.S. Food and Drug Administration. Section 9 compares the risks of disease and serious complication to the risk of serious reaction to a vaccine. Section 10 presents news stories about individuals who have contracted diseases because of not being vaccinated. Section 11 presents a list of resources. (SM)

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PLAIN TALK ABOUT CHILDHOOD IMMUNIZATIONS

Special Acknowledgment

We would like to thank the many parents and health care professionals who volunteered their time and input to help us make this booklet useful and accurate for all Alaskan families.

Thank you.

This booklet was originally developed in 1996 by the by Seattle-King County Department of Public Health and Snohomish Health District, for specific use within the state of Washington, with assistance from the following public and private agencies: Children's Hospital and Medical Center; Healthy Mothers, Healthy Babies Coalition of Washington; Immunization Action Coalition of Washington; Rotary International; Washington State Department of Health; Watcom County Health Department.

The booklet was revised by the State of Alaska Department of Health and Social Services, Immunization Program, with the research assistance of the **Vaccinate Alaska Coalition**. The content of this brochure was adapted to include Alaska-specific facts, charts and other information pertinent to Alaskans. Financial assistance was provided by the State of Alaska, Division of Public Health, Medicaid Services Unit.

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This publication was produced by the Department of Health and Social Services, Division of Public Health, Section of Epidemiology, in order to provide parents with factual information about vaccines and vaccine preventable diseases. It was printed by Alaska Printing Inc. at a cost of 40¢ per copy, in Anchorage, Alaska.

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1. A MESSAGE TO PARENTS

Thank you for your interest in finding out more information about immunizations. As parents, we are asked to make many important decisions concerning our children. Some of the most difficult decisions can be in regard to their health care. For most, to have your child immunized is one of the easiest decisions. For others, it is more difficult. We all want to make the right choices and do what is best for our children. As a community, we also need to protect the public's health. We recommend that you have your child immunized, but ultimately the decision is yours.

We designed this pamphlet in response to requests by parents, health care professionals, school nurses, child care providers and others to:

- ♦ provide more information about immunizations and vaccine-preventable diseases, much in the same way you look for information on car seats, bicycle helmets, and age-appropriate toys;
- ♦ balance the benefits and risk of vaccination and assist you in making an informed decision;
- ♦ respond to inaccuracies or misinformation about immunizations and vaccine-preventable diseases.

We have arranged the information so you can read each section independently. We use a question and answer format in many areas, but may not have included all the answers you need. We encourage you to discuss these issues with other parents, a health care professional or your local Health Department.

GLOSSARY

DTP - Diphtheria, Tetanus, and Pertussis vaccine
DTaP - Diphtheria, Tetanus, and acellular Pertussis vaccine
MMR - Measles, Mumps, and Rubella vaccine
OPV - Oral Polio vaccine
IPV - Inactivated Polio vaccine
Hib - *Haemophilus influenzae*, type B
Hep A - Hepatitis A
Hep B - Hepatitis B
VZV - Varicella zoster virus (chickenpox)
CDC - U.S. Centers for Disease Control and Prevention
FDA - U.S. Food and Drug Administration
VAERS - Vaccine Adverse Event Reporting System

2. THE FACTS ABOUT VACCINE-PREVENTABLE DISEASES

MEASLES, MUMPS, & RUBELLA (MMR)

Measles, mumps and rubella are all viruses that spread from person to person very easily through coughing, sneezing, or just talking.

Measles causes a high fever, rash, and cold-like symptoms. It can lead to hearing loss, breathing problems, brain damage, and even death. Measles spreads so easily that a child who has not been immunized will most likely get the disease if exposed to it. And in fact, studies have shown that the measles virus can remain in the air (and be contagious) for up to three hours after a person with the disease has left the room.

Mumps causes headache, fever, and swelling of the cheeks and jaw. It can lead to hearing loss, meningitis (inflammation of the brain and spinal cord) and brain damage.

Rubella (German Measles) causes a slight fever and a rash on the face and neck. Pregnant women who get rubella can lose their babies, or have babies with severe birth defects.

DIPHTHERIA, TETANUS, & PERTUSSIS (DTP)

Diphtheria, easily spread through coughing or sneezing, is caused by a toxin from diphtheria bacteria. Diphtheria that can cause paralysis, breathing and heart problems, and death.

Tetanus ("lockjaw"), a toxin from tetanus bacteria, occurs when a tetanus germ enters a cut or wound. It can cause muscle spasms, breathing and heart problems, and death.

Pertussis ("whooping cough"), also from a bacteria that is spread through coughing or sneezing, causes very long spells of coughing that make it hard for a child to eat, drink, or even breathe. Pertussis can cause lung problems, seizures, brain damage and death.

POLIO (OPV/IPV)

Polio causes fever and may progress to meningitis and/or lifelong paralysis. Polio can be fatal. Persons infected with the polio virus shed the virus in the stool and can transmit the virus to others.

HAEMOPHILUS INFLUENZAE TYPE B (Hib)

Hib disease can cause infections of the joints, skin and blood, meningitis (inflammation of the brain and spinal cord), brain damage and death. Before the introduction of effective vaccines, *Haemophilus influenzae* was the leading cause of bacterial meningitis among children under 5 years of age. This bacterial disease is most serious in infants under one year of age. Despite receiving appropriate medical care, 2 to 5 of every 100 children infected with Hib die. For children who survive, 15-30% have lingering brain damage or other serious health problems.

HEPATITIS A (Hep A)

Hepatitis A is a serious viral infection of the liver which causes fever, yellow skin and eyes, loss of appetite, and nausea. It is spread from person-to-person. You can also catch it by eating food (including shellfish from polluted water) or drinking water that has been contaminated with fecal material from a person infected with the hepatitis A virus. Hepatitis A infection is a major health problem in Alaska.

HEPATITIS B (Hep B)

Hepatitis B is a serious liver infection. It can be passed from an infected mother to her newborn during childbirth and from one person to another through blood or body fluids or by sexual contact. A lifelong infection with this virus can cause liver cancer and death.

VARICELLA (Chickenpox)

Varicella is a very contagious viral disease causing rash and fever. It is spread by coughing and sneezing or direct contact with drainage from the rash. Among children, a common complication is bacterial infection of the skin lesions. The disease is usually mild and symptoms last only a few days, but in rare cases it can lead to serious complications such as encephalitis, pneumonia and even death. It is more serious in adults and persons with impaired immune systems. If a woman has this disease while pregnant, it can cause birth defects and infant death. In addition, varicella virus remains "hidden" in the body after infection and may become reactivated into herpes zoster ("shingles") later in life.

PROPER IMMUNIZATION SAVES LIVES

Eleven serious childhood diseases are preventable with vaccines. In unimmunized populations of the world, 600,000 children die each year from pertussis (whooping cough), and over 1,000,000 children per year die from measles.

The 1989-1991 measles epidemic in the United States was responsible for 55,000 cases and more than 130 deaths. Nearly half of these deaths were in children under the age of 2.



HOORAY FOR ME!

IMMUNIZATIONS PREVENT THE SPREAD OF DISEASE

Many childhood diseases are easily spread from child to child and to and from adults. The biggest cause of the 1989-1991 national measles epidemic was the failure to vaccinate children between 12-18 months of age on time.

During the years 1986 through 1990, an average of 29 cases of Hib meningitis were reported yearly in Alaska. From 1991 to 1995, after Hib vaccine became available throughout the state, an average of only 4.6 cases were reported each year.

IMMUNIZATIONS SAVE MONEY

Immunizations are one of the most cost-effective medical procedures available. Vaccine-preventable diseases cost 25 times more than the vaccines that prevent these diseases.

The 1989-1991 measles outbreak in the U.S. caused 44,000 days of hospitalization, resulting in \$100 million in direct medical costs; this does not include the indirect costs to the family, such as lost days of work, school and child care.

Current estimates of direct medical costs and indirect (work loss) costs of hepatitis B-related liver disease exceed \$500 million annually.

AND, DID YOU KNOW...

A 1996 survey revealed that only 66% of children in Alaska were fully immunized by the age of two; in some regions of the state, the rate was as low as 49%. Children need the majority of their immunizations in the first two years of their lives, when they are most vulnerable to vaccine-preventable diseases.

An infant's immune system cannot easily fight off disease-causing bacteria or viruses. Of the 4 cases of Hib meningitis reported in Alaska in May, 1996, all were in infants less than 7 months of age. Often, the effects of disease are more serious in infants than in older children. Many vaccine-preventable diseases have no cure or treatment, making prevention our only weapon.

A disease may not currently be present in a community, but disease outbreaks can and do occur in communities that are not protected. In Spring, 1996, 63 cases of measles occurred during an outbreak in Juneau; this was more than twice the number of cases reported in Alaska during the previous five years combined. These 63 cases gain even more significance when compared with the rest of the country. Although Alaska has less than 0.5% of the country's population, the state accounted for 16% of all U.S. measles cases in 1996.

"Some parents feel that these diseases are from the distant past, and we don't have to worry about them anymore," states Dr. Jim Raelson, a pediatrician at Alaska Native Medical Center. "However, as recently as 10 years ago, I cared for a significant number of children every year who either died or were severely affected by Hepatitis B and Hib disease. [Vaccine-preventable] diseases are more rare now in Alaska [due to vaccines], but we know that the germs are still waiting for the unprotected child."

3. THE IMMUNE SYSTEM AND HOW VACCINES WORK

The immune system is the defense mechanism in each person that helps the body fight disease. Medical science has found an effective way to help the immune system fight disease through the use of vaccines.

When you get an infection, your body reacts by producing substances called antibodies. These antibodies fight the foreign substance (antigen) or disease and help you get over the illness. The antibodies usually stay in your system, even after the disease has gone, and protect you from getting the same disease again. This is called *immunity*.

Newborn babies often have immunity to some diseases because they have antibodies that they received from their mothers during pregnancy or through breastfeeding. But this immunity doesn't last. It wears off during the first year of life. We can keep children immune to many diseases, even after they lose their mothers' antibodies, by immunizing them.

Vaccines make the body think it is being invaded by a specific disease, and the body reacts by producing antibodies. Then, if the child is exposed to the disease in the future, he or she is protected. Even in the rare instances that a vaccinated child gets a vaccine-preventable disease, the symptoms are usually much less severe, and the child recovers more quickly than if he or she had not been vaccinated.

Vaccines can be given to children as shots or as drops to be swallowed. Some vaccines consist of weakened disease virus. These vaccines are extremely effective with only one or two doses. Some other vaccines are made of "inactivated" or "killed" virus or bacteria and require multiple doses to build up the immune response. Some inactivated vaccines, like the vaccine against tetanus and diphtheria, require booster doses throughout life.

QUESTION: *Do vaccines decrease the immune system's natural ability to fight disease?*

ANSWER: No. A vaccine produces an immune response that is very specific to the organism or antigen which produced it. For example, the antibodies produced in response to measles virus have no effect on the body's ability to respond to another illness.

QUESTION: *I heard that the less you "bombard" the immune system at one time, the better, so you should not give several vaccines on the same day. Is this true?*

ANSWER: No. A child's body is not harmed by receiving more than one childhood vaccination at the same time. While there is clearly much more to learn about the immune system, some things we do know. Scientific data show that giving a child many vaccines at the same time has no adverse effect on a normal immune system.

According to William Atkinson, MD, U.S. Centers for Disease Control and Prevention, "The immune system is an extremely capable system. It can manage and respond to literally millions of antigens (foreign substances) at the same time. Take for example, walking outside on a spring day with flowers and trees in bloom. Through your mouth, nose and lungs, your immune system will constantly respond to multiple antigens (like pollen and dust) as it does its work in your bloodstream. In the same way, in daily interactions, you may be exposed to multiple cold viruses and your body will respond successfully. But the immune system needs help to ward off the serious infectious diseases that immunizations can prevent."

QUESTION: *Is the method of injecting vaccines harmful for the body?*

ANSWER: Injecting the vaccines is a safe method. Just as the method of injecting valuable antibiotics for illness is okay, it also is safe for giving vaccines. Vaccines are not injected directly into the bloodstream; most vaccines are injected into muscle or fat, or just below the skin. In addition, the syringe and needle used for a vaccination are sterile and are used only once and then thrown away, so there is no possibility for the spread of bloodborne diseases.

QUESTION: *I've heard that some people who get these diseases had been vaccinated against them - how could this be true?*

ANSWER: For reasons related to the individual, not all vaccinated people develop immunity. Most routine childhood vaccines are 85 to 95% effective in vaccinated individuals. Also, most vaccines require more than one dose to reach the maximum amount of immunity, and as mentioned above, some require booster doses throughout life to continue that immunity.

QUESTION: *I heard that because of better hygiene and sanitation, vaccine-preventable diseases began to disappear before vaccines were introduced. Is this true?*

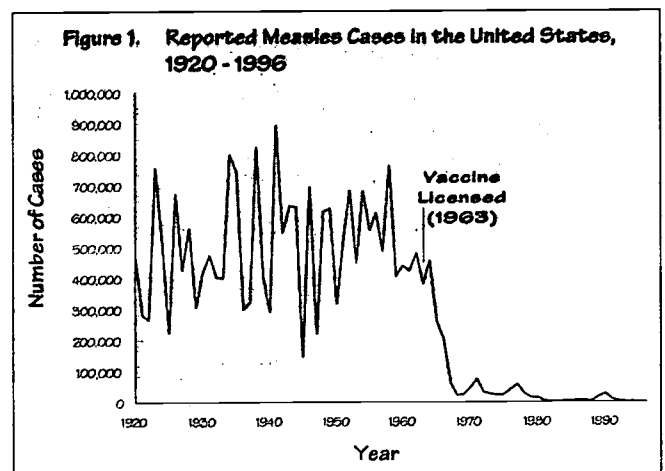
ANSWER: Yes; most infectious diseases became less common as living conditions and hygiene improved. However, they remained as serious threats. It often takes a combined approach to effectively combat disease. Several factors have helped the work of vaccines in preventing disease, including:

- ♦ better nutrition
- ♦ less crowded living conditions and better sanitation
- ♦ the development of more effective antibiotics

In spite of these advances, vaccine-preventable disease outbreaks still occur because of lack of vaccination or under-immunization. Diseases like measles and pertussis are highly contagious, regardless of hygiene and living conditions.

"As a lifelong resident of the Bristol Bay region, I have personally seen vaccines prevent infectious diseases," states H. Sally Smith, Chairman of the Board, Bristol Bay Area Health Corporation. "I encourage parents to protect their children's health with vaccinations."

Looking at the actual number of cases of disease over the years can leave little doubt of the significant direct impact vaccines have had, even in modern times. The number of cases of measles, pertussis, Haemophilus influenzae type B (Hib) and other vaccine-



preventable diseases has decreased dramatically since the introduction of immunizations against these diseases. For example, Figure 1 shows the reported number of cases of measles from 1920 to the present. There were periodic peaks and valleys throughout the years, but the real, permanent drop coincided with the licensure of measles vaccine in 1963.

QUESTION: *Since vaccine-preventable diseases have been almost eliminated from the United States, do I still need to vaccinate my child?*

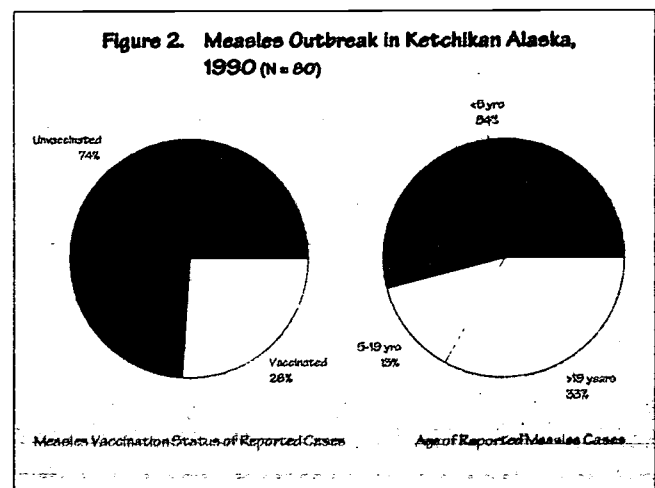
ANSWER: Yes. It's true that vaccination has enabled us to reduce most vaccine-preventable diseases to very low levels in the United States. However, some of these diseases are still quite common, even epidemic, in other parts of the world. Travelers can unknowingly bring these diseases into Alaska, and if we are not protected by vaccinations, these diseases could quickly spread throughout the population and cause epidemics here.

We should still be vaccinated, then, for two reasons:

- To protect ourselves. Even if we think the chances of our child getting any of these diseases is small, the diseases still exist and can still infect anyone who is not protected. A few years ago in California, a child who had just entered school caught diphtheria and died. He was the only unvaccinated pupil in his class.
- To protect those around us. There are a small number of people who cannot be vaccinated (because of severe allergies to vaccine components, for example), and a small percentage who do not respond to the vaccine (for reasons related to those individuals). These people are susceptible to disease, and their only hope of protection is that people around them are immune and cannot pass the disease along to them. We would think it irresponsible of a driver to ignore all traffic regulations on the presumption that other drivers will watch out for him. In the same way, we shouldn't rely on people around us to stop the spread of disease without doing what we can as well.

Figure 2 illustrates an outbreak of measles that began in Ketchikan, Alaska, in 1990. The majority of the cases in this outbreak were in pre-school aged children who were infected with the measles virus at their day care centers or in medical settings.

Nearly three-fourths of the people infected with measles during this outbreak were unvaccinated.



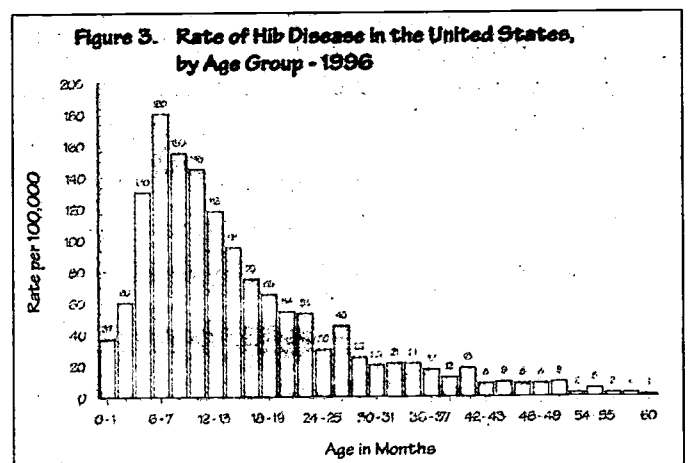
4. **T** WAIT OR NOT TO WAIT

Parents frequently ask why immunizations are given at different ages. You may wonder if you can wait until your child is entering school to get the required vaccinations. You may also wonder about the risk if your child does not receive all recommended immunizations.

QUESTION: *Is it okay to wait until my child is getting ready to start school to get all his or her immunizations?*

ANSWER: No. Waiting until kindergarten, or even until after your child's first birthday, to have your child immunized can put him/her at increased risk of contracting serious diseases that could be prevented. Maternal antibodies that your child may have received during pregnancy begin to fade during his or her first year of life. At the same time, she or he is also more frequently exposed to other children and adults who may be carrying these diseases.

Finally, most of these diseases are more dangerous in infants and very young children. For example, Hib meningitis most often attacks infants between 6 and 18 months of age, as shown in Figure 3. Likewise, pertussis is most severe in infants less than 1 year old. Postponing your child's immunizations reduces their benefit to your child and leaves them at risk of getting these serious diseases.



QUESTION: *Can my child catch-up if she is behind in immunizations?*

ANSWER: Yes, but it is best to stay as close as possible to the recommended ages and intervals between doses.

An interruption in the schedule does not require a child to start the series over. However, until the entire vaccine series is received, the individual will not have the maximum amount of protection against the disease. If a child is behind on the immunization schedule, a catch-up schedule can be determined by the child's doctor, nurse, or clinic.

QUESTION: *Are immunizations okay even if my child has a minor illness?*

ANSWER: Immunizations can be given and should be requested during any visit to your doctor or nurse, even if your child has a minor illness, such as mild fever, a cold, diarrhea, or is taking antibiotics. The vaccine will still be effective. It will not make your child's illness worse. Receiving all immunizations when they are due is an important way to complete each vaccine series on time and prevent extra visits.

QUESTION: *Are there times that vaccines should NOT be given?*

ANSWER: Yes, sometimes there are medical reasons for not giving a vaccine or for delaying it. These are referred to as "contraindications" and "precautions".

In general, a child should not receive a vaccine if he or she:

- ♦ has a condition that is likely to result in a serious medical or life-threatening problem if the vaccine were given, or
- ♦ has a condition which could reduce the ability of the vaccine to produce the desired immunity (such as severe illness).

Examples:

- ♦ A child is allergic to a vaccine component (e.g. neomycin, thimerosal) that would cause an allergic response, such as difficulty breathing, low blood pressure or shock.
- ♦ A child has recently received blood products (such as immune globulin or a blood transfusion), or has a moderate or severe illness.

In most instances, factors such as breast feeding, ear infections, antibiotic treatment, mild diarrhea and milk allergy do not contraindicate vaccine use. Check with your health care provider if you have specific questions regarding these or other circumstances.

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Q

QUESTIONS & ANSWERS ABOUT SPECIFIC VACCINES

HEPATITIS A

Hepatitis A vaccine protects against the serious liver infection caused by the hepatitis A virus. It is an extremely safe and effective vaccine with very few side effects, and it only requires two doses.

For the past 20 years, public health officials have tried to reduce the impact of this serious disease in Alaska. In spite of their efforts, Alaska continues to have major hepatitis A outbreaks every 5 to 7 years. In 1993, four people in Alaska died from hepatitis A infection. It is recommended now that all Alaska children between the ages of 2 and 14 years receive the hepatitis A vaccine.

"We now have a safe and effective vaccine against hepatitis A," says Dr. John Middaugh, Chief of the State of Alaska Section of Epidemiology. "At last, we can protect our children and prevent future outbreaks of this disease. All Alaskan children should be vaccinated."

HEPATITIS B

QUESTION: *Why is it recommended that the hepatitis B vaccine series be started between birth to two months of age?*

ANSWER: National immunization recommendations call for the routine immunization of **all infants** against hepatitis B because it is impossible to predict who will be at high risk for hepatitis B in the future. In addition:

- The earlier in life a child is exposed to the disease, the more likely they are to become a lifelong carrier. By adding hepatitis B to the already established immunization schedule, it helps us protect more people from becoming lifelong carriers.
- There is no specific treatment for acute hepatitis B. The virus can cause liver damage, liver cancer and death. Those who become lifelong carriers face significant health care problems, and can infect others with the disease.
- Unfortunately, vaccinating just "high-risk" individuals against hepatitis B has not proved to be an effective method for decreasing the incidence of this disease.

DIPHTHERIA, TETANUS AND PERTUSSIS

DTP vaccine protects against diphtheria, tetanus and pertussis (whooping cough). Of these diseases, pertussis currently poses the most serious threat to infants and children in the United States.

In the mid-1970's, two countries, Great Britain and Japan, cut back on the use of pertussis vaccine because of their concerns about the safety of the vaccine (see below for explanation). The effect was dramatic and immediate:

- In Great Britain, the drop in pertussis vaccination in 1974 was followed by an epidemic of more than 100,000 cases of pertussis and 36 deaths by 1978.
- In Japan, a drop in vaccination coverage from 70% to 20-40% led to a jump in pertussis from 393 cases and no deaths in 1974 to 13,000 cases and 41 deaths in 1979.

Of more immediate interest to Alaskans is the major epidemic of diphtheria now occurring in the former Soviet Union. The decline in diphtheria vaccination rates of children and adults has resulted in an increase from 839 cases in 1989 to nearly 50,000 cases and 1,700 deaths in 1994. There have already been at least 20 cases of diphtheria imported from the former Soviet Union to Europe and 2 cases in U.S. citizens working in the former Soviet Union.

QUESTION: *What is the new acellular pertussis vaccine?*

ANSWER: The new vaccine for pertussis is known as "acellular" vaccine because it contains only the specific parts or products of the pertussis bacteria thought to be important for immunity. It differs from the "whole-cell" vaccine that was made from whole, killed pertussis organisms. The "whole-cell" vaccine was associated with a higher frequency of local reactions (e.g., redness, swelling, pain at the injection site), fever, and, in rare instances, more severe side effects.

Alaska now offers and recommends the use of DTaP in place of DTP vaccine in the childhood immunization schedule.

A full series of DTaP shots protects approximately 80 children out of 100 from getting severe pertussis (whooping cough), if exposed. A full series of four DTaP shots by 15 months of age is recommended. This is important because:

- Children, especially young infants, who catch pertussis are often critically ill.
- There has been an alarming increase in pertussis cases in the United States recently, partly due to the spread of pertussis from young adults to insufficiently immunized infants.
- Most individuals who have had three or more shots of DTaP vaccine are protected from diphtheria and tetanus for many years, and from pertussis for at least 10 years.
- Even children who do become ill with pertussis after vaccination with DTaP have a much milder illness than if they had not been vaccinated.

QUESTION: *What are the side effects of the DTaP vaccine?*

ANSWER: The majority of children who receive DTaP vaccine will experience only minor soreness, swelling, and redness at the site of the injection. Some children may also have some fussiness, drowsiness, and/or loss of appetite. Usually these problems only last from one to three days. Very rarely, a child will have a fever of more than 101 degrees (Fahrenheit), continuous crying for three hours or more, or convulsions or collapse, all followed by full recovery. In extremely rare instances, a very small number of children may experience more severe side effects, such as long seizures or other brain disturbance (i.e., acute encephalopathy), although no cases of these severe side effects have been reported to date after vaccination with DTaP. Further doses of pertussis-containing vaccine would not be recommended for a child who experiences these severe side effects.

QUESTION: *Is it true that DTP vaccine caused SIDS (Sudden Infant Death Syndrome, or "crib death")? Is there any risk of SIDS with the new DTaP vaccine?*

ANSWER: No. This belief came about because some of the children who died from SIDS had been vaccinated with DTP shortly before their deaths. At first glance, these events seem to be related because one event (vaccination with DTP) occurred directly before another (SIDS). However, it is similar to saying that eating bread causes car crashes, because most drivers who are in car accidents could probably be shown to have eaten bread within the past 24 hours.

If you consider that most SIDS deaths occur during the age range when three shots of DTP/DTaP are given (2 - 6 months), you would expect a certain number of SIDS deaths to occur following DTP/DTaP shots simply by chance. In fact, when a number of well-controlled studies were conducted during the 1980s, the medical investigators found that the number of SIDS deaths associated with DTP vaccination was within the range expected to occur **by chance alone**.

In other words, the SIDS deaths would have occurred even if no vaccinations had been given. In fact, in several of the studies, children who had recently received a DTP shot were less likely to have SIDS. **The Institute of Medicine reports: "All controlled studies that have compared vaccinated vs. non-vaccinated children have found either no association... or a decreased risk... of SIDS among vaccinated children," and concludes that "the evidence does not indicate a casual relation between [DTP] vaccine and SIDS."** Although no similar studies have been conducted with DTaP vaccine, it can be assumed that this evidence would hold true for DTaP vaccine as well, since DTaP vaccine is more purified than DTP vaccine.

POLIO

QUESTION: *Is it still worth being immunized against polio?*

ANSWER: Polio disease has been eliminated from the United States since 1979 and the Western Hemisphere since 1991. There are plans for the total elimination of polio disease by the year 2000. Therefore, at some time in the future, we may be able to cease polio vaccination. However, as long as polio exists in the world, our children need protection. Poliovirus is highly infectious: in fact, 90-100% of household contacts of an infected person will be infected with poliovirus. Polio is still a major public health problem in many countries of the world, and if children are not immunized, the disease could spread quite rapidly to the United States. One could say, "**Polio is just an airplane ride away.**"

QUESTION: *Are there two different types of polio vaccine?*

ANSWER: Yes. They are live oral polio vaccine (OPV) and inactivated polio vaccine (IPV). OPV has been the vaccine of choice for routine immunization of most children in the United States since 1963.

QUESTION: *Are there any risks associated with polio vaccine?*

ANSWER: Yes. Oral polio virus vaccine has been associated with a very rare occurrence of paralysis in vaccine recipients and their contacts. There are approximately 8 cases of vaccine-associated paralytic poliomyelitis (VAPP) in the United States each year. This represents **one case per 2.5 million doses given**. It is most likely to occur in persons with serious immune system diseases or with the first dose of vaccine.

The State of Alaska continues to recommend the use of oral polio vaccine because of the very low risk of complications with what has been an extremely successful vaccine. In addition, its use reduces the number of injections a child needs to receive during one visit. However, Alaska does offer the inactivated polio vaccine (IPV), the injectable form of the vaccine, as another option for protecting children from polio. The major advantages of IPV are that there is no risk of VAPP from IPV, and the child is protected from paralytic polio disease. However, a disadvantage is that persons who are vaccinated with IPV can still "carry" the wild polio virus in their bodies if exposed, and pass it on to unvaccinated household members through their stools. In addition, IPV requires an injection.

Parents can discuss these issues with their health care provider to decide which form of the polio vaccine best meets their needs.

Varicella

QUESTION: *For whom is the varicella (chickenpox) vaccine recommended?*

ANSWER: The varicella vaccine was approved by the FDA in March 1995 and is recommended for:

- ♦ children 12-18 months of age and older who have not had chickenpox;
- ♦ individuals over one year of age who will have close contact with persons at high risk for serious complications from the disease (such as those with weakened immune systems);
- ♦ adolescents 11-12 years of age who have not been previously vaccinated and have not had the disease.

Complications from varicella disease, such as pneumonia and encephalitis, are more likely to occur in adults. Vaccinating against the illness during childhood will help reduce the incidence of the disease (and related complications) in later years.

This FDA-approved vaccine is **NOT** recommended for:

- ♦ children under one year of age;
- ♦ individuals on aspirin therapy;
- ♦ individuals with weakened immune systems due to disease or immunosuppressive medications or treatments;
- ♦ pregnant women.

Note: This vaccine is not currently offered by the Alaska Immunization Program because it is a very fragile vaccine which is extremely difficult to transport and store in Alaska. It is anticipated that these handling issues will be resolved, and the varicella vaccine will be available in Alaska in 1998. Check with your health care provider about the current availability of this vaccine in your area.

6. THE ADOLESCENT HEALTH VISIT: SHOTS AREN'T JUST KIDS' STUFF!

Although immunization programs in the United States which focus on infants and children have greatly decreased the occurrence of many childhood infections, vaccine-preventable diseases such as hepatitis A and B, measles and rubella continue to affect adolescents and young adults.

In order to protect adolescents and young adults from these serious vaccine-preventable diseases, Alaska strongly recommends an **Adolescent Health Visit** at 11 to 12 years of age. This visit will enable parents and their health care providers to discuss the recommended vaccines and decide which immunizations their child needs. An Adolescent Health Visit, of which immunizations are a part, also helps to affirm that child's lifelong commitment to good health.

QUESTION: Which vaccines are recommended for my adolescent?

ANSWER: The recommended vaccines for adolescents are Hepatitis A, Hepatitis B, MMR (2nd dose), Tetanus/Diphtheria, and Varicella (where available). Contact your health care provider for information about scheduling your adolescent for these vaccinations.

Immunizations Recommended for Adolescents

- ☞ Hepatitis A
- ☞ Hepatitis B
- ☞ MMR (Measles/Mumps/Rubella)
- ☞ Td (Tetanus/Diphtheria)
- ☞ Varicella ("chickenpox") where varicella vaccine is available

7. LEGAL REQUIREMENTS AND CONSIDERATIONS

QUESTION: *What are the legal requirements for immunizing children?*

ANSWER: The legal requirements for childhood immunizations vary from state to state. In Alaska, the requirements are defined in the Alaska School Immunization Regulations (4AAC 06.055), the Department of Education's Child Care Facilities Regulations (7AAC 50.450), and in the Department of Family and Youth Services Child Care Facilities Regulations (7AAC 50.455).

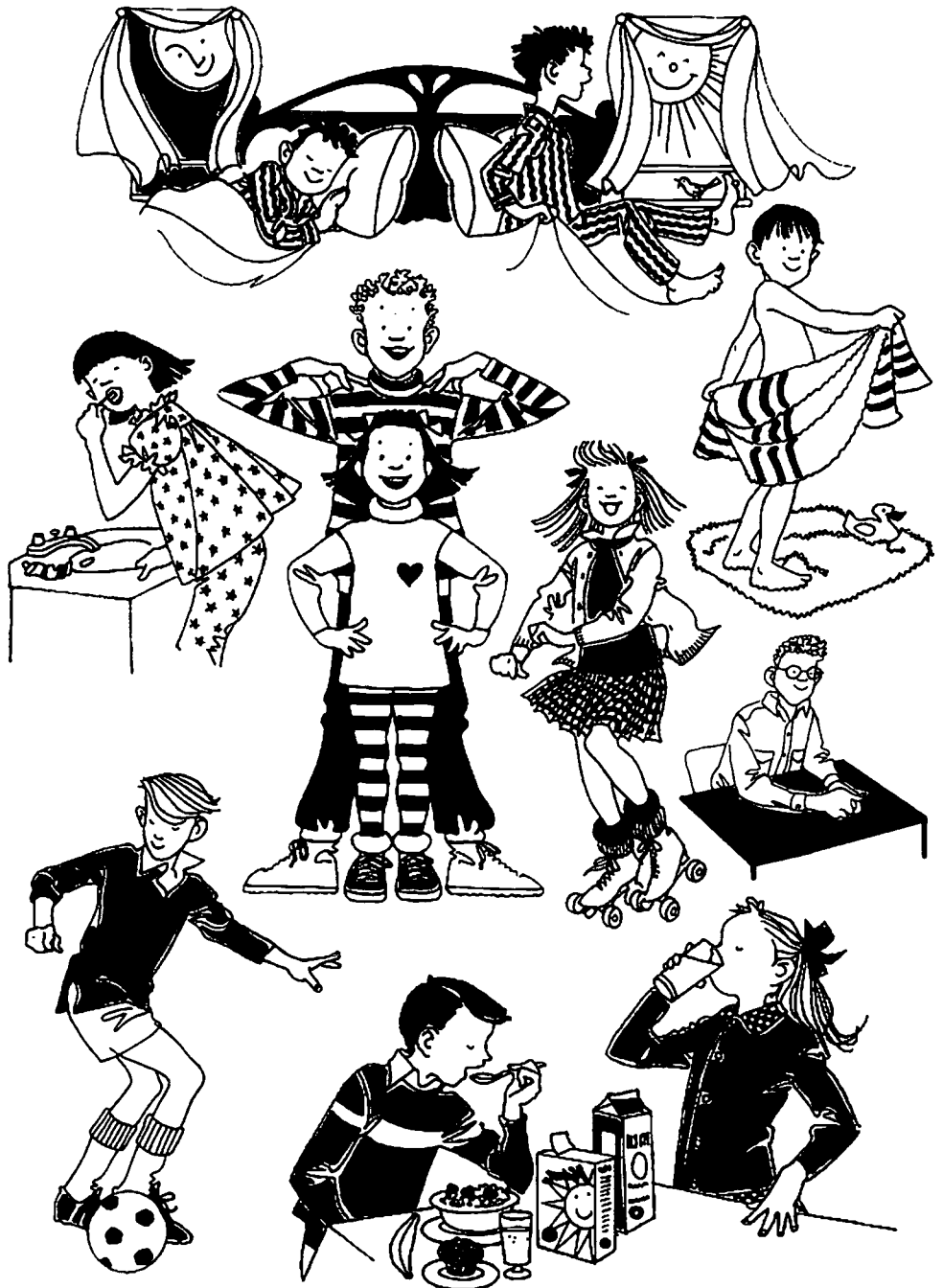
The law requires the parents or guardians of each child being enrolled to give the child care program or school a copy of the child's original immunization record. These immunization records are updated by the doctor or nurse every time a child receives his/her vaccinations. **It is important for the parents or guardians to keep these records of their child's immunizations.**

To legally attend child care (including Head Start Programs) or school, children must:

- ♦ be fully vaccinated for their age, or
- ♦ be in the process of catching up on late immunizations, or
- ♦ have a signed exemption from vaccinations for medical or religious reasons.

School immunization requirements in Alaska have nearly eliminated the transmission of vaccine-preventable diseases which, in the past, caused significant illness and death. Before immunization requirements for school and child care attendance were strictly enforced, many Alaskan children suffered from vaccine-preventable diseases. The effects of these vaccine-preventable illnesses ranged from minor inconveniences to death; at a minimum, they disrupted school and child care attendance and caused logistical problems for parents. At the worst, they resulted in complications such as pneumonia, deafness, brain damage or even death. The goal of these immunization regulations is to assure that children receive maximum protection against these preventable diseases.

Immunizations aren't just the law,



they're part of a healthy lifestyle.

8. VACCINE SAFETY

Some parents have concerns about vaccine safety. In licensing vaccines, the U.S. Food and Drug Administration (FDA) has developed scientific criteria for approving vaccines and for monitoring side effects once approval has been given.

Approval of Vaccines

The approval process for a biological product such as a vaccine is based on federal regulations and involves clinical trials in three phases.

Phase One: Studies concerned primarily with learning more about the safety of the product.

Phase Two: Studies which usually are longer and involve more patients; designed to demonstrate the ability of a vaccine to induce the production of antibodies, as well as to further evaluate side effects and risks.

Phase Three: Studies involving a larger number of patients for longer time. They provide verification that a vaccine is effective in preventing a particular disease as well as information on risks vs. benefits.

After completing the three phases, the manufacturer submits the safety and effectiveness data to the FDA in an application for licensure to market the product. The FDA has the responsibility to review the clinical studies data, the facilities to be used and the methods to be used in the manufacture of the product for safety and effectiveness. On average, it takes over 5 years from the time of application for licensure until FDA approval of a product.

Monitoring Vaccine Safety

After a product is approved for marketing, the FDA continues to monitor the safety and effectiveness by various means, including on-site inspection of the manufacturing facility.

There is also a national system sponsored by the FDA and CDC for reporting any possible adverse reactions following vaccinations. This system is called the Vaccine Adverse Events Reporting System (VAERS). The system receives reports from providers, patients, parents or anyone who witnessed or merely heard of a possible adverse reaction that occurred after the receipt of any vaccine. Since 1988, health care providers who give vaccines and vaccine manufacturers have been required by law to report certain serious adverse events.

Other notable features of the vaccine monitoring system are:

- The U.S. FDA staff reviews manufacturers' vaccine lot (batch) tests and, as a protective measure, may repeat some of the tests themselves. After vaccine lot release, the FDA conducts reviews of the weekly VAERS reports.
- Because VAERS information is limited to what is reported, it cannot establish causation. It can only look for trends and pinpoint the need to investigate further.
- **A VAERS report does not mean the vaccine caused the adverse event.** It only means the vaccination *preceded* the adverse event.
- If VAERS is to work, the public should report any serious adverse event following any vaccine given. Report forms may be obtained by calling (800)822-7967.

QUESTION: *Are certain vaccine lots associated with more adverse events than other lots?*

ANSWER: Vaccine lots are closely monitored by the VAERS reporting system (see previous section). The FDA has the legal authority to recall a vaccine lot if the numbers of reports indicate that it is unsafe. There is no benefit to either the FDA or the manufacturer in allowing unsafe vaccines to remain on the market.

Occasionally, people have interpreted VAERS information incorrectly, which has led to unsubstantiated media reports about "unsafe lots" of vaccine. The VAERS system accepts all reports of any medical problems that have occurred following vaccination; sometimes as long as six months after administration. The VAERS system does not discard a report simply because it is unlikely to be caused by vaccination, nor does it discard a report because it is about a minor problem. For instance, if a person is vaccinated and has unrelated symptoms of illness one week later, the VAERS report would list that vaccine lot number. Vaccine lots vary by size; the larger lots are likely to receive more reports than smaller lots with fewer doses distributed. The fact that there are more reports does not mean that the lot is unsafe, or that the vaccine caused the problem.

9. COMPARE THE RISKS

Risk of Disease and Serious Complications	Risk of <u>Serious</u> Reaction From Being Vaccinated:
<p><i>Haemophilus influenzae</i> type B (Hib disease):</p> <p>Before Hib vaccine, 1 in 200 children developed meningitis or other invasive Hib disease by age five.</p> <ul style="list-style-type: none"> ♦ Was leading cause of bacterial meningitis. ♦ 50% of cases in children less than one year old. ♦ Death: 1 in 20 children with invasive Hib disease. ♦ Neurologic damage: 19 to 45 in 100 children with invasive Hib disease. 	<p>Hib Vaccine:</p> <p>None recorded to date.</p>
<p>Diphtheria:</p> <p>40 cases in U.S. 1980-93. Due to decreased immunizations, 15,000 cases in Russia in early 1990s.</p> <ul style="list-style-type: none"> ♦ Death: 1 in 10. <p>Tetanus:</p> <p>50-100 cases per year in U.S., greater than 500,000 deaths per year worldwide.</p> <ul style="list-style-type: none"> ♦ Death: 1 in 3. <p>Pertussis (whooping cough):</p> <p>69% of all reported U.S. cases less than 5 years old, 45% in less than 12 month-old children. Many infants hospitalized.</p> <ul style="list-style-type: none"> ♦ Pneumonia: 1 in 8. ♦ Convulsions/seizures: 1 in 100. ♦ Death: 1 in 500. 	<p>DTaP Vaccine:</p> <p>Diphtheria:</p> <p>None recorded to date.</p> <p>Tetanus:</p> <p>Severe neuritis or severe allergic reaction: 1 in 1,000,000.</p> <p>Acellular Pertussis:</p> <ul style="list-style-type: none"> ♦ Convulsions or seizures: 2 to 5 in 100,000 doses administered. ♦ Prolonged crying for 3 hours or more: 12 in 100,000 doses administered. ♦ High fever (greater than 101 degrees Fahrenheit), then full recovery: 5.2 in 100 doses administered.

CMPARE THE RISKS

Risk of Disease and Serious Complications	Risk of Serious Reaction From Being Vaccinated:
<p>Measles:</p> <p>Prior to the introduction of vaccine, 400,000 reported cases per year. In 1989-91 epidemic: 55,622 cases due to large number of unimmunized children, 45% of cases were less than 5 years old; 20% hospitalized, 126 deaths.</p> <ul style="list-style-type: none"> ♦ Pneumonia: 1 in 20. ♦ Encephalitis (brain fever): 1 in 2,000. ♦ Thrombocytopenia: 1 in 6,000. ♦ Death: 1 in 3,000. <p>Mumps:</p> <p>Cases: 3,000-5,000 per year.</p> <ul style="list-style-type: none"> ♦ Encephalitis: 1 in 300. ♦ Testicular swelling: 1 in 5 adults. ♦ Deafness: 1 in 20,000. ♦ Death: 1 in 3,000 to 10,000. <p>Rubella:</p> <p>1.2 million cases in 1964-65, 2,100 infant deaths, 11,250 fetal deaths, 20,000 cases of nervous system disorders.</p> <ul style="list-style-type: none"> ♦ Arthritis: 7 in 10 adults. ♦ Thrombocytopenia: 1 in 3,000. ♦ Congenital Rubella Syndrome: (deafness, cataracts, mental retardation) in 1 in 4 infants if women are infected in early pregnancy. 	<p>MMR Vaccine:</p> <p>Thrombocytopenia (bleeding tendency from decreased blood platelets): 1 in 100,000.</p> <p>Measles:</p> <p>Severe allergic reaction: less than 1 in 1,000,000 people vaccinated.</p> <p>Mumps:</p> <p>None recorded to date.</p> <p>Rubella:</p> <p>Arthritis: 1 in 10-20 <u>adults</u>.</p>

CMPARE THE RISKS

Risk of Disease and Serious Complications

Risk of Serious Reaction From Being Vaccinated:

Hepatitis A:

Hepatitis A has been a large problem in Alaska; four deaths occurred here during an outbreak in early 1990s.

- Most common among school-aged children and young adults.
- Illness from hepatitis A can be mild, lasting 1 to 2 weeks, or severely disabling, lasting several months.

Hepatitis A Vaccine:

None reported to date.

Hepatitis B:

Nine of 10 infants infected at birth will become lifelong carriers of the disease, and one out of four of these infants will ultimately die of liver failure.

Estimated number of persons infected each year in U.S.: 200,000 to 300,000.

- Hospitalizations per year: 15,000
- Deaths: 5,900

Hepatitis B Vaccine:

None reported to date.

CMPARE THE RISKS

Risk of Disease and Serious Complications	Risk of <u>Serious</u> Reaction From Being Vaccinated:
<p>Varicella (Chickenpox):</p> <p>Varicella virus is extremely contagious. Nine out of 10 people in a household who have not had chickenpox already will catch the virus if exposed to an infected household member. Although usually quite mild, potential complications can include:</p> <ul style="list-style-type: none"> ◆ Bacterial infection of skin lesions and scarring. ◆ Pneumonia. ◆ Hospitalization: 3 in 1000 cases. ◆ Death: 1 in 60,000 cases. ◆ 50-100 deaths per year in the U.S., mostly in healthy children and adults. ◆ Disease is more severe and complications more frequent in children older than 13 years of age. ◆ Reactivation of varicella virus into Herpes Zoster (Shingles) later in life; chance of recurrent episodes of shingles increases with age. 	<p>Varicella Vaccine:</p> <p>None reported to date.</p>
<p>Polio:</p> <p>38,000 cases per year prior to vaccine; 21,000 cases with paralysis. 58,000 cases in 1958. During 1970s several outbreaks in non-vaccinated populations, none in U.S. since 1979.</p> <ul style="list-style-type: none"> ◆ Poliovirus is highly infectious: 90-100% of household contacts of an infected person will be infected with poliovirus. ◆ <i>Permanent paralysis:</i> 1 in 100. ◆ <i>Death:</i> 1 in 20 children and 1 in 4 adults with paralytic polio. 	<p>Oral Polio Vaccine:</p> <p>Permanent paralysis: 1 in 2,500,000 doses.</p> <p>Inactivated Polio Vaccine:</p> <p>None reported to date.</p> <p style="text-align: center;">BEST COPY AVAILABLE</p>

10 NEWS STORIES

Miss America's Hearing Loss

Miss America 1995, Heather Whitestone, is deaf. Ms. Whitestone had an infection with high fever in 1974, when she was 18 months old. A media item reported that an immunization had caused the fever and subsequent deafness, but this was a false report.

The real cause of her illness, according to her pediatrician, was *Haemophilus influenzae* (Hib) infection. She was treated with Gentamicin, one of the powerful antibiotic drugs used for this life-threatening infection. Unfortunately, hearing loss is one of the possible side effects of Gentamicin, particularly in infants. Deafness is also a common result of Hib meningitis infection.

Had Ms. Whitestone been born after 1985, she could have been immunized against the Hib infection and her disability prevented. Hib infections have been reduced by 90% since the vaccine was made available in 1985.

Polio: Her Story

In the 1940s, Kay, a young girl from a southwest Alaskan village, would hunt, fish, chop wood, and go berry picking. One day while walking home from church, Kay tripped and fell, and by the time she got home, she was "real sick". She remained in bed for a month. Her leg curled up and she wasn't able to move it. Kay's family was finally able to get a plane to take her to the hospital where the examining doctor told her she had polio. He said, "***There is nothing we can do for you; you'll never walk again,***" and he sent her home.

Her mother would warm up rocks three times a day and put them in a tub. Even though it was painful and throbbed when Kay moved, she would put her legs over the tub with a blanket covering them and stretch her curled leg while it was being warmed. Gradually, her leg straightened enough so that she could stand. Then began the slow process of learning to walk again. Eventually, Kay could push a chair across the floor while walking behind it. No longer could she go berry picking or chop wood. Instead, she stayed in the house and helped her mother with the dishes and preparing food for the winter.

Kay's brother and sister also were infected with the polio virus. Her brother was paralyzed but recovered; however, her nine-year-old sister became very ill and died.

Kay has weakness in her left leg that is worse in cold weather. She walks with a limp that even surgery has not cured and has suffered with leg and back pain most of her life. **Kay says, "It's better if children get the vaccine when they're small, so they won't get sick like I got sick."**

A Mother and Child with Pertussis

Mary, a resident of Washington state, got pertussis (whooping cough) in 1990, a week before the birth of her second child. She caught it from the siblings of her son's friend, who visited one day while they had racking coughs.

After recognizing the telltale whoop in the cough, Mary discussed the issue with the friend's mother, who indicated she did not believe in immunizations.

Mary was seriously ill for six months and passed the disease on to her newborn son, who was hospitalized with pertussis at one week of age. (The child who originally infected Mary was also hospitalized for pertussis-related seizures.)

"My baby would cough 40 to 50 times in a row until he turned blue and threw up," Mary said. "I quite literally did not let go of him for the first six to nine months because I was afraid he was going to die."

The first four and a half years of his life have been full of bouts with infections and an uncontrollable cough. Many people who had been exposed to Mary and her son, especially young children and those over 60, had to be treated with antibiotics because of their increased risk of complications if they caught the disease.

The out-of-pocket cost to the family was extraordinary, even though both parents had excellent health insurance coverage. The community cost included many hours of investigation of contacts and the cost of the needed antibiotics ... and this was a healthy pregnancy.

11.

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"Universal Hepatitis A Immunization Program", State of Alaska Section of Epidemiology Bulletin. No. 32, December 14, 1996.

What Parents Need To Know About Vaccination And Childhood Disease: Guidelines For Parents. American Academy of Pediatrics, 1994.

OTHER SOURCES OF INFORMATION:

Alaska Immunization Hotline: **(toll free) 1-888-430-4321, or in Anchorage 269-8088.**

Healthy Alaskans Information Line (HAIL): **1-800-478-2221**

State of Alaska, Department of Health and Social Services, Division of Public Health, Section of Epidemiology, Immunization Program: (907) 269-8000.

Vaccine Information Statements, available from the State of Alaska Immunization Program, most public health clinics and other immunization providers, and from the Centers For Disease Control and Prevention (CDC).

Parents Guide to Childhood Immunization, Department of Health and Human Services, National Immunization Program, Atlanta, Georgia 30333.

Further information about the FDA's responsibility in drug development is provided in the publication, *FDA Consumer*. This yearly magazine is available through the Government Printing Office, Superintendent of Documents, PO Box 371954, Pittsburgh, PA 15250-7954.

For information or questions about recommended **Adult Immunizations** write the State of Alaska, Immunization Program; 3601 "C" Street, Suite 540; Anchorage, Alaska 99503 or call (907) 269-8000.

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