FALL '98 Volume 2.1

CT DPH IMMUNIZATION PROGRAM

NEW DRUG MANUFACTURER ENTERS PEDIATRIC VACCINE MARKET

N-Beltsville, Maryland-July 30, 1998 North American Vaccine announced that it has received approval from the U.S. Food and Drug Administration (FDA) to manufacture and market CERTIVA ™, a combined diphtheria, tetanus and acellular pertussis (DTaP) vaccine. The FDA approval of CERTIVA™ establishes North American Vaccine as the first independent vaccine manufacturer to clear the many hurdles required to enter the U.S. pediatric vaccine market in more than a decade and one of only a handful of FDA approved vaccine manufacturers for U.S. infants and children. Moreover, North American Vaccine becomes the first and only U.S.-based manufacturer of the acellular pertussis component used in combined DTaP vaccines.

Under the FDA approval, CERTIVA™ is indicated for active immunization against diphtheria, tetanus and pertussis in infants and children six weeks to seven years of age. CERTIVA™ will be marketed and distributed in the United States by the Ross Products Division of Abbott Laboratories, Inc. to private physicians and managed care markets, and by North American Vaccine to government purchasers, including state governments and the Centers for Disease Control and Prevention (CDC). This FDA approval, along with approvals for the European formulation of CERTIVA™ and other company products in select European countries, firmly establishes North American Vaccine as a long-term player in a rapidly expanding vaccine market. "We firmly believe that these approvals along with the over 15 other vaccines in our pipeline, will serve as a solid foundation from which the company will grow to become a recognized leader in the research, development, manufacturing and marketing of innovative vaccine products intended to prevent infectious diseases, improve the quality of life for children and adults, and lower total health care costs", stated Sharon Mates, Ph.D., President of North American Vaccine. The Connecticut Immunization Program, however has no plans to offer CERTIVA to our providers at this time. ■

SMITHKLINE BEECHAM'S *ENGERIX-B* VACCINE APPROVED FOR USE IN PATIENTS WITH CHRONIC HEPATITIS C INFECTION

S-Philadelphia, PA mithKline Beecham announced August 13,1998 that its *Engerix-B®,* Hepatitis B vaccine has been approved by the U.S. Food and Drug Administration (FDA) for use in individuals suffering from chronic hepatitis C infection. "It is important that people with hepatitis C get vaccinated against hepatitis B," said Raymond S. Koff, MD. chairman, department of medicine and chief of hepatology, MetroWest Medical Center. While hepatitis C patients are not more likely to contract hepatitis B than others exposed to the virus, if infected with hepatitis B, hepatitis C patients are at increased risk for acute liver failure, a severe form of infection that may lead to death." *Engerix-B®* is the first and only hepatitis B vaccine to be approved for use in patients suffering from hepatitis C. A consensus panel convened by the National Institutes of health has recommended that all hepatitis C virus-positive patients be vaccinated against hepatitis A and B.

Nearly four million Americans are infected with hepatitis C, a common infection that can lead to chronic hepatitis, cirrhosis, and liver cancer. Currently, an estimated 30,000 acute new infections occur each year: only 25-30 percent of those are diagnosed. Hepatitis C accounts for 20 percent of all cases of acute hepatitis. An estimated 8,000 to 10,000 hepatitis C deaths occur annually.

Like hepatitis B, hepatitis C is transmitted through blood and body fluids, intravenous drug use, close continuous contact with an infected person and sexual activity. The infection can also be transmitted from mother to child during birth. Hepatitis C is rarely cured and is the only currently approved anti-viral treatment which works in only about 10-20 percent of patients.

In a clinical trial of subjects with chronic hepatitis C, *Engerix-B* was administered in the usual 0,1,6 month schedule. All subjects responded with seroprotective titers. The most frequently reported side effect was swelling and redness at the site of injection. For more information on SmithKline Beecham visit their website at http://www.sb.com. N

INSIDE:

REGISTRY UPDATE......... 2

VACCINE UPDATE........... 2

NOTABLE ACHIEVEMENTS.............. 3

ASK THE EXPERTS.......... 4

98 MORBIDITY.................4

VACCINE UPDATE

VFC resolutions: *The Advisory Committee on Immunization Practices (ACIP) met on June 24-25 in Atlanta to discuss key issues regarding immunization policy. The following summarizes major outcomes of the meeting regarding childhood vaccines.*

Rotavirus

Several informational items were presented regarding the recently licensed rotavirus vaccine. An updated cost analysis which included estimates of adverse-event costs demonstrated relatively minor impact on the overall benefit to society favoring rotavirus vaccine use. Adverse events seem to be limited to fever, mostly post -dose 1, with 1-2% of recipients experiencing fever up to 39 degrees F occurring mostly on days 3-5 after the first dose. Laboratory surveillance data from multiple sites demonstrated a higher than expected prevalence of serotype 9 isolates: the implications for the tetravalent vaccine (which contains serotypes 1-4) are unclear at this time. Analysis of risk factors for hospitalization for viral gastroenteritis in children 1-11 months of age demonstrated that infants with low birth weight, those born to young or unmarried mothers, and those with Medicaid insurance are at higher risk of hospitalization. An informal policy analysis examining possible options for vaccination policy was also presented which supports a universal recommendation: a dissenting commentary from a representative from the American Academy of Family Physicians was also presented which focused on issues of disease importance and possible "mandatory" use of this vaccine. After full discussion, the ACIP endorsed the draft recommendation for universal use of rotavirus vaccine at 2,4, and 6 months of age, with all three completed by 1 year of age.

Highlights from National Immunization Conference
Atlanta, GA

The Connecticut Immunization Program received National recognition for having the highest immunization rates in the country. Dr. Orenstein, Director of the National Immunization Program, presented a plaque to Vincent Sacco, Program Supervisor acknowledging Connecticut's achievement. Connecticut tied two New England neighbors, Maine and Massachusetts with 87% coverage for the 4:3:1 primary childhood immunization series in the 1997 calendar year. The results were obtained from the National Immunization Survey, and cover 19-35 month-old children who were born between February 1994 and May 1996. The official data was printed in the July 10,1998 issue of *Morbidity and Mortality Weekly Report.* Connecticut is now only 3 percentage points away from reaching the Year 2000 goal of 90% coverage.

Rita Kornblum, Hartford IAP Coordinator delivered a presentation at a workshop entitled *Public/Private Coordination of Immunization Outreach for Infants at Risk.* The workshop essentially outlined the "Take Five" program started in Hartford to improve the on-time immunization rates of Hartford infants to 90% at ages 7 and 24 months. The program matches 5 at-risk infants with well-trained volunteer advocates who call and/or write new mothers reminding them to get their children vaccinated. They work with each family for 12-15 months. The preliminary results of the program show that the first 175 infants in the program have an on-time immunization rate 15-35% higher than the Hartford baseline. For more information, or to enroll a child in the program, call Rita Kornblum at the Hartford Health Department at (860) 547-1426 X7188.

Sue Gran, Danbury IAP Coordinator, and Patricia Reape from the Danbury VNA presented a workshop entitled, *Using a Mobile Health Van to Immunize Under-served Children*. This workshop served to describe strategies for developing and implementing community partnerships that promote disease prevention through immunization. A collaboration was initiated between the Danbury Immunization Program, the Danbury Health Department, the Danbury VNA and Danbury Hospital to implement a mobile health van. Launched in July 1997, "Wellness on Wheels" visits various community sites to provide immunizations, outreach, education, and clinical care to sick and will children. As a result of the health van, more than 200 children had been immunized.

Joan Christison-Lagay, Director of the Connecticut Immunization Registry and Tracking System, gave a presentation entitled *A Collaborative Program Between the Managed Care Industry and State Government Agencies to Improve Immunization Rates in the Under Two Population*. Her workshop described the advantages of collaboration between the managed care industry and a state centralized registry for ensuring timely immunization.

REGISTRY UPDATE

The State Immunization Program has been diligently preparing for the roll out of the statewide immunization registry. Recently, state registry personnel met with the software vendor contracted to provide the product and service to receive a demonstration of how the software will work and ask questions.

The surveys regarding computer capability and compatibility that were sent to all pediatric immunization providers in the state have started to come back. Soon the statistics from the surveys will be used to determine a starting point as well as the hardware needed on a per practice basis. Providers have begun to ask some valid questions about the Connecticut Immunization Registry and Tracking System. In response, registry personnel have put together the answers to some commonly asked questions.

What are the hardware requirements for running this application in my office?

- Pentium class PC
- 16 MB RAM for Windows 95 or 24 MB RAM for Windows NT
- 2 MB space on the hard drive for Thin Client or 500 KB space on hard drive for Web Browser /Java Client
- 28.8 KB modem

(Registry Update ctd.)

What will this software or access via the modem cost me?

There will be no cost for the software or access to the central database in Hartford.

What are the benefits of this software for my practice?

- Identify children who are behind in their immunizations
- Automatically generate follow-up reminder notices to parents of those children who are behind
- Immunization histories on patients who transfer from one practice to another resulting in fewer calls to previous providers
- Electronically print out immunization histories on school and daycare forms resulting in less time spent on manually filling out school and daycare forms
- If using the vaccine inventory module, the capability to electronically order vaccines from the state and report their inventory and doses administered based on the data entry of immunizations
- Decrease the risk of over immunization
- Determine the immunization coverage levels for their practice
- Generate pre-appointment reminders to parents for upcoming scheduled immunizations

How will my practice get connected to use the registry on-line?

From the Windows 95 or Windows NT desktop, an icon will be visible. By double clicking this icon, the application to dial up to the central registry will start. A login screen will appear where the practice will key in their user login identification and password a second time. This will bring the end user into CIRTS. The state is working towards only two login screens to ensure that only authorized users are accessing the registry. Presently, the system requires three login screens to run.

How will my practice get connected to use the registry through phone/fax back service?

The practice must have a touch-tone phone and a fax machine to use this interface. The practice will call the telephone number provided to use this service; the voice response unit will process the information prompting the call to enter in the necessary information after the call has been authenticated. The caller will be able to request the following reports:

- Immunization history
- Immunization recommendation
- Both of the above
- Immunization certificate school form
- Daycare form

The caller will be prompted to key in enough information to uniquely identify the child. The practice may request information on more than one child during any session. Once the caller is finished with this session, the voice response unit will break the connection. The system will process the request and will call the fax machine at the practice. Once the fax machine connection has been made, the requested reports will be faxed.

How will my practice know when they will be targeted to be connected?

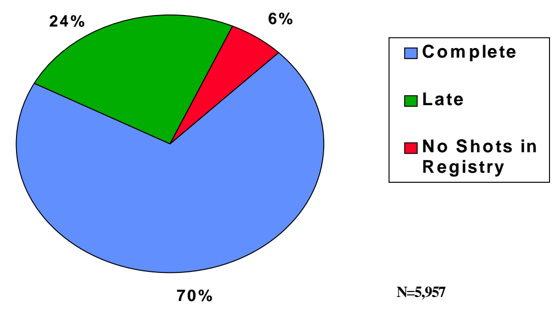
There will be an enrollment process. The enrollment packet will need to be completed and returned to the Department of Public Health. There will be several different types of enrollment information needed to set up the practice in the registry. There will be a section for information related to the practice including demographics about the practice, contact people and phone numbers, type of immunization schedule the practice uses for their patients, whether the practice wants to use reminder/recall, inventory tracking, type of access (on-line or fax back service), etc. There will be a section to be completed for each person actually running the system (end user). This will provide registry personnel with information to set up the proper access for the end user and determine the training needs of the practice. Once the practice has been set up in the new software, the practice will be called by a trainer and a scheduled appointment will be made for training to occur.

When will implementation begin and where?

The planned implementation schedule at this time based on delivery and system acceptance is to begin in Hartford in January 1999. After the Hartford area, the planned implementation is in the larger cities, most likely New Haven, Bridgeport, and Waterbury.

The following graph represents data collected using the CIRTS database. Individual providers will have the capability to generate this type of data in their own practice.

Immunization Status of Children Enrolled Medicaid Managed Care
Children born January 1, 1995 - December 31, 1995*
4DTP, 3Polio, 1 MMR, 2Hib, 2HepB @ 24 mos. of age**



* Preliminary data on Children continuously enrolled in Medicaid 11 of 12 months prior to 2nd birthdate

**Met HEDIS reporting requirements for Medicaid Managed Care

NOTABLE ACHIEVEMENTS

New London

Debra Frank visited Lawrence & Memorial's "Caring for your Baby" class. She gave a presentation on the importance of immunizations and answered several parents questions on immunization. She also distributed immunization literature and gave a brief discussion of CIRTS with sample copies of the CIRTS enrollment form. She showed the video, "BABY TALK- A vaccination message for parents" by Merck. Twenty-six parents were present. Parents were encouraged to call her at the New London Health Department with any further questions.

East Hartford

Carol Walsh has collaborated with the corporate headquarters of BIG Y grocery stores to have a printed immunization message from CDC's National Immunization Program appear on grocery bags. The slogan, "Don't Wait, Vaccinate!" along with an informational message and phone number to call for immunizations will be printed on the bags. This ad campaign will span both Connecticut and Massachusetts.

Naugatuck Valley

Kim Blount sponsored a Teddy Bear clinic at the Warsaw Park health fair. Children were able to bring in their stuffed animals for an exam to help alleviate fears. An immunization was part of the exam. After the exam, a rainbow pad was given to the child to serve as a medical record. Immunization coloring books were also distributed. Videos such as "Chickenpox- A Disease worth preventing", and "Protecting Our Kids Against Childhood Diseases Through Vaccination" were also playing throughout the fair hours. Approximately 350 people attended from the Valley.

Meriden

Kate Baker provided an immunization in-service at a local community church in Meriden. There were a variety of churches from the Meriden Health Ministries Association that participated.

New Haven

Carmen Valencia was interviewed on New Haven Public Access TV about childhood immunization. She discussed the services provided by the New Haven Health Department in addition to explaining the immunization schedule. This interview was parent oriented and geared toward the high risk population.

Middletown

Barbara Ricketts initiated a "school readiness" program in Middletown. Part of preparation for school entails making sure that children are up to date with their required immunizations. Barbara visited over 22 daycare centers in the area to identify children's immunization needs, and present appropriate educational materials to staff and parents to assist them in getting their child immunized on time for school.

♥ Ask the Experts ♥

Editor's note: This information is provided by the Centers for Disease Control and Prevention's National Immunization Program.

♥ ***Which vaccinations can be given to a pregnant health care worker?***
Inactivated vaccines (Td, hepatitis B, influenza, IPV) may be given to pregnant women if indicated. Pnemococcal vaccine should not be given to a pregnant woman or one who is trying to become pregnant.

♥ ***When giving two IM injections in the same limb, what is the minimum spacing between the two injection sites?***
The vaccines should be sufficiently separated (one or two inches) in the body of the muscle so that any local reactions are unlikely to overlap.

♥ ***Why are some vaccinations given subcutaneously while others must be given intramuscularly?***
In general, inactivated vaccines are administered intramuscularly (IM), and live virus vaccines are given subcutaneously (SC). Inactivated polio and pnemococcal vaccines may be given either SC or IM. Vaccines intended to be given IM may cause local reactions (such as irritation, induration, skin discoloration, inflammation, and granuloma formation) if injected into subcutaneous tissue. Response to the vaccine may also be reduced if not given by the recommended route.

♥ ***Which vaccines are contraindicated if a child is breast-feeding?***
Breast-feeding is not a contraindication to the administration of any vaccine, either to the mother or to the child.

♥ ***Some doctors do not vaccinate children with minor illnesses. Are minor illnesses a contraindication to vaccination?***
The ACIP, the AAP and the AAFP recommend that children with minor illnesses, with or without low-grade fever, should be vaccinated. Minor illness would include upper respiratory infections, most cases of otitis media, colds, and diarrhea. There is no consistent evidence that these minor illnesses interfere with response to the vaccine, or increase adverse events. Children with more serious illness should be vaccinated as soon as the illness resolves.

♥ ***We are finding that the personnel at our clinic are concerned about the liability issues if we don't ask for the parent's signature of consent when administering vaccines. Are signatures needed?***
Neither Federal law not the National Vaccine Injury Compensation Program require a signature as evidence of informed consent prior to administration of vaccines.

IMMUNIZATION TIPS FOR 98' SCHOOL ENTRY (CT)

DTP	Minimum of 4 doses with last dose on or after 4th birthday else a 5th dose is needed
Polio	Minimum of 3 doses with last dose on or after 4th birthday else an additional dose is needed
Pertussis TD (no	Children 7 years of age or older need only Pertussis component)
HiB	<60 mo.: 1 dose needed after 12 mo. of age >=60 mo. (5 yrs.) of age **no** HiB needed
Hepatitis B	3 dose series required for children born or after Jan. 1,1994
MMR	1 dose given after 1st birthday, 2nd dose of measles before entry to 7th grade

CONNECTICUT DEPARTMENT OF PUBLIC HEALTH, IMMUNIZATION PROGRAM
MORBIDITY REPORT

Disease	1/1/98-10/05/98	Total 1997
Measles	0	1
Mumps	0	1
Rubella	29	5
CRS (congenital rubella syndrome)	0	0
Diphtheria	0	0
Tetanus	0	0
Pertussis	34	36
Hib	1	3

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