



Indian Health Service

Division of Diabetes Treatment and Prevention

Update on Immunizations for Adults with Diabetes

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Amy Groom:

Let's go ahead and I'll quickly introduce myself. My name is Amy Groom and I'm a CDC Public Health Advisor and I've been assigned to the Indian Health Service since 2001. I serve as the IHS Immunization Program Manager based here in Albuquerque, New Mexico.

Ann Bullock:

Thanks, Amy. We sure appreciate you're doing this for us today. I'm Ann Bullock, I'm the Acting Director and Clinical Consultant for the IHS Division of Diabetes Treatment and Prevention. I'm a family physician who's worked with IHS for almost 24 years, and I'm an enrolled member of the Minnesota Chippewa Tribe. We're delighted to talk with you all today about this really important topic and one we often don't speak about a lot in diabetes, but really, we sometimes worry about a lot of other things in diabetes care and forget some of the most important things because they seem sort of basic. And immunizations are certainly one of those.

So Jan, if you've got my slides up first, I'm just going to give a short introduction to some audit data and where we're all at with immunizations and a little bit of background. Then Amy is our immunization expert and she's going to talk more with us about specific immunizations and current recommendations because there have been some changes. Looks like Jan is getting my slides up. All right Jan, are we getting that?

Jan Frederick:

It's loading. For some reason, they got dropped off. Sorry about that, Dr. Bullock.

Ann Bullock:

Okay.

Jan Frederick:

But they are going up right now.

Ann Bullock:

Okay. Well we're going to focus today on immunizations for adult patients with diabetes, but we are going to talk a little bit about that bridge between childhood immunizations and adult immunizations. Amy will give you more details about things like the pneumococcal vaccines and what we do with children who received the newer vaccine. The children who are now aging into a time of their life where they may be developing diabetes and what we do for -- or bridging over to diabetes recommendations. There we go. Thank you, Jan.



So I'm going to do a quick introduction here for about 10 minutes and then turn it over to Amy. So we know that we can't prevent all infections or problems of course that people, including those with diabetes can get, but we have some immunizations that certainly can make a huge difference. So for vaccine preventable infections as with some others, we know that diabetes makes it more likely to develop complications of vaccine preventable infections. For example, we know that for someone who develops pneumococcal pneumonia that if they have diabetes, they are even more likely to have to be hospitalized or to have respiratory difficulties because of that. The diabetes making that more likely to have a complication.

We know that these infections, in turn, are more likely to complicate diabetes and any other underlying chronic conditions. We all know what it's like to try and help patients who are dealing with influenza to try and control their blood sugars, or their heart failure, or other sorts of things. So they can make the underlying chronic conditions worse.

In some situations, diabetes can even make it more likely that people will be exposed to infection. Amy will talk a bit about that, but part of the reason for the new hepatitis B recommendations is because people with diabetes sometimes are inadvertently exposed potentially to the blood of others on fingerstick devices, on insulin pens, and other things that shouldn't be shared but sometimes are. Hopefully, a lot of you were with us last month to hear that discussion that Dr. John Redd and Dr. Ty Reidhead did on that. If you didn't have a chance to hear that excellent presentation, it's available as a recording on our website.

So these are the current recommendations for immunizations in people with diabetes. On the left is what the American Diabetes Association's 2014 Clinical Practice Recommendations list: influenza, the pneumococcal polysaccharide vaccine, which we'll talk more about, the different pneumococcal vaccines, hepatitis B, but also they go on to remind us that people with diabetes because they are people like anyone else have, there are number of vaccines that are recommended for the general population. CDC's and ACIP's 2014 recommendations for people with diabetes list the same- influenza, pneumococcal polysaccharide, and hepatitis B, but remind us more specifically to be sure that patients have also had a tetanus shot and at least one Tdap version of that, the appropriate varicella vaccines, the HPV, zoster, MMR vaccines, all of those are also important. So those are the current recommendations for people with diabetes from those two organizations.

So for us in Indian Health, the Diabetes Care and Outcomes Audit, as you all know, assesses elements of diabetes care for American Indian/Alaska Native people and that of course, as you all are familiar with, does include some immunizations and these are the four that we look at on the audit: influenza, pneumococcal, and tetanus but also hepatitis B.

So, the one that we sort of add on there and it's there for historical reasons part is the tetanus, on top of the three that are recommended specifically for people with diabetes by the American Diabetes Association. We know the audit results, we hope, people use them at facilities to identify areas for improvement and so when we look at immunization data, hopefully, we're looking for things we can improve. So for Audit 2013, Audit 2014 is just about wrapped up but we don't have numbers yet for that. So for Audit 2013, being our most recent completed audit, 330 facilities around the I/T/U system participated, so that's IHS, Tribal, and Urban programs. Over 105,000 charts were audited. Now, two-thirds of those are audited electronically because so many of us have RPMS EHR or other electronic health records allowing us to audit ever greater numbers of charts in the annual audit. So this is a wonderful tool.

So what we found in Audit 2013 and this goes back and this is for flu vaccination, for influenza, from 1999 at the far left, with each year up to 2013, and you could see that we've gotten a little bit better but pretty flat the last few years since about 2008, right around 60% of our patients with diabetes having

documentation that they received an influenza vaccination in the audit year. Obviously for flu, you have to do it each year in order to be up to date.

Pneumovax, which is of course a trade name, we've used that clinically for a long time, but this is the pneumococcal polysaccharide vaccine. We've gotten a little bit better in the last few years and we're up to right around 80% of our patients with diabetes have had at least one pneumococcal polysaccharide vaccine. Amy will go over the recommendations on that in a few minutes. A little bit of improvement, but of course unlike flu vaccine which is every year, the current recommendations for the pneumococcal vaccine are much less stringent than yearly. Then for tetanus and/or the Tdap, the one that adds the acellular pertussis component is the Tdap. You can see that we're doing pretty well on that, in somewhere around just shy of 90% of our patients have received one of those in the last 10 years.

So hepatitis B, as you all know, is a recent addition to the recommendations for people with diabetes, and you can see that in order to get counted here, you have to have completed the three-shot series. So we're somewhere around 20% of our patients with diabetes have completed the three-shot hepatitis B series. And of course, many of our younger people with diabetes would have received that series as part of their childhood immunizations.

So immunizations we know are awfully important for everyone, especially people with diabetes. And as I said at the outset, we may do more good for people by being sure they get their flu shot for example, than any of the other things we spend a lot of time worrying about. Having someone avoid the flu altogether or at least have a less intense version of it, means a lot in terms of helping someone's short and long-term outcomes.

So audit data shows that overall we're continuing to improve. Flu shots are little on the flatter side around 60%. We know there are a lot of reasons for that. People have allergies both genuine as well as those that -- they believe that they have had, they call an allergy. Many people refuse flu shots, they feel like it gives them the flu, that sort of thing. Amy will address some of that. And now, of course, there are so many options for getting flu shots besides our clinics. You can get them at many drug stores and even some of the big-box stores now that have pharmacies are offering immunizations. So even more important than ever to document historical immunizations for flu for sure, but for others as well as more and more immunizations are offered in so many types of venues, which is good in many ways.

We want people to be immunized appropriately but it doesn't always do well for us with keeping records of this and making sure that we're getting it into our system so it can be counted that our patients with diabetes are getting good care. So with that introduction, I want to turn it over to Amy Groom. Amy is a wonderful colleague and very much an expert in immunizations and will have a lot of good information to share with us. So with that, thank you Amy for joining us today.

Amy Groom:

Thank you so much Ann and I'm really delighted to have been invited to speak to a slightly different cohort of people than I normally speak with. I did recognize some immunization names in the list of people signing in and I'm glad to hear all of you. I'm also really happy to see some faces and names that I don't actually know.

So today, Ann had asked me to pull together some information about immunizations among patients with diabetes. Then as we were discussing through the slide, we sort of realized that maybe this is an opportunity to broaden it because as Ann mentioned it in her introduction, of course, people with diabetes are also just regular adults who need other vaccines. So in terms of what I'd like to cover today, I did want to do it a little bit broader and talk about immunizations recommendation for adults,

just all adults, as well as those specifically with diabetes. Then because Ann mentioned also that we're getting to this point where you may have patients who are adolescents who are getting to the time in their life where they could be diagnosed with diabetes, I also wanted to go over what the adolescent vaccine recommendations are.

I'm going to share a little bit of data with you on current immunization coverage. This is using some of the diabetes audit data that Ann shared, but also some other sources of data in the U.S. as well as data that we collect through the immunization program. Touch briefly on a few educational resources that I know of that are available that might be of use to you. Then I wanted to talk very specifically about some of the tools in the RPMS or Electronic Health Record System to help you increase immunization coverage. I also have some slides for those of you who are not RPMS users but I am going to focus pretty technically on the RPMS and EHR side of the house as well.

So in terms of the first topic, this is the routine adult immunization. Ann mentioned that ACIP, or the Advisory Committee on Immunization Practices, this is the group that advises CDC and comes up with recommendations for the general U.S. population, so not military but just the general U.S. population. And if you go to the websites that I have on the bottom here, the CDC website has all this information collected there. For adults, they would routinely recommend that adults who have not previously received HPV vaccines should get it, and that's for females 19 through 26 and males 19 to 21 years of age. Everybody should get a Td Booster every 10 years. Everybody should have a dose of Tdap and this is regardless if you got Td one year ago, two years ago, you should still receive one dose of Tdap and that protects against pertussis or whooping cough which is an ongoing concern especially in many of our American-Indian communities.

Zoster vaccine is recommended for everybody starting at the age of 60, of course influenza is an annual recommendation. Then we have the pneumococcal polysaccharide 23-valent which I have abbreviated throughout this presentation as PPSV23 and this is also known as Pneumovax. Routinely, this is recommended for adults starting at 65 years of age, although there is some language in the recommendations specific to American-Indian/Alaska Native populations in certain geographic areas. And we do have some of our IHS areas that start routinely forecasting pneumococcal polysaccharide at a younger age such as 50 or 55. That's primarily some tribes in the Southwest and in Alaska.

So those are the routine adult immunization recommendations. One of the questions that we've been getting quite a bit recently is the cost, particularly for those newer vaccines, zoster and HPV for the adult population, and a lot of our sites really feeling that they don't have the money to provide these vaccines. One of the things that I wanted to let people know is that moving forward our clinical decision support in the RPMS system for immunizations is actually going to no longer give you the option of whether or not to forecast HPV and zoster for your adult patient. It is automatically going to show up. And I wanted to just go through some of the rationale behind that decision.

When it comes to wondering whether or not to provide or not to provide these vaccines, the reality is that the landscape is changing, and with health care reform and the Affordable Care Act, new health plans are required to cover all the ACIP recommended vaccines at no cost. And I really feel that as more and more insured people are getting covered, for us within the Indian Health Service system to say, well, the rest of the country should get this covered in their insurance plans but if you get care from just the IHS or an IHS-funded facility, you don't have that right. It's just becoming pretty untenable as we move forward.

Provision of all recommended adult vaccines is a standard of care endorsed by many professional organizations as well the Indian Health Service. And the reality is that to address this, the IHS actually made the decision to have all of the ACIP recommended vaccines automatically included on to IHS core formulary. I know this only directly relates to the federally funded sites. But for the federally funded sites, the IHS National Pharmacy & Therapeutics Committee or the P&T Committee has said

that all of the products that are on that core formulary should be made available for patient use if a provider orders them.

So really in this environment, we're getting to that point where not providing some of these more costly vaccines is really not going to be an option moving forward, and I'm very curious to see, I put up a poll here, how many of you are doing zoster and HPV for your adults. And it looks like the majority of you are, and that's great. And for those of you who aren't, perhaps this is a topic that you could continue to discuss with your providers and your pharmacy at your site.

Because I do recognize the reality of the cost of these vaccines, I did want to offer a few strategies that other sites have implemented to help cover the cost. The Patient Assistance Program that many pharmaceutical companies offer can be a great way to help offset some of that cost. The Merck Vaccine Patient Assistance Program is obviously specifically for the Merck products, but that does include zoster vaccine as well as pneumococcal polysaccharide and some of the MMR and varicella vaccines. The way that it works is, you have to have a supply of vaccine on hand. But then for every patient that you go through a prescreening, and it takes about 15 minutes, you have to collect a little bit of information about income and then you send that to Merck and then they make a decision within 15 minutes and fax you back right away.

If that patient is then approved at the end of the month or at the end of the quarter, you send Merck the total number of doses that you gave to patients who qualified and they actually send you replacement vaccines for those doses. It does require preapproval. One of the advantages we have is, in any patient whose only source of care is the Indian Health Service or the tribally run program is considered uninsured for the purposes of these programs. We do have some really large sites, such as the Alaska Native Medical Center that have successfully implemented this and used this to help offset the cost of both zoster and HPV, and some of the other Merck products.

In addition, in some places, we've seen a lot of success with immunization clinics, mostly pharmacy-based immunization clinics that are walk-in immunization clinics and in some states like Arizona, a pharmacist is totally a billable provider under Medicaid. So by having these walk-in immunization clinics, any patient they have that comes in who is Medicaid eligible, they can vaccinate and actually bill them for the full flat fee that Medicaid has negotiated with the Indian Health Service.

Now, obviously pharmacists may not be billable providers in your state, but even before pharmacists were billable providers for Medicaid, we did have sites that would hire providers whose specific responsibility was to oversee an immunization clinic to really try to more aggressively reach out to patients around vaccines and make them more accessible, and then they were also able to bill and recoup some of that cost. So I did want to leave you with some of those specific strategies that you might be interested in learning more about.

Now, to switch gears and really to focus in on immunizations for those with diabetes. As Ann mentioned this is pneumococcal polysaccharide, the 23-valent, influenza, and of course hepatitis B. I wanted to talk a little bit about pneumonia and influenza, because this is one of the diseases that disproportionately impacts the native communities across the U.S. What we have found, actually for some very recent data that has been adjusted for racial misclassification, is that American-Indian/Alaska Native people are almost two times more likely to die from pneumonia and influenza compared to non-Hispanic whites. If you look at different age groups or in different regions, the rate is actually even higher. In some of our age groups we have four to eight times higher the mortality rate. In certain regions, particularly the Southwest, the northern plains, and Alaska, we see even greater disparity than twice as high the mortality rate.

Certainly, this was borne out in 2009 with the H1N1 influenza pandemic where a 12-state study found that American-Indian/Alaska Native people were four times more likely to die from influenza related

complications than other race groups. So despite our great efforts at vaccinating, we still have a significant burden of disease with pneumonia and influenza in the American-Indian/Alaska Native population. There are myriad reasons for this disparity but one of those is certainly the higher rate of chronic medical conditions including of course diabetes.

So in terms of the pneumococcal and the influenza immunization recommendations, the influenza probably wins the prize by being one of the most straightforward recommendations, but as you'll see as I get into my slides about the vaccine products, one of the more complicated products to deliver, and I will provide a little bit more information on influenza. For pneumococcal polysaccharide vaccine, this gets a little bit more tricky. Basically, in addition to the routine recommendation for everybody to get it at 65 years of age, there is a recommendation that people who have certain risk factors should receive a dose upon diagnosis. So before they turn 65, they may need to get a dose of the pneumococcal polysaccharide. Diabetes is of course one of the risk factors for invasive pneumococcal disease, and so everybody who is diagnosed with diabetes is recommended to receive a dose of the polysaccharide vaccine upon diagnosis.

Then anybody who receives the dose of the PPSV23 before 65 years of age should also receive a booster at 65 years of age. And it needs to be at least five years after the last dose. So if you had a patient who was 45 and was diagnosed with diabetes, they should get a dose of pneumococcal polysaccharide vaccine and then they would get one additional dose when they turned 65 years of age.

If you had a patient who received their first dose at 62 years of age, then you would need to wait at least five years, and so that patient would not be due for their booster until 67 years of age. And this logic is programmed into the RPMS clinical reminders for pneumococcal polysaccharide vaccine. And again, on the bottom of the slide, I have included specific links where you can see the actual language of the recommendation.

Now, pneumococcal becomes a little bit more complicated, because there is actually a second pneumococcal vaccine. This is the pneumococcal conjugate vaccine, this 13-valent. This is the vaccine that is routinely recommended for children, so all children receive four doses of the pneumococcal conjugate vaccine, or PCV, as children. But the vaccine is also used very limitedly among adults. One of the disconnects is that in the package insert, what the product is actually licensed for, is for adults who are 50 years and older. But ACIP has not made a recommendation to provide PCV13 to adults over 50 years of age, but they have made a recommendation for adults with immunocompromising condition. So that is the only adult group that the PCV vaccine is currently recommended to be used in. And I've included the list of those conditions which are considered immunocompromising, and the first thing that I wanted to draw your attention to is the fact that diabetes is not on that list.

I put this on here because I do get a lot of calls because of course there is some immunosuppression related to diabetes. But for the purposes of this particular vaccine, it is not considered immunocompromising conditions. So just because the patient has diabetes, is not a reason that they should receive the pneumococcal conjugate vaccine. Some of the conditions that you may actually see among your patients with diabetes include acquired asplenia. So we certainly see this in the Indian Health Service particularly people who had motor vehicle accidents and may have had their spleen removed. So you may come across it there and then of course, nephrotic syndrome or solid organ transplants.

So again, you would not be giving PCV13 to your patients just because they have diabetes but if they did have one of these other conditions on the list, then pneumococcal conjugate vaccine would be a vaccine that you would want to consider.

The recommendation, again, if it's just for immunocompromised adults, would be that if the patient never received any pneumococcal vaccine, so you had a patient who had never received pneumococcal polysaccharide, you would want to give that conjugate vaccine first, and then you would give a dose of the polysaccharide vaccine at least eight weeks later. Then revaccination with polysaccharide is only for certain groups but it would need to be at least five years after that first dose of the polysaccharide vaccine. Probably the more common scenario that you're going to run into is the patient who has already received a dose of pneumococcal polysaccharide vaccine. In that case, you should give a dose of the PCV13, but it needs to be at least one year after the pneumococcal polysaccharide dose was received. And then, if anybody needs and an additional dose of pneumococcal polysaccharide, if they're in that subset of people who would require revaccination, you should not give that any sooner than eight weeks after the PCV13, so really looking at an eight-week interval between PPSV and PCV13. Then again, of course the pneumococcal polysaccharide revaccination would be at least five years.

I wanted to cover this information briefly, but I don't expect many of you would retain this and from this presentation be out and go out and be able to understand exactly what to do. So I want to make sure that you are aware of where you can find the recommendation for these vaccines and there's actually a very nice table in the CDC recommendations that really breaks it down as to which patients would need PCV13 and pneumococcal polysaccharide and who would need revaccination with the polysaccharide vaccine.

Again, from the poll, I was curious to know how many of you are providing PCV13. This currently isn't something that we have a reminder for in RPMS and it is a fairly complicated one, and it looks like many of you aren't aware of whether you are providing it or not, and a smaller subset of you are providing it, but really most of you are not doing it or don't know. That's actually interesting information for me to know.

So now we come to flu vaccine, which I think every program manager in immunizations has to make their bread and butter with influenza vaccine, because over time it's become increasingly complicated and I really love this slide that just sort of physically highlights the point of, now we have so many different influenza vaccine products that it can get very confusing. Before we do that, I wanted to take a quick poll and just kind of see how many people had received their flu vaccine, and I'm very gratified to see that the majority of you did receive your flu vaccine. It looks like we'll keep it open for a little bit longer so we can see what the results are.

I'm really interested to know what the reasons are for not getting vaccinated. Vaccination, in addition to making sure our patients are vaccinated, there really is a priority and an emphasis and really an obligation among health care personnel to also make sure that they receive the vaccine. The reason being is the last thing you would want is that your very sick patient comes in to see you for care and you inadvertently give them influenza because you're carrying it. The reality of influenza is that you may be infected with influenza and be infecting other people before you even know you're sick.

So for a healthcare professional who's working in a healthcare setting and seeing very fragile people who may have lots of underlying medical conditions that would make flu particularly difficult for them, really getting your influenza vaccine is a priority and this is certainly something that CDC and almost all professional organizations are now really encouraging healthcare personnel influenza vaccination, and some facilities have even gone so far as to make it a mandatory requirement. So I was curious to see those of you who didn't get it. Again, this might be something. If you have concerns about safety or other reasons, there is a lot of good information out there at CDC and other non-governmental websites about the safety of flu vaccine, which has been used over the last 50 years in millions of millions of people. And it's really a very safe vaccine and a vaccine for which we've been able to study safety for quite a long time. So, I'd really encourage you to reach out and get a little bit more information about that.

So in terms of the influenza vaccine, we sort of -- this flu season were able to divide them into two different categories. We have influenza vaccines that are egg-based, which means the virus is actually grown in eggs. We have several different versions. So we have your standard, inactivated influenza vaccine, some of the acronyms for that are IIV. And then we have both the trivalent and this year we had a quadrivalent influenza vaccine. So the quadrivalent includes protection against two strains of influenza B, whereas the trivalent only protects against one influenza B, and both vaccines protect against two different types of A influenza.

These products are licensed for those six months and older and the major contraindication, really the only contraindication, is people who have a severe allergic reaction to a vaccine component. And that includes egg protein, but there were some changes to the recommendation that I'm going to cover regarding what constitutes a severe allergic reaction, and really what we're talking about is an anaphylactic type reaction to eggs. So it is contraindicated in people who have basically an anaphylactic reaction to egg protein.

We have another product on the market which is the intradermal. So instead of an intramuscular shot, this is actually just goes into the top layer of the skin. It is only available as a trivalent vaccine and was licensed for those 18 to 64 years of age, and like the traditional vaccine it is contraindicated in people who have had a severe allergic reaction to a component of the vaccine. Then we have a high dose influenza vaccine, which is also an inactivated influenza vaccine. This is trivalent only and licensed for those in 65 years and older. Basically, it has more antigen than the standard doses and it's designed to try to elicit a better response in our older patients, and like the other ones also the contraindicated in people who have a severe allergic reaction to a vaccine component.

Then finally, we have the live attenuated quadrivalent influenza vaccine, which is called FluMist, so that's the nasal spray. This year, this was only available as a quadrivalent vaccine and moving forward, they are only going to be making quadrivalents. And this vaccine is limited to people who are healthy, 2 to 49 years of age.

So for your patients with diabetes, this will not be an option. It is contraindicated, and the specific contraindications include both of those who have an allergic reaction to a vaccine component including eggs, but also those with chronic medical conditions such as diabetes or asthma, pregnant women, anybody who's immunosuppressed, and then caregivers of those with severe immunosuppression. This has caused a lot of confusion among the healthcare personnel, "Is it safe for me to get this vaccine?" When they talk about caregivers of people with severe immunosuppression, they are talking about people who are living in a protective environment. So in most of our IHS facilities, these are probably not patients that you're going to have in your facility, so it would be perfectly fine for a healthcare personnel to receive the live attenuated influenza vaccine.

There were a couple exciting new developments with regard to influenza vaccine and we now actually have two products, they're non egg-based which means they don't rely on eggs to grow the vaccine virus. The first one is the cell culture, and this is abbreviated as the cclV3, available only as a trivalent and licensed for those who are 18 years and older. Even though it's not grown in eggs, the initial reference strain was in fact propagated in eggs. So we can't actually consider the cell culture vaccine to be an egg-free vaccine. So it is also contraindicated for people who have a severe allergic reaction to the vaccine component.

One of the advantages of the cell-culture vaccine and also the recombinant that I'm going to talk about, is they can be produced much more quickly. So the process for growing traditional flu vaccine in eggs is actually pretty time consuming, and if we have a new strain of flu, we're looking at six to twelve months just to be able to grow that strain and produce the vaccine. With cell culture, we can do that extremely quickly.

The other one is the recombinant influenza vaccine, this is trivalent only and it's licensed for those 18 to 49 years of age. And because it is completely egg free, it in fact can be used in people who have an egg allergy so it would be contraindicated to anybody who has had a severe allergic reaction to any other vaccine components, but eggs are not one of the components of the vaccine. So this is a vaccine that is safe to use even in your patients who may have anaphylactic egg allergy.

Then I did want to cover this again. Your best bet for getting all these information is to go to the source, to go to the CDC website and to download these recommendations, but they included this very schematic, this nice schematic this year for the 2013-2014. Basically, it really walks you through what is an egg allergy and how does it influence vaccination. The reality is that if the individual can eat lightly cooked eggs, then that is not considered an allergic reaction and you can administer the vaccine just as you would to any other patients. Sometimes, I think we have some patients who may not like eggs. They think eggs make them kind of nauseous and they don't want to eat them but they actually can eat these eggs and not have a reaction and so that would not constitute an egg allergy.

Then there are also people who may eat eggs or egg-containing food and they may only have hives. Even for that group of people, it is safe to administer one of the regular egg-based flu vaccines but you would observe for at least 30 minutes afterwards just to make sure that there was no reaction. The other alternative of course would be to use that recombinant vaccine which is 100% egg free.

If the person has something more than hives, so they have some sort of cardiovascular changes or other anaphylactic type reactions, then you would really want to refer them to a physician, and there are protocols in place for how to administer flu vaccine even to people who are severely allergic to eggs. You give it in little bits of doses, but you would want to refer them to a physician who has expertise in managing allergic conditions or alternately, if the patient is 18 to 49 years of age, you could use the recombinant vaccine.

So that was my coverage on flu vaccine. Again, there may be some new products that come on the market before the next flu season. I encourage you to keep up with that on the CDC website. Now, I wanted to switch to really what was the impetus for this talk, and this was the hepatitis B in patients with diabetes. It was very interesting because I attend the advisory committee meetings on behalf of the Indian Health Service and they first started talking about this recommendation maybe a year or 18 months ago.

When I first got wind of it, I talked with Dr. Bullock about it and said, "Are you aware of this?" Actually, we've been able to sort of keep up with what's going on and so very quickly after they made this recommendation, Dr. Bullock and her team moved really quickly to include this in the diabetes audit. So I think we're one of the few health systems in the country that's actually really proactive about monitoring our hepatitis B coverage among our patients with vaccines, because it is a relatively new recommendation.

As most of you I'm sure are aware, hepatitis B virus can cause acute and chronic infection of the liver. The motivation for ACIP to consider a recommendation for this vaccine among those with diabetes was related to outbreaks that had occurred in long-term care facilities. They found that in the majority of these outbreaks, they were related to adults who had diabetes and they were receiving assistance with glucose monitoring. The single sticks were not being used for just one patient and there was some cross contamination and they did in fact have outbreaks in several long-term care facilities related to that.

So with that as the sort of initial motivation, the committee asked them to drill down a little bit more and really try to look at what the risk was among people with diabetes for hepatitis B. They cobbled together from different data sources and the details of that are outlined quite nicely in the hepatitis B

recommendations, but the bottom line was in the data that they've looked at. The risk of hepatitis B infection was twice as high among adults who had diabetes compared to those who did not. When they actually looked at antibody to hepatitis B core antigen, which would tell you if somebody has had a past or present hepatitis B virus infection, they found that it was much higher among adults who had diabetes compared to those without diabetes.

So based on that information as well as these outbreaks, the committee did go forward and make a recommendation, and the recommendation is that hepatitis B should be administered to unvaccinated adults who have diabetes between the ages of 19 to 59 years of age. As most of you are probably aware, we've been doing routine hepatitis B vaccination of children for many, many years. In fact your patients who are about 22, 23 years of age, probably have already received their hepatitis B vaccination series as children. If they have received it, they do not need to get revaccinated. This is just for those who have never received the complete hepatitis B vaccine series. If you had a patient who received two of the three doses for hepatitis B and still hadn't received that third one, even though that may have been 10 years ago, you should go ahead and you can just give that one dose and then that patient would be considered up-to-date with hepatitis B vaccination.

Because there were some concerns around the efficacy of the vaccine, the effectiveness in older patients, they did not go quite as strongly with the recommendation for that group but did say that it could be considered at the discretion of the clinician to adults who are over the age of 60. So that was the rationale around hepatitis B vaccine.

Finally, here I wanted to switch gears and just share with you some of the adult vaccine coverage data that I was able to pull. The blue line is basically data that we get through the immunization program. These are canned reports. They're generated out of the RPMS system and submitted to the immunization program. The red bar is the data for the general U.S. population, mostly, the National Health Interview Survey, and then the green bar is the Diabetes Audit.

You can see that when it comes to influenza high risks, so high risks for the IHS reports includes diabetes but also other conditions, and also for the U.S. population whereas high risks for the diabetes audit is obviously just your patients with diabetes, but you can see that we're doing considerably higher than these other groups. We've had coverage of 60% among the patient population with diabetes which, while good, is really not where we need to go considering the severe burden of disease in our population.

Tdap vaccine, we are really rocking the house. If you look at Td or Tdap among the IHS population, it's over 70%. If you look at the U.S. general population, it's at 60%, and among patients with diabetes, over 80% which is really extraordinary. I will say, when you look at the IHS data, if you were to look at just those who had Tdap, then we really are doing phenomenally well. For the U.S. population, only 14% have received the dose of Tdap, and in the Indian Health Service, we are well over 70%. One of the reasons for that is that we have a clinical reminder in our system to remind people to give Tdap vaccine, and that's one of the issues we may have with hepatitis B that I'll talk about.

Again, for pneumococcal polysaccharide among those 65 and older, we have coverage in the Indian Health Service of over 70%, 60% for the U.S. population. If we look more specifically at just the high risk group in the U.S. general population, only about 20% have received it. Whereas among those with diabetes in the Indian Health Service, we have 80% coverage so then we're doing very well there. You see something different with hepatitis B among those with diabetes. If we look at the U.S. general population, almost 30% of patients with diabetes have received a complete hepatitis B series, and in the Indian Health Service as Ann had shown us, we are under 20% with that. So that's the area where as we look to make improvements, there's probably the most improvement could be done with this hepatitis B among those with diabetes.

So I do just quickly want to mention adolescents because as Ann pointed out, you may be having younger patients coming to you and presenting for diabetes care. Adolescents with diabetes are the same as adults with diabetes, and they should get all the vaccines that are recommended for the person with diabetes, so they should get a dose of pneumococcal polysaccharide vaccine even if they've received all four doses of their conjugate vaccine, and they should also be sure that they are completely vaccinated with hepatitis B. In addition, there are recommended adolescent vaccines, specifically HPV. This is recommended at 11 to 12 years of age and it's a three-dose series, the Tdap vaccine, the meningococcal conjugate vaccine which is one dose at 11 to 12 years and then a booster at 16 years of age, and then of course flu vaccine.

So if you have patients coming in to your clinic, your specialty clinic for care and you see in the patient reminders that maybe this patient is due for a second or a third dose of HPV, it would be nice to think that that patient could receive those routinely recommended vaccines as part of their care for their diabetes and not have to make a separate appointment to get those from their pediatrician or as part of their well-child care. So I just want to encourage people that if you're seeing these vaccines showing up as due for patients that you're seeing, you might want to have that conversation in your facility about how you might be able to integrate some of these routine adolescent vaccines into the care that you're providing. The big one is really HPV. Getting the first dose in is fairly straightforward but we're really struggling with that second and that third dose and this is a place where every opportunity the patient is receiving care, if we can be offering them the vaccine, we're really going to increase the coverage rates.

We do have provider reminders for all of the routinely recommended vaccines in the IHS RPMS system. For those of you who aren't on RPMS, you may want to look at your state immunization registries or state immunization information systems. Most of them will also include clinical decision support to help remind you when your adolescent patients are due for vaccines and what those vaccines are.

So finally, I wanted to cover a few educational resources. For those of you who are not familiar with the Immunization Action Coalition, this is a fabulous website. It is a nongovernmental, nonprofit website and they do a lot of education materials for both patients and providers. They have a really nice page for the public that includes a lot of personal stories and testimonials. So for people who are interested in learning more about these vaccines, and we actually have one of the stories that we created in the Indian Health Service related to the Tdap vaccine. We had a grandmother, an American Indian grandmother who inadvertently gave pertussis to her six-month-old granddaughter and she talked about what that felt like and realizing that there was this vaccine and she had never gotten it, and just really a nice story to try to educate people about why vaccines are important, not just to protect yourself, but to protect those around you. So that's a great website with lots of personal stories as well as some provider resources. And then of course the CDC website, the governmental website, that has the official recommendations as well as some patient handouts, adult schedules and screening tools and things like that.

This next slide here just sort of gives you a pictorial. I did find on the CDC website some specific materials geared specifically to people with diabetes. We have our American Indian/Alaska Native materials for influenza vaccine that you can order there. On the right hand side of the screen, you see the materials from the Immunization Action Coalition which also includes the nice worksheet for vaccinations for adults with diabetes, so helping to educate your parents about what vaccines they may need that they may not be aware of.

So what can we do to improve our coverage rates? So the first thing, and this is part of the standards of care that CDC and others recently published, is to really make sure that at every visit you're assessing for vaccine, that you're recommending them. We'll talk a little bit more about the importance of the recommendation from the provider. That you're vaccinating if your facility is able to provide those

vaccines, or if you're not able to vaccinate that you're at least referring that patient for vaccination, and then to of course document it.

So the first step is to really make sure that you're assessing the vaccination status at every visit. We do this in the RPMS system because you get a provider reminder that will say, "This patient is due for their flu vaccine." In the absence of that, it's always a good idea to ask the patient because as Ann mentioned, more and more were seeing a lot of these vaccines particularly flu, pneumococcal, and Tdap available at pharmacies and other locations. You may have patients who have actually received these vaccines, so you want to make sure that you're asking about them at every visit.

The next step is to really make a strong recommendation as a provider. Study after study has shown us that really, if the provider strongly recommends it, the patient is more likely to do it. They've actually done a very interested study in looking at flu vaccine among pregnant women, and what they found is that even among women who had very negative attitudes towards flu vaccine, sort of like concerned about the safety of it. If their provider recommended it, they were more likely to end up getting the flu vaccine than the group of people who had no concerns about flu vaccine but their provider didn't recommend it.

So actually, even the patient who may not be comfortable with vaccines or might be a little bit resistant or hesitant to it, if the provider talks with them about it and the provider recommends it, that can make a big difference in whether or not the patient is willing to accept it, and this becomes I think particularly important when we talk about flu vaccine. If you're a provider who didn't get vaccine with the flu but you're telling your patients to get it, "Well, I didn't get it but you should get it," that sort of sends a very mixed message. So again, just the importance of sort of practicing what we preach and making sure that we're making strong recommendations to our patients.

Then finally, vaccinating, and there are definitely a lot of strategies that we've used very successfully in the Indian Health Service to facilitate actual vaccination. Obviously, if they come to see the provider and the provider screens and orders the vaccine, but also having standing orders in place particularly for things like flu vaccine and pneumococcal polysaccharide. Pharmacy-based clinics. So if you have a pharmacy-based immunization clinic and the patient is coming in to pick up some meds and the pharmacist can look and say, "Hey! I see that you're due for your Tdap vaccines. Do you want to get that?" That can really help to facilitate the provision of these vaccines.

Finally, something we do very well in the Indian Health Service as well is holding immunization clinics out in the community. So particularly for influenza, some of those clinics have started to look at providing both pneumococcal and Tdap as well, so really looking at alternative venues to try to expand access to vaccines.

And then of course documenting and following up. If you document it in our system, the system will remind you when the patient is due for the second and third dose. We also have some tools that I'm going to cover. You can actually do lists of patients who are due and send them a letter that's automatically generated from the system to remind them to come back in for that second dose of hepatitis B, that second dose of HPV vaccine, and then some types had even used home visits. Of course documenting vaccine for making sure that you're getting that complete immunization history for your patients and documenting it in your system so that the next time they come in, you have that information there.

So some of the specific EHR or RPMS tools, again, we have clinical decision support for immunization. This shows you what vaccines the patients are due for and it takes into account the minimum intervals and the ages and all the complexity of the immunization rules. We basically provide the support for all the routine age-based recommendations. For the pneumococcal polysaccharide, we will provide a reminder for those who have a high-risk medical condition. For hepatitis B, you're only going to get a

reminder for your adult patients if they've received a previous dose. So you have to initially identify that first patient to get the hepatitis B vaccine, and then our system will remind you for the second and third dose. The real challenge is how do we get that first patient with diabetes, and make sure they get that initial dose of hepatitis B vaccine. And this is where the RPMS immunization package and the EHR reminders can be very helpful.

Looking at the poll, it looks like the majority of you that have voted so far are using RPMS, so thankfully a lot of this information should be very fairly useful for you. I don't want to get into a lot of the technical details but for those of you who have an immunization person or your CAC on site. If you aren't aware of this, you might want to explore how you can use the tools in the RPMS immunization package. We have a function specifically called "lists and letters". It's only in the roll and scroll environment so you cannot get to this in the electronic health record. Now, the electronic health record sits on top of RPMS and you can enter immunizations that you give into the EHR, but we have a lot of functionality that's not available through the EHR. You have to get into what we call the old-fashioned roll and scroll and that's where "lists and letters" is, and you can use that to generate lists of patients who are due for certain vaccine and then to send letters to them, and you can use this in conjunction with QMAN to help really refine your list.

So my next few slides, again, I'm keeping them in here as reference. This is what the immunization package menu looks like, the "lists and letters" sits in the patient menu, it's called "lists and letters". If you want to help working on this, then I would really encourage you to contact your immunization person. In "lists and letters", these are all the different parameters that you can slice and dice and set up and then you can get list of people who meet these specific criteria. The one that might be most interesting to you is this patient group parameter.

Here, you can actually pull in a QMAN template. So for example, if you had a QMAN template that already identified all of your patients who were people with diabetes, or people with diabetes who didn't get a hepatitis B vaccine, you could pull that group into the "lists and letters" just what I've done here, I'm just pulling in a QMAN template, and then you could run a list of, among my patients with diabetes, how many of them are due, for example, for a hepatitis B vaccine or a flu vaccine or pneumococcal polysaccharide vaccine?

So you add which vaccine that you wanted to look for and then you create this list and it will give you a list of patients and you can print due letters to all of those patients that might say, "We looked at our records and noticed that you haven't received your pneumococcal polysaccharide vaccine. Please make an appointment to come in." Or, "We're having a vaccination clinic this Saturday, it looks like you're due for your second hepatitis B vaccine. You can get it at our walk-in immunization clinic." Whatever the letter wants to say, but you can create that and send it out automatically, and this is what that list of patients look like. It gives you the list of the patients and their health record number, and you can actually go from this list directly into that patient record to take a look at their health summary and see which vaccines it is that they might need.

So the summary, again, we have clinical decision support for most vaccines and that will remind you for the second and third dose of hep B vaccine but not for the first dose. In the immunization package, we have an ability to write, to run lists of patients who might be due for vaccines and you can automatically generate letters. Again, your immunization coordinator or the trainings that we offer can give you more information about how exactly to do that.

In QMAN, you can certainly develop your template to identify your patients with diabetes and figure out which of those haven't received hepatitis B and get them started on that series. Of course, I've heard in the EHR, there's a way to do reminders, it's not something I'm particularly savvy about but I do know that there is a way to set up reminders. I think we have some sites that have actually developed a

reminder in the EHR to remind providers about the first dose of hepatitis B. In fact, if anybody has done that, I'd be really interested in getting more information about that so we can share that with others.

Again, these are just some additional resources including on the IHS, in the immunization package, these lists and letters and things that I kind of blew through. If you click on this link, that will take you to some of the PowerPoints and Adobe Connect trainings that we've done around how to actually use those. So that's the information that I had, and I think now perhaps we can open it up to questions.

Jan Frederick:

Thank you Amy and Dr. Bullock and we do have a few questions for you, and Kelli has been nice enough to gather those up for us. So we can walk you through those or if you want, they're on the right hand side of your screen there, if you want to walk through them – do you have a preference?

Amy Groom:

Okay. Well, I mean it looks like the first one is really related to the diabetes audit. It looks like Kelli had already answered that. Am I understanding that correctly?

Ann Bullock:

The audit does allow for refusal. Still, for immunizations, it's the only part of the audit where we still count refusals in there because we know it's still an issue for a lot of immunizations and are interested in that data. So yes, refusals are still accounted for immunizations in the audit.

Amy Groom:

Here, we have regarding updating the patient record if they say that they've gotten their vaccine elsewhere. In the immunization package and in EHR, you can document that as a historical vaccine and we encourage folks to do that, but you need something, you need at least to have a specific timeframe. It can't be, oh, I think I got the flu vaccine but no date or anything. I mean sort of, does the provider believe that the patient has accurate information. What we typically do with children for example, is if you look them up in the registry and the registry said they've gotten a shot then we would just enter it as historical and the provider might just be per state registry.

I think you could document flu vaccine. For example, patient received at Walgreens on January 1st, 2014, per patient. There are ways in the RPMS that you can certainly document those historical vaccines.

I think Jamie had a comment on that. Yeah, she brings up a really good point and this also true with Td and Tdap, and pneumo and especially with the conjugate vaccine out there. Patients may be very confused as to what they actually got. So, did they really get the Tdap or did they get the Td? In those cases, you probably would want to refrain from documenting that and actually try to get a little bit more information and verification that they had in fact received their Tdap vaccine because once you've given that and documented it, the system is going to say they don't need another one. So you do want to make sure that the information you have is accurate. So being aware that vaccines are really confusing, and patients may not always know exactly which vaccine they have received.

There is a question here about egg-free vaccine not licensed for children. This has to do with how the pharmaceutical companies set up their trials and they typically tend to do these safety trials in adults first and they just didn't do the trials in children. There is no reason for us to think that it wouldn't be safe in children at this point in time but the studies have not officially been done. Until they're done, they will not license this vaccine in the pediatric population.

What are recommendations for Twinrix, hep A and B vaccine over hep B only? That's a great question. Hepatitis A vaccine is not one of the vaccines that's routinely recommended for people with diabetes. There are certain adult groups for whom hepatitis A vaccine is recommended. That would include food handlers, men who have sex with men, and then also, if you're traveling to a country that's endemic with hepatitis A vaccine, and chronic liver disease. Those patients should receive both hepatitis A and hepatitis B vaccine, whereas the specific recommendation for diabetes is just around hepatitis B vaccine. So that's a specific recommendation there.

A comment regarding HPV, "it's licensed for adolescents. However, did you say it should be given to adults with diabetes?" Thanks Linda. This did get a little bit complicated. You're absolutely correct. HPV is licensed for people 11 years of age through 26 for females and 21 for males and the routine recommendation would be to give it to adolescents at 11 to 12. However, people who are 13 through 26 for females, or 13 to 21, if they did not get the vaccine, they're also recommended to receive it. So HPV vaccine is not recommended for a patient just because they have diabetes. But if you had a 19-year-old patient who had diabetes and had not received HPV vaccine, you would want to make sure that they get HPV vaccine. So HPV isn't recommended because you have diabetes, but it is recommended for certain age groups and you may have some of your patients with diabetes who fall into that age group. We wanted to make sure that HPV and some of these other vaccines that are recommended for patients generally, such as the Tdap and the meningococcal are also provided to your patients with diabetes if it's indicated. Hopefully, that clarifies that.

Jan Frederick:

Amy, I know we have just a couple of more questions but I'm going to pause since we are at the top of the hour. We'll come back to those last couple of questions, but for people that are in a time bind here, let me get the link to the handouts, note that in the bottom left hand corner of your screen. We have copies of the slides from Dr. Bullock and also from Amy Groom so you can download them..