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IMMUNIZATION ACTION PLAN

CT DEPT. PUBLIC HEALTH IMMUNIZATION PROGRAM

Commissioner: Joxel Garcia, M.D., M.B.A. *Governor: John G. Rowland*

IAP ON TIME

NEW COMBINATION VACCINE APPROVED FOR PROTECTION AGAINST TWO HEPATITIS VIRUSES

On May 11, the Food and Drug Administration (FDA) approved a new combination vaccine that protects individuals 18 years of age or older against diseases caused by the hepatitis A virus (HAV) and the hepatitis B virus (HBV). The vaccine, called Twinrix, combines two already approved vaccines, Havrix (Hepatitis A vaccine, Inactivated) and Engerix-B (Hepatitis B vaccine, recombinant) so that people at high risk for exposure to both viruses can be immunized against both at the same time.

For example, Twinrix is recommended for travelers who, due to certain behaviors or occupations, are at high risk for HBV, and are visiting countries where there is a high or intermediate rate of both HAV and HBV disease.

Areas with a high rate of both HAV and HBV include Africa, parts of South America, and most of the Middle East, South and Southeast Asia.

HAV infection can be contracted by ingestion of contaminated water or food. Travel to certain areas of the world with poor hygienic conditions or being in places where usual sanitary conditions have broken down, such as a flood region, can increase the risk of HAV infection. HAV infection may be symptomatic. However, symptoms occur more frequently in older age groups and typically include fever, malaise, and jaundice. Rarely, patients with HAV infection progress to liver failure and death

HBV infection is spread through contact with infected blood or other body fluids, through using contaminated needles or having unprotected sex with an infected person. Health care workers are also among those considered at risk. HBV infection may also be asymptomatic or result in similar symptoms to HAV infection. However a small number of HBV infection in adults result in chronic hepatitis leading to cirrhosis and liver cancer.

Clinical trials of Twinrix, given in a three dose series at 0-, 1– and 6 months, demonstrated that the combination vaccine was as safe and effective as the already licensed separate HAV and HBV vaccines.

SmithKline Beecham Pharmaceuticals, in Philadelphia, PA. will market and distribute Twinrix.

FDA ADVISORY PANEL URGES NOT TO APPROVE GLAXOSMITHKLINE VACCINE

While one combination vaccine has been approved another has been asked to submit further data before being licensed. The combination vaccine that would have dramatically reduced the number of injections a child would receive has been rejected by the FDA. A closely divided advisory panel to the FDA voted that the agency should not approve GlaxoSmithKline's Infanrix DTaP-Hepatitis B-IPV combination vaccine for infants. The proposed vaccine combines four already-approved infant vaccines with an as-yet unlicensed formulation of inactivated polio vaccine Availability of the combination would have cut from 20 to 9 the number of injection infants need in order to be up-to-date with their immunizations in the first 18 months of life. However, several panelists felt that the sponsor's studies containing more than 7,000 patients in the US and Germany were too small to conclusively support results suggesting that giving the 5-vaccine combination was just as effective at eliciting an immune response as giving its components separately. Experts were also troubled by pivotal trials that did not look at how the combination's overall immunogenicity might be affected by other vaccines on the immunization schedule. Other concerns included the lack of knowledge about how the vaccine will behave when given with the pneumococcal conjugate vaccine, Prevnar, and increased rates of fever in infant subjects who had received the 5-combination vaccine. In the company's largest trial, 43% of infants who received the combination vaccine developed fever within 4 days compared with 26% of infants who received sequential vaccinations. In the end, several panelists had asked the company to submit a new efficacy and safety trial with larger numbers and a greater ethnic diversity of patients. The largest trial in the company's series was performed in Germany, where more than 96% of the subjects were Caucasian. Those numbers had some experts questioning how the vaccine would function in a more genetically diverse US population.

IOM COMMITTEE REJECTS CAUSAL RELATIONSHIP BETWEEN MMR AND AUTISM

At a public briefing on Monday, April 23, the Institute of Medicine's (IOM) Committee on Immunization Safety Review released a report in which they reject a causal relationship between the measles-mumps-rubella (MMR) vaccine and autism spectrum disorder, commonly known as autism. The committee concluded that:

- The epidemiological evidence shows no association between MMR and autism;
- Case studies based on small numbers of children with autism and bowel disease do not provide enough evidence to draw a conclusion about a causal relationship between these symptoms and administration of the vaccine
- Biological models linking MMR and autism are "fragmentary"

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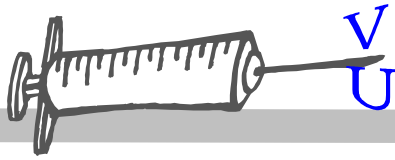
- There is no relevant animal model linking MMR and autism.

Therefore, the committee recommended maintaining the current policies relating to licensure and administration of the MMR vaccine in the Untied States. The committee chair, Marie C. McCormick, M.D., Sc. D., professor of maternal and child health at the Harvard School of Public Health, stated at the briefing that while no vaccine is 100% safe, the MMR vaccine is "as safe as a vaccine can get."

The committee reviewed published and unpublished material, and also heard testimony from a variety of witnesses, including Dr. Andrew Wakefield, the author of a well-publicized study published in the Lancet in 1998. This study seemed to indicate that the onset of autism and gastrointestinal problems were associated with the receipt of the MMR vaccine. Dr. McCormick noted that the Wakefield study was published as an observation for further investigation and never claimed to prove the relationship. She further noted that the committee reviewed numerous studies that examined Wakefield's hypothesis and were unable to find evidence to support it.

Current research on autism has established that there is a strong genetic component to the disease, however the committee report notes that other factors, including infectious, neurologic, metabolic, immunologic, and environmental insults, may play significant roles." Therefore, although the committee felt that a relationship between MMR vaccine and autism would be extremely rare, if it occurred at all, they recommend that research to examine this possible relationship continue.

The IOM's Committee on Immunization Safety Review was convened in fall 2000 to provide an independent review and assessment of increasingly prominent vaccine safety concerns. It will examine nine vaccine-safety hypotheses over the next three years. The 15 committee members have expertise in pediatrics, internal medicine, immunology, neurology, infectious diseases, epidemiology, biostatistics, public health, risk perception, decision analysis, nursing, genetics, ethics, and health communications. To prevent any perception of conflict of interest, anyone with financial ties to vaccine manufacturers or their parent companies, and anyone who had served on vaccine advisory committees, provided expert testimony, or published papers on issues of vaccine safety are excluded from participating on the committee.



VACCINE UPDATE

DTaP

Beginning with June's vaccine orders, the State Immunization Program switched over to preservative-free Tripedia (manufactured by Aventis Pasteur) which comes packaged in ten single-dosed vials per box. We will also continue to supply Infanrix (manufactured by Glaxo SmithKline), which is also thimerosal-free. As a reminder, whenever possible, the same brand of DTaP vaccine should be used for all doses of the vaccination series.

Finally, many providers have seen their DTaP orders reduced from what they had originally ordered. Providers should keep in mind that we are limiting each provider to a 2 month supply of DTaP based on their previous month's usage and current inventory. The Centers for Disease Control and Prevention (CDC) is limiting the amount of DTaP each state can have in their inventory so with a limited supply we need to make sure every provider has at least some DTaP on hand. We anticipate that the DTaP supply will improve in the coming months.

Hepatitis A

A working group on Hepatitis A has been formed among members of the infectious Disease Division of the state health department to deal with an increase in the reported number of cases of the disease, especially in New Haven County. Since the beginning of the year, 39 cases of Hep. A have been reported amongst males 18 years of age and older, compared to just 20 cases reported all of last year. New Haven county has seen a 300% increase in Hep. A (18 cases in 2001 from just 6 in 2000). Many of these cases are occurring in the MSM (men who have sex with men) population. A meeting with members of the New Haven Health Department, DPH staff, the Hartford Gay & Lesbian Health Collective, and community based organizations in the New Haven area was held to address the issue and formulate a plan to vaccinate high risk individuals.

Varicella

Since varicella (chickenpox) became a vaccine reportable disease on January 1, 2001, nearly 500 cases have been reported to the Immunization Program. All day care providers, schools, physicians, and local health departments are required to report any case of varicella.

Hepatitis B

Since the Regulations of the State of Connecticut were changed to require proof of immunity against hepatitis B for entry into 7th and to 8th grade, several new regimens for hepatitis B vaccination of adolescents have been approved by the FDA. These regimens are either compressed in time (3 doses over 4 months) or require fewer doses (2 doses of adult formulation instead of 3 doses of formulation for children). In addition, with a complete series of hepatitis B vaccinations now required for entry into 8th grade, the timing between doses of the vaccine has generated a considerable amount of interest. After consulting with several individuals at the Centers for Disease Control and Prevention (CDC), new guidelines have been established with regards to what should be considered adequate vaccination for school entry for adolescents. These guidelines supercede Section 10-204a-2g(3a) of the school immunization regulations until such time that the regulations can be modified.

Any adolescent student shall be considered adequately protected against hepatitis B if that individual was:

1. Immunized with **at least 21 days** spacing between doses 1 and 2, **at least 2 months** spacing between doses 2 and 3, and **at least 4 months** spacing between doses 1 and 3.

1. Immunized between the ages of 11-15 years old with Merck's 2 dose adolescent hepatitis B vaccine (brand name: RecombivaxHB, 10 mcg), with the two doses spaced at least 4 months apart. Documentation of the brand name and dosage must be submitted for this regimen to be considered complete for school entry purposes.

Td

A shortage of tetanus and diphtheria toxoids (Td) and tetanus toxoid (TT) in the United States has resulted due to one of two manufacturers discontinuing production of tetanus toxoid-containing products.

Aventis Pasteur is the only major manufacturer of tetanus and Td in the US. In response to the shortage, Aventis has increased production of Td to meet national needs: however, since 11 months are required for vaccine production, the shortage is expected to last for the remainder of 2001. To assure vaccine availability for priority indication, all routine Td boosters in adolescents and adults should be delayed until 2002. Td use should follow exiting recommendation for all other indications, which include 1) persons traveling to a country where the risk for diphtheria is high; 2) persons requiring tetanus vaccination for prophylaxis in wound management; 3) persons who have received fewer than 3 doses of any vaccine contain-

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ing Td; and 4) pregnant women who have not been vaccinated with Td during the preceding 10 years. The complete text of this notice is available online at www.cdc.gov/mmwr//preview/mmwrhtml/mm5020a8.htm

TWO NEW IAP SITES ADDED

The IAP Program is expanding. Bristol-Burlington Health District and East Hartford Health Department have been added to the existing sites to bring the total to 18 IAP sites strategically situated in areas of the state considered to be at risk for under-immunization. Each IAP site has been contracted by the State Health Department to: (1) improve immunization coverage by convening an immunization advisory meeting with members of the community, collect and maintain referrals of children at risk for being late with immunizations, and conduct outreach (2) conduct educational outreach activities for the general public to increase awareness of the importance of early childhood immunization, (3) perform immunization assessments of public immunization providers in the community to determine the immunization rate for the practice and monitor compliance with standards of pediatric immunization practice, and (4) assist in the statewide implementation of the CIRTS immunization registry. The addition of these two sites will facilitate a broader network of immunization outreach to Connecticut's under-served population.

REGISTRY UPDATE

Since the rejection of the preferred vendor's registry software, State Immunization Registry personnel have been fine tuning the existing CIRTS system. In the near future, staff will be upgrading current software to give more accessibility to end-users. The Remote Application Manager, which allows access to CIRTS will be replaced with new clients on the remote end users PC. In addition to allowing more providers to access the system, providers will now have a local number to call instead of an 800 number resulting in NO busy signals and no denied access while other operations are performed. This upgrade will allow individual practices/clinics who are already on-line with CIRTS to generate state Health Assessment Record forms for school, day care and camp (i.e. "blue forms" needed for school entry). All three forms will have the immunization history of the child printed in the appropriate place on the form.

In 1998, all children born in the state of Connecticut were enrolled into CIRTS. By now, these children should have completed their primary series of vaccinations. CIRTS can generate, upon request, customized immunization rate reports for this birth cohort for any individual practice/clinic.

School Immunization Survey-Statewide

Results from the 2000-2001 retrospective school survey are complete and show the overall statewide immunization rate for 4:3:1 (4 doses of DTP, 3 doses of polio, and 1 dose of MMR) at 24 months of age is **86.8%**, and increase of nearly 5% from last year's figure. The retrospective study is compiled from an audit of 25 records at 40 randomly selected kindergartens throughout the state.

Connecticut Participates in Nationwide Study

Connecticut is one of 9 states nationwide that have special surveillance systems for invasive, culture-confirmed pneumococcal disease that will be participating in a CDC-coordinated case-controlled study to be conducted over the next 2-3 years . Cases will involve children 3 to 59 months of age with invasive pneumococcal disease, whose isolates are routinely reported to the Connecticut Department of Public Health. Controls will be randomly selected from the DPH birth registry and matched according to date of birth and mothers zip code at the time of birth. The Connecticut portion of the study is being done jointly by DPH and Dr. Eugene Shapiro and Dr. Marietta Vazquez of the Yale University School of Medicine. This study has been approved by institutional research boards at the Centers for Disease Control and Prevention, the Connecticut DPH and Yale University.

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Meningococcal Vaccine Required For College Students Residing On Campus

On June 6th, Governor Rowland signed into law, a bill requiring all college students living in on-campus housing to be vaccinated against meningitis.

The new law, which will apply to all public and private colleges and universities will be in effect for the 2002-2003 school year, and each year thereafter. Students must show proof of immunization with meningococcal vaccine or (1) present a certificate from a physician stating that , in the opinion of such physician, such vaccination is medically contraindicated because of the physical condition of such student, or (2) present a statement that such vaccination would be contrary to the religious beliefs of such student.

In addition to the vaccine requirement, all Connecticut schools of higher education will be required to (1) provide information about meningitis to all prospective students prior to their matriculation and include with that information notice of the availability and benefits of a meningitis vaccine, and (2) develop procedures for receiving and keeping a record of student vaccination status.

Recent studies have shown college freshmen who live in dormitories to be at a moderately increased risk of meningitis relative to other people their age in the general population. More detailed information can be found at www.cga.state.ct.us under bill #5675.

CDC's
Live Satellite Broadcast,

Immunization Update

September 20, 2001

Call the State Immunization Program for the location nearest you
(860) 509-7929
(Continuing education credits offered)

DEPARTMENT OF PUBLIC HEALTH
IMMUNIZATION PROGRAM
MORBIDITY REPORT

Disease	1/1/01-6/30/01	Total 2000
Measles	1	0
Mumps	0	3
Rubella	0	1
Congenital Rubella Syndrome	0	0
Diphtheria	0	0
Tetanus	0	0
Pertussis	14	50
Hib	0	0
Varicella	~500	N/A

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