

COCA Call: Promoting Health and Preventing Disease: Childhood and Adult Vaccine Updates and Recommendations

Date/Time: July 27, 2010 (1:00 PM- 2:00 PM ET)

Speaker: Dr. Yabo Beysolow, Medical Officer, National Center for Immunization and Respiratory Diseases (CDC)

Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode. After today's presentation, there will be a question-and-answer session. At that time to ask your question, you press star then 1 on your phone.

Today's conference call is being recorded. If you have any objections, you may disconnect at this time. I would now like to introduce your host. We have Ms. Loretta Jackson and ma'am, you may begin.

Loretta Jackson-Brown: Thank you, (Lori). Good afternoon. I'm Loretta Jackson-Brown and I am representing the Clinician Outreach and Communication Activity - COCA - with the Emergency Communications System at the Centers for Disease Control and Prevention.

I am delighted to welcome you to today's COCA conference call "Promoting Health and Preventing Disease, Childhood and Adult Vaccine Updates and Recommendations.

We are pleased to have with us today Dr. Yabo Beysolow, Medical Officer, National Center for Immunization and Respiratory Diseases at Centers for Promoting Health and Preventing Disease:

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Disease Control and Prevention to discuss how clinicians can foster the promotion of childhood and adult immunizations in clinical practice.

During today's call, you will hear the presenter referring to slides in her PowerPoint presentation. The PowerPoint slide set is available from our COCA Web site at emergency.cdc.gov/coca. Click on conference calls. The slide set can be found under the call-in number and call passcode.

The objectives for today's call are that participants will be able to discuss two recent vaccine recommendations made by the Advisory Committee on Immunization Practices, identify the types and location of immunization resources in steps for accessing resources, describe two vaccine administration issues. Following the presentation, you will have an opportunity to ask our presenter questions. Dialing star 1 will put you into the queue for questions.

In compliance with continuing education requirements, all presenters must disclose any financial or other relationship with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters as well as any use of an unlabeled product or products under investigational use.

This presentation will not include the discussion of the unlabeled use of a product or products under investigational use with the exceptions of certain vaccine use that is recommended by the Advisory Committee on Immunization Practices but not approved by the Food and Drug Administration.

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The names of the vaccines can be found on Slide 4 of the presentation slide set located on the COCA Web page. CDC, our planners and our presenter wish to disclose that they have no financial interest or other relationships with the manufacturers of commercial products, suppliers of commercial services or commercial support.

There's no commercial support for this presentation. Today's presenter Dr. Yabo Beysolow graduated from the University of Medicine and Dentistry of New Jersey- Robert Wood Johnson Medical School with a joint M.D/M.P.H. concentration in family health. She completed her pediatric residency at Emory University in Atlanta.

She is board-certified in pediatrics. Dr. Beysolow has worked as a practicing pediatrician in various clinical settings to include the Whitefoord Elementary School Health Clinic, a large private pediatric practice, her own pediatric practice, Children's Healthcare of Atlanta, and Emory University School of Medicine.

Since June 2008, Dr. Beysolow has worked as a Medical Officer in the education, information and partnership branch of the National Center for the Immunization and Respiratory Diseases at the CDC.

Her responsibilities include the development and implementation of immunization education and training materials for vaccine providers, lectures on vaccine-preventable diseases, and presentations at courses as well as Web and Net conferences.

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If you're following along on the slides, you should be on Slide 6. Again, the PowerPoint slide set is available from our COCA Web site at emergency.cdc.gov/coca. At this time, please welcome today's presenter, Dr. Beysolow.

Dr. Yabo Beysolow: Good afternoon. It's a pleasure to be able to provide you with recent updates to childhood and adult vaccine recommendations from the CDC.

As providers continue to see an increasing number of patients on a daily basis, challenges remain such as ensuring that providers are keeping up with all the new recommendations in the vaccine world, the need to train staff on immunizations and also explain the benefit of vaccines to patients.

Once a vaccine is licensed by the FDA the Advisory Committee on Immunization Practices or ACIP meets and votes on recommendations for use of the vaccine. ACIP then advises CDC and the Department of Health and Human Services on the vaccines used in the U.S. population.

Today we'll discuss some of the updated recommendations made within the last year as well as recommendations for newer vaccines. We'll also spend some time on how and where one can access vaccine resources quickly including the published ACIP recommendations, clinical tools such as immunization schedules, as well as tips for increasing vaccine coverage rates.

We'll now move on to Slide 8. We'll begin by briefly looking at the 2010 immunization schedule and changes you may or not have been aware of and then we'll move on to more specific vaccines in the pediatric and adult world.

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At the end of this session as Mrs. Brown mentioned, we'll have a few minutes for a question and answer segment.

Now on to Slide 9. Here's a copy of the 2010 Childhood Immunization Schedule. Immunization schedules are an integral part of immunization practice. Because immunization recommendations change frequently, the schedules for the United States have been revised at least annually since 1995.

The schedule for children and adolescents through 18 years of age and for adults 19 years and older are issued separately. The immunization schedules represent a concise summary of existing recommendations. There are two additional childhood schedules, one for 17 through 18-year-olds [*correction: 7 – 18 years old*] as well as a catch-up schedule.

For the childhood schedule, updates this year have included the use of meningococcal conjugate revaccination, an updated statement regarding the use of combination vaccines, updated intervals for the dosing of polio vaccine as well as when the last dose of polio vaccine is recommended in childhood and the use of human Papillomavirus vaccine in females and males.

Please remember though to always refer to the footnotes in all of the immunization schedules as you view them. Next slide.

The adult schedule did not have as many changes, but again the reminder there is to please read the footnotes as you utilize the schedules.

We'll begin our vaccine discussion with the new pneumococcal conjugate vaccine or PCV-13. You should now be on Slide 13. PCV-13 was licensed for

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use by the FDA in February of 2010. PCV-13 and PCV-7 are manufactured in a similar fashion and PCV-13 will replace PCV-7 for prevention of pneumococcal disease in children.

Streptococcus pneumoniae can present as (bacteremia), meningitis, pneumonia or otitis media in children. Bacteremia without a known site of infection is the most common invasive clinical presentation of pneumococcal infection among children two years and younger.

With the decline of invasive Hib disease, Strep pneumo has become the leading cause of bacterial meningitis among children under five years old in the U.S. and of course Pneumococci also a common cause of acute otitis media in children.

Middle-ear infections are the most frequent reason for pediatric office visits in the U.S. resulting in more than 20 million visits per year. Since the introduction of PCV-7 vaccine in the year 2000, there's now significantly less pneumococcal disease caused by the seven strains contained in that vaccine. Even though there is less disease overall, other strains of streptococcus pneumoniae that are not in PCV-7 have become more common.

PCV-13 includes six additional serotypes protecting against more disease than PCV-7. In particular, PCV-13 vaccine protects against serotype 19A which has become the most common pneumococcal serotype and is often resistant to antibiotics. PCV-13 as you can see on the slide was approved by the FDA for use among children six weeks through 71 months of age. Next slide.

Like PCV-7, ACIP recommends that PCV-13 be given to all infants at two, four and six months of age followed by a booster dose for 12 through 15-month-olds.

As with PCV-7 in the past, children who start the series late will require fewer total doses. Infants and children not immunized or incompletely immunized with PCV-7 should begin or complete the schedule with PCV-13.

Slide 15 shows you an example of the very many helpful tables in the MMWR article that addresses ACIP recommendations for the use of PCV-13. This table illustrates the routine dosing of PCV-13 and number of doses needed depending on when the series was started.

The table also shows you on the right the use of a booster dose at 12 to 15 months of age who begin the series under a year old. Please remember that this only pertains to children who are completing the series with only PCV-13 doses.

There are several other tables we show you how you can complete the series with PCV-13 if PCV-7 was used to start the series. These tables are available within the MMWR article cited.

ACIP made additional recommendations for what is called a supplemental dose. Because of the extra serotype in PCV-13 versus PCV-7, we want to make sure that all children have the benefit of receiving that extra protection.

Hence, healthy children 14 through 59 months old who are fully vaccinated with PCV-7 should receive one dose of PCV-13 as a supplemental dose. ACIP nor AAP did not recommend routine vaccination of PCV-13 for healthy children five years of age or older.

However, ACIP recognizes that there are some older children with certain medical conditions that put them at an increased risk of invasive pneumococcal disease and so ACIP extended this age for the supplemental dose to 71 months in these children.

Some of the children in this higher-risk group may have already received PPSV-23, the pneumococcal polysaccharide vaccine; however, they are still recommended to also receive the PCV-13 supplemental dose.

Slide 17. This is a table from the MMWR listing the medical conditions and indications that would place a child in the higher-risk group for pneumococcal disease or its complications.

Children who fall into one of these groups are recommended to receive a supplemental dose of PCV-13 through age 71 months. This includes immunocompetent children with chronic lung or heart disease, diabetes, or cochlear implants.

Children with functional or anatomic asplenia including children with sickle cell disease, immunocompromised people including children with HIV, chronic renal failure, diseases associated with immunosuppressive chemotherapy or radiation therapy including leukemia, lymphoma and other malignant neoplasms and congenital immunodeficiency.

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Lastly ACIP made an off-label recommendation to allow use of PCV-13 in certain children over the age of six. Remember that FDA licensed the vaccine for use in children six weeks through 71 months old. ACIP saw that there were older children at even higher risk for invasive pneumococcal disease because of certain underlying conditions.

These include children with anatomic or functional asplenia, those with HIV infection and other immunocompromising conditions, those with cochlear implants or have a CSF leak.

Next on Slide 19 we'll move onto a discussion of meningococcal conjugate vaccines. Meningococcal disease is an acute potentially severe illness caused by *Neisseria meningitidis*. It is the leading cause of bacterial meningitis infections in the United States.

The case fatality rate of invasive meningococcal disease is nine to 12% even with appropriate antibiotic therapy. The fatality rate of meningococemia is up to 40%. As many of 20% of survivors have permanent sequelae such as hearing loss, neurologic damage or loss of a limb.

Next slide. Meningococcal conjugate vaccine is routinely recommended for all persons ages 11 through 18 years old and if not previously vaccinated, all college freshmen living in a dormitory.

The vaccine is also recommended for anyone two through 55 years of age at increased risk for meningococcal disease including shown on the next slide those with functional or anatomic asplenia, frequent travelers to and U.S.

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citizens residing in countries in which *Niesseria meningitidis* is hyperendemic or epidemic, those of persistent complement component deficiency. Microbiologists routinely exposed to isolates of *Niesseria meningitidis*, military recruits and children with HIV infection.

Back in 2005 when ACIP made recommendations for the use of meningococcal conjugate vaccine which is Menactra, the only vaccine available at that time, data was lacking on whether revaccination would be needed. Serologic data are now available that show significant decline in antibody levels three to five years after vaccination although few break through cases have been reported. That is, there have been very few cases of invasive meningococcal disease in persons who previously received meningococcal conjugate vaccine.

This signifies that not everyone would need revaccination. Because of the higher risk for meningococcal disease among certain groups and limited data on duration of protection, at its June 2009 meeting, ACIP recommended that persons previously vaccinated with either meningococcal conjugate vaccine or meningococcal polysaccharide vaccine Menommune who are at prolonged increased risk for meningococcal disease should be revaccinated with meningococcal conjugate vaccine.

You should now be on Slide 23 and it shows a graph. Persons with prolonged increased risk for meningococcal disease have increased susceptibility to the disease or ongoing increased risk for exposure to *Niesseria meningitidis*.

In higher levels of serum bacteriocidal antibodies against *Niesseria meningitidis* or SBA can provide these groups increased protection against

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disease. SBA is a measure of the ability of sera to kill a strain of *Neisseria meningitidis* in the presence of complement.

The SBA titer of 1 to 128 was used as a conservative correlative protection. A small number of participants from the original Menactra pre-licensure clinical trial were revaccinated three years or five years after first receiving Menactra.

Of those who have been vaccinated with meningococcal conjugate vaccine, Menactra, three years previously, sera was collected before revaccination and only 75% and 86% had SBA titer greater than 1 to 128 for sera groups C and Y respectively, that is, before being revaccinated.

Of those that had been vaccinated with meningococcal conjugate vaccine five years previously, again sera collected before revaccination showed that only 55% and 94% had SBA titers greater than 1 to 128 for sera groups C and Y respectively.

In both studies upon revaccination with meningococcal conjugate vaccine, subjects achieved SBA titers greater than 1 to 128 for sera groups C and Y. On the basis of these data, ACIP approved the proposal for revaccination in certain high-risk groups. Next slide.

Based on the recommendations, the interval between vaccination and revaccination would depend on the age when the initial dose was given. So for children who received their first dose at age two through six years and remain at increased risk for meningococcal disease, they should receive an additional dose three years after their first dose and then every five years indefinitely if they remain in the high risk group.

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Next slide. For those persons who received their first dose at age seven or older and remain at increased risk for meningococcal disease because of a high-risk condition or situation, then they should receive an additional dose five years after their initial dose. If that person remains in a high-risk group, they will need revaccination every five years thereafter with meningococcal conjugate vaccine. Once the age of 56 years is reached, meningococcal polysaccharide vaccine should be used as meningococcal conjugate vaccines are only licensed through age 55 years old.

Now you should be on Slide 26- so who are the high-risk persons who should be revaccinated with meningococcal conjugate vaccine? Those with persistent complement component deficiency, anatomic or functional asplenia, microbiologists with prolonged exposure to *niesseria meningitidis*, frequent travelers to or persons living in areas with high rates of meningococcal disease. Next slide.

Although the duration of protection from meningococcal conjugate vaccine is not known, most entering college students will have received meningococcal conjugate vaccines within the preceding four years. Because of the limited period of increased risk, ACIP currently does not recommend that college freshmen living in dormitories who were previously vaccinated with meningococcal conjugate vaccine be revaccinated.

Said another way, healthy children who received a routine dose of meningococcal conjugate vaccine do not need to be revaccinated if their only risk from meningococcal disease is living in a college dormitory.

The ACIP meningococcal working group continues to discuss this issue. Of note is that college freshmen living in dormitories who were vaccinated with meningococcal polysaccharide vaccine more than five years previous are recommended to be revaccinated with meningococcal conjugate vaccine.

Lastly on this subject, Slide 28, we now have two meningococcal conjugate vaccines available for use, Menveo produced by Novartis was approved by the FDA in February of this year for use in persons 11 through 55 years of age. There is an application pending with FDA to allow use down to age two years old. As with the other conjugate vaccine, Menactra produced by Sanofi, either vaccine may be used for persons 11 through 55 years of age for whom meningococcal conjugate vaccine is recommended.

At this time we'll now move on to our next topic, Slide 29. We'll now discuss updated recommendations for the use of the two currently available vaccines for protection against human papillomavirus infections.

Human papillomavirus HPV is the most common sexually-transmitted infection in the United States. More than 100 HPV types have been identified. Of these about 40 types are associated with the development of cervical cancer.

Infection with low-risk, non-oncogenic types such as types 6 and 11 can cause benign or low-grade cervical cell abnormalities or genital warts. Higher-risk or oncogenic types such as 16 and 18 can cause low-grade cervical cell abnormalities, high-grade cervical cell abnormalities that are precursors to cancer as well as ano-genital cancers.

Types 16 and 18 together account for about 70% of cervical cancer. Next slide, Slide 30. We currently have two vaccines for protection against human papilloma virus infection. HPV-4 contains HPV types 16, 18, 6 and 11. HPV-2 contains HPV types 16 and 18.

ACIP recommends vaccination with HPV-2 or HPV-4 for prevention of cervical cancers and pre-cancers. Both vaccines might provide protection against some other HPV-related cancers in addition to cervical cancer although there are currently only data sufficient to recommend HPV-4 for protection against vulvar and vaginal cancers and pre-cancers.

HPV-4 is recommended also for prevention of genital warts. Whenever feasible, the same HPV vaccine should be used for the entire vaccination series. No studies address interchangeability of HPV vaccines; however, if the vaccine provider does not know or have available the HPV vaccine product previously administered, either HPV vaccine can be used to complete the series to provide protection against HPV-16 and 18.

For protection against HPV-6 or 11 related genital warts, a vaccination series of less than three doses of HPV-4 might provide less protection against genital warts than a complete three-dose HPV-4 series.

Next slide, Slide 31. ACIP recommends routine vaccination of females ages 11 or 12 years with three doses of either HPV-2 or HPV-4. The vaccination series can be started beginning as early as nine years old.

Vaccination is recommended for females ages 13 through 26 years who have not been vaccinated previously or who have not completed a three-dose series.

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If a female turns 26 years old before the series is complete, the remaining doses can be given after age 26 years. Ideally vaccines should be administered before potential exposure to HPV through sexual contact.

HPV-4 only may be administered to males to reduce their likelihood of acquiring genital warts. This slide is just a reminder that only HPV-4 is licensed for use in males, not HPV-2. The recommendation for use in males is based on prevention of genital warts.

Next slide. As far as the future of HPV vaccines, there are pending applications with FDA which include the extension of the age indications for HPV-4 vaccine for older females as well as an additional indication in males for prevention of anal cancers in addition to the current indication for prevention of genital warts.

You should now be on Slide 34 if you're following along and now we'll turn our discussion to the use of influenza vaccine. Next slide. In February of this year, history was made with the unanimous vote by ACIP to expand the influenza vaccination recommendations to include everyone six months and older to receive an annual influenza vaccination.

This includes all adults. It is no longer necessary to inquire about age or risk groups to determine who is eligible for influenza vaccination. Everyone six months and older is eligible.

Last year we all dealt with the complexity of having to administer two separate vaccines, the seasonal vaccine and the novel H1N1 vaccine. We're happy this year that the novel H1N1 vaccine has been combined with seasonal

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components to make only one vaccine for this season, the trivalent vaccine that is noted on this slide, on Slide 36.

Next slide. With this landmark recommendation to vaccinate everyone, there is still the need to make a special effort to vaccinate persons at increased risk for complication from the flu and their close contacts. This includes persons over 65 years old, persons with chronic illness such as diabetes, asthma, as well as pregnant women, residents of nursing homes, and healthcare workers.

We have received many questions about dosing of children six months through eight years old this season. As in previous seasons, all children ages six months through eight years who receive a seasonal influenza vaccine for the first time should be given two doses.

Children who receive only one dose of a seasonal influenza vaccine in the first influenza season that they are vaccinated should receive two doses rather than one in the following influenza season.

In addition for the 2010 to '11 influenza season, children ages six months through eight years who did not receive at least one dose of an influenza H1N1 (monovalent) vaccine should receive two doses of the 2010 to '11 seasonal influenza vaccine regardless of previous influenza vaccination history.

And finally children ages six months through eight years for whom the seasonal 2009-10 vaccine or influenza monovalent vaccine history cannot be determined, those children should receive two doses of a 2010 to 2011 seasonal influenza vaccine.

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In the next few weeks when the MMWR document containing the ACIP recommendations for flu vaccine are released for the upcoming season, an easy-to-follow flow chart or table will be provided that'll make it quick and easy for busy practitioners to determine how many doses the patient will need.

Now we're on Slide 39 and we'll discuss other recommendations. Next slide, Slide 40. Additional updates in the last year have included a recommendation to routinely vaccinate household members and other close personal contacts of adopted children who are newly arriving from countries with high or intermediate hepatitis A endemicity.

This updated recommendation was based on increased reports of hepatitis A infection among persons in close contact with new adoptees from countries of high or intermediate Hep A endemicity.

The risk for hepatitis A among close personal contacts of international adoptees is estimated at 106 per 100,000 household contacts of international adoptees within the first 60 days of their arrival in the United States.

By comparison according to surveillance data, the estimated rate of symptomatic hepatitis A in the U.S. general population in 2007 was one per 100,000 population.

Next slide. You should now be on Slide 41. Another recent update involved the use of two specific vaccines. A general rule regarding vaccine administration is that all vaccines can be administered at the same visit as all other vaccines.

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In December 2009, Merck Pharmaceuticals revised the package insert for herpes zoster vaccine to advise that zoster vaccine and pneumococcal polysaccharide vaccine or PPSV-23 vaccine should not be administered at the same visit.

This recommendation was based on a Merck study that showed the average titer against varicella zoster virus was lower in persons who received both of these vaccines at the same visit compared to persons who received these vaccines four weeks apart.

However, the clinical relevance of this observation is not known because there is no evidence to indicate that antibody titers against varicella zoster virus are a true measure of protection against herpes zoster.

Antibody levels for some of the PPSV-23 serotypes were also assessed during this study and were not affected by simultaneous administration. The significance of this observation is also not known. Finally, the safety profile of zoster vaccine is not affected by simultaneous administration of PPSV-23.

Consequently to avoid introducing barriers to patients and providers who are interested in these two important vaccines, CDC has not changed its recommendation for either vaccine and continues to recommend that zoster and PPSV vaccines be administered at the same visit if the person is eligible for both vaccines.

Next slide. We'll now turn our attention to pertussis, or whooping cough, which is highly contagious and one of the most commonly-occurring vaccine-

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preventable diseases in the United States. As you know, people with pertussis usually spread the disease by coughing or sneezing while in close contact with others who then breathe in the pertussis bacteria.

Many infants who get pertussis are infected by older siblings, parents or other caregivers who might not even know they have the disease. Pertussis once it's caught is most severe for babies. Pertussis symptoms in toddlers and older children and adults may be mild at first and mimic a typical upper respiratory infection.

It is often not suspected or diagnosed until a persistent cough with spasm sets in after one to two weeks. In infants the cough may be mild or absent. Infants may actually present with apnea.

There have been recent news articles regarding increased pertussis activity or outbreaks in several states. In particular, California has reported over 1300 cases and five infant deaths due to pertussis. Approximately 700 additional cases are also under investigation. In June of this year, California declared a pertussis epidemic.

In response to the epidemic in California, efforts are underway to increase awareness of pertussis and get more people vaccinated. Among other efforts, California hopes to prevent pertussis transmission to the most vulnerable population - that is infants less than one year of age.

It's important to note that while a number of states are reporting an increase in the number of pertussis cases in 2010, other states are reporting less pertussis activity in comparison to this time last year.

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All providers should make sure that their patients as well as themselves are up-to-date with recommended pertussis vaccines: DTaP for infants and children and Tdap for adolescents and adults. Further information may also be found on the CDC pertussis page at the URL shown on the slide, Slide 42.

Next I would like to turn your attention to how as providers we can help increase vaccine coverage rates. Next slide, Slide 44. The findings from a 1990s task force on community preventive services still holds true today with regards to what it takes to increase vaccination levels.

We have newer challenges now including an increase in the number of new vaccines and new vaccine combinations, increases in the cost of purchasing vaccines, coupled with a lack of adequate payment to practitioners to buy and administer vaccine, and finally increased anti-vaccine sentiment from the public. So much remains to be accomplished.

As practicing providers, some practical ways we can address this issue are by enhancing access to care. This could include for example extending office hours by providing shot-only visits or vaccine-only visits and looking at other suitable venues for vaccination within the community.

Secondly, increasing demand from the public through increasing their awareness of available vaccines and finally by addressing provider barriers with the help of physician organizations. Next slide.

Some practical tips in a provider setting include of course increasing awareness amongst not only the provider but also their staff and the patients

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of the recommended vaccines at a particular visit, sending out patient reminders or recalls, avoiding missed opportunities to vaccinate through the use of standing orders as an example, and using true contraindications only as a reason to defer vaccination, for example, not deferring vaccines only because of a minor illness. Also the use of available registry systems to help keep track of vaccine status would be one additional tip.

As providers, studies have shown that parents and patients really do listen to what we say. Now you should be on next slide, Slide 47. An example is a 2008 Journal of Pediatrics article which showed that parents who had doubts about vaccines and either refused or delayed their child vaccines cited information and assurances from their physician as the main reason to change their mind and get vaccines.

We'll now turn our attention to resources. We have discussed a lot of information today so I would like to spend the last few minutes directing you to where you can easily access all of the information we discussed today and more. Slide 49.

Some great vaccine Web sites to include in your favorites list include the CDC's vaccine Web page, the Web site for the Immunization Action Coalition which has some excellent standing order samples, the American Academy of Pediatrics Web site, the FDA, and other Web sites shown on this slide.

This is the CDC's vaccine homepage. There are pages also dedicated solely to healthcare professionals such as yourself and as you can see on this slide

which is Slide 50, there are two ways to access this page, two portals of entry for the healthcare provider page.

Next slide. Once on the healthcare provider portal, you will see that you can access clinical resources such as immunization schedules, the most recent ACIP recommendations including all of the ones we mentioned today.

The majority of the information you access can be easily downloaded. Other sections include administrative tools such as vaccine storage and handling guidelines as well as vaccine administration guidelines to help with staff training.

This next slide is the ACIP recommendations homepage which lists the recommendations by vaccine. It also gives you access to provisional recommendations which are posted after ACIP makes a vote on a particular subject but before the longer MMWR document is actually published.

Next slide. I would also like to bring your attention to some new material we have on the site including some great material for providers on how to discuss vaccines with their patients.

You can see in the top corner and we'll move to the next slide for a closer look one of the new tools called vaccine conversations with parents. It includes material for both the provider as well as downloadable sheets for patients.

On this next slide you see topics for providers which include communication strategies for successful vaccine conversations with parents as shown, entitled

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“Talking with Parents About Vaccines for Infants” and there’s a larger picture of this on this next slide, Slide 56.

This page offers some practical tips for providers on how to communicate effectively with parents about vaccines including taking the time to listen, using a mix of science and personal anecdotes and acknowledging benefits and risks of vaccines. On this slide, this is an example of a sheet addressing concerns about vaccine safety issues, this one about MMR. It includes scientific research references. It can primarily be used for healthcare providers to assist them in answering parents’ concerns about MMR vaccine but it can also be used by parents themselves who are concerned about vaccine safety and again it includes scientific research references.

On our next slide, Slide 58, this is an example of disease-specific sheets that are available with the risk and benefits of the vaccine. Most of them actually include a personal story of infection with a vaccine-preventable disease.

On Slide 59 you see one of the more popular sheets which is titled “If you choose not to vaccinate your child, understand the risks and responsibilities.” There is also a great video to show in your waiting room or online that shows real mothers with real concerns and a pediatrician answering their questions. This is the “get the picture” video which is shown here on Slide 60.

Parent-friendly immunization schedules can also be found on this site and lastly for those who see adults, a very handy adult immunization scheduler is included. As we can see more closely on Slide 63, this scheduler is downloadable.

It asks the client to input some basic questions including birthdate, medical conditions and past vaccines and then the scheduler will output the list of vaccine doses the person will need based on ACIP recommendations. Here's an example of a page you will see if you access this scheduler shown on Slide 64.

For those interested, there are more in-depth vaccine education and training opportunities available through the CDC including a two-hour satellite broadcast and Webcast that will go into more detail about immunization updates on August the 5th. You can receive free CE credit for the majority of our products which can all be found on the Web site listed on the slide.

There are a variety of self-study options including a module just on adult immunizations as well as a more comprehensive DVD on all vaccine-preventable diseases and their respective vaccines.

And then finally on Slide 66 before we close, I would like to remind you of your responsibility - our responsibility really - to ensure that we and our staff are immunized against the flu every year, that we're adequately up-to-date on our Tdap or Td vaccine, hepatitis B vaccines, to make sure that we're immune against varicella, measles, mumps and rubella.

I know we've discussed a lot of information today and in addition to the question-and-answer session, to ask further questions you may do so by telephone or e-mail and on Slide 67, you will see our phone number listed for providers and the public, 1-800-CDC-INFO.

Providers may also e-mail questions to nipinfo - nip info - nipinfo@cdc.gov and of course our vaccines Web page at www.cdc.gov/vaccines. That has all the information we discussed today and much more. Thank you so much for your attention and I'll now turn you over to Ms. Loretta Jackson-Brown.

Loretta Jackson-Brown: Thank you, Dr. Beysolow for that wealth of information that you've provided to our COCA audience. We will now open up the line for the question-and-answer session.

Coordinator: Thank you very much. If you would like to ask a question, please press star then 1 on your phone. Please be sure that your line is unmuted and record your name when prompted. I will need your name in order to introduce the question. If you need to withdraw your request, you press star 2. Once again it is just star then 1 on your phone. The first question is from (Bob Benjamin). Sir, your line is open.

(Bob Benjamin): Thank you very much for a very broad and thorough presentation. We have a question here that's surfacing fairly frequently. If a child - and this is having to do with pertussis vaccine - if a child had adverse reactions such as persistent crying, fever for more than 24 hours, etc., having received DTaP and never completed the full immunization in childhood and is now a young adult, what are the recommendations for use of Tdap in the face of increasing numbers of pertussis in our community?

Dr. Yabo Beysolow: Very good question. Thanks (Bob) for that. We get this often and really the precautions and contraindications for DTaP vaccine during childhood are not the same for Tdap vaccine so the history of temperature of 105 or higher, collapse or shock-like state, persistent crying for three hours or longer, seizure

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with or without fever that may have occurred after a pediatric DTaP do not apply to Tdap. Those precautions do not apply to Tdap.

This patient can safely receive Tdap vaccine. There are only two true contraindications to Tdap vaccine: that would be an anaphylactic reaction to a prior dose of the vaccine or its components or if there was encephalopathy within seven days of a prior dose of pediatric DTaP.

There are also some other precautions for Tdap such as history of an Arthus reaction following a prior dose, Guillain Barre syndrome six weeks or sooner after a prior dose of tetanus (toxoid) vaccine or if there was a progressive or unstable neurologic disorder, you would wait until that condition has stabilized before giving Tdap so I hope that answers your question.

(Bob Benjamin): It does, thank you very much.

Dr. Yabo Beysolow: You're welcome.

Coordinator: The next question is from (Dan Field). Your line is open.

(Dan Field): Thank you. I'm from Glen Memorial Hospital. I am wondering regarding the upper age limit for the human papilloma virus vaccine. Is it based on a lack of a study group beyond that upper age limit or are there other considerations?

Dr. Yabo Beysolow: Very good question. Really it is just based on FDA receiving enough data to show that it is efficacious and safe in that age group though again that application is pending with FDA now to be used in women up to age 45 so once all of that data is reviewed, we hope that that will happen.

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(Dan Field): Thank you.

Loretta Jackson-Brown: Operator, are you there?

Coordinator: Yes, the next question is from (Dara Bradnick). Your line is open, ma'am.

(Dara Bradnick): Thank you. Hi. I just had some questions about the high-dose influenza vaccines. I just needed some comments pro or con on this.

Dr. Yabo Beysolow: Sure. As you know, Sanofi has a new vaccine called Flu Zone High Dose that was licensed and approved by the FDA and this vaccine contains about four times as much antigen as standard dose flu vaccine and studies have shown this information was presented to the ACIP back in February of this year and the study section on that is it may have some increased efficacy over the standard dose.

There were also some increased rates of injection site and systemic reactions most frequently with the high-dose vaccine; however, CDC has not expressed a preference for use of either vaccine over the other so practitioners may use either the standard dose or the high-dose vaccines for their patients at this time who are over 65.

(Dara Bradnick): Thank you very much.

Dr. Yabo Beysolow: You're welcome.

Coordinator: The next question is from (Kelly Mattson). Your line is open.

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(Kelly Mattson): Thank you. I had a quick question about influenza season for greater than eight years of age if they had not received monovalent H1N1 in the previous year. Is there a different recommendation for them than the 6 months to 8 years of age?

Dr. Yabo Beysolow: Great question and really those two-dose recommendations would only apply for the six months through eight years so for everyone nine and older, it would just be one dose of influenza vaccine.

(Kelly Mattson): Great, thanks so much.

Dr. Yabo Beysolow: I'm sorry?

(Kelly Mattson): Thank you.

Dr. Yabo Beysolow: Oh, you're welcome.

Coordinator: Your next question is from (David Boyer). Your line is open, sir.

(David Boyer): Yes. My question is also related to influenza vaccine children six months to eight years old. The recommendation is for two doses but what's the timeframe between the two doses that there should be? How much timeframe should there be between the doses?

Dr. Yabo Beysolow: Currently it's planned that that will be four weeks minimum interval between doses and as in previous years between other flu doses. And the

official recommendations will be out within the next week on the ACIP Web page...but 28 days minimum interval.

(David Boyer): Okay, thank you.

Dr. Yabo Beysolow: You're welcome.

Coordinator: This question comes from (Janice Collins). Your line is open, ma'am.

(Janice Collins): Thank you. I've been getting inquiries from our providers as to what is meant by the permissive use of the HPV vaccine. Can you explain that a little?

Dr. Yabo Beysolow: Sure, (Janice). Really the issue is that HPV vaccine 4 - HPV-4 vaccine - is not routinely recommended for males by the ACIP. It was only based on again the prevention of genital warts and the issue here is that unlike with females where the routine recommendation has been made, with males it's still being looked at as to whether or not this should be an overall recommendation for all males to receive this.

And at this time, it's permissive meaning that providers may choose to offer it and give the vaccine to males and parents may ask for it. It is also covered by the VFC program through age 18 for males but it's not a routine recommendation so it's permissive meaning that yes, you may give it.

(Janice Collins): Thank you and see you soon.

Dr. Yabo Beysolow: I'm sorry, I missed that.

(Janice Collins): I said thank you and see you soon.

Dr. Yabo Beysolow: Okay, thank you.

Coordinator: Your next question is from (Roger Miller). Your line is open, sir.

(Roger Miller): Yes. I had a question about the meningococcal conjugate revaccination. Do we know when there may be a package insert change and/or FDA licensure for the revaccination recommendations since that often has an impact on insurance coverage for additional doses? Thank you.

Dr. Yabo Beysolow: Well, currently there is an MMWR document for meningococcal revaccination. It was listed on one of the slides. I can go back to it, I believe MMWR 2009, volume 58, number 37, so that does address it and that is an official ACIP recommendation.

As to when the package insert itself would be updated, we would have to check with the manufacturer on that but it is an official MMWR document at this time.

(Roger Miller): Thank you very much.

Coordinator: This next question comes from (Neal Conoshero). Your line is open, sir.

(Neal Conoshero): Hi, thank you. I had a question. What are the current recommendations for follow-up Tdap vaccines after the first one was given? We're coming to that point now where kids are going to be eligible for revaccination.

Dr. Yabo Beysolow: Very good question. At this time, there's only a recommendation for one lifetime dose of Tdap vaccine for anyone and then that would be followed every 10 years by a Td booster so it will be a couple more years before we get to that and then if data of course would show that we have decreasing or waning immunity, that may be considered but at this time it's for one lifetime dose.

(Neal Conoshero): Thank you.

Coordinator: The next question is from (Janine). Your line is open.

(Janine): Hello. I had a question about package inserts versus ACIP recommendations. Sometimes they differ so I wanted to know which one takes precedent and why.

Dr. Yabo Beysolow: Very good question. Rarely that happens from time to time and again, the vaccines are licensed by the FDA but then ACIP actually has working groups that sit and meet and brings it to the forefront at the time of the ACIP meeting for a vote to determine what would be the best recommendations for the general public based on the safety and efficacy data that they have reviewed.

So yes, there may be some difference from time to time and it really will be provider-dependent at that point as to which recommendation they would want to follow but again, the ACIP recommendations are usually a joint collaboration between not only the AAP, AAFP, as well as other medical organizations that come together to make those recommendations for the use of the vaccine.

(Janine): Thank you.

Coordinator: Your next question is from (Debra). Your line is open. Please check your phone for a mute button, (Debra).

(Debra): My question is kind of two-fold. If I'm giving the first HPV and it's a long time before I give the second one, is there a shorter period that I can give the second one?

Dr. Yabo Beysolow: Okay, let me repeat. I'm sorry, let me repeat your question to make sure I understood. You were talking about the HPV vaccine and if you give the first dose and then there's a longer interval before the second dose, well we know that you do not need to restart the series.

You may complete the series but there needs to be a minimum interval of 24 weeks between Dose Number 1 and Dose Number 3 of the entire HPV series and so along those lines, if someone got a vaccine say in 2009 but didn't show up again until 2010 for their second dose in this series, you may still continue the series. There's no need to restart the series.

And also another question we get often about that is what if someone began the series - a female before the age of 26 - and now is 27 or 28. Can you complete the series and yes, you can. You can basically continue where you left off.

(Debra): Thank you.

Coordinator: This next question is from (Russell Eggert). Your line is open, sir.

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(Russell Eggert): Yes, thank you. Could you please clarify the influenza vaccination for children six months through eight years old again? I'm sorry. Children six months through eight years who've never received seasonal influenza vaccine should get two doses.

If they received one or more doses of H1N1 monovalent, does that count as having received prior seasonal influenza vaccine?

Dr. Yabo Beysolow: No, and I empathize with you because I know this is very confusing, the wording in that. Like I said, I hope that flow charts will be out very soon but to recap on your question, if a child received one or more doses of monovalent vaccine, this would not have any bearing or influence on their need for seasonal influenza vaccine because remember they would still need coverage from the other components of the seasonal influenza vaccine, the H3N2 and the B component.

So if they for example received one dose of H1N1 last year but no seasonal vaccine, they would still need seasonal influenza vaccine this year as well.

(Russell Eggert): Okay, so they would need two doses of seasonal influenza vaccine, even if they received at least one dose of H1N1 but had never received seasonal flu vaccine previously?

Dr. Yabo Beysolow: Can you repeat that one for me, please?

(Russell Eggert): Okay. Let's take the example of a child under nine who never received seasonal flu vaccine prior but did receive one or two doses of H1N1 vaccine. They would still need two doses of the new seasonal flu vaccine?

Dr. Yabo Beysolow: That's correct, so for a child who's never received seasonal influenza vaccine at all so this would be their first they would receive two doses.

(Russell Eggert): Thank you.

Dr. Yabo Beysolow: You're welcome.

Coordinator: There are no further questions in the queue.

Loretta Jackson-Brown: Thank you. On behalf of COCA, I would like to thank everyone for joining us today with a special thank you to our presenter, Dr. Beysolow. If you have additional questions for today's presenter, please e-mail us at coca@cdc.gov. Put Dr. Beysolow in the subject line of your e-mail and we will ensure that your e-mail is forwarded to her for a response.

Again, the e-mail address is coca@cdc.gov. The recording of this call and the transcript will be posted to the COCA Web site at emergency.cdc.gov/coca within the next few days.

Continuing education credits are available for this call. Those who participated in today's COCA conference call and would like to receive continuing education credit should complete the online evaluations by August 31, 2010 using course code EC1648, that is E as in Echo, C as in Charlie and the numbers 1648.

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Thank you again for being a part of today's COCA conference call. Have a great day.

Coordinator: This does conclude today's conference. Thank you for joining and you may disconnect.

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