

Novel Influenza A H1N1 and Pregnant Women: An Update

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Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode. To ask a question during the question and answer session please press star 1 on your touchtone phone.

Today's conference is being recorded, if you have any objections you may disconnect at this time. I would now like to turn the meeting over to Alycia Downs. Ma'am, you may begin.

Alycia Downs: Good afternoon and welcome to today's COCA conference call, Novel Influenza A H1N1 and Pregnant Women: An Update. We are very excited to have subject-matter experts from the Centers for Disease Control and Prevention present on this call.

With us today we have Dr. Denise Jamieson who's the Medical Officer in the Division of Reproductive Health. We also have Dr. Peggy Honein who is the Chief of the Birth Defects Branch here as well as Dr. Janet Cragan who is a Medical Officer in the Birth Defects Branch.

We will not be using a PowerPoint presentation for this call and there will be continuing education credits or contact hours available for this call.

I would now like to turn the call over to Dr. Denise Jamieson.

Denise Jamieson: Thank you very much and thanks for the opportunity to speak today. I'm an Obstetrician/Gynecologist in the Division of Reproductive Health. And I wanted to do two things; the first was to highlight some of the findings from a recent Lancet paper that we published. And then the second was to review some key messages to healthcare providers.

Last week we published a paper in Lancet that was posted online on Wednesday. And it'll be published in print within an accompanying commentary on August 7.

And the paper summarized two groups of patients, it summarized 34 cases of influenza during the first month of the outbreak so from April 15 to May 18 including 31 confirmed cases and three probable cases. The paper also summarized deaths within the first two months of the outbreak from April 15 to June 16 in pregnant women.

And there were six deaths among a total of 45 influenza deaths representing 13% of all influenza deaths in the United States. Now we know this is a very unstable number. And we mentioned in the discussion that if you increased the reporting period by one week you would come up with seven deaths, so one additional death reported, out of an increased 87 overall deaths representing 8% of all influenza deaths.

And then in addition we looked last week when there were 302 total influenza deaths reported and we had relatively complete information on 266. And of those 15 were pregnant which would bring you to about 6% proportion of all influenza deaths that were among pregnant women.

Some of the key findings were that pregnant women with novel influenza were relatively healthy. So among the case series of 34 women seven reported a history of asthma but only one was on medication for asthma. Two other women reported taking drugs for chronic health conditions; one took insulin for diabetes and one in the first trimester did not realize she was pregnant was on an anti-hypertensive and a hyperthyroidism medication.

By trimester three women were in the first trimester, 19 were in the second trimester and nine were in the third trimester with three unknown what trimester.

Among the six deaths one had mild asthma and psoriasis but was not on any medications, one was possibly obese although it was reported that she was morbidly obese, we didn't have any pre-pregnancy body mass index, and one had factor five Leiden deficiency.

So we know that overall both among the cases and among the deaths these women represented fairly healthy pregnant women.

We also know that the clinical presentation of pregnant with novel influenza was similar to non-pregnant women. Pregnant women were more likely to report shortness of breath however this is really not surprising given that dyspnea is quite common in pregnancy.

We also noted a delay in the initiation of antiviral therapy. So in the case series of 34 8 of the 34 or 24% of pregnant women received antivirals within two days of symptom onset. And among the six deaths women received antivirals 6-15 days after symptom onset.

So we gathered from this that there seems to be hesitancy in general on the part of healthcare providers or patients to initiate antivirals. We also know that the hospitalization rate was four-fold higher for pregnant women compared with the general population.

And again although we know this decision to admit pregnant women is complex and may include considerations beyond disease severity this does seem to suggest an increased risk of complications or severe disease.

Something else we know is that the vaccination rates in this group were fairly low with about 9% of women in this case series known to be vaccinated for seasonal influenza. And this is consistent with what we know from other studies of uptick of seasonal influenza vaccine by pregnant women.

And among the six pregnant women who died they all developed primary viral pneumonia and subsequent acute respiratory distress syndrome requiring mechanical ventilation. In three out of the six cases the mothers were not stable enough to transport to labor and deliver and Caesarian delivery was performed either in an intensive care unit or in the emergency department. So there seems to be rapid disease progression from their initial presentation.

I'm now going to move onto sort of key health messages to healthcare providers. And these are all drawn from guidance documents that are posted on the CDC Website.

So we know that pregnant women are at risk for complications if they're infected with novel influenza. And this is consistent with what we know about pandemic - prior pandemics as well as seasonal influenza. It is not clear that they are more susceptible to influenza.

So what should a pregnant woman do if she suspects that she has influenza and has influenza-like symptoms? She should call her healthcare providers - or healthcare provider and the healthcare providers should have a system in place for segregating and rapidly evaluating pregnant women with influenza-like illness so that pregnant women who are well are not sitting in the same waiting room as pregnant women with symptoms.

Pregnant women with confirmed or suspected influenza infections should be promptly treated. And we're recommending oseltamivir as the treatment of choice in pregnant women, five day medication. And fever should be treated with acetaminophen since we know that untreated fever in pregnancy is associated with an increased risk of adverse outcomes.

In addition most exposure prophylaxis can be considered for pregnant women who are in close contacts of cases. And we're recommending zanamivir as first line prophylaxis however the inhaled route of administration may limit its usefulness in women with respiratory issues. And oseltamivir is another option.

In terms of a woman - sick woman on labor and delivery with influenza we're recommending that a surgical mask be placed on the ill mother during labor and delivery if it can be tolerated. An ill mother should be placed in isolation after delivery.

A mother who has influenza-like illness at delivery should consider avoiding close contact with her infant until she's received antivirals for 48 hours, her fever has resolved and she can control her coughs and secretions. And after that the mother should be encouraged to wear a mask to change - to clean clothing when in contact with her infant for at least seven days after the onset of symptoms or symptom-free for 24 hours.

The newborn should be considered potentially infected if delivery occurs two days before through seven days after illness of onset in the mother. Ill women should be encouraged to breastfeed. And the other big issue is vaccinations. ACIP and American College of OB/Gyns have been recommending since 2004 that all pregnant women be vaccinated.

And despite this guidance we know that vaccination rates among pregnant women are low. So I think this is going to be a major public health challenge with the fall flu season and with recommendations that pregnant women be in the high priority group for vaccination against both seasonal influenza as well as novel influenza.

I'm going to now turn it over. Okay.

Peggy Honein: Thank you very much for the opportunity to participate in this call. So my name is Peggy Honein and I'm an Epidemiologist and the Chief of the Birth Defects Branch here at CDC. And we've been working collaboratively with CDC's Influenza Division and the Division of Reproductive Health to monitor the impact of novel H1N1 flu on pregnant women.

And as you've just heard from Dr. Denise Jamieson, CDC initiated more intensive surveillance efforts in May of 2009 in response to a number of case reports about H1N1 flu in pregnant women.

While we recognize this is just the tip of the iceberg so far over 80 pregnant women with confirmed and probably H1N1 flu in the spring and summer of 2009 have been reported to CDC by state health departments. And CDC is now initiating follow-up to collect the outcome information on these mothers and their infants following delivery.

Outcome data that we plan to collect as part of this spring and summer cohort of cases includes maternal prescription and over the counter medications that they received both initially and subsequent to the initial report of the case.

Any hospitalizations for H1N1 flu including those subsequent to the initial case reports, acute and chronic health conditions of the mother, any complications that are experienced during pregnancy, the mode of delivery and any complications with delivery, the pregnancy outcome, the infant outcomes including birth weight, gestational age of delivery, any congenital defects that are present and any other illnesses in the infant and any testing that's been done on the infants to confirm influenza in the presence of influenza-like illness symptoms.

In addition to these limited follow-up activities of the cases that were initially reported to CDC we're also initiating more comprehensive surveillance activities for the fall of 2009.

We're planning to launch a prospective study in three or four sites that have large obstetric practices and can enroll women with confirmed influenza early in their pregnancy, follow the maternal course of infection and treatments throughout pregnancy and ascertain maternal outcomes at delivery including infant outcomes up through six months of age.

We're planning a case control study approach and to enroll approximately 900 women with confirmed influenza of any type so both seasonal influenza strains and novel and approximately 900 matched controls. And the controls will be women who have not reported any influenza-like illness symptoms up to that point in pregnancy.

So with this strategy we should have approximately 300 cases and 300 controls enrolled at each trimester of pregnancy so we can look at the impact of infection at various times in pregnancy.

In addition CDC is now working to develop some approaches to make it simpler for states and healthcare providers to report any cases of severe illness or deaths due to novel H1N1 flu among pregnant women.

Because, as Dr. Jamieson mentioned, among the 266 deaths that have been reported to CDC with relatively complete information 15 have been among pregnant women representing almost 6% of the deaths. We're very concerned about this disproportionate representation of pregnant women among the deaths.

We've also received numerous reports of pregnant women who've required admissions to an intensive care unit and would like to gather more complete data on that occurrence.

We're hopeful that the data that we collect on these severe and fatal cases will help us understand which factors might be contributing to the rapid decline experienced by some women.

And finally I want to make you aware of a complimentary effort that will be undertaken this fall to evaluate the safety of antiviral medications and influenza vaccination during pregnancy. There are some academic research groups that are going to be working together to conduct studies that are complimentary to the study that CDC has planned.

While the CDC study will focus on influenza infection and will gather information on the use of antiviral medications and vaccination the academic

effort will focus on vaccination and the use of anti-influenza medications for either treatment or prophylaxis.

Thus the CDC effort will include all influenza infections among women in the participating sites which will include some women who are treated, some women who were vaccinated, some that had both but will also include some women who did not receive treatment and had not been vaccinated.

In contrast the academic effort is going to focus on treatment, prophylaxis and vaccination and thus will be able to evaluate the use of antivirals and vaccination even among women who did not ever become infected with influenza in addition to those who have experienced influenza.

And while the details of this are still being finalized there'll be a reporting phone number for this effort and we expect that to be available by early September and will work to rapidly disseminate that information to healthcare providers.

Thank you very much and now I'd like to turn it over to my colleague Dr. Janet Cragan to provide an update on laboratory-related issues.

Janet Cragan: Thank you very much. I'm also very glad to be here today. I'm a Medical Officer in the Birth Defects Branch at CDC.

And I'm wanting to explain a little further about the laboratory testing that will be conducted during the prospective study of approximately 900 pregnant women with confirmed influenza and 900 controls and how this differs from the testing routinely conducted during clinical management of pregnant women with novel H1N1 illness.

During the prospective study for the fall systematic laboratory testing will be conducted for all participants. The intention is to confirm influenza infection of any type or subtype in pregnant women through PCR testing of nasopharyngeal swabs. They'll comprise the case cohort.

We will also confirm seroconversion of influenza antibodies in case women with confirmed influenza.

The study will look for evidence of vertical transmission of influenza virus from mother to fetus through testing of cord blood for influenza antibodies specifically looking for fetal IGM and identification of viral particles in fetal tissues.

And it will also identify pregnant women who experience seroconversion of influenza antibodies but do not develop acute respiratory illness. So we'll be looking at the control group to see what proportion of them have seroconversion to influenza but were asymptomatic.

Once pregnant women have been enrolled the exact tests conducted will depend on whether and when they had influenza illness in relation to when they deliver.

All women in this study will have serum collected at the time of enrollment and a second serum sample collected at the time of delivery to look for influenza antibodies indicating seroconversion.

If a pregnant woman has onset of confirmed influenza illness within 14 days of delivery cord blood will be collected for influenza antibody testing to look for seroconversion in the fetus at the time of delivery and the cord and

placenta will be sent for identification of viral particles to look for vertical transmission of virus.

If the pregnancy ends in miscarriage or stillbirth fetal tissue will also be sent for identification of viral particles.

If a pregnant woman has onset of confirmed illness more than 14 days prior to delivery only the cord blood will be collected at the time of delivery for influenza antibody testing. But if the pregnancy ends in miscarriage or stillbirth the cord, placenta and fetal tissue will also be sent for identification of viral particles.

Now I'm going to switch to focus on laboratory testing and the general clinical management of pregnant women with novel H1N1 outside of research settings.

Ideally pregnant women who have suspected novel H1N1 influenza infection should have nasopharyngeal swabs sent for PCR testing. However, treatment should not be delayed pending results of testing and treatment should not be withheld in the absence of testing.

This is because antiviral treatment is most effective when started as early as possible within the first two days after the onset of symptoms.

In reality testing will not be available in many clinical settings and when available the results often take several days. Clinicians should be aware of circulation of novel H1N1 virus in their area and should not wait for testing to initiate treatment in pregnant women who have suspected novel H1N1 infection.

Because a negative result from a rapid influenza diagnostic test or the rapid test does not rule out influenza virus infection it is not recommended that treatment decisions in pregnant women with suspected novel H1N1 be made on the basis of rapid tests alone.

Treatment should not be delayed or withheld based on a negative result of a rapid influenza test.

There are no recommendations for additional routine testing of pregnant women with novel H1N1 at the time of illness onset or at delivery. Whether the maternal serum, cord blood, cord and placenta or fetal tissue is sent to identify seroconversion or vertical transmission of virus particles is an individual case decision. However these tests are unlikely to impact clinical management.

And so now I think we're ready for questions.

Coordinator: Thank you. At this time if you would like to ask a question please press star 1 and record your name clearly; to withdraw your request press star 2. Again to ask a question please press star 1 and record your name. One moment please.

Your first question. Your line is open. Please check your mute button, ma'am, your line is open.

We'll move to the next question, one moment. Your line is open.

Question: Thank you for taking my question. I apologize for the fact that it's going to be a bit off base from this content that we've been in the audience for.

But I was wondering has there been any discussion at a policy level either with ACOG or at the CDC in terms of looking upstream in the prevention pathway of considering a fairly strong or consistent recommendation to young families who are looking at procreation right now that perhaps now is not the time to be pursuing expanding the family and that there would be some consideration of recommending voluntary contraception? And I'll just leave it at that and see if I have any takers.

Denise Jamieson: This is an issue that's been brought up and we are looking into this and convening a panel to discuss this. And I think there are serious considerations in reproductive issues in terms of how we counsel patients about future pregnancies.

I mean I think some of this has been - has been talked a lot about in Europe and both limiting the activities of pregnant women as well as counseling couples to consider postponing pregnancy. And I think there are a lot of ethical and public health issues. And it has been brought to our attention and we are in the process of trying to convene a panel to look at this issue.

Coordinator: Your next question, your line is open.

Question: Yes, thank you very much for some outstanding presentations. The animal studies have shown that females may be more resistant to viral infection but once infected not very robust responses. And certainly in pregnant females that immune response may be altered in order to not reject the fetus but the inflammatory response is still quite vigorous.

So in regard to your data do you have any - in regard to number of those who are hospitalized are women and percentage of deaths in women? And then if

you have it in regard to the denominator, the percentage of pregnant women versus women overall for death and hospitalization.

And then the second question is in regard to vaccine studies; is there any thought to look at perhaps different dosage in women as well as in pregnant women?

Peggy Honein: Just give us a moment.

Denise Jamieson: We did in the paper look at comparing admission rates and hospitalization rates with comparing pregnant women to both the general population as well as non-pregnant women of reproductive age.

And pregnant women did have a higher hospitalization rate compared to women of reproductive age. I'm just looking at the - women of reproductive age did not have a higher hospitalization rate compared to the general population. Actually they did, they're - no. Find the rate - point three two - it's in the paper and I'm just looking to see.

I hadn't though about looking at women of reproductive age versus the general population. Sorry for the delay. And then - we're going to look at those rates, just a sec we'll get back to that. But in terms of the dosing for pregnant women, I mean, clearly we don't know a lot about changes - there aren't a lot of drugs for which we know a lot about how - actually I should have let you answer this - how dosing should be adjusted or maybe adjusted in pregnancy.

And certainly with the antivirals that's an unanswered question. And in the practice of obstetrics there aren't that many instances where we adjust doses for pregnant women with one notable exception being the antiretrovirals. And

in those cases we have the pharmacokinetic studies have been done and we know from those that in some cases we need to adjust medication doses.

I don't know, Jan, do you want to comment on that?

Janet Cragan: No, I think - I agree with that. And I don't think there's any difference in vaccine dosage in pregnant women as well.

((Crosstalk))

Denise Jamieson: I think we took the - there was a lot of discussion whether we should include hospitalization rates among women of reproductive age. And it was in the manuscript and then it was out and we think we took it out at the last minute. But we have that data and we'd be happy to post the answer for you.

Did we answer your questions?

Question cont'd: Yes you have, thank you very much. I'm just also curious do you know that women often have more side effects to vaccines and certainly the whole issue of autoimmune diseases so it might be interesting to see in general independent of whether a woman is pregnant or not if they may require less vaccine because they do mount such strong inflammatory responses.

But thank you very much for answering some of my questions.

Denise Jamieson: Sorry, we did find the answer in the manuscript. And the bottom line is the pregnant women and the women of reproductive age who are not pregnant - I'm sorry, the women of reproductive age who are not pregnant and the general population are not significantly different, the confidence intervals overlap.

Peggy Honein: But pregnant women are at increased of hospitalization compared to both of those groups.

Denise Jamieson: Is there another question?

Coordinator: Yes, your next question, your line is open.

Question: Thank you. What recommendations do you have for pregnant healthcare workers?

Denise Jamieson: So the current guidance is that for healthcare providers who are pregnant and are in high risk - have high risk occupational exposure that they may consider reassignment.

Janet Cragan: They should follow standard precautions as with non-pregnant healthcare providers. And they may consider reassignment to other areas where they will not be exposed. That's one option.

Question cont'd: Thank you.

Coordinator: Your next question. Your line is open. (Debra), please check your mute button, your line is open.

Question: Was it (Debra Howell) or (Karen Howell)?

Coordinator: It was probably (Karen), I apologize.

Question cont'd: That's okay, no, no. I wonder if Dr. Jamieson could just review again the care of the postpartum mom in labor and delivery or shortly afterwards in regards to contact with the infants?

Denise Jamieson: So at this time the recommendation is that mothers who have influenza-like illness at delivery should consider avoiding close contacts with her infant until three conditions are met, she's received the antivirals for 48 hours, her fever has resolved and she can control coughs and secretions. And I should mention before that the recommendation is that she wear a surgical mask during labor and delivery if it's tolerable.

And then after that - so after the resolution of the - she's gotten antivirals, the fever is resolved and she can control cough and secretions mothers are encouraged to wear a mask, change into clean clothing or gown when she's in contact with her infant for at least seven days after the onset of symptoms or she's symptom-free for 24 hours.

Question cont'd: Okay and then you mentioned about the breastfeeding; you encourage breastfeeding but that's after those conditions are met?

Denise Jamieson: Well she should be pumping during that period - she should be encouraged and supported in breastfeeding and during the time when she is avoiding close contact she should be pumping.

Question cont'd: Great. All right, thank you very much.

Denise Jamieson: Encouraged to pump.

Coordinator: Your next question, your line is open.

Question: Well thank you but the lady in front of me just answered my question.

Denise Jamieson: Very good, okay.

Coordinator: Next question.

Question: Yes thank you. Part of my question was just answered but the other thing I wanted to have repeated was the risk to the baby that Dr. Jamieson mentioned when she spoke. Hello?

Denise Jamieson: Sorry we - no, we've struggled a lot to be honest with you with this particular guidance because of, you know, it's difficult to make evidenced-based practice recommendations when there's not a whole lot of evidence. And people feel very strongly - all of us included - about the importance of, you know, mother infant - mother baby bonding and so forth.

And so it's been a real struggle. And this is interim guidance that is evolving. But again, you know, the risks of disrupting the bond and the benefits of breastfeeding have to be weighed against the infectious disease risks to the baby.

And so this interim guidance that we've come up with or that has been developed here at the CDC really tries to strike that balance.

Question cont'd: I wanted to back up a little bit because I understood you to say that the baby was at risk at birth of having the disease.

Peggy Honein: Well I think that's not known at this point whether or not there's a risk of vertical transmission of this virus.

Question cont'd: But I think the statement was that an infant born to a mother with acute active disease should be considered infectious in terms of infection control procedures in the rest of the nursery and visitors not that you necessarily think the baby is infected and required treatment automatically.

Coordinator: The next question, your line is open.

Question: Hi, thank you for taking my question. I had a question it does relate to your guidance on care of the newborn postpartum. I'm wondering if this is consistent with guidance that you normally give for a mother that has influenza-like illness or other infectious disease?

I just wonder where - if this is taken at a greater level of precaution than other infectious diseases like seasonal flu for example?

Denise Jamieson: Yes, the guidance was definitely developed with the understanding that this was more concerning and more than what we do for general seasonal influenza. And, you know, again it's hard to know where to strike the right balance because there's not a whole lot of evidence. And this interim guidance tries to strike that balance but there has been a lot of discussion about it.

Do you have any thoughts?

Question cont'd: Well I just had a follow-up - I don't want this to come across the wrong way. But if a nurse has a patient who is postpartum and wants to hold and see her baby so, you know, I'm just wondering how we would react if we just kind of say what the guidance is and what the known - the hypothetical risks are and sort of - do we need to provide any documentation of the mother's counseling but yet her decision to be in contact?

Denise Jamieson: Yes, and again this interim guidance is not based on a whole lot of evidence so I...

Question cont'd: Okay.

Denise Jamieson: ...think you have to counsel the patient carefully about what the potential risks are, what we really do know and what we don't know and then help her make a reasonable decision.

Question cont'd: Okay that sounds like a great answer. Thank you.

Coordinator: Next question, your line is open.

Question: Hi, thank you. I was wondering if you could tell us the mortality rate in pregnant women due to seasonal influenza year to year?

Peggy Honein: I think that's one of the challenges that I don't think we have a very good estimate of that number.

Question cont'd: Okay, thank you.

Coordinator: Your next question, your line is open.

Question: Thank you. I have a question about the patient who presents with suspected H1N1, the recommendation was to start them on the antiviral medication. If the test comes back negative would you then discontinue the antivirals? And then also is there a concern about building resistance?

Denise Jamieson: So if a patient has started presumptively on antivirals and confirmatory testing reveals that it is in fact not influenza then we would recommend stopping the antivirals. It's only a five-day - it's a five-day course.

In terms of resistance, I mean, I think you're absolutely right I think as we use more antivirals and as the - we get into the flu season there are going to be increasing concerns about patterns of resistance. And so I think we're going to have to keep in mind that at some point, you know, antiviral recommendations may change.

Question cont'd: Thank you.

Coordinator: Next question.

Question: Yes, I would like to - I would appreciate your comments on the CDC recommendation to considering moving the pregnant healthcare provider from patient contact. And we're in an acute care setting and that presents some significant challenges. If CDC is recommending that it also morphs into some legal ramifications.

And, you know, the logistics of knowing who's pregnant is that laboratory confirmed or somebody that's, you know, a couple of days late, that situation can change very quickly. It may mean that we won't have adequate coverage in some areas because we have, you know, several people that all of them think they might be pregnant or are.

It also sends a message that to the non-pregnant folks and to our male workers that the current recommendations may not be adequate and reliable.

Denise Jamieson: Yes, and this is another issue that, as you can imagine, has been very controversial here. And we have gotten quite a bit of feedback about this. Right now we're suggesting that pregnant women who are in direct contact with patients - with confirmed probable or suspected influenza should consider reassignment to lower risk activities.

And it may be a step - you're absolutely right, it does sort of send a mixed message as to what the - how well protected other healthcare providers are who don't happen to be pregnant. And again I think it really has to be individualized at a - in a case by case basis.

And, you know, a respiratory therapist who is taking care of a patient in the intensive care unit and suctioning secretions of a highly viremic patient is much different than a nurse who's working in a triage setting where she's evaluating patients with influenza-like illness.

So I think - this is a tough recommendation but I do think it has to be tailored to the specific situation.

Question cont'd: But if that nurse in the triage area has a bad outcome from her pregnancy there's a huge liability on that.

Denise Jamieson: Yes, I mean, it's hard to create guidance that applies to all situations. And I think it really has to be tailored. Also where we are in terms of, you know, what the burden on the healthcare system is in terms of number of influenza cases; is it like now or is in the fall when there are a lot more cases.

Question cont'd: Right, and one of our issues too will be for a while we will not know - we know we have an influenza A but we won't know we have an H1N1. So how early we need to implement some of those is going to be challenging.

Denise Jamieson: Yes, and the other issue is that we need to be very careful about making sure that all healthcare workers are properly protected and wearing masks appropriately and so forth. But you're right, as the - as we get into the fall flu season we're going to have to be carefully monitoring what viral strains are out there and what appropriate medications are.

And there may be a point in time when we're recommending more than one antiviral for pregnant women.

Question cont'd: Is the current recommendation that for seasonal flu that we need to limit contact with healthcare providers that are pregnant?

Denise Jamieson: Nothing beyond standard precautions.

Janet Cragan: Yes, this guidance is solely for suspected probable/confirmed novel H1N1 infections. I think that some of the recommendations about seasonal influenza for this year because it will be circulating along with the novel H1N1 are still being considered whether there need to be any changes in the management or guidance related to seasonal influenza. But that is still very much in development.

Question cont'd: Also is the recommendations that you had for the peri-partum moms is that published someplace that we can get a lit of those?

Denise Jamieson: It's in the guidance - the obstetric guidance that's on the CDC Website. Let me get you the exact title. It's www.cdc.gov and it's - there's...

((Crosstalk))

Denise Jamieson: ...novel H1N1 flu virus in obstetric settings.

Question cont'd: Thank you.

Peggy Honein: And I assume if it would be helpful along with the transcripts to this we can post some of these links that directly relate to questions that have come up to make that easier for people to find.

Alycia Downs: Yes, absolutely. We can place those on the COCA Website under the call information.

Coordinator: Next question, your line is open.

Question: Thank you. Most of my question has been answered but is - it's about the pregnant healthcare workers. Is there any evidence that a surgical mask and goggles do not protect people from influenza whether it's seasonal or novel H1N1?

Janet Cragan: I think - I don't know that there's good evidence either way. I think much of the effectiveness of those measures have to do with the type of mask - the proper type of mask being used, how it's worn, how well it's fitted, how consistently worn, all of those kinds of issues that are - that can be difficult in clinical settings.

But I don't know that there's hard evidence to show that it prevents these kind of influenza transmissions, I don't know.

Question cont'd: Is that - I didn't hear what, you know, in the - whether that's going to be collected looking forward and all the data that's going to be collected about pregnant women. Might that be one of the things that is looked at because I

know in - after the SARS they decided well maybe it should be (droplet) masks as opposed to surgical masks and three feet and six feet and which healthcare workers seem to be at greater risk etcetera.

And just like the other caller our non-pregnant healthcare workers would also like to know that they're being adequately protected wearing the proper droplet precaution masks. So is there any chance that there - might be able to have some data collection that could give us some information about that?

Janet Cragan: Yes, there is guidance on the CDC Website for interim recommendations for face mask and respirator use to reduce novel influenza A virus transmission. And that applies to all healthcare workers and all persons not just pregnant women.

And again like - as Denise was saying with the other recommendations these are all interim recommendations that are evolving as we collect more information and learn more about the transmission of these viruses. So I expect that they may be modified in the future as well.

Question cont'd: Thank you.

Coordinator: Next question.

Question: Yes, thank you very much for this discussion. I would like to comment about the reassignment of pregnant healthcare workers. I think that will be a recommendation that would be difficult to implement and would cause a lot of problems in the healthcare setting because there are many healthcare workers who have underlying conditions that put them at increased risk.

And we will be having a pandemic and we will be having increased need for healthcare workers. And to pick and choose and tell people they should go elsewhere when really there's no place they can go where they won't have contact with people who have H1N1.

So I would really like to see stressed the proper protection with masks, goggles, gowns, gloves and hygiene and that sort of thing because if we do the proper things we should not be able to get influenza. And I think that's been shown with seasonal influenza.

So I would really ask you to reconsider the recommendation for reassignment because in pediatrics we deal with this with CMV all the time and there's no reason to reassign. And it's a very difficult problem.

And the other thing is I would just say that the first person's comment about prevention of pregnancy I would certainly support - it's not taking away anyone's rights of course anyone can get pregnant when they want to it's merely making a recommendation that if you're young and you have time that perhaps waiting until after the influenza season would be to the benefit of the couple. Thank you.

Denise Jamieson: Yes, thanks for your comments. I mean, you - we've certainly heard this view expressed and like I said there's going to be a panel next week to consider some of these issues.

And I just want to point out that pregnant women are at risk for severe disease and complications from influenza. We have no evidence suggesting that pregnant women are more susceptible to influenza.

Coordinator: Next question.

Question: Yes, thank you for taking my call. I needed - I actually had two things, one of them which is clarification of the rapid testing. During the section there was a comment that was made that with rapid tests alone recommendation or treatment decisions should not be based on that just because of the false negative issue with the rapid test.

Someone had asked a question about that earlier. And there was some confusion on that. Can you please clarify that again please?

Janet Cragan: Yes, we said that because a negative result from a rapid test does not rule out influenza virus infection. It's not recommended that treatment decisions in pregnant women with suspected novel H1N1 be made just on the basis of the rapid test. In other words treatment should not be delayed or withheld based on a negative result of a rapid test.

Question cont'd: Okay, thank you. The second one that I had there has been some discussion about the pneumococcal vaccination in the general public. Previously it's been kind of recommended just for those with chronic illnesses, after a certain age group, that type of thing. Is there any consideration to possibly give the pneumococcal vaccine to pregnant women at this time?

Denise Jamieson: So this has been considered and there's no evidence to suggest that pregnant women should be in the group for whom, you know, high priority for pneumococcal vaccination.

And just to clarify the deaths that have occurred that we've heard about to date have all been primary viral pneumonia.

Question cont'd: Viral, okay, thank you.

Denise Jamieson: There's been no evidence of super infection with bacterial pneumonia.

Question cont'd: Thank you.

Coordinator: Next question, your line is open.

Question: Hi, thank you for taking my phone call. And thanks for the presentation. I have two questions, one is nationwide statistics so there's any like among the all reported hospitalized patients and how many percentage pregnant women? This is the first question.

The second question is for the treatment antiviral medication treatment among the pregnant women who is a confirmed case or prophylactic treatment - chemoprophylaxis among the pregnant women who exposed to the confirmed case.

So are those treatments when we recommend to give to the treatment among these pregnant women? So are there any difference among their different trimester period?

Denise Jamieson: So the first question is the national hospitalization rate I think you were asking about pregnant versus non-pregnant women. We were able to report the hospitalization rates for the first month of the outbreak. However after that because the states went to aggregate reporting we are unable to continue to report those rates.

So the rate of hospitalization among pregnant women was higher in the first month and that's consistent with what we would expect based on both

seasonal influenza and prior pandemics. But we can't say that we have great data after the first month.

The second question was about treatment recommendations. So in terms of the...

Janet Cragan: By trimester.

Denise Jamieson: ...oh by trimester. I think she also asked about the - overall treatment we're recommending because of the systemic absorption that pregnant women be treated with oseltamivir preferentially for five days just as the general population.

In the post exposure prophylaxis what's different is the pregnant women should be considered for post exposure prophylaxis just like other high risk groups. And for that we are recommending zanamivir as first-line treatment for 10 days again mostly because of - in this case less systemic absorption.

However, you know, because of its inhaled route of administration women with asthma or other respiratory conditions may not be candidates. And oseltamivir is certainly another good option.

And again depending on the specific clinical situation you may or may not want to recommend post exposure prophylaxis.

Question cont'd: Okay so for the treatment there's any difference but because of the pregnant women are in a different period of trimester?

Denise Jamieson: No...

Question cont'd: Oh okay.

Denise Jamieson: We have not - making different recommendations by different trimester.

Question cont'd: Okay great. Thank you.

Denise Jamieson: And we've seen severe disease in all trimesters.

Question cont'd: Okay.

Denise Jamieson: Although we know from seasonal influenza that, you know, you would expect greater complications as the pregnancy progressed so the worst complications in the third trimester, second trimester then first trimester although the cases have been distributed across all trimesters.

Question cont'd: Okay great. Thank you.

Coordinator: Next question, your line is open.

Question: Hi and thank you for taking my call. I still do have a question. I know that we haven't finalized the vaccine as of yet but assuming the pregnant woman will need to take both the seasonal flu and the H1N1 flu vaccine my practitioners were asking can these be taken at the same visit and if not if there's a wait in between?

Denise Jamieson: Yes, that hasn't been determined yet. We don't have that information yet.

Question cont'd: Okay and the follow-up was is there any thought into - again with this problem of trying to keep healthcare workers that are at high risk out of that

area, is there any thought to prophylactically treating like say an ER nurse who may or may not know if she's been in contact with it?

Denise Jamieson: Yes that's part of what I was getting at when I mentioned the post exposure prophylaxis can be considered. It really depends on the exposure, you know, your index of suspicion in terms of how risky you think the exposure was and whether or not it's an ongoing exposure. You know, if it's a discrete exposure that you can provide prophylaxis to cover that exposure I would view that differently as ongoing exposure of healthcare provider.

Question cont'd: Right. And just one more follow-up again with the vaccine, I mean, we're really trying - we're in a very rural area and trying to get the word out; we have a very poor compliance rate with people taking the flu vaccine especially in pregnant women.

And I wondered if we knew about how soon that that information would be in there so we can try and start pumping that information out there?

Janet Cragan: I don't think we know for certain yet. There are vaccine trials that are being conducted at present. But what those are going to show how soon and how soon after that recommendations will actually be formulated I'm not sure we know. But we expect it will be after the start of the fall flu season.

Question cont'd: Okay thank you.

Coordinator: Next question, your line is open.

Question: Hi, thanks for taking my call. I'd like to know if there are any discussions or planning going on to provide guidance on using out of hospital birth settings as a means of preventing (unintelligible) infection of moms and newborns -

healthy moms and newborns when a hospital in a given locality or region is inundated with the virus? And what type of guidance you might be able to give us on that?

Denise Jamieson: So that was one of the issues that came up, you know, alternative sites for well pregnant women to deliver. And just to mention there was a meeting that was held in April of 2008 when we tried to talk about some of these issues in advance. And those proceedings are now published in the American Journal of Public Health - that was a meeting of experts.

And basically we drew from the SARS example where it's important to have a system in place in case of a bad flu season where pregnant women and ill women are separated and whether that be separated, you know, there are a variety of mechanisms depending on the community that could make that happen.

And I think we have a lot to learn from the SARS experience of - from Canada and Hong Kong and other places that successfully were able to separate out well women from ill women all of whom need access to safe delivery services. So it really need to be individualized at the community level.

And obviously we know more about transmission of influenza than we knew about transmission of SARS.

Janet Cragan: So I think that the kind of thing that hospitals in their own pandemic planning would hopefully take into consideration when looking at pregnant women.

Question cont'd: Okay thank you.

Coordinator: Next question, your line is open.

Question: Oh I'm sorry I didn't have a question.

Coordinator: Okay I'll remove your question, one moment. The next one, your line is open.

Question cont'd: Hi. You've pretty much answered my question but I guess I don't know if there's any clarification on this whole issue around high risk assignments. You know, I know obviously if we're talking about a respiratory therapist and we're talking about direct patient secretions then obviously that's high risk.

But, I mean, it could be as simple as working in a pediatric setting or a college setting or a school setting. So I guess I'm just looking for a little bit more clarification around healthcare workers and what is kind of considered to be a high risk assignment. Thank you.

Denise Jamieson: Thanks. So right now the guidance states that pregnant women who will likely be in direct contact with influenza patients should consider reassignment. But in earlier versions we did try to provide - try to separate out higher risk versus lower risk exposures.

And I think that's, you know, again, based on really no evidence it's hard to separate out those issues and decide what is a high risk exposure and a low risk exposure.

And so that's where I think hospitals are really going to need to look at, you know, staffing needs and burden of disease and the type of exposure and come up as they start to develop their pandemic influenza plan really decide in their setting how they are going to implement this guidance.

Janet Cragan: And I think this may vary somewhat depending on how widely H1N1 is circulating in a specific community and that can vary in different areas. And that's one thing to take into consideration when looking at these things and the likelihood of exposure.

Question cont'd: Thank you.

Coordinator: Next question.

Question: Hi. I just wanted clarification on how long does the mother who's suspected or confirmed H1N1 need to wear a mask and all these things when she's in close contact with her baby?

Denise Jamieson: So the recommendation is that for seven days, you know, wear a mask for seven days after the onset of symptoms or symptom-free for 24 hours.

Question cont'd: Okay thank you.

Coordinator: Next question, your line is open.

Question: Yes, thank you for answering our questions. On the recommendation of giving seasonal influenza vaccine to pregnant women I'm sure a lot of my patients will be asking me is that particular vaccine effective against the H1N1 virus as well?

Denise Jamieson: No its' not. The specific seasonal influenza vaccine is not thought to have any efficacy against the novel H1N1.

Question cont'd: So in the event there is a vaccine that comes out for the H1N1 we would definitely need to recommend both vaccines to a pregnant patient?

Denise Jamieson: Yes, pregnant women it would be recommended that they be vaccinated against both the seasonal influenza as well as the novel influenza.

Question cont'd: Okay thank you.

Coordinator: Next question.

Question: Am I on or muted?

Denise Jamieson: We can hear you.

Question cont'd: Okay. How are you? Thank you for this call. This has been very beneficial. Tied into a question a couple minutes ago we have a large county hospital, about 5000 births a year. In the last few weeks we've had several women admitted simply to await their rapid testing results.

Is there any plan for guidance as far as what would be appropriate admission criteria? Because on one hand we want to balance identifying those women at risk for true respiratory and other complications and yet the other hand a woman who could otherwise be ambulatory might pose a lot of risks to exposing staff and other pregnant patients.

Denise Jamieson: I think you bring up a really good point. And no we do not have guidance about sort of appropriate thresholds for hospitalization of pregnant women with expected influenza.

You know, I think it's hard to say, I mean, I can say that what has surprised me is that relatively healthy pregnant women have presented with what seemed like relatively mild disease and gone home and then come back three

or four days later in acute respiratory distress and really quite severely ill at that point.

And when and how to intervene - when and how to intervene I'm not sure we at CDC certainly don't have those answers. But I think it's an important point that we need to think more about and continue to collect information about these cases so that we can have a better idea of whether or not this disease progresses differently than what we know about seasonal influenza.

Question cont'd: We're aggressive with starting women who are suspicious for disease on meds and even without getting the cultures back. And I'm just curious for the women you're describing who initially presented then returned several days later were they on antivirals?

Denise Jamieson: They were not. And that's a good point. For the most part what I've described has been among women who were thought to have mild disease and there was some reluctance to start antivirals because she was pregnant and then returned ill.

Janet Cragan: So you're absolutely right, the focus of our guidance has been to initiate therapy rapidly in early - in pregnant women with suspected H1N1.

Question cont'd: For all listeners I've just to give props to their Website, it's a really wonderful resource. And it provide a lot of the down to Earth nitty gritty questions that have been coming up.

Denise Jamieson: Thank you for saying that.

Coordinator: Next question.

Question: Thanks very much. This question is for Peggy. And I'm a state epidemiologist so I'm interested in this call-in line that you're setting up. And I didn't hear if that was September or December that you wanted to start having people submit data on pregnant women who are admitted to the ICU?

And I was just wondering if you could describe a little your plans for sharing that information back with states or localities. Thanks very much.

Peggy Honein: Yes, no happy to clarify. It is still under development but we're hoping to get some kind of hotline set up in the next couple of weeks. So we hope it will happen very rapidly. And definitely part of that plan will be involvement of state and local health officials and discussing how best that can be set up.

And then if we do receive reports directly from healthcare providers making sure that the information is fed back to the appropriate state health department so that we keep those officials in the loop on any cases from their area that have been reported to CDC.

We definitely want to involve them. So I think the date that I provided though of September was referring to the academic effort to monitor antivirals and vaccination for any adverse events among pregnant women. And there will be a separate call-in number to the academic setting for that.

Question cont'd: Oh thank you for clarifying that. Could I ask one last question?

Peggy Honein: Certainly.

Question cont'd: In the discussion about the reassignment of healthcare workers who are pregnant in some of the other conference calls I'm on I know that people in the States are being pushed pretty hard to get information out about why there's a

difference in the healthcare workers that may be exposed to a person with influenza seasonal or novel and reassigning them compared to the teacher since so many of the outbreaks and activities are in school-age populations.

And I was just wondering if from your group's perspective you discussed this and have some communication messages that we can share back with teacher groups to help lessen their worries that they're being treated differently and at lower risk than when they're dealing with, you know, kids at school who may be sick?

Denise Jamieson: It's a good point and this did come up in our discussions when we thought about this during the meeting I mentioned in April of 2008. And there was discussion about school teachers and other groups. I think the difference is the - and certainly women are going to be, you know, lots of women are going to be exposed.

And in fact pregnant women often have other children, they may be exposed to a greater number of young children and others who may be at risk of having influenza. So it's complicated.

I think the difference we felt was that healthcare providers working in a hospital setting may have very risky exposures to very sick people with high viral loads who are viremic and even like I mentioned in the secure unit setting who are suctioning viremic patients.

So we felt that qualitatively it was a different risk level.

Question cont'd: Yes, I think as one of the other questioners was asking earlier this is where, you know, any further guidance on the healthcare workers is useful because that's a broad range of individuals.

And, you know, I can imagine some school teachers might be more exposed than some healthcare workers but of course we've got, you know, a Venn diagram with an area of overlap and areas that don't touch each other. So thanks very much. This is a great call.

Denise Jamieson: Yes and we appreciate your comments. This has been an area that we struggled with. And this is interim guidance. And I think we need it to constantly be considered, you know, as the flu season begins and as things evolve we need to constantly try and better refine this guidance.

Coordinator: Next question.

Question: Yes, can you hear me?

Denise Jamieson: Yes.

Question cont'd: Thank you. We want to know if a mother refuses to be separated from her newborn what our approach should be short of course encouraging her and informing her, educating. But if she refuses then should we do special treatment for the baby, etcetera?

Denise Jamieson: You bring up a great point. And I mean this - the woman should be informed of what we know and what we don't know and what the recommendations are and then absolutely it's her decision regarding, you know, the risks and benefits of having her separated from her baby.

So I don't at all think that this should be interpreted as absolute so I mean I think it has to be a discussion with her and shared with her the recommendations and what evidence are behind the recommendations.

And there's not...

Question cont'd: Should we use tamiflu for the baby, I mean...

Denise Jamieson: Yes, no, just routine precautions would be recommended.

Question cont'd: Really?

Denise Jamieson: Wash your hands, a mask, cover your cough, clean clothes.

Question cont'd: Okay. Well we've discussed in the event this should happen and we are anticipating - we do 6000 deliveries a year that it definitely is going to happen that we would continue to provide care by rooming in which is not our pure model if you will, we encourage rooming in but we surely go back and forth to the nursery.

And if this has occurred we don't anticipate that we would even be able to take that baby back to the central nursery from an exposure standpoint and all the issues that it creates are significant including if it's a male child and needs to be circumcised before going home, etcetera, etcetera.

Denise Jamieson: Yes, you definitely bring up good difficult issues.

Janet Cragan: And if I can just add that prophylaxis in infants less than three months old is not recommended unless there's a really compelling, you know, life threatening reason to do so.

Question cont'd: We are the organization that had an exposure in our NICU that was quote/unquote questionable in North Carolina. You know, we had the one

hospital in North Carolina that had an exposure that chose not to treat in their NICU. We did, we're still in collaboration with the CDC to research that group as a cohorted group.

So I know we're looking at all that research but I will admit that that is us and that was our situation. As we still have six remaining babies in our NICU today. Of course none of the tests on those babies turned out to be positive, we tested them all and prophylactically treated them with collaborating with the CDC.

Janet Cragan: Great, that's good to know. And as we said these are interim guidelines that are going to be developing over time as new information like your experience is accumulated.

Question cont'd: Thank you so much. Any more questions? Thank you.

Peggy Honein: You're most welcome.

Coordinator: Next question, your line is open.

Question: Yes, two questions. I wanted to know what is the false positive rate for the rapid influenza test?

Denise Jamieson: So I don't have the...

Question cont'd: I'm sorry, false negative rate.

Denise Jamieson: We don't have the false negative rate for the rapid test. And of course, you know, your predictive value is going to depend on the prevalence in your population. But the issue basically is are the rapid tests good enough to be

used in the context of ruling out influenza in a pregnant woman and the answer is no at this point.

So if a woman comes in - a pregnant woman comes in, has influenza-like illness and the rapid test is negative you still need to go ahead and start antivirals.

Peggy Honein: And we - some of the case reports that CDC has received of severely ill pregnant women include women who initially had negative rapid test results.

Question cont'd: So is there any reason to perform the rapid test?

Denise Jamieson: You know, at this point the rapid test at least in this setting of a pregnant woman are not good enough to be used for clinical decision making.

Question cont'd: Okay.

Janet Cragan: I mean it can be reassuring if it comes back positive but we would not recommend changing the course of treatment prior to that.

Denise Jamieson: I mean it may help in counseling the pregnant woman if you've got a positive test.

Janet Cragan: Right.

Denise Jamieson: I'm not sure how it helps you if you've got a negative test.

Janet Cragan: Exactly.

Question cont'd: Right. And we just recently had a case where a mother delivered and 12 hours later started developing symptoms. Well she had already been with her newborn breastfeeding her newborn. And at that point we were deciding well should we separate her and her newborn or then just cohort the two together since she's already been exposing the newborn.

Denise Jamieson: And what did you decide?

Question cont'd: We gave mom the risks and benefits and she decided to keep the baby with her.

Denise Jamieson: Yes, I mean, I would think that at that point you'd want to, you know, emphasize the standard precautions and at that point not separate baby from mother.

Question cont'd: Good, thank you very much.

Alycia Downs: I want to thank our presenters for providing our listeners with this information. I'd also like to thank our participants for joining us today. If you have any additional questions or comments please send an email to coca@cdc.gov. That is coca@cdc.gov.

We will probably not be able to reply to individual inquiries but we will use your questions and comments to inform future COCA calls and possibly guidance.

The recording of this call and the transcript will be posted to the COCA Website emergency.cdc.gov/coca as soon as they become available.

Please remember to keep an eye out for future COCA conference calls on this topic as well as previous calls that are archived to our Website. Please remember to check the CDC H1N1 flu site regularly for any updated information or guidance, cdc.gov/h1n1flu. And if you're signed up for COCA you should receive any updated or guidance in our email updates.

Thank you again for participating and I hope everyone has a wonderful day.

Coordinator: Thank you for participating in today's conference. All participants may disconnect at this time. Speakers, please stand by.

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