



Mark Your Calendars:

CHOP Vaccine Education Center Webinars

September 11, 2013

<http://vaccine.chop.edu/webinars>

20th Annual Immunize Georgia Conference

September 12, 2013

Callaway Gardens, Pine Mountain, GA

Pediatrics on the Perimeter

October 10-12, 2013

Crowne Plaza Ravinia Hotel, Atlanta

FDA extends FluLaval IIV (GlaxoSmithKline) age range to include children and teens age 3–17 years; licenses quadrivalent FluLaval product

IAC Express Issue 1073: August 27, 2013

On August 16, FDA approved a request by GlaxoSmithKline (GSK) to supplement its biologics license application for FluLaval trivalent inactivated influenza vaccine (IIV3) to include children and teens age 3 through 17 years. Previously, FluLaval IIV3 was licensed for the prevention of influenza disease in people age 18 years and older.

On the same day, FDA approved GSK's request to supplement its biologics license application for FluLaval to include a quadrivalent inactivated influenza vaccine (IIV4) formulation. FluLaval IIV4 is licensed for the prevention of influenza disease in people age 3 years and older.

Filling Line 'Anomaly' Extends Sanofi's DTaP Vaccine Shortage Through Mid-October

AAFP News Now

August 20, 2013 12:29 pm [Matt Brown](#)

Just weeks before previously announced summer allocation restrictions on two of its combination vaccines are set to expire, Sanofi Pasteur now has said the shortages will continue into October and will expand to include other products, as well (www.vaccineshoppe.com).

In a teleconference with representatives from the CDC and various health organizations, William Averbeck, Sanofi's vice president of U.S. marketing, said the vaccine manufacturer will be unable to meet demand for several products until mid-October. Those products are its

- diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and *Haemophilus influenzae* type b conjugate vaccine (DTaP-IPV-Hib: Pentacel);
- diphtheria and tetanus toxoid and acellular pertussis vaccine adsorbed (Daptacel);
- tetanus toxoids, reduced diphtheria and acellular pertussis vaccine adsorbed (Adacel); and
- tuberculin purified protein derivative (Tubersol Diagnostic Antigen).

"This delay resulted from an anomaly identified during a routine test procedure of one of our filling lines, and, since a repeat test is now required, all products from that line are delayed," said Averbeck. "To manage the supply, we are implementing allocations where possible, but we will stock out of multiple vaccines prior to resolution of this issue in mid-October."

Averbeck said all of the supplies currently released for distribution have passed the required tests, and no known safety issues exist.

According to Jeanne Santoli, M.D., M.P.H., deputy director of the Immunization Services Division in the CDC's National Immunization Program, DTaP vaccine manufacturer GlaxoSmithKline is prepared to fill supply gaps until Sanofi begins ramping up vaccine production again in October. The CDC also will make vaccine from its Strategic National Stockpile available to address any remaining gaps, she said.

"We will have enough of the infant and adult pertussis-containing vaccines available in the marketplace so that we will not have to make changes to the ([routine vaccine recommendation schedules](#))," she said. (*continued on page 2*)

(continued from page 1) "We have also spoken with (Merck and Co.) regarding its ability to make additional Hib products available, and they will be able to fill those gaps."

Santoli said that although this will be a "challenging time" because people might need to use a vaccine presentation or brand they're not accustomed to, the issue amounts to nothing more than inconvenience. "The good news is that we are able to make up for the gaps at this point with available supply," she said.

Averbeck said the current shortfall is unrelated to the earlier challenges Sanofi has had producing Pentacel in each of the last two summers. "We've been working to implement process improvements on Pentacel, specifically, for quite some time," he said. "The issue we are having today is an independent one -- outside those process improvements -- tied to the anomaly on the filling line. So although I can tell you we are making progress on the (Pentacel) process improvements, unfortunately, this separate issue also impacts Pentacel, as it is filled on this line."

Vaccination Coverage Among Children in Kindergarten--United States, 2012-13 School Year

Morbidity and Mortality Weekly Report (08/02/13) Vol. 62, No. 30, P. 607

The Centers for Disease Control and Prevention (CDC) reports that vaccine coverage for children entering kindergarten for the 2012-2013 school year was at or near the national Healthy People 2020 targets of 95 percent for two doses of MMR vaccine, four doses of DTaP, and two doses of varicella vaccine. However, the CDC researchers noted that low vaccination and high exemption levels can form within communities and raise the risk for disease. Each year, the CDC analyzes school vaccination coverage data from federally funded immunization programs as well as exemption rates. Among 48 states and the District of Columbia, vaccination coverage averaged 94.5 percent for two doses of MMR, 95.1 percent for local requirements for DTaP, and 93.8 percent for two doses of varicella vaccine. Among 49 states and the District, exemption rates had a median total of 1.8 percent. Kindergartners were considered up-to-date on each vaccine if they met all of the doses required for school entry in their jurisdiction. Exemptions included medical exemptions, religious exemptions, or philosophic exemptions.

Longitudinal Predictors of Human Papillomavirus Vaccination Among a National Sample of Adolescent Males

American Journal of Public Health (08/13) Vol. 103, No. 8, P. 1419 Reiter, Paul L.; McRee, Annie-Laurie; Pepper, Jessica K.; et al.

A study of human papillomavirus (HPV) vaccine uptake among male adolescents has found low vaccination rates and decreased willingness to vaccinate. The researchers suggest that vaccination rates may improve if more physicians recommend and educate patients about HPV vaccine for males. Their findings were based on online surveys completed in 2010 and 2011 by 228 males aged 11 to 17 years and 327 parents. Only 2 percent of sons had received any doses of HPV vaccine at baseline, though this rate increased to 8 percent at follow-up. Among parents who had ever received a doctor's recommendation to get their sons vaccinated for HPV, about 55 percent did vaccinate between baseline and follow-up. Only 1 percent of parents who never received a physician's recommendation had their sons vaccinated. Fathers and non-Hispanic white parents were less likely to have sons vaccinated against HPV, the data indicated.

Novartis announces Australian approval of meningococcal B vaccine

Published on [August 19, 2013](#) by [Paul Tinder](#) Vaccine News Daily

Novartis, a Basel, Switzerland-based healthcare solutions company, announced on Thursday that the Australian Therapeutic Goods Administration added the company's meningococcal B vaccine to the Australian Register of Therapeutic Goods.

Bexsero, Novartis' multi-component MenB vaccine suspension for injection, was approved for use in individuals two months of age and older. The vaccine is the first and only broad coverage vaccine to help protect all age groups against MenB, including infants.

"Novartis welcomes the Australian health authorities' decision to license Bexsero, which is further testament to the vaccine's demonstrated robust efficacy and safety profiles and an important step in preventing further suffering caused by MenB disease," Andrin Oswald, the division head of Novartis Vaccines and Diagnostics, said. "We are committed to bringing Bexsero to parents around the globe that want to protect their children against this devastating disease."

In Australia, approximately 85 percent of all meningococcal disease and sepsis cases are caused by MenB. MenB is a possibly deadly disease that is easily misdiagnosed and can kill within 24 hours of onset. Approximately one in 10 individuals who contract the disease will die despite treatment and up to one in five survivors may suffer from life-long disabilities like hearing impairment, limb loss and hearing impairment.

"Today marks another victory, particularly for Australian children, parents and pediatricians, in the fight against meningococcal disease," Bruce Langoulant, the president and Asia Pacific regional leader of the Confederation of Meningitis Organisations, said. "We are now entering a critical period for public health authorities to provide funding to include the new MenB vaccine in the routine immunization schedules to ensure community-wide protection against the tragic deaths and lasting disabilities MenB can cause."

Going forward, Novartis will work with Australian regulatory authorities to make Bexsero doses available in the private market in the coming months.

Five main groups of meningococcal bacteria cause most of all cases of bacterial meningitis around the world. Before Bexsero, vaccines were only available against the other four strains: A, C, W-135 and Y.



Somalia Facing an 'Explosive' Rise in Polio

Washington Post (08/17/13) P. A7

Somalia now has 105 cases of polio, according to recently released figures, and an additional 10 cases have been confirmed across the border in a Kenyan refugee camp filled with Somalis. The total is more than the rest of the world combined. "It's very worrying because it's an explosive outbreak," said Oliver Rosenbauer of the Global Polio Eradication Initiative at the World Health Organization. Vaccination teams have reached 4 million people since the outbreak began in May, but seven of 10 children in areas controlled by al-Qaeda-linked militants are not fully immunized. About 600,000 children live in these areas. Somalia was removed from the list of endemic polio countries in 2001, but this year's outbreak marks its second since then.

IAC's Give birth to the end of Hep B initiative helps birthing hospitals adopt and strengthen hepatitis B birth dose policies

IAC Express August 6, 2013

With the July launch of IAC's initiative urging the nation's birthing institutions to Give birth to the end of Hep B, IAC asked all of its immunization partners to get involved in promoting the hepatitis B vaccine birth dose.

Our partners' help is needed because, unfortunately, nearly one in three U.S. newborns leaves the hospital unvaccinated against hepatitis B. As a result, approximately 800 U.S. newborns become chronically infected each year because of perinatal exposure. These newborns would be afforded a "safety net" if a birth dose were universally administered before hospital discharge.

To help birthing hospitals increase the rate of birth dose vaccination, IAC has created a new website section that provides complete information and resources about the birth dose at www.immunize.org/protect-newborns.

Two new resources from IAC

In addition to increasing awareness about the need for the hepatitis B birth dose, the initiative offers tools to help birthing institutions adopt or strengthen their birth dose policies.

Guidebook. The centerpiece of this supportive effort is IAC's comprehensive new guidebook, *Hepatitis B: What Hospitals Need to Do to Protect Newborns*. Endorsed by the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the Centers for Disease Control and Prevention, the guide contains a wide range of resources to help birthing institutions establish, implement, and optimize their hepatitis B birth dose policies.

Visit www.immunize.org/protect-newborns/guide to view the guidebook's table of contents and download some or all of its sections.

Apply for inclusion into IAC's new Hepatitis B Birth Dose Honor Roll

IAC Express Issue 1073: August 27, 2013

On July 16, 2013, the Immunization Action Coalition (IAC) launched the Hepatitis B Birth Dose Honor Roll. The honor roll recognizes hospitals and birthing centers that have attained high coverage rates for administering hepatitis B vaccine at birth and have met specific additional criteria. These criteria help define the important elements of a birth dose policy that are needed to ensure newborns do not fall through the cracks when medical errors occur.

To be included in IAC's Hepatitis B Birth Dose Honor Roll, a birthing institution must have

- Achieved, over a 12-month period, a coverage rate of 90% or greater for administering hepatitis B vaccine before hospital discharge to all newborns (regardless of weight), including those whose parents refuse vaccination.
- Implemented written policies, procedures, and protocols to administer the universal hepatitis B vaccine birth dose to all newborns prior to hospital discharge, which include specific additional criteria.

For a complete listing of criteria for inclusion on the honor roll, visit www.immunize.org/honor-roll/birthdose

Tdap for Teens, Adults Not Enough to Block Whooping Cough Outbreaks

Jul 31, 2013 By Anne Harding

NEW YORK (Reuters Health) Jul 31 - Giving adolescents and adults the reduced acellular pertussis (Tdap) vaccine offers some protection against infection, but not enough to prevent outbreaks, according to a new case-control study.

"The take-home message is, we need a new vaccine," lead author Dr. Roger Baxter, co-director of the Vaccine Study Center at Kaiser Permanente in Oakland, California, told Reuters Health.

The original whole-cell vaccines against pertussis, tetanus and diphtheria were highly effective in preventing whooping cough outbreaks, Dr. Baxter and his team note in their July 17 report in *BMJ*. But safety concerns led to the introduction of acellular vaccines in the 1990s.

Studies have suggested the acellular vaccines are weaker than the earlier versions, which may help explain why pertussis outbreaks are becoming more common despite high vaccine coverage in the U.S. Consequently, the Tdap vaccine for adolescents and adults, who often serve as a reservoir of infection, was introduced in 2005. The U.S. Advisory Committee on Immunization Practices recommended use of the Tdap vaccine instead of the next scheduled tetanus diphtheria booster shot for everyone aged 11 to 64. In 2012, USACIP recommended the vaccine for everyone 65 and older.

To investigate whether giving adolescents and adults the Tdap vaccine was effective in fighting outbreaks, Dr. Baxter and his colleagues looked at data from 2006 to 2011, during which time California saw the highest incidence of pertussis in the last 50 years. The researchers matched 668 PCR-confirmed cases of pertussis in people 11 and older from Kaiser Permanente Northern California (KPNC) records to 10,098 PCR-negative controls and an additional 21,599 matched controls drawn from KPNC records. Twenty-four percent of the PCR-positive pertussis cases had been immunized with Tdap, versus 32% of the PCR-negative controls ($p < 0.001$). The adjusted odds ratio for cases versus PCR-negative controls was 0.47, and 0.36 when compared to the Kaiser Permanente controls.

Based on the adjusted odds ratio, the vaccine was 53% effective when the PCR-negative control group was used, and 64% effective for the larger matched control group. By comparison, a single dose of the current measles-mumps-rubella vaccine confers immunity to all three viruses in 95% of people who receive it, according to the Centers for Disease Control and Prevention.

The rate of pertussis infection was highest among 11- to 14-year-olds, who had only received acellular vaccines; this younger age group also saw a greater absolute benefit from Tdap vaccination compared to older individuals who had received at least some whole-cell vaccines. "Strategies to decrease the incidence of pertussis should prioritize giving the Tdap booster to people who received only acellular pertussis vaccines as children, as California has done since the 2010 outbreak, requiring Tdap vaccination for middle school students," Dr. Baxter and his team write.

Immunity conferred by the acellular pertussis vaccines is known to fade more quickly than that offered by the original whole-cell formulation, Dr. Baxter noted. While the Tdap had been introduced to address this issue, he added, the new findings show that giving it to adolescents and adults isn't going to solve the problem.

"That strategy would only work if we repeatedly vaccinated people who were around infants during pertussis season, and that's probably not going to happen," he said.

"It's going to blunt those epidemics a little bit, but it's not going to be like the old whole-cell pertussis vaccine that really took those outbreaks away. We expect that we will see these periodic outbreaks actually increase over the next few years as we reach a time that no one has had whole-cell vaccines," Dr. Baxter added.

"I think we knew at the time we moved to the acellular vaccine that we traded safety for efficacy," Dr. Paul Offit, chief of the division of infectious diseases and director of the Vaccine Education Center at the Children's Hospital of Philadelphia, told Reuters Health. "I don't think it's been until the last few years that we realized how big of a trade that was."

Dr. Offit was not involved in the new study. He said the findings are consistent with a number of other recent reports showing that immunity from the newer vaccine fades more quickly, and that it's just not that effective. "This is the best tool available and it clearly and definitely decreases your risk of getting whooping cough, it's a no-brainer," he added. "But we would do better with a better vaccine, there's room for a better vaccine."

BMJ 2013

Reuters Health Information © 2013

Vaccine Push Targets Older Youths

Dekalb Daily Chronicle (08/19/13) Sarver, Felix

As part of National Immunization Awareness Month, the DeKalb County (Ga.) Health Department is stressing the need for older youth to get vaccinated, especially as immunity from childhood vaccines weakens over time. The department has partnered with local school districts to notify parents of vaccine requirements. The state requires students in grades 6-12 to provide proof of having received the Tdap vaccine, and some districts have first-day exclusion policies that prevent students without documentation or a scheduled appointment to receive the vaccine from attending classes. Hundreds of students were vaccinated last year at the county health department's immunization clinics.

New from IAC and ACOG! "Vaccinations for Pregnant Women" patient handout

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IAC, in partnership with the American College of Obstetricians and Gynecologists, recently developed Vaccinations for Pregnant Women. This patient handout informs pregnant women about which vaccinations are specifically recommended, which are allowed if indicated, and which are contraindicated during pregnancy. The information is presented in a simple table format that is easy to read and understand.

"Vaccinations for Pregnant Women" is part of a suite of five handouts that focuses on adults in risk groups for vaccination. IAC will alert IAC Express readers as new adult handouts become available. All these handouts, as well as available translations, can be accessed from IAC's Patient Schedules web page.

New: 2014 edition of the Yellow Book--CDC's travel-health guide--now available

The 2014 edition of CDC Health Information for International Travel (also known as the Yellow Book), is now available online and in print.

CDC publishes this guide every two years for those who advise international travelers of health risks, as well as others who might find it useful. The Yellow Book is written primarily for clinicians, including physicians, nurses, and pharmacists. Others, such as the travel industry, multinational corporations, missionary and volunteer organizations, and travelers themselves, can also find a wealth of information here.

The most recent version includes special guidance for people who will be living for an extended period in areas with malaria. The 2014 edition also offers an expanded chapter on select destinations, providing insiders' knowledge and information on specific health risks about popular tourist destinations.

Features from previous editions can still be found in the 2014 edition, including information on cruise ship travel, food and water precautions, international adoptions, and recent immigrants returning home to visit family and friends.

Access the Yellow Book online.

The book is also available as a hard copy (\$38.00). Visit Oxford University Press online or call (800) 451-7556 (toll-free USA) or (919) 677-0977, Monday–Friday, between 8:00 am and 6:00 pm ET and ask for ISBN#978-0-19-994849.

CDC's Travelers' Health web section includes links to the Yellow Book as well as additional useful information for healthcare professionals and travelers.