

Advancements in Diabetes Seminar Immunizations for Patients with Diabetes

Amy Groom, MPH
IHS Immunization Program Manager

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Karen and Dr. Bullock, I really appreciate the opportunity to talk. For those of you who are on the frontlines working with the patients with diabetes, to talk about immunizations, I really appreciate the opportunity to be able share some of information with you. As Jan mentioned, I am a CDC public health advisor and I'm assigned to the Indian Health Service and I oversee the IHS Immunization Program for IHS and I'm located in Albuquerque, New Mexico. We have a team of immunization folks, so Cheyenne Jim and Jillian Doss-Walker, the other two CDC assignees who work with me on immunizations and we're all here in Albuquerque, but we do work with tribes and facilities across the country.

So today, I'm going to provide you a little bit of an update around immunization for patients with diabetes. But it's a little bit broader than that. As an overview, I just wanted to go ahead and give people immunization recommendations in general for all adults, so not just those with diabetes. And then of course, cover those that are specific to folks who have diabetes. And then, I'm going to provide some updates for immunizations.

I had just attended the advisory committee on immunization practices. I represent IHS on that committee and they make the schedule, make the recommendations for new vaccines and current vaccines that are licensed in the U.S. They meet three times a year and they actually just had their meeting last week and there were two new developments there related to Shingles vaccine and Hepatitis B vaccine and so, I'll share some of that information with you as well.

I did want to give you some coverage information for U.S. adults and then also IHS adults and this is data that Karen Sheff kindly provided to me from the diabetes audit within the Indian Health Service. Not all of the data is apples to apples, because the U.S. data is not necessarily just for people with diabetes. But I did put some comparisons in there just so you can get a sense of where we are as an agency compared to the general U.S. population, in terms of vaccine coverage.

And then finally, I'll talk real briefly about some of the tools and strategies in our electronic Health Record, in the immunization software in RPMS that you could use to help increase vaccine coverage among your patients.

So, just in terms of routine adult immunization recommendations, so vaccines are not just for children and I always want to make sure that people recognize that there are lots of vaccines that adults need to. The vaccines that are recommended for adults include the human papillomavirus. And this is just for people who haven't been vaccinated as an adolescent that, ideally this vaccine would be given at 11 to 12 years of age. But, if you haven't been vaccinated, we do recommend vaccination with the HPV vaccine for females, 19 to 26 years and males, 19 to 21 on a routine basis. And then, there are certain populations, for which high risk populations for which you would also consider vaccination. This is probably going to become less common as more and more of our patients have been, as adolescents and received their HPV vaccines. But there are still a segment of the population that should be getting HPV vaccine.

We also have recommendations for Td. I think everybody knows about the booster every 10 years. But in addition to that, everybody should receive at least one dose of Tdap in their lifetime. So usually, what happens is one of those booster doses of Td, instead you would get a Tdap and then you'd go back to getting a Td booster every 10 years.

Influenza is a very important vaccine for everybody and this is one of the vaccines that we recommend on an annual basis, because the viruses that circulate change, and so our vaccine changes every year as a result. And we of course right now are in the peak of influenza vaccination activity. And that is the vaccine that's recommended annually, for everybody six months and older, so of course including our adult population.

We have pneumococcal vaccines, then actually have two different pneumococcal vaccines. One is what's called the pneumococcal polysaccharide 23 valent. You can see it's abbreviated as PPSV23, so it protects against 23 different strains of the pneumococcal. And then, you may also see it's abbreviated as Pneumo PS for pneumo polysaccharide and also the brand name of Pneumovax. So those all three are basically the same vaccine and this is routinely recommended for everybody at 65 years and older. There are certain populations where that routine recommendation might be younger. So we do have some American-Indian/Alaska Native communities that start routine pneumococcal polysaccharide vaccination for everybody at a younger age at 50 or 55, based on the epidemiology in their area but, for the most part, in the lower 48, we routinely give it to everybody 65 years and older. And then there are special indications for high risk populations which I will talk about in a little bit.

And then, in 2014, we had a new pneumococcal vaccine licensed for use in adults. This is the pneumococcal conjugate vaccine, the 13 valent. So, it's called PCV13 or the brand name, Prevnar13. And this vaccine was one that we've been using in children for quite a while, since

about 2000, but then in 2014, they also recommended that everybody 65 years and older get a dose of PCV13. So, that's another pneumococcal vaccine indicated for routine use in adults.

And then finally, the Shingles vaccine, until just last week, we had one Shingles vaccine, the Zostavax vaccine that was recommended at 60 years of age. We now have a new recommendation and I will be talking about that a little bit later.

And if you ever want to see the most current schedule in some of the slides that I have coming up that show you the schedule, you can certainly go to the CDC website. In there they have easy to read schedules for adults that you can see all of these laid out in a graphical format. And this is what that looks like. Again, this is the 2017 schedule. This is the routine one, by age. So, based on your age, what vaccines should you get? Green means that you should get it, everybody should get it. Blue means that maybe you should get it, but it would depend on if you had a certain health condition or another risk factor that might put you at an increased risk. So, if it's green, that means basically if you're that age, you should get it and you can see flu, Td, Tdap, Shingles starting at 60, the pneumococcal starting at 65. Everything to the right of that, the MMR and HPV, the really vaccines that you probably got as a child, if you didn't get them, then you would need to get them. And then, the blue bars means you should get this at this age, if you have another health risk condition. And just keep in mind, this is the 2017 schedule. So 2018 schedule is usually published in very early January and that will include some of the updated information about Shingles that I'll be sharing with you.

So, in terms of vaccines that are specifically recommended for patients because they have diabetes, one vaccine again that is universally recommended for everybody is influenza. But this is particularly important for patients with diabetes, and even before we had a universal recommendation, people with diabetes are one of the high risk groups that were called out to receive influenza vaccine. So, it's a very important vaccine for patients with diabetes. And then, other vaccines that are recommended for adults specifically because they have diabetes include that pneumococcal polysaccharide, the 23 valent. And also, Hepatitis B and I'll be talking a little bit more about those two specific recommendations.

So, we do have a couple polling questions here. Sorry Jan, you were so on it, I wasn't even prepared for it. I wanted to just stop here quickly and have everybody take a moment to answer the poll questions, again because flu is so important, I'm always curious to know how many of you have received your flu vaccine this year? So, the options are "Yes", "Not yet, but I will", "No" and then, "No vote." So, it looks like the majority of you have already received your influenza vaccine this year which is fantastic and that, those of you who have not, hopefully most of you, it looks like are going to get it even though you haven't yet. And some people who said no, they may have some reasons why they can't get that flu vaccine. But again, just to remind you that this is recommended, not just to protect you but to protect your patient as well.

And then, the second question I had was, “Do you recommend influenza vaccine for your patient with diabetes?” We have 93% of you who said yes and four of you who said no. So, that would be interesting to know who was saying no and what your reasons might be for not recommending it for your patients with diabetes. Again, influenza is a pretty important condition that really impacts our communities and particularly those with health conditions. And so influenza vaccine is the best way to help prevent influenza-related illness and complications from influenza. So, thanks Jan.

I’m going to move on now to the recommended schedules by health conditions. So again, these are the vaccines that are recommended specifically because somebody has diabetes, or has another health risk condition. So again, the green would mean, if you have this condition, you absolutely should get vaccinated. So, pregnancy for example is on there. People who are immune compromised. If you scroll all the way down to, I just remembered, you don’t see my cursor, but maybe now you do. Here, this line here, this is if you have diabetes, you can see that flu is recommended. Obviously, Td, Tdap is very important. Shingles, if you’re age-based and you should be getting that if you have diabetes. And then the pneumococcal one, the pneumococcal polysaccharide is recommended for you, if you have diabetes. The PCV 13, this blue bar here is only recommended if you had a health condition that would require you to get it and diabetes in itself is not a condition for which PCV13 is specifically recommended, and I will talk a little more about that.

So again, just to talk a little bit more about pneumonia and influenza. Influenza causes disease and death across the country. But we have seen that it definitely impacts our American-Indian/Alaska Native communities. And that the death rates from influenza and pneumonia are almost two times higher among American-Indian/Alaska Native people compared to non-Hispanic whites. There is significant variation by region and by age group, but in general we do see higher mortality from influenza-related disease in native communities.

And then, when we were during the 2009 H1N1 pandemic, we actually had mortality rates that were four times higher compared to other races. Some of the reasons for this disparity definitely includes some of those socio-economic conditions that we all know about. Crowded housing can be an issue, lack of running water in the household, certainly access to care if you live very remotely where you are very difficult to go and get care for it, but the burden of chronic medical conditions in our community and including diabetes is definitely one of the risk factors that puts the population at increased risk for influenza-related death and complications.

So, in terms of the influenza vaccine recommendations, again as I mentioned, it is recommended for everybody six months and older. And I also want to let folks know that IHS did implement a mandatory flu vaccination policy for all of our healthcare personnel that work in an IHS facility, are required to receive an influenza vaccination and unless you have a medical exemption or a religious exemption. And I will just note that for those of you who said no, that you hadn’t received your flue vaccination, or remind you that our definition of healthcare personnel is really anybody who is working within the healthcare facility. So it’s not

just people with direct patient care, because influenza is a respiratory illness and it can be on doorknobs and handles, and computer keyboards and it can be in the air. Even people who may be only working in medical records or not necessarily providing direct care are considered healthcare personnel under this particular policy. So, really anybody who is working in our IHS healthcare facilities is required to receive an influenza vaccination every year. So, hopefully folks are aware of that and there is information about that policy on the IHS website. And this picture here is our Chief Medical Officer, Dr. Michael Toedt receiving his annual influenza vaccine at the National Foundation for Infectious Diseases kick off and he also did send out an IHS all email about flu and the importance of getting vaccinated.

So now, I want to switch gears a little bit and talk about the pneumococcal vaccines. Specifically, the pneumococcal polysaccharide 23 valent which is I mentioned referred to by all three of those different names there, and then also the pneumococcal conjugate vaccine, because the recommendations are different.

So, in terms of PCV13 for adults, the PCV13 as I mentioned was recommended starting in 2014 for all adults, 65 years and older. I will say this is a temporary recommendation; the Advisory Committee on Immunization Practices will be revisiting this in 2018. And by that, they mean the end of 2018. So in December or probably at their October and then maybe their February 2019 meeting, they'll be revisiting this recommendation to see if there has been sufficient impact from that recommendation to continue to require it or recommend it for adults, 65 years and older. So, it is a time-limited recommendation. But for now, everybody who is 65 years and older should receive a dose of pneumococcal conjugate vaccine, in addition to them receiving a pneumococcal polysaccharide. There is an interval required between the PCV13 and the pneumococcal polysaccharide, and that is one year. And just because, it can be very complicated to determine the ordering, because you may have patients that already received the pneumococcal polysaccharide, and then the question is, "Well when should they get that conjugate or vice versa?" And then, you may have had people who received the dose of polysaccharide before 65. This really nice algorithm about when you should give, what and what the interval is, is included in the actual recommendation from the ACIP on this vaccine. So I've included it here, but I realize it's very, very small. But, if you have questions or concerns about that, I would encourage you to go and find that actual recommendation and you can look up this particular flowchart.

In our Electronic Health Record system in the RPMS with the immunization clinical decision support that we offer, does incorporate this logic. So, if a patient receives the pneumococcal conjugate at 65 years and older, it will not forecast that pneumococcal polysaccharide until that interval of one year has passed. And similarly, if you have a patient who just received their pneumococcal polysaccharide at 65, it will not forecast the PCV13 until at least a year had passed. So, it does take this into account.

In terms of who should get pneumococcal conjugate vaccine as an adult less than 65 years, this is really limited to those adults who have an immune compromising condition and they did

actually spell out what they considered to be an immune compromising condition and you can see them all listed here. And again, you can always go to the recommendation to see this. And the thing that I just really want to point out here is that diabetes is not considered an immune compromising condition for the purposes of this vaccine. So, your adults who have diabetes should absolutely get PCV13 at 65, but just because they have diabetes, is not a reason for them to get it sooner than 65.

So, pneumococcal polysaccharide however is a little bit different. As I mentioned, the routine recommendation is basically all adults regardless of their health status should receive a dose at 65 years and older and they should get that PCV13 first and then, get their pneumococcal polysaccharide. However, for the pneumococcal polysaccharide, the high risk indications, so the adults less than 65 who should get it, does include patients with diabetes. And the way the recommendation is written is, as soon as an adult patient is informed that they have diabetes, you should administer the pneumococcal polysaccharide at the time of diagnosis. So, as a result, we have a lot of patients in the Indian Health Service, who probably had already received the dose of pneumococcal polysaccharide before they turn 65. So, you would get a PPSV23 at the time of your diabetes diagnosis. And then when you turn 65, you should get one additional dose at 65 years of age. But we have to also keep in mind, there has to be a five-year interval between doses of the polysaccharide. So, if you received your pneumococcal polysaccharide at 62, because you were diagnosed with diabetes, then you can't get that pneumococcal polysaccharide at 65. You would actually wait until you are 67. And again, there are intervals of PCV13 and just to take the stress off of you; our logic does take all of this into account. So, it knows to forecast this pneumococcal polysaccharide to the five-year interval and also the intervals that are required for the PCV13.

Okay. So, the question that I wanted to ask people here is in the RPMS Electronic Health Record, clinical decision support for immunizations we do have a reminder that you can turn on for your pneumococcal polysaccharide to show up as due for patients who have one of those high risk medical conditions and that includes diabetes. And my question is, how many of you know if you have turned this reminder on at your facility? So, do you have a reminder for pneumococcal vaccine for your high risk patients enabled at your facility in your Electronic Health Record system? It looks like about 30, a little less than 30% of you said yes. Some of you had said no, and not surprisingly, I can understand why a number of you are not sure. This isn't something that probably you are necessarily aware of, but if this is something that you feel is important or if you've been looking at your diabetes audit data and realizing that your pneumococcal coverage is low among the patients that you serve with diabetes, you may want to check with whoever oversees either the immunization point of contact at your facility or your site manager, to ask them if this reminder is turned on in your system. It's not an automatic reminder. It's something that you have to choose to turn on, and then it will look for patients who have had a diagnosis of diabetes and other high risk medical conditions based on ICD-9 and ICD-10 Codes. And if they have that, it will show up as "Due" for the patient who hasn't yet been vaccinated. So, if you're not sure, this might be something that you'd want to check at your facility to make sure that you have that reminder turned on.

So, I do just quickly want to talk about PCV13 in children and also just touch on the recommendation specific to this vaccine in children with diabetes. So, PCV13 again, we've been routinely using this in all children less than five years of age. They're supposed to get four doses at two, four, six months and then again a booster dose at 12 to 15. If you start it late or you get off track however, you might end up needing fewer doses and that's an issue that we struggle with a lot in the Indian Health Service and across the country.

Once the child turns five years of age, basically you would stop. So, if they haven't received PCV13 or they received an incomplete series, you normally would not continue that for healthy children. However, if you have children between the ages of two and five who received an incomplete series, they may need to continue to get additional doses and high risk children does include those with diabetes. So, children who may be over the age of two years of age and didn't receive complete PCV13. If they have diabetes, there are specific recommendations and you should make sure that they get those PCV13 doses. And then, for children between ages of 6 to 18, patients with diabetes are not included here. So, if you had a child with diabetes who is six years of age and did not receive PCV13, at the current time there is no recommendation that they should get a dose or any doses of PCV13.

And then in terms of polysaccharide, if you want to include this here, right now, there used to be a very clumsily-worded recommendation many years ago around children who should get pneumococcal polysaccharide routinely. We do not have any routine use of pneumococcal polysaccharide in children. Basically, now that we have PCV13, it's a better vaccine with the more immunogenic response even though it doesn't have a quite the same number of serotypes and so we do not use pneumococcal polysaccharide routinely in healthy children. However, if you have a high risk child who is two years and older, in addition to getting their PCV13, they should also get a dose of the pneumococcal polysaccharide and this high risk criteria does include those with diabetes. They should first get their PCV13 and then get that pneumococcal polysaccharide and there is of course an interval required between the polysaccharide and the PCV13.

Basically, it's important to note that for children who receive a dose of pneumococcal polysaccharide, so if they receive their polysaccharide at the age of five, there is currently no recommendation for revaccination of that person until they turn to 65 years of age. So, for children with diabetes, you basically get, anybody with diabetes should get the one dose at the time of diagnosis and then next time you would get a dose would be at 65 years and older.

Then I also want to talk about Hepatitis B in patients with diabetes. We all know Hepatitis B virus causes acute and chronic infection of the liver. We've seen really dramatic declines in this because of our vaccination program. But we have noted in the recent past, outbreaks and long-term care facilities, specifically related to adults with diabetes who are receiving assistance with glucose monitoring. This is really the data that was shared with the advisory committee when they made this recommendation. When they were reviewing the data they

found that the risk of acute Hepatitis B infection was twice as high among those adults with diabetes compared to those without suggesting that there were something related to diabetes and most likely the glucose monitoring that was putting people at increased risk.

Also in seroprevalence studies that has been done, we have seen a higher seroprevalence of Hepatitis B core antigen, so it's indicating that they've had an HPV infection in adults with diabetes compared to those without diabetes. And it was really based on this data that in 2011, that the committee voted to routinely recommend Hepatitis B vaccine for any adults who had diabetes between the ages of 19 through 59 years. That cut off is because the vaccine is less immunogenic, the older you get, and particularly with people with diabetes already. So, we see less immunoresponse that's very robust over the age of 60. So the recommendation reads that it should be given to those 19 to 59. And then based on your clinical judgment, you could also consider giving it to those unvaccinated adults with diabetes who are 60 and older.

I think, do I have another polling question? Yeah, thanks Jan. So, the question that I have here is again related to the immunization reminders in your Electronic Health Record. Do you have an immunization reminder for Hepatitis B for your patients with diabetes turned on your Electronic Health Record at your facility? So, this would be in RPMS. Or if you're using another product, do you have a reminder for Hepatitis B specifically for adults with diabetes. I see that about 30% of you say yes you do, 23% of you say no. And then again, a large proportion of you are not sure. And again, this is the question that you may want to pose to whoever is your immunization coordinator or your site manager at your site. And if you look at your Hepatitis B vaccine coverage in the audit, and you feel that this is something that you'd like to improve upon we do have a reminder in RPMS that if you turned that on, then any patient who has a diagnosis of diabetes between the ages of 19 through 59, there will be a reminder telling you to begin that Hepatitis B vaccination series and then it will show you reminders to complete that series. So, for those of you who aren't sure, if this is an area that you'd like to work on, I really encourage you to reach out again to your immunization point of contact, or your site manager and ask them if that reminder has been turned on.

The question box is small, I can hardly read it. So, I will take these questions that are related to flu before I get into coverage. I'm trying to figure out how to make that box slightly bigger Jan, the way to make it, the font larger. So, the first question was, does the policy include urban sites? So, the way the policy is worded, is it for anybody who works in an IHS facility, anybody who works in those facilities is required to be vaccinated. So, with regards to urban sites, those aren't typically considered to be solely funded by the Indian Health Service. However, we certainly strongly encourage that all healthcare personnel receive an influenza vaccination. And if you have folks who are IHS employees, so they're paid by the Indian Health Service working in the urban facility, that person would be required to receive an influenza vaccination. And the same has to do with tribal health clinics, again tribes can determine if it's a tribal health facility whether or not they choose to implement this policy. But if you have any IHS employees working in that facility, they would be required to be vaccinated. I will say that we have many tribal sites that had also adopted or had actually even

before we had a policy in Indian Health Service, had created a mandatory influenza vaccination policy for all of the employees in their health centers.

So, yes, and then a question here about the flu shot being mandated. It is on the IHS web page. I believe if you go to www.ihs.gov/flu, we have a Resources section there and there should be a link there that will take you to the policy for healthcare personnel. So, actually outlining it there, and I do know that in the IHS all email that Dr. Toedt sent out, I believe he also provided the link to that policy. If you have any difficulties finding that, please feel free to shoot either Cheyenne Jim or Jillian Doss-Walker an email and they can certainly point you in the right direction for that and I've included their contact information at the end of this presentation. And they are in the IHS global address so you can find them there as well. So, thanks for those questions.

I'm going to move forward to talk about immunization coverage and again I really want to thank Karen Sheff for sharing these data with me from the Diabetes Care and Outcomes Audits. These are data selected, for selected outcomes, so specifically the immunization coverage ones, through the audit of 2017. And then for the U.S. data, I used sources that CDC supports, they have what's called AdultVaxView and FluVaxView. These take data from different surveys including the National Health Interview Survey, the (BRFS) Survey, the Behavioral Risk Factor Surveillance Survey and then also a flu survey that they do every year that combines all of that different data so that you can go to their website and take a look at what coverage. And so where possible, I have looked at those coverage, information for patients with diabetes. That's not always possible. So, in those other situations I've had to substitute that with just high risk data. I'll tell you exactly what the comparison group is as we go through these particular sites.

So, this first one is basically looking at either a Td or Tdap, so basically looking for any Td containing vaccine in the last 10 years. So, this is really getting at Td booster dose. We have great coverage data from the diabetes audit going back all the way to 1997, and you can see that in general we have sustained very high coverage with Td booster among patients with diabetes in the Indian Health Service with just under 90%. So, definitely you see some increases there. So folks clearly have been working on this over the years, and we now have very high coverage with that. By comparison, this is just the U.S. general population. So this is not just for those with diabetes, but among our U.S. adult population, you can see that we only have Td booster coverage of about 60%. So, definitely doing a better job with our patients with diabetes in the Indian Health Service which is good to see.

This next one here is looking at pneumococcal vaccine. Even though only pneumococcal polysaccharide is the recommended vaccine for patients with diabetes, the logic that we use includes either a dose of conjugate or pneumococcal recognizing that there are these interval issues. So, this is basically just saying among our patients with diabetes, how many of them received the pneumococcal vaccine. For most folks, this will be the pneumococcal polysaccharide. And then the comparison group is high risk 18 to 64-year olds. So, this is

obviously, doesn't include anybody over the age of 64, but also includes people with conditions other than diabetes. So, it's not just diabetes, it includes patients with asthma and heart disease, et cetera. So not just among the patient with population with diabetes. And you can see in the Indian Health Service, we've achieved about 80% coverage among patients with diabetes with the pneumococcal polysaccharide vaccine and then in the U.S general population for high risk folks, we have coverage just over 20%. So definitely clearly doing something different in Indian Health Service and I know that this is an area of real strength, and that for many, many years, Indian Health Services has focused a lot of efforts and really supported pneumococcal vaccination among patients with diabetes. And this is obviously a testament to all the work you guys are doing on the frontlines.

Here is our influenza vaccine coverage data. So again, our IHS data are from the diabetes audits and the comparison group again is that U.S. high risk population. So including patients with conditions not just diabetes, but other high risk conditions. And you can see coverage is a little bit lower for flu vaccine than it is for these other routine vaccines that we were talking about and this is what we see in the general U.S. population as well. We have very high coverage of those vaccines and then somehow when it comes to flu, we just don't have the uptake that we feel we should. But among patients with diabetes in the Indian Health Service, we get coverage at about 55%. So that's definitely higher than what we have for the general population in the Indian Health Service which has been about 37-38% for the last several years. So it's nice to see that our sites are making a concerted effort to get flu vaccine to this very high risk population and that's reflected in the data here. And you can see in the general U.S. population, again slightly higher coverage for the high risk group than for the general U.S. population and a little bit lower than what we see in Indian Health Service. But as a reminder, our Healthy People 2020 Goal for everybody, six months and older is to get that 70% coverage. So we definitely have a ways to go if we hope to reach that goal.

And then finally this one I think is really, really exciting. This is Hepatitis B vaccine coverage and patients with diabetes. The comparison group for both the IHS and the U.S. is patients with diabetes. You can see the green line there is the U.S. So coverage was about 30% and actually decreased which is sort of ironic given that the recommendation came out in 2011. You can see the percent coverage in the Indian Health Service however has been steadily increasing. From 16% in 2012, which was the first year after that recommendation was made and seen a very steady increase in the coverage at about 32%.

So again, while we can definitely always do better, it's really nice to see this upward trend. And for those of you that have looked at your Hepatitis B vaccine coverage among your patients with diabetes and are looking for ways to increase that, that reminder for Hepatitis B vaccine that's available in RPMS might be one way to help with that. And then you can see the red line there, is just basically immune because you wouldn't be vaccinating people who are already immune, but have a very low proportion of patients who are actually immune to Hepatitis B.

So now I'm going to switch gears here. I don't see any specific questions related to the coverage data that I shared. So I'll go ahead and move into some of the very exciting updates from the most recent Advisory Committee on Immunization Practices meeting, that was just last week, October 2017. The two things that I'm going to cover are the Shingles vaccine recommendation and then a new Hepatitis B vaccine that is not licensed yet. But I will say I'm only sharing information that was shared publicly at the ACIP meeting. So all of this information was publicly made available at ACIP. So I'm just going to be sharing that level of information with you today.

So as most of you know, the previous Shingles vaccine recommendation was we had one vaccine, it was called Zoster Vaccine Live. It was a live virus vaccine called Zostavax made by Merck. And it was recommended for all immune competent adults 60 years and older. So people with immunosuppression could not receive this vaccine. Patients with diabetes were not considered immunosuppressed for the purposes of this vaccine. So it was recommended for anybody who was 60 years and older and it was basically just a one-time dose.

So I think I have a polling question Jan, thank you. So I'm just kind of curious because this vaccine is costly and there are also some storage issues related to it and that's been a real challenge particularly for many of our small sites. So I'm just curious if at your particular facility, how many of you are routinely providing the Zostavax Shingles vaccine to your patients 60 years and older? Looks like we have about 45% say yes, a very small proportion say no which is good to hear. But then there are a number of you who are not sure. So again if this is something that you're interested in just knowing what your site is doing around that, you could check with either your immunization person or often times the pharmacy will know because they are stocking this vaccine. So if you wanted to see if you're able to provide this vaccine at your facility that would be a place to start. So thanks Jan.

So at the meeting, there's a new Shingles vaccine and this is pretty exciting stuff. It's called Shingrix and it was actually licensed by the FDA on October 20th, so right before the ACIP meeting, but just in time for the ACIP meeting so that they could actually vote on a recommendation for this vaccine. It's a Recombinant Herpes Zoster Subunit Vaccine and the abbreviation for that is HZ/su. So you'll be seeing that and they're referring to the Zostavax vaccine as ZVL for Zoster Vaccine Live. So this is the two abbreviations that they're using for the Shingles vaccine we currently have available.

And this new Shingles vaccine is different that it contain, not only is it not a live virus vaccine, but it contains an adjuvant and it's really the adjuvant that gives it a much better immune response in the clinical trial. The manufacturer is GlaxoSmithKline and this vaccine was licensed at 50 years and older which actually so was Zostavax but the ACIP recommendation for Zostavax was made for 60 years because there were supply issues and also because the vaccine, the live virus one doesn't seem to last very long. It seems to only really provide protection for about five years before we start to see pretty dramatic declines. But because this vaccine and then the data that you can read about online and then I'll share some of it with

you shows a much more robust response in all age groups and lasting for a much longer time. So as a result to that, the indication for this vaccine is at 50 years and older and ACIP is actually now made a change to the recommended age based on this. It is IM vaccine, an Intramuscular vaccine and it's two 0.5 mL doses, two to six months apart. So you get your first dose and then from two to six months after which you get the second dose. So it is a two-dose vaccine whereas Zostavax is only a one-dose vaccine. This vaccine is not really available on the market just yet. We've been hearing internally that around February, March is when we expect to start having supply available. The price again has yet to be determined but they did present some cost modeling data at ACIP and they're looking at about a \$140 a dose is what they were using in their projections. So it would be \$280 to receive both doses. So this is again a costly vaccine. And if you really want to get into the details of the product information, I provided the link here to the package insert.

But to share with you some of the data that again were shared and that came into consideration when ACIP made the recommendation, they actually recommended this vaccines starting at 50 years and older, so again, for immune competent adults, 50 years and older. And the other thing that they recommended is that if you have a patient who's already received the Zoster Vaccine Live, vaccine at 60, they are recommending that person should also now get a dose of this new vaccine. And again that has to do with the much better, longer-term protection that this vaccine provides, and the fact that the Zoster Vaccine Live virus, the protection wanes pretty rapidly. So they are saying that basically anybody who's already received Zoster Vaccine Live should now also get a dose of the new one, the Shingrix.

Then finally, if you have a patient who's 60 and older, they made a preferential recommendation to receive Shingrix. So the Herpes Zoster subunit vaccine over the Zoster Vaccine Live. So if you have a patient who's 60 years and older, it's not like with other vaccines where you could give them one or the other. They're saying you should basically give those patients Shingrix, not Zostavax. So that was a pretty controversial and there was a lot of consternation around this preferential recommendation, but that is what ACIP has decided. So to share with you some of the data that went into that consideration, they did look at safety. And they compared the safety of Shingrix to Zostavax and they were really very comparable.

The most common side effect was mild to moderate pain at the injection site which is what we see with most vaccines. And they really didn't see any serious adverse events that were observed in those clinical trials. So they will of course continue to do post marketing safety surveillance. One thing to be aware of however is the proportion of people who received the vaccine who did have some sort of side effects at the pain site that was sufficient to interfere with their daily activities was actually a little bit higher than what we see with Zostavax. So about 17% of folks did report more local site reaction that could potentially inhibit their day-to-day activities for a couple of days until that resolved. This is believed to be because of the adjuvant, and this is actually an education piece that folks really want to make sure that those patients and providers are aware that you might see more reactogenicity at the local injection

site with this vaccine than we did see with Zoster. However there were no serious adverse events that made them think that there were particular safety concerns.

But really the key reasons for the recommendation and the preferential recommendations had to do with the efficacy. So with Zostavax, while we saw better protection in younger age groups, the efficacy of the vaccine really was much lower the older you get. Again, it's a live virus vaccine and your ability to develop an immune response goes down as you age, and we saw that Zostavax was much less effective the older you got. With this vaccine, they found high levels protection in all age groups, against Shingles and Postherpetic neuralgia in all age groups. So 97% protection against Shingles in adult 50 to 69, over 90% in adult 70 years and older, 91% in those 50 and older against PHN. And that protection of over almost 80% was maintained for at least four years after vaccination. Whereas Zostavax, by year four we basically saw very little protection particularly in older age groups. So this was really the data that led to that preferential recommendation. And again if you're interested in seeing more of a head to head comparison of Shingrix efficacy versus Zostavax, that was shared at the ACIP meeting and they do make those slides publicly available on the CDC ACIP website.

Then the other vaccine that I do want to talk about has to do with the Hepatitis. This vaccine has not yet been licensed. It is in front of the FDA and they are anticipating a decision in the very, very near future. But the decision was not made prior to the ACIP meeting. So they were not able to actually vote on a recommendation for this new vaccine, because we aren't sure if it will be licensed or not. It's called Heplisav-B and it's made by Dynavax Technologies Corporation.

It's a different adjuvant, but like the Shingrix vaccine it does contain an adjuvant in it. And the differences between this vaccine, it's recommended for adult 18, it will be licensed for adult 18 years and older is what they're looking at, and it's two doses, one month apart. So our Hepatitis B vaccine that we have been using for years, all the different formulations are basically a three-dose series, at zero, one, and six. So you have three doses and it's over a much longer interval. With this vaccine, it's actually just two doses and it's in one month. So the idea being that hopefully you could increase completion of the Hepatitis B vaccination series because you don't have quite the long interval and you don't have the three doses to try to get in.

The other thing that I will tell you that I haven't included on the slides here is that in their clinical trial data (ok, do I have the slide on here, let me see. Can't remember if I put it on. No.) I didn't include it here, but they did share this data, is it this vaccine appears to have a more robust immune response in older age groups, so our Hepatitis B vaccine again, the ones that we've been using typically as you age we see -- not as good an immune response to the vaccine. This vaccine appears to have better immune response in older people. And they actually did do clinical trials in patients with diabetes and they found a more robust response to this vaccine. So that's yet to be determined and this is something that ACIP will be monitoring very closely. But the reason that our current Hepatitis B vaccine recommendation is only

routine through 59 and then consider at 60, had to do with fact that the vaccine response isn't great in those older folks. But we may have a vaccine if this one gets licensed that could prove to be better in patients who are older and in patients who have this kind of underlying health conditions. So that may be something that the ACIP will consider in the future. But again it is still pending licensure.

So then my question to this group here is in terms of completing the Hepatitis B vaccine series among your patients with diabetes, is the fact that it's three doses. Is that a big challenge for completing the series or are there other factors that come into play there? So people are responding and it looks like for okay about 60% of you, the fact that the Hepatitis B vaccine is a three-dose series does appear to be a challenge. So that's something to take into consideration if we do have this new one out there and available that gets recommended for use and it's only two doses in one month. That might be an option for helping to increase coverage. A small percentage of you don't seem to feel that that is an issue, and then again some of you don't know. But again if Hepatitis B coverage and Hepatitis B vaccination is an area that you wanted to focus on with your patients who have diabetes, you just be aware of the fact and understanding is that three-dose completion is a barrier, what other options might be available to use, so just something to be aware of. So thanks Jan.

So finally just to close here, I wanted to just briefly cover some of the tools for those of you who use RPMS in the Electronic Health Record in RPMS that are available to help you make sure that your patients are vaccinated. So in the Electronic Health Record and in RPMS, so basically the Electronic Health Record sits on top of our RPMS system. We do have a clinical decision support for immunizations. And what this basically means, if the patient is due for vaccine, you will get a reminder in the Electronic Health Record that will say, "Hey this patient is due for this vaccine." The logic is quite robust and it takes into account minimum intervals and ages. So if you can't get a vaccine dose, you have to wait a certain amount of time like the PCV13 and pneumococcal polysaccharide, the logic knows that. It's smarter than we are, and can figure that out for us, since it does take that into account. And also what the minimum age is for a particular vaccine.

And then we have that in place for all of the routine age-based recommendations. So that first ACIP schedule that basically said, "If you're this age, you should get this vaccine." We have that logic in our clinical decision support. We have also added what we call Optional Reminders because you have to actually turn them on. They don't automatically pop-up, but if you turn them on in the RPMS Immunization Package, as I mentioned, we have the pneumococcal polysaccharide for folks who are less than 65 years of age, who have a high risk condition. So if you turn that on, you'll get a reminder to do that vaccination for folks who meet that criteria. We also did add-in the Hepatitis B for adults 19 to 59 years with diabetes. And then just recently in August, we released a version of the software that includes Hepatitis A and B in adult who have an ICD-9 or 10 Code diagnosis for chronic liver disease or Hepatitis C. So if you have patients that have one of those conditions and you turn on this reminder, it will initiate the Hepatitis A and B vaccination series by providing a reminder for you to give that

vaccine and then we'll also forecast those remaining doses. So these are some tools to be aware of if it's an area that you wanted to work on.

And then also for those of you likes to get into weeds of the RPMS, we have an immunization package. While much of the functionality in terms of what a patient needs and adding a shot is available too in the EHR, there's a lot of functionality that you can't get to unless you get into the RPMS environment. And one of those things is a feature we call Lists and Letters, and you could basically use this to create lists of the patients who are due for a vaccine or who received a vaccine. And you can also use this QMAN. So, if you already have a template of patients with diabetes. You could use that to pull in and then say, "Among this group of patients, tell me how many are due for Hepatitis B vaccine." And you could actually use, or pneumococcal polysaccharide, you can use that information to help you target your reminder recall letters or to do some kind of special outreach to them to bring them in.

So in summary, we have the clinical decision support and reminders in EHR for both the pneumococcal polysaccharide and Hep B for patients with diabetes, but you have to turn them on in order for them to work. We also have the immunization package which can allow you to do Lists and Letters and you can also send reminder letters to patients. And then of course Qmail which many of you are very familiar with and that would be a great way to create a template for patients that have diabetes, and then you can pull that into the immunization package and use that in conjunction to determine who needs vaccines and to focus reminder recall efforts.

So some additional resources here again, all of those CDC vaccine recommendations are available on the CDC website. If you go to the ACIP records, you should be able – it's cdc.gov/vaccines and it's the resources for healthcare personnel. That's where you can find all of the ACIP recommendations that I referenced and pulled this information from. We also do have some resources about the immunization package. And I also have some online trainings that have been recorded that you can take advantage of if you're interested in finding out more about how to turn on those different reminders that I mentioned in RPMS. And then finally if you ever have any immunization related questions whatsoever, I do encourage you to reach out to Cheyenne Jim.

Sorry Cheyenne we left off an "e" at the end of your name there. So it's Cheyenne.Jim@ihs.gov or Jillian Doss-Walker. You can find both of them in the Global. So either IHS or Jilian CDC, e-mail addresses are available there and you can certainly reach out to them and they can help to route your question to whoever would be the most appropriate person to answer it if they can't. So that's all the information that I have and I think I left about five minutes for questions. So I'll see if there's any in the chat box, but I'm happy to take questions.

Jan Frederick:

Thank you Amy. We really appreciate your presentation you are so knowledgeable, such a great resource for us and I think a great teacher as well. So thank you so much. I'm going to invite Dr. Ann Bullock, the Director of the Division of Diabetes to make any closing remarks that she might have. And feel free everyone to put any questions you have in the chat box. Dr. Bullock?

Dr. Ann Bullock:

Thanks Jan! Thanks very much Amy. As always, a great presentation. Amy, as many of you know, for many years has been a great partner with IHS and with the Division of Diabetes on immunization issues. There's a lot of things we do in diabetes care. All of them are important. Sometimes it's easy to think of immunization as just being that other thing we have to do, but can be the most important thing we end up doing, and sometimes the quickest. Although it does require some conversation and we know that with flu season, at least flu shot season upon us. We're all having those conversations with patients about how the flu shot does not give you the flu. And you can get another viral infection. In the meantime, it may look like the flu. It wasn't from your flu shot. The flu shot did not fail you. So we know that it takes extra time to talk with patients about all these things. But indeed, in the long run and maybe one of the most important things we do for the long term health and wellbeing of our patients with diabetes. So, it's one of those things that it's good for us to be thinking about and remembering. And again, thank you Amy for a great presentation. And perhaps if -- while we're waiting to see if anyone has any questions. I don't see any others in the chat right now, but perhaps you would be willing to give your thoughts on how to respond to all of those patient concerns about why they shouldn't get a flu shot.

Amy Groom:

Yeah I think you summarized it really nicely and the big ones we hear are the flu vaccine makes me sick and I think I get the flu vaccine. So really CDC does have some nice resources that give you very clear and straight forward answers to that. But the bottom line is there's nothing in the flu vaccine that could give you the flu because the virus that we use to make the flu vaccine is killed. So it can't suddenly reassemble itself and come alive in your body and cause the flu. So it's just pieces of the flu virus that are contained in that and especially now that we do not have the live virus flu vaccine available to us, we really can say that we are using inactivated virus in those flu vaccine. But I think your other point too Dr. Bullock is the vaccine doesn't work or I got sick or I got sick anyway even though I got the flu vaccine. The reality is there's all kinds of respiratory illnesses that are circulating during flu season, not just flu. It takes two weeks after you get vaccinated for your body to actually mount protection to it. So in the interim, after you get your flu vaccine, there is that window in which you could be exposed to the flu, or you could also be exposed to some other viral thing. There's a lot of other things going around and you may think it's a flu, but it's actually probably something else.

So even though flu vaccine effectiveness does vary year to year, depending on how well we get it matched, it may also not be as effective in certain groups of people. We do know it's the best tool we have to prevent influenza vaccination and so that's why we recommend it for all patients. And there are studies that would show that even among people who get the flu vaccine and still get the flu, they are much less likely to end up in the hospital or to have a serious outcome. So you may still get some protection from the vaccine even if it doesn't completely prevent influenza. But there are some really good resources and there's also some really great public service announcements on Good Health TV and CDC has some as well that just talk about some of these issues with the flu. And so I encourage you to explore. If you go to the CDC website or even the IHS website, we have a link to some of those resources out there. There's some fun ways that they're sharing information that might be more appealing to our community.