

NWX-DISEASE CONTROL & PREVENTI

**Moderator: Dale Babcock
April 2, 2014
11:00 am CT**

Coordinator: Welcome and everyone thank you for standing by. At this time all participants are in a listen-only mode.

During today's conference we will be conducting a question and answer session. To ask a question please press Star 1.

Today's conference is being recorded. If you have any objections you may disconnect at this time.

I would now like to turn the conference over to Dr. Andrew Kroger. Thank you and you may begin.

Dr. Andrew Kroger: Thank you very much. Welcome to Current Issues and Immunizations Net Conferences a CDC net conference.

I'm Andrew Kroger a Medical Officer in the Immunization Services Division of the National Center for Immunization and Respiratory Diseases (that's NCIRD) at CDC. And I will be the moderator for today's session.

We're bringing you the latest immunization updates to your office, laptop, or conference room.

To participate in today's program you need a telephone connection and a separate Internet connection.

The learning objectives for this session are one describe an emerging immunization issue, two list a recent immunization recommendation made by the Advisory Committee on Immunization Practices or ACIP, three locate resources relevant to current immunization practice, and four obtain, assess, and apply patient information to determine the need for immunization.

Today is April 2, 2014 and we will have three speakers today. First Dr. Amanda Cohn a Medical Officer in the Meningitis and Vaccine Preventable Diseases Branch will present on control of serogroup B meningococcal outbreaks.

Next Dr. Elizabeth Briere will outline the 2014 ACIP Hib vaccination statement. And then finally JoEllen Wolicki will talk about CDC immunization resources for providers. A question and answer session will follow Ms. Wolicki's presentation.

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CDC, our planners, and our presenters wish to disclose they have no financial interest or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters.

Presentations will not include any discussion of the unlabeled use of a product or a product under investigational use with the exception of Dr. Cohn's discussion of meningococcal vaccine and Dr. Briere's discussion of Hib vaccine in a manner recommended by the Advisory Committee on Immunization Practices but not approved by the Food & Drug Administration. CDC does not accept any commercial support.

Before proceeding to Dr. Cohn's presentation would like to ask a polling question taking advantage of a new technology we'll ask this question and we'll give you ten seconds to input your answer.

We're not going to reveal the results of this preconference question right now but we'll tell you the answer at the end of today's program.

So here is the question, true or false, a 23 month - an unvaccinated 23 month old with a history of Haemophilus influenza type b infection which occurred at 11 months of age does not need Hib vaccine because of a history of natural disease? The choices are true or false.

Give you ten seconds. Okay time is up. We'll reveal the answers at the end of the presentations. And so now I will turn the mic over to Amanda Cohn. You may begin.

Dr. Amanda Cohn: Good afternoon. Today I will be talking about serogroup B meningococcal disease epidemiology and recent serogroup B meningococcal outbreaks and steps taken to control those outbreaks on college campuses.

Meningococcal disease is a spectrum of illnesses caused by *Neisseria meningitidis*. There are three primary symptoms of invasive *Neisseria meningitidis* disease infection including meningitis, bloodstream infection, and pneumonia.

Meningococcal disease frequently presents with flulike symptoms early but can be rapidly progressive.

Meningococcal disease has high morbidity or mortality, 10% to 15% of cases die. And an additional 11% to 19% have long term sequelae such as skin scarring, limb loss or neurological deficits. Most disease occurs in healthy people.

This is a picture of the *Neisseria meningitidis* bacteria. On the very outside of this picture you can see the *Neisseria Meningitidis* capsule.

There are 13 types. And this is what we call serogroups. There are six that cause most disease globally and three serogroups B, C, and Y which cause most disease in the United States. This is the target for conjugate vaccines.

You can also see in this picture below the capsule more towards the inner portion of this of the bacteria are outer membrane proteins.

These are on the surface of the cell but are not as immunogenic as the capsule. These outer membrane proteins are the targets for serogroup B vaccines.

As you can see we're at a historic low from a meningococcal disease incidence. Prior to the year 2000 meningococcal disease was typically about one case per 100,000 annually which turned into about 3000 reported cases annually. In recent years we've had between 500 and 600 cases caused by all serogroups reported annually.

This decline in meningococcal disease has been seen in all serogroups. As you can see in orange serogroup B incidence has also declined with about 0.3 per hundred thousand in the 1990s and is currently less than 0.1 per hundred thousand.

Serogroup C and Y which caused more disease in the 1990s have now declined even more than serogroup B which is likely some impact of the meningococcal conjugate vaccine introduced and recommended routinely in adolescence which has been introduced since the year 2005.

As you can see as coverage has increased with the meningococcal conjugate vaccine in adolescence the proportion of total meningococcal disease cases in the United States caused by serogroup B has been increasing.

The solid line here are the total number of reported cases which includes about 20% to 30% of meningococcal disease cases which are unknown.

Amongst all of the cases serogroup B has increased from 10% to 20% which is more like 30% to 40% of known serogroup cases.

This shows you serogroup incidence by single year of life. And the important thing to notice here is the peak of disease that you see in late adolescence.

This peak of disease if we had shown you this same slide prior to conjugate vaccine introduction in adolescence would have been serogroup C, and Y much higher than the line that's serogroup B but now you can see most disease in this age group is caused by serogroup B.

What's also important to notice is this peak of disease is right about the time the kids go to college.

To put this into some perspective because we're at low disease incidence in total although more cases are caused by serogroup B than other serogroups we still have very few cases of serogroup B disease in adolescence each year in the United States.

In the 1990s there were about 138 cases reported annually in this age group in 11 to 21 and 11 to 24 year olds.

In more recent years 2010 through 2012 there's an estimated 28 cases of serogroup B disease reported in adolescence annually.

I'm now going to move on and start to talk about serogroup B meningococcal outbreaks. It's important to know that only 2% of US cases are outbreak related so most cases are going to be sporadic cases that we see in the United States.

The definition of a meningococcal disease outbreak and this is looking specifically at an organization such as a college, a jail, or a school is two to three cases in the same serogroup in less than three months which also resulted in an attack rate of ten per 100,000.

So in smaller organizations you'll have fewer cases that you'll need to meet the outbreak definition.

In larger organizations such as colleges with 20,000 or 30,000 people - they will have to be more than three cases to meet that outbreak definition.

More than 80% of cases of meningococcal disease outbreaks occur in persons less than 25 years of age. And in university outbreaks 97% are undergraduates.

College students living in dorms are at a three to 23 fold increased risk from meningococcal disease. And this is both sporadic disease and in outbreaks.

And there are other risk factors that have been identified such as Greek society member, attending bars, alcohol consumption, and kissing and smoking.

However it's important to note that many cases of meningococcal disease even in outbreaks, occur in kids who don't have any of these risk factors.

I'm now going to talk about recent college outbreaks of serogroup B meningococcal disease. These five University outbreaks have occurred in the last several years and this is all serogroup B.

We haven't seen any serogroup C or Y outbreaks in many years since we've had I coverage with meningococcal conjugate vaccine.

The first two outbreaks occurring in 2009 and 2011 were outbreaks that consisted of four and two cases. In both of these outbreaks there were cases

that occurred within a couple of weeks of each other. And there were no additional cases after this outbreak.

In the third outbreak which began in January of 2008 this is a much more prolonged outbreak which continued until November of 2010. This occurred in a large university campus. And there were a total of 13 cases in this outbreak.

But what's different about this outbreak and is similar in the next two outbreaks that I'll describe is there was evidence of sustained transmission of serogroup B disease over a long period of time as opposed to a couple of weeks which is what we were used to seeing with serogroup C outbreaks on college campuses and what we saw in these first two outbreaks of serogroup B disease.

The two more recent outbreaks that occurred in 2013 I'll describe in more detail. The Princeton University outbreak consisted of eight cases from March to November 2013.

And at the University of California Santa Barbara there was an outbreak of four cases in November of 2013.

This slide shows the epidemic curve of 13 meningococcal cases associated with University A from January 2008 to December 2010.

As you can see most of these were university students. There were a couple of linked students that were associated with University such as being a boyfriend or girlfriend of a student.

These cases occurred over years and through different semesters. And instead of seeing several cases in one month like you see in February of 2010 for the rest of the outbreak you saw one to two cases every month or every couple of months.

In Princeton University in 2013 there were eight cases of serogroup B meningococcal disease in Princeton University students or with persons linked to the University from March to November 13.

This resulted in an attack rate of 134 per 100,000 among undergraduates. And this is compared to a current serogroup B attack incidence rate of about .1 to .2 per 100,000 in the US population.

There were no fatalities in this - in these original eight cases. There were two cases with sequelae such as a neurocognitive deficit and unilateral hearing loss.

And laboratory testing showed that all seven isolates were identical. There was one case that did not have an isolate.

But all of the cases that were evaluated had an identical isolate. And it was an ST409 which was one that was seen very rarely prior to this outbreak in the United States.

There was also a serogroup B meningococcal disease outbreak at the University of California Santa Barbara.

This consisted of four cases in an undergraduate population in a few week period of time which is what we had seen more frequently in prior outbreak. These were all in undergraduates.

There was also an additional case on the epidemiologic investigation that was identified from March 2013.

And this isolate also matched two of the four cases that were identified in November which raised concern that this was also an ongoing - this also demonstrated ongoing transmission at the University.

Among these five cases four recovered, one had severe sequelae, had bilateral foot amputation. And this resulted in an attack rate at this University of 21 per 100,000. And this is among UCSB students seven to 22 years of age.

This is a 234 fold higher difference than the regular incidence rates for 17 to 22 year olds in the US population.

All five of these isolates were closely related. There was a small difference between the PFGE patterns in two of the isolates from November but all of the other molecular testing that was done show that these isolates were identical.

And this was a different strain compared to Princeton that was SP32 which is very commonly circulating serogroup B strain in the United States.

So to look at serogroup B and C outbreaks more generally in the United States this is a compilation of multiple outbreaks that have been evaluated in the United States over the last several years.

And as you can see except for the situation of the Princeton University outbreak and the outbreak at University C the 13 cases that occurred in 2008 through 2010 most - outbreaks on college campuses are actually short lived and cause fewer than four cases so most outbreaks will be two to three cases.

Or occasionally four to five cases. But it's been rare that we've seen more than five cases on a college campus except for these recent outbreaks.

This shows the interval reported between cases in school based serogroup B or C outbreaks. This excludes the three recent University serogroup B outbreaks that we've been talking about.

And it shows that prior to the last couple of years most serogroup B outbreaks had an interval of about three days which was very similar to historically to serogroup C outbreaks.

If you add in those three recent outbreaks on college campuses the median time between cases actually increases from three to 15 days for serogroup B with a range of one to 294 cases between days between cases.

As you can see our prior outbreak guidelines with the three months between cases may not be the best way to evaluate serogroup B outbreaks.

I'm now going talk about prevention and management of these two recent serogroup B outbreaks on college campuses.

There's currently no licensed serogroup B vaccine in the United States. Novartis has a vaccine named Bexsero which is a recombinant menB outer membrane vesicle vaccine which is licensed in Europe, Australia, and Canada in 2013.

Importantly this is a two dose series in adolescence. And it contains four antigenic components. So these are those outer membrane proteins that you saw in the earlier slide. And those are themed fHBP, NHBA, NadA and PorA.

Those four different antigenic components are to provide broad protection against multiple MenB strains.

There's an additional vaccine that's under development in the United States made by Pfizer. This would be a three dose series in adolescence.

And it contains two antigens of the same two different types of the same antigen factor H binding protein. And this is also developed to achieve broad protection against multiple MenB strains.

Because Bexera had been licensed outside of the United States with the onset of the cases at Princeton University the CDC, the State Health Department and the University made the decision to inquire with FDA if we could use this vaccine as an investigational new drug to prevent additional cases in this outbreak.

So CDC submitted what we call an IND. And the FDA approved that IND in November 2013. This is also produced by the CDC Institutional Review Board.

The two really important components of doing a vaccine campaign under an IND that is different than doing a vaccine campaign with a licensed vaccine is that you have to have a safety monitoring plan in place.

And that you have to have consent forms developed for all persons being vaccinated but you have to have for example parental consent for students who are less than 18 years old.

And there were additional consents for pregnant women to follow those women who were being vaccinated. We also had to develop vaccine information sheets and additional data collection instruments.

There were also multiple contractual agreements which were finalized between CDC, Novartis, and Princeton University in December 2013.

And this involved multiple different aspects of logistics. But for example one thing that was really important was to ensure that this section would be covered under the Vaccine Injury Compensation Program.

And it was determined that it would be. We'd have to ensure that there was good safety reporting to Novartis. And vaccine handling and storage was a very critical aspect of this.

All of these vaccines had to be imported from Europe and relabeled with this IND number. And vaccines could not be returned to central storage after removal.

So getting students vaccinated was another critical piece of the success of this vaccination campaigns on these college campuses.

There was emphasis on education about the vaccine and the IND process. The safety data from the clinical trials was summarized for the students.

It was made clear that this is not a research study or a clinical trial. This is an expanded access IND which is to really use this vaccine because of its urgency to prevent additional cases.

And it was only available to the defined population at risk. So we actually had to indicate in the IND who was eligible to receive the vaccine. And this is entirely voluntary to the student population.

There were several different communication campaigns to inform and encourage students to get vaccinated.

There was information sent out to students and parents. There were town hall meetings that took place prior to the campaign.

And there was advertising which was actually done by the Student Health Advisory Board at Princeton University.

The clinics at Princeton University were modeled after flu vaccine clinics each fall. And the University took on the vaccine storage security and maintaining the cold chain to the vaccine.

So this shows a picture of what the vaccine campaign looked like at Princeton University. The eligible groups were the entire undergraduate student population, graduate students who lived in undergraduate or graduate dormitories, and students, faculty and staff with medical conditions that increased risk for meningococcal disease, and spouses or parents living with undergraduates in dorms.

So at Princeton University there were about 5500 persons eligible for the vaccine. And 95% received one dose. And 89% of the eligible population received two doses of the vaccine.

So UCSB the CDC's sponsored expanded access IND was approved. And this occurred in February 2014.

The target population was similar. It was all undergraduates, graduate students and faculty living in dormitories, and others with high risk conditions such as asplenia, complement component deficiency.

The big difference between Princeton University and UCSB is the number of eligible persons. So while it was about 5000 people at Princeton University at UCSB the estimated number of persons eligible was about 20,000 persons.

The first dose campaign was at the end of February and lasted two weeks. And the coverage with the first dose was close to 50%.

And there is a safety surveillance plan ongoing in collaboration with University of California Santa Barbara and CDC.

So there were multiple challenges associated with using an expanded access IND to vaccinate during these two outbreaks with serogroup B meningococcal vaccine.

The IND preparation time process and vaccine procurement takes time. So there were several weeks between the time it was recognized that we needed to use the vaccine of these college campuses and the time that we were actually able to have the campaign.

Fortunately UC Santa Barbara for example there were no additional cases. There was an additional case that occurred during that time period at Princeton University.

It's also really difficult to determine when additional cases might occur. So if the University does have two or three cases on the college campus in a very

short period of time it's difficult to say in this situation there's going to be additional cases of meningococcal disease that we might worry about in the future and in the situation there won't be.

So because we're really unable to determine that we need to be clear about guidance about when to initiate this IND process for serogroup B vaccine.

And the hope is that this vaccine one of these vaccines or both of these vaccines will be licensed in the near future and will no longer need to be used under this IND process.

A final challenge is that many B vaccines may protect the vaccinated individual from developing disease but may not prevent transmission to other persons.

So while a person may be immune from getting invasive disease that may not mean that they don't carry it in the back of their throats and can't transmit it to other people.

And while we can't be sure one way or the other with these vaccines there was an additional case that occurred in the last several weeks in a student at Drexel University who did have close contact with cases - with students from Princeton University.

And the strain from that case unfortunately did match the Princeton University case. And so that leads us to believe that we may not be able to reduce transmission on serogroup B outbreaks in the same way that we can with serogroup C and Y outbreaks with the use of conjugate vaccines.

Other control measures to prevent additional cases in serogroup B outbreaks are difficult. We do of course, as with sporadic cases, recommend chemoprophylaxis for close contacts of all cases.

However mass chemoprophylaxis is not recommended to control large outbreaks as it's often impractical and unlikely to succeed.

It may be considered in some cases such as outbreaks involving limited populations like a 300 to 500 person boarding school. But if mass chemoprophylaxis is undertaken it needs to be administered to all targeted persons at the same time.

So offering 5000 or 20,000 students Cipro and expecting them to all take it at the same time and for there to not be side effects or complications from that is problematic.

Additionally chemoprophylaxis is not 100% effective. So you're unlikely to completely reduce transmission at that University. And it's much better to vaccinate and provide long term protection to the students at the University.

Other interventions that are not recommended are restricting travel to outbreak areas, closing schools and canceling events.

And the rationale for this is that it's never been shown that any of these restrictions actually reduce the number of cases.

Students are going to be students. And there's going to be close interactions between students. And so canceling events doesn't change that.

The really critical part of awareness for meningococcal disease outbreaks on college campuses is to educate the communities, physicians and other healthcare personnel which is really critical for early detection of cases.

I think that part of the reason we didn't see more deaths or long term sequelae from some of these cases in these two outbreaks is that there was quite a bit of awareness especially at Princeton University which was sort of a long outbreak and these cases were treated early and had better outcomes.

So in summary recent serogroup B outbreaks on college campuses have occurred in the setting of very low disease incidence, and although outbreaks are uncommon the disease can be devastating and serious impact on these organizations.

Vaccination is now possible in response to MenB outbreaks however implementation of an unlicensed vaccine requires coordinated efforts between the institutions, state and local health departments, the manufacture, FDA, and CDC.

We are developing some guidance for use of MenB vaccines for outbreak control. And we expect for those to be completed in the next several months.

And this guidance will be specifically for use of these vaccines as an unlicensed vaccine product.

But the hope is that these vaccines will be licensed in the near future. And that we will be replacing those guidelines with guidelines for how to use these vaccines as a licensed product. Thank you.

Dr. Andrew Kroger: Thank you very much Amanda for that important update. Now I will turn the mic over to Dr. Elizabeth Briere. Please begin.

Dr. Elizabeth Briere: Good afternoon. Today I will summarize the information on the recently published ACIP Hib Vaccination Statement.

The last ACIP Hib vaccine recommendation statement was published in 1993. Since then several more Hib containing vaccines have been licensed in the United States including Hiberix, Comvax, Pentacel and MenHibrix.

Recommendations for these vaccines were published in separate MMWR policy notes. The purpose of the 2014 Hib statement is to summarize all the previously published ACIP recommendations on Hib vaccination in one document to be used as a one stop resource for immunization providers, public health officials and immunization program personnel. In the 2014 statement no changes were made to the routine Hib vaccine recommendations.

Guidance for Hib vaccination of special high risk populations was not included in the 1993 statement however this guidance has been published in other statements.

The 2014 statement includes guidance for both immunocompetent and special high risk populations.

The guidance included in the 2014 statement is consistent with that in the 2013 IDSA guidelines for the immunocompromised, the 2012 AAP Redbook, the ACIP general recommendations, and the ACIP HIV guidelines for adults and adolescents.

The epidemiology of Hib disease in the United States has changed since the 1993 Hib statement. Therefore the 2014 report also includes a summary of the current information on Hib epidemiology.

As you can see by this figure which is included in the 2014 statement since the introduction of Hib vaccines in the 1980s the incidence of Hib disease in less than five year olds has decreased by 99% to less than one case per 100,000 children.

As shown in the insert figure on the right during 2000 to 2012 the average annual incidence rate of Hib disease remained below the healthy people goal of 0.27 cases per 100,000. Hib disease is uncommon in adults and children older than five years of age.

The continued importance of Hib vaccination is highlighted by the fact that the majority of Hib disease in the United States occurs in the unimmunized and under immunized infants and children or those with an incomplete primary series or a missing booster dose and among infants too young to have completed the primary series.

The 2014 statement summarizes the current licensed and available Hib vaccines and the recommended schedules. Hiberix, Comvax, Pentacel and MenHibrix were licensed since the 1992 statement.

I won't go through the dosing schedules for these vaccines since they have not changed however I would like to highlight that all these vaccines are licensed for the primary series except for Hiberix which is licensed only as a booster dose.

Also note that PedvaxHIB and Comvax are PRP-OMP vaccines and only require two doses for the primary series. I'll talk about the use of these vaccines more in a bit.

MenHibrix is the newest Hib vaccine. It was just licensed in June 2012. Routine meningococcal vaccination is recommended only for infants at increased risk for meningococcal disease.

However MenHibrix may be used in any infant for routine vaccination against Hib. This information is included in the text of the statement and the footnote in the table directs readers to the infant meningococcal vaccination statement for further information about recommendations for the Men C Y component of MenHibrix.

In the 2014 statement, recommendations for routine Hib vaccine use and guidance for catch up Hib vaccination remained unchanged from previously published statements and policy notes.

Guidance for special populations including children and adults is included in the 2014 statement and is consistent with previously published guidance.

Regarding Hib vaccine special populations include Alaskan natives and American Indians, children less than 24 months of age with invasive Hib disease, preterm infants, and other high risk groups including patients with functional or anatomic asplenia, HIV infections, IgG deficiency, or early component complement deficiency, recipients of a stem cell transplant, and those receiving chemotherapy or radiation therapy for malignant neoplasms.

The updated statement includes a brief history of the American Indian/ Alaskan Native experience with Hib vaccines and the rationale for

recommending PRP-OMP vaccines, which include Comvax and PedvaxHIB, for these children.

Hib meningitis incidents peaks at a younger age at four to seven months among American Indian and Alaskan Native infants in comparison with a Hib disease peak at six months to seven months in other US infants.

PRP-OMP vaccines produce a productive antibody response after the first dose. So they provide early protection.

For this reason they are preferred for the primary series for American Indian and Alaskan Native children. There is no preferred vaccine type for the booster dose in these children.

The importance of this early protection was demonstrated in Alaska. From 1991 to 1996 Alaska used the PRP-OMP vaccines statewide and saw a greater than 90% decrease in Hib disease among Alaskan Native and non-native children.

During 1996 to 1997 Alaska switched to a non-OMP vaccine and saw significant increases in incidence among native children but not non-native children.

After returning to using a PRP-OMP vaccine statewide incidence of Hib disease in Alaskan Native children decreased again.

Children less than 24 months of age who develop invasive Hib disease remain at risk of a second episode because natural infection in this age does not reliably result in development of protective antibodies therefore these groups should be considered unvaccinated and should be revaccinated.

Preterm infants should follow the routine Hib schedule starting at two months of age based on chronological age.

Guidance for patients at increased risk for invasive disease is broken down by age and high risk group. The tables in the next few slides are included in the updated Hib statement. Again this guidance is consistent with other published guidance.

For all high risk patients less than 12 months of age, the routine Hib recommendations are followed.

For all high risk patients 12 months to 59 months of age who are unimmunized or received zero or one dose before age 12 months should receive two doses of Hib vaccine eight weeks apart.

Those who received two or more doses before age 12 months only need one dose, eight weeks after the last dose.

And those who completed a primary series and received a booster dose at age 12 months or older need no additional doses.

Hib vaccination during chemotherapy or radiation therapy should be avoided because of possible sub-optimal antibody response.

Patients vaccinated within 14 days of starting immunosuppressive therapy or while receiving immunosuppressive therapy should be considered unimmunized and doses should be repeated beginning at least three months following completion of therapy.

Patients vaccinated more than 14 days before therapy do not need to be revaccinated.

Patients greater than or equal to 15 months of age who are undergoing elective splenectomy and asplenic patients greater than 59 months of age should receive one dose of Hib vaccine if they are unimmunized.

Patients who received a primary series and a booster dose or at least one dose of Hib vaccine after 14 months of age are considered immunized.

On the basis of limited data on the timing of Hib vaccination before splenectomy experts suggest vaccination at least 14 days before the procedure.

HIV infected children 60 months of age or older should receive one dose of Hib vaccine if they are unimmunized.

It is unknown whether HIV infected children who have completed the full Hib series will benefit from additional Hib doses.

Because the incidence of Hib infections among HIV infected adults is low Hib vaccine is not recommended for HIV infected adults regardless of vaccination history.

And all recipients of stem cell transplant should receive three doses of Hib vaccine starting six to 12 months after transplant regardless of prior Hib vaccine history.

So in summary the last ACIP Hib Vaccine Recommendation Statement was published in 1993. Since then several more Hib containing vaccines have been

licensed in the United States and the 1993 statement did not include guidance for special populations.

The 2014 Hib statement is intended to be a one-stop resource for immunization providers, public health officials and immunization program personnel.

There are no changes to the recommendations for routine or catch up vaccination. And the guidance for special populations which is newly included in the 2014 statement is consistent with previously published guidance. Thank you.

Dr. Andrew Kroger: Thank you very much Elizabeth for clarifying the new recommendations. I'll now turn the mic over to JoEllen Wolicki. You may begin.

JoEllen Wolicki: Thank you Dr. Kroger. Staying up to date is not only a challenge for patients and parents it's also a challenge for immunization providers and their staff.

Just a few of the recent changes and updates over the last year include new 2014 schedules for children and adults, new vaccine products, updated FDA approved indications, new Advisory Committee on Immunization Practices, immunization recommendations and vaccine storage and handling guidance.

This slide shows some of the areas healthcare personnel that deliver vaccines need to be familiar with and knowledgeable of.

Knowledgeable staff are a facility's best resource but with busy clinic schedules it can be difficult for immunization providers to stay up to date and current.

CDC IZ Learn is the newest way we are reaching out to a connecting with healthcare personnel. Join the CDC IZ Learn community on Twitter to find the latest immunization related education resources for immunization providers including events, studies, updated materials, job aids, and educational programs.

Most of CDC immunization education programs offer free continuing education credit for physicians, nurses, pharmacists, medical assistants and other healthcare personnel.

Here are some examples of recent tweets from IZ Learn. I have highlighted one about the storage and handling toolkit.

We hope you'll follow CDC's IZ Learn on Twitter and encourage you and your colleagues to join the conversation.

Next I'd like to talk a little bit of about updated resources for storage and handling. Here is the main page for the storage and handling information on the CDC web site.

From this page immunization providers can find numerous resources and tools on proper vaccine storage and handling.

Immunization providers can access updated resources from this landing page that include educational programs, materials and job aids.

The first resource listed on this page and one I'd like to highlight today is the vaccine storage and handling toolkit.

The vaccine storage and handling toolkit pictured here is a comprehensive resource for immunization providers on vaccine storage and handling recommendations and best practices.

Vaccine storage and handling mistakes are avoidable and costly. Errors can result in loss of vaccines worth millions of dollars.

In addition failure to adhere to required protocols for storage and handling can reduce vaccine potency resulting in inadequate immune responses in patients as well as inadequate protection against disease.

Patient confidence and vaccines and their providers is diminished when repeat vaccinations are required to replace invalid doses administered with potentially reduced potency vaccines.

This toolkit provides best practice strategies that will help immunization providers prevent storage and handling mistakes.

Vaccine quality is the shared responsibility of all parties from manufacturing until administration. The toolkit provides guidance for immunization providers on storing and handling vaccines in their facility.

It is based on recommendations of the advisory committee on immunization practices, vaccine manufacturer's product information, and studies from the National Institute for Standards and Technology.

The toolkit includes considerations for equipment both for storage units and thermometers, strategies for maintaining the cold chain, and routine storage and handling practices, inventory management, and emergency procedures for protecting vaccine inventory.

The toolkit also contains many practical resources to help providers integrate strategies to promote the best storage and handling practices.

One example is vaccine labels which can be used to assist staff to easily identify vaccines within a storage unit. With look alike, sound alike vaccines, and crowded storage units staff can easily confuse the vaccines.

Labeling the area where vaccines are stored can help staff quickly locate and choose the correct vaccine perhaps preventing a vaccine administration error.

Depending on how the vaccines are organized within the storage unit labels can be placed on the containers or bins or directly attached to the shelves where the vaccines are placed.

Other helpful strategies include color coding of labels. For example one color for pediatric and another for adult vaccine and including additional information such as age indication, gender, or other information unique to the vaccine that can help prevent a vaccine administration error. Here's a photo of labels from the toolkit being used to identify and organize vaccines in a storage unit.

Next I would like to take a few moments to talk to you about the education and training main web page. This page outlines immunization courses that are available for healthcare personnel.

Educational programs are offered in several formats. Net conferences such as we're doing today, web based learning modules, and web based courses.

And as I mentioned earlier these are free of charge and continuing education credit for a variety of healthcare personnel is available.

One educational program with recently updated content is You Call the Shots an interactive web based immunization training course.

It consists of a series of modules that discuss vaccine-preventable diseases, and explain the latest immunization recommendations.

Each module provides learning opportunities, self-test practice questions, reference and resource materials and an extensive glossary.

The course is intended for nurses, nursing students, medical assistants, pharmacists, and other healthcare professionals who provide immunizations. It is available free of charge and continuing education credits are offered.

There are three modules that have been updated since January of this year. These include vaccine storage and handling, influenza, and the Vaccines for Children modules.

Last but not least I would like to highlight HPV resources. The HPV You Are the Key web portal is one stop shopping for healthcare personnel looking for HPV educational material and resources.

We have updated the HPV web portal where many of the materials can be found. And we encourage all of you to visit the site and make use of the various items that you can find there.

A variety of materials are available for multiple audiences including healthcare personnel that administer vaccines, patients and parents.

A short video pictured here has recently been added to share with patients and parents about HPV disease and the vaccine.

Other patient and parent materials include handouts discussing HPV vaccine, safety, and fact sheets. These are available in English and Spanish. There is also a section of references and tools for immunization providers about HPV vaccination.

You can see in the resource spotlight section of the web page shown on this slide a tip sheet for providers when talking to parents about HPV is currently being highlighted.

There are a wealth of other resources for immunizations provided - for immunization providers available from specific HPV articles, and educational programs, to other resources on all routinely recommended vaccines for adolescents. We hope you will visit this site soon.

I have outlined only a few of the many CDC immunization resources and materials included on the web site.

There are many more which can make keeping up with changes and updates to the web site a challenge by itself.

One way to make this easier is to sign up for email updates. In the upper right-hand corner of the web pages is a box which I have highlighted in red on the slide.

In this box you can sign up for email alerts to the web page. It's really very simple. Put your email address in the appropriate box and click Submit.

Whenever there is a change or an update to that page we will send you an email letting you know.

In addition to email alerts you can send web pages to others. In the same box in the upper right-hand corner you will find an “email this page” link.

When you click on the link a pop-up box will appear shown here on this slide asking you to type in the email addresses of the persons you would like this page to be sent to.

Once you have entered all the email addresses click the Send button. Both are great ways for staying up to date for yourself and for others.

In conclusion this slide outlines general resources and web pages for immunization information for providers and the general public on all vaccines.

If you have any questions about vaccines we encourage you to visit these sites or the resources mentioned today or email your specific questions to nipinfo@cdc.gov.

Dr. Andrew Kroger: Thank you very much JoEllen for sharing that information. Before moving on I now would like to present another polling question.

Please input your information within ten seconds of my reading the question. The question harkens back to the Hib presentation.

How many doses of Hib vaccine are recommended for an unvaccinated 15 month old with asplenia? The choices are zero doses, one does, two doses, or three doses. Take ten seconds to answer.

Okay times up and we will reveal. The correct answer is two doses. And you can see that 41% of you got that question correct.

So now CDC and ACIP now make a full recommendation for two doses of vaccine for unvaccinated high risk persons through 59 months of age with functional anatomic asplenia as well as IG deficiency, complement deficiency, HIV infection and chemotherapy recipients so the correct answer is two doses, a lot of information in the new recommendations.

I'm now going to share the results of that pre-conference question that I asked. The question was true or false an unvaccinated 23 month old with a history *Haemophilus influenzae* type b infection that occurred at 11 months of age does not need Hib vaccine because of a history of natural disease?

And the correct answer is false. And actually 92% of you got that question right. For Hib infections occurring through 23 months of age we do not consider a child to be adequately immunized via natural disease. And so these children do require routine vaccination thereafter.

And as this child was 11 months old when natural disease occurred he or she should be considered unvaccinated and requires a dose of Hib vaccine.

I'm now going to invite our listeners to call in and ask questions. To do that please dial Star 1 on your telephone.

Please be sure to restrict your questions to the contents discussed today. Tell us your first and last name and where you are from. And so now I'm going to temporarily turn the mic over to our operator.

While we wait for our first question to come in I will provide some additional information. First a recast as well as the slide set will be available at www.cdc.gov/vaccines/ed/ciinc and the slide set will be available the week of April 14, 2014.

For CE credit please go to www.2a.cdc.gov/tceonline. The course number for this net conference is EC2064. And the verification code is Current 42. And remember that CE credit does expire on May 5, 2014.

So now I am happy to take the first question in the queue. While we wait for that first question to come in I will ask a question that comes to us often to Dr. Cohn.

What are the specific factors that make chemoprophylaxis impractical for outbreak control in a university setting?

Dr. Amanda Cohn: So giving a large group of people chemoprophylaxis at the same time is challenging logistically and is also expensive. But there's a couple of key reasons why we don't recommend it.

And first is that if you're going to try to eliminate an organism which is circulating in a university during an outbreak you need to eliminate carriage from their noses.

So you would need to give chemoprophylaxis to 100% of those people at the same time. And they would all have to take it and would all have to be effective in all of those people.

So chemoprophylaxis with Cipro was about 90% effective which is really great. But then getting 100% of students many of whom will have reasons why they can't take Cipro would also be challenging.

So then if you get 90% coverage really only about 80% of students actually were able to eliminate nasal phalangeal carriage.

So even if you eliminate it from 80% of students and there's just a couple of students who may be carrying that organism it has the opportunity 24 to 48 hours after everyone's taken Cipro to restart circulating in the community.

So what we've found is even with the universities having given several thousand doses of Cipro after a couple of cases sometimes it works and they don't see additional cases.

Whether or not that's because of the chemoprophylaxis or not is challenging to know. But they have seen additional cases after giving chemoprophylaxis to several thousand students.

It's just impractical to give Cipro two very large universities. And there are serious side effects that occur from Cipro used that we do have to worry about as well.

So if it's in a place in a jail with 500 people and it's it may actually be a practical way when you can really control it.

But in a university setting where there's people coming in and out and it would be really challenging to eliminate transmission with use of chemoprophylaxis.

And vaccination is really just such a better prevention strategy in the sense that it provides long term protection or at least protection through the outbreak period for those individuals.

Dr. Andrew Kroger: Thank you very much. Yes we get that question a lot. So it's really helpful to have that clarification. Do we have any questions in the queue? Okay if not I'll ask a question to Dr. Briere.

You mentioned that if Hib vaccine is given within 14 days of the start of chemotherapy that the dose needs to be repeated.

And so aside from chemotherapy talking about splenectomy Hib is also recommended to be given 14 days prior to splenectomy. If the dose isn't if it's given within that 14 day window does that dose need to be repeated?

Dr. Elizabeth Briere: So there are actually limited data on the timing of Hib vaccination before a splenectomy. We do know looking at data for pneumococcal vaccine that higher antibody concentrations are seen if vaccine is given further out than two weeks either before or after the surgery.

And so this recommendation is really based on limited data but we are looking at the data that we have for pneumococcal disease.

So we don't have any specific recommendations on this situation if a Hib dose is given within that 14 day window but a physician may choose to repeat that dose after the splenectomy if it was given within 14 days or closer to 14 days before the actual surgery. And if the dose is repeated it should be given greater than two weeks after the surgery.

Dr. Andrew Kroger: Okay. Thank you very much. Any questions in the queue?

Coordinator: First question is from (XXXXXX).

We'll take one question. Okay thank you.

(XXXXXX): Hi. This is (XXXXXX). I'm in XXXXXXXX,
XXXXXX, and a public health nurse. The question I have is I'm a slow
listener.

I was also not able to pull up the slides. Could you please repeat a little more
slowly the web site for reviewing the slides later this month and then also how
to get the CE use?

Dr. Andrew Kroger: Absolutely. Yes I'll take that. So the recast -- this is Andrew -- the recast
will be available at you might be able to see it now
www.cdc.gov/vaccines/ed/ciinc.

And the slides will be available and the recast and the slide set will be
available the week of April 14, 2014. Was that the information you needed?

(XXXXXX): Yes partly and then the CEU?

Dr. Andrew Kroger: Yes. So for CE credit you go to www.2a.cdc.gov/tceonline.

(XXXXXX): Excuse me T as in Tom?

Dr. Andrew Kroger: Tom yes. Tom...

(XXXXXX): TCE?

Dr. Andrew Kroger: ...Charlie, Echo online.

(XXXXXX): Okay. TCE...

Dr. Andrew Kroger: Online all one word.

(XXXXXX): Online okay.

Dr. Andrew Kroger: And then the course number EC2064. And verification code...

(XXXXXX): Oh wait, wait EC2064?

Dr. Andrew Kroger: Correct.

(XXXXXX): And then...

Dr. Andrew Kroger: Verification code current 42.

(XXXXXX): Current 42. Thank you very much.

Dr. Andrew Kroger: Okay thank you.

(XXXXXX): By the way it was a marvelous lecture today. I learned a lot.

Dr. Andrew Kroger: Well thank you very much. It's good to hear that feedback. Why don't we take one last question if there's any more in the queue?

Coordinator: The next question comes from (XXXX).

Dr. Andrew Kroger: Hi (XXXX).

(XXXX): Hi. This question is for JoEllen about storage and handling. Recently the ISMP Medication Safety Alert put out a bulletin about reducing vaccine errors and around part of it was around storage and handling.

And they say things like put vaccines together in sealable plastic bags, discard cartons, all the things that really as I know from being a VFC person you're not supposed to do. So how do we juggle these two different views?

JoEllen Wolicki: Hi (XXXXX). Thanks for that question. That's a really, really good question. I too saw that report and from the ISMP and our guidance has not changed.

(XXXX): Okay.

JoEllen Wolicki: That we continue to say that vaccines should be stored in their boxes. And that they should be placed in bins. And they should be clearly labeled so that people can identify them.

(XXXXX): Yes because it's a little worrisome that they send out this kind of information that says do things that are totally against VFC storage and handling practices.

JoEllen Wolicki: I understand.

(XXXXX): Okay thank you.

Dr. Andrew Kroger: Thank you very much. And due to time restraints we'll move on to some closing information and review some housekeeping items again.

For continuing education credits please go to www.2a.cdc.gov/tceonline. The course number for the net conference is EC2064 in the verification code is Current 42.

I'll repeat that the Current 42 capital C-u-r-r-e-n-t 42. Keep in mind that CE credit for this net conference will expire on May 5, 2014.

Once you become familiar with the online system you'll find it easy to use and a great way to keep track of CE credit earned from CDC training programs.

If you are having any difficulty or are new to the system you can get assistance by phoning 1-800-41 train, T-R-A-I-N or 4187246 with availability from 8:00 AM to 4:00 PM Eastern Time.

To get help by way of email you can contact CE as cdc.gov.

We've received many great questions today. If you were unable to ask your question today or if you have other questions related to this net conference you can contact us at the email question and answer service at the address nipinfo@cdc.gov.

Another way you can ask a question is to contact the CDC info program. One way to do that is to call 1- 800-CDC-info I-N-F-O. This phone line is staffed from 8:00 AM to 8:00 PM Monday through Friday.

Another way to contact the CDC info program is to go to the CDC homepage www.cdc.gov and click on the link CDC info at the bottom of the page.

This is a general question and answer service that handles immunization related questions in addition to other public health related questions.

I really want to thank everyone for joining us today with special thanks to our subject matter experts Amanda Cohn, Elizabeth Briere, and JoEllen Wolicki. Thank you very much from Atlanta and goodbye.

END