ANDREW: Before taking questions we'd like to provide a Vaccine Flash Update: Hot off the policymaking table, information of use to immunization providers. This update concerns revisions to the prioritized recommendations for the use of pneumococcal conjugate vaccine.

ANDREW: Just to give some background: in February 2004, due to production problems, a shortage was declared of the pneumococcal conjugate vaccine, or PCV7. That month, the CDC issued prioritized recommendations to withhold the 4th dose of Prevnar from healthy children. In March of 2004, CDC issued follow up recommendations to withhold the 3rd dose of Prevnar from healthy children. So healthy children were to receive two doses, children at high risk for invasive pneumococcal disease were to maintain the routine four dose schedule.

ANDREW: Production Problems now appear to have been resolved!

ANDREW: The new recommendations reflect a step wise approach to return to the routine schedule, as we are constantly monitoring the supply and distribution of this vaccine. The new recommendations are not a complete return to the previously recommended schedule. Healthy children now ought to receive 3 doses, and at risk children should receive four doses.

ANDREW: There has been an update with respect to the definition of at-risk (also known as high risk) children in the context of this shortage. At-Risk children include those with sickle cell disease, anatomic asplenia, chronic heart and lung disease, diabetes, a Cerebrospinal Fluid or CSF, leak, those having received cochlear implants or receipt of solid organ transplant, children with an immunocompromising condition, and children in certain racial/ethnic groups. Today's update involves this last bullet, newly added to the list of at-risk children who are recommended to receive four doses even during the shortage.

ANDREW: The At-Risk Racial and Ethnic Groups include Alaska Native/American Indian children living in Alaska, Arizona, or New Mexico, or Navajo children living in Colorado or Utah. These populations of children have a risk for invasive pneumococcal disease more than twice the national average.

ANDREW: In light of these new recommendations, providers should check their lists of deferred candidates and recall them for vaccination. Catch up vaccination ought to be prioritized according to the following groups. At-risk children less than five years old, healthy children less than 24 months old with 0 doses, Healthy children less than 12 months old with less than 3 doses, and then any child that may need catch up doses thereafter. All of the recommendations that I've mentioned today will appear in tomorrow's MMWR, dated July 9th, 2004.

ANDREW: Here is some information about how to obtain more vaccine. Public providers should contact the health department in their state, or grantee. The health department may contact their corresponding project officer at CDC. Private providers should contact Wyeth. Wyeth ships directly to providers and not to wholesalers or other distributors. The general number is 1-800-666-7248. A secondary phone number is 1-866-447-8888. Ask for Rosemary Talley at extension 37932.

ANDREW: We'd like to open the floor to our audience for questions. Please limit your questions to those that pertain to the subjects discussed today. To ask a question, press *1 on your telephone. (Operator) we'll open the queue

FILLER QUESTIONS AND ANSWERS: ONLY IF NEEDED

- 1. TO SHARON Q. If a child who should have gotten two doses of influenza vaccine this year only received one dose, will the child need one or two doses next year?
- 1. A. The child will only need one dose next year. The first dose the child already received is a "priming" dose, which is only necessary the first time the child is vaccinated. The second dose, regardless of when it is given, will provide protection.

2. TO CAROLYN **Q**. The literature and direct communication with influenza infectious disease experts suggests a duration of immunity ranging from 3 months to 1 year in the general population and less than 4 months in the 65+ age group. Also, there is no mention in this document of the benefits of a booster dose for adults after 3 to 6 months. I would appreciate if you could comment on these two issues - duration of immunity and value of a booster dose in adults.

2. A. Duration of immunity following inactivated influenza vaccination is believed to be a year or less, and depends on several factors including the match with circulating strains and the age and health status of the recipient. This is a very difficult issue to study, and most investigations have looked at antibody persistence at or above a certain level as a crude surrogate for "protection". We believe most recipients will have some protection for at least 6 months. We have never recommended a second influenza vaccine in the same season except for children <9 years receiving the vaccine for the first time. There is no evidence that a second dose improves protection. TO CAROLYN

3. TO SHARON Q. Why do I need to get vaccinated against the flu every year?

3. A. Flu viruses change from year to year, which means two things. First, you can get the flu more than once during your lifetime. The immunity (natural protection that develops against a disease after a person has had that disease) that is built up from having the flu caused by one virus strain doesn't always provide protection when a new strain is circulating. Second, a vaccine made against flu viruses circulating last year may not protect against the newer viruses. That is why the influenza vaccine is updated to include current viruses every year.

Another reason to get flu vaccine every year is that after you get vaccinated, your immunity to the disease declines over time and may be too low to provide protection after one year.

4. TO CAROLYN Q. What are the complications of Influenza virus infection?

4. A. Complications include pneumonia, otitis media, sinusitis, myocarditis, Reye's Syndrome, and exacerbation of existing chronic lung disease.

5. TO ANDREW Q. With respect to the new Prevnar recommendations and catch-up of children that have previously been deferred, should we recall children between 12 and 24 months that have only received one dose prior to the first birthday?

- 5. A. Yes. These children can receive up to three doses as per the new recommendations
 - 6. To Carolyn Q. Can you give more detail regarding what is a "protected environment" for health care workers that work with immunosuppressed patients and may be considering the Live Attenuated Influenza Vaccine? For instance can neonatal intensive care workers receive this vaccine? What if they have received it; do they need to be furloughed.?

6. A As per dress rehearsal; Carolyn, give the same answer; it was good.

7. Q. Are health care providers required to give the influenza VIS to all influenza vaccinees regardless of whether or not the vaccine is recommended versus simply encouraged?

7.To Judy A Yes, the National Childhood Vaccine Injury Act (NCVIA) requires the relevant VIS to be provided to vaccine recipients. As the influenza vaccine is covered by this act, the influenza VIS ought to be provided to everyone receiving influenza vaccine.

- 8. To Judy Q. Are VIS's "informed consent" forms?
- 8. To Judy A . No. Informed consent requirements are determined by state law. The VIS's were written to fulfill the information requirements of the NCVIA, and are not informed consent documents. However, because the materials cover both benefits and risks associated with vaccinations, they provide enough information that anyone reading them should be adequately informed. Nevertheless, you should consult your state law to determine if there are any specific "informed consent" requirements relating to immunization. The requirements could include procedural requirements (e.g. whether informed consent is required prior to vaccination, whether it may be oral or must be in writing, whether state law requires a signature prior to vaccination) or substantive requirements (e.g. the types of information the state would require to be included in any informed consent.) VIS's must still be used, even if state law requires use of other informed consent materials.
- 9. To Andrew Q. Where can I get information about the current supply of Prevnar?
 - 9. A. This information is available on the website <u>www.cdc.gov/nip/news/shortages/default.htm</u>
 - 10. To Andrew Q I keep seeing the term "unvaccinated" with respect to recommendations for catch-up vaccination with Prevnar. Does "unvaccinated" mean having received no vaccines, or does this refer to "no Prevnar".
- 10. A In this context "unvaccinated" means zero doses of Prevnar. Vaccination history with other vaccines is irrelevant in this context.
- 11. To Andrew Q How many doses of Preservative-free vaccine will be available this upcoming flu season?

11. A. Of the eight million doses for which the public sector has contracted, three million doses will be preservative free. The

recommendations for influenza vaccination apply regardless of whether the vaccine is preservative-free or contains trace amounts of thimerosal. You should contact the manufacturers with questions about availability of different types in the private sector.

ANDREW: Let's take one final question:

LAST QUESTION

ANDREW: Thank you (last respondent). We'd like to thank you all for joining us today for this Netconference, with a special thanks to our speakers Dr. Bridges, Dr. Roy, and Dr. Schmidt.

ANDREW: I want to mention a few housekeeping items before signing off. As mentioned previously, CE credit is available for a variety of professions for this course. Please go to CDC's online learning system at <u>www.phppo.cdc.gov/PHTN Online/</u> to obtain CE credit. The course number for this program is EV0378. You must complete the course evaluation no later than August 9th, 2004.

ANDREW: The verification code is CRO54F. That's Capital C- Capital R- zero, 5, 4, Capital F. It is case sensitive. I'll repeat, Capital C – Capital R, zero, 5, 4, Capital F. You can print your CE certificate to have in hard copy.

ANDREW: If you were unable to ask your question today, or if you have other questions related to this net conference or in general, there are several ways to contact us. NIP manages a hotline service for immunization related questions, called the National Immunization Information Hotline, at 1-800-232-2522. The line is staffed from eight am to eleven pm eastern time from Monday through Friday.

ANDREW: NIP also staffs an email hotline service at the address N-I-P Info (spell out) at C-D-C-dot-Gov. If you have a question that relates specifically to the Net Conference

please write Netconference in the subject heading. We look forward to receiving feedback from everyone, and we look forward to webcasting more Net Conferences in the Future.

ANDREW: Thank you very much for joining us today!