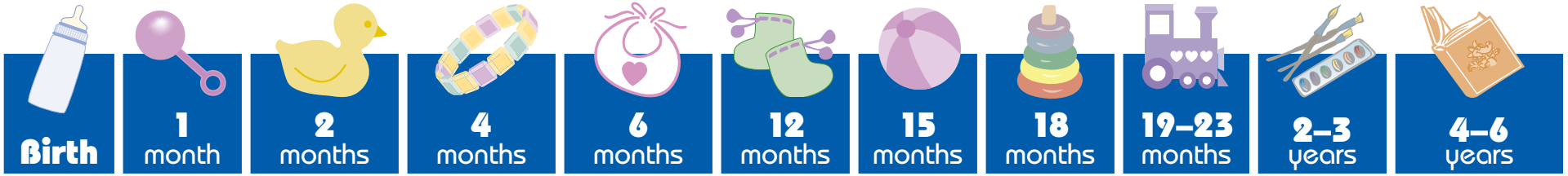
COMMON QUESTIONS PARENTS ASK about infant immunizations

Is it okay for my baby to have so many shots at once?	Yes. Studies show that kids' bodies—even infants—can handle many shots at once. **Having several vaccines at once is safe, even for a newborn.** Combination vaccines protect your child against more than one disease with a single shot. This reduces the number of shots and office visits your child would need. It's not your imagination; there are a greater number of shots now than even a few years ago. That's because as science advances, we are able to protect your child against more diseases than ever before.
Don't infants have natural immunity?	Babies get some temporary immunity (protection) from mom during the last few weeks of pregnancy—but only for the diseases mom is immune to. **These antibodies do not last long, leaving the infant vulnerable to disease.**
Haven't we gotten rid of most of these diseases in this country?	Thanks to vaccines, most diseases prevented by vaccines are no longer common in this country. Even the few cases we have in the U.S. could very quickly become **tens or hundreds of thousands of cases if we stopped vaccinating**. It's not uncommon to have measles outbreaks, whooping cough outbreaks, chickenpox outbreaks, and other diseases when vaccination rates drop. Kids that are not fully vaccinated can become seriously sick and spread it through a community.
I heard that some vaccines can cause autism. Is this true?	**No. Scientific studies and reviews have found no relationship between vaccines and autism.** Groups of experts, including the American Academy of Pediatrics and the Institute of Medicine (IOM), also agree that vaccines are not responsible for the number of children now recognized to have autism.
Can't I just wait until my child goes to school to catch up on immunizations?	Many of the diseases vaccines protect against can be very dangerous to infants. Newborns, babies, and toddlers can all be exposed to diseases from parents and other adults, brothers and sisters, on a plane, at child care, or even at the grocery store. International travel is easier than ever—your baby can be exposed to diseases from other countries without you knowing. **Don't wait to protect your baby and risk these diseases** when he or she needs protection now. It is easier to stay up to date than to catch up!
Why does my child need a chickenpox shot? Isn't it a mild disease?	**Chickenpox can actually be a serious disease** for kids if the blisters become infected. Before vaccine was available, about 50 kids died every year from chickenpox, and about 1 in 500 kids who got chickenpox were hospitalized.
My child is sick right now. Is it okay for her to still get shots?	Yes, usually. **Talk with the doctor, but children can usually get vaccinated even if they have a mild illness** like a cold, earache, mild fever, or diarrhea. If the doctor says it is okay, your child can still get vaccinated.
Where can I get more information?	Centers for Disease Control and Prevention (CDC) • **www.cdc.gov/vaccines or 800-CDC-INFO (232-4636)** American Academy of Pediatrics • **www.aap.org** The Children's Hospital of Philadelphia • **www.vaccine.chop.edu** Immunization Action Coalition (IAC) • **www.immunize.org** Every Child By Two • **www.ecbt.org**

2010 Recommended Immunizations for Children from Birth Through 6 Years Old

The Recommended Immunization Schedule for Persons Aged Birth Through 6 Years Old is approved by the Centers for Disease Control and Prevention, the American Academy of Pediatrics, and the American Academy of Family Physicians



Shaded boxes indicate the vaccine can be given during shown age range.

See back page for more information on vaccine-preventable diseases and the vaccines that prevent them.

NOTE: If your children miss a shot, you don't need to start over, just go back to your healthcare provider for the next shot. The healthcare provider will keep your children up-to-date on vaccinations. Talk with your healthcare provider if you have questions.

FOOTNOTES

§ HepA vaccination is recommended for high-risk children older than 2 years, along with a dose of meningococcal vaccine (MCV4) and pneumococcal vaccine (PPSV). HepA vaccination may be administered to any child over 2 for whom immunity is desired. See vaccine-specific recommendations at **www.cdc.gov/vaccines/pubs/ACIP-list.htm**.

* Children 6 months or older should receive flu vaccination every flu season. If this is the first time for flu vaccine, a child 6 months through 8 years of age should receive two doses, separated by at least 4 weeks. If this child only receives one dose in the first season, he or she should receive two doses the next season, if still younger than 9 years. Ask your child's healthcare provider if a second dose is needed.

For more information, call toll free **1-800-CDC-INFO** (1-800-232-4636) or visit **http://www.cdc.gov/vaccines**

CDC

National Infant Immunization Week

Vaccine-Preventable Diseases and the Vaccines that Prevent Them

Diphtheria (Can be prevented by DTaP vaccine)*

Diphtheria is a very contagious bacterial disease that affects the respiratory system, including the lungs. Diphtheria can be passed from person to person by direct contact with droplets from an infected person's cough or sneeze. When people are infected, the diphtheria bacteria produce a toxin (poison) in the body that can cause weakness, sore throat, low-grade fever, and swollen glands in the neck. Effects from this toxin can also lead to swelling of the heart muscle and, in some cases, heart failure. In severe cases, the illness can cause coma, paralysis, and even death.

Haemophilus influenzae type b (Can be prevented by Hib vaccine)

Hib disease is caused by bacteria called *Haemophilus influenzae* type b. The disease is very serious for children younger than age 5, especially infants. Hib is spread from person to person by direct contact, or by contact with respiratory droplets from an infected person's cough or sneeze. Hib is most commonly spread by people who have the bacteria in their noses and throats but who are not sick. Hib can cause meningitis—an infection around the brain and spinal cord—which can lead to life-long disability, mental retardation, or death. Hib can also cause epiglottis (infection in the throat) and pneumonia (infection in the lungs). All these infections can be life threatening.

Hepatitis A (Can be prevented by HepA vaccine)

Hepatitis A is an infection in the liver caused by a virus. The virus is spread primarily person-to-person through the fecal-oral route. In other words, the virus is taken in by mouth from contact with objects, food, or drinks contaminated by the feces (stool) of an infected person. Symptoms include fever, tiredness, loss of appetite, nausea, abdominal discomfort, dark urine, and jaundice (yellowing of the skin and eyes). An infected person may have no symptoms, may have mild illness for a week or two, or may have severe illness for several months that requires hospitalization. In the U.S., about 100 people a year die from hepatitis A.

Hepatitis B (Can be prevented by HepB vaccine)

Hepatitis B is an infection of the liver caused by a virus. It spreads through contact with blood or other body fluids, for example, from sharing personal items, such as toothbrushes or eating utensils. Hepatitis B causes a flu-like illness with loss of appetite, nausea, vomiting, rashes, joint pain, and jaundice. The virus stays in the liver of some people for the rest of their lives and can result in severe liver diseases, including fatal cancer.

Influenza (Can be prevented by annual flu vaccine)

Influenza is a highly contagious viral infection of the nose, throat, and lungs. It spreads easily through droplets when an infected person coughs or sneezes and can cause mild to severe illness. Typical symptoms include a sudden high fever, chills, a dry cough, headache, runny nose, sore throat, and muscle and joint pain. Extreme fatigue can last from several days to weeks. Influenza may lead to hospitalization or even death, even among previously healthy children.

Measles (Can be prevented by MMR vaccine)**

Measles is one of the most contagious viral diseases. Measles is spread by direct contact with the airborne respiratory droplets of an infected person. Measles is so contagious that just being in the same room after a person who has measles has already left can result in infection. Symptoms usually include a rash, fever, cough, and watery eyes. Fever can persist, reaching 104˚F or higher, rash can last for up to a week, and coughing can last about 10 days. Measles can also cause pneumonia, seizures, brain damage, or death.

Mumps (Can be prevented by MMR vaccine)**

Mumps is an infectious disease caused by the mumps virus, which is spread in the air by a cough or sneeze from an infected person. A child can also get infected with mumps by coming in contact with a contaminated object, like a toy. The mumps virus causes fever, headaches, painful swelling of the salivary glands under the jaw, fever, muscle aches, tiredness, and loss of appetite. Severe complications for children who get mumps are rare, but can include meningitis (infection of the covering of the brain and spinal cord), encephalitis (inflammation of the brain), permanent hearing loss, or swelling of the testes, which can lead to sterility in men.

Pertussis (Whooping Cough) (Can be prevented by DTaP vaccine)*

Pertussis is caused by bacteria that spread through direct contact with respiratory droplets when an infected person coughs or sneezes. In the beginning, symptoms of pertussis are similar to the common cold, including runny nose, sneezing, low grade fever, and cough. After 1-2 weeks, pertussis can cause spells of violent coughing and choking, making it hard to breathe, drink, or eat. This cough can last for weeks. Pertussis is most serious for babies, who can get pneumonia, have seizures, become brain damaged, or even die. About two-thirds of children under 1 year of age who get pertussis must be hospitalized.

Pneumococcal Disease (Can be prevented by PCV vaccine)

Pneumococcal disease is a bacterial infection that invades the lungs, causing the most common kind of bacterial pneumonia. The bacteria are commonly found in many people's noses and throats and are spread by droplets when people who have the bacteria in their throats or noses cough or sneeze. People—especially children—often have the bacteria in their throats without being ill. In fact, the bacteria are present in about 25% of people. Why the bacteria suddenly invade the body and cause disease is unknown. The bacteria can invade both the bloodstream (bacteremia) and the brain (meningitis, that is infection of the covering of the brain and spinal cord). Symptoms include high fever, cough with chest pain and mucus, shaking chills, breathlessness, and chest pain that increases with breathing. Pneumococcal disease can result in hospitalization and even death.

Polio (Can be prevented by IPV vaccine)

Polio is caused by a virus that lives in an infected person's throat and intestines. It spreads through contact with the feces (stool) of an infected person and through droplets from a sneeze or cough. Symptoms typically include sudden fever, sore throat, headache, muscle weakness, and pain. In about 1% of cases, polio can cause paralysis. Among those who are paralyzed, up to 5% of children may die because they become unable to breathe.

Rotavirus (Can be prevented by RV vaccine)

Rotavirus is caused by a virus and is the most common cause of severe diarrhea among children. Rotavirus is spread primarily person-to-person through the fecal-oral route. In other words, the virus is taken in by mouth from contact with objects, food, or drinks contaminated by the feces (stool) of an infected person. Common symptoms of rotavirus include vomiting, watery diarrhea that lasts for 3-8 days, fever and abdominal pain. Approximately 55,000 children are hospitalized each year in the United States from severe diarrhea and vomiting caused by rotavirus.

Rubella (German Measles) (Can be prevented by MMR vaccine)**

Rubella is caused by a virus that is spread through coughing and sneezing. In children rubella usually causes a mild illness with fever, swollen glands, and a rash that lasts about 3 days. Rubella rarely causes serious illness or complications in children, but can be very serious in pregnant women. If a pregnant woman is infected, the result to the baby can be devastating, including miscarriage, serious heart defects, mental retardation and loss of hearing and eye sight.

Tetanus (Lockjaw) (Can be prevented by DTaP vaccine)*

Tetanus is caused by bacteria found in soil that enters the body through a wound, such as a deep cut. When people are infected, the bacteria produce a toxin (poison) in the body that causes serious, painful spasms and stiffness of all muscles in the body. This can lead to "locking" of the jaw so a person cannot open his or her mouth, swallow, or breathe. Complete recovery from tetanus can take months. Three of ten people who get tetanus die from the disease.

Varicella (Chickenpox) (Can be prevented by Varicella vaccine)

Chickenpox is caused by the varicella zoster virus. Chickenpox is very contagious and spreads very easily from infected people. It can spread from either a cough, sneeze. It can also spread by contact with virus particles that come from the blisters on the skin, either by touching them or by breathing in these virus particles. Typical symptoms of chickenpox include an itchy rash with blisters, tiredness, headache and fever. Chickenpox is usually mild, but it can lead to severe skin infections, pneumonia, encephalitis (brain swelling), or even death.

* DTaP is a combination vaccine that can prevent Diphtheria, Tetanus, and Pertussis
** MMR is a combination vaccine that can prevent Measles, Mumps, and Rubella.

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Rotavirus: Questions and Answers

Information about the disease and vaccines

What causes rotavirus disease?
Rotavirus disease is caused by a virus, the rotavirus. The name rotavirus is derived from the Latin rota, meaning "wheel," because the rotavirus has a wheel-like appearance when viewed by an electron microscope.

How does rotavirus spread?
The rotavirus enters the body through the mouth and then infects the lining of the intestines. Rotavirus is very contagious, spreading easily from children who are already infected to other children and sometimes adults. Large amounts of rotavirus are shed in the stool of infected persons and the virus can be easily spread via contaminated hands and objects, such as toys. Children can spread rotavirus both before and after they become sick with diarrhea.

Rotavirus is very stable and may remain viable in the environment for months if not disinfected.

How long does it take to show signs of rotavirus after being exposed?
The incubation period for rotavirus diarrhea is 1-3 days. Symptoms of infection vary and depend on whether it is the first infection or a repeat infection.

What are the symptoms of rotavirus?
In young children, rotavirus disease commonly begins with fever and vomiting, followed by diarrhea. Vomiting and diarrhea may last from three to seven days; the diarrhea may be watery. Children may lose interest in eating and drinking and become dehydrated from loss of fluids.

How serious is rotavirus?
All three symptoms of rotavirus disease (fever, vomiting, and diarrhea) cause children to lose fluids. Vomiting is especially dangerous because it's difficult to replace fluids in children who are vomiting persistently.

Prior to the availability of rotavirus vaccine, rotavirus infection was responsible for more than 400,000 doctor visits, more than 200,000 emergency room visits, 55,000-70,000 hospitalizations, and 20-60 deaths in the U.S. on an annual basis. In the first five years of life, four of five children in the United States were expected to develop rotavirus gastroenteritis, one in seven would require a clinic or emergency room visit, one in 70 would be hospitalized, and one in 200,000 would die from this disease.

Rotavirus infection is even more problematic in the developing world because children with rotavirus disease are less likely to receive the medical intervention necessary to prevent death from dehydration. In developing countries, rotavirus causes more than 500,000 deaths each year in children younger than age five years.

What are possible complications from rotavirus?
Rotavirus infection in infants and young children can lead to severe diarrhea, dehydration, electrolyte imbalance, and metabolic acidosis. Immunodeficient children may have more severe or persistent disease.

How do I know if my child has rotavirus?
Rotavirus disease is difficult to differentiate from illness caused by other pathogens. As a result, laboratory testing of the stool is needed to confirm a diarrheal illness as rotavirus disease.

Are children more likely to become infected at certain times of the year?
In the United States, rotavirus is a winter/spring disease (children are most likely to get infected between November and May). In tropical climates, the disease occurs year round.

Is there a treatment for rotavirus?
Children are typically treated by replacing lost body fluids through drinking liquids specifically made for rehydration; these liquids are called oral rehydration solutions. These products contain specific amounts of water, sugars, and salts. In severe cases, body fluids are replaced with fluids given directly through the veins by use of an intravenous line in the hospital.

How long is a person with rotavirus contagious?
Infected persons shed large quantities of virus in their stool beginning 2 days before the onset of diarrhea and for up to 10 days after onset of symptoms. Rotavirus may be detected in the stool of persons with immune deficiency for more than 30 days after infection.

Are any people at greater risk than others of being infected with rotavirus?
Groups at increased risk for rotavirus infection are usually those with increased exposure to virus. This includes children who attend childcare centers, chil-

Technical content reviewed by the Centers for Disease Control and Prevention, April 2010.

www.immunize.org/catg.d/p4217.pdf • Item #P4217 (4/10)

dren in hospital wards, caretakers and parents of children in childcare or hospitals, and children and adults with immunodeficiency-related diseases.

Can you get rotavirus more than once?
A person may develop rotavirus disease more than once because there are many different rotavirus types, but second infections tend to be less severe than the first infections. After a single natural infection, 40% of children are protected against a subsequent rotavirus illness. Persons of all ages can get repeated rotavirus infections, but symptoms may be mild or not occur at all in repeat infections.

Wouldn't good hygiene be enough to prevent rotavirus disease?
Better hygiene and sanitation have not been very effective in reducing rotavirus disease. This is illustrated by the fact that virtually everyone in the world is infected by rotavirus disease by age five years, despite differences in sanitation between countries.

When did a rotavirus vaccine become available?
A vaccine to prevent rotavirus gastroenteritis was first licensed in August 1998 but was withdrawn in 1999 because of its association with an uncommon type of bowel obstruction called "intussusception."

In February 2006, the U.S. Food and Drug Administration (FDA) approved a new rotavirus vaccine, RotaTeq (by Merck). In April 2008, FDA approved a second rotavirus vaccine, Rotarix (by GlaxoSmithKline).

What kind of vaccine are they?
RotaTeq and Rotarix are both live attenuated (weakened) viral vaccines.

How is this vaccine given?
Both RotaTeq and Rotarix are given to babies orally (swallowed).

Who should get this vaccine?
National experts on immunization (such as the Centers for Disease Control and Prevention and the American Academy of Pediatrics) recommend routine vaccination of all infants with rotavirus vaccine.

What is the recommended schedule for getting this vaccine?
Both vaccines are given in a series: RotaTeq vaccine is given in a 3-dose series with doses given at ages 2, 4, and 6 months; Rotarix vaccine is given in a 2-dose series with doses given at ages 2 and 4 months.

The first dose of either vaccine can be given as early as age 6 weeks or as late as age 14 weeks, 6 days. Vaccination should not be started for infants once they reach their 15 week birthday. There must be at least 4 weeks between doses and all doses must be given by age 8 months. Rotavirus vaccine may be given at the same time as other childhood vaccines.

Should an infant who has already been infected with rotavirus still be vaccinated?
Yes. Infants who have recovered from a rotavirus infection may not be immune to all of the virus types present in the vaccine. Therefore, just like infants who have never had rotavirus disease, infants who have previously had rotavirus disease should still complete the vaccine series if they can do so by age 8 months.

How safe is this vaccine?
Clinical trials to determine the safety and effectiveness of the RotaTeq vaccine involved more than 70,000 infants in 11 countries. Because of the association of the earlier rotavirus vaccine with a type of intestinal blockage called intussusception, a study designed specifically to assess a risk of intussusception was conducted before licensure of RotaTeq. The vaccine was given to 35,000 children and another 35,000 were given a placebo (salt water). There was no difference in the incidence of intussusception between the two groups.

As with all vaccines, the safety of this vaccine is being monitored after licensure by the U.S. Food and Drug Administration (FDA) and by CDC through the Vaccine Adverse Event Reporting System. In addition, Merck and Co., Inc., has committed to monitoring the safety of the vaccine in a large number of U.S. infants. CDC will also conduct a large study in its Vaccine Safety Datalink Program, which evaluates vaccine safety among approximately 80,000 U.S. infants every year. Also, for the first three years of licensure, the manufacturer will report cases of intussusception to FDA within 15 days of receiving them, and all other serious side effects will be reported on a monthly basis.

As a result of this aggressive monitoring, on February 13, 2007, the FDA released a report on the number of intussusception cases reported since RotaTeq licensure. The number reported fell within what was expected and gives assurance that the vaccine does not pose an elevated risk for intussusception. To read the report, go to www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm142404.htm. To read a CDC Q&A about the report, go to www.cdc.gov/vaccinesafety/vaers/rotateq.htm.

In clinical trials, infants who received RotaTeq vaccine and those who didn't were monitored to deter-

mine if there were other possible side effects associated with the vaccine. Compared with infants who did not receive the vaccine, infants who did receive the vaccine had a slightly higher rate of diarrhea and vomiting within the first week and within the first 42 days after receiving the vaccine.

The FDA's approval of Rotarix in 2008 was based on clinical trials involving nearly 75,000 infants. These clinical trials were conducted in the Americas, Europe, Asia and Africa and reflect an ethnically diverse population.

In a controlled safety study conducted in Latin America and Finland, the risk of intussusception was evaluated in 63,225 infants. No increased risk of intussusception was detected among those infants who received the vaccine and those who did not.

As with all vaccines, the safety of this vaccine is being monitored after licensure by the U.S. Food and Drug Administration (FDA) and by CDC through the Vaccine Adverse Event Reporting System and other systems. In addition, GlaxoSmithKline has committed to monitoring the safety of the vaccine in a large number of U.S. infants. Also, for the first three years of licensure, the manufacturer will report any serious and unexpected adverse events to FDA within 15 days of receiving them, and all other initial adverse experience reports will be reported on a monthly basis.

In clinical trials, infants who received Rotarix vaccine and those who didn't were monitored to determine if there were other possible side effects associated with the vaccine. Compared with infants who did not receive the vaccine, infants who did receive the vaccine had a slightly higher rate of cough or runny nose within the first week after receiving the vaccine and a slightly higher rate of irritability within the first month after receiving the vaccine.

How effective is rotavirus vaccine?

Rotavirus vaccine is very effective against rotavirus disease. Studies show the vaccine to be highly effective (85%-98%) against severe rotavirus disease and very effective against rotavirus disease of any severity (74%-87%) through approximately the first rotavirus season after vaccination. Chances that children will need to be hospitalized for rotavirus disease are also greatly decreased (96%) by the vaccine. Neither vaccine will prevent diarrhea or vomiting caused by other germs.

What side effects have been reported with rotavirus vaccine?

Vaccinated infants are slightly (1%-3%) more likely to be irritable or to have mild, temporary diarrhea or vomiting after getting a dose of vaccine than infants who did not get the vaccine. Moderate or severe reactions have not been associated with the vaccine.

Who should NOT receive rotavirus vaccine?

Any child who has had a severe (life-threatening) allergic reaction to a previous dose of rotavirus vaccine should not get another dose. A child with a severe (life-threatening) allergy to any component of rotavirus vaccine should not get the vaccine. Because the oral applicator for Rotarix contains latex rubber, infants with a severe (anaphylactic) allergy to latex should not be given Rotarix; the RotaTeq dosing tube is latex-free. Rotavirus vaccine is contraindicated in infants diagnosed with the rare genetic disorder severe combined immune deficiency (SCID). Although this vaccine has not been associated with intussusception, as a precaution it is suggested that the risks for and the benefits of vaccination should be considered when vaccinating infants with a previous episode of intussusception.

Children who are moderately or severely ill at the time the vaccination is scheduled should probably wait until they recover, including children who are experiencing diarrhea or vomiting. Healthcare providers will decide on a case-by-case basis whether to vaccinate a child with an ongoing digestive problem, an immune system weakened because of HIV/AIDS or another disease that affects the immune system, or a child who is receiving treatment with drugs such as long-term steroids or treatment for cancer.

ROTAVIRUS VACCINE

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.
Hojas de Informacián Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite http://www.immunize.org/vis

1 What is rotavirus?

Rotavirus is a virus that causes diarrhea (sometimes severe), mostly in babies and young children. It is often accompanied by vomiting and fever, and can lead to dehydration.

Rotavirus is not the only cause of diarrhea, but it is one of the most serious. Before a vaccine was available, rotavirus was responsible for:

- more than 400,000 doctor visits,
- more than 200,000 emergency room visits,
- 55,000 to 70,000 hospitalizations, and
- 20-60 deaths

in the United States each year. Almost all children in the U.S. were infected with rotavirus before their 5th birthday.

2 Rotavirus vaccine

Better hygiene and sanitation have not reduced rotavirus diarrhea very much in the United States. **The best way to protect your baby from rotavirus disease is with rotavirus vaccine.**

Rotavirus vaccine is an oral (swallowed) vaccine, not a shot.

Rotavirus vaccine will not prevent diarrhea or vomiting caused by other germs, but it is very good at preventing diarrhea and vomiting caused by rotavirus. Most babies who get the vaccine will not get rotavirus diarrhea at all, and almost all of them will be protected from **severe** rotavirus diarrhea.

Rotavirus vaccine has been used since 2006 in the United States. By 2010 it had reduced the number of babies and young children needing emergency department care or hospitalization for rotavirus disease by about 85%.

3 Who should get rotavirus vaccine and when?

There are two brands of rotavirus vaccine. Both vaccines are effective.

Your baby could get either 2 or 3 doses, depending on which brand is used. Your provider can tell you which brand your baby will be getting.

The doses are recommended at these ages:

First Dose: 2 months of age

Second Dose: 4 months of age

Third Dose: 6 months of age (if needed)

The first dose may be given as early as 6 weeks of age, and should be given by age 14 weeks 6 days. The last dose should be given by 8 months of age.

Rotavirus vaccine may be given at the same time as other childhood vaccines.

4 Some people should not get rotavirus vaccine or should wait.

- A baby who has had a severe (life-threatening) allergic reaction to a dose of rotavirus vaccine should not get another dose. A baby who has a severe (life-threatening) allergy to any component of rotavirus vaccine should not get the vaccine. Tell your doctor if your baby has any severe allergies that you know of, including a severe allergy to latex.
- Babies with “severe combined immunodeficiency” (SCID) should not get rotavirus vaccine.
- Babies with mild illnesses can usually get the vaccine. Babies who are moderately or severely ill should probably wait until they recover. This includes babies who have moderate or severe diarrhea or vomiting. Ask your doctor or nurse.
- Check with your doctor if your baby’s immune system is weakened because of:

- HIV/AIDS, or any other disease that affects the immune system
- treatment with drugs such as long-term steroids
- cancer, or cancer treatment with radiation or drugs

• Tell your doctor if your baby has ever had intussusception, a type of bowel blockage that is treated in a hospital.

5 What are the risks from rotavirus vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of any vaccine causing serious harm, or death, is extremely small.

A virus (or parts of a virus) called porcine circovirus is present in both rotavirus vaccines. There is no evidence that this virus is a safety risk or causes illness in humans. For more information, visit http://www.cdc.gov/vaccines/vpd-vac/rotavirus.

Most babies who get rotavirus vaccine do not have any problems with it.

Mild problems

Babies might become irritable, or to have mild, temporary diarrhea or vomiting after getting a dose of rotavirus vaccine.

Serious problems

Some studies have shown a small increase in cases of intussusception within a week after the first dose of rotavirus vaccine. Intussusception is a type of bowel blockage that is treated in a hospital. In some cases surgery might be required. The estimated risk is 1 intussusception case per 100,000 infants.

6 What if there is a moderate or severe reaction?

What should I look for?

During the first week after the first dose of vaccine, look for episodes of **stomach pain** with severe **crying** (which may be brief), several episodes of **vomiting**, or **blood in the stool**. Your baby could act **weak** or be very **irritable**.

Look for any unusual condition, such as a severe allergic reaction or a high fever. If a severe allergic reaction occurred, it would be within a few minutes to an hour after the vaccination. Signs of a serious allergic reaction can include **difficulty breathing**, **weakness**, **hoarseness** or **wheezing**, a **fast heart beat**, **hives**, **dizziness, paleness**, or **swelling of the throat**.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine may file a claim with VICP by calling **1-800-338-2382** or by visiting their website at **www.hrsa.gov/vaccinecompensation**.

8 How can I learn more?

- Ask your health care provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (1-800-CDC-INFO)
  - Visit CDC's National Immunization Program website at: **www.cdc.gov/vaccines**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

Vaccine Information Statement (Interim)
Rotavirus 42 U.S.C. §300aa-26 12/6/2010

VACUNA CONTRA EL ROTAVIRUS

LO QUE USTED DEBE SABER

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.
Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite http://www.immunize.org/vis

1 ¿Qué es el rotavirus?

El rotavirus es un virus que causa diarrea (a veces severa) mayormente en bebés y niños pequeños. Suele estar acompañada de vómitos y fiebre y puede traducirse en deshidratación.

El rotavirus no es la única causa de diarrea severa, pero es una de las más graves. Antes de aplicarse la vacuna contra el rotavirus, el rotavirus era responsable de:

- más de 400,000 visitas al médico,
- más de 200,000 visitas a la sala de emergencias,
- entre 55,000 y 70,000 hospitalizaciones y
- entre 20 y 60 muertes

anualmente en los Estados Unidos. Casi todos los niños en los EE.UU. se infectan con el virus del rotavirus antes de cumplir los 5 años de edad.

2 La vacuna contra el rotavirus

Las mejoras en la higiene y en las medidas sanitarias no han reducido los casos de diarrea por rotavirus en gran medida en los Estados Unidos. **La mejor manera de proteger a los bebés es vacunándolos contra el rotavirus.**

La vacuna contra el rotavirus es una vacuna oral (se traga); no se inyecta.

La vacuna contra el rotavirus no prevendrá la diarrea o los vómitos provocados por otros gérmenes, pero es muy eficaz en la prevención de la diarrea y los vómitos que provoca el rotavirus. La mayoría de los bebés que reciben la vacuna no presentan diarrea por rotavirus y, casi todos ellos, quedan protegidos de las diarreas por rotavirus **severas**.

La vacuna contra el rotavirus se viene utilizando en los Estados Unidos desde 2006. Para 2010, disminuyó en un 85% el número de bebés y niños pequeños que requirieron atención de emergencia u hospitalización debido a la enfermedad por rotavirus.

3 ¿Quién debería recibir la vacuna contra el rotavirus y cuándo?

Hay dos marcas de vacunas contra el rotavirus. Ambas vacunas son eficaces.

Su bebé podría recibir 2 ó 3 dosis, dependiendo de la marca que se utilice. Su proveedor puede informarle la marca que recibirá el bebé.

Las dosis se recomiendan a las edades siguientes:

Primera dosis: 2 meses

Segunda dosis: 4 meses

Tercera dosis: 6 meses (de ser necesaria)

La primera dosis puede dársele incluso a las 6 semanas de haber nacido, y deberá dársele antes de que llegue a las 14 semanas y 6 días de vida. La última dosis debe darse antes de cumplir los 8 meses.

La vacuna contra el rotavirus puede darse junto con otras vacunas infantiles.

4 Algunas personas no deben recibir la vacuna contra el rotavirus o deben esperar para recibirla.

- Los niños que hayan tenido una reacción alérgica severa (que haya puesto su vida en peligro) a una dosis de la vacuna contra el rotavirus no deben recibir otra dosis. Los bebés que hayan tenido una reacción alérgica severa (que haya puesto su vida en peligro) a cualquiera de los componentes de la vacuna contra el rotavirus no debe recibir la vacuna. Informe al médico si su bebé tiene alguna alergia severa de la que usted sepa, incluida la alergia al látex.
- Los bebés que presentan "inmunodeficiencia combinada grave" (SCID por sus siglas en inglés) no deben recibir la vacuna contra el rotavirus.
- Por lo general, los bebés que están ligeramente enfermos pueden ser vacunados. Los bebés severa o moderadamente enfermos deberían esperar a mejorarse para ser vacunados. Esto incluye a los bebés que presentan diarrea o vómitos moderados o severos. Hable con el médico o la enfermera.
- Consulte al médico si el sistema inmunológico del bebé está debilitado debido a:
  - infección de VIH o SIDA, o cualquier otra enfermedad que afecte el sistema inmunológico
  - tratamientos con fármacos como los esteroides de uso prolongado

– cáncer o tratamientos para el cáncer por medio de radiación o fármacos
- Informe a su médico si el bebé ha padecido alguna vez intususcepción, un tipo de obstrucción intestinal que debe tratarse en el hospital.

5 ¿Cuáles son los riesgos relacionados con la vacuna contra el rotavirus?

Las vacunas, al igual que cualquier medicamento, podrían causar problemas graves tal como reacciones alérgicas severas. El riesgo de que cualquier vacuna provoque daños graves o la muerte es mínimo. Un virus (o parte de un virus) llamado circovirus porcino se encuentra presente en ambas vacunas contra el rotavirus. No hay prueba alguna de que el virus atente contra la seguridad ni de que cause enfermedad en los ser es humanos. Para obtener más información, visite http://www.cdc.gov/vaccines/vpd-vac/rotavirus. La mayoría de los bebés que reciben la vacuna contra el rotavirus no presentan problemas.

Problemas leves

Los bebés podrían tornarse más irritables o presentar diarrea o vómitos leves y temporales después de haber recibido una dosis de la vacuna contra el rotavirus.

Problemas graves

Algunos estudios han demostrado un aumento menor en los casos de intususcepción en la semana de haberse recibido la primera dosis de la vacuna contra el rotavirus. La intususcepción es un tipo de obstrucción intestinal que debe tratarse en el hospital. En ciertos casos podría requerirse cirugía. El riesgo que se calcula es de 1 (un) caso de intususcepción en cada 100,000 lactantes.

6 ¿Qué sucede si se produce una reacción moderada o severa?

¿De qué debo estar pendiente?

Durante la primera semana tras haber recibido la primera dosis de la vacuna, fíjese si el bebé presenta episodios de **dolor de estómago** con **llanto** marcado (el cual podría ser breve), varios episodios de **vómitos** o de **sangre en las heces.** El bebé podría mostrarse **débil** o muy **irritable.**

Fíjese si hay algún padecimiento inusual, tal como una reacción alérgica severa o fiebre alta. Si se produce una reacción alérgica severa, sería a los pocos minutos (una hora como máximo) de haber recibido la vacuna. Entre las señales de una reacción alérgica severa se hallan: **dificultad para respirar**, **debilidad**, **ronquera** o **sibilancia** (silbido en el pecho), **ritmo cardiaco acelerado**, **urticaria**, **mareos**, **palidez** o **inflamación de la garganta**.

¿Qué debo hacer?

- Llame al médico o lleve a la persona a ver al médico de inmediato.
- Informe al médico de lo sucedido, la fecha y la hora en que ocurrió, y cuándo se le aplicó la vacuna.
- Pida al médico, a la enfermera o al departamento de Salud que reporte la reacción enviando un informe al Sistema para Reportar Reacciones Adversas a las Vacunas (*Vaccine Adverse Event Reporting System* o VAERS). O bien, usted mismo puede presentar el reporte a través del sitio Web de VAERS ubicado en **www.vaers.hhs.gov**, o por teléfono a **1-800-822-7967**.

VAERS no ofrece consejos médicos.

7 El Programa Nacional de Compensación por Daños Derivados de Vacunas (*National Vaccine Injury Compensation Program*)

Se ha creado un programa federal para ayudar a las personas que puedan haber sufridos daños relacionados con vacunas.

Para obtener los detalles sobre el Programa de Nacional por Daños de Vacunas, llame al **1-800-338-2382** o visite su sitio Web ubicado en **www.hrsa.gov/vaccinecompensation**.

8 ¿Cómo puedo informarme más?

- Hable con el médico o la enfermera. Ellos podrán darle la información que se adjunta a la vacuna o sugerirle otras fuentes de información.
- Llame al departamento de salud local o estatal.
- Comuníquese con los Centros para el Control y la Prevención de Enfermedades (*Centers for Disease Control and Prevention* o CDC):
  - Llame al **1-800-232-4636 (1-800-CDC-INFO)**
  - Visite el sitio Web del Programa Nacional de Inmunización de CDC ubicado en: **www.cdc.gov/vaccines**

DEPARTAMENTO DE SALUD Y SERVICIOS HUMANOS
CENTROS PARA EL CONTROL Y LA PREVENCIÓN DE ENFERMEDADES

Vaccine Information Statement (Interim)
Rotavirus 42 U.S.C. §300aa-26 (12/6/10) Spanish
Form # DSP 8027
Translation Provided by
The State of Oregon Immunization Program

Vaccine Safety: The Facts

Why vaccinate? Vaccines save lives and protect against the spread of disease. If you decide not to immunize your child, you put your child at risk. Your child could catch a disease that is dangerous or deadly. Getting vaccinated is much better than getting the disease.

Your pediatrician knows that you care about your child's health and safety. That's why you need to get all the scientific facts from a medical professional you can trust before making any decisions based on stories you may have seen or heard on TV, the Internet, or from other parents. Your pediatrician cares about your child too and wants you to know that…

- **Vaccines work.** They have kept children healthy and have saved millions of lives for more than 50 years. Most childhood vaccines are 90% to 99% effective in preventing disease. And if a vaccinated child does get the disease, the symptoms are usually less serious than in a child who hasn't been vaccinated. There may be mild side effects, like swelling where the shot was given, but they do not last long. And it is rare for side effects to be serious.
- **Vaccines are safe.** All vaccines must be tested by the Food and Drug Administration (FDA). The FDA will not let a vaccine be given unless it has been proven to be safe and to work well in children. The data get reviewed again by the Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics, and the American Academy of Family Physicians before a vaccine is officially recommended to be given to children. Also, the FDA monitors where and how vaccines are made. The places where vaccines are made must be licensed. They are regularly inspected and each vaccine lot is safety-tested.
- **Vaccines are necessary.** Your pediatrician believes that your children should receive all recommended childhood vaccines. In the United States vaccines have protected children and continue to protect children from many diseases. However, in many parts of the world many vaccine-preventable diseases are still common. Since diseases may be brought into the United States by Americans who travel abroad or from people visiting areas with current disease outbreaks it's important that your children are vaccinated.

Also, children with certain health problems may not be able to get some vaccines or may need to get them later. Since each child is different, your child's doctor will know what is best for your child. You should get information about each vaccine at the doctor's office. Ask your child's doctor if you don't understand what you've read.

Vaccine Safety: The Facts

- **Vaccines are studied.** To make sure the vaccine continues to be safe, the FDA and the CDC created the Vaccine Adverse Event Reporting System (VAERS). All doctors must report serious side effects of vaccines to VAERS so they can be studied. Parents can also file reports with VAERS. For more information about VAERS, visit www.vaers.hhs.gov or call the toll-free VAERS information line at 800/822-7967.

  Based on VAERS reports, vaccine safety professionals continuously look for any problem with a vaccine, study the problem, and decide what to do. And if there is a problem, changes are made as soon as possible. For example,

  - If a vaccine is no longer safe, it is no longer given.
  - If there are new side effects, safety alerts are sent out to your health care providers.

  Another way the CDC checks vaccine safety is by studying information about side effects collected from 8 large insurance companies. The Vaccine Safety Datalink (VSD) helps identify if there are any serious problems or safety issues from the records of thousands of children.

  In the rare case that a child has serious side effects to a vaccine, parents can contact the National Vaccine Injury Compensation Program (VICP) at 800/338-2382 or www.hrsa.gov/vaccinecompensation. This federal program was created to help pay for the care of people who have been harmed.

Resources

American Academy of Pediatrics
www.aap.org
www.cispimmunize.org

Food and Drug Administration
www.fda.gov

Centers for Disease Control and Prevention
www.cdc.gov/vaccines

National Network for Immunization Information
www.immunizationinfo.org

From your doctor	
If you have any questions or concerns, feel free to ask your pediatrician.	Please note: Listing of resources does not imply an endorsement by the American Academy of Pediatrics (AAP). The AAP is not responsible for the content of the resources mentioned in this publication. Phone numbers and Web site addresses are as current as possible, but may change at any time. The information contained in this publication should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.

Unprotected People: #104 Rotavirus

Two Children Hospitalized with Rotavirus

The Immunization Action Coalition (IAC) publishes Unprotected People Reports about people who have suffered or died from vaccine-preventable diseases.

Rotavirus is a virus that causes severe diarrhea, mostly in babies and young children. In developing countries, rotavirus infection is a major cause of childhood death and is responsible for approximately a half million deaths annually among children younger than 5 years. There are vaccines to prevent rotavirus. Be sure to protect your child from serious illness caused by rotavirus by getting him or her vaccinated.

Originally published by the Vaccine Education Center at the Children's Hospital of Philadelphia (CHOP), the following report is reprinted with permission of the author Brooke Matthys and CHOP.

It was late in the evening when I realized that my 2-year-old daughter was very sick. She lay on the couch not moving, just staring off into the distance. We rushed to the urgent care clinic where she received IV fluids that seemed to perk her up. Filled with relief we went home. The next day however, our beautiful daughter was once again on the couch unable and unwilling to move. She had been vomiting and suffering from diarrhea for three days. This time we went straight to the emergency room. She was dehydrated and would once again need IV fluids. They attempted to start an IV line in her left arm, but ended up blowing all three viable veins. They then tried her right arm, her hands, her feet and even her forehead, but all 12 attempts failed. She was so dehydrated that starting an IV was next to impossible.

I can't tell you the pain I felt in my heart as I watched my daughter suffer. Weak and scared, all she could do was cover her head with her "blankie" as they stuck her again and again. She was so dehydrated her little eyes couldn't even produce tears as she cried. There was talk of calling in the NICU team to make an attempt to find a vein, then talk of calling in the vascular team and even talk of hydrating her by drilling directly into her bone marrow. My heart broke as I watched helplessly.

Diagnosis and prevention

What was causing all of this? Why was my child so sick? It wasn't until the next day, after we had been transferred to a children's hospital and the vascular team had established an IV, that we found out rotavirus was the cause. According to the Centers for Disease Control and Prevention, rotavirus is the most common cause of wintertime diarrhea and vomiting. It is characterized by a low-grade fever followed by three to eight days of vomiting and diarrhea, sometimes accompanied by abdominal pain. It is a highly contagious virus that is usually transferred by fecal-oral contact and can live for days on hard surfaces. Rotavirus is a preventable disease. There are currently two different vaccines on the U.S. market, both of which have proven to be safe and effective. This immunization was of course one of those my daughter was supposed to have gotten at the Platte County Health Department [Missouri].

I couldn't believe it. My older children had suffered from rotavirus, but they had never been this ill. It was at this moment that I had a flash back. I was sitting in my doctor's office rolling my eyes at the thought of taking my children to the Platte County Health Department for yet more vaccines. My child was paying a high price for my foolish decision, and unfortunately, she wouldn't be the only one.

Just a few short hours after I had returned to the hospital and heard the diagnosis, our friend, who was home babysitting our other three children, called to say that my 8-month-old son was not doing well. Instinctively, I knew that he too was suffering from rotavirus as I had been splitting my time between home and the hospital. When she called to say he had gotten worse, I met her at the urgent care clinic. That night I took my second ambulance ride in two days. Like his sister, my son was severely dehydrated and needed IV fluids and close monitoring. I now had two children suffering because of me.

My husband and I spent four sleepless days and nights in the hospital with our two young children, just five rooms apart. We would meet occasionally in the hallway to trade rooms and get updates. It was a long and stressful ordeal that I would not wish on any child or parent. The worst part was that it was totally preventable. If I had taken the time to have my children immunized against rotavirus, this could have all been avoided. Watching your children suffer is awful, but knowing that you could have prevented it, is much worse.

Unprotected People #92 Rotavirus

Holly's Experience with Rotavirus

In August 2006, the federal Advisory Committee on Immunization Practices recommended routine vaccination of infants with 3 doses of rotavirus vaccine (RotaTeq) administered orally at ages 2, 4, and 6 months.

Rotavirus is the most common cause of severe diarrhea among children, resulting in the hospitalization of approximately 55,000 children each year in the United States. In developing countries, rotavirus infection is a major cause of childhood death and is responsible for approximately half a million deaths annually among children younger than 5 years.

In the following article, actress Holly Robinson Peete describes her experience as the mother of a toddler with rotavirus infection. It is reprinted courtesy of the National Foundation for Infectious Diseases.

A few years ago, while on a family vacation, Holly's son, then two years old, became very ill. He started vomiting profusely and had trouble keeping down any liquids. Extremely concerned, Holly and her husband took him to the nearest emergency room where he was diagnosed with rotavirus diarrhea and received intravenous fluids to treat his dehydration.

"As the wife of a football player and mother of three boys, I always thought I would have to take one of my sons to the emergency room for a broken arm or cut, but not for something like diarrhea," said Holly. "It was heart-wrenching to see my son so sick and even scarier, I had never heard of rotavirus before the doctor talked about it. Now it's my turn to get the word out, so others can be aware of rotavirus and the potential effect it can have on a family."

Holly's son has recovered from his experience with rotavirus, but there are too many stories like Holly's every year in the United States.

"My story shows that this can happen to any young child, at any time," adds Holly. "It happened to my child, it can happen to yours."

Holly Robinson Peete
Mom, Film and Television Actor