

Influenza Immunization Coverage Rates

Assessment of 2005 infant influenza vaccine supply

CDC vaccine recommendations: All 6-23 month old infants, 2 doses for first vaccination

Immunization coverage rate: 48% in 2004-05 (from CDC)

Size of this age group in the U.S. Approximately 7.5 million (per US Census Bureau)

Number of doses pediatric doses available from Sanofi-Aventis 2005-06: up to 8 million

Number of pediatric doses need to vaccinate all US infants this age (at least 2 doses): 7.2 million

Projection for 2006-2007: GlaxoSmithKline will also produce pediatric doses containing 1.25 mcg mercury per dose or less. Sanofi Pastuer has capacity to produce 8-10 million for 2006-2007 and is still booking.

Review of effectiveness of influenza vaccination in children

“Inactivated influenza vaccine did not reduce the attack rate of influenza A infection in 6-24 month old children.”

Failure of inactivated influenza A vaccine to protect healthy children aged 6-24 months. Maeda T, et al., Pediatr Int. 2004 Apr;46(2):122-5.

“We conclude that influenza vaccination did not result in a significant reduction of the number, severity, or duration of asthma exacerbations caused by influenza. Additional studies are warranted to justify routine influenza vaccination of children with asthma. “

Influenza vaccination in children with asthma: randomized double-blind placebo-controlled trial. Bueving HJ, et al. Am J Respir Crit Care Med. 2004 Feb 15;169(4):488-93,2003

“Inactivated vaccines had lower efficacy (65%) than live attenuated vaccines, and in children aged 2 years or younger they had similar effects to placebo....If influenza immunisation in children is to be recommended as public-health policy, large-scale studies assessing such important outcomes and undertaking direct comparisons of vaccines are urgently needed.”

Assessment of the efficacy and effectiveness of influenza vaccines in healthy children: systematic review. Jefferson T, et al., Lancet. 365(9461):773-80, 2005.

“This study failed to provide evidence that the influenza vaccine prevents paediatric asthma exacerbations.”

Effectiveness of influenza vaccine for the prevention of asthma exacerbations. Christy C, Aligne CA, Auinger P, Pulcino T, Weitzman M. Arch Dis Child. 2004 Aug;89(8):734-5.

Assessment of vaccine supply for pregnancy:

CDC vaccine recommendations: all pregnant women, regardless of trimester or risk factors

Immunization coverage rate: 12% in 2004-05 (from CDC).

Size of this age group in the U.S. Approximately 6.2 million pregnancies per year (National Vital Statistics, 1996)

Number of adult doses need to vaccinate US pregnancies: 750,000 doses

Number of doses (thimerosal-free) available from Sanofi-Aventis 2005-06: unknown

Current thimerosal-free supply: no remaining adult dosages from manufacturers or distributors.

Projection for 2006-2007: GlaxoSmithKline will produce adult doses for the US market containing 1.25 mcg mercury per dose or less. The capacity of Sanofi-Aventis is unknown. Chiron may produce adult, thimerosal-free formula.

Review of the effectiveness of influenza vaccination in pregnancy: “Women who received influenza vaccine during pregnancy had the same risk for ILI [influenza-like illness] visits compared with unvaccinated women... Hospital admissions for influenza or pneumonia for women in the study population were quite rare and no women died of respiratory illness during pregnancy. Infants born to women who received influenza vaccination had the same risks for influenza or pneumonia admissions compared with infants born to unvaccinated women... Maternal influenza vaccination was also not a significant determinant of risk of ILI (excluding otitis media) outpatient visits for infants, nor did it significantly affect the risk of otitis media visits. Influenza vaccination during pregnancy did not significantly affect the risk of cesarean section, adjusting for the woman's age. It also did not affect the risk of preterm delivery. ... we were unable to demonstrate the effectiveness of influenza vaccination with data for hospital admissions and physician visits.”

Effectiveness of influenza vaccine during pregnancy in preventing hospitalizations and outpatient visits for respiratory illness in pregnant women and their infants. Black SB, et al., Am J Perinatol.;21(6):333-9, 2004

Autism Society of Boulder County

February Emails to Len Lavenda – Sanofi Pasteur US Media Relations – Regarding Preservative Free Influenza Vaccine Supply 2006/2007 Season

ASBC Questions to Mr. Lavenda are in black, understandings of our conversation in blue and Mr. Lavenda's corrections to our understandings are in red.

-----Original Message-----

From: Autism Society of Boulder County [mailto:asbc@mho.com]
Sent: Tuesday, February 07, 2006 10:58 AM
To: Lavenda, Len (sanofi pasteur)
Subject: Follow up on conversation with Len Lavenda
Importance: High

Hi Len,

Below is the email I sent Friday....thanks again for your help. Please edit in another color so I can easily catch my mistakes!

Best Regards,

Theresa K. Wrangham, President
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An Autism Society of America Chapter
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From: Len.Lavenda@sanofipasteur.com [mailto:Len.Lavenda@sanofipasteur.com]
Sent: Tuesday, February 07, 2006 2:32 PM
To: asbc@mho.com
Subject: RE: Follow up on conversation with Len Lavenda

1. We understand that CDC is estimating 12 million doses to vaccinate all children ages 6 mo to 23 mo. This is based on 100% uptake...hard to say what real uptake/demand will be.
2. Is Sanofi Pasteur able to meet that demand? Currently Sanofi has a total production capacity of 50 million doses. Sanofi has **prebooked 42 million doses in multi-dose vials** (sold out), and has the capacity for 8 million preservative free (**supplied in single dose syringes and vials**) (not sold out as yet, but has never to date sold out of this version) and may (not able to determine at this time) be able to produce an additional 2 million single dose vial (preservative free) for the 2006/2007 flu season. **Our no preservative formulation will be available until it is fully committed. We are accepting prebooking requests for this product continuously. I can't predict when it will be fully committed.** Estimates from other manufacturers indicate a surplus **in overall flu vaccine supply for 2006-7**. It has only been recent that the US has experienced shortages – most other years surplus has had to be thrown out.
3. What is the projected amount of vaccine available for 2006? See above
4. Is there a projection for 2007? Not at this time
5. Does Sanofi Pasteur see changes in price or production in the event GSK is approved for their version of this vaccine? If so, please explain. Hard to say at this time. Sanofi has invested in a new packaging facility that is due to be completed 2007/2008 (depending on approval process) that will allow them to **increase capacity for** the preservative free flu vaccine – packaging is **a major issue** in this version. Another production facility has also broke ground and is due for completion in 2008/2009 (upon approval)

