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The Importance of Maternal Immunization

Rachel Breidster (Moderator): Hello and welcome to Public Health Live, the Third Thursday Breakfast Broadcast. I'm Rachel Breidster and I'll be your moderator today. Before we get started, I would like to ask that you please fill out your online evaluation at the end of the webcast. Continuing education credits are available after you take our short post-test, and your feedback is helpful in planning future programs. I also want to let you know that the planners and presenters of Public Health Live do not have any financial arrangements or affiliations with any commercial entities whose products, research or services may be discussed in this activity, and no commercial funding has been accepted for this activity. As for today's program, we will be taking your questions throughout the hour by phone at 1-518-880-3516, or via email at: Phlive.ny@gmail.com. Today's program is The Importance of Maternal Immunization, and our Guests are Dr. Rhoda Sperling, a Professor of Obstetrics, Gynecology and Reproductive Science and Infectious Disease Medicine at the Mount Sinai Medical Center, and Dr. Elizabeth Rausch-Phung, the Director of the Bureau of Immunization at the New York State Department of Health. Thank you for joining us.

Moderator: So, good morning. Thank you both so much for joining us today.

Dr. Elizabeth Rausch-Phung: Hi, thank you for having us.

Dr. Rhoda Sperling: Thank you.

Moderator: Now Dr. Rausch-Phung can you get us started today by reviewing what are the objectives for today's program.

Dr. Rausch-Phung: Well after viewing today's webcast participants will be able to name identify recommendations for maternal vaccines, name at least three benefits of internal immunization and recognize evidence best practices for maternal immunization.

Moderator: Excellent. Now Dr. Sperling let me start by talking to you about vaccinations for adults. I think we typically hear vaccinations conversations that center around children, so can you tell us about the importance of vaccinating adults and the professional associations that recommend doing so.

Dr. Sperling: Yes. In the United States, the ACIP makes recommendations to the CDC, the CDC accepts those recommendations and then distributes that information to the different professional organizations including ACOG. ACOG will endorse the recommendations and ACOG, the American college of OB/GYN wants obstetrician gynecologists to be vaccinators. They recognize the importance of vaccination. Adult vaccines save lives. Each year in the United States 60,000 adults will die from vaccine preventable illnesses, if you just look at pneumonia and influenza combined, it's the eighth leading cause of deaths so adult vaccines are important.

Moderator: Now despite those numbers that you shared that convey the importance of vaccination and the medical endorsements from the medical community, we still see that vaccine rates among adults remains fairly low. How do you explain this?

Dr. Sperling: I think it's engrained in the psyche that vaccines are for children or vaccines are for travelers and adults just don't recognize that they need vaccines too. There's lots of missed opportunities for vaccinations that occur in OB/GYN offices as well as among other providers because we don't necessarily routinely assess vaccinations or routinely recommend vaccinations and we know from years of research that a recommendation from your own provider is the best and strongest predictor that you're going to accept a vaccine and be vaccinated.

Moderator: Now, Dr. Rausch-Phung, we hear about recommended vaccines who is it that's making the recommendations and what is that decision to recommend a vaccine based on?

Dr. Rausch-Phung: Well before vaccines can be recommended they go through an extensive research and development and clinical trial process just like any other medication in the U.S. And then they're licensed by the Food and Drug Administration. So the FDA looks at data on safety, efficacy, dosage, use in different populations as appropriate and then they'll make a licensure and a package insert based on that data. The CDC's advisory committee on immunization practices then reviews all that data as well as additional data if it's available to make recommendations. The ACIP is a body made up of 15 voting members, 14 of them are experts in vaccines, virology, infectious disease, public health, et cetera, and one consumer representative. As well as a large number of non-voting members representing federal agencies and other organizations that give guidance and expertise. The ACIP often revisits their recommendations when additional data becomes available. So sometimes the ACIP recommendations will differ from the FDA licensure and when that happens we recommend going with the ACIP recommendations because they're based on broader, more current and more complete data. The ACIP also then annually issues a schedule of immunizations, schedules actually for children, adolescents, and adults and that gets revised, updated, and posted online every year.

Moderator: And now where can providers and patients find out what vaccines are currently recommended?

Dr. Rausch-Phung: The CDC hosts the annual immunization schedules at www.cdc.gov/vaccines/schedules and there's a very detailed version with a lot of footnotes, information on timing, spacing of vaccines, et cetera, for healthcare providers as well as simpler easier to read version for the public. People who are interested can view them online, print them, download them, you can also order laminated versions directly from CDC at no cost and CDC also have apps for mobile devices both iOS and Android, which have all the details and footnotes that are available on the schedule online.

Moderator: Seems like a very comprehensive set of resources.

Dr. Rausch-Phung: It is, yes.

Moderator: Now, is there specific information available for pregnant women?

Dr. Rausch-Phung: Yes, the adult schedule has two figures. One looks at vaccines given for specific ages and then a second looks at different medical and other indications. And pregnancy is one of the conditions or indications that they look at. It's color-coded you can see an example here it looks at vaccines specifically recommended for pregnancy or another indication, vaccines that are contraindicated and shouldn't be given and then vaccines that can be given if some other indication exists.

Moderator: Excellent. Now, Dr. Sperling, what role does an obstetrician or gynecologist play in vaccinating women?

Dr. Sperling: I think that vaccinations can and should be part of routine reproductive healthcare for women. There are many opportunities for OB/GYNs to discuss vaccines with their patients, there's opportunities for preconception planning during prenatal care when you have two patients to consider both the mother and the child and also in the post-partum period as part of well women care. So during the continuum of reproductive healthcare there's really is many opportunities for OB/GYN providers to discuss vaccines with their patients.

Moderator: Now for OB/GYN providers who might not have much experience with immunizing patients, what are basic items that you would recommend they might need to know?

Dr. Sperling: I think in order to be an effective vaccinator you need to understand some things about the vaccine. So I think you need to have to have at least a basic understanding of what is the disease that's being prevented, what is the antigen in the vaccine, is there an adjuvant that's given to enhance the immune response and what is the vaccine's efficacy? No vaccine is 100% effective, so you need to consider the efficacy, you need

to understand the vaccine safety profile and again as obstetrician gynecologists you need to understand the unique pregnancy aspects of it, either in terms of the recommendations or in terms of safety consideration. So again basic background information about the vaccine makes you a better recommender, a better vaccinator and makes things easier for your patients to understand.

Moderator: Now are there requirements for what providers must tell patients before a vaccine is given?

Dr. Sperling: Some of the elements of the discussions about what you should know about the vaccine are incorporated into what are called the vaccine statements and those VIS documents need to be provided to patients before a vaccine is given. And it has really elements of an informed consent discussion. It talks about the recommendations and indications for the vaccine. The contraindications, how well the vaccine works, how long it works for, what are the potential side effects, can other vaccines be given along with that vaccine. So again you're giving sort of basic information so a patient has a very good understanding of what they're receiving before they receive that vaccine.

Moderator: Excellent. Now, considering that information, what vaccines specifically are recommended for pregnant women or are there any vaccines that women who are pregnant or thinking about getting pregnant should not be receiving?

Dr. Sperling: Sure. I think that there are two vaccines that are now routinely recommended for use during pregnancy. One is the seasonal influenza vaccine and the other is TDAP vaccine. And we're gonna be discussing those two vaccines in greater detail during the program. In terms of the ones that are contraindicated that should not be given during pregnancy or to people considering pregnancy are the live virus vaccines because the concern about the live virus vaccines is that in order to make an immune response you're getting a weakened version of the what's the wildtype naturally circulating virus. You're going to become viremic, a virus in your circulation and that can potentially become a trans-placental infection, it can go to the developing embryo fetus. So the idea is to not give live virus vaccines during pregnancy. The ones that are contraindicated are measles, mumps, rubella, varicella, and the live attenuated influenza vaccine. Just a quick thing about LAIV, it's not going to be recommended this flu vaccine season it's because of the past three vaccine seasons showed diminished efficacy, so actually the only flu vaccine that's going to be available this vaccine season is actually the inactivated flu vaccine, which is given to pregnant women.

Moderator: Okay, now could you talk a little bit more about why live vaccines aren't safe specifically for pregnant women.

Dr. Sperling: I think that again I mentioned that the idea is that when you get a live virus vaccine it's a weakened version of the wildtype virus and

again people become viremic, there's a virus in the circulation when there's a virus in the maternal circulation it can cross the placenta and it can set up an infection in the embryo or fetus we know certain that viral infections for example: rubella can cause something like a congenital rubella syndrome. So there was always the theoretical concern even at this attenuated this weakened virus might result in something like a congenital rubella syndrome. So the recommendation is don't give the vaccine during pregnancy and also don't give it to people who are considering pregnancy. And the question often asked how soon after getting the live vaccine can I be pregnant? The current recommendation is at least four weeks and the knee-jerk with most object obstetricians is to say three months. So three months after you get a live virus vaccine you get the green light to conceive.

Moderator: Thank you. Now Dr. Rausch-Phung, one of the vaccines we'll focus on today is the influenza vaccine. Can you start by telling us what is the flu and what are the symptoms and I know it seems like an obvious question but I think there are nuances that we need to cover?

Dr. Rausch-Phung: Sure. Influenza or flu is a highly contagious viral illness and it's the most common vaccine preventable disease in the U.S. and the world. We already heard that combined with pneumococcal diseases, it is the number eight cause of death in the United States. A lot of people confuse the flu with the common cold but generally the flu symptoms are much more severe. Although some people will have milder illness. Typical symptoms are high fever, headache, people can have chills, fatigue, body aches, as well as cough and other respiratory symptoms similar to cold. Now children sometimes have GI symptoms such as nausea, vomiting, diarrhea. Adults don't have them as often but they can from time to time.

A lot of times people will say I had the stomach flu and if that GI nausea, vomiting, et cetera, was the primary symptom they probably are talking about other viruses but presence of those symptoms doesn't entirely rule out the flu. People -- people can become contagious starting about a day before they have any symptoms at all and can spread the flu before anyone even knows they have the flu and remain contagious for up to a week after they start to have symptoms. And young adults -- excuse me, young children and senior citizens, people with chronic conditions and pregnant women have the highest risk of complications or severe infection.

Moderator: Thank you. Now, Dr. Sperling, considering that information, can you expand on the risk of complications from the flu specific for pregnant women?

Dr. Sperling: I think the maternal risks are real. Compared to non-pregnant adults, there's four times the rate of complications in hospitalizations. There's increased death, increased mortality associated especially in the end of pregnancy. There's an increased risk for preterm delivery and preterm labor, and there's also fetal risks involved. Although the influenza infection is not one that's characterized by a lot of virus in the maternal circulation, so that trans-placental infection that we talked about

for example: rubella doesn't occur there are risks of maternal high fever, hyperthermia has been associated with birth defects. So and also we know from some international studies including a recently reported Bangladeshi study that if you give maternal influenza vaccine you see higher birthweights in children. So I think there appears to be, clearly appears to be benefits to both the mom and to the young infant when moms are vaccinated during pregnancy.

Moderator: Now Dr. Rausch-Phung, what does this look like this data for in New York state specifically?

Dr. Rausch-Phung: Well in New York State's individual cases of flu aren't reportable to the health department but the health department participates along with 15 county health departments in the capital district in western regions of New York in flu serve net influenza surveillance program. And one of the data we collect is on hospitalizations from the flu and what we see is pretty striking is that pregnant women have about three times the rate of hospitalization from the flu than other women of similar age. And most seasons pregnant women have about 30% higher hospitalization rate than the general public.

Moderator: Now, we've talked about the serious complications that pregnant women experience in the flu, what about their babies and children?

Dr. Rausch-Phung: Absolutely. Young children, less than two years of age, have very high risk of severe influenza, complications, hospitalizations, even death from the flu. And this is particularly concerning because the youngest age that we can give flu vaccine in our country is at six months. So the newborns and young infants really rely on protection from people around them both from vaccination of the mother when she's pregnant as well as what we call cocooning. Everyone else in the household and who will have close contact with the baby really should be vaccinated themselves to prevent the baby getting exposed to influenza before they can be vaccinated. About 300 -- in the 2014 to 15 season almost 300 young children died of the influenza. And in the season that just ended in our state, almost half of the children who were hospitalized with influenza had no underlying medical condition. So even healthy young children can have severe influenza infection.

Moderator: So given that information and these potential complications, Dr. Sperling, what -- how does this impact the recommendations of the CDC and other groups in terms of what we should be doing to vaccinate and protect not only the women but these young children and babies.

Dr. Sperling: Sure. I think that since the morbidity and mortality among adults, among pregnant women and young children is so well recognized that it is really recommended as a routine vaccine for all people greater than age six months of age. So again seasonal influenza vaccine should be given to everyone.

Moderator: And can you review for us exactly what the seasonal influenza vaccine is composed of?

Moderator: Sure. The traditional flu shots. So the traditional flu shot was, had previously been what's called a trivalent vaccine, it had two antigens against, I'm sorry, three influenza strains with two antigens against influenza A and one against influenza B. A modification of that was introduced in the past few vaccine seasons what's called the quadrivalent vaccine, which now provides protection against two strains of influenza A and two strains of influenza B. So the quadrivalent vaccine, the inactivated quadrivalent vaccine is the sort of the vaccine of choice now. In terms of other things that are available, there's recombinant vaccines that is available and there will be other vaccines that use different technology available soon as well.

Moderator: Now, it looks as though the CDC schedule included some recommendations for when the influenza vaccine is contraindicated. Is that right?

Dr. Sperling: Yes, it is. I mean, as an obstetrics gynecologist, I get lots of questions about can I give the flu shot. So I want to actually start with what are not contraindications. I think that it's important that minor illnesses, you know minor upper respiratory infections, diarrheal illnesses, someone coming in and saying they're just not feeling well those are not reasons not to give an influenza vaccine. The contraindications really are absolute. If you had an anaphylactic reaction to a previous vaccine, that's important. And again there's some precaution with moderate or severe disease but it's trying to eliminate whether someone has is sick, truly sick that you can distinguish what's going on with them medically from what might be a vaccine side effect. So there are very few people that you can't give the flu shot to. In terms of efficacy, it varies from season to season.

Moderator: Does the efficacy vary among different populations?

Dr. Sperling: Yes, it does. You know, it takes a while to produce protective antibodies. It takes at least two weeks to produce protective antibodies and not everyone makes the same type of robust immune response. So in fact, children make a better immune response than adults. The elderly don't make a great immune response at all. But again the other thing about the vaccine itself is that the antigen in the vaccine varies from season to season and it will depend upon how close the antigens in the vaccine are to the circulating viruses to see how well that vaccine works. So when there's a very good antigen match you're going to get efficacy that approaches 90%. When you have dissimilar match between the circulating strains and the strains that are in the vaccine, you're going to see diminished efficacy.

Moderator: Now, let's focus a bit on where we stand with vaccine rates for influenza. Can you talk a little bit about that?

Dr. Sperling: Sure. One of the things that has been a goal a nationwide goal is to improve vaccine rates. There's something called healthy people 2020, which was an effort of the U.S. Department of Health and Human Services. The idea was to identify things that can improve public health and again one of the goals was to improve influenza vaccine rates. The idea was to have 70% of the adult population vaccinated against influenza. So we're creeping towards that. The vaccine efficacy rates in the United States hover around 55%. And from the different seasons the past few seasons are being tracked by ACOG and again we're sort of seeing a creepup of the vaccine acceptance rates among obstetric providers and patients as well.

Moderator: Now Dr. Rausch-Phung, let me ask you, how are we doing in New York state with immunizing pregnant women against the flu.

Dr. Rausch-Phung: Well in New York state we look to the pregnancy risk assessment monitoring system or PRAMS, which is an annual survey sent to new mothers who have delivered an infant in the past year. I should note the New York state and New York City health departments conduct their surveys separately so the PRAMS data I'm going to be showing is for New York state outside of the city but I understand the coverage in New York City is pretty similar. So the most recent year we have final data we have available was in 2013 and in that year about 54% of new mothers reported having had flu vaccine in the past year and 42.5% had it during their recent pregnancy. That was about an 8 percentage point increase over the previous year, so it's good news that we're improving but we still have a long way to go to get to that 70% target.

Moderator: Now, can you talk to us about the flu season itself and when does it start, when does it end, and how does that relate to when we should actually be providing vaccinations?

Dr. Rausch-Phung: Absolutely. There's an expression in public health, if you've seen one flu season you've seen one flu season. It's very variable. So traditionally a lot of people have tended to think flu vaccine, I start giving it on October by the new year I'm done. But I really would like people to think more broadly than that. Because there have been some flu seasons where activity has started to pick up in November. And there have been three flu seasons in the last 18 years when it didn't peak until March. In fact this past season was very quiet in the beginning and then really picked up in the spring. So generally speaking flu vaccine most years becomes available in mid to late August or September. And I recommend start offering it as soon as you have it in your office, in stock, and continue to offer it all the way through the season into the spring as long as you have flu vaccine in stock and unvaccinated patients there are opportunities to protect people well into the spring.

Moderator: Excellent. Thank you. Now, to learn more about an individual practice's approach to vaccination of pregnant women we recently visited the Mount Sinai Medical Center in New York and spoke

with Clinical Manager Heather Isola and Dr. Fahimeh Sasan. They talked with us about important aspects of their office culture and flu vaccination practices, as well as about how they talk to their patients about vaccination. Let's take a look.

>>>>Clip Roll-in<<<

Heather Isola: Pregnant women can be vaccinated at any time, at any time during their pregnancy, and any time during the flu season. Flu season usually begins in around September, October, usually gains steam from October and goes basically until May. The highest peak seasons usually around January and February. One of the unique things that we do as a practice and as a division in obstetrics and gynecology here at Mount Sinai is we've developed flu pods where providers come together and actually give vaccinations to the other providers and that really kick off the vaccination season. What we do is we start disseminating the information early, so around middle of August – end of September we do these flu pods and once it starts with providers then it goes to the patients and the patients know we have the vaccinations in the office.

Dr. Fahimeh Sasan: The way I talk to the patients about the importance of the flu vaccine is threefold. First I think it's really important to explain to them the science behind why you're recommending the vaccine. Secondly, I think it's really important to debunk very common myths that patients bring with them to the doctor's office. And finally it's important to let them know family-centered vaccination processes, which is very important for keeping everyone healthy. A very common myth that women have is that I got the shot last year so I don't need the flu vaccine this year. And the reason why it's important to get the flu vaccine every year is that the flu vaccine each year is doctored by scientists to contain the strain of the flu that they think is going to be the most prominent that year. Another common myth especially nowadays with so much attention to autism is that women will come and think that the flu vaccine is going to cause autism. And that's actually been very well studied and no study to date has shown any evidence or link between the flu vaccine and autism. A lot of patients will also come with another myth that they're healthy and they've never had the flu before so that means they don't need the flu vaccine. It's very important for patients to understand that even the healthiest person can get the flu and can become severely ill from the flu. And in particular it's important for pregnant women to get the flu vaccine because during pregnancy your immune system is slightly diminished and as a result you can actually get sicker from the flu than you would when you're not pregnant. A family-centered approach to vaccination is really important. And the reason behind it is that we don't live in a cocoon as a person, and so you want to get everyone that's going to be around the baby, for example, in the center of our pregnant patients everyone who is going to be around the baby to get vaccinated what does that mean? It means you want mom, dad the other primary caregivers such as grandparents, aunts, siblings, nannies, whomever is going to be around baby a great deal of the

time or is going to be providing a lot of care to the baby should be vaccinated. The more people that come into contact with the baby that are vaccinated the less likely the flu is going to come into your home and even less likely that the baby would get the flu.

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Moderator: So Dr. Sperling with all the information that pregnant women receive from a number of different resources and goodness knows we're bombarded by things on the Internet, all the information coming in, how important is the recommendation that comes from the provider in terms of how it influences a woman's decision about becoming vaccinated?

Dr. Sperling: Well this is sort of a no brainer. The recommendation from your physician is the single most important thing in terms of deciding to receive a vaccine. And when we look at those vaccines that where you're recommended and you're actually offered, it's there in the office, you can hear the recommendation, you can accept the recommendation, you can roll up your sleeve and get a vaccine, those are the best vaccine rates. So if your provider recommends and actually offers the vaccine right, the vaccine, you'll see an uptake of about 70% if it's recommended but it's not there and available and you have to go to another place, another location to get the vaccine that acceptance rate goes down. And if it's not recommended, it really is negligible. So although we're bombarded with public health messages, it really is the provider that patient's trusted provider who is reviewing that patient's medical history, their needs and makes that recommendation. That's when patients accept that recommendation.

Moderator: So the providers really have an opportunity to make a significant difference.

Dr. Sperling: Absolutely.

Moderator: Now, let's turn to some of the other major vaccinations that we're going to focus on today and one specifically is pertussis. So can you explain to us what this is?

Dr. Sperling: Okay, so I wanted to start off with talking about what the clinical disease is. Pertussis isn't a cough, a simple cough, it's recognized as a clinical disease it's the clinical definition is a cough that lasts for at least two weeks and is characterized by other things either paroxysm of coughing, you're coughing so much you can't catch your breath or a whoop, which is why pertussis is called whooping cough or vomiting after you know you're coughing so violently you're vomiting. And this is all the type of cough that occurs without any other cause. The causative organism of pertussis is *Bordetella pertussis*, this is a bacterial infection, it is a gram-negative bacteria and it is a uniquely human pathogen. The incubation period from the time you're exposed to clinical illnesses is about seven to ten days and it starts off with sort of watery eyes, runny nose looks like any

other cough but it's followed by paroxysms of coughing and that type of coughing can last from four to six weeks if not longer.

Moderator: And what are the other symptoms of pertussis beyond the ones you've described already?

Dr. Sperling: Sure, I mean you can see, people can get very, very ill with pertussis. You can see substantial weight loss, substantial sleep disturbances. It really is a very infectious disease so within households the secondary attack rate is very high. It's estimated to be 80%. And you know just a few other things that despite high childhood vaccine levels we're seeing cases of pertussis reported throughout the United States within these sorts of epidemics. And we know that pertussis is a vaccine preventable illness, we know that it's a fatal and can be prevented by appropriate vaccination. So pertussis vaccination is very important.

Moderator: So now what are the particular risks specific to pregnant women and their babies?

Dr. Sperling: You know the biggest issue with pregnancy really is protecting the young infant. You know, sometimes, for example, with the influenza vaccine, the vaccine is protecting both the woman and the baby. But primarily the woman. But in pertussis the protection is for the woman and the baby but it's primarily the baby. We're vaccinating pregnant women in order to have moms make immune responses that can go across the placenta to protect young infants. Infections in young infants is severe and life threatening. They have they bear the morbidity and mortality of pertussis.

Moderator: And what other data do we have about the impact of pertussis?

Dr. Sperling: You know that in infants less than one year of age who get pertussis, they count for a significant amount of hospitalizations, especially those less than three months of age, and they also, the infants less than three months of age account for a significant number of deaths associated with pertussis in infancy. The morbidity and mortality of pertussis really is in the young infants and that's important again for maternal vaccination that's the only way to protect those young infants.

Moderator: Thank you. Now Dr. Rausch-Phung this certainly sounds like a serious illness. Do we see many infants here in New York state with pertussis?

Dr. Rausch-Phung: Absolutely. And similar to the national pictures, in New York state infants less than a year of age have the highest incidence rate of pertussis as well as the most complications. Our last peak year of pertussis was in 2012 which means it was the last year there was a very large outbreak but we have cases of pertussis every year outside of the peak years about 75 infants alone get reported to the state health department a

year and several hundred across the lifespan. Now, pertussis, although pertussis happens all the time, large outbreaks tend to occur cyclically every three to five years it's a bit concerning it's been four years since the last major outbreak, so we might be unfortunately staring down another large increase coming anytime now.

Dr. Sperling: Just to say a few things nationally I think what's going on nationally really is similar to what's going on in New York state. 2012 was the peak year nationally for pertussis outbreaks and although those numbers leveled off in 2013 there was still pertussis outbreaks reported in 49 out of 50 states and in Washington D.C. so pertussis is really an ongoing issue for us as providers.

Moderator: Even when we're not in a peak year it's not something to minimize or to forget about.

Both: Absolutely.

Moderator: Now, we've talked about infants in particular being vulnerable to pertussis and even hospitalized. Has it caused other long-term complications or even death in infants or young children in New York state?

Dr. Rausch-Phung: Yes. So every time that I hear a report of pertussis in a baby, especially a newborn or very young child/infant, it worries me because the infants do have the most complications and the most severe infection. So I selected one case history to sort of illustrate some lessons but I do want to emphasize this is not an isolated event. Unfortunately. You know, there have been similar stories in the last several years. This is a six week old infant who had been born at full gestation, full term. Had an entirely uncomplicated pregnancy and delivery, health mom and on retrospective review of the records, it was found that the mother had not been offered TDAP vaccine during pregnancy and had been noted in the chart she had it when she was a teenager, she doesn't need it. This was after the recommendation was in place for TDAP with each pregnancy, so it was a missed opportunity the doctor didn't know the latest recommendations hadn't offered it. When the baby was five weeks old the baby was seen in the pediatric office with about one day's worth of cough as well as several days cold symptoms, congestion, and at that time it was recommended to keep an eye on things, come back if the situation doesn't improve. But unfortunately one week later, the baby came into the emergency room with severe respiratory distress, cyanosis turning blue, and as well as the paroxysmal cough, respiratory whoop and was consistent with pertussis and the baby did end up testing positive for *Bordetella pertussis*, the bacteria that produces whooping cough. The baby was immediately intubated, admitted, started on antibiotics, treated in the pediatric ICU, but unfortunately despite aggressive and appropriate treatment the baby died one day later. No source of infection was ever identified and that's fairly typical. Adults usually have milder disease maybe even no symptoms. But even with a very mild course or no symptoms adults can still pass pertussis on to infants who can go on to

have very, very severe illness. So this was a missed opportunity and I think it illustrates the opportunity that every pregnant woman needs TDAP with every pregnancy, even if she's had it before and the consequences of not offering it can be severe and tragic.

Moderator: Yeah that is certainly, it's hard to know what to say after hearing a story like that. That is just really heartbreaking. So now TDAP is a combine vaccination for three different illnesses. Dr. Sperling could you talk about the specific recommendations for administering that vaccine?

Dr. Sperling: Sure, so TDAP is a combined vaccine for tetanus, diphtheria, and acellular pertussis, so you can't get a separate pertussis vaccine so it's given as TDAP. And there's different versions of the vaccine that are meant for infants and are meant adolescents and adults. In terms of pregnancy the recommendation is to give it each and every pregnancy and to give it preferably at 27 to 36 weeks and I'll go into that a little bit more about why that time period is important. But for non-pregnant adults the TDAP is actually recommended just once in your lifetime and usually it's given as replacement for tetanus, because tetanus shots are recommended every 10 years and the current recommendation is when your next tetanus booster is due give TDAP instead. What we also encourage when we're talking about vaccination in pregnancy programs is a family-centered approach. We encourage people to make sure that caregivers and other family members are appropriately vaccinated. So it's not just dad who needs a vaccine but it's grandma, grandpa, whoever handles the baby, baby-sitters, siblings, to make sure that those who will be taking care of the baby, close to the baby, touching the baby, kissing the baby, that they're also appropriately vaccinated. But this group of people doesn't need to be vaccinated for every pregnancy. They need one adult vaccine.

Moderator: Thank you. Now to hear how a practice approaches providing the TDAP vaccination, we visited with Dr. Angela Bianco at Mount Sinai Medical Center. Let's take a look.

>>>> *Clip Roll-in*<<<<

Dr. Angela Bianco: So some of the most common questions that I encounter in my clinical practice with regard to TDAP vaccination is do I need to be vaccinated with each pregnancy, why do I need to be vaccinated and does my partner or close family members do they need to be vaccinated. Vaccinating the mother during pregnancy protects her newborn child in a couple of different ways probably the first and foremost is it prevents the mother from contracting pertussis in the perinatal period, so in late pregnancy as well as shortly after delivery so by preventing direct maternal infection that thereby prevents the mom from transmitting to the baby in the newborn period. Secondly, it also confers passive immunization, because when we vaccinate moms they develop antibodies to the specific virus which then cross the placenta and confer trans-placental immunity or protection to the fetus and then those antibodies

persist and reduce the risk of post-partum infection in a newborn. It's a very good idea to vaccinate anybody who plans on coming into close contact on a regular basis with your newborn. So with regard to the question should my partner or other close household family members be vaccinated, the answer is yes because just like the mother could transmit so can any of the other household contacts that a newborn may come into contact with on a regular basis. TDAP should not be provided routinely just during preconception care, because again we don't know exactly how long immunity persists. So we don't know how long antibodies persist and are thereby sort of granting a protective effect. So right now the current sort of standard of care is not to incorporate them into any sort of preconception program. And there is an ideal time where this vaccine should be administered, and that is after 27 weeks preferably within 27 to 36 weeks, because it allows immunization to occur before the due date, but it's because we don't know how long these antibodies persist, it doesn't -- it's not giving the vaccine too early whereby the immunity may no longer be valid. So really the ideal time to be vaccinated is anywhere from 27 to 36 weeks of pregnancy.

>>>>Clip Roll-out<<<<

Moderator: Now Dr. Sperling you mentioned just a few minutes ago that there's a recommended best time to give the TDAP vaccination to a pregnant woman can you talk a little more about the recommendations why we're looking at that time period and why each and every pregnancy?

Dr. Sperling: Sure. I think Dr. Bianco had mentioned some of the things in the roles she was talking about how it gets integrated into a practice because it's a common question that patients ask why each pregnancy, why at this time during pregnancy and it has to do with the function of the vaccine and the function of trans-placental passage of antibodies. So this is a vaccine where after immunization you produce fairly high antibody levels but they really do taper off fairly quickly and the issue about trans-placental passage of antibodies is this is something that gets concentrated at the end of pregnancy. So you're trying to leverage the fact that the vaccine, you know the boost of maternal antibodies is short-lived and the trans-placental passage occurs in the third trimester, so you're trying to find that sweet spot when to give it in the third trimester that you have good maternal immune response that you have good trans-placental passage of antibodies that you protect the newborn. So you don't want to give it too early and then the maternal antibodies peak and you don't have good trans-placental passage of antibodies and the newborn doesn't have sort of a good level of antibody protection and you don't want to give it too late and miss the opportunity to have a newborn that has protection. Especially also babies can be delivered a little bit premature, and not necessarily going to be delivered at 40 weeks. So you're trying to find that sweet spot where you leverage the maternal immune response, leverage the antibodies that cross the placenta and provide the maximum protection that you can to the newborn.

Moderator: Now pregnant women are often told to avoid this medication or that medication during pregnancy. So how do we know that the TDAP virus is safe for not only the pregnant woman but for the developing fetus?

Dr. Sperling: Sure, I think that safety of vaccine, safety of efficacy of vaccines are really important. That's the underpinning of the recommendation, and this is what ACIP really debates and you know American college of OB/GYN and other professional organizations debate what is the risk benefit of the vaccine and what is the safety of the vaccine. And I think there's was a lot of discussion that went into TDAP especially because we're talking about giving a vaccine that's in a different way during pregnancy than you would give it to people who are not pregnant. You're talking about giving the vaccine each and every pregnancy, so if you have four children you can conceivably have four TDAP vaccines in a short interval. So safety was looked at differently and efficacy was looked at carefully. A lot of recommendations were made before theoretically before there was a lot of hard data. But since the recommendations were made, there is hard data. So the hard data about the efficacy comes from the UK experience. The UK had adopted this type of vaccination during pregnancy before the United States did and they already have reports about how well it works in terms of the public health sphere that you're seeing protection and decreased rates of infant pertussis and that was extremely reassuring and that's been reported and my understanding that it may even refine the time period when we ideally aim for vaccination but that's probably going to be discussed at the next ACIP meeting. The safety issues are really ongoing, and people are looking at safety in two different ways. They're looking at pregnancy safety. Pregnancy losses, pregnancy complications such as preterm birth and preeclampsia, growth restriction and also looking at sort of maternal safety what's the safety of getting a vaccine again and again during pregnancy. So I'm aware of two large reports. One was published in JAMA at the end of November 2014, and a second study that was published in November of 2015, I believe. And they've both looked at sort of different aspects of safety and the answer is so far so good from these large datasets and the first one was just a California-based report, the second was a multi-state report from the CDC. We're not seeing any increased maternal complications associated with getting multiple TDAP vaccines and we're not seeing adverse pregnancy outcomes. So I would tell you so far so good. No efficacy seems to be there where we theoretically predicted it and safety seems not to be a concern.

Moderator: Excellent. Now, Dr. Rausch-Phung, how are we doing in New York state with TDAP and influenza coverage rates?

Dr. Rausch-Phung: Well, the good news is that pregnant women reports much higher TDAP and flu vaccine coverage than the general non-pregnant adult population. But we do have room for improvement you know Dr. Sperling talked about the 70% target set by the Department of Health and Human Services and I'll show you data that we have quite a ways to go. There's also some concerning disparities. It's not the same coverage across the board. There are higher and lower populations and I think that's

important to look at and consider how we can do better and perhaps target recommendations. The, all the data I'm going to be showing you is from the New York state PRAMS as I discussed before. The PRAMS asks two questions about influenza vaccination, so the first is did a doctor offer a vaccine to you while you were pregnant in your recent pregnancy and the second were you vaccinated, was it before or during the pregnancy? And of course before is in the most recent flu season not ever in your lifetime. And the good news is across the board about 80% of the women recalled having been offered the vaccine in their recent pregnancy. You know, I'd obviously prefer that to be 100 but you know there don't seem to be too many disparities by offering the vaccine and the vast majority are apparently offering it. But the maternal vaccination coverage is much higher as with the increasing age of the pregnant woman. So women who are 35 years of age and older had the highest flu vaccination coverage in 2013, the most recent year we have data available. 64% of women over 35 had a flu vaccine. And compared with women under 25 who had the lowest coverage less than half had influenza vaccine. The PRAMS doesn't get into questions about why people were or were not vaccinated. So we can only really hypothesize. It could be that older mothers might be more receptive perhaps if you're on a second or third pregnancy they had flu vaccine before and had a positive experience or neutral experience they might be more open to it. Or perhaps there might be some unidentified barriers, experienced by the younger mother. There were some disparities noted by insurance status. Less than half of new mothers who had been enrolled in Medicaid when they were pregnant had had flu vaccine in the past year compared with nearly 60% of those who were enrolled in commercial or other insurances. Now, New York state Medicaid does cover flu vaccine in pregnancy and has for several years, so I don't think that this reflects a lack of insurance coverage. I think this is probably a proxy for some other socioeconomic barriers or issues that might be affecting women of lower socioeconomic status.

Moderator: Now, looking at the New York state prevention agenda goals of reducing health disparities are there differences in maternal immunization rates by race or ethnicity?

Dr. Rausch-Phung: Yes, there are some serious disparities by race and ethnicity. Only 43% of African-American new mothers in our state reported having had flu vaccine in 2013 compared with 56% of white mothers, 53% of Hispanic mothers and 58% of mothers of mixed or other race and ethnicity. And one thing that's particularly concerning is that only 76% of the black new mothers recalled having been offered flu vaccine compared with 82% of white mothers. Now, the difference in being offered flu vaccine was not what we call statistically significant. It's also they didn't check the actual documentation in the medical record. This was their remembering and for some of them they may have been pregnant months earlier so people could have misremembered but I think it is something important to keep in mind and an important question to ask ourselves whether people might be recommending perhaps less strongly in a less memorable way if

there could be any doctor healthcare provider behaviors that might be contributing to the lower coverage rate.

Moderator: Absolutely. Now, are there specifics about the uptake of TDAP specifically among pregnant women in New York state?

Dr. Rausch-Phung: Yes the PRAMs had surveys about vaccinations, TDAP vaccinations before, during, and after pregnancy since 2011. And it's important to note that the recommendations for TDAP have evolved in that time. So before late 2011 we were primarily looking at preventing neonatal tetanus. So if a woman hadn't had the primary tetanus series they recommended a tetanus containing vaccine and for everyone else they recommended waiting until after delivery. And so you can see coverage during pregnancy was very low in 2011. In late 2011 that was the first time they recommended that women who had never had specifically TDAP vaccine, which is a much larger number than those who hadn't had the tetanus go ahead and get it during pregnancy rather than waiting. And so you can see there was a small increase just from 2011 to 2012 in the percent who got it in pregnancy but not really much changed in the percent who had it overall. In late 2012, the ACAP made the recommendation that stands today to give TDAP with every pregnancy and after that in just the first year, the percent of New York state new mothers who reported having had TDAP in pregnancy doubled, which is great news except that it's only 23%. So we have a very long way to go to really reach the coverage that we'd like to see to optimize protection of the babies.

Moderator: Thank you. Now, Dr. Sperling, we've talked a lot about the current recommendations and benefits for pregnant women and the infant. Is the practice of immunizing pregnant women supported by different professional or medical groups?

Dr. Sperling: Absolutely. Really across the board. I think that there's enormous support from the American college of OB/GYN for OB/GYN providers to be vaccinators and it's true of the American Academy of Pediatrics and The American Academy of Family Practice. I mean the recognized benefits of vaccination during pregnancy are you know, tangible, they're real and there are benefits again for both mom and for the infant. I think that one of the things I wanted to emphasize sort of intellectually is this shift in thinking, I think when I started to practice medicine, the idea was don't do anything to pregnant women. You know treat them all after delivery. And thank God pregnant women are adults, too, so we recognize that we should be vaccinating women for their own health. But also understanding the opportunity to vaccinate women in order to protect babies. So it's not just true of TDAP there are other vaccines that are really in development to thinking about how we can leverage that observation that if you give a vaccine, you boost the maternal immune response you get trans-placental passage of antibodies and you can protect the young infant before they themselves can be vaccinated. So that's scientific concept, trying to leverage that that we can actually do a

better job with maternal health and also do a better job in protecting young infants.

Moderator: Excellent. Now let me ask you where can providers find more information about these different immunizations?

Dr. Sperling: There's so much good information out there, alright. The American college of OB/GYN has a website that's called immunizationforwomen.org and the Immunization Action Coalition has a great website called immunize.org. I particularly like their website because they have VIS statements in 34 different languages, so you can print out a VIS statement in a language that's someone's first language or preferred language and really give them information that they can see and digest. The CDC has excellent guidance, New York state has wonderful guidance. There's lots of great resources out there. And it really is, they're both provider-friendly and also patient-friendly. So I think that's important. Again when I talk to my patients I tell them go read the stuff yourself. You know I don't have to be your source of information. You're out on the Web, go check out ACOG's website and New York state's website, go check out immunize.org and really ask the questions. There's really lots of you know FAQs and other things on these websites and people can become very very well informed about vaccines for themselves and vaccines for their family.

Moderator: Excellent. And Dr. Rausch-Phung, are there specific resources in New York state that you'd like to share?

Dr. Rausch-Phung: Yes. We do also have vaccinating women of reproductive age website as well as other resources for healthcare providers on our state health department website and people whether it's healthcare providers, the public, local health, anybody can always e-mail us at immunize@health.ny.gov.

Moderator: Excellent. Thank you both so much. We've covered a lot of information and we've got some time left in the show to see if we've got questions from the audience. So our first question: Why do pregnant women have to be immunized against pertussis in every pregnancy when the recommendation for adults is once in their lifetime? Will getting this immunization in each pregnancy potentially hurt the mother?

Dr. Sperling: Okay, I think we went over a lot of that territory but I'd be happy to answer that again. It really is to leverage the boosting of the maternal immune response to cross those, have those antibodies cross the placenta, protect the baby and protect the infant before they themselves can be vaccinated. So that's the reason each and every pregnancy, even if you've got vaccinated in a prior pregnancy you lose those antibodies. Those antibody levels go down and that even though there is some trans-placental passage of antibodies they're not adequate to protect a young infant. It's really boosting immunity, each and every pregnancy during a targeted time.

Moderator: Thank you. Alright, the next question, if I'm vaccinated early in my pregnancy in May, say, do I have to be vaccinated again for the next flu season before I deliver if my pregnancy crosses two flu seasons?

Dr. Sperling: Yes, with three exclamation marks. I think the flu vaccine is for each season. And so you're getting protection for that flu season and not for a subsequent flu season. So if your pregnancy does cross those the two flu seasons then you need two flu shots.

Dr. Rausch-Phung: Right and the flu viruses do shift and drift every year. So the protection you might have had from the previous year's vaccine might not be enough for the new year if there has been a change in the circulating viruses.

Moderator: Sure and that goes back to what you said earlier about if you've seen one flu season you've seen one flu season.

Dr. Rausch-Phung: Right.

Moderator: We have another question. How do we know that flu and TDAP vaccines are safe in pregnancy when the FDA does not allow clinical trials on vaccines with pregnant women?

Dr. Sperling: There actually are ongoing trials with pregnant women as vaccines become available. But I think the efficacy and safety of vaccines are followed in the post marketing experience, and they're closely followed and there's particular concern and attention paid to influenza vaccine in pregnancy, TDAP vaccine in pregnancy. As far as influenza vaccine and pregnancy go, we have 20 years of both documented as well as anecdotal experience about its safety and its safety throughout pregnancy. I don't know if I emphasized the fact that this vaccine can be given each and every trimester and should be given each and every trimester we don't have to wait for a specific trimester for the vaccine to be given and there's no concern about safety in any of the different trimesters.

Moderator: Excellent. Are there specific strategies underway to address the racial and ethics health disparities that you mentioned in vaccination among pregnant women?

Dr. Rausch-Phung: Well you know, I think that's a really, it's a good question and it's one that the state health department is thinking a lot about as well as I'm sure a lot of other health care providers and public health partners.

Dr. Sperling: We began to collaborate on a project, I think it's extremely important to make sure that everyone is hearing the same public health message, having opportunities to ask the questions and make appropriate informed decision, so maybe you want to collaborate, I'm game.

Moderator: Alright and are there laws in New York state that mandate TDAP and flu vaccines for pregnant women or for other people who will be around the infant?

Dr. Rausch-Phung: They're not mandated for adults certainly for certain kids in middle school and high school. They do have to get TDAP vaccine for school. It's strongly recommended and certain healthcare providers who work in certain healthcare facilities might have to, they're not necessarily mandated to get flu vaccine but they might have to wear a face mask while flu is circulating and again this is to protect their patients whether they're pregnant women, new babies or anyone really from getting the flu.

Dr. Sperling: I know in our practice we actually give providers the vaccine before we give the patients because we really don't want nosocomial spread of infection we don't want our providers to make patients sick. So the culture in our office is to offer the vaccine to our providers and our staff as early as we can in flu vaccine season make sure people are vaccinated and hopefully lead by example.

Moderator: Excellent. Well that's all the questions we have for today. Are there any final words, final messages that you really want to impart with our audience before we wrap up the show?

Dr. Sperling: I think that I think education is important. I think education is important for providers, education is important for patients. There are lots of good resources out there on the Web and I encourage both providers and patients to use those resources, ask those questions, feel comfortable with the public health recommendations why they're made and what are the benefits and what are the risks. But again education is super important.

Moderator: And Dr. Rausch-Phung?

Dr. Rausch-Phung: Yeah I absolutely encourage healthcare providers to learn more about it. They can certainly contact the health department anytime if they want to learn more about it. And absolutely be recommending flu and TDAP vaccines to all of their pregnant patients.

Moderator: Excellent. Well thank you both so much, I think we've covered a lot of really valuable information today.

Dr. Sperling: Thank you.

Moderator: And thank you very much for joining us today. Please remember to fill out your evaluations online. Your feedback is always helpful to the development of our programs and continuing education credits are available for today's program. To obtain Nurse Continuing Education Hours, CME and CHES credits, learners must visit

www.phlive.org and complete an evaluation and the post-test for today's offering. This webcast will be available on demand on our website within two weeks of today's show. Please join us on August 4th for the 2016 Breastfeeding Grand Rounds, "Building Continuity of Care to Support Exclusive Breastfeeding in New York State". Additional information on upcoming webcasts and relevant public health topics can also be found on our Facebook page. Don't forget to like us on Facebook to stay up to date! And now, you can also let us know how you use Public Health Live by taking a brief survey at phlive.org. I'm Rachel Breidster. Thanks for joining us on Public Health Live!