MCHB/DHSPS February, 2007 Webcast

Preventing Mother to Child HIV Transmission:

Achieving Greater Success in the United States

March 18, 2007

JOHANNIE ESCARNE: Good afternoon. My name is Johannie Escarne from HRSA's Division of Healthy Start. On behalf of the division I would like to welcome the audience to this webcast titled "Preventing Perinatal HIV Transmission". Achieving greater success in the United States. This is the first webcast in a two-part series that will continue March 25th at the same time. Participation in both remember webcasts is strongly encouraged. The second session builds upon the first. Before I introduce our presenters today I would like to make some technical comments.

Slides will appear in the central window and should advance automatically. The slide changes are synchronized with the speaker's presentations. You don't need to do anything to advance the slides. You may need to adjust the timing of the slide changes to match the audio by using the slide delay control at the top of the messaging window.

We encourage you to ask speaker's questions at any time during the presentation. Type your question in the white message window on the right of the interface, select question for speaker from the dropdown menu and hit send. Please include your state or organization in your message so that we know where you are participating from. If we don't have the opportunity to respond to your question during the broadcast, we will email you afterwards. Again, we encourage you to submit questions at any time during the presentation.

On the left of the interface is the video window. You can adjust the volume of the audio using the volume control slider which you can access by clicking the loudspeaker icon. Those of you who selected accessibility features when you registered will see text captioning underneath the video window. At the end of the broadcast the interface will close automatically and you'll have the opportunity to fill out an online evaluation. Your responses will help us plan future broadcasts in the series and improve our technical support.

I would like to welcome our two presenters with us today. Our first presenter is Margaret Lampe. A health education specialist with the Center for Disease Control and Prevention. Division of HIV/AIDS division. Our other presenter is Shannon Webber. She's the perinatal HIV hotline coordinator for the aids clinician consultation center at the University of California/San Francisco. In order to allow ample time for the presentations we'll defer questions and answers to fol the presentations. We encourage you to submit questions via email at any time during the presentation. Please identify which speaker the question is for so we can direct the questions appropriately. Without further delay, we'd like to welcome our presenters and the audience and begin the presentations. Margaret.

MARGARET LAMPE: Good morning. Hello, everyone. It's a pleasure for me to be here to talk to you about perinatal HIV prevention. This is an issue near and dear to my heart working in this area for quite a while. And as we get started, if we could show the first slide which I think technically is the second slide. You'll see a curve. And this is really one of the most exciting graphs we have at CDC with regard to the HIV epidemic domestically. What this slide shows is an approximate 95% reduction in the number of perinatally acquired aids cases in the United States. In 1994 it was shortly after the number of AIDS cases started to decline. It was when the PGAE076 trial very successful results were

announced. Shortly thereafter in 1995 was the first time that CDC recommended that all pregnant women be offered HIV testing during pregnancy.

The next slide is the estimated number of AIDS cases of female adults and adolescents in the United States. I put this here. From what I understand the folks attending the web conference today work with pregnant women but also women who may become pregnant. Women of childbearing age. I think it's important for us to look back historically where women stood in the epidemic, if you will. On this slide the blue bars represent the number of AIDS cases among female adults and adolescents and you saw a steady increase until the mid 1990s and a slight decrease after 1996 as therapy became more available. The yellow line represents the percent proportion of cases. Proportion of total AIDS cases that were women as opposed to men and we've seen a steady increase in that over the years. So I'm sure you've heard this before but it is no longer a white men who have sex with men as many of us worked with HIV/AIDS are used to seeing.

If we advance to the next slide, please, on this map you'll see the AIDS rates for females and adolescents reported in 2005 in the U.S. I show you this to see that not only is AIDS not distributed equally among men and women and changing over time but geographically distributed somewhat differently. The states that are in bright orange had the highest AIDS case rates followed by those in yellow and then those in a light green color have lower rates. As you can see, the rates are more prominent in the northeast and southeast among women.

On the next slide we've talked about gender, geography and now let's talk about race ethnicity. As you can see, black non-Hispanic women are quite disproportionately represented with women with AIDS particularly in the south and where we're devoting our

attention in terms of HIV prevention among women. But we're here to talk about -- we're primarily here to talk about HIV -- perinatal HIV prevention. I want to orient you again with some of the data in terms of what one can expect if women take advantage of all of the interventions that are available to them. So in this slide, this first bar on the X axis is an estimated perinatal HIV transmission rate, if you will and then the Y is the timing of when prophylaxis might be started. If a woman is HIV infected, becomes pregnant. Goes through the pregnancy and goes on to breastfeed the risk of transmitting HIV to her infant is between 35 and 40%. Which is something -- that's the worst case scenario and something we would not want to see especially in this country. And then the second bar, the white bar, is a woman who has no prophylaxis provided, however does not breast feed. Breastfeeding accounts for an additional 15 to 16% of transmission. Then the third bar is if a woman, for instance, is offered rapid testing in labor and delivery. Learns she's HIV infected and offered -- a transmission risk is expected around 9% to 13%. Which is a tremendous opportunity but even greater is if a woman knows she's infected before she becomes pregnant, and is offered anti-partum intra-partum and transmission rates of less than 2% can be achieved. This is the medical intervention that's available and that we're trying to make sure all women with HIV can take advantage of. So with that sort of orientation to what is possible in terms of the medical interventions I want to walk through on the next slide, I have something called a perinatal HIV cascade looking at it from a public health perspective and population base. And this is adopted from something that the Institute of Medicine did in 1998 and if you think about it, in terms of looking at the number of infected babies, it is sort of a cascade, if you will. So there is women who become HIV infected is the first sort of pool of the population. Then of those infected women, those who become pregnant and then of those women who become pregnant, those who have inadequate pre-natal care. The risk factors that lead to an infected baby. And then even women who are in care, for instance, they may not get an HIV test or they

get a late HIV test that can be a very big missed opportunity. If a woman is infected and not known as infected and misses the opportunity all these things lead to a chain of events that leads to an infected baby. So I want to in my presentation today talk about each of these stages but rather than focusing on the missed opportunities, focus on the prevention opportunities, things that we can work on to help minimize or mitigate any of these issues.

So in the next slide, please, this is slide number eight on my handouts. The going back up to HIV-infected women, clearly the prevention opportunity and the ultimate opportunity for preventing HIV transmission to infants is to prevent women from getting HIV infected themselves.

So if you go to the next slide, some of the very basic ways to do that, of course, is reproductive and sexual health counseling for all women that enter healthcare services and also during school health. And then in addition to that, another sort of primarily prevention opportunity, if you will, is screening. That is routine opt out HIV screening in healthcare settings for all women and adolescents. There is a lot more to say about preventing HIV in women but we have a limited amount of time. Our focus is on perinatal prevention. To be perfectly clear it's the number one priority. Once a woman is infected there is also things that can be done.

If you go to the next slide, slide number ten, we'll focus down the cascade a little more looking at women who become pregnant and sort of the important aspects here is the prevention of unintended pregnancy and HIV-infected women and preconception counseling and care.

Next slide. In terms of preconception counseling and care for women with HIV it's important that counseling and services include discussions around safe and effective contraceptive methods and reproductive options that both prevent HIV exposure to her uninfected partners and as well as exposure to STDs and something we don't think about so much is an HIV-infected woman if she's having unprotected sex she can also expose herself to more virulent strains of HIV. The woman still needs to think about her health and think very cautiously how she plans her pregnancy if she wants a pregnancy. Another thing for all pregnant women S of course, to eliminate alcohol, drugs and smoking. I won't say that's something you say in one sentence and it's easy. I think you all are as good of experts on that as I am, or better. That's an important part of preconception counseling for any woman considering pregnancy. Of course, again, there is -- if she's HIV infected there are things to consider in terms of her HIV care and treatment. I won't get into a lot of detail about that because it is a little bit complex but basically when considering the treatment choices, treating the woman's HIV to suppress her viral load versus the risk to the fetus and when to time her treatment. But really the primary aim is to reduce her viral load as low as possible so that she cannot only maintain her optimal health during pregnancy but reduce transmission to her infant. I should say before I move on, there are the recommendations for an HIV-infected woman with an HIV-uninfected partner in terms of becoming -- planning a pregnancy would be artificial intrauterine insemination so she is not exposing her partner. In the case where you have an HIV-infected man and uninfected woman it is a bit more common and we don't have any recommendations around that in the United States currently but those are being considered.

So if you proceed to the next slide as we move down the cascade, if you will, in talking about inadequate prenatal care, I am choosing not to spend a lot of time on this, this is an MCH audience and you know more about it than I do but you have to provide affordable

prenatal care. HIV-infected women have described experiences in prenatal care where they felt discriminated against or had very unpleasant experiences and often wished to avoid prenatal care because of those experiences. And so I think particularly with HIV-infected women it's important to nurture a healthy and accepting environment during prenatal care and they're especially sensitive to their disease and therefore.

So the next slide, which is slide number 13, moving down the cascade a bit further, I'm going to spend a lot of time on HIV testing and down the cascade it says no or late HIV test is a missed opportunity. There is a lot of things that CDC recommends around HIV screening and so I'll spend a bit of time talking about this. Of course, for the main things we'll cover are routine HIV screening, prenatal opt out HIV testing and I'll tell you what I mean by that. In some jurisdictions and some women reoffering HIV testing to women who decline. Reoffering them testing and doing a second test in the third trimester and I'm also going to talk a bit about rapid testing and labor and delivery.

If you go to the next slide, our -- slide number 14 -- you'll see CDC recommended in 2006 they revised our recommendations for screening in healthcare settings. Before I get into those recommendations I want to just describe a little bit of terminology. I think it's important that we have our definitions all in line.

So the next slide, slide 15, when I refer to diagnostic testing or when the recommendations refer to diagnostic testing, for example, that refers to performing an HIV test based on clinical findings or symptoms. A patient comes in with pneumonia and you're trying to rule in and out HIV infection and you opt to do testing in that way. Screening is when I refer to screening that means performing an HIV test for all persons in a defined population. All pregnant women we would offer HIV screening to all women, not because

of any particular risk behaviors or anything like that but all women who are pregnant. Targeted testing refers to performing an HIV test on sub populations of persons at higher risks based on different characteristics. In community-based organization or say an emergency department they may opt to offer testing only to men who have sex with men, for example. And then when I refer to opt-out screening. I think this is the definition that most people are interested in, I'm referring to performing an HIV test after notifying the patient that the test will be done, consent is inferred unless the patient declines.

So let's jump into what the recommendations actually say.

If you look to your next slide, slide number 16, CDC recommends routine voluntary HIV screening for all persons age 13 to 64 in healthcare settings not based on risk. So not based on race, not based on behavior, not based on anything other than their age. And then secondly all patients with tuberculosis or seeking treatment for STD should be screened for HIV. That's pretty obvious. How often should someone be screened? Repeat testing for HIV screening should be done for persons with known risk at least annually and then when acute infection is a possibility use an RNA test in conjunction with an antibody test to rule out or in acute HIV infection.

You go to your next slide, slide 17, opt-out HIV screening we recommend it with the opportunity to ask questions and the option to decline testing. A separate signed and formed consent is not recommended. Prevention counseling in conjunction with HIV screening in healthcare settings is not required for HIV testing. We're not saying that HIV counseling is not important however, it shouldn't be a barrier to being able to offer someone HIV testing. Communicate test results in the same manner as other diagnostic

screening tests. As you would say, for example, a screening for STD you would communicate HIV test results in the same way.

If you go to your next slide, the revised recommendations three, we recommend testing in settings with low or unknown prevalence. We should go ahead and initiate screening. If the yield from screening is less than one per thousand continuing screening may not be warranted. This has been one of the recommendations. CDC puts recommendations out for the whole country. Certainly screening in Kansas or Montana is different than it is in Florida or New York. Rather than not recommending screening in low prevalence areas, none of us know how much HIV we have in our communities, really. So we recommend that screening go ahead and be initiated. And then if -- many states have laws regarding HIV screening and some states there may be some conflicts with state or local regulations so you would want to pay attention to that and many states have actually taken some initiative in terms of modifying their state laws regarding HIV screening. So moving on to pregnant women, I will continue talking about CDC's recommendations but I want to mention from the American College of obstetricians have to say about it. Our recommendations are quite similar. The last set of wreckdations from ACOG were published in 2004. The next couple of slides I compare what CDD and ACOG both have to say about different aspects of HIV screening during pregnancy.

So if you look at slide number 20 -- I advanced two slides. I'm not sure what you are being able to see right now. In terms of CDC and ACOG recommendations for HIV testing we both -- both CDC and ACOG recommend opt out early in care at the first prenatal visit. For repeat testing in the third trimester CDC recommends in jurisdictions or states with elevated HIV incidents. ACOG does not currently have that recommendation and I'll talk more about that in the next slide. But repeat testing in third trimester is recommended in

elevated prevalence healthcare facilities both by CDC and ACOG. It is recommended for women known to be at high risk for HIV infection and also for women who decline testing earlier during pregnancy.

If you go to the next slide, please, you'll see a map. And if you -- on the previous slide I mentioned that CDC recommended repeat testing in jurisdictions with elevated incidence. Well, I think I had mentioned earlier that few folks know what their prevalence is in their community much less their incidence. In fact, the reason we recommended repeat testing for elevated incidences is based on cost effectiveness models. So in order to help jurisdictions, clinicians and others know if they're in an area with an elevated incidence we created a proxy. On the map here in the states that are in blue, with their 2004 AIDS case rates and HIV case rates these states were determined to have elevated incidence based on this proxy. I won't get into the details on that unless you have a question I'm happy to. I want to keep moving to the slides but I'm happy to address it if you'd like.

Moving on to the next slide, regarding CDA and ACOG recommendations for testing, both CDA and ACOG recommend opt-out rapid testing for women in labor with an undocumented HIV test during pregnancy. A woman had no prenatal care they should be eligible for testing and had prenatal care declined or was not offered a test or nothing in the record, she would be -- testing would be recommended for her. And then sort of a sub part of that is that based on a positive or reactive rapid test, clinicians should initiate interviral prophylaxis. It outweighs the risk of a false positive and providing the prophylaxis unnecessarily. Lastly, CDC recommends rapid testing of the newborn if the mother's HIV status remains unknown postpartum. ACOG doesn't say much about that because they don't provide recommendations around pediatrics. That's kind of a summary of CDC's recommendations for HIV testing in healthcare settings. Non-pregnant women, pregnant

women and newborns and I've shown you where ACOG confers with us and differs. Johannie mentioned that the next webcast is a complement to this one and the next webcast they'll talk quite a bit about using rapid HIV testing in Healthy Start settings, for example. I think it's relatively new technology and so I had said that I would give you a background on that. So the role of rapid test. I don't want to give the perception that rapid test is the better way or the only way to do HIV screening. There is a specific role for rapid testing, however. And one thing that rapid testing does it increases the test results. You're seeing a patient. You're able to give them the results in say 20 minutes as opposed to waiting for the turn around time of a week. Rapid test also helps to increase the identification of HIV-infected pregnant women to receive effective prophylaxis in labor and delivery as I just mentioned. Rapid testing increases feasibility of testing with same day results. For emergency departments, for example, where patients typically don't come back for a follow-up visit rapid testing plays a very important role and increases the venues that. Many of the tests that are FDA approved can be done at the point of care and do not need to be performed in a laboratory so it opens up a lot of possibilities in terms of where and how HIV screening can be performed.

If you go to the next slide, this is a slide with pictures of six rapid tests, slide number 24. There are six rapid tests that are currently FDA approved and available in the United States. I will talk about four of them very briefly. The Uni-Gold recome by again. The Clearview quick advance are what we call clear wave tests meaning they can be performed point of care. The multi-spot and reveal tests have an additional level of complexity and must be performed in the laboratory. I'll talk about the four clear wave tests today. If you skip forward two slides, I'll start talking about the OraQuick advance HIV-1 and 2 test. OraQuick is -- it can be stored at room temperature. It screens for HIV-1 and 2 and results are available in 20 minutes. Then I'm going to go through the slides pretty

quickly. I hope that the viewers are able to see this as quickly as I speak. So you go to the next slide, slide 27. I just want to show you how an oral fluid sample is collect Wednesday the paddle of the device. It's collected by swabbing the gums with the test device just once around the area where the teeth meet the gums and this is an ideal sort of testing methodology for field settings, for example. After the specimen is collected you insert the device into the solution that's provided with the test kit and the results -- the test develops and you have results in 20 minutes and you have up to 40 minutes to read the results. Again, OraQuick can also be performed with whole blood. So if you -- we said I'm now on slide 31 talking about the Uni-Gold Recombigen test. It's the clear wave for finger stick whole blood and can also be performed with plasma but it needs to be done in the lab. It has to be centrifugeed, most folks don't have that out in the field. It can be stored at room temperatures. This test has results in ten minutes.

If you go to the next slide, you do a finger stick. This requires a good bit more specimen than some of the other tests. But you perform a fingerstick with disposal pipette. The company provides things that work quite well.

Go to the next slide you add one drop of the specimen to the well.

The next slide you can read the results in ten minutes. Like the OraQuick assay but you can see a positive and negative test result. Both the OraQuick and Uni-Gold have a clear line and a test line. If the test itself is -- had worked correctly, you will see a line across the control area and then there will be no line across the test area for a negative result but a line across -- but there will be a line across the test area for a positive result. For the Uni-Gold test, it's important also that you see a red dot here because you could add another type of specimen and still get a control line because it's testing the flow-through of the strip

rather than testing for human specimen. An important factor -- an important part of performing this test is assuring that blood has been added to it.

Moving on to the next slide, clear view complete HIV-1 and 2. It's performed on whole blood, serum or plasma. Clear waved for whole blood. This slide is a little outdated. It is clear waved. It detects HIV-1 and 2 and results can be read in 15 to 20 minutes. Stored at room temperature. Like the Uni-Gold, you obtain a fingerstick blood sample but in this case the device can be put directly to the blood spot to obtain the specimen. It only needs five microliters of specimen.

The next slide, you insert the device into the vile. You push it down and they provide a stand.

You go to the next slide and you can read the results in 15 to 20 minutes. And like the OraQuick and Uni-Gold there is a control line and test line. On this particular slide the specimen on the left in specimen hole number four is a positive or reactive result and the device on the right is a negative result.

If you go to the next slide, the clear view HIV-1-2 stat pack this is essentially the same test, just the platform is slightly different. They call the previous test complete because it comes with a Band-Aid. And so that's really the major difference. Then, of course, as you can see the device is structured but the strip is the same and the solutions are the same. So I won't go into the specifics because they're the same device but in this example you don't put the test device directly to the blood spot, you obtain the specimen with a loop. I'm on slide 40 now.

Then if you go to the next slide, slide 41, you put the five microliters that is obtained in the loop into the specimen. I'm sorry, into the test device.

Then next slide, slide 42, add three drops of buffer to the well and then slide 43 you read the results in 15 to 20 minutes. Again, the specimen on the left is the positive and reactive result and the one on the right is the negative. That's a very quick and dirty overview of the clear wave to rapid HIV test. As you can see they're pretty straight forward and simple to use particularly in healthcare settings where folks are more accustomed to working with blood and body fluids. And reading results. So we talked a little bit about rapid testing. I mentioned early on that if a woman is diagnosed in labor that you can reduce the risk of transmission down to 9 to 13%. I want to talk a little bit more about rapid HIV testing for women in labor. So you know the biomedical reason but from a public health perspective why would we be promoting this so much?

And if you look on slide 44, these data are a little bit old. We had a challenge getting more current data. Of the 280 to 370 HIV-infected infants born in 2000, 40% of the infected infants were born to women who had unknown HIV status prior to delivery. This is a very important opportunity for intervention. If we are not as successful with getting women into care or getting them tested early, at least we'll have that opportunity at labor and delivery and in 2002 only 69% of women who had recently given birth reported that they had been tested during prenatal care. We have some strides to go in terms of making sure that all women who deliver have an HIV result in their L & D chart. I'll talk a few seconds about the MIRIAD study. I'm on slide 46. It took place in 17 hospitals.

Next slide. The objective with MIRIAD were to determine the feasibility of rapid testing for women in labor with a documented HIV status to provide timely prophylaxis to reduce

perinatal transmission and have follow-up care for HIV-infected women and their infants. I'm running a little short on time so I'll go quickly.

On the next slide the -- which is slide 48, we screened at the 17 hospitals over 150,000 labor and delivery visits. In them during those visits there were about 12,481 women who were eligible to participate, meaning that they were at least 24 weeks gestation and had no HIV test result documented on their records during that pregnancy. Of the women who were eligible, 38% of them had no prenatal care. 74% of the women were offered MIRIAD which meant they were offered rapid HIV testing but they were also offered lots of other research-type activities. They were asked to conduct an interview, participate in an interview, to have several specimens drawn and we've seen in clinical practice that labor and delivery have been able to offer more of the women without test results rapid testing than we were able to in the research study. And then of the women who were offered participate, 86% consented for testing and participating in the study and I think one sort of interesting thing about accepting it is that women -- this seems kind of intuitive. We wouldn't have thought it would be that much. That there would be a significant difference. Women were more likely to accept testing when rapid testing was performed using residual blood from other labs. Versus when they were asked to do an additional finger stick. They wanted to avoid a finger stick. I think that's kind of a pearl from the MIRIAD study in terms of implementation in healthcare settings for rapid testing.

On the next slide, slide 49, this is a little bit busy but this is just breaking down the number of women who were screened from whom we've had both rapid test and other results available. In this study we did both the OraQuick rapid test and ELIZA. So of the 7,753 women who were -- had the rapid and ELIZA test available there were 52 HIV-infected women. .7% overall. And interestingly you see that thought bubble off to the side, about

half of the women had actually been diagnosed with HIV prior to this pregnancy and did not disclose when they were offered rapid testing in labor and delivery. That was very much an unanticipated finding and we unfortunately did not have more in-depth interview data of those women about why they didn't disclose. But I think this might speak to what we were talking about earlier in terms of their fear of being discriminated against or having challenges or fear of discussing that during labor and delivery. Again, we didn't collect hard data on their reasons for not disclosing. So of the 52 women who were HIV infected we had data on 50 deliveries. Two women were not fully in labor and left the hospital and delivered elsewhere. So 50 deliveries. There were 51 babies. And five -- of which we had data on 43. Eight of the infants were lost to follow-up for the study. So we were able to achieve what we wanted, that is in terms of achieving transmission rates of 9 to 13% as would be expected. We had a transmission rate of 12%. 5 out of 43 HIV-infected infants versus 38 uninfected infants. Some folks had concern that the rapid test wouldn't perform as the standard or conventional test. When comparing OraQuick and the reason we chose that was nothing about that test itself except where it was in the FDA approval process. The other tests are quite good as well. We had six false positive OraQuicks versus 18 false positive ELIZAS. Our sensitivity was 100% and specificity was 99.9%. The value when comparing the OraQuick, the positive value was 90% using OraQuick and 74% using EIA. If you have specific questions about that I'll be happy to answer those. In terms of implementing rapid testing during labor and delivery, we at CDC as well as with others out in the field, other experts, developed what we call rapid HIV testing during labor and delivery. The practical guide and model protocol.

Slide 51 in your handouts. What this does is provide a general structure of a rapid HIV testing protocol that can be adopted locally. This is put out in 2004. We're currently updating it in a new updated version that will be available quite soon.

So if you go to your next slide we're back to the cascade. And we're looking at missed prevention opportunities again. Now we're into the prophylaxis prevention opportunity and as I mentioned earlier, prophylaxis is a wonderful intervention to reduce transmission to her infant. Optimally a woman should receive it and it's important she get adherent support. Anti-retroe rivals are not always easy to take, especially when you're pregnant. This slide summarizes some of the perinatal HIV transmission studies in the United States. As you see in 1993 this is prior to 076 that I mentioned earlier, the transmission rate was approximately 25% and again we've -- through studies we've seen we can reduce transmission rates to less than 2% as demonstrated by PSCG316 in 2002. Shannon, who will be the next speaker will talk a little bit more about the next document.

SHANNON WEBBER: Go to the next slide, please, slide 54. This is a really complete set of recommendations on the use of anti retroviral. Antepartum care and intrapartum care and -- I picked out highlights from the guidelines for clinical management, just the general principles. I apologize for the laundry list. This is the best way to present this. Essentially in terms of preventing perinatal transmission in clinical management the earlier the diagnosis of the woman or the pregnancy the better opportunities you have and the better outcomes you'll achieve for both mom and baby. Basically anti-retroviral drugs provide -- that's how they work. It works -- they work in many ways and serve a couple of functions. Again antepartum, intrapartum and neonate always are recommended. Combination drugs are recommended. The O76 trial in 1994 was very effective but that is, you know, that's not the standard of care today to use that alone, although AVT is recommended to be added to almost all regimens. For preventing perinatal transmission. Starting the medications by 28 weeks gestation is the best. ARV's prevent mother to child transmissions for all HIV-infected women. It's important they be on medication. And again

counseling regarding adherence is very important. Particularly to help prevent resistance. If a woman is getting sub optimal therapy or intermittent therapy it's more common that it will create a resistant virus which we believe and all evidence supports an increased risk of transmission and infected baby with a resistant virus is much more harder to treat for sure.

If you go to the next slide, slide 56, in terms of the principles of general clinical management the real goal during pregnancy is the maximal reduction of the mother's viral load. The number of particles of virus per millimeter of blood. The intrapartum during labor and delivery interveneous is recommended for all women. C-sections are recommended for women with -- again that's the viral load I was just mentioning and the studies have not shown that C-sections has any additional benefit in terms of reducing perinatal transmission with women who have a viral load less than 1,000. It's -- so getting -- moving on to if a woman has a later diagnosis she had rapid testing in labor and delivery like we just discussed the recommendations are to initiate A -- on a reactive rapid test and then discontinue if later it's confirmed that she's HIV uninfected. All neonates should get it orally for six to eight weeks. This is important in this country where we have access to formula, in our culture promoting breastfeeding. That really is best but breastfeeding is not best for HIV-infected women as you saw on my early slides. That accounts for quite a good proportion of -- adds quite substantially to the risk of perinatal HIV transmission. Supporting women about not breastfeeding is really important. And we realize that clinical management and actually sometimes the testing can be quite complicated. So clinical expert consultation is really important and there are resources available. Shannon will talk about one of those key resources in a minute.

Going on to slide 57, you know, what -- if everything has gone right, the odds of having an infected child are quite small. But it does happen and it happens still more than we would like it to in the United States but if it does happen, not only for an infected child but for all of them it's really important to link the mom and the infant to comprehensive care and services. And Shannon is also going to talk a little bit about that.

My next slide I list some resources, the rapid testing model protocol I mentioned, the website is there. Our link to HIV screening in healthcare settings, the U.S. Public Health Treatment Guidelines, a link for that and then a really wonderful resource around HIV infection for women and children is also listed there as well. And then very -- my last thing I wanted to just point out is that CDC has somewhat we call social marketing campaign called one test, two lives. It's a campaign promoting prenatal HIV screening not only to patients but also to providers. The website is listed there on slide 59. What it is, it's a kit and the kit includes scripts and patient materials. There is a obstetric date wheel as part of that with messages reminding providers about HIV testing and patient materials in both English and Spanish that have been thoroughly tested out in the field and folks have generally had quite a favorable response to. If you would -- those are available for free. If you would like those, please go to the website or let me know and move on to my last slide, my email address if you would like to contact me about anything I presented today or any other questions about perinatal transmission, I'd be very happy to help you. Thanks so much.

>>Thank you, Margaret. We'll now in the interest of time move on to Shannon Webber who will talk to us a little bit about the perinatal/HIV hotline.

SHANNON WEBBER: I want to thank the Maternal and Child Health Bureau and give a greeting to our friends in the Ryan white clinic program who joined us for these webcasts as well. It is a treat for me to follow Margaret in talking about perinatal H.I.V. prevention in this country. She's probably one of the most knowledgeable people in the country and provides so much leadership. From Margaret's presentation I will talk about provider resources and you can see that clinicians have needs in this country to be able to continue to keep the rates of transmission and to work toward eliminating transmission in this country. Slide two clinicians have needs around information and expert consultation for HIV testing for women while they're pregnant and infants exposed to HIV, ARV abuse during pregnancy, labor and delivery and care of newborns.

Next slide. Clinicians also have urgent consultation needs for taking rapid HIV tests, management from ARVs during labor and delivery. The initial post exposure prophylactic choice for the infant. Physicians want to provide the highest quality care for pregnant women and their infants. To meet these needs the national perinatal HIV consultation and referral service was launched. It is two components. The hotline and then the second component is the clinicians network.

The next slide. These services were on the infrastructure at the national HIV/AIDS clinician consultation center based at San Francisco general hospital. They run two other hot lines which you may be familiar with. One is the national -- [inaudible] Also we run another line which is a consultation on all aspects that H.I.V. testing to complicated -- [inaudible] Next slide.

The perinatal HIV hotline is staffed by clinical pharmacists and physicians with expertise in perinatal HIV care. It is a 24 hour live consultation. It is free, it is available to all healthcare providers in the United States and it is confidential.

Next slide. Margaret referenced the United States Public Health Service task force guidelines which we also refer to as the perinatal infant guidelines. All the consultations at the perinatal HIV hotline are based on these guidelines. Guidance that helps clinicians to prevent transmission.

Slide 9. The next few slides are some data about calls to the perinatal HIV hotline that I'll go through fairly quickly. This data was published in September of last year. Slide 10 stratifies callers to the hotline by profession. There are a variety of clinicians to access the hotline for questions about perinatal HIV care. Family medicine, infectious disease doctors and OBs are equally represent and we have calls from nurse practitioners, physicians assistants and registered nurses.

Next slide. This slide shows that HIV positive patient load of clinicians who call the hotline. As you might expect, there is a large number of calls, about 20%, from clinicians who have 10 or less HIV-positive patients in their care. What is also interesting is that about 27% of our callers have over 50 HIV positive patients in their caseload. It demonstrates both clinicians with little experience and less expertise and clinicians with a lot of expertise and a lot of experience.

Next slide. This shows callers by facility type. Over 50% of our calls are from out patient settings. We also receive calls from labor and delivery and other public health clinics and whatnot. Slide 13, the final data slide shows a variety of calls that are broken down by

topic. Clearly the largest volume of calls is pregnancy -- [inaudible] I think what the data demonstrates by calling the perinatal HIV hotline you can get a customized expert consultation that's free and available 24 hours a day. Slide 14 will talk about the second component of the services available to the national HIV/AIDS consultation center which is the perinatal HIV clinicians network. The hotline callers can be linked with local and regional specialists or resources. This can be for support, for consultation, for co-management or referral of their patients. Currently we have about 265 participants in the network. I'm the contact for the network and look forward to working with you and talking with you more about this service.

Next slide. The perinatal HIV clinicians network is built of HIV experienced clinicians. When building the network, we look to collaborate with existing resources or networks in various communities in the country.

Slide 16 shows a map where the providers are located. In many ways it is near the slide that Margaret showed which shows the number of HIV positive pregnant women of childbearing age in various regions of the country.

Slide 17. I'm going to share with you some calls to the perinatal hotline. What I did in pulling the calls is looked at the calls demonstrating the key points that Margaret has talked about earlier in the webcast. So the first sample call is a question, this patient HIV positive is a 17-year-old pregnant woman with a positive ELIZA. Test repeated six week later. The viral load was undetectible. The caller asks how should it be interpreted and should the woman be started on ARV.

>> Pregnancy increases the number of false positives and no need to start ARVs at this time. A straight forward testing question, extremely appropriate to call the perinatal hotline to get assistance with how it should be interpreted or the information given to the patient.

Next slide. Need help now. So this call was pulled from some of the rapid testing points that Margaret made. 31-year-old woman 32 weeks pregnant with no prenatal care presents for labor and delivery delay. Crack use. Having contractions every two to three minutes. Received a dose of steroids. The rapid H.I.V. test returned positive. What are your recommendations? Slide 20 has the answer which is complicated and long as it should be in this case and it demonstrates the reason why it's important to be able to have the 24-hour access to expert consultation because every case has different nuances that may make the answer different. But the perinatal hotline answers it you consider this a true positive and asks -- confirmatory test. It gives the testing for the ARV, gives some information to avoid -- [inaudible] what to start the infant on and the mom -- until the confirmatory western block returns and the confirmatory test is positive then the mother should not breast feed.

Slide 21. This is from the perinatal HIV clinicians network. This is one of my favorite stories to tell. A midwife in a rural area calls the hotline when a woman who is 16 weeks pregnant, her routine HIV screen returns positive. The midwife and an OB at the trition and they've never seen an HIV positive patient before. How to tell the patient about the test results and they're eager to learn how to care for her. So we contacted clinicians within a two-hour radius of this midwife obstetrician team and I was able to find an HIV hepatitis specialty nurse with title IV money who travels to this town. This nurse was willing to meet with this team to consult with them so that the woman could remain close to home to receive her prenatal care. We also set up a clinician the perinatal H.I.V. hotline

that the midwife and obstetrician would regularly call in through the patient's pregnancy the check on the case and prepare for the next step. It was really wonderful to watch this case unfold and watch this midwife/obstetrician team prepare and the hospital prepare so the woman could deliver the baby near her home. The final two cases that I'll present are called missed opportunity cases. From Margaret's perinatal transmission cascade, I think there are many things that we can learn about how we as HIV care providers and you as Maternal and Child Health providers can work together to bridge the gap that may exist for women as they access prenatal care or if they access HIV care and then we can work toward eliminating perinatal HIV transmission in this country. So these are two recent transmission cases that occurred that demonstrate for us that at least in these cases and as is often the case there are opportunities for clinicians to prevent transmission.

Case number one slide 23. The couple wished to conceive. They both get tested and HIV negative. Three to four months later they conceived. She declined a test saying I was just tested and neither of us have had outside relations.

Next slide. The baby was delivered at full term and was breast fed for one month. At three months the baby was admitted to the hospital with a variety of symptoms and confirmed to have HIV, PMP and CMD. In this case where were the missed opportunities?

Next slide. HIV test during pregnancy. A rapid test when there was not a confirmed HIV test in her chart at labor and delivery. ARV prophylaxis and formula feeding for the infant. Slide 27 missed opportunity case number two. A 32-year-old woman presents to care at 37 weeks, her HIV test returns positive and her ARV treatment is given. The infant is born five days later and turns out to be HIV confirmed negative. A review of the mom's medical chart reveals a positive HIV antibody test who years earlier during a previous pregnancy.

Next slide. During the previous pregnancy the mom had presented to care similarly at 37 weeks and was tested at that time for HIV. The results came back positive. Two weeks later on the day she was delivering at another hospital. Neither the patient nor the hospital were aware of her results at that delivery. Her first child tested positive for HIV after her HIV status was rediscovered and disclosed during the second pregnancy.

Next slide. What were the missed opportunities in this case?

Next slide. During the first pregnancy an HIV test results being delivered to the patient to the attending clinician and labor and delivery staff. Without a confirmed HIV test in her chart at labor and delivery a rapid H.I.V. test should have been performed. ARV prophylaxis for the infant. Missed opportunities for the second pregnancy. A timely H.I.V. test and ARV prophylaxis.

Next slide. So what are some of the other resources that are -- how can the perinatal HIV hotline help clinicians to prevent perinatal HIV transmission in the country? We're the only resource with a nationwide perspective, a network of providers that have helped people like you prevent transmission. We can provide telephone consultations, a one-time consultation including a second opinion or questions about a controversial issue and help you follow patients. We can keep you informed of changes in the perinatal HIV guidelines and new testing and treatment protocols. We can also connect you with clinicians and specialists through the perinatal HIV clinicians network.

Next slide. How can you help the perinatal HIV hotline? Put the telephone number in vital area. I would love for you to put stickers on all the labor and delivery units where you

work. Promote the hotline and referral network that specialize in local conferences and participate in the perinatal HIV clinicians network.

Slide 33. What are some of the other perinatal H.I.V. resources? Margaret mentioned some as well but I'll go through them quickly. HRET and the website is a great listserv for those working on implementing rapid testing. The American College of obstetricians have wonderful provider and patient tools. Their website is listed as well. [Inaudible]. The folks who speak next week on the webcast have a lot of information including model protocols. Slide 34, I have one of the CDC links, Margaret has another one. The CDC has information about model protocols in rapid testing. And Margaret has a website as well. It has resources for both developing and undeveloping countries around HIV transmission.

Slide 35, Margaret talked about this at the end of her presentation and I can tell myself to do the same. I campaign and I brought the materials because they're so beautiful. I want you to go to their website and order them and share them with the providers in your community. They have a great, fabulous meal, a great poster for the office. It is the obstetric provider to further reduce the number of infants born in this country by having HIV screening as part of prenatal care.

Slide 36 the last slide this is referring you back to the national HIV/AIDS clinicians consultation center website. We have a state testing compendium at the state. It's recently updated so it's all current. This could be quite helpful for you as you look to implement the HIV testing recommendations that Margaret presented. That's the end of my presentation. We'll send it back to you. Thank you.

>> Thank you, Shannon. I think we do have just a few questions and we have a couple minutes so I will turn it over to Taylor to read the questions for us. Taylor, do you have the questions ready?

>> I'll take that question. There is in terms of states allowing rapid HIV testing, yes, states are allowed. There are different regulations in terms of what type of consent is required. There are three states that actually mandate newborn testing if a mother's status is unknown so there is no consent from the mother even required at all. The states are New York, Connecticut and more recently -- actually, Illinois is not in effect yet. It will take effect in June. But there are no prohibitions from doing rapid testing on infants. Most states, you know, certainly request that, well, the general principle is to test the mother because you're essentially testing the mother by testing the infant. You're detecting maternal antibodies. We recommend trying to get the mom tested first. If she out and out declines or would prefer her baby be tested her baby can and should be tested. Thanks.

>> Thank you, Margaret. Taylor, do you have some other questions? I think Margaret pretty much answered it. I don't know if Shannon has anything else to add.

>> Margaret is right. I like that. [no sound being heard by captioner]

>> Thank you for that comment, Taylor. Shannon or Margaret, do you have anything to add to that comment?

>> I don't know that website off the top of my head but I want to say that I think I agree it is so important for us -- one of the reasons for doing the webcast is to look at how we can do outreach and collaborate and bridge the gap by collaborating with various public health

departments. So here we are kind of HIV looking to collaborate to work with Maternal and Child Health providers and I'm pleased to see these kind of collaborations happening around the country.

>> Thank you, Shannon. Taylor, do you have any other questions? [No question being heard by captioner]

>> That's a good question. Margaret?

>> Thanks. CLIA or CLIA is a -- there is a regulatory body about diagnostic testing. So, for example, complete blood count is not a CLIA wave test. That determines where and how a test can be performed. A complete blood count is not something that I would do at home or at the patient's bedside. When it's CLIA-waived the test is not so complex it can't be performed at the patient bedside and so in the case of these rapid tests, clinicians and others simply need to follow the package insert in terms of performing the test. And that's -- that's the sort of concise, short answer about CLIA. It's a complex regulatory process. There was a lot of discussion whether or not rapid CLIA tests should be waived or not. Since these HIV tests, it's very important to make testing more widely available, and that these tests are so easy to do and have very good internal controls in the device that if one follows the package insert they can get a good result.
Thanks. Thanks for that question.

>> Thank you, Margaret. Taylor, any other last minute questions? [No audio being heard by captioner]

>> Okay. Oh, okay. That first question that we have responded to was do all states require newborns to be tested if the mother's HIV status is unknown. And Margaret gave us a pretty good explanation of what states allow that and what the regulations are on that. What was the second question? That second one was a comment. The second question was what does it mean when a test is CLIA waived and Margaret just gave us a synopsis of what that meant. Okay. The question is, are there any UCSF materials that can be mailed to Healthy Start sites and Shannon, that's a question for you.

>> The answer is yes and we would love to do it. So you can call the perinatal HIV hotline or email me and I would be very pleased to ship the materials to you.

>> Thank you, Shannon. Just in case some of the audience doesn't realize, I am listening to someone give me questions and I'm reading them back so you guys can hear them. Go ahead, Taylor. [No audio being heard by captioner]

>> Wow, okay. The question is -- could you give that to me in parts again, Taylor? Should an indeterminant western blot should be resolved quicker with DNA and or RNA PCR testing versus repeating EIA versus/WB in XY week. I think that's a question for Margaret.

>> Yeah. Thanks for that question. It is -- thanks for rereading it. There is some evidence that, though not conclusive evidence, but there is some evidence that western blots are more likely to be indeterminate in pregnant women than in non-pregnant women or in men. And then, of course, I think the nature of the question is that don't you really need to have a good answer right away because you would be initiating prophylaxis or not initiating prophylaxis based on whatever decision and time is of the essence. I would agree with that sentiment 100%. Some of the data is still a little bit out. I think most -- and

we don't have formal recommendations for a diagnostic algorithm, although that's certainly in the works at the moment here at CDC through consulting with lots of others, but many folks do add to their algorithm qualitative or quantitative to have a better answer. If it were me this isn't the formal recommendations, but if it were me that's something that I would, I think, choose to do. Thanks. Good question.

>> Thank you, Margaret. Okay. That's -- we have no more questions. And I think we're nearing our end time now. Before I make any closing remarks, Margaret or Shannon, do you have anything else you would like to add?

>> This is Margaret. I'll just thank you again for the opportunity and if folks want to contact me with any of their other specific questions I'm always happy to talk to folks in the field. This is as much a learning experience for me as it hopefully is for you. Thanks.

>> Thank you, Margaret.

>> Shannon, do you have anything to add?

>> I look forward to working with the Healthy Start programs and giving you information that we have from your areas and like Margaret said learning from you what is working well in your area so that if I get a call from someone in your area we can get them connected with you and the great things that you're doing. I look forward to speaking with you on the phone or connecting with you at various conferences.

>> Johannie, could I say one thing? Hopefully I'm not preempting you, just encourage folks to participate next week. If my talks were exciting, I think next time will be even more

exciting with more case studies and geared toward Healthy Start settings. This is really providing the foundation and background on perinatal HIV and resources but the folks at the center really have some interesting things planned for next week. I hope you're able to make it. Thanks.

>> Thank you, Margaret. Okay, on behalf of the Division of Healthy Start and Perinatal Services I would like to thank our presenters and the audience for participating in the webcast and thank our contractor the Center for Advancement of Distance Education at the University of Illinois at Chicago School of Public Health for making this technology work. As Margaret mentioned I would like to ask you guys to join us next Tuesday, March 25th for part two of our series. The next webcast is titled, healthy mom, healthy baby, routine and rapid HIV testing in Healthy Start. The session will include role plays and case discussions that participants can use in their settings during the second half of the presentation. A live audience will participate in the role play/case discussion for participants who are observing the webcast without a group. Today's webcast will be archived and available in a few days on the website mchcom.com. The role play and case discussions are also available on the website for review prior to next week's webcast. We encourage you to let your colleagues know about this webcast. Thank you and we look forward to your participation in future webcasts.