**Practice Trends** PEDIATRIC NEWS • May 2007

#### POLICY æ PRACTICE

## Texas Legislators Bar Gardasil Mandate

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Texas lawmakers last month rejected Gov. Rick Perry's mandate that 11- to 12-yearold girls in the state be vaccinated against human papillomavirus before entry into the 6th grade. The legislature overwhelmingly approved a bill that bars the state from ordering the shots for at least the next 4 years. In February, Gov. Perry signed an executive order requiring the shots, but many legislators opposed the move, saying parents should decide whether to vaccinate against a sexually transmitted disease. The Texas Medical

Association (TMA) did not support the state mandate, even though "the science behind the HPV vaccine is strong and physicians are excited that this vaccine will prevent about 70% of cervical cancer cases and 90% of cases of genital warts," Dr. William Hinchey, TMA President, said in

#### **AAP Alarmed at Vaccine Prices**

The American Academy of Pediatrics said it is very concerned that the soaring costs of vaccines-combined with lower reimbursements from insurance companieswill lead to the underimmunization of U.S. children and unnecessary outbreaks of preventable diseases. The warning comes at a time when state legislatures are debating adding Gardasil, the new cervical cancer vaccine, to the list of vaccines required for schoolchildren. AAP noted in a statement released last month that pediatricians spend tens of thousands of dollars on vaccines and frequently must wait months before being reimbursed by payers. For example, RotaTeq, the vaccine against diarrhea-causing rotavirus, costs \$190 for the recommended three doses. Meanwhile, AAP said that payers are not recognizing the true costs of delivering

vaccines, which include the costs of ordering, storing, inventory control, insurance, and spoilage. Results from a national survey that AAP conducted in 2006 indicated that fewer than half of pediatricians think vaccine reimbursement is ad-

## **High-Deductible Plans Penalize Some**

medication are likely to suffer financially in health plans with high deductibles, according to a study from Harvard Medical School, Boston. The study also found that high-deductible plans penalize women and adults with any chronic condition by leaving them with far higher out-of-pocket health bills than those healthy men pay. Under the plans, patients must pay at least \$1,050 before their health coverage kicks in. In 2006, the 12.1 million children who took one or more prescription medications had median expenditures (both insurance and out of pocket) of \$1,305. "High-deductible health insurance penalizes anyone who's sick," said Dr. David Himmelstein, study coauthor and an advocate of a single-payer system.

## **Resources for Children Challenged**

Children will see their share of federal domestic spending and the gross national product decline by double digits over the next decade, according to a report from the nonpartisan Urban Institute. Federal resources for children are caught between ever-rising expenditures on adult health care and on retirement programs, and programs for children often lack provisions for automatic growth, the report said. As a piece of the federal domestic budget, spending on children will decline from more than 15% in 2006 to 13% in 2017, a nearly 15% drop, said economists Adam Carasso, Eugene Steuerle, and Gillian Reynolds. "Despite frequent rhetoric from policy makers on the priority given to children, the federal budget makes fairly clear that children are less of a priority and more of an afterthought in

# **SCHIP Benefits Adolescents**

When given health insurance through the state children's health insurance program (SCHIP), teenagers see their doctors more often, racial disparities are eliminated, and more preventive care is received, according to a study from the University of Rochester (N.Y.) Medical Center. The study, published in the April issue of Pediatrics, also found that teens received more counseling from their health care providers about guns, smoking, drugs, alcohol, and sexuality when receiving health insurance from SCHIP. "Adolescents have the worst access to health care among children," said Dr. Jonathan Klein, professor of adolescent medicine at the University of Rochester, who surveyed about 1,000 adolescents and their parents for the study. "The increase in access to a usual source of care and reduction of unmet needs are the most important finding[s] of this study. Getting access to care is key to adolescent health," Dr. Klein said in a statement. Authorization for SCHIP expires Sept. 30, and Congress currently is debating reautho-

Families with children taking even one

the budget process," they said.

rization.

Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) ActHiB®

Caution: Federal (USA) law prohibits dispensing without prescription.

Brief Summary: Please consult package insert for full prescribing information

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Miblications And USAGE ActHIB vaccine or ActHIB vaccine combined with Sanofi Pasteur Inc. DTP vaccine by reconstitution is indicated for the active immunization of infants and children? through 18 months of age for the prevention of invasive disease caused by Hindhenzae type b and/or diphtheria, tetanus, and perfussis.

TriHIBIt vaccine, AcHIBI vaccine combined with Tripedia vaccine by reconstitution, is indicated for the active immunization of children 15 to 18 months of age for prevention of invasive disease caused by Hindhenzae type b and diphtheria, tetanus

and pertussis.

Antibody levels associated with protection may not be achieved earlier than two weeks following the last recommended dose.

Only Sanofi Pasteur Inc. whole-cell DTP, Tripedia vaccine or 0.4% Sodium Chloride diluent may be used for reconstitution of lyophilized Actifile vaccine. TriHiBit vaccine, Actifile vaccine combined with Tripedia vaccine by reconstitution, should not be administered to infants younger than 15 months of age.

As with any vaccine, vaccination with Actifile vaccine reconstituted with Sanofi Pasteur Inc. DTP or Actifile vaccine reconstituted with Tripedia vaccine (TriHiBit vaccine) or 0.4% Sodium Chloride diluent may not protect 100% of individuals.

A single injection containing diphtheria, tetanus, pertussis, and Haemophilus b conjugate antigens may be more acceptable to parents and may increase compliance with vaccination programs. Therefore, in these situations it may be the judgment of the physician that it is of benefit to administer a single injection of whole-cell DTP or DTaP and Haemophilus b conjugate

Vaccines.

CONTRAINDICATIONS ACHIB VACCINE IS CONTRAINDICATED IN CHILDREN WITH A HISTORY OF HYPERSENSITIVITY TO ANY COMPONENT OF THE VACCINE AND TO ANY COMPONENT OF DTP OR Tripedia VACCINE WHEN COMBINED BY RECONSTITUTION WITH THESE VACCINES. ANY CONTRAINDICATION FOR DTP IS A CONTRAINDICATION FOR ACHIB VACCINE RECONSTITUTED WITH DTP. ANY CONTRAINDICATION FOR TRIPED VACCINE IS A CONTRAINDICATION FOR THIRDIR VACCINE, (ACHIB VACCINE RECONSTITUTED WITH Tripedia VACCINE.) (Refer to product inserts for Sanoti Pasteur Inc., whole-cell DTP and Timedia vaccine.)

VACCINE RECONSTITUTED WITH DTP ANY CONTRAINUIGATURE FOR THE PROBLEM TO A CONTRAINUIGATION FOR THE PROBLEM TO A CONTRAINUIGATION FOR THE PROBLEM THE PR

uearment with corticosteroids, alkylating drugs, antimetabolites or radiation.<sup>2</sup> (Refer to product inserts for Sandif Tasteur Inc. whole-cell DTP and Tripedia vaccine.)

TrillBit vaccine, AcHIB vaccine combined with Tripedia vaccine by reconstitution, should not be administered to infants younger than 15 months of age.

PRECAUTIONS GENERAL: Care is to be taken by the health-care provider for the safe and effective use of this vaccine. 
PEPICHPHIRINE INJECTION (1:1000) MUST BE IMMEDIATELY AVAILABLE SHOULD AN ANAPHYLACTIC OR OTHER ALLERGIC REACTIONS OCCUR DUE TO ANY COMPONENT OF THE VACCINE.

Prior to an injection of any vaccine, all known precautions should be taken to prevent adverse reactions. This includes a review of the patient's history with respect to possible sensitivity and any previous adverse reactions to the vaccine or similar vaccines, and to possible sensitivity to dry natural latex rubber, previous immunization history, current health status (see CONTRAINDICATIONS; WARNINGS sections), and a current knowledge of the literature concerning the use of the vaccine under consideration. (Refer to product inserts for Sandif Pasteur Inc. whole-cell DTP and Tripedia vaccine.)

The health-care provider should ask the parent or guardian about the recent health status of the infant or child to be immunized including the infant's or child's previous immunization history prior to administration of ActHIB vaccine, Sandif Pasteur Inc. DTP and Tripedia vaccine.

Minor illnesses such as upper respiratory infection with or without low-grade fever are not contraindications for use of ActHIB vaccine.

or Author Vaccine.\*

As reported with Haemophilus b polysaccharide vaccines.4 cases of H influenzae type b disease may occur subsequent to vaccination and prior to the onset of protective effects of the vaccine.5 (See INDICATIONS AND USAGE section.)

The evidence favors rejection of a causal relation between immuniza-tion with Hib conjugate vaccines and early-onset Hibit disease.6

Hib disease.§

Antigenuría has been detected in some instances following receipt of ActHIB vaccine; therefore, urine antigen detection may not have definitive diagnostic value in suspected H influenzae type b disease within 1 week of immunization.7

Special care should be taken to ensure that ActHIB vaccine reconstituted with Sanofi Pasteur Inc. DTP or Tripedia vaccine or saline dilluent (0.4% Sodium Chloride) is not injected into a blood vessel.

Administration of ActHIB vaccine reconstituted with Sanofi Pasteur Inc. DTP or ActHIB vaccine reconstituted with Tripedia vaccine (TriHIBIt vaccine) or saline diluent (0.4% Sodium Chloride) is not contraindicated in individuals with HIV infection.²

vaccine (infinity accine) of same unemit (U-4's South inchiner) is not contaminated in individuals with int inectioni-A separate, sterile syringe and needle or a sterile disposable unit should be used for each patient to prevent transmission of hepatitis or other infectious agents from person to person. Needles should not be recapped and should be properly disposed. Caution: The stopper of the diluent vial contains dry natural latex rubber which may cause allergic reactions. The lyophilized vaccine vial contains no rubber of any kind.

vaccine vial contains no rubber of any kind.

DRUG INTERACTIONS When Sanof Pasteur Inc. DTP is used to reconstitute ActHIB vaccine or Tripedia vaccine is used to reconstitute ActHIB vaccine (TrilliBit vaccine) and administered to immunosuppressed persons or persons receiving immunosuppressive therapy, the expected antibody response may not be obtained.

Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune response to vaccines. Short-term (<2 weeks) corticosteroid therapy or intra-articular, bursal, or tendon injections with corticosteroids bould not be immunosuppressive. Although no specific studies with perfussis vaccine are available, if immunosuppressive therapy will be discontinued shortly, it is reasonable to defer vaccination until the patient has been off therapy for one month; otherwise, the patient should be vaccinated while still on therapy.<sup>3</sup>

on therapy.<sup>3</sup>

If AcHIB vaccine reconstituted with Sanofi Pasteur Inc. DTP or AcHIB vaccine reconstituted with Tripedia vaccine [TriHIBit vaccine] has been administered to persons receiving immunosuppressive therapy, a recent injection of immunoglobulin or having an immunodeficiency disorder, an adequate immunologic response may not be obtained.

In clinical trials, AcHIB vaccine was administered, at separate sites, concomitantly with one or more of the following vaccines: DTP, DTaP, Poliovirus Vaccine Live Oral (DPV), Measles, Mumps and Rubella vaccine (MMR), Hepatitis B vaccine and occasionally Inactivated Poliovirus Vaccine (IPV), No imperiment of the antibody response to the individual antigens, diphtheria, tetanus and perfussis, was demonstrated when AcHIB vaccine was given at the same time, at separate sites, with IPV or MMRS in addition, more than 47,000 infants in Finland have received a third dose of AcHIB vaccine concomitantly with MMR vaccine with no increase in serious or unexpected adverse events.<sup>5</sup>

No significant Impairment of antibody response to Measles, Mumps and Rubella was noted in 15- to 20-month-old children who received TriHIBIt vaccine, ActHIB vaccine reconstituted with Tripedia vaccine, concomitantly with MMR. No data are available to the manufacturer concerning the effects on immune response of OPV, IPV or Hepatitis B vaccine when given concurrently with ActHIB vaccine reconstituted with 0.4% Sodium Chloride or Sanofi Pasteur Inc. DTP or ActHIB vaccine reconstituted with Tripedia vaccine (TriHIBIt vaccine).

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY ACHIB vaccine reconstituted with Sanofi Pasteur Inc.
DTP or ActriB vaccine reconstituted with Tripedia vaccine (TriHIBit vaccine) has not been evaluated for its carcinogenic
mutagenic potential or impairment of tertility.

midagenic potential or impairment of terruity.

PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with ActHIB vaccine reconstituted with Sanofi Pasteur Inc. DTP or ActHIB vaccine reconstituted with Tripedia vaccine (TriHBIR vaccine) or saline diluent (0.4% Sodium Chloride). It is also not known whether ActHIB vaccine reconstituted with Sanofi Pasteur inc. DTP or ActHIB vaccine reconstituted with Tripedia vaccine (TriHBIR vaccine) or saline diluent (0.4% Sodium Chloride) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ActHIB vaccine reorstituted with Tripedia vaccine (TriHBIR vaccine) or saline diluent (0.4% Sodium Chloride) is NOT recommended for use in a pregnant woman and is not approved for use in children 5 years of age or older.

PEDIATRIC USE
SAFETY AND EFFECTIVENESS OF TrIHIBIL VACCINE, ACHIB VACCINE RECONSTITUTED WITH Tripedia VACCINE, IN
INFAINTS BELOW THE AGE OF 15 MONTHS HAVE NOT BEEN ESTABLISHED. (See DOSAGE AND ADMINISTRATION Section.)
SAFETY AND EFFECTIVENESS OF ACHIB VACCINE RECONSTITUTED WITH Sanofi Pasteur Inc. DTP OR SALINE DILUENT
(0.4% SODUM CHLORIDE) IN INFAINTS BELOW THE AGE OF SIX WEEKS HAVE NOT BEEN ESTABLISHED.
(See DOSAGE AND ADMINISTRATION Section.)

See DOSAGE AND ADMINISTRATION section.)

ADVERSE REACTIONS More than 7,000 infants and young children (<2 years of age) have received at least one dose of

ActHIB vaccine during US clinical trials. Of these, 1,064 subjects 12 to 24 months of age who received ActHIB vaccine alone

reported no serious or life threatening adverse reactions.

TABLE 15

eported no senous or life threatening adverse reactions. Table 15

Percentage of Infants presenting with Local reactions at 6, 24, and 48 hours of immunization with
Achibe Vaccine administreed simultaneously, at separate sites, with Sanofi Pasteur Inc. DTP Vaccine

				AGE A	T IMMUNI	ZATION			
REACTION	2 Months Reaction % (N=365)		4 Months Reaction % (N=364)			6 Months Reaction % (N=365)			
	6 Hrs.	24 Hrs.	48 Hrs.	6 Hrs.	24 Hrs.	48 Hrs.	6 Hrs.	24 Hrs.	48 Hrs.
Local* Tenderness Erythema Induration	46.3 14.3 22.5	11.5 4.1 6.3	2.2 0.3 1.9	23.4 8.8 12.4	7.4 5.8 4.7	1.1 0.6 0.8	19.2 11.5 9.6	6.0 6.9 3.8	1.1 1.6 1.1

\*Local reactions were evaluated at the ActHIB vaccine injection site.

Adverse reactions commonly associated with a first ActHIB vaccine immunization of children 12 to 15 months of age who were previously unimmunized with any Haemophilus b conjugate vaccine, include local pain, redness and swelling at the injection site. Systemic reactions include lever, irritability and lethargy 5.8 in a US trial, safety of TriHIBH vaccine, ActHIB vaccine combined with Tripedia vaccine by reconstitution, in 110 children aged 15 to 20 months was compared to ActHIB vaccine given with Tripedia vaccine at separate sites to 110 children. All children received three doses of Haemophilus b conjugate vaccine (ActHIB vaccine or HibTITER®) and three doses of who cell DTP at approximately 2, 4, and 6 months of age.

TABLE 29
PERCENTAGE OF 15 TO 20-MONTH-OLD CHILDREN PRESENTING WITH LOCAL OR SYSTEMIC
REACTIONS AT 6, 24 AMD 48 HOURS OF IMMUNIZATION WITH THIRBIT VACCINE COMPARED TO ACHIB VACCIN

AND TRIPEDIA VACCINE GIVEN CONCOMITANTLY AT SEPARATE SITES							
	6 Hrs. P	ost-dose	24 Hrs. F	Post-dose	48 Hrs. Post-dose		
REACTION	Separate Injections*	TriHIBit vaccine	Separate Injections*	TriHIBit vaccine	Separate Injections*	TriHIBit vaccine	
Local Tenderness Erythema >1" Induration** Swelling	N=110 17.3/20.0 0.9/0.0 3.6/5.5 3.6/3.6	N=110 19.1 3.6 2.7 3.6	N=110 8.2/8.2 2.7/0.9 2.7/3.6 2.7/1.8	N=110 10.0 3.6 8.2 5.5	N=110 1.8/0.9 0.9/0.0 4.5/0.9 0.9/0.0	N=110 1.8 1.8 3.6 4.5	
Systemic Fever >102.2°F Irritability Drowsiness Anorexia Vomiting Persistent cry	N=103-110 0 27.3 36.4 12.7 0.9	N=102-109 2.0 22.9 30.3 9.2 1.8 0	N=105-110 1.0 20.9 17.3 10.0 0.9	N=103-108 1.9 17.6 13.9 6.5 1.9 0	N=104-110 1.9 12.7 12.7 6.4 0.9 0	N=103-109 0 10.1 11.0 2.8 2.8 0	
Unusual cry	l ŏ	l ő	l ň	Ιň	l ň	l ña	

In a randomized, double-blind US clinical trial, ActHIB vaccine was administered alone as a booster,

In a randomized, double-blind US clinical trial, ActHIB vaccine was given concomitantly with DTP to more than 5,000 infants
and Hepatitis B vaccine was given with DTP to a similar number. In this large study, deaths due to sudden infant death
syndrome (SIDS) and other causes were observed but were not different in the two groups. In the first 48 hours following
immunization, two definite and three possible seizures were observed after ActHIB vaccine and DTP in comparison with
none after Hepatitis B vaccine and DTPs This rate of seizures following ActHIB vaccine and DTPs was not greater than
previously reported in infants receiving DTP alone. (Relet to product insert for Sanoti Pasteur Inc. DTP, Other adverse
reactions reported with administration of other Haemophilus b conjugate vaccines include urricaria, seizures, hives, renal
failure and Guillain-Barré syndrome (GBS).<sup>53</sup> A cause and effect relationship among any of these events and the vaccination
has not been established.

has not been established. When ActHIB vaccine was given with DTP and inactivated poliovirus vaccine to more than 100,000 Finnish infants, the rate and extent of serious adverse reactions were not different from those seen when other Haemophilus b conjugate vaccines were evaluated in Finland (ie, HibTITER®, ProHIBIT®).

were evaluated in Finland (ie, HibTiTER®, ProHIBIT®),5
However, the number of subjects studied with TriHiBit vaccine, ActHIB vaccine combined with Tripedia vaccine by reconstitution, was inadequate to detect are serious adverse events.

DOSAGE AND ADMINISTRATION Parenteral drug products should be inspected visually for particulate matter and/or discontinuation of the administration, whenever solution and container permit. If these conditions exist, the vaccine should not be administered.

RECONSTITUTION: Using Sanofi Pasteur Inc. DTP, cleanse both the DTP and ActHIB vaccine vial rubber stoppers with a suitable germicide prior to reconstitution. Thoroughly augitate the vial of Sanofi Pasteur Inc. DTP then withdraw a 0.6 m.L does and inject into the vial of lyophilized ActHIB vaccine. After reconstitution and thorough agitation, the combined vaccine will appear whitish in color. Withdraw and administer 0.5 m.L dose of the combined vaccines intramuscularly. Vaccine should be used within 24 hours after reconstitution.

snounu be used witnin 24 nours after reconstitution. To prepare TriHIBIt vaccine, cleanse both the Tripedia vaccine and ActHIB vaccine vial rubber stoppers with a suitable germicide prior to reconstitution. Thoroughly agitate the vial of Sanofi Pasteur Inc. Tripedia vaccine then withdraw a 0.6 mL dose and inject into the vial of tyophilized ActHIB vaccine. After reconstitution and thorough agitation, the combined vaccines will appear whitish in color. Withdraw and administer 0.5 mL dose of the combined vaccines intramuscularly. Vaccine should be used immediately (within 30 minutes) after reconstitution.

A IMPROVED THE INTERIOR OF INTERIORS A CHEEN TECHNIQUE.

In gasline diluent (0.4% Sodium Chloride) cleanse the vaccine vial rubber stopper with a suitable germicide and inject entire volume of diluent contained in the vial or syringe into the vial of lyophilized vaccine. Thorough agitation is advis ensure complete reconstitution. The entire volume of reconstituted vaccine is then drawn back into the syringe before soling one 0.5 mL dose intramuscularly. The vaccine will appear clear and colorless. Vaccine should be used within 24 urs after reconstitution.

hours after reconstitution. Before injection, the skin over the site to be injected should be cleansed with a suitable germicide. After insertion of the needle, aspirate to ensure that the needle has not entered a blood vessel.

Do IN INJECT INTRAVENOUSLY.

Each dose of ActHIB vaccine reconstituted with Sanofi Pasteur Inc. DTP or ActHIB vaccine reconstituted with Tripedia vaccine (TriHIBIt vaccine) or saline diluent (0.4% Sodium Chloride) is administered intramuscularly in the outer aspect of the vastus lateralis (mid-thigh) or delibot. The vaccine should not be injected into the gluteal area or areas where there may be a nerve trunk. During the course of primary immunizations, injections should not be made more than once at the same site. When Actifity vaccine is reconstituted with Sandri Pasteur Inc. DTP; the combined vaccines are indicated for infants and children 2 through 18 months of age for intramuscular administration in accordance with the schedule indicated in Table 3.8 When Actifity accine; here combined vaccines are indicated in Table 3.8 to 18 months of age for intramuscular administration in accordance with the schedule in Table 3.8 to 18 months of age for intramuscular administration in accordance with the schedule in Table 3.8

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RECOMMENDED IMMUNIZATION SCHEDULE FOR ACHIBI VACCINE AND DITP OR TRIPEDIA VACCINE
LOD DESCRIPTION INVANCEMBET CHILDREN

DOSE	AGE	IMMUNIZATION
First, Second and Third	At 2, 4 and 6 months	ActHIB vaccine reconstituted with DTP or with saline diluent (0.4% Sodium Chloride)
Fourth	At 15 to 18 months	ActHIB vaccine reconstituted with DTP or with Tripedia vaccine (TriHIBit vaccine) or with saline diluent (0.4% Sodium Chloride)
Fifth	At 4 to 6 years	DTP or Tripedia vaccine

For Previously Unvaccinated Children
The number of doses of Haemophilus b Conjugate Vaccine indicated depends on the age at which immunization is begun. A
full of 10 11 amonths of age should receive 2 doses of Haemophilus b Conjugate Vaccine at 8-week intervals and a booster
dose at 15 to 18 months of age. A child 12 to 14 months of age should receive 1 dose of Haemophilus b Conjugate Vaccine
followed by a booster 2 months later.

reterm infants should be vaccinated according to their chronological age from birth. 10

erruption of the recommended schedule with a delay between doses should not interfere with the final immunity achieved th AcHIBI vaccine reconstituted with Sanofi Pasteur Inc. DTP or AcHIBI vaccine reconstituted with Tripedia vaccine (TriHIBI ciscine) or saline dillount (0.4% Sodium Chloride). There is no need to start the series over again, regardless of the time psed between doses.

sed between doses.

acceptable to administer a booster dose of TriHlBit vaccine, ActHIB vaccine reconstituted with Tripedia vaccine, wing a primary series of Haemophilus b conjugate and whole-cell DTP vaccines, or a primary series of a combination in containing whole-cell DTP.

STORAGE Store lyophilized vaccine packaged with saline diluent, Diphtheria and Tetanus Toxoids and Pertussis or Tripedia vaccine between 2° to 8°C (35° to 46°F). DO NOT FREEZE.

Journal Advertising References From Previous Page:

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1995;126:206-211-4. Granoff DM, Anderson EL, Osterholm MT, et al. Differences in the immunogenicity of three Haemophilius influenzae type b conjugate vaccine in infants. J Pediatr. 1992;121:187-194.

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-Jane Anderson