

miniupdate

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TO: Medical Directors, Community-Based Clinics
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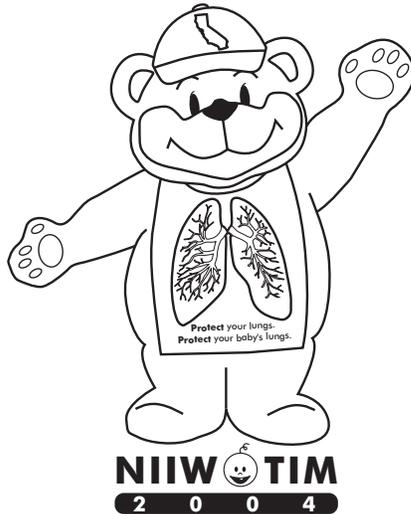
April 10, 2004

FROM: Howard Backer, MD, MPH, Acting Chief
Immunization Branch



Below for your information and reference is an abbreviated copy of the Immunization Branch's bimonthly UPDATE memorandum. The edited version contains medical and technical information on immunization and vaccines. We hope it is helpful. If you have questions on immunizations, please contact the Immunization Coordinator at your local health department.

2004 National Infant Immunization Week April 25–May 1



2004 Flu Vaccine Includes A/Fujian

On March 17, 2004, the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) adopted World Health Organization (WHO) recommendations for the composition of the influenza vaccines for the 2004-2005 influenza season. Both bodies recommend that these vaccines utilize seed strains similar to two influenza A viruses, A/New Caledonia/20/99 (H1N1) and A/Fujian/411/2002 (H3N2), and one influenza B virus, B/Shanghai/361/2002. Of these three, only the type A/New Caledonia-like H1N1 strain was included in the 2003-04 influenza vaccine. A/Fujian virus caused the majority of influenza in the US during the 2003-04 season, but was absent from the vaccine because of difficulties in obtaining a seed strain in time for production.

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DISEASE ACTIVITY AND SURVEILLANCE

The surveillance data reviewed in this section are reported in Table 1 on page 2. The table includes a provisional number of cases of CRS, Hib, Hepatitis A, Hepatitis B, measles, pertussis, rubella, and tetanus reported with

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onset in 2004 (as of February 29, 2004). For comparison, the numbers of cases reported with onset in 2003 (as of February 28, 2003) are included. For details on reported cases in 2004 to date, please contact Alan Chan at (510) 540-2118 or AChan2@dhs.ca.gov.

Reporting of Hospitalized Varicella Cases

Letters have been sent to local health departments and to hospitals requesting that hospitals report hospitalized cases of varicella to their local health departments. Cases to be reported include those with a primary or secondary diagnosis of varicella, not cases of hospitalized herpes zoster (shingles). It is important for prevention and control efforts to characterize hospitalized varicella cases and related complications. The California Conference of Local Health Officers (CCLHO) Disease Control and Prevention Committee supports the recommendation to implement case-based surveillance for hospitalized varicella cases.

In November 2001, California's disease reporting regulations (Title 17, CCR, §2500) were amended to include the immediate reporting of varicella deaths as a means of improving the state's bioterrorism preparedness. One death was reported in 2002. Using rates derived from the

Antelope Valley California Varicella Project, we estimate that approximately 97,000 varicella cases currently occur each year in California and that of these, approximately 230 cases are hospitalized.

ASSESSMENT ACTIVITY

Going Up: California Childhood IZ Coverage

The most recent National Immunization Survey (NIS) results, for the period July 2002 through June 2003, show that California immunization coverage rates for surveyed children (19-35 months) continue to rise. For the state as a whole, every indicator measured by the NIS is higher than the 2001-2002 NIS results. The latest results show California immunization levels exceeded 90% for all antigens except varicella (85.6%) and fourth dose of DTaP (83.5%). The full series 4:3:1:3:3:1 coverage is more than 72%, and our 4:3:1 coverage has edged above 80% for the first time! Results for all antigens are present in Table 2.

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Table 1: Reported Cases with Onset in 2004, by Age Group and Incidence of Selected Vaccine Preventable Diseases California, 2004 (Provisional – as of 2/29/04)

DISEASE	Age Groups			Age Unknown	All Ages	
	0-4 yrs	5-17 yrs	18+ yrs		Cases	Rate ¹
Congenital Rubella Syndrome	0	0	0	0	0	0.0
<i>H. influenzae</i> , type B (Hib) ²	0	0	1	0	1	0.0
Hepatitis A	3	12	73	0	88	0.2
Hepatitis B	0	0	57	0	57	0.2
Measles ³	1	1	0	0	2	0.0
Pertussis	11	4	4	9	28	0.1
Rubella ³	0	0	0	0	0	0.0
Tetanus	0	0	0	0	0	0.0

¹ Incidence Rate = cases/100,000 population

² *H. influenzae* is reportable only for cases ≤30 years

³ Confirmed cases only

Source: California Department of Health Services, Immunization Branch

Prepared by California Department of Health Services, Immunization Branch

Table 2: California Immunization Levels, by Vaccine or Series Among Children 19-35 Months of Age

Antigen(s)	HP 2000/2001 Goal	CA 2001-2002	CA 2002-2003	US 2002-2003
3+DTaP	90%	92.4% ±2.6	96.1% ±2.1	96.0% ±0.5
4+DTaP	90%	79.2% ±3.6	83.5% ±3.4	83.2% ±0.9
3+Polio	90%	88.8% ±2.9	92.3% ±2.3	91.0% ±0.7
1+MMR	90%	91.4% ±2.7	91.7% ±2.5	92.6% ±0.6
3+Hib	90%	90.2% ±2.8	92.5% ±2.6	93.7% ±0.6
3+HepB	90%	87.3% ±3.0	90.6% ±2.7	91.9% ±0.7
1+Var	90%	84.7% ±3.3	85.6% ±3.2	82.5% ±0.9
4:3:1 ¹	80%	76.2% ±3.7	80.7% ±3.6	80.7% ±0.9
4:3:1:3:3:1 ²	80%	N/A	72.3% ±3.9	69.7% ±1.0

¹ 4+DTaP, 3+Polio, 1+MMR

² 4+DTaP, 3+Polio, 1+MMR, 3+Hib, 3+HepB, 1+Varicella

Source: National Immunization Survey

Prepared by: California Department of Health Services

No statistically significant disparity was found between White and Hispanic children. Rates for Asian children on 4+DTaP and 3+HepB are significantly higher than for White and Hispanic children. Comparisons could not be made for African American or Native American children, due to the small sample for these two groups.

California NIS rates are statistically equivalent to national rates. Compared to other states, California is 14th overall on 4:3:1:3:3:1 coverage, and 28th overall on 4:3:1 coverage, but these numbers do not tell the full story. In fact, only three states have statistically significant higher 4:3:1:3:3:1 coverage, and only six states have statistically significantly higher 4:3:1 coverage than California.

Los Angeles County shows a significant increase from last year: 85% for 2002-03, up from 76% in 2001-02, while San Diego and Santa Clara Counties' 4:3:1 rates remained stable. However, as reported in the February UPDATE, San Diego County's own Random Digit Dial survey, which uses nearly identical methods as the NIS survey but samples larger numbers with multilingual interviewers, estimates their 4:3:1 coverage rates as considerably higher (89% vs. 77%). Complete IAP estimates are available from the National Immunization Program website, www.cdc.gov/nip/coverage.

IMMUNIZATION SERVICES

Recall of Human Rabies Vaccine and Patient Prophylaxis

Aventis Pasteur just announced that it is recalling four lots of rabies vaccine that were distributed in the U.S. The four recalled lots (Imovax®) and expiration dates are: X0667-2 6/24/2006, X0667-3 6/24/2006, W1419-2 12/6/2005, W1419-3 12/6/2005. Although these four lots passed testing to confirm the absence of live virus, Adventis Pasteur acknowledges a theoretical possibility that persons who received vaccine from a recalled lot could have been exposed to the non-inactivated virus. They were produced at the same time as a lot found to contain the live virus. Any patients who received vaccine from the recalled lots should receive treatment equivalent to post-exposure prophylaxis, similar to published guidelines at www.cdc.gov/ncidod/dvrd/rabies/professional/publications/ACIP/ACIP99.pdf.

Aventis has posted a set of Rabies Recall recommendations at www.vaccineshoppe.com and a special toll-free number, 1-800-835-3587. The FDA recall notice is available at: www.fda.gov/cber/recalls/rabave040204.htm.

Measles Immunization and International Travel

Measles remains endemic in many countries and presents a significant threat to persons who live in or visit these areas. Standard immunization schedules recommend immunization with a measles containing vaccine (commonly MMR) at 12 months of age; however, measles vaccine should be given to infants aged 6–11 months before travel outside the U.S. to a measles-endemic country, preferably 10 days before departure. Children who receive an early measles vaccine should be reimmunized at 1 year and 4–6 years of age, as per the standard immunization schedule. International travelers over 12 months of age who do not have a history of disease should have two documented doses of a measles-containing vaccine such as MMR prior to travel. Any patient with unknown etiology rash-illnesses, especially accompanied by fever, should be promptly isolated in a health care facility until a definitive diagnosis is made. Further recommendations on measles immunization are available at www.cdc.gov/travel/diseases/measles.htm.

VACCINE RISKS AND BENEFITS

Triumphs and Possible Limitations of Immunization Against Varicella

A recent article from CDC reviewed the decreased incidence of varicella associated with immunization in Illinois, Michigan, Texas, and West Virginia. (*MMWR* 2003 Sep 19;52:884-5). The incidence of varicella in all four states was stable from 1990-1994 before immunization began. Compared with this baseline, varicella had decreased by 67%-82% in 2001, corresponding with a steady increase in vaccination coverage. States that implemented child care or school entry requirements sooner had higher vaccination coverage. These findings are consistent with ongoing data from three active surveillance sites nationwide monitored by CDC (*JAMA* 2002;287:606-611), one of which is in collaboration with Los Angeles County Department of Health Services (LACDHS). An abstract from Dr. Civen and colleagues at LACDHS indicates that the incidence of Herpes Zoster (shingles) declined at this surveillance site during a period of increased immunization coverage between 2000 and 2002 (IDSA 2003 Meeting, Poster 896, Page 140 in www.journals.uchicago.edu/IDSA/2003Abstracts/Posters.pdf). In a bizarre development, a former colleague of this surveillance team published, without authorization, 3 articles with a conflicting interpretation of the incidence of zoster (*Vaccine* 2003 Oct;21:4238-55).

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One of the serious complications of varicella occurs when chickenpox lesions are infected with bacteria such as streptococcus. Patel and colleagues described the rate of invasive group A streptococcus (GAS) infections at Children's Memorial Hospital in Chicago from 1993-2001 (*Journal of Pediatrics* 2004 Jan;144:68-74.) Although there was no change in hospitalization rates for invasive GAS infections during the study period, the percentage of hospitalizations for GAS that were associated with chickenpox decreased from 27% in the pre-vaccine era (1993 to 1995), to 16% during vaccine implementation (1996 to 1998) and 2% during widespread vaccine use (1999 to 2001).

As successful as varicella immunization has been in preventing serious illness, there may be room for improvement. In a well-publicized study, a team of pediatricians at Yale and Columbia University compared 339 children in Southern Connecticut who had both clinical and laboratory diagnoses of chicken pox with age-matched controls (*JAMA* 2004;291:851-855). The overall effectiveness of varicella vaccine was 87%, and its overall effectiveness against severe varicella was 98%, as breakthrough chickenpox in vaccinated children was usually mild. The vaccine's effectiveness in the first year after vaccination was 97%, but decreased to 81-86% from years 2-8 after vaccination. The vaccine's effectiveness in the first year after vaccination, but not thereafter, was lower if the vaccine was administered earlier than 15 months of age (73%) than if it was administered at 15 months or older (99%). When data for all these years are combined, the effectiveness for children immunized at younger than 15 months was not statistically different than for those immunized at 15 months or older (81% vs. 88%). Among vaccinees who developed chickenpox, the disease was at least as mild in those vaccinated at younger than 15 months as in those vaccinated at 15 months or older. The lead author of the Connecticut study, Dr. Vazquez, has also reviewed the evidence that young age, asthma (or its therapy), and recent immunization with MMR may be possible risk factors of varicella immunization failure (*Current Opinion in Pediatrics* 2004 Feb;16:80-4).

CDC assisted the Oregon Department of Health Services in their investigation of a chickenpox outbreak affecting 21 children at an elementary school where 97% of the students had been vaccinated against varicella (*Pediatrics* 2004 Mar;113:455-459). Vaccine effectiveness in this setting was 72%. In the 9 classrooms where cases occurred, 12% of vaccinated students and 43% of unvaccinated students developed chickenpox. Twenty-three percent of students vaccinated over 5 years before the outbreak vs. 3% of those vaccinated less than 5 years before the outbreak were affected. In contrast to the Connecticut study, vaccination before age 15 months was not associated with the development of chickenpox.

In a trial conducted at Kaiser Permanente in Northern California and other centers, 2216 children between 12 months and 12 years of age were immunized with varicella vaccine from 1991-1993 (*Pediatric Infectious Disease Journal* 2004 Feb;23:132-7). All of the children received a first dose, and half received a second dose 3 months later. The estimated vaccine efficacy for the 10-year observation period was 94.4% for one injection and 98.3% for two injections. The risk of developing varicella more than 6 weeks post-vaccination was 3.3-fold lower in children who received two injections than in those who received one injection (2.2% vs. 7.3%, respectively). Over 75% of the breakthrough cases of varicella in the vaccinated children were mild regardless of the number of immunizations.

The results from these studies have not yet changed existing ACIP and AAP recommendations for a single dose of varicella vaccine to be given to children aged 12 months and older. Immunization using the current schedule continues to offer substantial benefits. As the authors of the Connecticut study discuss, if an increased efficacy from delaying immunization to 15 months is confirmed, the improvement would have to be measured against the risks of exposure to chickenpox between 12 and 15 months and of children not returning promptly at 15 months to their provider for immunization. The separate decision of whether to provide a second dose of varicella immunization may be influenced by any future licensure of a tetravalent vaccine in which varicella is combined with MMR (*Clinical Infectious Disease* 1997 May;24:925-31; IDSA 2003 Meeting, Poster 904, Page 141 in www.journals.uchicago.edu/IDSA/2003Abstracts/Posters.pdf). Stay tuned for continued research, debate, and policy recommendations on immunization against varicella.

Autism Controversy and Retraction

The debate over theoretical links between immunization and childhood autism has received extensive media coverage recently. The March/April 2004 edition of *Mother Jones* magazine sympathetically reviews the arguments that thimerosal, the mercury-containing antibacterial preservative that has recently been removed from most vaccines, may cause autism. (www.motherjones.com/news/feature/2004/03/02_354.html). In contrast, recent articles in *JAMA* and *Pediatrics* add to the list of rigorous studies failing to find an association between thimerosal and autism (www.immunize.org/safety/thimerosal.htm, www.pediatrics.aappublications.org/cgi/eletters/112/5/1039). Additional information about thimerosal is available from the CDC and FDA at www.cdc.gov/nip/vacsafe/concerns/thimerosal and www.fda.gov/cber/vaccine/thimerosal.htm.

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In 1998, Dr. Andrew Wakefield and colleagues in London described an apparent syndrome of bowel disease and autistic behavior in 12 children, 8 of whom had been immunized with MMR (*Lancet* 1998;351:637). In the press conference held at the time of publication of this article in the prominent medical journal *The Lancet*, Dr. Wakefield repeated his concern that MMR caused this syndrome and urged parents to receive MMR as three separate antigens instead of in combination. In the wake of the 1998 article and related advocacy, use of MMR decreased from 91% to 84% in the UK. A recent report describes how measles outbreaks in England have spread as MMR coverage has declined (Jansen et al., *Science* 2003;301:804).

Six years later, the March 6, 2004 edition of *The Lancet* contains several articles responding to recent revelations appearing in *The Sunday Times* of London. Dr. Wakefield failed to disclose to *The Lancet* or to his co-authors that at the same time of his work on the 1998 study, he was paid about \$100,000 by a legal foundation to assist with a separate study to investigate grounds for pursuing a legal action against vaccine manufacturers on behalf of parents of allegedly vaccine-damaged children. Dr. Wakefield included five children in both of these studies. *The Lancet's* Editor, Dr. Richard Horton, has stated that he would not have published the 1998 study had he known of Dr. Wakefield's conflict of interest. In the March 6, 2004 edition of *The Lancet*, ten of Dr. Wakefield's twelve co-authors on the 1998 article formally retracted the interpretation that MMR was responsible for the bowel disease and autism described in the paper.

VACCINES FOR CHILDREN (VFC) PROGRAM

Pneumococcal Conjugate Delays Again

Wyeth again is having production problems with Pediatric Pneumococcal Conjugate Vaccine (PCV-7, commercially known as Prevnar®). They expect the situation to last into the summer. California VFC Providers began receiving notification of delays in mid-February. All providers have been asked to temporarily suspend the routine third and fourth dose in healthy children to conserve vaccine. High risk children should continue to receive all doses. Further information is available at www.cdc.gov/nip/news/shortages/default.htm.

More Emphasis on Temperature Logs

The VFC Program has expanded its efforts to increase awareness about proper temperature storage for vaccine. The VFC Provider Agreement for 2004 now includes

the requirement that VFC providers use the VFC temperature log for their daily temperature checks and then retain them in a file for six months. Later this month VFC will be mailing providers a tablet of the two-color Fahrenheit temperature log (IMM-682) tear off sheets; a sample of the log was enclosed in the December UPDATE. A Celsius version is available to providers who prefer it, and supplies can be requested from a VFC Field Representative. Providers should use color versions to emphasize the out-of-temperature range, not black and white copies.

PUBLIC INFORMATION AND EDUCATION

Stop Whooping Cough Event!

Whooping cough cases last year reached their highest levels in decades. The California Coalition for Childhood Immunization (C3I), the California Distance Learning Health network (CDLHN), the California Department of Health Services (CDHS), and local coalitions and health departments are partnering to stage educational events involving hundreds of California children throughout National Infant Immunization Week, April 25-May 1, and Toddler Immunization Month, May 2004. Youngsters will wear lung costumes and participate in statewide "lung activities" aimed at educating parents and childcare providers about the seriousness of childhood diseases that affect the lungs, most notably pertussis (whooping cough).

National Hepatitis Awareness Month in May...Vaccinate Before You Graduate!

National Hepatitis Awareness Month will be observed in May. Now is the time to remind high school seniors to get their hepatitis B shots if they have not completed the 3-shot series. Hepatitis B campaign kits were sent to the health centers at state universities and UC campuses to encourage college campuses to reach more of their students with hepatitis B vaccine messages. A variety of young adult "Anyone Can Get Hepatitis B" campaign materials are available from local health departments.

April and May Advertising Efforts

In support of National Infant Immunization Week and Toddler Immunization Month outreach activities, the California Coalition for Childhood Immunization (C3I) in partnership with local coalitions will be running

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“Grandma” ads in African American newspapers. This ad was originally developed by the Fresno-Madera Coalition with a grant from the California Endowment.

DHS will be using Spanish radio and TV spots to promote infant and toddler immunizations, while health departments in selected jurisdictions will be using movie slides with the "Anybody can get Hepatitis B" message during May, targeting young adults.

Immunization Materials: Easy to Find On-line

The California Department of Health Services (CDHS) is committed to providing helpful websites for the general public and the health care community in California. They have made documents easier to find through a feature called the Health Publications Finder which was recently named as Public Health Institute’s “favorite website.” The Finder is a search tool located on the right hand side of the CDHS website at www.dhs.ca.gov that enables the site visitor to easily sift through CDHS materials. By entering immunizations as a topic choice, the Finder gives you a list of many materials produced by the Immunization Branch with a description, links to a PDF, links to our Immunization Branch website, and ordering

information that refers users to their local health departments. The Immunization Branch website also can be reached directly by going to www.dhs.ca.gov/ps/dcdc/izgroup. Many new materials have been added recently, such as the appendix to the School Handbook.

IMMUNIZATION REGISTRIES

Managed Care Providers Get Registry Information

Over 4,000 pediatricians and family practice physicians are being offered new computers (courtesy of Blue Cross of California) to improve their practices’ technological capabilities. They will also receive a DHS letter telling them about immunization registries. Accolades go to Blue Cross of California for their efforts to help their extensive provider network learn more about immunization registries. This collaborative effort highlights private sector initiative and demonstrates a partnership model that is beginning to emerge between California’s managed care plans and the Immunization Branch to bolster immunization registry recruitment.

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