

New Jersey VACCINE VOICE

A semi-annual publication providing New Jersey's healthcare professionals with timely immunization information

Spring 2009

National Immunization Survey Places New Jersey Near Bottom for Timely Immunizations

Recently released National Immunization Survey (NIS) data reveal that New Jersey is doing poorer than most states nationwide in delivering timely immunizations. The National Immunization Survey is the only population-based, provider-verified survey to provide national, state, and local area estimates of vaccination coverage among children aged 19-35 months. New Jersey's Q3 2007-Q2 2008 data rank the State seventh from bottom, and below the national average of 77.2, with only 70.5% of children fully immunized for the 4:3:1:3:3:1 series. These data represent a 10% drop compared to Q1-Q4 2007 when 80.5% of children statewide were fully immunized.

Coverage with the combined 4:3:1:3:3:1:4 vaccine series (i.e., the 4:3:1:3:3:1 series plus >4 doses of 7-valent pneumococcal conjugate vaccine [PCV7]) was reported for the first time in the September 5, 2008 MMWR. For this newly reported series, the State ranked even lower – fifth from bottom, with only 58.3% of children immunized, compared to 68.1% nationwide. This represents a 4% drop from Q1-Q4 2007 when 62.3% of children statewide were immunized.

As of this NIS survey, varicella is not a required reportable disease or vaccination in New Jersey. However, by spring of 2009, with publication of the updated Communicable Disease Rules, N.J.A.C. 8:57-2, reporting of varicella disease and vaccination will be required in New Jersey

with compliance rates being manifest in the Q4/2009 NIS.

Increasing coverage for the fourth dose of DTaP and the fourth dose of PCV7 would improve national coverage for the 4:3:1:3:3:1 series and the 4:3:1:3:3:1:4 series, which will be used to monitor the Healthy People 2010 immunization objectives beginning with 2009 NIS data. Use of effective interventions, such as parent and provider reminder/recall, reducing out-of-pocket costs, increasing access to vaccination, and multi-component interventions that include education might further improve overall vaccination compliance.

Sources: *MMWR Weekly, September 5, 2008 57(35); 961-966. National Immunization Survey Q2 2007-Q3 2008.*



New Jersey Immunization Action Group...Calling All Interested Health Care Providers

Help us reach out and share scientific and reliable information regarding vaccine importance and safety as part of keeping New Jersey's children healthy in your community.

The American Academy of Pediatrics, New Jersey Chapter (AAP NJ) and the NJ Pediatric Council on Research and Education, the Foundation for the AAP NJ Chapter are seeking Pediatricians, Family Physicians, Internists, Physician Assistants, Nurse Practitioners, Midwives, Nurses and Parents who are interested in community outreach efforts designed to educate the general public and parent groups about the critical role immunizations have in preventing diseases and promoting health. Interested? Please contact Fran Gallagher, MEd, Executive Director, PCORE at fgallagher@njpcore.org or call 609.588.9988.



American Academy of Pediatrics
NEW JERSEY CHAPTER



EMIC
Essex Metro Immunization Coalition

Medical Society of New Jersey
MSNJ



Vaccine Policy Statement

Ready for you to adapt for your practice

To reinforce your practice's commitment to delivering timely immunizations, consider tailoring or using as is, the following vaccine policy to support the vital role vaccination plays in safeguarding the health of children. Your practice's clearly expressed commitment to immunization can be powerfully persuasive with parents who are hesitant to have their child vaccinated. The link to the vaccine policy statement at the end of this article was developed by clinicians at All Star Pediatrics in Pennsylvania, where it is posted in every exam room and handed to parents at their infant's one-month well-check appointment. Results have been that parents new to All Star Pediatrics know exactly where their doctors stand on immunization, and the families of established patients feel supported in the choice they've made to immunize their children.

The text of the policy statement is available as a pdf or MS Word document at: www.immunize.org/catg.d/p2067.pdf. You can cut and paste it to make your own vaccine policy statement.



New Vaccines

Kinrix - (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine) Manufacturer: GlaxoSmithKline Biologicals, Rixensart, Belgium.

Indication for use: Vaccine for active immunization against diphtheria, tetanus, pertussis, and poliomyelitis as the fifth dose in the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine series and the fourth dose in the inactivated poliovirus vaccine (IPV) series in children 4 through 6 years of age whose previous DTaP vaccine doses have been with INFANRIX® and/or PEDIARIX® for the first three doses and INFANRIX® for the fourth dose. Approval Date: June 24, 2008.

Pentacel - Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine, Manufacturer: Sanofi Pasteur Limited.

Indication for use: Vaccine for active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease caused by Haemophilus influenzae type b when administered to infants and children 6 weeks through 4 years of age (prior to fifth birthday). Approval Date: June 20, 2008.

Importance of Maintaining the **Cold Chain**

Vaccine Potency

Excessive heat or cold exposure damages vaccine, resulting in loss of potency. Once potency is lost, it can never be restored. Furthermore, each time vaccine is exposed to heat or cold, the loss of potency increases and eventually, if the cold chain is not correctly maintained, all potency will be lost, and the vaccine becomes useless.



Excessive heat or cold damages vaccines.

Vaccine Appearance After Exposure to Inappropriate Storage Conditions

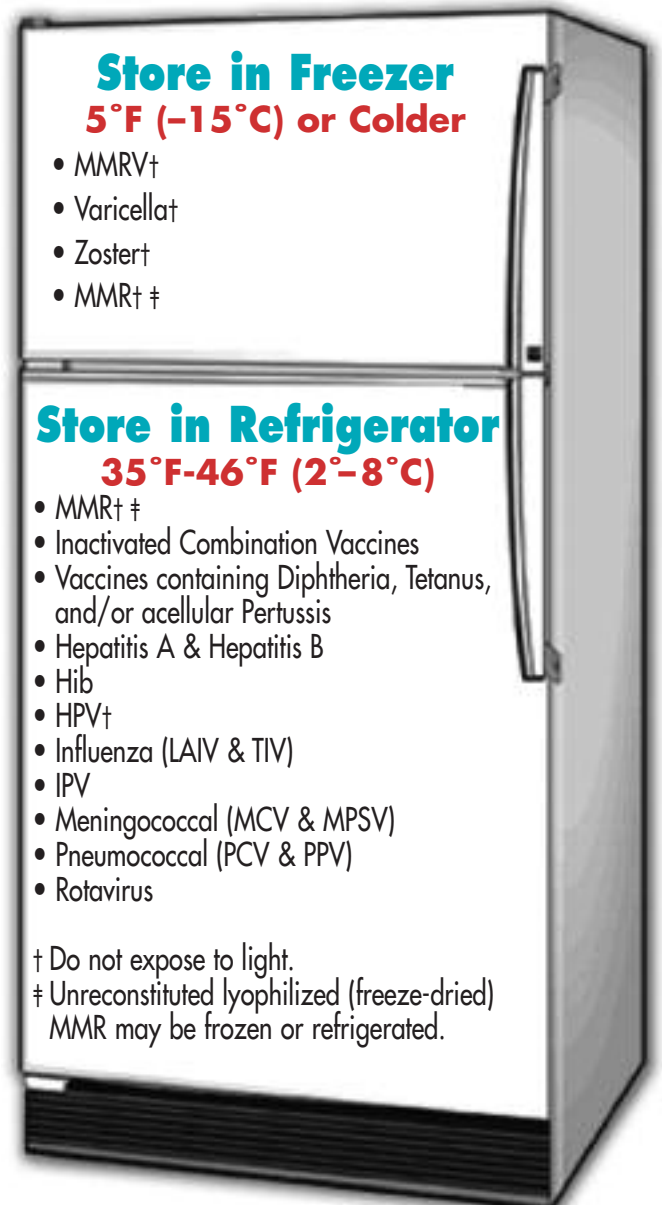
Some vaccines may show physical evidence of altered potency when exposed to inappropriate storage conditions, such as clumping in the solution that does not go away when the vial is shaken. Other vaccines may look perfectly normal when exposed to inappropriate storage conditions. For example, inactivated vaccines exposed to freezing temperatures [i.e., 32° F (0° C) or colder] may not appear frozen and give no indication of loss of potency. Therefore, visual inspection of vaccines is an unreliable method of assuring potency.

An estimated 17% to 37% of providers expose vaccines to improper storage temperatures. Refrigerator temperatures are more commonly kept too cold rather than too warm. Out-of-range temperatures require immediate action. For example, if the refrigerator temperature is at 35 degrees, adjust the refrigerator thermostat to be slightly warmer and recheck the temperature within one hour to verify the temperature is approximately 40 degrees. Regarding freezer temperatures, colder is better. Temperatures below five degrees Fahrenheit are preferable.

Loss of vaccine potency due to improper storage conditions is a costly mistake. Patients receiving vaccine with decreased potency caused by improper storage conditions may not be fully protected against the vaccine preventable disease. In the General Recommendations on Immunizations, the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP) state that mishandled vaccine doses should not be counted as valid doses and should be repeated unless serologic testing indicates a response to the vaccine. (MMWR 2002;51(No. RR-2):1-36). Recalling patients to repeat vaccine doses because vaccine has been stored improperly can damage public confidence in vaccines and in your practice.

Source: CDC Vaccine Storage & Handling Toolkit: <http://www.cdc.gov>

Store each vaccine in its proper location.



Reliable Sources of Immunization

WEBSITES

- www.cispimmunize.org** American Academy of Pediatrics (AAP). AAP's Childhood Immunization Support Program website contains information for both parents and clinicians.
- www.cdc.gov/vaccines** Centers for Disease Control and Prevention (CDC). The information on this website ranges from official vaccine recommendations for healthcare professionals to information for the general public about vaccines.
- www.ecbt.org**
www.vaccinateyourbaby.org Every Child by Two (ECBT). ECBT, founded by Rosalynn Carter and Betty Bumpers, has created these two websites. Each contains a broad array of educational materials and information about vaccine's their safety, vaccines research and science, vaccine misperceptions, and many other topics to help clinicians and parents.
- www.immunize.org**
www.vaccineinformation.org Immunization Action Coalition (IAC). IAC is a nonprofit organization that promotes immunization for all people against vaccine-preventable diseases. These websites offer educational materials, photos, and video clips for parents, healthcare professionals, the media, and the general public. clinicians and parents.
- www.immunizationinfo.org** National Network for Immunization Information (NNii). NNii provides current, sciencebased, extensively reviewed information to healthcare professionals, the media, policy makers, and the public.
- www.vaccine.chop.edu** Vaccine Education Center (VEC). The goal of the VEC at Children's Hospital of Philadelphia is to accurately communicate the facts about each childhood vaccine. VEC publishes a monthly vaccine e-newsletter for parents titled "Parents PACK." For more information or to subscribe, visit www.vaccine.chop.edu/parents

PHONE NUMBERS

- (800) CDC-INFO or (800) 232-4636** CDC-INFO Contact Center. A toll-free number for consumers and healthcare professionals who have questions about immunization and vaccine-preventable diseases. Call (800) CDC-INFO or (800) 232-4636. The Center operates 24/7 in English & Spanish. TTY: (888) 232-6348.

BOOKS FOR PARENTS

- Baby 411, 3rd edition** By Ari Brown, MD, and Denise Fields, Windsor Peak Press, 2007. Written by a Harvard-trained pediatrician (Brown) and the author of the best-selling Baby Bargains (Fields), this book is the ultimate compilation of frequently asked questions for baby's first year. It includes a special section on vaccines. To purchase, visit your local bookstore or www.windsorpeak.com/baby411
- Do Vaccines Cause That?! A Guide for Evaluating Vaccine Safety, 1st edition** By Martin Myers, MD, and Diego Pineda, MS. Published by Immunizations for Public Health, 2008. Get straight, science-based answers to parents' questions about the safety of vaccines. To purchase, visit your local bookstore or www.dovaccinescausethat.com
- Parents Guide to Childhood Immunization, 2008** This 68-page booklet from CDC introduces parents to 14 childhood diseases and the 10 vaccines that can protect children from them. Parents can order a free booklet or print their own copy by visiting www.cdc.gov/vaccines/pubs/parents-guide
- Vaccines: What You Should Know, 3rd edition** By Paul Offit, MD, and Louis Bell, MD, John Wiley & Sons, Inc., 2003. This third edition was written to help parents sort through the latest information about vaccines to determine what is right for their family. It includes a discussion of vaccines and autism, mercury in vaccines, and the ability of children to tolerate receiving numerous vaccines at once. To purchase, visit your local bookstore or www.wiley.com
- Vaccinating Your Child: Questions & Answers for the Concerned Parent, 2nd edition** By Sharon Humiston, MD, MPH, and Cynthia Good, Peachtree Publishers, 2003. To purchase, visit your local bookstore or go to www.peachtree-online.com

VIDEOS

- "Vaccines & Your Baby" & "Vaccines: Separating Fact from Fear"** Available in English and Spanish and in VHS and DVD formats, these videos answer many questions that new parents have. Each is available at a nominal charge from the Vaccine Education Center. To order, call (215) 590-9990 or order online at www.vaccine.chop.edu

Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.vaccineinformation.org • www.immunize.org

HIB UPDATE

Since December 2007, there has been a nationwide shortage of Hib vaccine. This shortage is due to a manufacturing problem with the Hib-containing vaccines manufactured by Merck & Co. (PedvaxHIB and Comvax). Only one vaccine manufacturer, Sanofi Pasteur, is currently producing Hib-containing vaccines. Sanofi Pasteur is manufacturing Hib vaccine as



both ActHIB and the combination vaccine Pentacel (DTaP, Hib, IPV). In response to the shortage, CDC recommends deferral of the Hib vaccine booster dose, usually given at age 12-15 months.

According to CDC, supply of the remaining Hib vaccine should be sufficient to cover all infants for the primary 3-dose series using vaccine available from Sanofi Pasteur. To cover the first three doses, all medical providers must use the newly licensed combination vaccine Pentacel, when necessary. Combination vaccines should be used to complete the primary series, even when it results in additional doses of another antigen.

Merck expects Hib supplies to be limited throughout 2009 and does not expect to return to fully supply of the pediatric formulation RECOMBIX HB until some time in 2010.

The following non-high risk children should be scheduled to receive the primary series of Hib vaccine:

- If the child is at least 6 weeks but less than 12 months and has received 0, 1, or 2 Hib doses, schedule him/her for the first or next dose(s) immediately with a minimum of 4 weeks between doses. These children will need one booster dose when the shortage is over.

- If the child is between 12 and 14 months and has not had any doses of Hib vaccine, schedule appointments for two doses, eight weeks apart.
- If the child is between 12 and 14 months old, and has received Hib vaccine but did not complete the primary series before turning 1 year old (i.e. had 1 dose of the Merck product OR 1-2 doses of the Sanofi product), schedule an appointment for 1 additional dose, a minimum of eight weeks from the last dose.
- If the child is 5 years old or older and has not received any Hib vaccine, Hib vaccine is not necessary.

All children at increased risk of Hib diseases should continue to receive the full series of Hib vaccine (including the booster dose) for whichever product they receive, including children with asplenia, sickle cell disease, HIV and certain other immunodeficiency syndromes, and malignant neoplasm's, as well as children who are American Indian/Alaska Native.

For questions, please contact CDC: 1.800.232.4636 or 1.800.CDC.INFO or www.cdc.gov/vaccines/about/contact/nipinfo_contact_form.htm.

FREE ● AAP Q&As on Vaccine Ingredients & the Childhood Immunization Schedule

Two AAP Q&As, one on Vaccine Ingredients and another on the Childhood Immunization Schedule provide succinct answers to popular questions many parents ask healthcare providers and are excellent handouts for distribution. The Q&A The Childhood Immunization Schedule: Why Is It Like That? addresses questions including: Why is the schedule "one size fits all?" Aren't there some children who shouldn't receive some vaccines? There are 25 shots recommended in the first 15 months of life; why not spread these out over 2 or 3 years? Isn't it overwhelming to a child's immune system to give so many shots in one visit?

The Q&A about Vaccine Ingredients, answers the questions: What ingredients are in vaccines? Do vaccines contain antifreeze? Do vaccines contain mercury? Should vaccines be "greener"?

To access the Q&A on Vaccine Ingredients, go to: <http://practice.aap.org/content.aspx?aid=2641&nodeID=4008>

To access the Q&A on the Childhood Immunization schedule, go to: <http://practice.aap.org/content.aspx?aid=2642>



The Great Avian Flu: soon, later...or never?

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Since its initial heightened press debut and subsequent crescendo-decrescendo pattern of public interest/response, avian flu outbreaks continue in different countries with potential threat of worldwide spread looming in the horizon. With other pressing matters capturing our attention, notably, stabilization of national and international markets and trade with all associated cost containment implications; avian flu epidemic awareness, preparedness and response may soon find itself in the back seat. However, the threat remains real; local and international government agencies continue to monitor and take active steps toward preparation but uncertainties remain.

The influenza virus is probably the most popular virus infecting humans. There are 3 types of influenza viruses: A, B and C. A and B are the main types responsible for the seasonal yearly flu epidemics. Unlike the other subtypes that are mostly contained to humans and exhibits minor genetic changes, Influenza A viruses are also found in different animals (ducks, chickens, pigs, whales, horses and seals) and undergo major genetic rearrangements or reassortments with potentially serious public health consequences. When reassortments occur, people are suddenly exposed to a new virus with limited or no protection. If the new virus demonstrates high pathogenicity-ability to cause severe disease and transmissibility – efficient spread, a pandemic is born. This phenomenon previously created the deadly pandemics of the twentieth century in 1918, 1947 and 1958 with estimated over 50 million deaths worldwide. Genetic reassortments between influenza A viruses in humans and birds has been implicated in the appearance of new pandemics of human influenza.

Influenza A (H5N1) virus – also called H5N1 virus – a commonly occurring influenza A virus subtype in birds, is one result of such reassortment. Of the hundreds of strains of avian influenza A viruses, only four are known to have caused human infections and only the H5N1 virus has caused by far the greatest number of severe disease and deaths in humans. Unlike our yearly and mostly expected influenza epidemic, an uncontained avian flu pandemic may simulate previous pandemics with global health, economic and other consequences.

While the H5N1 outbreaks became popular in 2003 following other events like SARS that received significant media coverage and generated public awareness, the first known human outbreak occurred in China in 1997 following previously recognized poultry outbreak. Since then, outbreaks have occurred typically following recognized or unrecognized outbreaks in wild and domestic livestock, spreading through close poultry-human contact, overcrowding and transportation across regions, states and continents. The human H5N1 infection has spread to 15 countries causing 251 deaths in 399 laboratory confirmed cases in Asia, Africa, the Pacific, Europe and the Near East with majority of cases and deaths in children and adults aged less than 40 years old. Indeed, H5N1 infections continue; the most recent cases reported as of January 19, 2009 occurred in a 2-year-old girl and 16-year-old male in China. There have been no reported human cases in North America.

Like previous pandemics with devastating consequences, the potential for worldwide

spread remains. However, in order for another pandemic to occur, H5N1 must continue to infect humans, cause serious illness and spread easily and sustainably among humans. While there have been rare reports of prolonged close contact spread, the Avian flu has yet to show evidence of easy and sustainable human to human spread. If and when it does, a pandemic will ensue.

Early identification and disease containment is the key to preventing another flu pandemic: to address this, there has been considerable joint efforts by major organizations including Centers for Disease Control and Prevention, World Health Organization, World Organization for Animal Health and other local and international collaborators towards the implementation of a streamlined and effective pandemic containment and response strategy that includes prompt identification, vaccine/antiviral stockpiles, and coordinated containment response across public health networks. Planning and response activities for individuals, families, schools, community and other organizations, healthcare providers, state and local government are also available on the pandemic flu planning and response webpage: <http://www.pandemicflu.gov/plan/index.html>

Other resources include the CDC Avian influenza response page <http://www.cdc.gov/flu/avian/outbreaks/cdcresponse.htm>

Vaccine Safety

The Rigors of Continuous Testing

All licensed vaccines are rigorously tested before and after licensure. They are held to the highest standards of safety by the US government and World Health authorities. Before being licensed, vaccines must complete three phases of clinical trials.

Pre-licensure Steps

Before an “agent” is considered for clinical trials, it is reviewed by the developer to determine whether it is safe enough to be tested further. Basic research and toxicities are reviewed for both safety and efficacy. If the product appears to be both safe and effective, the company submits an Investigational New Drug Application to the Food and Drug Administration (FDA). The FDA doesn’t necessarily allow clinical trials; they make ask for more information. If they decide it is safe and effective, it goes to the next level, clinical studies or trials.

Phase 1 – These involve small numbers of adults who are monitored very closely to see if this agent is safe and does its job? For vaccines, we’re very careful since generally, these are designed to be given to larger numbers of healthy people. If phase 1 results show safety and efficacy, the company proceeds to phase 2 trials.

Phase 2 Trials – Hundreds of people are enrolled; again they are very closely controlled and monitored for both safety

and efficacy. If these studies are promising, then phase 3 begins.

Phase 3 – involves thousands of people. For the rotavirus vaccine recently licensed, 70,000 children were studied to ensure safety and efficacy.

If the vaccine appears safe and it works, the company submits a Biologics License Application. The FDA reviews the application and visits the manufacturer; they often request more studies and more data. If the FDA licenses a product, they often request ongoing studies.

After licensure, the manufacturer conducts post-licensure investigations. Scientists at universities worldwide continuously monitor vaccines to see how well they are working. They look at disease incidence to see if it drop and they look for unanticipated side-effects.

Once vaccine is licensed, it is widely used. Safety continues to be monitored by 3 groups at the federal level:

VAERS (Vaccine Adverse Event Reporting System) – A passive reporting system that relies on families and physicians – and anyone who’s had an adverse event following immunization. It does not mean it was the vaccine that caused the adverse event. The age the patient received the

vaccine and what happened afterward is recorded. This reporting system was established in 1990. All physicians are mandated to report adverse events. These reports are monitored closely and if several similar reports appear, further studies are undertaken using the Vaccine Safety Datalink.

The Vaccine Safety Datalink Project was established in 1990. Eight large managed care organizations contribute data to the project. Data includes vaccine, date and concurrent vaccines, medical outcomes, birth and census information. This large database can be queried to test hypotheses generated by VAERS or by other reports.

The Clinical Immunization Safety Assessment (CISA) Network was established in 2001. This is a collaborative between the Immunization Safety Office, 6 medical research centers and American’s Health Insurance Plans. The research centers are Boston University Medical Center, Columbia University Medical Center, Johns Hopkins University, Northern California Kaiser Permanente, Stanford University and Vanderbilt University. The goals of the collaborative are to study adverse events, risk factors for developing adverse events and to determine whether there are genetic factors which increase risk for adverse events.

Source: Meg Fisher, MD, Chair, Department of Pediatrics, Medical Director, The Children’s Hospital at Monmouth Medical Center, Chair, Executive Committee, Section of Infectious Diseases, American Academy of Pediatrics



Vaccines Mandated for Jersey Sixth Graders

Information for parents on the new immunizations required for 6th graders; the New Jersey Department of Health’s guidance regarding immunization exemptions for religious and health reasons; and resources on the role of parents in improving their adolescent’s health, can be found on the website of the Statewide Parent Advocacy Network at <http://www.spannj.org/newvaccine.htm>.

Fact Sheet FOR Parents

“Too many vaccines? What you should know”, a new Q&A fact sheet for parents written by *The Vaccine Education Center (VEC)* of the Children’s Hospital of Philadelphia is available for free download and purchase. The fact sheet addresses parents’ concerns that too many vaccines might overwhelm a baby’s immune system. It is available in English and Spanish from the Children’s Hospital of Philadelphia’s Vaccine Education Center’s Webpage: www.chop.edu/vaccine. Click on “Order Educational Materials” then “Materials for Healthcare Professionals”.

What is the importance of giving Hepatitis B birth dose?

Q & A

The birth dose provides protection for the infant from HBV infection being transmitted from their mothers at the time of birth. Reporting and transcribing errors of maternal HBV testing or lack of maternal testing for HBV or lack of testing in late pregnancy in women at risk for HBV infection may result in unidentified pregnant women who are infected with HBV. Prevention based on risk rather than routine vaccination resulted in ongoing infections of HBV infection in children born to HBV infected mothers.

The birth dose also provides protection from HBV infection for infants after the perinatal period. In 2005 about 51,000 people in the US became infected with HBV and about 1.25 million people have chronic HBV infection. Each year about 3,000 to 5,000 people die from cirrhosis or liver cancer caused by HBV. About 30-40% of HBV infections acquired in the US are a result of childhood infections.

Routine HBV vaccination of US children was recommended in 1991. Since then the incidence of acute HBV among children and adolescents has decreased by more than 95%.

Sources: Patricia N. Whitley-Williams, MD, Professor and Interim Chair, Department of Pediatrics, UMDNJ-Robert Wood Johnson Medical School, One Robert Wood Johnson Place, MEB 306, New Brunswick, NJ 08903, Phone: 732-235-7900 Fax: 732-235-6102



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