YOUR BABY’S FIRST VACCINES
WHAT YOU NEED TO KNOW

Babies get six vaccines between birth and 6 months of age.

These vaccines protect your baby from 8 serious diseases (see the next page).

Your baby will get vaccines today that prevent these diseases:

☐ Hepatitis B ☐ Polio ☐ Pneumococcal Disease
☐ Diphtheria, Tetanus & Pertussis ☐ Rotavirus ☐ Hib

(Provider: Check appropriate boxes)

These vaccines may be given separately, or some might be given together in the same shot (for example, Hepatitis B and Hib can be given together, and so can DTaP, Polio and Hepatitis B). These “combination vaccines” are as safe and effective as the individual vaccines, and mean fewer shots for your baby.

These vaccines may all be given at the same visit. Getting several vaccines at the same time will not harm your baby.

This Vaccine Information Statement (VIS) tells you about the benefits and risks of these vaccines. It also contains information about reporting an adverse reaction, the National Vaccine Injury Compensation Program, and how to get more information about childhood diseases and vaccines.

Please read this VIS before your child gets his or her immunizations, and take it home with you afterward. Ask your doctor, nurse, or other healthcare provider if you have questions.

Individual Vaccine Information Statements are also available for these vaccines. Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Vaccine Information Statement (Interim)
42 U.S.C. § 300aa-26
9/18/2008
Vaccine Benefits: Why get vaccinated?
Your children’s first vaccines protect them from 8 serious diseases, caused by viruses and bacteria. These diseases have injured and killed many children (and adults) over the years. Polio paralyzed about 37,000 people and killed about 1,700 each year in the 1950s before there was a vaccine. In the 1980s, Hib disease was the leading cause of bacterial meningitis in children under 5 years of age. About 15,000 people a year died from diphtheria before there was a vaccine. Most children have had at least one rotavirus infection by their 5th birthday.

None of these diseases has completely disappeared. Without vaccination, they will come back. This has happened in other parts of the world.

### How Vaccines Work

**Immunity from Disease:** When a child gets sick with one of these diseases, her immune system produces immunity, which keeps her from getting the same disease again. But getting sick is unpleasant, and can be dangerous.

**Immunity from Vaccines:** Vaccines are made with the same bacteria or viruses that cause a disease, but they have been weakened or killed to make them safe. A child’s immune system responds to a vaccine the same way it would if the child had the disease. This means he will develop immunity without having to get sick first.
Vaccines can cause side effects, like any other medicine. Mostly these are mild “local” reactions such as tenderness, redness or swelling where the shot is given, or a mild fever. They happen in up to 1 child out of 4 with most childhood vaccines. They appear soon after the shot is given and go away within a day or two.

More severe reactions can also occur, but this happens much less often. Some of these reactions are so uncommon that experts can't tell whether they are caused by vaccines or not.

Among the most serious reactions to vaccines are severe allergic reactions to a substance in a vaccine. These reactions happen very rarely – less than once in a million shots. They usually happen very soon after the shot is given. Doctor’s office or clinic staff are trained to deal with them.

The risk of any vaccine causing serious harm, or death, is extremely small. Getting a disease is much more likely to harm a child than getting a vaccine.

**Other Reactions**

The following conditions have been associated with routine childhood vaccines. By “associated” we mean that they appear more often in children who have been recently vaccinated than in those who have not. An association doesn't prove that a vaccine caused a reaction, but does mean it is probable.

**DTaP Vaccine**

**Mild Problems**: Fussiness (up to 1 child in 3); tiredness or poor appetite (up to 1 child in 10); vomiting (up to 1 child in 50); swelling of the entire arm or leg for 1-7 days (up to 1 child in 30) – usually after the 4th or 5th dose.

**Moderate Problems**: Seizure (jerking or staring)(1 child in 14,000); non-stop crying for 3 hours or more (up to 1 child in 1,000); fever over 105°F (1 child in 16,000).

**Serious Problems**: Long-term seizures, coma, lowered consciousness, and permanent brain damage have been reported very rarely after DTaP vaccine. They are so rare we can't be sure they are caused by the vaccine.

**Polio Vaccine / Hepatitis B Vaccine / Hib Vaccine**

These vaccines have not been associated with mild problems other than local reactions, or with moderate or serious problems.

**Pneumococcal Vaccine**

**Mild Problems**: During studies of the vaccine, some children became fussy or drowsy or lost their appetite.

**Rotavirus Vaccine**

**Mild Problems**: Children who get rotavirus vaccine are slightly more likely than other children to be irritable or to have mild, temporary diarrhea or vomiting. This happens within the first week after getting a dose of vaccine. Rotavirus vaccine does not appear to cause any serious side effects.
Precautions

If your child is sick on the date vaccinations are scheduled, your provider may want to put them off until she recovers. A child with a mild cold or a low fever can usually be vaccinated that day. But for a more serious illness, it may be better to wait.

Some children should not get certain vaccines. Talk with your provider if your child had a serious reaction after a previous dose of a vaccine, or has any life-threatening allergies. (These reactions and allergies are rare.)

- If your child had any of these reactions to a previous dose of DTaP:
  - A brain or nervous system disease within 7 days
  - Non-stop crying for 3 or more hours
  - A seizure or collapse
  - A fever over 105°F
  Talk to your provider before getting DTaP Vaccine.

- If your child has:
  - A life-threatening allergy to the antibiotics neomycin, streptomycin, or polymyxin B
  Talk to your provider before getting Polio Vaccine.

- If your child has:
  - A life-threatening allergy to yeast
  Talk to your provider before getting Hepatitis B Vaccine.

- If your child has:
  - A weakened immune system
  - Ongoing digestive problems
  - Recently gotten a blood transfusion or other blood product
  - Ever had intussusception (an uncommon type of intestinal obstruction)
  Talk to your provider before getting Rotavirus Vaccine.

What if my child has a moderate or severe reaction?

What should I look for?

Look for any unusual condition, such as a serious allergic reaction, high fever, weakness, or unusual behavior.

Serious allergic reactions are extremely rare with any vaccine. If one were to happen, it would most likely come within a few minutes to a few hours after the shot.

Signs of a serious allergic reaction can include:

- difficulty breathing  - weakness  - hives
- hoarseness or wheezing  - dizziness  - paleness
- swelling of the throat  - fast heart beat

What should I do?

Call a doctor, or get the child to a doctor right away.

Tell your doctor what happened, the date and time it happened, and when the shot was given.

Ask your healthcare provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report yourself through the VAERS website at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

The National Vaccine Injury Compensation Program

A federal program exists to help pay for the care of anyone who has a serious reaction to a vaccine.

For information about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at www.hrsa.gov/vaccinecompensation.

For More Information

Ask your healthcare provider. They can show 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) at 1-800-232-4636 (1-800-CDC-INFO).