Infant Sleep Positioning and SIDS

Parents and caregivers should place healthy infants on their backs when putting them down to sleep. This is because recent studies have shown an increase in Sudden Infant Death Syndrome (SIDS) in infants who sleep on their stomachs. There is no evidence that sleeping on the back is harmful to healthy infants.

Keep the following points in mind:

- Placing a child to sleep on the back has the lowest risk and is preferred. Sleeping on the side, however, is a reasonable alternative and is safer than sleeping on the stomach.
- Do not place your infant to sleep on waterbeds, sofas, soft mattresses, or other soft surfaces. Pillows, quilts, comforters, or sheepskins should not be placed under your infant.
- Soft materials such as pillows, quilts, comforters, sheepskins, or stuffed toys should be kept out of an infant's bed. These items can cover your child's airway - even if he is lying on his back.
- Devices designed to maintain sleep position or to reduce the risk of rebreathing are not recommended since many have not been tested sufficiently for safety. None have been shown to reduce the risk of SIDS.
- This recommendation is for healthy infants. Some infants with certain medical conditions or malformations may need to be placed on their stomachs to sleep. For these children, talk to your pediatrician about which sleep position is best.
- This recommendation is for sleeping infants. A certain amount of "tummy time." while the baby is awake and observed, is recommended for developmental reasons and to avoid flat spots on the head.

Additional tips to reduce the risk of SIDS

- Do not smoke during pregnancy; continue to provide a smoke-free environment for your baby.
- Make sure your baby does not become overheated. Keep the temperature in the baby's room so it feels comfortable for an adult, and dress your baby in as much or little clothing as you would wear.
- Share all of these important tips for preventing SIDS with baby-sitters. grandparents, and other caregivers.

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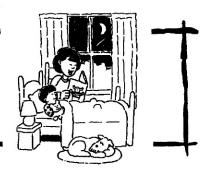


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Sleep Problems in Children Part I Infants, Toddlers, and Preschoolers



Sleep problems are very common among children during the first few years of life. Problems may include a reluctance to go to sleep, waking up in the middle of the night, nightmares, and sleepwalking. In older children, bed-wetting can also become a challenge.

Children vary in the amount of sleep they need and the amount of time it takes to fall asleep. How easily they wake up and how quickly they can resettle are also different for each child. It is important, however, that as a parent you help your child develop good sleep habits at an early age. The good news is that most sleep problems can be solved and your pediatrician can help.

Infants

Newborn infants have irregular sleep cycles, which take about 6 months to mature. While newborns sleep an average of 16 to 17 hours per day, they may only sleep 1 or 2 hours at a time. As children get older, the total number of hours they need for sleep decreases. However, different children have different needs. It is normal even for a 6 month old to wake up briefly during the night, but these awakenings should only last a few minutes and children should be able to go back to sleep on their own. Here are some suggestions that may help your baby (and you) sleep better at night:

- 1. Try to keep her as calm and quiet as possible. When feeding or changing your baby during the night, avoid stimulating her or waking her up too much so she can easily fall back to sleep.
- 2. Don't let your infant sleep as long during the day. If she sleeps for large blocks of time during the day, she will be more likely to be awake during the night.
- 3. Put your baby into the crib at the first signs of drowsiness. Ideally it is best to let the baby learn to relax and settle herself to sleep. If you make a habit of holding or rocking her until she falls asleep, she may learn to need you to get back to sleep when she wakes up in the middle of the night. This may interfere with her learning to settle herself and fall asleep alone.
- 4. Try to avoid putting your baby to bed with a pacifier. Your baby may get used to falling asleep with it and have trouble learning to settle herself without it. Pacifiers should be used to satisfy the baby's need to suck, not to help a baby sleep. If your baby falls asleep with a pacifier, gently remove it before putting her in bed.

- 5. Begin to delay your reaction to infant fussing at 4 to 6 months of age. Wait a few minutes before you go in to check her, because she will probably settle herself and fall back to sleep in a few minutes anyway. If she continues to cry, check on her, but avoid turning on the light, playing, picking up, or rocking her. If crying continues or begins to sound frantic, wait a few more minutes and then recheck the baby. If she is unable to settle herself, consider what else might be bothering her. She may be hungry, wet or soiled, feverish, or otherwise not feeling well.
- 6. Ideally, by a few weeks of age a baby should sleep in a separate room from his parents.

If your baby is ill, these suggestions should be relaxed. After she feels better, begin to reestablish sleep patterns.

Infant sleep positioning and SIDS

The American Academy of Pediatrics recommends that parents and caregivers place healthy infants on their backs when putting them down to sleep. This is because recent studies have shown an increased incidence of Sudden Infant Death Syndrome (SIDS) in infants who sleep on their stomachs. There is no evidence that sleeping on the back is harmful to healthy infants.

Common Illnesses and Conditions

Toddlers and preschoolers

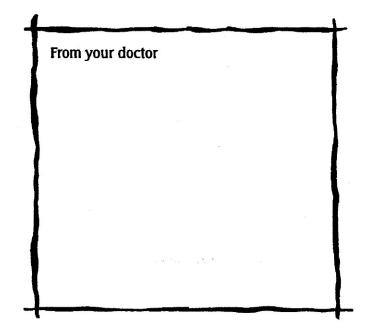
Many parents find their toddler's bedtime one of the hardest parts of the day. It is common for children this age to resist going to sleep, especially if there are older siblings who are still awake. However, remember toddlers and preschoolers usually need 10 to 12 hours of sleep each night. If your child's sleeping time does not approach this level, talk to your pediatrician.

Following are some tips to help your toddler develop good sleep habits:

- 1. Make sure there is a quiet period before your child goes to bed. Establish a pleasant routine that may include reading, singing, or a warm bath. A regular routine will help your child understand that it will soon be time to go to sleep. If parents work late hours, it may be tempting to play with their child before bedtime. However, active play just before bedtime may leave the child excited and unable to sleep. Limit television viewing and video game play before bed.
- 2. Try to set a consistent schedule for your child and make bedtime the same time every night. His sleep patterns will adjust accordingly.
- 3. Allow your child to take a favorite teddy bear, toy, or special blanket to bed each night. Such comforting objects often help children fall asleep-especially if they awaken during the middle of the night. Make sure the object is safe. A teddy bear may have a ribbon, button, or other part that may pose a choking hazard for your child. Look for sturdy construction at the seams. Stuffing or pellets inside the stuffed animal may also pose a danger of choking.
- 4. Make sure your child is comfortable. Check the temperature in your child's room. Clothes should not restrict movement. He may like to have a drink of water before bed, have a night-light left on, or the door left slightly open. Try to handle your child's needs before bedtime, so that he doesn't use them to avoid going to bed.

- 5. Try to avoid letting your child sleep with you. This will only make it harder for him to learn to settle himself and fall asleep when he is alone.
- 6. Try not to return to your child's room every time he complains or calls out. A child will quickly learn if you always give in to his requests at bedtime. When your child calls out, try the following:
 - · Wait several seconds before answering. Your response time can be longer each time to give your child the message that it is time for sleep. It also gives him the opportunity to fall asleep on his own.
 - Reassure your child that you are there. If you need to go into his room, do not stimulate the child or stay too long.
 - Move farther from your child's bed every time you go to reassure him, until you can dothis verbally without entering his room.

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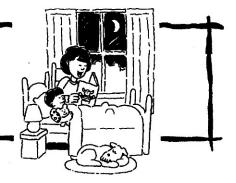


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Sleep Problems in Children Part II Common Sleep Problems



Common sleep problems

For a young child, many things can interrupt a good night's sleep. As a parent, you may be able to prevent some of them.

Nightmares

Nightmares are scary dreams that usually happen during the second half of the night, when dreaming is most intense. This may occur more than once a night. After the nightmare is over, your child may wake up and can tell you what occurred. Children may be crying or fearful after a nightmare but will be aware of your presence. They may have trouble falling back to sleep because they can remember the details of the dream.

How to handle nightmares:

- Go to the child as quickly as possible.
- · Assure her that you are there and will not let anything harm her. Allow the child to have the bedroom light on for a short period to reassure her.
- If your child is fearful, comfort and calm her.
- Keep in mind that a nightmare is real to a young child. Listen to her and encourage her to tell you what happened in the dream.
- Once the child is calm, encourage her to go back to sleep.

Night terrors

Night terrors are more severe or frightening than nightmares, but not as common. They occur most often in toddlers and preschoolers. Night terrors come out of the deepest stages of sleep, usually within an hour or so after a child falls asleep. During a night terror, children usually cannot be awakened or comforted. Night terrors may also cause the following:

- Uncontrollable crying
- · Sweating, shaking, and fast breathing
- · A terrified, confused, and glassy-eyed appearance
- · Thrashing around, screaming, kicking, or staring
- Child may not realize anyone is with him
- Child may not appear to recognize you
- Child may try to push you away, especially when you try to restrain him

Night terrors may last as long as 45 minutes, but are usually much shorter. Children seem to fall right back to sleep after a night terror, but they actually have not been awake. Like nightmares, night terrors may occur more often in times of stress or may relate to difficult feelings or fears. However, unlike a nightmare, a child will not remember a night terror.

How to handle night terrors:

- · Remain calm. Night terrors are usually more frightening for the parent than for the child.
- Do not try to wake your child.
- Make sure the child does not injure himself. If the child tries to get out of bed, gently restrain him.
- Remember, after a short time, your child will probably relax and sleep quietly again.
- If your child has night terrors, be sure to explain to your baby-sitters what they are and what to do.

Keep in mind that night terrors do not always indicate serious problems. Your child will be more likely to have night terrors when he is overly tired and during periods of stress. Your child can become overly tired when he gives up a daytime nap, wakes up too early, or his nighttime sleep is interrupted. Try to keep your child on a regular sleep schedule or increase the amount of sleep he gets to prevent night terrors. Night terrors usually disappear by the time a child reaches grade school. If they do persist, talk to your pediatrician.

Sleepwalking and sleep talking

Like night terrors, sleepwalking and sleep talking happen when a child is in a deep sleep. While sleepwalking, your child may have a blank, staring face. She may not respond to others and be very difficult to awaken. When your child does wake up, she will probably not remember the episode. Sleepwalking children will often return to bed by themselves and will not even remember that they have gotten out of bed. Sleepwalking can be common, and tends to run in families. It can even occur several times in one night among older children and teenagers. If you have concerns or the condition persists, talk to your child's pediatrician.

How to handle sleepwalking and sleep talking:

- Make sure your child doesn't hurt herself while sleepwalking. Clear the bedroom area of potential hazards that your child could trip over or fall on.
- Lock outside doors so your child cannot leave the house.
- Block stairways so your child cannot go up or down.
- There is no need to try to wake your child when she is sleepwalking or sleep talking. Gently lead her back to bed and she will probably settle down on her own.

Sleepwalking and sleep talking are more likely to occur when your child is overly tired or under stress. Keeping your child's sleep schedule regular may help prevent sleepwalking and sleep talking.

Common Illnesses and Conditions

Bed-wetting (also called enuresis)

Nighttime bed-wedding is normal and very common among preschoolers. It affects about 40% of 3 year olds and may run in families. The most common reasons your child may wet the bed include the following:

- A bladder that has not yet developed enough to hold urine for a full night.
- Your child may not yet be able to recognize a full bladder and wake up to use the toilet.
- Stress. Changes in the home, such as a new baby, moving, or a divorce can lead to a sudden case of bed-wetting for a child who has been dry at night in the past.

How to handle bed-wetting:

- Do not blame or punish the child for bed-wetting.
- Have your child use the toilet and avoid drinking large amounts of fluid just before bedtime.
- Until your child can stay dry during the night, put a rubber or plastic cover over the mattress to protect against wetness and odors. Keep the bedding
- If your child is old enough, involve him in handling the problem. Encourage him to help change the wet sheets and covers. This will help teach responsibility and avoid the embarrassment of having other family members know about the problem every time it happens. Do not, however, use this as punishment for the child.
- Talk to your pediatrician about other approaches to bed-wetting, such as rewards for younger children or alarm devices for the older child.

Most importantly, don't pressure your child. Bed-wetting is beyond a child's control and he may only become sad or frustrated if he cannot stop. Set a "no-teasing" rule in the family. Make sure your child understands that bedwetting is not his fault and it will get better in time.

Teeth grinding

It is also common for children to grind their teeth during the night. Though it produces an unpleasant sound, it is usually not harmful to your young child's teeth. It may be related to tension and anxiety and usually disappears in a short while. However, it may reappear with the next stressful episode.

Give it time

Handling your child's sleep problems may be a challenge and it is normal to become upset at times when a child keeps you awake at night. Try to be understanding. A negative response by a parent can sometimes make a sleep problem worse, especially if it is associated with a stressful situation like divorce, a new sibling, a tragedy in the family, problems at school, or some other recent change in your child's life.

If the problem persists, there may be a physical or emotional reason that your child cannot sleep. If you feel you need additional help, start a sleep diary and discuss the problem with your pediatrician. Keep in mind that most sleep problems are very common, and with time and your pediatrician's help, you and your child will overcome them.

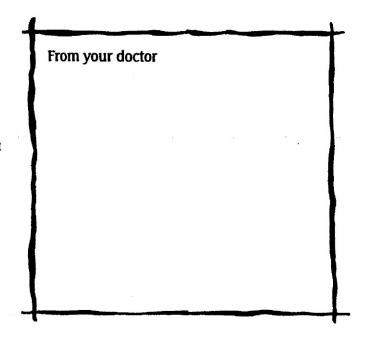
Keeping a sleep diary

It may be helpful for you in preparation for discussing a sleep problem with your pediatrician to keep a sleep diary for your child. Chart the following:

- Where your child sleeps
- · How much sleep she normally gets at night
- What time she was put to bed
- What the child needs to fall asleep (favorite toy, blanket, etc)
- The time it takes for her to fall asleep
- The time that you went to bed
- · The time awakened during the night
- · How long it took to fall back to sleep
- What you did to comfort and console the child
- The time the child woke up in the morning
- · The time and length of naps
- Any changes or stresses in the home

Keep in mind that every child is different and no two children may have the same sleep patterns or problems.

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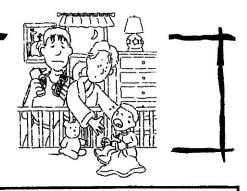
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Patient Education for Children, Teens, and Parents

Fever and Your Child



If your child has a fever, it is probably a sign that her body is fighting an infection. When your child becomes ill because of a virus or bacteria, her body may respond by increasing body temperature. It is important to remember that, except in the case of heat stroke, fever itself is not an illness—only a symptom of one. Fever itself also is not a sign that your child needs an antibiotic.

Many conditions, such as an ear infection, a common cold, the flu, a urinary tract infection, or pneumonia, may cause a child to develop a fever. In some cases, medication, injury, poison, or an extreme level of overactivity may produce a fever. An environment that is too hot may result in heat stroke, a potentially dangerous rise in body temperature. It is important to look for the cause of the fever.

Fevers are generally harmless and help your child fight infection. They can be considered a good sign that your child's immune system is working and the body is trying to rid itself of the infection.

The main purpose for treating fever is to help your child feel better. Reducing her temperature may make her more comfortable until the illness that has caused the fever has been treated or, more likely, run its course.

What is a fever?

A fever is a body temperature that is higher than normal. Your child's normal body temperature varies with his age, general health, activity level, the time of day, and how much clothing he is wearing. Everyone's temperature tends to be lower early in the morning and higher between late afternoon and early evening. Body temperature also will be slightly higher with strenuous exercise.

Most pediatricians consider any thermometer reading above **100.4°F (38°C)** a sign of a fever. This number may vary depending on the method used for taking your child's temperature. If you call your pediatrician, say which method you used.

Signs and symptoms of a fever

If your child has a fever, her heart and breathing rates naturally will speed up. You may notice that your child feels warm. She may appear flushed or perspire more than usual. Her body also will require more fluids.

Some children feel fine when they have a fever. However, most will have symptoms of the illness that is causing the fever. Your child may have an earache,

When to call your pediatrician right away

Call your pediatrician immediately if your child has a fever and

- Looks very ill, is unusually drowsy, or is very fussy
- Has been in an extremely hot place, such as an overheated car
- Has additional symptoms such as a stiff neck, severe headache, severe sore throat, severe ear pain, an unexplained rash, or repeated vomiting or diarrhea
- Has a condition that suppresses immune responses, such as sickle-cell disease or cancer, or is taking steroids
- Has had a seizure
- Is younger than 2 months of age and has a rectal temperature of 100.4°F (38°C) or higher

What if my child has a febrile seizure?

In some young children, fever can trigger seizures. These are usually harmless. However, they can be frightening. When this happens, your child may look strange for a few minutes, shake, then stiffen, twitch, and roll his eyes.

- Place him on the floor or bed, away from any hard or sharp objects.
- Turn his head to the side so that any saliva or vomit can drain from his mouth.
- · Do not put anything into his mouth.
- Call your pediatrician.

Your pediatrician should always examine your child after a febrile seizure, especially if it is his first one. It is important to look for the cause of the febrile seizure.

More information about febrile seizures is available in the AAP brochure. Febrile Seizures.

a sore throat, a rash, or a stomachache. These signs can provide important clues as to the cause of your child's fever.

Managing a mild fever

A child older than 6 months of age who has a temperature below 101°F (38.3°C) probably does not need to be treated for fever, unless the child is uncomfortable. Observe her behavior. If she is eating and sleeping well and is able to play, you may wait to see if the fever improves by itself.

in the meantime.

- Keep her room comfortably cool.
- Make sure that she is dressed in light clothing.
- Encourage her to drink fluids such as water, diluted fruit juices, or a commercially prepared oral electrolyte solution.
- Be sure that she does not overexert herself.

Over-the-counter medications for fever

There are also medications you can give your child to reduce his temperature if he is uncomfortable. Both **acetaminophen** and **ibuprofen** are safe and effective in proper doses. Be sure to follow the correct dosage and medication schedule for your child. Remember, any medication can be dangerous if you give your child too much.

Ibuprofen should only be used for children older than 6 months of age. It should not be given to children who are vomiting constantly or are dehydrated. Do not use aspirin to treat your child's lever. Aspirin has been linked with side effects such as an upset stomach, intestinal bleeding, and, most seriously, Reye syndrome.

If your child is vomiting and unable to take medication by mouth, your pediatrician may recommend a rectal suppository for your child. Acetaminophen suppositories can be effective in reducing fever in a vomiting child.

Read the label on all medications to make sure that your child receives the right dose for his age and weight. To be safe, talk to your pediatrician before giving your child any medication to treat fever if he is younger than 2 years of age.

How to take your child's temperature

While you often can tell if your child is warmer than usual by feeling his forehead, only a thermometer can tell if he has a fever and how high the temperature is. There are several types of thermometers and methods for taking your child's temperature.

Mercury thermometers should not be used. The American Academy of Pediatrics (AAP) encourages parents to remove mercury thermometers from their homes to prevent accidental exposure to this toxin.

Rectal: If your child is younger than 3 years of age, taking his temperature with a rectal digital thermometer provides the best reading.

- Clean the end of the thermometer with rubbing alcohol or soap and water. Rinse it with cool water. Do not rinse with hot water.
- Put a small amount of lubricant, such as petroleum jelly, on the end.
- Place your child belly down across your lap or on a firm surface. Hold him by placing your palm against his lower back, just above his bottom.
- With the other hand, turn on the thermometer switch and insert the thermometer 0.5" to 1" into the anal opening. Hold the thermometer in place loosely with 2 fingers, keeping your hand cupped around your child's bottom. Do not insert the thermometer too far. Hold in place for about 1 minute, until you hear the "beep." Remove the thermometer to check the digital reading.

Oral: Once your child is 4 or 5 years of age, you may prefer taking his temperature by mouth with an oral digital thermometer.

Clean the thermometer with lukewarm soapy water or rubbing alcohol. Rinse with cool water.



- Turn on the switch and place the sensor under his tongue toward the back of his mouth. Hold in place for about 1 minute, until you hear the "beep." Check the digital reading.
- For a correct reading, wait at least 15 minutes after your child has had a hot or cold drink before putting the thermometer in his mouth.

Ear: Tympanic thermometers, which measure temperature inside the ear, are another option for older babies and children.

- Gently put the end of the thermometer in the ear canal. Press the start button. You will get a digital reading of your child's temperature within seconds.
- While it provides quick results, this thermometer needs to be placed correctly in your child's ear to be accurate. Too much earwax may cause the reading to be incorrect.

Underarm (Axillary): Although not as accurate, if your child is older than 3 months of age, you can take his underarm temperature to see if he has a fever.

- Place the sensor end of either an oral or rectal digital thermometer in your child's armpit.
- Hold his arm tightly against his chest for about 1 minute, until you hear the "beep." Check the digital reading.





Other methods for taking your child's temperature are available. They are not recommended at this time. Ask your pediatrician for advice.

Sponging

Your pediatrician may recommend that you try sponging your child with lukewarm water in cases such as the following:

- Your child's temperature is above 104°F (40°C).
- She is vomiting and unable to take medication.
- She has had a febrile seizure in the past (see "What if my child has a febrile seizure?").

Sponging may reduce your child's temperature as water evaporates from her skin. Your pediatrician can advise you on this method.

Do not use cold water to sponge your child, as this could cause shivering. That could increase her temperature. Never add alcohol to the water. Alcohol can be absorbed into the skin or inhaled, causing serious problems such as a coma.

Usually 5 to 10 minutes in the tub is enough time for a child's temperature to start dropping. If your child becomes upset during the sponging, simply let her play in the water. If she is still bothered by the bath, it is better to remove her even if she has not been in long enough to reduce her temperature. Also remove her from the bath if she continues to shiver because shivering may increase body temperature.

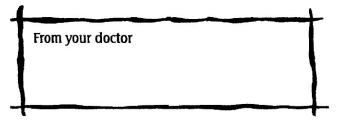
Do not try to reduce your child's temperature to normal too quickly. This could cause the temperature to rebound higher.

Be sure to call your pediatrician if your child still "acts sick" once her temperature is brought down, or if you feel that your child is very sick. Also call if the fever persists for

- More than 24 hours in a child younger than 2 years of age
- More than 3 days in a child 2 years of age or older

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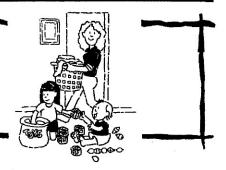


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Toy Safety

Part I Guidelines for Parents



Few things make a child happier than a new toy or game. However, what seems to be harmless fun could result in a serious injury. Due to tough government regulations and efforts by US toy makers to test products, most toys on the market today are safe. Still, thousands of children suffer toy-related injuries every year. By knowing what to look for when buying toys and practicing a few simple ideas for safe use, you can often prevent problems before they occur.

How children are injured

Although most toy-related injuries are minor cuts, scrapes, and bruises, children can sometimes be seriously injured or even killed by dangerous toys or misuse of toys. Some common causes of injury are:

- Abuse and misuse of toys. Throwing toys, jumping on them, or taking
 them apart can be dangerous. When a toy breaks, sharp or pointed edges
 may be exposed that can cause a serious injury. Something as innocent as
 a doll or teddy bear may quickly become a hazard when your child pulls off
 an eye, removes a button, or exposes a sharp edge.
- Small, loose, or broken toys and parts. A small toy or part can easily
 become lodged in a child's ear, nose, or throat. Children can be seriously
 injured or killed from inhaling, swallowing, or choking on objects such as
 marbles, small balls, toy parts, or balloons. Small toys and parts intended
 for older children are also involved in choking deaths among toddlers.
- Loose string, rope, ribbons, or cord. These items can easily become
 tangled around your child's neck and strangle her. Dangling objects such as
 crib mobiles can be deadly if your child becomes entangled in them. Loose
 or long pieces of clothing, such as hood cords, can also strangle your child
 when the cords get tangled or caught on playground equipment. Strings or
 cords tied to pacifiers have been involved in numerous strangulation
 deaths in young children as well.
- Toy guns. Eye injuries often result from toys that shoot plastic objects or other flying pieces. Arrows, darts, or pellets can also be choking hazards.
 Very loud snapping or machine-gun noises can damage hearing. "Caps" are a hazard when used indoors or closer than 12 inches from your child's ear.
- Riding Toys. Injuries are caused not only when children fall off riding toys, but also when they ride them in the street when traffic is present or into swimming pools, ponds, and lakes.
- Beach and pool toys are usually not approved flotation devices. Never leave your child unattended at any time near a pool, beach, or pond. It only takes a few moments for a child to drown, even in very shallow water.
- Electric plug-in toys. Even if the label on a toy says it is UL-approved, burns and shocks can still result from frayed cords, misuse, or prolonged use of the toy.
- Chemistry sets and hobby kits. These kits can cause fires, explosions, or poisoning. They may contain chemicals that are often poisonous if swallowed, and they can catch fire or explode, causing serious burns and eye injuries.

 Toy chests and other storage containers. Toy chests can pinch, bruise, or break tiny fingers and hands if a lid closes suddenly. Death can even occur when a heavy lid without a safety support hinge traps and strangles a small child. Your child can also suffocate if trapped inside a toy chest. Open containers without lids are safest for toy storage.

Although children may like to play by themselves, injuries often occur when there is no proper supervision. Young children are more interested in having fun than in safety. As a result, improper play could lead to a serious toy-related injury. Proper supervision and teaching safe play are very important. Always supervise your child.

A word about...toy guns

It has been shown that toy guns can cause serious or fatal injuries to children. This is especially true for pellet and BB guns. Although these are often thought of as toys, they can be high-powered, lethal devices. Parents should also be aware that studies in recent years have raised questions about the effect playing with toy firearms has on a child's developing personality. Playing with toy weapons and firearms may cause more aggressive, violent behavior in some children. Playing with toy firearms may also make it easier for a child to mistake a real firearm for a toy.

Tips for buying toys

Use the following guidelines to choose safe and appropriate toys for your child.

- Read the label before buying the toy. Warning labels provide important information about how to use a toy, what ages the toy is safe for, and whether adult supervision is recommended. Be sure to show your child how to use the toy properly.
- 2. Think LARGE when it comes to choosing toys. Make sure all toys and parts are larger than your child's mouth to prevent choking. Avoid small toys intended for older children that could fit into your child's mouth. This will decrease the risk of choking.
- 3. Avoid toys that shoot small objects into the air. They can cause serious eye injuries or choking.
- 4. Avoid toys that make loud or shrill noises to help protect your child's hearing. Ask to try the toy in the store. Check the loudness of the sound it makes. Don't buy toys that may be too loud for your child's sensitive hearing.
- 5. Look for sturdy toy construction. When buying a soft toy or stuffed animal, make sure the eyes, the nose, and any other small parts are secured tightly. Make sure it is machine washable. Check to see that seams and edges are secure. Remove loose ribbons or strings to avoid strangulation. Avoid toys containing small bean-like pellets or stuffing that can cause choking or suffocation if swallowed.

Safety and Prevention

Age recommendations

Age recommendations printed on toy packages are very important. They reflect the safety of a toy based on four categories. These include:

- · The safety aspects of the toy and any possible choking hazards
- . The physical ability of the child to play with the toy
- The ability of a child to understand how to use a toy
- · The needs and interests at various levels of a child's development

These recommendations are based on general developmental levels of each age group. However, every child is different. What is right for one child may not suit the skills and needs of another. Match the toy to your child's abilities. A toy that is too advanced or too simple for your child may be misused, which could lead to an injury.

- 6. Watch out for sharp points or edges and toys made from thin plastic or other material that may break easily. Don't buy toys with metal parts for a baby or toddler. If your older child plays with darts or arrows, make sure they have blunt tips made of soft rubber or flexible plastic. Tips should be securely fastened.
- 7. Avoid toxic items and materials that could cause poisoning. Look for paint sets, crayons, and markers that are labeled nontoxic. Small batteries are not only toxic, they also can pose a choking or swallowing hazard.
- 8. Avoid hobby kits and chemistry sets for any child younger than 12 years old. If these kits are purchased for older children (12 to 15 years of age), make sure you provide proper supervision and store them out of reach of young children.
- Electric toys should be "UL Approved" Check the label to make sure the toy is approved by the Underwriters Laboratories.
- 10. Be careful when buying crib toys. Strings or wires that hang in a crib should be kept short. They may pose a serious strangulation hazard when a child begins to crawl or stand. Remove crib gyms and mobiles as soon as your child can push up on her hands and knees.
- 11. Choose a toy chest carefully. Look for smooth, finished edges that are nontoxic. If it has a lid, make sure it is sturdy, with locking supports and safe hinges. It should stay open in any position and hinges should not pinch your child's skin. The chest should also have ventilation holes to prevent suffocation if your child becomes trapped inside. The best toy chest is a box or basket without a lid.

How to prevent toy injuries

Use the following guidelines to keep your child safe:

Supervise your child's play

Injuries can happen despite your best efforts to choose the safest toy for your child. Supervision is the best way to prevent injuries.

- Keep all toys with small parts away from your young child until she learns not to put them in her mouth, usually by about the age of 5 years.
- Do not allow your child to play with a toy that was intended for an older child. Watch older children too, as they might put things in a smaller child's mouth.

- Keep uninflated and broken balloons away from children of all ages, as
 they are a serious choking hazard. When a child tries to inflate a balloon, he
 can easily inhale it. Also, never allow a child to place an inflated balloon in
 his mouth.
- To prevent injuries, stop reckless or improper play. Make sure your child never plays with toys near stairs, traffic, or swimming pools.

Store toys properly

- Store toys on a shelf or in a toy chest. They should be out of the way and off
 the floor, to avoid being stepped on or tripped over. A toy designed for an
 older child should be stored far out of reach of a curious toddler.
- Teaching your child to pick up and put toys away will help her learn to become responsible for her belongings.
- Never store a toy in its original packaging. Staples can cause cuts and plastic wrap can lead to choking or suffocation. To avoid injuries, immediately discard toy packaging before giving a new toy to your baby or toddler.

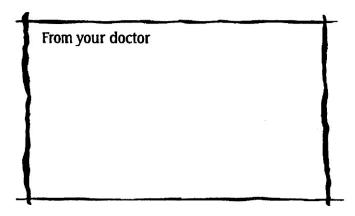
Keep toys in good condition

- Make sure you examine toys regularly. Look for damaged or broken parts
 that may pose a hazard. Look for splinters on wooden toys, loose eyes or
 small parts on dolls, rips or exposed wires in stuffed animals, or rust on
 metal toys.
- Never leave metal toys outside overnight. Rain, snow, or even dew may cause them to rust. Repair or replace any broken parts.
- · If you're ever in doubt about a toy's safety, throw it away.

Playtime should be fun...and safe

Playing with toys is an important part of your child's development and growth. Choosing toys carefully will assure that playtime is educational, fun, and, most importantly, safe. By using the guidelines listed above, you can help prevent toy-related injuries. If you're not sure about a toy's safety or proper use, call the manufacturer. Your child's pediatrician can also help you decide which toys are safe and appropriate for your infant, toddler, or young child.

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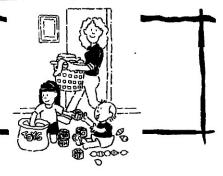
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Patient Education for Children, Teens, and Parents

Toy Safety

Part II Age-appropriate Toys and Toys to Avoid



Age-appropriate toys

The following is a list of toys that the American Academy of Pediatrics recommends for specific age groups. Use these recommendations when shopping for toys. Keep in mind, these are only guidelines. All toys can be dangerous when they are not used properly or are in poor condition. Parents should continue to watch out for mislabeled toys and always provide proper supervision for young children.

Newborn to 1-year-old baby

Choose brightly-colored, lightweight toys that appeal to your baby's sight, hearing, and touch.

- 1. Cloth, plastic, or board books with large pictures
- 2. Large blocks of wood or plastic
- 3. Pots and pans
- 4. Rattles
- 5. Soft, washable animals, dolls, or balls
- 6. Bright, movable objects that are out of baby's reach
- 7. Busy boards
- 8. Floating bath toys
- 9. Squeeze toys

1 to 2-year-old toddler

Toys for this age group should be safe and be able to withstand a toddler's curious nature.

- 1. Cloth, plastic, or board books with large pictures
- 2. Sturdy dolls
- 3. Kiddy cars
- 4. Musical tops
- 5. Nesting blocks
- Push and pull toys (remember—no long strings)
- 7. Stacking toys
- 8. Toy telephones (without cords)

2 to 5-year-old preschooler

Toys for this age group can be creative or imitate the activity of parents and older children.

- 1. Books (short stories or action stories)
- 2. Blackboard and chalk
- 3. Building blocks
- 4. Crayons, non-toxic finger paints, clay
- 5. Hammer and bench
- 6. Housekeeping toys
- 7. Outdoor toys: sandbox (with a lid), slide, swing, playhouse
- 8. Transportation toys (tricycles, cars, wagons)
- 9. Tape or record player

- Simple puzzles with large pieces
- 11. Dress-up clothes
- 12. Tea party utensils

5 to 9-year-old children

Toys for this age group should help your child develop new skills and creativity.

- 1. Blunt scissors, sewing sets
- 2. Card games
- 3. Doctor and nurse kits
- 4. Hand puppets
- 5. Balls
- 6. Bicycles with helmets
- 7. Crafts
- 8. Electric trains
- Paper dolls
- 10. Jump ropes
- 11. Roller skates with protective gear
- 12. Sports equipment
- 13. Table games

10 to 14-year-old boys and girls

Hobbies and scientific activities are ideal for this age group.

- 1. Computer games
- 2. Sewing, knitting, needlework
- Microscopes/telescopes
- 4. Table and board games
- 5. Sports equipment
- 6. Hobby collections

Safety and Prevention

Toys to avoid

Infants and toddlers should never be given toys with the following:

- · Parts that could pull off and/or fit into a child's mouth, nose, or ear
- · Exposed wires and parts that get hot
- · Lead paint
- Toxic materials
- · Breakable parts
- · Sharp points or edges
- · Glass or thin parts
- Springs, gears, or hinged parts that could pinch tiny fingers or become caught in your child's hair

To check whether a toy is unsafe or to report a toy-related injury, call the Consumer Product Safety Commission at 800/638-2772 or visit their Web site at www.cpsc.gov

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Dangers of Secondhand Smoke



Even if you don't smoke, breathing in someone else's smoke can be deadly, too. Secondhand smoke causes about 3,000 deaths from lung cancer and tens of thousands of deaths from heart disease to nonsmoking adults in the United States each year.

Millions of children are breathing in secondhand smoke in their own homes. Secondhand smoke can be especially harmful to your children's health because their lungs still are developing. If you smoke around your children or they are exposed to secondhand smoke in other places, they may be in more danger than you realize.

Read more to learn about the dangers of secondhand smoke and how to create a smoke-free environment for your children.

What is secondhand smoke?

Secondhand smoke (also known as environmental tobacco smoke) is the smoke a smoker breathes out and that comes from the tip of burning cigarettes, pipes, and cigars. It contains about 4,000 chemicals. Many of these chemicals are dangerous; more than 50 are known to cause cancer. Anytime children breathe in secondhand smoke they are exposed to these chemicals.

Smoking and your developing baby

If you smoke when you're pregnant, your baby is exposed to harmful chemicals, too. Smoking when you're pregnant may lead to many serious health problems for your baby, including

- Miscarriage
- · Premature birth (born not fully developed)
- · Lower birth weight than expected (possibly meaning a less healthy baby)
- · Sudden infant death syndrome (SIDS)
- Learning problems and attention-deficit/hyperactivity disorder (ADHD)
 The health risks go up the longer a pregnant woman smokes and the more she smokes. Quitting anytime during pregnancy helps—of course, the sooner the better. All pregnant women should stay away from secondhand smoke and ask smokers not to smoke around them.

Secondhand smoke and your children's health

Intants have a higher risk of SIDS if they are exposed to secondhand smoke. Children, especially those younger than 2 years, have a higher risk of serious health problems, or problems may become worse. Children who breathe secondhand smoke can have more

- Ear infections
- · Upper respiratory infections
- Respiratory problems such as bronchitis and pneumonia
- · Tooth decay

Children of smokers cough and wheeze more and have a harder time getting over colds. Secondhand smoke can cause other symptoms including stuffy nose, headache, sore throat, eye irritation, and hoarseness.

Children with asthma are especially sensitive to secondhand smoke. It may cause more asthma attacks and the attacks may be more severe, requiring trips to the hospital.

Long-term effects of secondhand smoke

Children who grow up with parents who smoke are themselves more likely to smoke. Children and teens who smoke are affected by the same health problems that affect adults. Secondhand smoke may cause problems for children later in life including

- · Lung cancer
- Heart disease
- Cataracts (an eye disease)

Secondhand smoke is everywhere

Children can be exposed to secondhand smoke in many places. Even if there are no smokers in your home, your children can still be exposed to secondhand smoke. Places include

- In a car or on a bus
- At child care or school
- At a babysitter's house
- At a friend's or relative's house
- In a restaurant
- At the mall
- At sporting events or concerts

Creating a smoke-free environment

The following tips may help keep your children from being exposed to secondhand smoke:

- Set the example. If you smoke, quit today! If your children see you smoking, they may want to try it, and they may grow up smoking as well. If there are cigarettes at home, children are more likely to experiment with smoking—the first step in developing the habit.
- Make your home and car smoke-free. Until you can quit, don't smoke around your children or in your home and car.
- Remove your children from places where there are smokers. Sit
 in nonsmoking sections in public places. Eat at smoke-free restaurants.
- Ask people not to smoke in your home. Don't put out any ashtrays.
 Remember, air flows throughout a house, so smoking in even one room allows smoke to go everywhere.
- Ask people not to smoke in your car. Opening windows isn't enough to clear the air.
- Choose a babysitter who doesn't smoke. If your babysitter does smoke, ask her not to smoke when she's caring for your children. Consider changing babysitters to find a smoke-free environment for your children.

Safety and Prevention

Encourage smoke-free child care and schools. Help your children's child care or school, including outdoor areas and teachers' lounges, become smoke-free. Get your children involved in the effort to make schools smoke-free!

An important choice

If you smoke, one of the most important things you can do for your own health and the health of your children is to stop smoking. Quitting is the best way to prevent your children from being exposed to secondhand smoke.

It may be hard to quit. Talk with your doctor if you need help. There are many over-the-counter and prescription medicines that may help you quit. Also, you may find it helpful to join a stop-smoking class. Contact the American Lung Association, American Heart Association, or American Cancer Society for more information about support groups where you live.

Parents need to make every effort to keep their children away from smokers and secondhand smoke. Parents who smoke should guit for their health and the health of their children.

Resources

For more information about tobacco use, read Smoking: Straight Talk for Teens and The Risks of Tobacco Use: A Message to Parents and Teens from the American Academy of Pediatrics. Other sources include

American Cancer Society

800/ACS-2345 (800/227-2345) www.cancer.org

American Heart Association

800/AHA-USA-1 (800/242-8721) www.americanheart.org

American Lung Association

800/LUNG-USA (800/586-4872) www.lungusa.org

American Legacy Foundation (Great Start Program [quitting during pregnancy))

866/66-START (866/667-8278) www.americanlegacy.org/greatstart

US Environmental Protection Agency (Smoke-Free Homes)

866/SMOKE-FREE (866/766-5337) www.epa.gov/smokefree

Fire safety

Children can be burned or start fires when they play with lit cigarettes, lighters, or matches. Many of these fires are caused by children younger than 5 years. Cigarette lighters are especially dangerous. Although butane cigarette lighters have to be made child-resistant, they are not childproof.

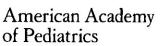
Keep your children safe from injury by following these guidelines:

- Never allow anyone to smoke while holding a child.
- Never leave a lit cigarette, cigar, or pipe inside or outside.
- Keep matches and lighters out of your children's reach.
- Remember that child-resistant doesn't mean childproof.

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 brochure. Phone numbers and Web site addresses are as current as possible, but may change at any time.

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DEDICATED TO THE HEALTH OF ALL CHILDREN

Diaper Rash

Diaper rash affects most babies, but it is usually not serious. Below we explain the causes of diaper rash, steps you can take to help prevent it, and how to treat it if it develops.

What is diaper rash?

Diaper rash can be any rash that develops inside the diaper area. In mild cases, the skin might be red. In more severe cases, there may be painful open sores. You will usually see a rash around the abdomen, genitalia, and inside the skin folds of the thighs and buttocks. Mild cases clear up within 3 to 4 days without any treatment. If a rash persists or develops again after treatment, consult your pediatrician.

What causes diaper rash?

Over the years diaper rash has been blamed on various causes, such as teething, diet, and ammonia in the urine. However, medical experts now believe it is caused by any of the following:

- Too much moisture
- · Chafing or rubbing
- · Prolonged contact of the skin with urine, feces, or both
- Yeast infection
- Bacterial infection
- Allergic reaction to diaper material

When skin stays wet for too long, the layers that protect it start to break down. When wet skin is rubbed, it also damages more easily. Moisture from a soiled diaper can harm your baby's skin and make it more prone to chafing. When this happens, a diaper rash may develop.

Further rubbing between the moist folds of the skin only makes the rash worse. This is why diaper rash often forms in the skin folds of the groin and upper thighs.

More than half of babies between 4 months and 15 months of age develop diaper rash at least once in a 2-month period. Diaper rash occurs more often in the following instances:

- As infants get older—mostly between 8 to 10 months of age
- · If babies are not kept clean and dry
- In babies who have frequent stools, especially when the stools stay in their diapers overnight
- · When babies begin to eat solid foods
- When babies are taking antibiotics, or in nursing babies whose mothers are taking antibiotics

Infants taking antibiotics are more likely to get diaper rashes caused by yeast infections. Yeast infects the weakened skin and causes a bright red rash with red spots at its edges. You can treat this with over-the-counter antifungal medications. If you see these symptoms, you may wish to consult with your pediatrician.

What can I do to prevent diaper rash?

To help prevent diaper rash from developing, you should:

- Change the diaper promptly after your child wets or has a bowel movement.
 This limits moisture on the skin.
- Do not put the diaper on airtight, especially overnight. Keep the diaper loose so that the wet and soiled parts do not rub against the skin as much.
- Gently clean the diaper area with water. You do not need to use soap with
 every diaper change or after every bowel movement. (Breastfed infants may
 stool as many as 8 times a day.) Use soap only when the stool does not
 come off easily.
- Do not use talcum or baby powder because they could cause breathing problems in your infant.
- Avoid over-cleansing with wipes that can dry out the skin. The alcohol or perfume in these products may irritate some babies' skin.

What can I do if my baby gets diaper rash?

If diaper rash develops despite your best efforts to prevent it, try the following:

- · Change wet or soiled diapers often.
- Use clear water to cleanse the diaper area with each diaper change.
- Using water in a squirt bottle lets you clean and rinse without rubbing.
- · Pat dry; do not rub. Allow the area to air dry fully.
- Apply a thick layer of protective ointment or cream (such as one that contains zinc oxide or petrolatum) to form a protective coating on the skin.
 These ointments are usually thick and pasty and do not have to be completely removed at the next diaper change. Remember, heavy scrubbing or rubbing will only damage the skin more.
- Check with your pediatrician if the rash:
 - Has blisters or pus-filled sores
 - Does not so away within 48 to 72 hours
 - Gets worse
- Use creams with steroids only if your pediatrician recommends them. They
 are rarely needed and may be harmful.

Which type of diaper should I use?

There are many different brands of diapers. Diapers are made of cloth or disposable materials. After they get soiled, you can wash cloth diapers and use them again and you throw away disposable diapers.

Research suggests that diaper rash is less common with the use of disposable diapers. In child care settings, children who wear super-absorbent disposable diapers tend to have lower rates of diaper rash. Regardless of which type of diaper you use, diaper rash occurs less often and is less severe when you change diapers often. If you use a cloth diaper, you can use a stay-dry liner inside it to keep your baby drier.

Newborns, Infants, and Toddlers

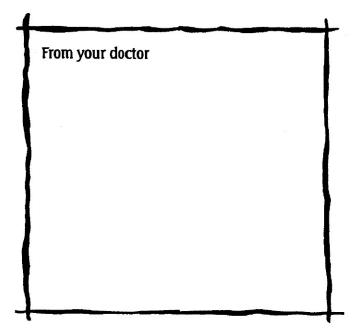
If you choose not to wash cloth diapers yourself, you can have a diaper service clean them. If you do your own washing, you will need to presoak heavily soiled diapers. Keep and wash soiled diapers separate from other clothes. Use hot water and double-rinse each wash. Do not use fabric softeners or antistatic products on the diapers because they may cause rashes in young, sensitive skin.

Whether you use cloth diapers, disposables, or both, always change diapers as needed to keep your baby clean, dry, and healthy.

Remember—never leave your baby alone on the changing table or on any other surface above the floor. Even a newborn can make a sudden turn and fall to the floor.

Diaper rash is usually not serious, but it can cause your child discomfort. Follow the steps listed above to help prevent and treat diaper rash. Discuss any questions you have about these steps with your pediatrician.

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When Do Children and Teens Need Vaccinations?

| Age | HepB Hepatitis B | DTaP/Tdap Diphtheria, tetanus, pertussis | Hib Haemophilus influenzae type b | Polio | PCV Pneumococcal conjugate | RV Rotavirus | MMR Measles, mumps, rubella | Varicella Chickenpox | HepA Hepatitis A | HPV Human papillo- mavirus | MCV4 Meningococcal conjugate | Influenza |
|--------------|-----------------------|---------------------------------------------------|------------------------------------------------|-----------------------|---------------------------------------|------------------------|-----------------------------------|-------------------------|----------------------------------|----------------------------------|------------------------------------|----------------------------------|
| Birth | ✓ | | | | | | | | | | | |
| 2 months | (1–2 mos) | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | | |
| 4 months | √ ¹ | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | | |
| 6 months | | ✓ | ✓ ² | | ✓ | ✓ ² | | | | | | |
| 12 months | / | ✓ ⁴ | | | | | | | ,, | | | |
| 15 months | (6–18 mos) | (15–18 mos) | (12–15 mos) | (6–18 mos) | (12–15 mos) | | (12–15 mos) | (12–15 mos) | (2 doses given 6 mos apart at | | | |
| 18 months | | | | | | | Catch-up ⁵ | Catch-up ⁵ | age 12–23 mos) | | | √ 3 |
| 19-23 months | | Catch-up ⁵ | Catch-up ⁵ (to 5 years) | Catch-up ⁵ | Catch-up ⁵ (to 5 years) | | Cattir-up | Саксп-ир | | | | (given each fall or winter to |
| 4-6 years | | ✓ | | ✓ | | | ✓ | √ | | | | children ages 6 mos–18 yrs) |
| 7-10 years | Catch-up ⁵ | Catch-up ⁵ | | | | | | | Catch-up ⁵ | | | |
| 11-12 years | | Tdap | | Catch-up ⁵ | | | Catch-up ⁵ | Catch-up ⁵ | | /// | ✓ | |
| 13-18 years | | Catch-up ⁵ (Tdap/Td) | | | | | | | | Catch-up ^{5,6} | Catch-up ^{5,7} | |

- 1. Your infant may not need a dose of HepB at age 4 months depending on the type of vaccine that your healthcare provider uses.
- 2. Your infant may not need a dose of Hib vaccine or RV vaccine at age 6 months depending on the type of vaccine that your healthcare provider uses.
- 3. One dose is recommended for most people. Children younger than age 9 years who are receiving influenza vaccine for the first time, or who received only 1 dose in the previous season (if it was their first vaccination season), should receive 2 doses spaced at least 4 weeks apart this season.
- 4. This dose of DTaP may be given as early as age 12 months if it has been 6 months since the previous dose.

- 5. If your child's vaccinations are delayed or missed entirely, they should be given as soon as possible.
- 6. All girls and women age 11 through 26 years should be vaccinated with 3 doses of HPV vaccine, given over a 6-month period. Boys and men age 11 through 26 years may also be vaccinated with one of the HPV vaccines (Gardasil) to reduce their likelihood of getting genital warts. The vaccine may be given to children as young as age 9 years.
- 7. If you have a teenager who is enrolling in college and planning to live in a dormitory and who hasn't previously been vaccinated against meningococcal disease, they should be vaccinated now.

Please note: Some children may need additional vaccines. Talk to your healthcare provider.

www.immunize.org/catg.d/p4050.pdf • Item #P4050 (1/10)

DIPHTHERIA VACCINES ETANUS & VACCINES PERTUSSIS

WHAT YOU NEED TO KNOW

1 Why get vaccinated?

Diphtheria, tetanus, and pertussis are serious diseases caused by bacteria. Diphtheria and pertussis are spread from person to person. Tetanus enters the body through cuts or wounds.

DIPHTHERIA causes a thick covering in the back of the throat.

• It can lead to breathing problems, paralysis, heart failure, and even death.

TETANUS (Lockjaw) causes painful tightening of the muscles, usually all over the body.

• It can lead to "locking" of the jaw so the victim cannot open his mouth or swallow. Tetanus leads to death in up to 2 out of 10 cases.

PERTUSSIS (Whooping Cough) causes coughing spells so bad that it is hard for infants to eat, drink, or breathe. These spells can last for weeks.

• It can lead to pneumonia, seizures (jerking and staring spells), brain damage, and death.

Diphtheria, tetanus, and pertussis vaccine (**DTaP) can help prevent these diseases.** Most children who are vaccinated with DTaP will be protected throughout childhood. Many more children would get these diseases if we stopped vaccinating.

DTaP is a safer version of an older vaccine called DTP. DTP is no longer used in the United States.

Who should get DTaP vaccine and when?

Children should get <u>5 doses</u> of DTaP vaccine, one dose at each of the following ages:

✓ 2 months \checkmark 4 months \checkmark 6 months \checkmark 15-18 months \checkmark 4-6 years

DTaP may be given at the same time as other vaccines.

Some children should not get DTaP vaccine or should wait

- Children with minor illnesses, such as a cold, may be vaccinated. But children who are moderately or severely ill should usually wait until they recover before getting DTaP vaccine.
- Any child who had a life-threatening allergic reaction after a dose of DTaP should not get another dose.
- Any child who suffered a brain or nervous system disease within 7 days after a dose of DTaP should not get another dose.
- Talk with your doctor if your child:
 - had a seizure or collapsed after a dose of DTaP,
 - cried non-stop for 3 hours or more after a dose of DTaP.
 - had a fever over 105°F after a dose of DTaP.

Ask your health care provider for more information. Some of these children should not get another dose of pertussis vaccine, but may get a vaccine without pertussis, called **DT**.

4 Older children and adults

DTaP is not licensed for adolescents, adults, or children 7 years of age and older.

But older people still need protection. A vaccine called **Tdap** is similar to DTaP. A single dose of Tdap is recommended for people 11 through 64 years of age. Another vaccine, called **Td**, protects against tetanus and diphtheria, but not pertussis. It is recommended every 10 years. There are separate Vaccine Information Statements for these vaccines.

Diphtheria/Tetanus/Pertussis

5/17/2007

5

What are the risks from DTaP vaccine?

Getting diphtheria, tetanus, or pertussis disease is much riskier than getting DTaP vaccine.

However, a vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of DTaP vaccine causing serious harm, or death, is extremely small.

Mild Problems (Common)

- Fever (up to about 1 child in 4)
- Redness or swelling where the shot was given (up to about 1 child in 4)
- Soreness or tenderness where the shot was given (up to about 1 child in 4)

These problems occur more often after the 4th and 5th doses of the DTaP series than after earlier doses. Sometimes the 4th or 5th dose of DTaP vaccine is followed by swelling of the entire arm or leg in which the shot was given, lasting 1-7 days (up to about 1 child in 30).

Other mild problems include:

- Fussiness (up to about 1 child in 3)
- Tiredness or poor appetite (up to about 1 child in 10)
- Vomiting (up to about 1 child in 50)

These problems generally occur 1-3 days after the shot.

Moderate Problems (Uncommon)

- Seizure (jerking or staring) (about 1 child out of 14.000)
- Non-stop crying, for 3 hours or more (up to about 1 child out of 1,000)
- High fever, over 105°F (about 1 child out of 16,000)

Severe Problems (Very Rare)

- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been reported after DTaP vaccine. These include:
 - Long-term seizures, coma, or lowered consciousness
 - Permanent brain damage.

These are so rare it is hard to tell if they are caused by the vaccine.

Controlling fever is especially important for children who have had seizures, for any reason. It is also important if another family member has had seizures. You can reduce fever and pain by giving your child an *aspirin-free* pain reliever when the shot is given, and for the next 24 hours, following the package instructions.

6

What if there is a moderate or severe reaction?

What should I look for?

Any unusual conditions, such as a serious allergic reaction, high fever or unusual behavior. Serious allergic reactions are extremely rare with any vaccine. If one were to occur, it would most likely be within a few minutes to a few hours after the shot. Signs can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness. If a high fever or seizure were to occur, it would usually be within a week after the shot.

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 doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice



The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call **1-800-338-2382** or visit the program's 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's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO)
 - Visit the National Immunization Program's website at www.cdc.gov/nip





U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention

Centers for Disease Control and Prevention

Vaccine Information Statement

DTaP (5/17/07)

42 U.S.C. § 300aa-26

Haemophilus Influenzae Type b (Hib) Vaccine

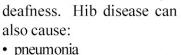
WHAT YOU NEED TO KNOW

1 What is Hib disease?

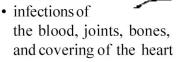
Haemophilus influenzae type b (Hib) disease is a serious disease caused by a bacteria. It usually strikes children under 5 years old.

Your child can get Hib disease by being around other children or adults who may have the bacteria and not know it. The germs spread from person to person. If the germs stay in the child's nose and throat, the child probably will not get sick. But sometimes the germs spread into the lungs or the bloodstream, and then Hib can cause serious problems.

Before Hib vaccine, Hib disease was the leading cause of bacterial meningitis among children under 5 years old in the United States. Meningitis is an infection of the brain and spinal cord coverings, which can lead to lasting brain damage and



 severe swelling in the throat, making it hard to breathe

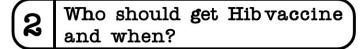


· death

Before Hib vaccine, about 20,000 children in the United States under 5 years old got severe Hib disease each year and nearly 1,000 people died.

Hib vaccine can prevent Hib disease.

Many more children would get Hib disease if we stopped vaccinating.



Children should get Hib vaccine at:

- ✓ 2 months of age ✓ 6 months of age*
- ✓ 4 months of age ✓ 12-15 months of age
- * Depending on what brand of Hib vaccine is used, your child might not need the dose at 6 months of age. Your doctor or nurse will tell you if this dose is needed.

If you miss a dose or get behind schedule, get the next dose as soon as you can. There is no need to start over.

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

Older Children and Adults

Children over 5 years old usually do not need Hib vaccine. But some older children or adults with special health conditions should get it. These conditions include sickle cell disease, HIV/AIDS, removal of the spleen, bone marrow transplant, or cancer treatment with drugs. Ask your doctor or nurse for details.

Some people should not get Hib vaccine or should wait

- People who have ever had a life-threatening allergic reaction to a previous dose of Hib vaccine should not get another dose.
- Children less than 6 weeks of age should not get Hib vaccine.
- People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting Hib vaccine.

Ask your doctor or nurse for more information.



What are the risks from Hib vaccine?

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

Most people who get Hib vaccine do not have any problems with it.

Mild Problems

 Redness, warmth, or swelling where the shot was given (up to 1/4 of children)

• Fever over 101°F (up to 1 out of 20 children)

If these problems happen, they usually start within a day of vaccination. They may last 2-3 days.



What if there is a moderate or severe reaction?

What should I look for?

Any unusual condition, such as a serious allergic reaction, high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat, or dizziness within a few minutes to a few hours after the shot.

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 doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at www.vaers.org, or by calling 1-800-822-7967.

VAERS does not provide medical advice



The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help you pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit the program's website at www.hrsa.gov/osp/vicp



How can I learn more?

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





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

National Immunization Program

Vaccine Information Statement

Hib (12/16/98)

42 U.S.C. § 300aa-26

HEPATITIS B VACCINE

WHAT YOU NEED TO KNOW

1 Why get vaccinated?

Hepatitis B is a serious disease.

The hepatitis B virus (HBV) can cause short-term (acute) illness that leads to:

- loss of appetite
- diarrhea and vomiting
- tiredness
- jaundice (yellow skin or eyes)
- · pain in muscles, joints, and stomach

It can also cause long-term (chronic) illness that leads to:

- liver damage (cirrhosis)
- · liver cancer
- · death

About 1.25 million people in the U.S. have chronic HBV infection.

Each year it is estimated that:

- 80,000 people, mostly young adults, get infected with HBV
- More than 11,000 people have to stay in the hospital because of hepatitis B
- 4,000 to 5,000 people die from chronic hepatitis B

Hepatitis B vaccine can prevent hepatitis B. It is the first anti-cancer vaccine because it can prevent a form of liver cancer.

2 How is hepatitis B virus spread?

Hepatitis B virus is spread through contact with the blood and body fluids of an infected person. A person can get infected in several ways, such as:

- by having unprotected sex with an infected person
- by sharing needles when injecting illegal drugs
- by being stuck with a used needle on the job
- during birth when the virus passes from an infected mother to her baby

About 1/3 of people who are infected with hepatitis B in the United States don't know how they got it.

Hepatitis B 7/11/2001

Who should get hepatitis B vaccine and when?

- 1) Everyone 18 years of age and younger
- 2) Adults over 18 who are at risk

Adults at risk for HBV infection include:

- people who have more than one sex partner in 6 months
- men who have sex with other men
- sex contacts of infected people
- people who inject illegal drugs
- health care and public safety workers who might be exposed to infected blood or body fluids
- household contacts of persons with chronic HBV infection
- hemodialysis patients

If you are not sure whether you are at risk, ask your doctor or nurse.

✓ People should get 3 doses of hepatitis B vaccine according to the following schedule. If you miss a dose or get behind schedule, get the next dose as soon as you can. There is no need to start over.

| Hepatitis B Vaccination Schedule | | WHO? | | | | | |
|----------------------------------------|----------------|---------------------------------------------------|---------------------------------------------------------------|-----------------------------------------|--|--|--|
| | | Infant whose mother is infected with HBV | Infant whose mother is <i>not</i> infected with HBV | Older child, adolescent, or adult | | | |
| w | First Dose | Within 12 hours of birth | Birth - 2 months of age | Any time | | | |
| HEN | Second Dose | 1 -2 months of age | 1 - 4 months of age (at least 1 month after first dose) | 1 - 2 months after first dose | | | |
| ? | Third Dose | 6 months of age | 6 - 18 months of age | 4 - 6 months after first dose | | | |

- The second dose must be given at least 1 month after the first dose.
- The third dose must be given at least 2 months after the second dose and at least 4 months after the first.
- The third dose should *not* be given to infants under 6 months of age, because this could reduce long-term protection.

Adolescents 11 to 15 years of age may need only two doses of hepatitis B vaccine, separated by 4-6 months. Ask your health care provider for details.

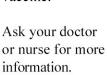
Hepatitis B vaccine may be given at the same time as other vaccines.



Some people should not get hepatitis B vaccine or should wait

People should not get hepatitis B vaccine if they have ever had a life-threatening allergic reaction to baker's yeast (the kind used for making bread) or to a previous dose of hepatitis B vaccine.

People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting hepatitis B vaccine.





5

What are the risks from hepatitis B vaccine?

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

Getting hepatitis B vaccine is much safer than getting hepatitis B disease.

Most people who get hepatitis B vaccine do not have any problems with it.

Mild problems

- soreness where the shot was given, lasting a day or two (up to 1 out of 11 children and adolescents, and about 1 out of 4 adults)
- mild to moderate fever (up to 1 out of 14 children and adolescents and 1 out of 100 adults)

Severe problems

• serious allergic reaction (very rare)



What if there is a moderate or severe reaction?

What should I look for?

Any unusual condition, such as a serious allergic reaction, high fever or unusual behavior. Serious allergic

reactions are extremely rare with any vaccine. If one were to occur, it would be within a few minutes to a few hours after the shot. Signs can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

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 doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at www.vaers.org, or by calling 1-800-822-7967.

VAERS does not provide medical advice

7

The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help you pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call **1-800-338-2382** or visit the program's website at www.hrsa.gov/osp/vicp

8 How can I learn more?

- Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
 - -Call **1-800-232-4636** (1-800-CDC-INFO) or **1-888-443-7232**
 - -Visit the National Immunization Program's website at www.cdc.gov/nip or CDC's Division of Viral Hepatitis website at www.cdc.gov/hepatitis





U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention

National Immunization Program

Vaccine Information Statement
Hepatitis B (7/11/01)
42 U.S.C. § 300aa-26

POLIO VACCINE

WHAT YOU NEED TO KNOW

1 What is polio?

Polio is a disease caused by a virus. It enters a child's (or adult's) body through the mouth. Sometimes it does not cause serious illness. But sometimes it causes *paralysis* (can't move arm or leg). It can kill people who get it, usually by paralyzing the muscles that help them breathe.

Polio used to be very common in the United States. It paralyzed and killed thousands of people a year before we had a vaccine for it.

(2| Why get vaccinated?

Inactivated Polio Vaccine (IPV) can prevent polio.

History: A 1916 polio epidemic in the United States killed 6,000 people and paralyzed 27,000 more. In the early 1950's there were more than 20,000 cases of polio each year. **Polio vaccination was begun in 1955.** By 1960 the number of cases had dropped to about 3,000, and by 1979 there were only about 10. The success of polio vaccination in the U.S. and other countries sparked a world-wide effort to eliminate polio.

Today: No wild polio has been reported in the United States for over 20 years. But the disease is still common in some parts of the world. It would only take one case of polio from another country to bring the disease back if we were not protected by vaccine. If the effort to eliminate the disease from the world is successful, some day we won't need polio vaccine. Until then, we need to keep getting our children vaccinated.

Who should get polio vaccine and when?

IPV is a shot, given in the leg or arm, depending on age. Polio vaccine may be given at the same time as other vaccines.

Children

Most people should get polio vaccine when they are children. Children get 4 doses of IPV, at these ages:

- ✓ A dose at 2 months ✓ A dose at 6-18 months
- ✓ A dose at 4 months ✓ A booster dose at 4-6 years

Adults

Most adults do not need polio vaccine because they were already vaccinated as children. But three groups of adults are at higher risk and *should* consider polio vaccination:

- people traveling to areas of the world where polio is common.
- (2) laboratory workers who might handle polio virus, and
- (3) health care workers treating patients who could have polio.

Adults in these three groups who have never been vaccinated against polio should get 3 doses of IPV:

- ✓ The first dose at any time,
- ✓ The second dose 1 to 2 months later.
- ✓ The third dose 6 to 12 months after the second.

Adults in these three groups who **have had 1 or 2 doses** of polio vaccine in the past should get the remaining 1 or 2 doses. It doesn't matter how long it has been since the earlier dose(s).

Oral Polio Vaccine: No longer recommended

There are two kinds of polio vaccine: **IPV**, which is the shot recommended in the United States today, and a live, oral polio vaccine (**OPV**), which is drops that are swallowed.

Until recently OPV was recommended for most children in the United States. OPV helped us rid the country of polio, and it is still used in many parts of the world.

Both vaccines give immunity to polio, but OPV is better at keeping the disease from spreading to other people. However, for a few people (about one in 2.4 million), OPV actually causes polio. Since the risk of getting polio in the United States is now extremely low, experts believe that using oral polio vaccine is no longer worth the slight risk, except in limited circumstances which your doctor can describe. The polio shot (IPV) does not cause polio. If you or your child will be getting OPV, ask for a copy of the OPV supplemental Vaccine Information Statement.

Adults in these three groups who have had 3 or more doses of polio vaccine (either IPV or OPV) in the past may get a booster dose of IPV.

Ask your health care provider for more information.

Polio - 1/1/2000



Some people should not get IPV or should wait.

These people should not get IPV:

- Anyone who has ever had a life-threatening allergic reaction to the antibiotics neomycin, streptomycin or polymyxin B should not get the polio shot.
- Anyone who has a severe allergic reaction to a polio shot should not get another one.

These people should wait:

 Anyone who is moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting polio vaccine. People with minor illnesses, such as a cold, *may* be vaccinated.

Ask your health care provider for more information.



What are the risks from IPV?

Some people who get IPV get a sore spot where the shot was given. The vaccine used today has never been known to cause any serious problems, and most people don't have any problems at all with it.

However, a vaccine, like any medicine, could cause serious problems, such as a severe allergic reaction. *The risk of a polio shot causing serious harm, or death, is extremely small.*



What if there is a serious reaction?

What should I look for?

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

If a serious allergic reaction occurred, it would happen within a few minutes to a few hours after the shot. 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 doctor, nurse, or health department 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.org, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

Reporting reactions helps experts learn about possible problems with vaccines.



The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, there is a federal program that can help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call **1-800-338-2382** or visit the program's website at **http://www.hrsa.gov/osp/vicp**

8

How can I learn more?

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





U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention National Immunization Program

Vaccine Information Statement

Polio (1/1/2000)

42 U.S.C. § 300aa-26

PNEUMOCOCCAL VACCINE CONJUGATE VACCINE

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

Pneumococcal disease

Infection with *Streptococcus pneumoniae* bacteria can make children very sick.

It causes blood infections, pneumonia, and meningitis, mostly in young children. (Meningitis is an infection of the covering of the brain.) Although pneumococal meningitis is relatively rare (less than 1 case per 100,000 people each year), it is fatal in about 1 of 10 cases in children.

Pneumococcal meningitis can also lead to other health problems, including deafness and brain damage.

Before routine use of pneumococcal conjugate vaccine, pneumococcal infections caused:

- over 700 cases of meningitis,
- 13,000 blood infections,
- · about 5 million ear infections, and
- · about 200 deaths

annually in the United States in children under five.

Children younger than 2 years of age are at higher risk for serious disease than older children.

Pneumococcal bacteria are spread from person to person through close contact.

Pneumococcal infections may be hard to treat because some strains of the bacteria have become resistant to the drugs that are used to treat them. This makes **prevention** of pneumococcal infections through vaccination even more important.

Pneumococcal conjugate vaccine (PCV13)

There are more than 90 types of pneumococcal bacteria. The new pneumococcal conjugate vaccine (PCV13) protects against 13 of them. These bacteria types are responsible for most severe pneumococcal infections among children. PCV13 replaces a previous conjugate vaccine (PCV7), which protected against 7 pneumococcal types and has been in use since 2000. During that time severe pneumococcal disease dropped by nearly 80% among children under 5.

PCV13 may also prevent some cases of pneumonia and some ear infections. But pneumonia and ear infections have many causes, and PCV13 only works against the types of pneumococcal bacteria targeted by the vaccine.

PCV13 is given to infants and toddlers, to protect them when they are at greatest risk for serious diseases caused by pneumococcal bacteria.

In addition to receiving PCV13, older children with certain chronic illnesses may get a different vaccine called PPSV23. There is a separate Vaccine Information Statement for that vaccine.

Who should get PCV13, and when?

Infants and Children Under 2 Years of Age

PCV13 is recommended as a series of **4 doses**, one dose at each of these ages: 2 months, 4 months, 6 months, and 12 through 15 months

Children who miss their shots at these ages should still get the vaccine. The number of doses and the intervals between doses will depend on the child's age. Ask your health care provider for details.

Children who have began their immunization series with PCV7 should complete the series with PCV13.

Older Children and Adolescents

- Healthy children between their 2nd and 5th birthdays who have not completed the PCV7 or PCV13 series before age 2 years should get 1 dose.
- Children between the 2nd and 6th birthdays with medical conditions such as:
 - sickle cell disease,
 - a damaged spleen or no spleen,
 - cochlear implants,
 - diabetes,
 - HIV/AIDS or other diseases that affect the immune system (such as cancer, or liver disease), or
 - chronic heart or lung disease,

or who take medications that affect the immune system, such as immunosuppressive drugs or steroids, should get 1 dose of PCV 13 (if they received 3

doses of PCV1 or PCV13 before age 2 years), or **2 doses of PCV13** (if they have received 2 or fewer doses of PCV7 or PCV13).

A dose of PCV13 may be administered to children and adolescents 6 through 18 years of age who have certain medical conditions, even if they have previously received PCV7 or PPSV23.

Children who have completed the 4-dose series with

PCV7: Healthy children who have not yet turned 5, and children with medical conditions who have not yet turned 6, should get one additional dose of PCV13.

Ask your health care provider if you have questions about any of these recommendations.

PCV13 may be given at the same time as other vaccines.

4

Some children should not get PCV13 or should wait

Children should not get PCV13 if they had a serious (life-threatening) allergic reaction to a previous dose of this vaccine, to PCV7, or to any vaccine containing diphtheria toxoid (for example, DTaP).

Children who are known to have a severe allergy to any component of PCV7 or PCV13 should not get PCV13. Tell your health care provider if your child has any severe allergies.

Children with minor illnesses, such as a cold, may be vaccinated. But children who are moderately or severely ill should usually wait until they recover before getting the vaccine.

5 What are the risks from PCV13?

Any medicine, including a vaccine, could possibly cause a serious problem, such as a severe allergic reaction. However, the risk of any vaccine causing serious harm, or death, is extremely small.

In studies, most reactions after PCV13 were mild. They were similar to reactions reported after PCV7, which has been in use since 2000. Reported reactions varied by dose and age, but on average:

- About half of children were drowsy after the shot, had a temporary loss of appetite, or had redness or tenderness where the shot was given.
- About 1 out of 3 had swelling where the shot was given.
- About 1 out of 3 had a mild fever, and about 1 in 20 had a higher fever (over 102.2°F).

• Up to about 8 out of 10 became fussy or irritable.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

6

What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell the 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 visiting their website at **www.hrsa.gov/vaccinecompensation**.

How can I learn more?

- Ask your 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) or
 - Visit CDC's website at www.cdc.gov/vaccines.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Vaccine Information Statement (Interim)

PCV13 **4/16/2010**

42 U.S.C. §300aa-26