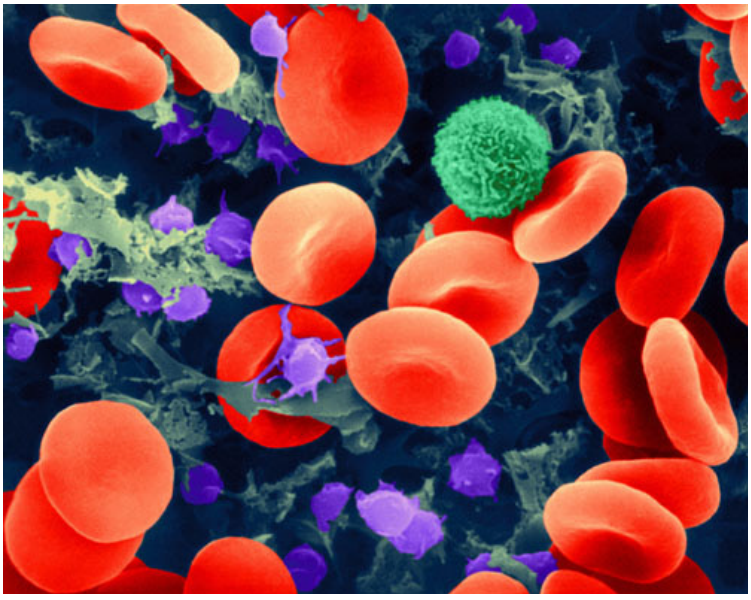
Unit 2: Disease Prevention

Instructor's Background Text
Part 2 of 3



PKIDs' Infectious Disease Workshop

Made possible by grants from the Northwest Health Foundation,
the Children's Vaccine Program at PATH and PKIDs.

PKIDs' Infectious Disease Workshop

Acknowledgements

Producing this workshop has been a dream of ours since PKIDs' inception in 1996. It has been more than two years since we began work on this project, and many people helped us reach our goal. It's not done, because it is by nature a living document that will evolve as science makes strides in the research of infectious diseases, but it's a great beginning.

There are people who've helped us whose names are not on this printed list. That omission is not deliberate, but rather from our own clumsiness in losing important pieces of paper, and we apologize.

Without the funding and support of the Northwest Health Foundation and the Children's Vaccine Program at PATH (Program for Appropriate Technology in Health), this would have been an impossible task. Dr. Katherine Vaughn, PKIDs' Medical Director and Dr. Karen Steingart, scientific advisor to PKIDs, provided excellent guidance through their editorial oversight and knowledgeable contributions to the Infectious Disease Workshop.

On PKIDs' staff are three individuals without whom this publication would never have been finished—Franji Mayes, Mylei Basich and Christine Kukka, all of whom gave their very best to ensure this workshop is accurate and user-friendly.

We are indebted to the following individuals who cheerfully gave us hours of their time and access to their resources: the American Society for Microbiology; Kathy A. Bobula, Ph.D., Coordinator, Early Childhood Education, Clark College, Vancouver, Wash.; Claudia Bratt, elementary school teacher, Truman Elementary, Vancouver, Wash.; Sue Campbell, Early Childhood Educator, Kindercare; many wonderful and helpful people at the Centers for Disease Control and Prevention, Atlanta, Georgia; Rachel Coyle, Case Aide and Residential Care Staff Lead, Jonathan's Place; Tammy Dunn, Early Childhood Director, Portland Christian Schools, Portland, Oregon; Bruce Gellin, M.D., Director of the National Vaccine Program Office in the Office of the Assistant Secretary for Health, Department of Health and Human Services; Shannon Harrison, M.D., Internal Medicine and Infectious Diseases, Teton Hospital, Jackson, Wyoming; the Immunization Action Coalition; Brad Jensen, M.D., Southwest Washington Medical Center Pathology Department; Edgar Marcuse, M.D., Professor of Pediatrics, University of Washington and Director of Medical Services, Seattle Children's Hospital and Regional Medical Center; Zack Mittge, law student, University of Oregon; the National Network for Immunization Information; Paul Offit, M.D., Chief, Section of Infectious Diseases and the Henle Professor of Immunologic and Infectious Diseases at The Children's Hospital of Philadelphia; Carol Porter, Red Cross health room volunteer, Garland Independent School District, Garland, Texas; Sarah Theberge, Curriculum Instructor, Early Childhood Education, Clark College, Vancouver, Wash.; James Whorton, Ph.D., Professor, Department of Medical History and Ethics, University of Washington School of Medicine.

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(Cover photo: Dennis Kunkel Microscopy, Inc./www.denniskunkel.com.)

Additional funding for this project provided by PKIDs (Parents of Kids with Infectious Diseases).

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Warning: This section contains certain disease-related images that may not be suitable for young children.

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Introduction

PKIDs (Parents of Kids with Infectious Diseases) is a national nonprofit agency whose mission is to educate the public about infectious diseases, the methods of prevention and transmission, and the latest advances in medicine; to eliminate the social stigma borne by the infected; and to assist the families of the children living with hepatitis, HIV/AIDS, or other chronic, viral infectious diseases with emotional, financial and informational support.

Remaining true to our mission, we have designed the ***Infectious Disease Workshop*** **(IDW)**, an educational tool for people of all ages and with all levels of understanding about infectious diseases. In this workshop, you will learn about bacteria and viruses, how to prevent infections, and how to eliminate the social stigma that too often accompanies diseases such as HIV or hepatitis C.

We hope that both instructors and participants come away from this workshop feeling comfortable with their new level of education on infectious diseases.

The IDW is designed to "train-the-trainer," providing instructors not only with background materials but also with age-appropriate activities for the participants. Instructors do not need to be professional educators to use these materials. They were designed with both educators and laypersons in mind.

The IDW is comprised of a master Instructor's Background Text, which is divided into six units: Introduction to Infectious Diseases, Disease Prevention, Sports and Infectious Disease, Stigma and Infectious Disease, Civil Rights and Infectious Disease, and Bioterrorism and Infectious Disease.

For each unit, instructors will find fun and helpful activities for participants in five age groups: 2 to 6 years of age, 6 to 9 years of age, 9 to 12 years of age, 13 to 18 years of age and adults.

We welcome any questions, comments, or feedback you may have about the IDW or any other issue relating to infectious diseases in children.

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Safer Sex: It Could Just Save Your Life

(Source: CDC, PKIDs and Planned Parenthood)

Warning: This article contains explicit sexual information. It is intended for the sexually active and those intending to become sexually active.

One of the best ways to guard against sexually transmitted infections such as HIV/AIDS, hepatitis B or herpes is to practice "safer sex."

Sexually transmitted diseases (STDs) in the United States have reached epidemic proportions with an estimated 15 million people becoming infected with one or more diseases each year. Approximately ¼ of these infections occur among teenagers. STDs are the most common diseases reported in the United States.

More than 65 million people—about one in five Americans—are believed to be infected with an incurable sexually transmitted disease.

Safer sex practices allow partners to reduce their chance of an infection from sexual activity. Safer sex is what partners do to lower the risk of infection. The basic rule for safer sex is to prevent contact with genital sores and prevent the exchange of body fluids, such as semen, blood and vaginal secretions.

What Are Some Sexually Transmitted Infections?

Infections commonly spread through sexual activity include:

- HIV/AIDS
- Hepatitis B
- Chlamydia
- Herpes
- Cytomegalovirus (CMV)
- Bacterial Vaginosis
- Gonorrhea
- Syphilis
- Genital Warts
- Human Papilloma Virus
- Molluscum Contagiosum
- Trichomoniasis

What Is Safer Sex?

Safer sex means taking action to make sure no one gets their partner's blood, semen or vaginal fluids in their body. Similarly, safer sex means you make sure your own body fluids don't enter your partner.

With safer sex, no body fluids enter a vagina, anus or mouth (during vaginal, anal or oral intercourse) or come into contact with mucous membranes, such as those around the eyes or inside the nostrils.

The best way to prevent body fluids from reaching someone during intercourse is to use a condom. A condom is a sheath that fits over the penis. It can be made of latex (the safest condom available), plastic or animal tissue. It is also called a rubber, safe or jimmy.

Today, nearly as many women as men buy and carry condoms, according to Planned Parenthood. It catches a man's semen before, during and after he ejaculates or "comes." Some condoms have a nipple-shaped tip to hold the semen so it does not spill out.

Experts consistently recommend latex because some animal tissue, such as lambskin, has pores small enough for the hepatitis B virus, HIV and other sexually transmitted viruses or bacteria to pass through. Polyurethane condoms break more often than latex.

A study cited by Planned Parenthood observed:

"Of couples in which one partner had HIV, all 123 couples who used condoms every time for four years prevented transmission of HIV.

"In 122 couples who did not use condoms every time, 12 partners became infected.

"A similar 1993 study showed that using condoms every time prevented HIV transmission for all but two of 171 women who had male partners with HIV. However, eight out of 10 women whose partners didn't use condoms every time became infected."

In short, nothing guards against hepatitis viruses, HIV and STDs like a latex condom and other safer sex practices. Spermicidal foams and jellies, diaphragms, implants and other devices do not block body fluids and may not kill all of the harmful bacteria and viruses in your partner's secretions.

The female condom fits inside the vagina like the diaphragm and also covers the vulva. It is a pouch with flexible rings that is inserted into the vagina. It has the advantage of not requiring a man to maintain an erection during use. Although it is not as effective as the male condom, the female condom is a valuable option for women who want to protect themselves against viral hepatitis, STDs and unintended pregnancy. However, the effectiveness of the female condom in preventing hepatitis virus transmission has not been studied extensively, according to the CDC.

The birth control pill, IUDs, Norplant, Depo-Provera, vasectomies and tubal sterilizations offer great protection against pregnancy, but no protection against hepatitis viruses and STDs. Many people use latex condoms along with these birth control methods for the best protection against both pregnancy and sexually transmitted infections.

Even Oral Sex Requires a Condom

Oral sex may not get one pregnant, but it can still transmit disease.

It is safer to put a condom on the penis before beginning oral sex to guard against secretions that may carry infection. It is important not to get secretions or semen in the mouth. A sore throat or small cuts on the gums may serve as entryways for viruses.

Vaginal secretions can also carry viruses, especially if a woman is having her period. Latex condoms can be cut with scissors up the middle for oral sex on the vulva or anus. Latex dams or squares, which are thicker than plastic wrap and more likely to resist tearing, may be used. Latex gloves also provide STD protection.

Proper Use of Condoms

A condom just might save a life, and should be treated like the valuable tool it is. Store condoms in a cool, dry place. Long exposure to air, heat or light makes them more breakable. Do not store them continually in a back pocket, wallet, purse or glove compartment.

Check the expiration date to make sure the condom is fresh and safe. Throw away condoms that have expired, been exposed to significant heat, carried around in a wallet, or washed in the washer or dried in the dryer. If they appear dry, stiff or sticky, toss them. If there are any doubts about a condom, buy a new one.

Condoms usually come rolled into a ring shape. They are individually sealed in aluminum foil or plastic. When opening the condom package, do it carefully to avoid tearing the condom.

To minimize mistakes, both partners should know how to put on and use a condom. Planned Parenthood Federation recommends learning in a safe place free of pressure or frustration. Practice on one's own penis or on a penis-shaped object like a ketchup bottle, banana or cucumber.

To ensure maximum protection, never use a condom twice and always put a new condom on an erect penis before there's any genital, anal or oral contact.

If intercourse has already begun, pulling out and putting on a condom right before ejaculation may be too late for protection against hepatitis, STDs and pregnancy.

The male should put on a condom as early as possible at the very beginning of sex play rather than waiting until his partner is ready for penetration. It's also a good idea to have extra, new condoms around in case a condom is put on too soon or if he loses his erection.

A condom is like a sock, with a right and wrong side. First, unroll it about half an inch to see in which direction it is unrolling. Then put it on. If a male has not been circumcised, pull the

foreskin back first. It should unroll easily down the penis. If it starts off on the wrong side, try again with a new condom. Don't be afraid to practice ahead of time.

Hold the tip of the condom gently between the fingers as it rolls down. This keeps out air bubbles or pockets that can increase the chance of a condom breaking. It also leaves space at the end for the cum or semen.

Roll the condom down as far as it will go.

Anal intercourse increases the chance of viral transmission tremendously, because there can be small tears or bruises in the anus during sex, which makes one tremendously vulnerable to bloodborne infections like viral hepatitis and HIV.

For anal intercourse, lots of lubrication is helpful. Using a water-based lubricant is also helpful for vaginal intercourse. The lubricant goes on after the condom is put on, not before, or else it could allow the condom to slip off easily. Add more lubrication often. Dry condoms break more easily than properly lubricated ones.

Using lubricant will make things go smoother and give added protection. Lubrication is especially helpful for women when they have intercourse for the first time, or if there is a tendency for soreness.

Always use a water-based lubricant (such as KY Jelly, Astroglide, Aqua Lube, Wet, Foreplay, or Probe) because oil breaks latex. Don't use vaseline, hand creams or lotions as a lubricant. Also, treatments for yeast infections contain oil and may break latex.

After ejaculation, hold the condom at the bottom of the penis so it doesn't slip off. Try to pull out while still erect or hard. The condom comes off only after the penis is completely out of the partner.

Use a condom only once. Never use the same condom for vaginal and anal intercourse.

Talk Contraception Before the Heat of the Moment

It may be embarrassing to talk to a partner about contraception and condoms, but it's essential, and should be done before a sexual situation begins. Don't wait until the heat of passion takes over. It can overwhelm good intentions.

Be honest about feelings and needs. Silence is not a virtue in this situation. Talking about condoms will make it easier for both partners. It can help create a relaxed mood and make sex even more enjoyable and safe.

Embarrassment should not become a health risk and increase chances of infection. It's important for partners to be open and share health concerns and sexual health history.

How Risky Is a Tattoo?

(source: CDC and Alliance of Professional Tattooists)

You can certainly contract HIV or hepatitis B or C if a practitioner does not sterilize or disinfect tattooing and piercing instruments and tattoo ink properly between clients. These instruments come into contact with blood during these procedures.

The Centers for Disease Control and Prevention (CDC) recommend that instruments used to penetrate the skin during tattoo or piercing procedures either be used once and then disposed of, or be thoroughly cleaned and sterilized between clients.

People who perform tattooing or body piercing should be educated about how bloodborne pathogens, such as HIV, are transmitted and take precautions to prevent transmission of these viruses in their settings.

If you are considering getting a tattoo or having your body pierced, ask the staff at the establishment what procedures they use to prevent the spread of HIV and other bloodborne infections, such as hepatitis B or C. You may call the local health department to find out what sterilization procedures and requirements are in place for these types of establishments.

When it comes to tattoos, the risk of contamination comes not only from the quality of the sterilization and needles, but also the ink. A disposable needle dipped in a bottle of ink that was also used on a person with hepatitis B or HIV can transmit those viruses.

The Alliance for Professional Tattooists (APT) has developed a set of infection control guidelines in association with the U.S. Food and Drug Administration. These are critical because during tattoo procedures bleeding is common.

APT suggests you insist that you watch your tattooist remove a new needle and tube set-up from a sealed envelope before receiving your tattoo. Also, insist that you watch while your tattooist pours a new ink supply into a new disposable container.

Make sure your artist follows standard precautions and that he or she wears a new pair of disposable gloves before setting up tubes, needles and ink supplies. The shop should also be as clean as a medical facility. If the condition of the shop doesn't make you comfortable, find another one.

Feel free to ask the tattooist about his or her sterilization procedures and isolation techniques. Take time to observe them at work and do not hesitate to inquire about the artist's experience and qualifications.

All equipment should be single service. This means that each needle and tube set is individually packaged, dated, sealed and autoclaved (sterilized). In addition to watching the artist open a fresh set of needles and tubes in front of you, remember that any ointments, pigments, nee-

dles, gloves, razors, plastic trays or containers used in applying your new tattoo should be discarded after their use.

An autoclave is the only acceptable means of equipment sterilization in the tattoo shop. It is a machine that uses a combination of heat, steam and pressure to kill all pathogenic microorganisms. If the shop does not use an autoclave, don't get tattooed there. Shops should keep regular records of their autoclave use and testing. Ask to see them if you feel uncertain.

Your artist should be wearing gloves any time he is touching broken skin and should change his gloves regularly. This protects both you and the artist from any bloodborne pathogens that may be present.

Currently, CDC researchers are conducting a large study to determine if tattooing is a potential risk for bloodborne infections. During the past 20 years, less than 1 percent of people with newly acquired hepatitis C infections reported having been tattooed, according to the CDC.

Additional studies are needed to determine if these types of exposures, and the settings in which they occur, are risk factors for HIV and viral hepatitis infection in the United States.

Vaccines

Preventing Disease

Disease prevention requires deliberate action, such as getting adequate sleep and exercise, dressing appropriately and washing our hands. It also requires an occasional shot in the arm.

Vaccines stop disease. They have dramatically altered the quality of life in America and have prevented millions of deaths here and around the world from diseases such as hepatitis B, measles and rubella.

The Immune System vs. Germs

Without any conscious effort on our part or medical intervention, the body can create its own defense against some infectious agents.

For example, when the virus that causes chickenpox invades a body, the immune system creates antibodies that bind to the virus and neutralize or inactivate it. While this is going on, memory B cells are produced and remain ready—often for a lifetime—to mount a quick, protective immune response against subsequent infection of the chickenpox virus.

So even though the number of antibodies created to fight the chickenpox virus subside, the memory B cells remain, forever on guard for that specific virus.

A vaccine causes a similar immune response. It is made from an antigen (a foreign substance that the body's immune system identifies as potentially harmful) from the chickenpox virus. The vaccine is injected into the blood stream. The memory B cells in the blood stream respond to the antigen by producing antibodies. As happens after an actual infection, the memory B cells remain ready to mount a quick protective immune response against subsequent infection by the chickenpox virus.

Vaccines exist for all sorts of diseases, both viral and bacterial. But not all diseases can be prevented by a vaccine. To date, scientists have been unable to develop vaccines against the viruses that cause the common cold, hepatitis C and HIV.

Efforts to create a vaccine against the common cold have failed because there are so many viruses that cause colds, and they are capable of mutating or changing so rapidly, antibodies that form to fight one cold virus don't recognize the new or mutated virus and can't fight it.

The hepatitis C virus and the human immunodeficiency virus remain challenges because they change ever so slightly every time they make copies of themselves. Developing a vaccine to fight one version of the hepatitis C virus would not work with the versions that have been slightly altered by replication. The same goes for the human immunodeficiency virus. Perhaps one day scientists will be able to design vaccines that go after the common denominators in

each virus, so that no matter what the slight variations are in each version, there will be some identifiers that won't change and will therefore be susceptible to vaccines.

Influenza is another example where vaccines can only be given against specific forms of the virus. For a vaccine to be effective against a flu epidemic, it must be designed for that specific influenza strain. That is why a new vaccine is developed for each flu season. If you are exposed to a different flu virus from the one you are vaccinated for, you will still catch the flu.

How Are Vaccines Made and Why Do They Work?

In their book *Vaccines: What Every Parent Should Know*, Dr. Paul Offit and Dr. Louis Bell take the complex question of how vaccines are made and answer it in a way we can all understand:

Vaccines are made by taking viruses or bacteria and weakening them so that they can't reproduce (or replicate) themselves very well or so that they can't replicate at all. Children given vaccines are exposed to enough of the virus or bacteria to develop immunity, but not enough to make them sick. There are four ways that viruses and bacteria are weakened to make vaccines:

1. Change the virus blueprint (or genes) so that the virus replicates poorly. This is how the measles, mumps, rubella, and varicella vaccines are made. The virus blueprint is changed by a technique called cell culture adaptation [adapting a virus to grow in specialized cells grown in the lab instead of the cells it normally grows in]. Because viruses can still, to some extent, make copies of themselves after cell culture adaptation (and therefore are still alive), they are often referred to as live, attenuated (or weakened) viruses.
2. Destroy the virus blueprint (or genes) so that the virus can't replicate at all. This is how the "killed" polio vaccine (or polio shot) is made. Vaccine virus is made by treating polio virus with the chemical formaldehyde. This treatment permanently destroys the polio genes so that the virus can no longer replicate.
3. Use only a part of the virus or bacteria. This is how the Hib, hepatitis B, and (in part) pertussis vaccines are made. Because the viral or bacterial genes are not present in the vaccine, the viruses or bacteria can't replicate.
4. Take the toxin that is released from the bacteria, purify it, and kill it so it can't do any harm. Some bacteria cause disease not by replicating but by manufacturing harmful proteins called toxins. For example, bacteria like diphtheria, tetanus, and pertussis (whooping cough) all cause disease by producing toxins. To make vaccines against these bacteria, toxins are purified and killed with chemicals (such as formaldehyde). Again, because bacterial genes are not part of the vaccine, bacteria can't replicate.

Vaccine Boosters

Because the immune response from some vaccines may decrease over time, vaccines known as "boosters" are sometimes given to restore the immune response against that particular germ. Protective immunity lasts longer when boosters are given. Tetanus boosters, for example, are recommended every 10 years starting at age 10 or 11.

A study published in May 2002 by the *Annals of Internal Medicine* revealed that millions of Americans are vulnerable to tetanus and diphtheria infections because their booster shots have not been kept up to date.

On other fronts in the vaccine field, scientists are trying to find new ways of producing vaccines, particularly using biotechnology and genetic engineering. These new methods would make it unnecessary to produce large quantities of the dangerous pathogens to make vaccines.

Passive Immunity

In addition to natural or "vaccine-induced" immunity to diseases, there is also "passive" immunity. Passive immunity occurs when someone is injected directly with large quantities of antibodies that are ready to immediately fight a specific virus or bacteria.

These antibodies go to work immediately against any antigen or pathogen. There is no waiting period, as is needed by some vaccines, before sufficient antibodies are produced.

However, protection from these antibody injections is temporary. Once the antibodies are cleared from the body, no new antibodies are made.

Doctors use this approach to treat people who have been exposed to hepatitis B, hepatitis A and rabies. Babies born to mothers with hepatitis B are immediately treated with hepatitis B antibodies (called HBIG or hepatitis B immune globulin) and simultaneously immunized against hepatitis B to prevent any infection that might have occurred during the birth process.

Monitoring Vaccines for Safety

The National Network for Immunization Information describes how vaccines are monitored in the United States:

The safety of vaccines is continuously monitored and studied by programs such as:
- Vaccine Adverse Events Reporting System
- Vaccine Safety Datalink Project
- National Vaccine Injury Compensation Program
- Task Force on Safer Childhood Vaccines
- Institute of Medicine research studies

Vaccine Adverse Events Reporting System

Sometimes a person will develop adverse signs or symptoms after receiving a vaccine. Healthcare providers are required to report certain adverse health effects that occur after a child is vaccinated. For example, if a child is hospitalized or dies after receiving a vaccine, this adverse event must be reported. The adverse event may have been caused by something other than the vaccine, such as an infection, a pre-existing illness, or an injury, but there is a small chance that

the event was caused by a vaccine. The monitoring systems allow scientists to gather enough data to determine which events may be related to vaccines.

In 1990, the FDA and the CDC established the Vaccine Adverse Events Reporting System (VAERS) so that reports could be collected and analyzed. As many as 12,000 reports have been made in a single year, and about 2,000 of these reported serious illness or death. All reports are entered into a database; the FDA and the CDC use the data to monitor vaccine safety and conduct research studies. However, with further examination, most of these events have been found to be unrelated to vaccines. VAERS reports do not establish cause and effect. Only large epidemiologic studies can show that the vaccine caused the adverse event.

To ensure that all relevant data are captured, the VAERS allows anyone to file a report if they suspect that their child or patient has a vaccine-related reaction. Because entries are not screened, the database contains events that are related and unrelated to vaccines. The FDA monitors the VAERS to determine whether any vaccine is associated with more adverse events than would be expected due to chance.

Recently, the rotavirus vaccine was withdrawn from the market after VAERS reports identified 15 cases of severe bowel obstruction in infants who received it. The VAERS data were used as a "signal" that the vaccine might be causing the problem; however subsequent epidemiological studies were necessary to establish that the vaccine was likely responsible. To date, a definite causal relationship has not been established.

VAERS Contact Information
Phone: 1-800-822-7967
Web: www.fda.gov/cber/vaers/vaers.htm
Email: vaers@cber.fda.gov

Vaccine Safety Datalink Project

Unlike the VAERS database, large linked databases allow research scientists to have access to the complete medical records of millions of people who receive vaccines. (Patient identity is not released).

In 1990, the CDC developed the Vaccine Safety Datalink Project to study rare side effects from vaccines. Four large health maintenance organizations provide the CDC with medical information on more than 6 million people. The large number of patients makes this project a powerful tool for examining the relationship between a specific vaccine and serious side effects.

Since its initiation in 1990, the Vaccine Safety Datalink Project has conducted surveillance on about 500,000 children from birth through age 6 years (2 percent of the U.S. population in this age group). These data were used to study the rate of Sudden Infant Death Syndrome (SIDS) after anecdotal evidence suggested a possible link to the DTP vaccine. The risk of SIDS was found to be the same for vaccinated children as for unvaccinated children enrolled in the partici-

pating health maintenance organizations. Such studies are known as "post-marketing" or "Phase IV" clinical studies because the vaccine has been approved by the FDA for marketing.

National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program compensates people who are determined to have been injured by vaccines. Established by the National Childhood Vaccine Injury Act of 1986, it is a federal "no-fault" system compensating individuals or families of individuals who have been injured by childhood vaccines. All routinely recommended childhood vaccinations are covered by the program. People who file claims are not required to prove negligence on the part of the healthcare provider or the manufacturer.

A panel of experts has established a list of serious injuries that are associated with certain vaccines. This list is updated as medical research uncovers more information on the side effects of vaccines. People who file claims may qualify for compensation in three ways:

- Show that the injury occurred within a certain time interval of receiving the vaccine;
- Prove that the vaccine caused the injury; or
- Prove that the vaccine worsened a pre-existing condition.

Funds accumulated from a tax on each dose of a vaccine purchased are used for the compensation awards.

Vaccines covered under the program are diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, *Haemophilus influenzae* type b, and varicella. It is anticipated that the pneumoccocal vaccine will soon be included.

NVICP Contact Information
Phone: 1-800-822-7967
Web: www.hrsa.gov/bhpr/vicp

Task Force on Safer Childhood Vaccines

In 1986, the Task Force on Safer Childhood Vaccines was established by the Secretary of Health and Human Services at the direction of Congress. Members of the Task Force include the Director of the National Institutes of Health, Commissioner of the Food and Drug Administration, Director of the Centers for Disease Control and Prevention, and other members of the Public Health Service.

The Task Force examines vaccine safety and makes recommendations to the Secretary of Health and Human Services for development of safe childhood vaccines and for improvements in manufacturing, processing, testing, licensing, labeling, distribution, storage, administration, adverse reaction reporting, monitoring, recalling batches, and research. Reports are published

on a periodic basis. The report from January 22, 1996, is available on-line at www.cdc.gov/od/nvpo/nvr12296.htm.

Institute of Medicine Reviews

The National Childhood Vaccine Injury Act established a committee at the Institute of Medicine—a prestigious medical research organization funded by Congress to provide objective, timely, authoritative information and advice concerning health to government, the corporate sector, the professions, and the public—to review the medical literature on health problems or injuries occurring after vaccination. The Act mandates these comprehensive reviews of vaccine-related adverse events.

The Institute of Medicine has published the following studies on the adverse events associated with vaccines given to children:

- Institute of Medicine. *Adverse effects of pertussis and rubella vaccines*. Washington, DC: National Academy Press; 1991.
- Institute of Medicine. *Adverse events associated with childhood vaccines*. Washington, DC: National Academy Press; 1994.

Why Are Vaccines Mandated?

Why does the government mandate that millions of children and adolescents receive certain immunizations for school entry?

The more people in a community who are vaccinated, the healthier that community is. Here is how Dr. Samuel Katz, a renowned vaccine expert and a member of PKIDs' Medical Advisory Board, explained it before Congress in 1999.

"We know too well that the level of [immunization] protection that we have now established in our children and our communities is a fragile one that depends on what we refer to as community or 'herd' immunity. From the standpoint of effectiveness, modern childhood vaccines are approximately 90 to 95 percent effective. What that means is that for every 20 children who are vaccinated one or two may not develop a sufficient immune response [or antibodies to fight an infection].

"It cannot be assured that these children will be protected from the virus or bacteria should they encounter it at school, at a playground, at a shopping mall, or at their church daycare. However, if sufficient numbers of children in a community are immunized, the vaccinated ones protect the unprotected by effectively stopping the chain of transmission in its tracks and drastically lowering the probability that the susceptible child will encounter the bacteria or virus," said Katz.

Community immunity also helps protect children and adults whose immune systems are com-

promised or weakened because of another illness or old age.

"As long as the great majority of children receive their vaccines, we will be able to maintain our current level of disease control," Katz explained. "However, should the level of community protection drop to the point where the viruses and bacteria travel unimpeded from person- to-person, from school-to-school, and from community-to-community, we instantly return to a past era when epidemics were an accepted part of life."

America experienced such an outbreak in 1989-91 with the resurgence of measles. There were 55,622 reported cases mainly in children less than 5 years of age, more than 11,000 hospitalizations and 125 deaths. States do allow personal exemptions, so parents can choose not to vaccinate their children, but those exemptions carry risk to the child and the public's health, emphasizing the importance of community immunity.

An article in the *Journal of the American Medical Association* found that, on average, those children who were exempted from immunizations ran a 35-fold greater risk of contracting measles compared to those who were nonexemptors.

Not only are these children at greater risk of disease, their infections can be the spark that ignites a disease outbreak in a community.

According to Dr. Katz, in the late 1960s and early 1970s, despite the availability of a safe and effective measles vaccine, the United States continued to experience regular epidemics of measles. Left to individual choice (as opposed to government mandates), only 60 to 70 percent of the community was immunized.

That coverage failed to provide adequate community immunity to prevent an outbreak.

"States without school immunization requirements had incidence rates for measles significantly higher than states with these requirements," noted Dr. Katz. "Recognizing these data, other states (not the federal government), quickly adopted similar requirements. These requirements are supported by the American Academy of Pediatrics.

"The results are striking," he added. "Before we had a measles vaccine, an estimated 500,000 cases of measles were reported each year. In 1998, there were 89 cases of measles in the United States with no measles-associated deaths. Most counties in the United States were free of measles. However, we have learned that nearly all of the cases of measles that did occur in the United States were imported from other countries. This would not have been possible without the "school exclusion" statutes that now exist in every state. While we hear dramatic stories of exotic diseases that are just a plane ride away, the importation of vaccine preventable diseases into a susceptible population is much more frightening. Should we allow our community immunity to wane, we will negate all the progress we have made and allow our communities to be at risk from threats that are easily prevented."

Compulsory vaccination laws in the United States have repeatedly been upheld as a reasonable exercise of the state's compelling interest even in the absence of an epidemic or a single case. As the U.S. Supreme Court held in 1905 in the case Jacobson vs. Massachusetts:

" ...in every well-ordered society charged with the duty of conserving the safety of its members, the rights of the individuals in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations as the safety of the general public may demand."

The Supreme Court makes clear that "the liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good. [Liberty] is only freedom from restraint under conditions essential to the equal enjoyment of the same right by others."

If There Is No Disease, Why Are Some Vaccines Still Necessary?

There hasn't been a single case of polio in the United States for decades. So why do we need to be immunized against it? While the United States has escaped polio for decades, other regions of the world have not been so lucky.

Travelers can unknowingly bring these diseases into the United States, and if the public is not protected by vaccinations, these diseases will quickly spread throughout the population causing epidemics.

Vaccinations are necessary to protect ourselves, even if we think our chances of getting any of these diseases are 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.

Another reason to get vaccinated is to protect those around us. There is a small number of people who cannot be vaccinated (because of severe allergies to vaccine components, for example), and a small percentage of people don't respond to vaccines. These people are susceptible to disease, and their only hope of protection is that people around them are immune and cannot pass disease along to them.

The CDC explains why, from a disease control and prevention perspective, parents should immunize their children:

Diseases are becoming rare due to vaccinations

It's true, some diseases (e.g., polio and diphtheria) are becoming very rare in the U.S. Of course, they are becoming rare largely because we have been vaccinating against them. But it

is still reasonable to ask whether it's really worthwhile to keep vaccinating.

It is like bailing out a boat with a slow leak. When we started bailing, the boat was filled with water. But we have been bailing fast and hard, and now it is almost dry. We could say, "Good. The boat is dry now, so we can throw away the bucket and relax." But the leak hasn't stopped. Before long we'd notice a little water seeping in, and soon it might be back up to the same level as when we started.

Keep immunizing until disease is eliminated

Unless we can "stop the leak" (i.e., eliminate the disease), it is important to keep immunizing. Even if there are only a few cases of disease today, if we take away the protection given by vaccination, more and more people will get infected and spread disease to others, and soon we will have undone the progress we made over the years.

Example case in Japan

In 1974, Japan had a successful pertussis (whopping cough) vaccination program, with nearly 80 percent of their children vaccinated. There were only 393 cases of pertussis that year in the entire country and no deaths. But then rumors began to spread that pertussis vaccination was no longer needed and that the vaccine was not safe. By 1976 only 10 percent of infants were getting vaccinated. In 1979 Japan suffered a major pertussis epidemic with more than 13,000 cases of whopping cough and 41 deaths. In 1981 the government began vaccinating with the acellular pertussis vaccine, and the number of pertussis cases dropped again.

What if we stopped vaccinating?

So what would happen if we stopped vaccinating here? Before long we would see epidemics of diseases that are nearly under control today. More children would get sick and more would die.

We vaccinate to protect our future

We don't vaccinate just to protect our children. We also vaccinate to protect our grandchildren and their grandchildren. With one disease—smallpox—we "stopped the leak" in the boat by eradicating the disease. Our children don't have to get smallpox shots any more because the disease no longer exists. If we keep vaccinating now, parents in the future might be able to look back at the "old days" when we had diseases like polio and measles for which children had to get vaccinated.

What If We Didn't Vaccinate?

The CDC describes life before and after vaccines were developed:

Polio
Polio virus causes acute paralysis that can lead to permanent physical disability and even death. Before polio vaccine was available, 13,000 to 20,000 cases of paralytic polio were reported each year in the United States. These annual epidemics of polio often left thousands of victims—mostly children—in braces, crutches, wheelchairs, and iron lungs. The effects were lifelong.

Development of polio vaccines and implementation of polio immunization programs have eliminated paralytic polio caused by wild polio viruses in the U.S. and the entire Western hemisphere.

In 1994, wild polio virus was imported to Canada from India, but high vaccination levels prevented it from spreading in the population. In 1999, as a result of global immunization efforts to eradicate the disease, there were about 2,883 documented cases of polio in the world.

Measles
Before measles immunizations were available, nearly everyone in the U.S. got measles. An average of 450 measles-associated deaths were reported each year between 1953 and 1963.
In the U.S., up to 20 percent of persons with measles are hospitalized. Seventeen percent of measles cases have had one or more complications, such as ear infections, pneumonia, or diarrhea. Pneumonia is present in about six percent of cases and accounts for most of the measles deaths. Although less common, some persons with measles develop encephalitis (swelling of the lining of the brain), resulting in brain damage.

It is estimated that as many as one of every 1,000 persons with measles will die in the U.S. In the developing world, the rate is much higher, with death occurring in about one of every 100 persons with measles.

Measles is one of the most infectious diseases in the world and is frequently imported into the U.S. In 1997-2000, most cases were associated with international visitors or U.S. residents who were exposed to the measles virus while traveling abroad. More than 90 percent of people who are not immune will get measles if they are exposed to the virus.

According to the World Health Organization (WHO), nearly 900,000 measles-related deaths occurred among persons in developing countries in 1999. In populations that are not immune to measles, measles spreads rapidly. If vaccinations were stopped, each year, 2.7 million measles deaths worldwide could be expected.

In the U.S., widespread use of measles vaccine has led to a greater than 99 percent reduction in measles compared with the pre-vaccine era. If we stopped immunization, measles would increase to pre-vaccine levels.

Hib
Before Hib vaccine became available, Hib was the most common cause of bacterial meningitis

in U.S. infants and children. Before the vaccine was developed, there were approximately 20,000 invasive Hib cases annually. Approximately two-thirds of the 20,000 cases were meningitis, and one-third were other life-threatening invasive Hib diseases such as bacteria in the blood, pneumonia, or inflammation of the epiglottis. About one of every 200 U.S. children under 5 years of age got an invasive Hib disease. Hib meningitis killed 600 children each year and left many survivors with deafness, seizures, or mental retardation.

Since the introduction of conjugate Hib vaccine in December 1987, the incidence of Hib has declined by 98 percent. From 1994-1998, fewer than 10 fatal cases of invasive Hib disease were reported each year.

This preventable disease was a common, devastating illness as recently as 1990; now, most pediatricians just finishing training have never seen a case. If we were to stop immunization, we would likely soon return to the pre-vaccine numbers of invasive Hib disease cases and deaths.

Pertussis

Pertussis can be a severe illness, resulting in prolonged coughing spells that can last for many weeks. These spells can make it difficult for a child to eat, drink, and breathe. Because vomiting often occurs after a coughing spell, infants may lose weight and become dehydrated. In infants, it can also cause pneumonia and lead to brain damage, seizures, and mental retardation.

Since the early 1980s, reported pertussis cases have been increasing, with peaks every 3-4 years; however, the number of reported cases remains much lower than levels seen in the pre-vaccine era. Compared with pertussis cases in other age groups, infants who are 6 months old or younger with pertussis experience the highest rate of hospitalization, pneumonia, seizures, encephalopathy (a degenerative disease of the brain) and death. From 1990 to 1996, 57 persons died from pertussis; 49 of these were less than six months old.

Before pertussis immunizations were available, nearly all children developed whooping cough. In the U.S., prior to pertussis immunization, between 150,000 and 260,000 cases of pertussis were reported each year, with up to 9,000 pertussis-related deaths.

The newer pertussis vaccine (acellular or DTaP) has been available for use in the United States since 1991 and has been recommended for exclusive use since 1998. These vaccines are effective and associated with fewer mild and moderate adverse reactions when compared with the older (whole-cell DTP) vaccines.

During the 1970s, widespread concerns about the safety of the older pertussis vaccine led to a rapid fall in immunization levels in the United Kingdom. More than 100,000 cases and 36 deaths due to pertussis were reported during an epidemic in the mid 1970s. In Japan, pertussis vaccination coverage fell from 80 percent in 1974 to 20 percent in 1979. An epidemic occurred in 1979, resulting in more than 13,000 cases and 41 deaths.

Pertussis cases occur throughout the world. If we stopped pertussis immunizations in the U.S.,

we would experience a massive resurgence of pertussis disease. A recent study* found that, in eight countries where immunization coverage was reduced, incidence rates of pertussis surged to 10 to 100 times the rates in countries where vaccination rates were sustained.

*Reference for study: Gangarosa EJ, et al. Impact of anti-vaccine movements on pertussis control: the untold story. Lancet 1998;351:356-61.

Rubella
While rubella is usually mild in children and adults, up to 90 percent of infants born to mothers infected with rubella during the first trimester of pregnancy will develop congenital rubella syndrome (CRS), resulting in heart defects, cataracts, mental retardation, and deafness.

In 1964-1965, before rubella immunization was used routinely in the U.S., there was an epidemic of rubella that resulted in an estimated 20,000 infants born with CRS, with 2,100 neonatal deaths and 11,250 miscarriages. Of the 20,000 infants born with CRS, 11,600 were deaf, 3,580 were blind, and 1,800 were mentally retarded.

Due to the widespread use of rubella vaccine, only six CRS cases were provisionally reported in the U.S. in 2000. Because many developing countries do not include rubella in the childhood immunization schedule, many of these cases occurred in foreign-born adults. Since 1996, greater than 50 percent of the reported rubella cases have been among adults. Since 1999, there have been 40 pregnant women infected with rubella.

If we stopped rubella immunization, immunity to rubella would decline and rubella would once again return, resulting in pregnant women becoming infected with rubella and then giving birth to infants with CRS.

Chickenpox
Chickenpox is always present in the community and is highly contagious. Prior to the licensing of chickenpox vaccine in 1995, almost all persons in the U.S. had suffered from chickenpox by adulthood. Chickenpox was responsible for an estimated 4 million cases each year, including 11,000 hospitalizations and 100 deaths.

Chickenpox is usually mild, but may be severe in some infants, adolescents, and adults. Some people who get chickenpox have also suffered from complications such as secondary bacterial infections, loss of fluids (dehydration), pneumonia, and central nervous system involvement. In addition, only persons who have had chickenpox in the past can get shingles, a painful inflammation of the nerves. There are about 300,000 cases of shingles that occur each year when the inactivated chickenpox virus is activated in people who have had chickenpox in the past.

Vaccine coverage among children 19-35 months was 67 percent in 2000.

Hepatitis B
More than 2 billion persons worldwide have been infected with the hepatitis B virus at some

time in their lives. Of these, 350 million are life-long carriers of the disease and can transmit the virus to others. One million of these people die each year from liver disease and liver cancer.

National studies have shown that about 12.5 million Americans have been infected with hepatitis B virus at some point in their lifetime. One and one quarter million Americans are estimated to have chronic (long-lasting) infection, of whom 20 percent to 30 percent acquired their infection in childhood. Chronic hepatitis B virus infection increases a person's risk for chronic liver disease, cirrhosis, and liver cancer. About 5,000 persons will die each year from hepatitis B-related liver disease resulting in over $700 million medical and work loss costs.

The number of new infections per year has declined from an average of 450,000 in the 1980s to about 80,000 in 1999. The greatest decline has occurred among children and adolescents due to routine hepatitis B vaccination.

Infants and children who become infected with the hepatitis B virus are at highest risk of developing lifelong infection, which often leads to death from liver disease (cirrhosis) and liver cancer. Approximately 25 percent of children who become infected with life-long hepatitis B would be expected to die of related liver disease as adults.

CDC estimates that one-third of the life-long hepatitis B virus infections in the United States resulted from infections occurring in infants and young children. About 16,000—20,000 hepatitis B antigen infected women give birth each year in the United States. It is estimated that 12,000 children born to hepatitis B virus infected mothers were infected each year before the implementation of infant immunization programs. In addition, approximately 33,000 children (10 years of age and younger) of mothers who are not infected with hepatitis B virus were infected each year before the routine recommendation of childhood hepatitis B vaccination.

Diphtheria

Diphtheria is a serious disease caused by a bacteria. This germ produces a poisonous substance or toxin that frequently causes heart and nerve problems. The death rate is 5 percent to 10 percent, with higher death rates (up to 20 percent) in the very young and the elderly.

In the 1920s, diphtheria was a major cause of illness and death for children in the U.S. In 1921, a total of 206,000 cases and 15,520 deaths were reported. With vaccine development in 1923, new cases of diphtheria began to fall in the U.S., until 2000 when only one case was reported.

Although diphtheria is rare in the U.S., it appears that the bacteria continues to get passed among people. In 1996, 10 isolates of the bacteria were obtained from persons in an American Indian community in South Dakota, none of whom had the classic diphtheria disease. There was one death reported in 2000 from clinical diphtheria caused by a related bacteria.

There are high rates of susceptibility among adults. Screening tests conducted since 1977 have shown that 41 percent to 84 percent of adults 60 and over lack protective levels of circulating

antitoxin against diphtheria.

Although diphtheria is rare in the U.S., it is still a threat. Diphtheria is common in other parts of the world, and with the increase in international travel, diphtheria and other infectious diseases are only a plane ride away. If we stopped immunization, the U.S. might experience a situation similar to the Newly Independent States of the former Soviet Union. With the breakdown of the public health services in this area, diphtheria epidemics began in 1990, fueled primarily by persons who were not properly vaccinated. From 1990-1999, more than 150,000 cases and 5,000 deaths were reported.

Tetanus

Tetanus is a severe, often fatal disease. The bacteria that cause tetanus are widely distributed in soil and street dust, are found in the waste of many animals, and are very resistant to heat and germ-killing cleaners. From 1922-1926, there were an estimated 1,314 cases of tetanus per year in the U.S. In the late 1940s, the tetanus vaccine was introduced, and tetanus became a disease that was officially counted and tracked by public health officials. In 2000, only 41 cases of tetanus were reported in the U.S.

People who get tetanus suffer from stiffness and spasms of the muscles. The larynx (throat) can close causing breathing and eating difficulties, muscles spasms can cause fractures (breaks) of the spine and long bones, and some people go into a coma, and die. Approximately 30 percent of reported cases end in death.

Worldwide, tetanus in newborn infants continues to be a huge problem. Every year tetanus kills 300,000 newborns and 30,000 birth mothers who were not properly vaccinated.

Tetanus in the U.S. is primarily a disease of adults. From 1995-1997, 33 percent of reported cases of tetanus occurred among persons 60 years of age or older and 60 percent occurred in patients greater than 40 years of age. The National Health Interview Survey found that in 1995, only 36 percent of adults 65 or older had received a tetanus vaccination during the preceding 10 years.

Even though the number of reported cases is low, an increased number of tetanus cases in younger persons has been observed recently in the U.S. among intravenous drug users, particularly heroin users.

Tetanus is infectious, but not contagious, so unlike other vaccine-preventable diseases, immunization by members of the community will not protect others from the disease. Because tetanus bacteria are widespread in the environment, tetanus can only be prevented by immunization. If vaccination against tetanus were stopped, persons of all ages in the U.S. would be susceptible to this serious disease.

Mumps

Before the mumps vaccine was introduced, mumps was a major cause of deafness in children,

occurring in approximately 1 in 20,000 reported cases. Mumps is usually a mild viral disease. However, rare conditions such as swelling of the brain, nerves and spinal cord can lead to serious side effects such as paralysis, seizures, and fluid in the brain.

Serious side effects of mumps are more common among adults than children. Swelling of the testes is the most common side effect in males past the age of puberty, occurring in up to 20 percent to 50 percent of men who contract mumps. An increase in miscarriages has been found among women who develop mumps during the first trimester of pregnancy.

An estimated 212,000 cases of mumps occurred in the U.S. in 1964. After vaccine licensure in 1967, reports of mumps decreased rapidly. In 1986 and 1987, there was a resurgence of mumps with 12,848 cases reported in 1987. Since 1989, the incidence of mumps has declined, with an estimated 327 cases in 2000. This recent decrease is probably due to the fact that children have received a second dose of mumps vaccine (part of the two-dose schedule for measles, mumps, rubella or MMR) and the eventual development of immunity in those who did not gain protection after the first mumps vaccination.

If we were to stop vaccination against mumps, we could expect the number of cases to climb back to pre-vaccine levels, since mumps is easily spread among unvaccinated persons.