

2009 H1N1 Influenza: Pregnant Women and Newborns

Sonja Rasmussen

Wanda Barfield

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Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode. During the question and answer portion please press star 1 to ask a question. I would now like to introduce your speaker, Alycia Downs. You may begin.

Alycia Downs: Thank you. Hello and welcome to today's COCA conference call, 2009 H1N1 Influenza Pregnant Women and Newborns. We are very excited to have CDC subject matter experts present on this call. We have with us today Dr. Sonja Rasmussen from the Division of Birth Defects and Developmental Disabilities and Dr. Wanda Barfield from the Division of Reproductive Health both with the Centers for Disease Control and Prevention.

We are using a PowerPoint presentation that you should be able to access from our Website. If you have not already downloaded the presentation please go to emergency.cdc.gov/coca. Again that's emergency.cdc.gov/coca. Click on Conference Call Information Summaries and Slide Sets. The PowerPoint can be found under the call-in number and pass code. If you have any issues locating the PowerPoint please send an email to coca@cdc.gov, again that is c-o-c-a@cdc.gov and they will help you locate the PowerPoint.

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CDC, our planners, and our presenters wish to disclose they have no financial interests or other relationships with manufacturers of commercial products, suppliers of commercial services, or commercial supporters. This presentation does not involve the unlabeled use of a product or product under investigational use. There is no commercial support. I will now turn the call over to Dr. Rasmussen.

Sonja Rasmussen: All right so we need to go through a couple of slides here. The first slide will be the next one, right there, so the first slide should say 2009 H1N1 Influenza Pregnant Women and Newborns Outline of Presentation.

It's my pleasure to talk with you today about 2009 H1N1 influenza and pregnancy. I will be providing some initial background on pregnant women as an at risk population for severe complications from influenza both seasonal and pandemic on H1N1 in general and the virus's effects on pregnant women, then briefly review CDC's guidelines related to testing, treatment, and vaccination. Dr. Barfield will be discussing CDC guidelines related to infection control and care of the newborn. Next slide please.

I'd like to begin with some background information we knew before the current outbreak. We have been making preparations for an influenza pandemic with specific consideration for pregnant women as an at risk population for three reasons.

First, physiologic changes occur during pregnancy that put women at increased risk for certain infections including influenza. These changes include alterations in the immune system with a shift away from cell mediated immunity and towards (humeral) immunity, and changes in the respiratory and cardiovascular systems including decreased lung capacity, increased heart rate, increased stroke volume, and increased oxygen consumption.

These changes can result in pregnant women being more severely affected by certain viral pathogens. In addition, data from previous pandemics, in particular those of 1918 and 1957, showed increased morbidity and mortality among pregnant women. And finally, pregnant women have been shown to be at increased risk for complications from seasonal influenza. Next slide please.

This slide you should see a figure with it says Risk of Hospital Admission at the top. It shows evidence for increased risk for influenza associated complications among pregnant women. These authors used data from a population based cohort study in Nova Scotia for the years 1990-2002 and compared rates of hospital admissions for respiratory illness during the influenza season and each trimester of pregnancy, and you can see the three trimesters on the X axis, with rates during the year before pregnancy.

The authors found an increased risk of hospital admissions in all three trimesters of pregnancy with a rate ratio of 1.7 in the first trimester, and you can see this was a borderline statistical significance compared to results in the second and third trimester which were statistically significant. You can see that during the first trimester the confidence intervals overlap one.

The risk was 2.1 in the second trimester and 5.1 in the third trimester meaning that women in their third trimester are five times more likely to be admitted to

the hospital for respiratory illness during influenza season than during the year before pregnancy.

This figure focused on women with no comorbidities like asthma, heart disease, etc. that would increase their risk for flu complications. When women with comorbidities were analyzed the risks during pregnancy were even higher. Next slide please.

Other reasons why pregnant women were considered to be an at risk population relates specifically to the fetus. The effects of influenza on the fetus in particular of a new influenza virus like H1N1 are unknown and difficult to predict. In seasonal flu viremia is believed to occur infrequently and placental transmission appears to be rare. However, that may not be the case with novel influenza strains.

We don't have data on this related to H1N1 but for H5N1, the Avian or bird flu virus, transmission across placenta to the fetus has been demonstrated in a single case report. In addition, even when the virus is not transmitted across the placenta the fetus can be affected.

For example, fever often occurs in influenza and has been associated with adverse outcomes including neural tube defects such as spina bifida and anencephaly when the fever occurs around the time of neural tube closure. Fevers later in pregnancy have been associated with some other adverse outcomes. Next slide please.

Next I'm going to focus on what is known about 2009 H1N1 virus and these are data from the New England Journal of Medicine paper that was published a few months ago that summarized data on the first 642 affected cases in the United States. Next slide please.

In April 2009 CDC identified a novel influenza A H1N1 virus in two children from California and since that time the virus has spread rapidly across the United States and the world. Illness in these cases resulted from infection with a quadruple reassortment virus with genes from the human, Avian, and two types of swine. These viruses were sensitive susceptible to the oseltamivir and zanamivir and resistant to amantadine and rimantadine. And with only a few exceptions this continues to be the case.

In the initial 642 confirmed cases described in the New England Journal of Medicine article, the median age was 20 years with a range of 3 months to 81 years with 60% of those infected being 18 years or younger. Next slide please.

In the United States most of these early cases were characterized by self-limited, uncomplicated, febrile respiratory illness similar to seasonal flu. In addition to fever, patients had cough, sore throat, rhinorrhea, headache, and myalgia. One difference was that the rate of vomiting or diarrhea was higher than for seasonal influenza with about 38% of these initial patients showing vomiting or diarrhea. Next slide please.

Next I'd like to focus on what we know about pregnant women with 2009 H1N1 influenza and this information is from a paper we published in Lancet earlier this year. However, information that we have collected since that time has been consistent with these early data. Next slide please.

In that paper we described 34 confirmed or probable cases of 2009 H1N1 influenza in pregnant women who reported during this time period April 15 through May 18, 2009 in the United States. Women were infected in all three trimesters of pregnancy and manifestations were similar to those seen in the

general population although the frequency and shortness of breath was higher among pregnant women than in the general population.

Of the 34 women reported in the Lancet paper, 32% were admitted to the hospital. And from the time period of April 15 to June 16 there were six deaths. This was 6 of the 45 deaths initially reported to CDC during that first two months time period. Next slide please.

We examined hospital admission rates for pregnant women and compared those to the general population. We found that the hospital admission rate among pregnant women was more than four times the rate among the general population and you can see that was a statistically significant finding. Next slide please.

This slide summarizes data on the six deaths that were reported in the Lancet paper. The key points here are that these women were generally healthy. You can see that many had no underlying medical conditions or medical conditions that were mild in nature, mild asthma that did not require daily meds, psoriasis, obesity and Factor V Leiden deficiency.

The women's ages spanned from 20 to 33 years and women who died were infected during all three trimesters of pregnancy ranging from 11 to 36 weeks gestation. Next slide please.

All the women who died appeared to have primary viral pneumonia with subsequent development of acute respiratory distress syndrome or ARDS requiring mechanical ventilation. Five of the six women delivered by cesarean delivery at 26 to 36 - 27 to 36 weeks gestation and 3 of these were performed in the ICU or in the emergency department. There was also a fetal loss at 11 weeks.

And the length of time from symptom onset to receipt of antiviral medications ranged from 6 to 15 days with a median of 9 days. The length of time from presentation for medical care until receipt of antiviral treatment was 2 to 14 days with a median of 4.5 days and both of these suggested a delay in institution of antiviral treatment for these women. Next slide please.

Some updated information on deaths among pregnant women. Our more current data through August 21 show that 28 pregnant women in the United States have died among a total of 484 H1N1 deaths. That means that pregnant women account for 6% of deaths from H1N1 in the United States and it's important to know that pregnant women make up only about 1% of the general population. This continues to suggest an increased rate for death. Next slide please.

And now I will be discussing the current CDC guidelines in three areas -- testing for 2009 H1N1 influenza; antiviral treatment and prophylaxis; and then seasonal and 2009 H1N1 influenza vaccination. Next slide.

First testing. Four types of diagnostic tests are available. Rapid influenza diagnostic tests that are based on antigen detection methods can provide results within a few minutes but their sensitivity for 2009 H1N1 virus is poor ranging from 10% to 70%. In addition, these tests are unable to distinguish between 2009 H1N1 influenza and other influenza A viruses.

Direct and indirect immunofluorescence assays performed in some hospital labs are also based on antigen detection and typically take about two to four hours for results. While the sensitivity of these tests is somewhat better than the rapid tests ranging from 47% to 93%, the sensitivity is still not 100% and

these tests are also unable to distinguish 2009 H1N1 virus from other influenza A viruses.

The low sensitivity of these tests means that a negative test does not exclude 2009 H1N1 virus infection. Just to repeat this key message, it is critically important that treatment is not delayed based on a negative rapid test.

Tests that can distinguish 2009 H1N1 virus infection from other viruses include nucleic acid amplification tests including real time reverse transcriptase polymerase chain reaction or rRT-PCR which depends on the detection of influenza specific RNA and a test for - that looks at viral isolation in tissue culture.

Results from these tests are not available in time to guide clinical decision making. For rRT-PCR processing time from specimen collection until results are available is typically 48 to 96 hours and for viral isolation processing time is 2 to 10 days. Next slide.

Now on to treatment, people with 2009 H1N1 who are healthy, not pregnant, between the ages of 5 and 65 years who have mild illness may not need treatment and that's an important comment. However, because of the severity of illness in pregnant women, treatment with an antiviral medication is recommended in women who have suspected or confirmed influenza regardless of trimester of pregnancy.

Treatment is also recommended for women who are up to two weeks post partum including following pregnancy loss so regardless of how the pregnancy ended up to two weeks after the pregnancy ends. Treatment should not be delayed because of a rapid influenza diagnostic test or because of the

inability to test or while waiting for test results. If influenza is suspected the woman should be treated. Next slide please.

The drug of choice for pregnant women with confirmed or suspected 2009 H1N1 influenza is oseltamivir or Tamiflu because of its systemic absorption. The dose is 75 milligrams by mouth twice a day for five days. Based on data from studies of seasonal influenza, benefits are expected to be greatest if the medication is started within 48 hours of symptom onset.

However, studies of seasonal influenza indicate benefits for hospitalized patients even if treatment is started more than 48 hours after onset. Thus, in this high risk group of women - of pregnant women, antiviral medications are recommended even for women who present for care more than 48 hours after illness onset.

Oseltamivir or Tamiflu and zanamivir or Relenza are both FDA pregnancy category C medications meaning that there are no adequate and well controlled studies in pregnant women. However, the available data on these medications suggest that they are not human teratogens. Given the severity of 2009 H1N1 influenza in pregnant women we believe that the benefit of treatment outweighs the potential risk.

Fever during pregnancy has been associated with adverse pregnancy outcomes in some studies. Thus, fever in pregnant women should be treated and acetaminophen appears to be the best option for treatment of fever during pregnancy. Next slide please.

Rapid access to antiviral medications for pregnant women is essential. Healthcare provider actions that might reduce delays in treatment initiation include informing women of the signs and symptoms of influenza and of their

need for early treatment; ensuring rapid access to telephone consultation and clinical evaluation; and considering empiric treatment of patients at higher risk for influenza complications based on telephone consultations - contact, telephone contact. Next slide please.

Post-exposure antiviral chemoprophylaxis can be considered for pregnant women who are in close contact with persons with suspected or confirmed 2009 H1N1 infection. The drug of choice for prophylaxis is probably zanamivir because of its limited systemic absorption.

However, respiratory complications that may be associated with zanamivir because of its inhaled route of administration needs to be considered especially in women at risk for respiratory problems such as women with asthma. For these women oseltamivir is a reasonable alternative.

Recommended duration of chemoprophylaxis is ten days after the last known exposure. Both monitoring and early treatment is an alternative to chemoprophylaxis after suspected exposure. And it's important to note that clinical judgment is a key factor in decisions about treatment in prophylaxis. Next slide please.

For post exposure chemoprophylaxis purposes close contact is defined as having cared for or lived with a person who is a confirmed, probable, or suspected case of influenza or having been in a setting where there was a high likelihood of contact with respiratory droplets and/or body fluids of such a person. Examples of close contact are sharing eating or drinking utensils and physical examination. Next slide please.

Now I will discuss issues related to influenza vaccines. Seasonal influenza vaccine is recommended for people at increased risk of severe infection and

that for many years has included pregnant women, women who will be pregnant during the influenza season.

The Advisory Committee on Immunization Practices or ACIP as well as the American College of Obstetricians and Gynecologists have recommended seasonal influenza vaccine for pregnant women for many years and this includes all pregnant women in any pregnancy trimester. Next slide.

In addition to the vaccine's protection of the mother, a recent clinical trial showed that the influenza vaccine given during pregnancy decreases the risk for influenza in infants up to six months of age, infants who are not able to get the influenza vaccine themselves. In this study influenza vaccine during pregnancy reduced proven influenza illness by 63% in infants up to six months of age. Next slide please.

The ACIP has also provided guidance for use of the 2009 H1N1 vaccines. As part of that guidance the committee listed five initial target groups for vaccination efforts, and these included pregnant women; household contacts and caregivers for children younger than six months of age; healthcare and emergency services personnel; children and young adults 6 months to 24 years; and persons age 25 to 64 years who have medical conditions that put them at higher risk for influenza related complications.

In addition ACIP established priority for a subset of persons within the initial target group and the important thing to note here, this was when vaccine availability was unable to meet the demand and pregnant women continued to be in the list of priority group. Next slide please.

The need for the 2009 H1N1 vaccine is based on the data that we presented earlier, that pregnant women who get 2009 H1N1 are at higher risk for

hospitalization, severe illness, and death. And of note, seasonal flu vaccine is not expected to protect against 2009 H1N1 influenza.

There are three different vaccine types. A live, attenuated vaccine, or nasal spray is not licensed for use in pregnant women but can be used in post partum women including while they're breast feeding. The inactivated vaccine, the flu shot, is available in two different formulations -- as a multi-dose vaccine or as a prefilled single dose vaccine which is preservative-free.

Either of the formulations of inactivated vaccine are recommended for use in pregnant women. Although there is no evidence that the preservative used, thimerosal, is harmful, a thimerosal-free formulation is available as an alternative for pregnant women.

Of note, there are no adjuvants such as squalene in either the 2009 H1N1 or seasonal flu shot used in the United States. Adjuvants are agents that are sometimes added to a vaccine to make it more effective and they are added in some other countries but not in the United States.

H1N1 vaccine -- I'm sorry, next slide -- can be given at any time during pregnancy. In addition, women who are post partum are also recommended to receive the vaccine as are all household contacts and caregivers for infants younger than six months of age. H1N1 vaccine is recommended even for women who have previously had suspected influenza since many different infections can cause influenza-like symptoms.

Seasonal flu and 2009 H1N1 vaccines may be administered on the same day but they should be given at different sites such as one shot in the left arm and the other in the right. Next slide please.

Seasonal influenza vaccine has been used for many years in pregnant women with an excellent safety record. A recent paper by Tamma and colleagues was published in the American Journal of Obstetrics and Gynecology and it summarized 11 studies published on the safety of seasonal influenza vaccine during pregnancy. None of these studies identified maternal or fetal problems with seasonal influenza vaccination.

The 2009 H1N1 influenza vaccine is made in the - used in the same process as in facilities that are used to make seasonal influenza vaccine, and therefore safety is expected to be similar to that for seasonal flu vaccine. Now I'll turn the presentation over to Dr. Wanda Barfield.

Wanda Barfield: Thank you Dr. Rasmussen. Good afternoon everyone. I'm Dr. Wanda Barfield and I will continue the discussion today on CDC's most recent guidance on considerations regarding 2009 H1N1 in intrapartum and postpartum hospital settings.

This newly revised guidance was issued on November 12, 2009 and replaces considerations regarding novel H1N1 flu virus in obstetric settings dated July 6, 2009. It applies to intrapartum and postpartum hospital settings for uncomplicated term deliveries and includes guidance upon discharge to home. This guidance does not include information on the care of the mother with suspected or confirmed H1N1 with severe illness or the care of the sick or premature newborn delivered as a result of severe maternal illness.

This guidance also incorporates feedback from relevant professional organizations involved in the care of mother and newborns during the perinatal period. This recent guidance is also consistent with updated CDC 2009 H1N1 infection control guidance dated on October 14, 2009. Lastly, this guidance considers the current design and staffing of labor, delivery, recovery,

and postpartum wards also known as LDRP wards which makes the recommendations easier to implement. Next slide please.

Prior guidance dated July 6, 2009 stated that the mother who has influenza-like illness at delivery should consider avoiding close contact with her infant until the following conditions have been met -- she has received antiviral medications for 48 hours; her fever has fully recovered; and she can control coughs and secretions.

Meeting these conditions may reduce but not eliminate the risk of transmitting influenza to the baby. Before these conditions are met the newborn should be cared for in a separate room by another person who is well and the mother should be encouraged and assisted to express her milk. Also, the infant is considered as potentially infected. However, since the posting of this guidance substantial feedback has been obtained from a variety of professional organizations. Next slide please.

The professionals who have contributed input to this guidance include external experts in infection control, influenza, obstetrics and gynecology, neonatology, pediatrics, human lactation, and immunobiology. Professional organizations included the American Academy of Pediatrics, Academy of Breast Feeding Medicine, and International Lactation Consultant Association. They have all provided important context.

In addition, feedback during other COCA and professional conference calls, professional meetings, as well as individual emails and phone calls have been extremely helpful. Next slide please.

Specific concerns raised by the nation's leading experts in the pediatric specialty of neonatal and perinatal medicine including the executive members

and regional representatives of the American Academy of Pediatrics, Perinatal Section, and members of AAP Committee of Fetus and Newborns include the following.

The configuration and staffing of current LDRP and newborn nurseries and isolation protocols made the prior guidance difficult to implement, particularly in the scenario of numerous admissions and the need for increased surge capacity. Also as mentioned by Dr. Rasmussen, there is limited evidence for infection of the fetus. This may influence the extent of infection control necessary for the newborn at delivery.

Separation of the mother and infant was a significant concern raised by many professional and lactation specialists including the concern of breastfeeding disruption and lactation failure. However, many of these experts felt that breast milk expression could be supported with appropriate expertise by lactation consultants.

Lastly, concerns that the newborn could be exposed to other potentially infected individuals either in the hospital or at home was a significant concern. This could include hospital staff, visitors, and other patients and/or siblings. Next slide please.

It's important to note that the current design of the LDRP rooms in many maternity hospitals need to be incorporated in the strategy to protect pregnant women and newborns from 2009 H1N1 infection, particularly in the maximum surge capacity scenario. Next slide please.

In considering the modes of transmission of 2009 H1N1, the first potential consideration is that of the mother to the fetus. However, currently for 2009 H1N1 virus there has been no confirmed reports of placental transmission.

However, it may be possible for this to occur in severe maternal illness with novel viruses.

In 2007 Gu et al. published a study in the Lancet which looked at a case of a maternal death from H5N1 in a woman in her second trimester of pregnancy. In addition to severe viral infection in the mother there were viral elements found in the placenta, mononuclear sites of the fetal bloodstream, (unintelligible) of the fetal lung, and (cut first) cells of the fetal liver. Next slide please.

Although we have yet to see placental transmission for H1N1 infection, we do understand the potential modes of transmission to the newborn starting right after delivery. Transmission of H1N1 virus is highly possible for the mother with H1N1 influenza and fever.

Small particle aerosols from the respiratory secretions of an infectious mother could be transmitted to a newborn in close vicinity. Virus contained in respiratory droplets from coughing could contact newborn mucosal surfaces and cause infection. In addition, newborn mucosal surfaces could be inoculated by the infant him or herself or by inoculation from caregivers. Next slide.

The newborn is a vulnerable target for infection due to its immature immune system. Newborns have less protection from the possibility of droplet infections from infected individuals and of course newborns and infants are in need of constant close contact for care, nurturing, and feeding.

It is important to note that potential exposure to 2009 H1N1 can occur from a variety of other individuals in the postpartum period to include infected caregivers, healthcare providers, or siblings particularly during a viral

(prodrome) when individuals are asymptomatic and not aware that they are infectious.

Unfortunately it is not feasible to provide vaccine to newborns or infants less than six months due to their inability to amount an adequate immune response to vaccine. Also, chemoprophylaxis is not currently recommended for infants less than three months as the effects are unknown. Next slide please.

Data on seasonal flu indicates that young infants are at increased risk of death due to infection. This slide shows a graph of the results of a national assessment of pediatric mortality associated with laboratory confirmed influenza that was conducted during the 2003-2004 influenza season.

This study by Bhat and colleagues published in the New England Journal of Medicine in 2005 found that children age less than six months have the highest mortality rate of 0.88 per 100,000 children compared with other pediatric age categories which had mortality rates ranging from 0.11 per 100,000 for those age 5 to 17 years to 0.77 per 1000 for children aged 1 year.

Because H1N1 infection in the pregnant woman during delivery is an illness for which a newborn would not have time to receive any passive antibodies to the mother -- next slide please -- CDC has chosen a conservative approach for the care and isolation of the mother and newborn.

In general the considerations for infection control in intrapartum and postpartum hospital settings should keep newborns separated from ill caregivers and providers and avoid transmission from infected infants to uninfected or critically ill infants, particularly those infants in the neonatal intensive care unit.

The consideration of flexibility is an important one given the current labor, delivery, recovery, and postpartum configuration of most maternity hospitals. Lastly, providers should have information for guidance upon discharge to the home setting where the newborn may actually be more vulnerable. Next slide please.

CDC's new guidance maintains a cautious approach that provides for flexibility based on hospital configuration, staffing, and surge capacity. The priority focus is to minimize the infant's risk of exposure to 2009 H1N1 virus via respiratory droplets.

Also, the new guidance considers the infant exposed rather than infected and provides more flexibility in the infant's location and care. CDC has also provided a two-step process for postpartum and newborn management which clarifies changes in precautions as the risk for infection via droplets diminishes. And as mentioned, this new guidance provides information for hospital discharge planning. Next slide please.

First I would like to discuss the care of the intrapartum mother with suspected or confirmed 2009 H1N1 virus from labor through recovery. A surgical mask should be placed on the ill mother during labor and delivery if tolerable. Ideally as soon as the mother with confirmed or suspected H1N1 virus has been identified, she should be treated with antiviral medication as soon as possible. There is no need to wait for laboratory confirmation and as Dr. Rasmussen mentioned rapid tests have low sensitivity.

As soon as the infant is delivered, temporarily separate the mother and infant by a distance of greater than six feet. The newborn infant should ideally be placed on an infant warmer to maintain thermal regulation. Once assessed as physiologically stable, the infant should be bathed early. Unless otherwise

clinically indicated the infant should be considered exposed and not infected.
Next slide please.

During the postpartum period the first step should be temporary separation. The mother should be placed in a single patient room with observation of infection control guidance. However, the newborn can accompany the mother and remain in her room if placed in an infant isolette. Other options include the placement in the mother's room at a safe distance to reduce droplet transmission.

One option includes a newborn bassinet with a curtain at a distance of greater than six feet. If this is not feasible for the newborn to remain in the same room as the mother the newborn can be cared for in the nursery with standard precautions if the infant is well. If the infant is ill and suspected to have H1N1 infection the infant should be placed in isolation with droplet and contact precautions. Next slide please.

During the postpartum period the healthy infant of a mother with suspected or confirmed 2009 H1N1 infection should be fed by a healthy caregiver. Mothers who plan to breastfeed should be highly encouraged and supported to provide breast milk or colostrum as an important source of nutrition and protection for the newborn. The mother would be able to initiate contact and direct feedings after she has one, been afebrile for 24 hours; two, received antiviral medication for 48 hours; and three, demonstrated that coughs and secretions can be covered or controlled. Next slide please.

In the second step of care during the postpartum period the mother with suspected or confirmed 2009 H1N1 influenza should continue precautions for a total of seven days after symptom onset and until symptom free for 24 hours.

CDC recommends that the mother should adhere to strict hand hygiene including frequent hand washing with soap and water. The mother should wear a face mask during close contact with her newborn to minimize the risk of droplet transmission. Lastly, she should use respiratory hygiene and cough etiquette when in the vicinity of her newborn. In addition, limit visitors in the hospital to those healthy persons necessary for the mother and newborn's emotional wellbeing and care. Next slide please.

With respect to newborn care, the infant should be considered exposed and not infected unless otherwise clinically indicated. It is not recommended that infants younger than three months of age receive prophylactic antiviral treatment due to the limited data on use in this age group. However, it can be used if the situation is judged as critical.

Antiviral treatment in cases of suspected 2009 H1N1 infection is authorized under the Food and Drug Administration's emergency use authorization for infants less than one year of age. The current weight based dose under FDA emergency use authorization for infants is 3 milligrams per kilogram BID for five days. Next slide please.

In order to prevent H1N1 transmission to healthy newborns in the home setting, the following recommendations have been included for discharge planning. Families should be instructed on the care of the newborn at home to include strict hand hygiene and cough etiquette.

Contact by all other ill persons with the newborn should be limited and avoided if possible. All caregivers of infants less than six months should obtain the 2009 H1N1 vaccine. This includes family members, day care providers, and siblings. Lastly, families should be educated on the signs and

symptoms of infant infection and steps to take if any are observed. Next slide please.

Additional CDC resources for the care of pregnant women can be found on the CDC Website. It is also important to note that this recent guidance as well as others will continue to be updated as new information becomes available. Next slide.

In summary, during an influenza pandemic pregnant women are expected to be a high risk population based on the experience with previous pandemics and with seasonal influenza. The data available thus far suggests that pregnant women are at increased risk for complications and death from 2009 H1N1 influenza. Next slide please.

Pregnant women should be informed about the signs and symptoms of 2009 H1N1 influenza. Pregnant women who present with symptoms consistent with influenza should be treated empirically with oseltamivir. Testing should not be used to inform treatment decisions.

Post-exposure prophylaxis with zanamivir or oseltamivir can be considered for pregnant women. Next slide. And regarding the vaccine, both seasonal and 2009 H1N1 influenza vaccines are recommended for pregnant women. 2009 H1N1 vaccine safety is expected to be similar to seasonal flu vaccine. Next slide please.

If a mother has suspected or confirmed 2009 H1N1 during labor and delivery, important steps can be taken in the hospital to protect the newborn from infection. Step one is to temporarily separate the mother and newborn in order to prevent droplet transmission to the newborn when the mother is most infectious. Step two is to implement precautions for the mother as well as

other household contacts to prevent droplet transmission to the infant. Next slide please.

Mothers with suspected or confirmed 2009 H1N1 should be encouraged and supported to provide breast milk and later breastfeed as it is the best protection for the newborn. Upon hospital discharge, counsel families on the ways to protect the newborn against H1N1 infection in the home.

And lastly, vaccinating pregnant women and caregivers of infants less than six months of age is the best prevention strategy against 2009 H1N1 infection. Next slide. I would like to thank the members of the audience as well as the National Perinatal Information Center Quality Analytic Service. Thank you.

Alycia Downs: All right we can go ahead and open the line up for a question and answer session.

Coordinator: Absolutely. If you would like to ask a question from the audience, please press star 1 and record your name. Your name is required to introduce your question. Again, star 1 and record your name. One moment while we wait for any questions to queue. One moment.

Again, a reminder, please press star 1 and record your name. Again, star 1 and record your name. Please press star 1 and record your name to ask a question. Our first question. Your line is open.

Question: I'm sorry, I don't have a question. I just was waiting to listen to the questions.

Coordinator: Your line is open.

Question: Are caregivers supposed to wear still N-95, is that correct?

Woman: Hello, can you just identify yourself again, sorry.

Question cont'd: Sure. The caregivers for the mothers that are suspected of having H1N1, are they still supposed to wear an N-95 mask when caring for the moms?

Wanda Barfield: We have another person on the line, Arjun Srinivasan.

Arjun Srinivasan: Hi, this is Arjun Srinivasan from the Division of Healthcare Quality Promotion. Yes that is correct. The recommendation for all healthcare personnel who are within six feet of a patient with suspected or confirmed H1N1 influenza do need to wear respiratory protection that's equivalent to an N-95 fit tested respirator.

However, that recommendation depends of course on the availability of respirators in the facility and so there are facilities that don't have adequate supplies and have shifted to what we call a prioritized use mode where the N-95 respirators are being used for high risk procedures like aerosol generating procedures and other healthcare workers are wearing surgical face masks.

So it depends on where your facility is in terms of respiratory equipment supplies but the - if the supplies are available the N-95 is the preferred recommended respiratory protection for healthcare workers.

Question cont'd: Thank you.

Wanda Barfield: Thank you Dr. Srinivasan.

Coordinator: Our next question, your line is open.

Question: Yes hello. So it's my understanding that mothers if they are suspected of having H1N1 to get them start pumping right away and then can we use that breast milk initially or do we just store that breast milk or can we use that breast milk?

Wanda Barfield: Yes hi, this is Wanda Barfield. Absolutely, breast milk should be offered to the infant right away. And, you know, using the help and support of a lactation consultant is an important strategy in terms of establishing breast feeding.

Question cont'd: Okay but we should get - we should have the baby bottle fed with the breast milk but the mother should pump?

Wanda Barfield: Correct.

Question cont'd: Okay, thank you.

Coordinator: Our next question, your line is open.

Question cont'd: We have a similar question about the breast milk. We wondered if there was presence of virus.

Wanda Barfield: Yes, this is Dr. Wanda Barfield and we have a lactation expert Kat Shealy who's on the line who will also address the question.

Kat Shealy: Hi there, yes. So the question is about using the milk and infectivity of the milk and those kinds of things. The milk should be used right away and in fact the milk is stable for several hours after expression and so it's best to use it right away without actually refrigerating it or doing any other kind of cold storage prior to feeding to the baby.

And in those first 24 hours especially it's often more effective to use another method to get the milk into the baby, because the colostrum is very low volume. So some facilities find that using an oral syringe works very well, a spoon, or a cup often works well as well.

There - because of the way that influenza virus is transmitted and processed in the body there's really no reason to expect that there would be presence of virus in the milk per se so the milk should not be considered infectious. And milk is actually not a fluid to which universal precautions apply in general and so the milk should be used right away and it's not considered to be - it would not be considered to be a problem because the mother is infected.

It's important to make sure that all of the parts of anything that's used to express the milk are kept clean so in those early days sometimes hand expression works well but if a pump is used make sure that the pump is clean. But there's no special precautions that would need to be used to use that pump for other patients as long as it's cleaned according to the procedures that are used to clean medical devices that are used between patients in the hospital overall.

And another important point about breastfeeding moms is also that oseltamivir and zanamivir are compatible with breastfeeding. So first a breastfeeding mother should never be denied medication because of breastfeeding and she should also never be encouraged to stop breastfeeding in order to take these medications but then also that milk is perfectly fine for the infant if she is on medication and she's breastfeeding. So it's important to make sure that there is appropriate guidance used related to breastfeeding.

Woman: (Unintelligible).

Coordinator: Thank you. Our next question. Your line is open.

Question cont'd: Yeah hi, I had a question about how to have the baby in the room with the mother. I'm not clear -- can they be in the room in an isolette less than six feet and then if the room is big enough then they can be in a bassinette greater than six feet? Can you clarify that?

Woman: Yes. If an infant is in an isolette in the mother's room she can be at any distance from the mother.

Question cont'd: Okay.

Woman: If you have a room that actually allows for more space and there is a preference to use a bassinette, for example some facilities may not have as much availability of isolettes, that's another option. Again we want to try to create as much flexibility based on the configurations of these rooms.

Question cont'd: And the part about the curtain, the curtain between the mother and baby. How does the curtain come into play?

Woman: So there - depending on your hospital configuration you can use the curtain to be between the mother and baby or even use a standing curtain that's used for breastfeeding.

Question cont'd: Okay, thank you.

Coordinator: Our next question. Your line is open.

Question: I actually have two questions. Should we be attempting to confirm the diagnosis of H1N1? That's my first question. And the second question is the vaccine is not 100% effective so I just want to, you know, be sure that we should be treating even if the patient has had H1N1 vaccine or not.

Woman: First to the question about should you confirm the H1N1 guidance - infection, I don't know that it really is going to make a difference. Right now 99% of the influenza viruses that are out there are H1N1 and so I don't know that it really is going to make a big difference.

Now if there would be some difference for infection control but it's going to take some time to get those results and so it's - I'm not sure that it's going to be helpful. I don't think we'd say absolutely don't do it but it's difficult for me to say that would be helpful. Emily, do you have anything more to say about that, Dr. Koumans?

Emily Koumans: Sorry, could you repeat the question?

Woman: It was about should - what sort of - what should be done about confirming the testing for H1N1. Is it necessary?

Emily Koumans: No, is this for the infant or for the mother?

Question cont'd: Mother.

Emily Koumans: Well if a woman is hospitalized, generally when patients are hospitalized they are in one of the suggested groups for testing, for confirmatory testing with rRT-PCR.

Woman: But your treatment should not wait.

Emily Koumans: The treatment should not wait, exactly, should not wait for any results.

Woman: And depending on your location we understand that for some obtaining rRT-PCR results in a timely manner may be a challenge and would not want to delay treatment based on that information.

Woman: The question with regard to vaccines, if a woman has received a vaccine and is more than two weeks after the vaccine, after receiving the 2009 H1N1 vaccine and shows symptoms of influenza, since the vaccine is not 100% effective she should still be treated. If it's thought that she has influenza she should be treated.

Question cont'd: Thank you.

Coordinator: Our next question. Your line is open.

Question: Thanks very much for updating this guidance. The new guidance indicates that the labor and delivery team may wear a surgical mask with face shield, gown, and gloves. I am assuming this is if the mother is able to tolerate wearing a surgical mask during labor and delivery. If the mother is unable to tolerate wearing a mask should the delivery team wear a surgical N-95?

Woman: Again Dr. Srinivasan.

Arjun Srinivasan: So the surgical N-95s are specifically designed to have some protection against splashes so, you know, if there are providers who are in an area where they anticipate that the mask might get splashed then a surgical N-95 might be a reasonable option. But for the providers who - where the risk of splashing to

the face mask is very low the surgical N-95 wouldn't be necessary, they could wear a standard N-95.

And if you don't have the surgical N-95s available the other option is to wear an N-95 and go on top of that with a plastic face shield that would protect against splashing. So surgical N-95 is a reasonable option if you anticipate a splash but there are ways around that too if the surgical N-95s are not available.

Question cont'd: Thank you.

Coordinator: Our next question. Your line is open.

Question: Thank you. This is (Jan Voshans), (Bartlett) Hospital in Juneau. On the discharge planning guidance there is a statement that says educate on signs and symptoms of infant infection and steps to take if any are observed for the family teaching. Is there some written guidance on signs and symptoms of infant infection or would we expect them to be similar?

Woman: We're still in the process of understanding the clinical manifestations for particularly newborn infants who may be infected. And as you may know, unfortunately infants who are clinically ill with viruses and bacteria have a set of really non-specific symptoms. So things to consider in terms of potential consideration include fever, temperature instability, respiratory distress, and feeding intolerance.

Question cont'd: Thank you.

Coordinator: Our next question comes. Your line is open.

Question: Hi, (Chris Alberts) had to step out of the room but I'll ask her question for her. She was wondering is there any difference in when a mother receives a seasonal flu vaccination as to the protection offered to the infant.

Wanda Barfield: Can you just clarify that question a little bit?

Woman: Sure. I think what she's wondering is, is there a difference say if a mother receives the seasonal vaccine in early pregnancy as compared to very late in pregnancy. Would that offer different protection to her infant?

Woman: No I think the protection would be similar unless it was given very shortly so the woman hadn't had - very shortly before delivery so the woman hadn't had an opportunity to mount an immune response. But earlier during pregnancy versus later during pregnancy would be expected to have a similar response.

Woman: Okay thank you.

Coordinator: Our next question. Your line is open.

Question: Thank you. My question is if the infant is bottle fed for a period of time because the mother is infected, is there a concern that resuming breastfeeding will be more difficult and how can that kind of be controlled?

Kat Shealy: Hi, this is Kat. Yeah absolutely that is definitely a risk that's involved in this guidance and it's one that we are very concerned about because of the importance of making sure that breastfeeding can continue in order to protect that infant especially up until they are old enough to be vaccinated themselves.

And so there is a really important role of the hospital and the immediate post discharge team to really consider her a high priority that diet, a high priority for lactation follow-up.

And so the pediatrician as well as lactation folks in the hospital and in the community really need to prioritize their resources to be sure that they have definitely observed - directly observed feedings prior to really sending them off into the community on their own. And also really making sure that both the mom and the baby and then also the other caregivers in the home know how to support them to get breastfeeding back on track.

So educating them on some of the really important things to know about those early days about breastfeeding and signs of the baby needing to feed, that they're all going to have to be sort of learning in sort of a remedial way. So it's extremely important that team see that as a priority activity to make sure that they can get breastfeeding going well.

Question cont'd: Okay thank you.

Coordinator: Our next question comes from. Your line is open. Your line is open.

Question: I already got my question answered because it had to do with the breastfeeding and the exposure to milk and whether or not the infants can get the expressed milk from the infected mother and I think that was answered so thank you.

Coordinator: Our next question. Your line is open.

Question: Hi, I had a question about visitation in the OB department during this season and just wondered what the experts' opinion was on allowing visitors.

Woman: Again, part of the issues on visitation are based on the specific configuration of your hospital maternity ward but it is discouraged for visitors who have H1N1 infected - infection to be in the hospital particularly in areas where infants might be most vulnerable such as intensive care units.

Question cont'd: Thank you.

Coordinator: Our next question. Your line is open.

Question: Yes, we had a question about the oral, I mean, the nasal mist vaccine being given to women postpartum who are breastfeeding and their family members. There's a lot of concern about that and I know that the BIS statement says that we can. We're just concerned about was there a lot of research done on that? It just seems like an unusual situation.

Naomi Tepper: Hi, this is Naomi Tepper here and we - this question does come up a lot. The issue is not really whether - well there are I think two concerns that people have, whether the live vaccine might be passed in - the virus might be passed in the breast milk and also whether someone who has received live vaccine can transmit that virus in close contact.

And neither of these really is a concern. There's really no evidence that the virus can be passed. It's an attenuated virus, it doesn't replicate in the body and it really can't be passed through close contact. So there's really not a concern with contacts of the infant getting the live vaccine.

Question cont'd: Okay, all right, thank you.

Naomi Tepper: Oh and all of these vaccines - sorry, one more thing. All of these vaccines, both the inactivated and the live vaccine are compatible with breastfeeding and, you know, again should be given in order to protect the infant.

Alycia Downs: Well I would like to thank our presenters for providing our listeners with this information. I would also like to thank all the other subject matter experts we had on the call to answer all these questions so thank you again for that.

The recording of this call and the transcript will be posted to our COCA Website at emergency.cdc.gov/coca, again that's emergency.cdc.gov/coca within the next week. If you were unable to ask your question during this call please send an email to coca@cdc.gov, again that's c-o-c-a@cdc.gov and we'll do our best to get a response to you.

You have one year to obtain continuing education for this call. All continuing education credits and contact hours for COCA conference calls are issued online through the CDC training and continuing education online system, www2a.cdc.gov/tceonline. Thank you again for participating and I hope everyone has a wonderful day.

Coordinator: This does conclude today's conference call. We thank you for your participation and you may disconnect at this time.

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