Continued from previous page

injury, and to guide them through the challenges of childhood. That requires a caring and helping nature, which—through constant communication—demonstrates that the child is not just a number or a billable E/M to you and your staff.

Remember that your staff members are critical allies in promoting your caring personality. Remind everyone that this is part of the job, and enforce it.

Then, minimize your risk. Communicate, communicate, communicate!

Tell the parent about your constant availability should there be any changes in the child's condition. Let the parent know when you expect a phone call to discuss an update on the illness. Better yet, you or a staff member should call the parents an hour before you asked them to call you. How better to get across that you care?

Keep a list of patients who have a worrisome illness, and be certain they don't fall through the cracks.

I am constantly amazed by the assumption that we physicians must be nearly perfect, whereas parents are allowed to be forgetful, to disregard medical advice, to overlook obvious problems. Yet, it's our fault if we don't pursue things to the nth degree!

Of course, it makes sense to counteract parental foolishness for the health and welfare of the patient alone, regardless of minimizing your liability risk. The fact that the goals are concordant is a plus.

But let me back up a bit to the beginnings of communication and the minimization of liability risk: The staff needs to be upbeat and pleasant when making appointments and greeting patients. Also, staff members should understand that their job does not include being a barricade to keep out unnecessary patients. If a parent truly wants to bring a child in, the staff should make the appointment. Remember that, quite possibly, the child may actually need your help!

Proper empathy toward an ill patient is important, with friendliness and helpfulness for sick and well patients alike. All of that communication occurs before you likely will even know the patient is scheduled to come in to the office unless you peruse the schedule in advance (which suggests you have loads of free time).

After the intake comes your all-important encounter. The first rule is to figuratively embrace the patient and parent.

What Do You Want to Know?

E FFICIENT PEDIATRICIAN PRACTICES wants to hear from you! What topics in practice management would you like Dr. Scott to address in the column? Do you want to hear about the ins and outs of hiring office personnel, or entry-level salaries for residents, or what's driving starting salaries?

Send your ideas by e-mail to pdnews@elsevier.com; by fax to 301-816-8738; or by regular mail to PEDI-ATRIC NEWS, 12230 Wilkins Avenue, Rockville, MD 20852.

Make them feel as though they are the most important part of your professional life and that you also personally take an interest in them. Hopefully, some part of that advice actually is true!

Do not rush the exam, even if you have a waiting room full of patients. The problem may be simple and straightforward to you, but it isn't to the parent; otherwise, they would not have come in. Sometimes we forget that our training and experience allow us to recognize the trivial nature of

You may need to change your approach. Speak slowly, stay seated, and ask whether there are any additional questions. You also should repeat treatment plans and any needed follow-up. All of these measures are important to show parents that their child is of utmost importance to you.

No matter how rushed you may feel, sit calmly and speak slowly. When you leave the room, open and shut the door slowly, and then run down the hall to the next chart. But never—absolutely never—give the patient the impression that you are rushed. Parents who feel you are not rushed are less inclined to become angry should outcomes not be optimal. Again, the better the communication and rapport with patients, the less chance there is of provoking parents.

Another critical part of making the patient and parents feel important is listening well. We have always been taught that if we let the parents speak, they likely will tell us the proper diagnosis. I have also been taught that we have two ears and one mouth, so we should listen twice as much as we talk!

In my next column, I will focus on specific techniques that help our practices and further enhance our relationships with our patients and their parents.

DR. SCOTT is in private practice in Medford, *N.J.*, and is a member of the PEDIATRIC NEWS Editorial Advisory Board.

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.

Brief Summary: Please consult package insert for full prescribing information.

INDICATIONS AND USAGE ActHIB® or ActHIB® combined with AvP DTP vaccine by reconstitution is indicated for the active immunization of infants and children 2 through 18 months of age for the prevention of invasive disease caused by H influenzae type b and/or diphtheria, tetanus, and pertussis.

TriHBit®, ActHIB® combined with Tripedia® by reconstitution, is indicated for the active immunization of children 15 to 18 months of age for prevention of invasive disease caused by H influenzae type b and diphtheria, tetanus, and pertussis. Antibody levels associated with protection may not be achieved earlier than 2 weeks following the last recommended dose. Only AvP whole-cell IDT, Tripedia® or 0.4% Sodium Chloride diluent may be used for reconstitution of lyophilized ActHIB®. TriHBIt®, ActHIB® combined with Tripedia® by reconstitution, should not be administered to infants younger than 15 months of age.

Now to minimal with a scaling with ActHIB® reconstituted with AvP DTP or ActHIB® reconstituted with Tripedia® (TriHIBit®) or 0.4% Sodium Chloride diluent may not protect 100% of susceptible 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 AcIHIB® IS CONTRAINDICATED IN CHILDREN WITH A HISTORY OF HYPERSENSITIVITY TO ANY COMPONENT OF THE VACCINE AND TO ANY COMPONENT OF THE VACCINE AND TO ANY COMPONENT OF DTP OR Tripedia® WHEN COMBINED BY RECONSTITUTION WITH HESE VACCINES. ANY CONTRAINDICATION FOR DTP IS A CONTRAINDICATION FOR ACHIB® RECONSTITUTED WITH DTP. ANY CONTRAINDICATION FOR TRIPEDIA®, (AcHIB® RECONSTITUTED WITH Tripedia®). (Refer to product inserts for AVP whole-cell DTP and Tripedia®. (AcHIB® RECONSTITUTED WITH Tripedia®). (Refer to product inserts for AVP whole-cell DTP and Tripedia®.) The Vaccine of the Vaccine

deficiency, hypogammaglobulinemia, or agammaglobulinemia; altered immune states due to diseases such as leukemia, lymphoma, or generalized malignancy; or an immune system compromised by treatment with corticosteroids, alkylating drugs, antimetabolities or radiation.² (Refer to product inserts for AVP whole-cell DTP and Tripedia®.) TriHIBI®, AcHIB® combined with Tripedia® by reconstitution, should not be administered to infants younger than

PRECAUTIONS GENERAL: Care is to be taken by the health-care provider for the safe and effective use of this vaccin

PRICACIONS GENERAL. Carle is to be taken by the inealincture provide not rise sate and energive use of this vaccine.

EPINEPHRINE INJECTION (1:1000) MUST BE IMMEDIATELY AVAILABLE SHOULD AN ANAPHYLACTIC OR OTHER ALLERGIC REACTION 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 AVP whole-cell OTP and Tripedia®.)

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®, AVP DTP and Tripedia®

Minor illnesses such as upper respiratory infection with or without low-grade fever are not contraindications for use of ActHIB®.3

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riu uisease.

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

Special care should be taken to ensure that ActHIB® reconstituted with AvP DTP or Tripedia® or saline diluent (0.4% Sodium Chloride) is not injected into a blood vessel.

Administration of ActHIB® reconstituted with AvP DTP or ActHIB® reconstituted with Tripedia® (TriHIBit®) or saline diluent (0.4% Sodium Chloride) is not contraindicated in individuals with HIV infection.

2

. 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

tion: The stopper of the diluent vial contains dry natural latex rubber which may cause allergic reactions. The lyophilized cine contains no rubber of any kind.

DRUG INTERACTIONS When AVP DTP is used to reconstitute ActHIB® or Tripedia® is used to reconstitute ActHIB® (TriHIBI®) and administered to immunosuppressed persons or persons receiving immunosuppressive therapy, the expected antibody response may not be obtained.

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 should not be immunosuppressive. Although no specific studies with pertussiv succine are available, if immunosuppressive therapy will be discontinued should, it is reasonable to defer vaccination until the patient has been off therapy for 1 month; otherwise, the patient should be vaccinated while still not herapy 3.

while still on therapy.³
If ActHIB® reconstituted with AvP DTP or ActHIB® reconstituted with Tripedia® (TriHIBit®) 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, ActHIB® was administered, at separate sites, concomitantly with 1 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 Impairment of the antibody response to the individual antigens, dibrheria, tetanus and perfussis, was demonstrated when ActHIB® was given at the same time, at separate sites, with IPV or MMR.⁵ In addition, more than 47,000 infants in Finland have received a third dose of ActHIB® concomitantly with MMR vaccine with no increase in serious or unexpected adverse events.⁵

Num for increase in serious or unexpected adverse events.*

No significant impairment of antibody response to Measles, Mumps and Rubella was noted in 15- to 20-month-old child who received TriHBIP®, AcHIB® reconstituted with Tripedia®, concomitantly with MMR. No data are available to the mar dacturer concerning the effects on immune response of OPV, IPV or Hepatitis B vaccine when given concurrently with AcHIB® reconstituted with 0.4% Sodium Chloride, or AvP DTP or AcHIB® reconstituted with Tripedia® (TriHBIP®).5

ActHIB® reconstituted with 0.4% Sodium Chloride, or AvP DTP or ActHIB® reconstituted with Tripedia® (TriHIBI®).5

As with other intramuscular injections, use with caution in patients on anticoagulant therapy.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY ActHIB® reconstituted with AvP DTP or ActHIB® reconstituted with Tripedia® (TriHIBI®) has not been evaluated for its carcinogenic, mutagenic potential or impairment of fertility.

PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with ActHIB® reconstituted with AVP DTP or ActHIB® reconstituted with Tripedia® (TriHIBI®) or saline diluent (0.4% Sodium Chloride). It is also not known whether ActHIB® reconstituted with AVP DTP or ActHIB® reconstituted with AVP DTP or ActHIB® reconstituted with AVP DTP or ActHIB® reconstituted with Tripedia® (TriHIBI®) or saline diluent (0.4% Sodium Chloride) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ActHIB® reconstituted with AVP DTP or ActHIB® reconstituted with Tripedia® (TriHIBI®) 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

EPDIATRIC USE

SAFETY AND EFFECTIVENESS OF TRIHIBINE, ACHIBINE RECONSTITUTED WITH Tripedian, IN INFANTS BELOW THE AGE OF

15 MONTHS HAVE NOT BEEN ESTABLISHED. (See DOSAGE AND ADMINISTRATION section.)

SAFETY AND EFFECTIVENESS OF ACHIBINE RECONSTITUTED WITH AVP DIP OR SALINE DILLUENT (0.4% SODIUM CHLORIDE), IN INFANTS BELOW THE AGE OF 6 WEEKS HAVE NOT BEEN ESTABLISHED. (See DOSAGE AND ADMINISTRATION

Section.)

ADVERSE REACTIONS More than 7,000 infants and young children (≤2 years of age) have received at least 1 dose of ActHIB® uning US clinical trials. Of these, 1,064 subjects 12 to 24 months of age who received ActHIB® alone reported no serious or life threatening adverse reactions.

no serious or life threatening adverse reactions.

Table 15

Percentage of infants presenting with local reactions at 6, 24, and 48 hours of immunization with achib® administered simultaneously, at separate sites, with avp DTP vaccine

AGE AT IMMUNIZATION									
REACTION	2 Months (n=365)			4 Months (n=364)			6 Months (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® injection site

Adverse reactions commonly associated with a first ActHIS® 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 fever, irribability, and lethary 5.8

In a US trial, safety of TriHIBit®, ActHIB® combined with Tripedia® by reconstitution, in 110 children aged 15 to 20 months was compared to ActHIB® given with Tripedia® at separate sites to 110 children. All children received 3 doses of

Haemophilus b conjugate vaccine (ActHIB® or HibTITER®) and 3 doses of whole-cell DTP at approximately 2, 4, and 6 months of age.

TABLE 2⁵

PERCENTAGE OF 15- TO 20-MONTH-OLD CHILDREN PRESENTING WITH LOCAL OR SYSTEMIC
REACTIONS AT 6, 24, AND 48 HOURS OF IMMUNICATION WITH THIHBI® COMPARED TO ACHHB®
AND TRIPEDIA® GIVEN CONCOMITANTLY AT SEPARATE SITES

	6 Hrs Post-dose		24 Hrs P	ost-dose	48 Hrs Post-dose		
REACTION	Separate Injections*	TriHIBit®	Separate Injections*	TriHIBit®	Separate Injections*	TriHIBit®	
Local Tenderness Erythema >1" Induration**	n=110 17.3/20.0 0.9/0.0 3.6/5.5	n=110 19.1 3.6 2.7	n=110 8.2/8.2 2.7/0.9 2.7/3.6	n=110 10.0 3.6 8.2	n=110 1.8/0.9 0.9/0.0 4.5/0.9	n=110 1.8 1.8 3.6	
Swelling Systemic	3.6/3.6 n=103-110	3.6 n=102-109	2.7/1.8 n=105-110	5.5 n=103-108	0.9/0.0 n=104-110	4.5 n=103-109	
Fever >102.2°F	0 27.3	2.0	1.0	1.9	1.9	0	
Drowsiness Anorexia	36.4 12.7	30.3 9.2	17.3 10.0	13.9 6.5	12.7 6.4	11.0 2.8	
Vomiting Persistent cry Unusual cry	0.9 0	1.8 0 0	0.9 0 0	1.9 0 0	0.9 0 0	2.8 0 0.9	

ITIPEGIA® INJECTION SITE/ACTHIB® INJECTION SITE.
*Induration is defined as hardness with or without swelling

"Induration is defined as hardness with or without swelling.

TriHBIR® ActHIB® combined with Tripedia® by reconstitution, was administered to approximately 850 children, aged 15 to 20 months. All children review 3 doses of a Haemophilus b conjugate vaccine (ActHIB® or HibTITER®) and 3 doses of whole-cell DTP at approximately 2, 4, and 6 months of age. Local reactions were bytically mild and usually resolved within 24 to 48 hour period after immunization. The most common local reactions were pian and tenderness at the injection site. Systemic reactions occurring were usually mild and resolved within 72 hours of immunization. The reaction rates were similar to those observed in Table 2 when TriHBIR® (ActHIB® reconstituted with Tripedia®) was administered and when Tripedia® was administered alone as a booster.§

In a randomized, double-blind US clinical trial, ActHIB® 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 2 groups. In the first 48 hours following immization, 2 definite and 3 possible seizures were observed after ActHIB® and DTP was not greater than previously reported in infants receiving DTP alone. (Refer product insert for APD DTP, Other adverse reactions reported with administration of other Haemophilus b conjugate vaccines include urticaria, seizures, hives, renal failure, and Guillain-Barré syndrome (GBS).^{3,9} A cause and effect relationship among any of these events and the vaccination has not been established.

When ActHIB® was given with DTP and inactivated poliovirus vaccine to more than 100,000 Finnish infants, the rate and

When ActHIB® 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 (i.e. HibTITER®, ProHIBT®).5

Towever, the number of subjects studied with TriHIBit®, ActHIB® combined with Tripedia® by reconstitution, was inadequate of detect rare serious adverse events.

DOSAGE AND ADMINISTRATION Parenteral drug products should be inspected visually for particulate matter and/or dis-coloration prior to administration, whenever solution and container permit. If these conditions exist, the vaccine should not

be administered.

RECONSTITUTION: Using Aventis Pasteur Inc. DTP, cleanse both the DTP and ActHIB® vial rubber stoppers with a suitable germicide prior to reconstitution. Thoroughly agitate the vial of AvP DTP then withdraw a 0.6 mL dose and inject into the vial of lyophilized ActHIB®. 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 within 24 hours after reconstitution.

To prepare TriHIBit®, cleanse both the Tripedia® and ActHIB® vial rubber stoppers with a suitable germicide prior to reconstitution. Thoroughly agitate the vial of AvP Tripedia® then withdraw a 0.6 mL dose and inject into the vial of lyoptical ActHIB®. 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.

auter reconstitution.

Using saline diluent (0.4% Sodium Chloride) cleanse the vaccine vial rubber stopper with a suitable germicide and inject the entire volume of diluent contained in the vial or syringe into the vial of lyophilized vaccine. Thorough agitation is advised to ensure complete reconstitution. The entire volume of reconstituted vaccine is then drawn back into the syringe before injecting one 0.5 ml. does intramuscularly. The vaccine will appear clear and colorless. Vaccine should be used within 24 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 NOT INJECT INTRAVENOUSLY.

DO NOT INJECT INTRAVENOUSLY.

Each dose of ActHIB® reconstituted with AvP DTP or ActHIB® reconstituted with Tripedia® (TriHBit®) or saline diluent (0.4% Sodium Chloride) is administered intramuscularly in the outer aspect of the vastus lateralis (mid-thigh) or deltoid. 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 ActHIB® is reconstituted with AvP 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 ActHIB® is reconstituted with Tripedia® (TriHBit®), the combined vaccines are indicated for children 15 to 18 months of age for intramuscular administration in accordance with the schedule in Table 3.8 TABLE 38

RECOMMENDED IMMUNIZATION SCHEDULE FOR ActHIB® AND DTP OR TRIPEDIA® For Previously Unvaccinated Children

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

The number of doses of Haemophilus b Conjugate Vaccine indicated depends on the age at which immunization is begundlift of 11 months of age should receive 2 doses of Haemophilus b Conjugate Vaccine at 8-week intervals and a boost 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 at 8-week intervals and a boost 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 at 8-week intervals and a boost followed by a booster 2 months later.

todes at 15 of 6 infinitions or agr. A chain 12 to 14 infinition age should receive 1 use of 1 hearing/initions to deploy a footbase 7 months later.

Preterm infants should be vaccinated according to their chronological age from birth. 10 interruption of the recommended schedule with a delay between doses should not interfere with the final immunity achieved with AcHIB9 reconstituted with Arib DTP or AcHIB9 reconstituted with Tippedia® (TriHBfte) or saline diluent (0.4% Sodium Chloride). There is no need to start the series over again, regardless of the time elapsed between doses. It is acceptable to administer a booster dose of TriHBfte (AcHIB9 reconstituted with Tripedia®) following a primary series of Haemophilus b conjugate and whole-cell DTP vaccines, or a primary series of a combination vaccine containing whole-cell DTP vaccines.

STORAGE Store lyophilized vaccine packaged with saline diluent, Diphtheria and Tetanus Toxoids and Pertussis or Tripedia® between 2°-8°C (36°-46°F). DO NOT FREEZE.

Journal Advertising References From Previous Page:

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