## Pediatric and Child Health Issues related to the novel Influenza A (H1N1) Outbreak Edwin Trevathan, MD, MPH Beth Stevenson Jacquelyn Polder, BSN MPH Deborah Levy, PhD MPH Susan Gorman, PharmD MS Jeff Hageman, MSPH Marshalyn Yeargin-Allsopp, MD May 11, 2009

NOTE: This transcript has not been reviewed by the presenters and is made available solely for your convenience. A final version of the transcript will be posted as soon as the presenters' review is complete. If you have any questions concerning this transcript please send an email to <u>coca@cdc.gov</u>.

Coordinator:	Welcome and thank you for standing by. At this time all participants are in a listen-only mode into the question and answer portion.
	At that time if you'd like to ask a question, please press star 1. Today's conference is also being recorded. If you have any objections, please disconnect at this time.
	And now I'll turn the call over to your host, Ms. Beth Stevenson.
	Ma'am, you may begin.
Beth Stevenson:	Thank you so very much. I welcome everyone to the call today and this call is from the Center of Disease Control and Prevention and a focus on pediatric and child health and the H1N1 outbreak.

We will start with a brief kind of overview by Dr. Ed Trevathan here at CDC who is the strategic lead for children during this novel influenza H1N1 outbreak. And then we will be going through a series of speakers who will talk briefly on a range of issues, about seven or eight issues related to

pediatrics and the H1N1 outbreak and then we will have time, hopefully about 30 minutes or so for questions that the operator will moderate.

And with that I'd like to turn it over to Dr. Ed Trevathan as strategic lead for children here at CDC for this outbreak.

Edwin Trevathan: Thank you, Beth.

First of all, I'd like to thank everyone for taking time to come together today to share information on this H1N1 outbreak and with particular emphasis on the issues as they relate to children. All of us on this call at CDC, like all of you I'm sure, have our daily responsibilities and our jobs and in many ways our response to this outbreak has been many of us coming together working extra hours to really address the needs of children from a variety of different backgrounds and perspectives.

I direct the National Center on Birth Defects and Developmental Disabilities here at CDC and my own clinical background as a pediatrician and pediatric neurologist. And we have a large number or a number of different people who are speaking today that have a variety of different backgrounds and interest that are all coming together to do the best we can to enhance CDC's response relative to children.

As all of you know, we've been monitoring this epidemic. As of a little while ago today or late this morning, we had approximately 2600 confirmed cases and 704 probable cases and throughout this outbreak, there's been compared to other outbreaks a relatively higher percentage of children than has been seen in many outbreaks with really over half the cases being children at various times of the outbreak. And it really is for that reason in our desire to enhance the response to children that our Acting Director for CDC Rich Besser himself a pediatrician asked that I take this role as a strategic lead for children.

As part of that activity, we've recently set up a pediatric health team that has their own desk area in our emergency operation center that coordinates with other teams at CDC on a wide range of pediatric and child health issues, including issues such as school and child care closures, information for parents, specific information for vulnerable populations of children such as children with neurological and disabling conditions, medication dosing for children and so forth.

This team, pediatric health team at CDC led by three very well qualified people, Dr. Georgina Peacock who is a pediatrician from the National Center on Birth Defects and Developmental Disabilities. As a co-lead (Carrie Glopen) has a background in Adolescent and School Health with our Division of Adolescent and School Health here at CDC.

And Beth Stevenson is the current CDC child goal team leader and is in the coordinating center for infectious diseases.

Our call today will have a brief presentation here with an influenza update and we'll touch on some of the current guidance and information related to schools and child care healthcare delivery, the strategic national stockpile, infection control, issues related to search capacity, issues related to infant feeding, breastfeeding and other issues. At the end of this call, we'll have time for questions and Beth Stevenson will moderate and introduce each speaker and we'll do our very best to answer your questions. I know given the large number of people joining us on this call that we won't be able to get to everyone's questions, but we urge you to certainly contact CDC and ask that your questions, if they relate to children's health, be directed to the pediatric help desk. And we will do our very best to get answers to your questions or responses to your comments as soon as possible.

Now back to you, Beth.

Beth Stevenson: Thank you, Ed.

The first person that will present - and these will be obviously very brief presentations hitting on some high points and some of the guidance and perhaps even some changes in guidance that happened over - has happened over the outbreak is Dr. Tim Uyeki who is with the Influenza Division.

Tim Uyeki: Thanks.

Just to re-iterate what was mentioned, there had been 2600 confirmed cases reported from 43 states and also the District of Columbia, the epidemic continues to spread in the United States and we can expect that more cases will continue.

The median age is approximately 15 years with a wide-age range with about 60% of the cases have been age less than 18 years so again a substantial proportion have been among children and the confirmed cases clearly are a large underestimate of all the illnesses that have occurred. There are some particularly important issues for children.

Clearly, with influenza - seasonal influenza we know that there's an association with influenza virus infection and aspirin with Reye's syndrome

and so for all children no aspirin should be administered for patients suspected or confirmed to have this new infection unless it is for medical reasons, specific medical reason.

This virus is susceptible to the antiviral medications Oseltamivir also known as Tamiflu and Zanamivir, also known as Relenza. It is resistant to the antiviral medications Amantadine and Rimantadine; therefore, CDC recommends for antiviral treatment of all hospitalized patients who are suspected or probably or confirmed cases of this novel influenza A H1N1 virus should receive treatment with a neuraminidase inhibitor. That again is Oseltamivir or Zanamivir.

In addition, patients who are not hospitalized who are higher risk for complication of seasonal influenza should also be considered for treatment even if they are not hospitalized. And it's important to realize for the pediatric community that would include children with certain underlying chronic medical conditions as well as - although we say the - that children less than 5 years are at high risk for complications of influenza, in particular those who are age less than 2 years are particularly much higher risk of complications for severe influenza. So it's the less-than-2-years-old group that should be considered for treatment even if they are not hospitalized.

For Oseltamivir normally it is approved for treatment in chemoprophylaxis of children age 1 year older; however, under emergency use authorization, Oseltamivir has been approved to be administered for treatment in less than 1 year of age. And for the less than 1 year of age we have those dosages posted on our CDC Web site's under our antiviral guidance. It is an age-base dosing, less than 3 months, 3 to 5 months, 6 to 11 months. For those children age 1 year and older it is a weight base as well as then when you get to age 13 it's

age based so you should consult CDC Web site antiviral recommendations for latest dosing.

For Zanamivir this is an orally inhaled drug that's administered with the use of a disk inhaler device and it is approved for treatment in children's age 7 years and older and chemoprophylaxis 5 years and older. There have been children hospitalized, confirmed cases. There has been 1 pediatric death in the United States that occurred in a 22-month old that had chronic underlying conditions. The child was actually from Mexico.

And the kinds of symptoms, the signs and symptoms that we are seeing both in children and adults are febrile influenza -like illness symptoms. So upper respiratory tract symptoms, fever, cough, sore throat, runny nose, headache, myalgias. But we're also seeing fairly higher proportion of cases that have both outpatient and some inpatients that have gastrointestinal symptoms such as vomiting and diarrhea at a higher proportion than we would typically see in seasonal influenza. So basically the constellation of illness is upper respiratory tract, febrile and gastrointestinal symptoms in some.

In addition, just to comment on some of the underlying conditions on preliminary data for hospitalized patients both in children and adults we're seeing about half the patients have underlying chronic medical conditions such as asthma being the leading underlying medical condition, but we are also seeing cases with no previous underlying conditions.

I think I'll just stop there.

Beth Stevenson: We'll have time for questions at the end of the call.

Next we've asked Jacquelyn Polder who is with the community mitigation out of the Division of Global Migration and Quarantine is addressing schools and child care issues.

Jacquelyn Polder: As most of you probably know, CDC has posted on its Web site the current recommendations for K to 12 and child care programs in terms of exclusion of children, who are ill, staff members, et cetera. You can find that at cdc.gov and following the trail for H1N1 guidance's.

The current recommendation of course is to focus on early recognition of children or staff who are ill and having them home isolate and for at least 7 days or 24 hours after illness resolves whichever is longer. We are in the process of updating this particular piece of guidance to include some more specific recommendations for child care facilities because we've gotten a lot of comments that this was not specific enough for child care.

Essentially we will be adding some language about, you know, following the usual recommended precautions careful evaluation of children when they come in to the facility for any kinds of symptoms of influenza-like illness.

We have also published and put up on the Web site yesterday our recommendations for large public gatherings. And one of the things that I want to bring your attention to is in that guidance we do recommend that people who have higher risks for complications and live in a community that has known H1N1 activity, they should really carefully evaluate their risk, but make a determination about whether they need to take any additional precautions or whether they should in fact not attend such gatherings.

And in our recommendations and definitions of high risk, we do include that children that are under the age of 5 so this does include them.

Beth Stevenson: Thanks, Jacque.

And now I'd like to introduce Dr. Deborah Levy who is with the healthcare delivery desk here at CDC in the emergency operations center and Chief of the Division of Healthcare Quality and Promotions.

## Deborah Levy: Good afternoon.

The Healthcare Preparedness Activity within CDC's Division of Healthcare Quality Promotion has been involved in preparedness for mass casualty event such as an influenza pandemic for the past several years. And so our work really falls under two distinct categories: community based stakeholders engagements through workshops and meetings and triage, and clinical algorithms to deal with a search capacity and capability.

So in the next few minutes I'm going to talk to you a little bit more about preparedness for a potential surge in the fault. Let me tackle first the community prospect workshops. The goal of the first two workshops that we conducted last year was to announce planning in communities towards a coordinated healthcare response by identifying issues associated with patient management, developing new strategies, identifying new resources and exploring coordination efforts within and among healthcare and supporting organizations.

And the goal of our third workshop was to develop an alternate care system to be used when surge capacity in healthcare systems is challenged and/or exhausted.

As part of the process, each community was expected to capture their process, relevant coordination diagrams, decisions and next steps. The participating

stakeholders from the community included call centers, emergency medical services, private clinicians, emergency department clinicians, hospital administrators, outpatient clinics, urgent care centers, public health, home health, long-term care, pharmacists, emergency management, local government, pod hospitals, VA medical center - if one existed in that community, and mortuary services as well as several other potential supporting sectors if that community deemed them part of their healthcare delivery response.

We anticipate conducting 2 to 3 more workshops in communities of varying sizes and geographic locations. Then we'll develop a standardize tool for communities to use to develop their framework for healthcare delivery.

In addition, we also conducted some stakeholder meetings and these meetings have focused on the issues of one component of the healthcare sector such as primary care providers or let's say call centers. We conducted the call centers meeting last year and are almost finished developing a workbook for community planners.

The meeting focused on how a community could use call centers in their healthcare delivery response and on how to coordinate multiple types of call centers including 911 and public health hotlines. Additional stakeholder meetings under consideration at the moment include primary care providers which will likely happen next as well as pediatrics, long-term care, pharmacy and third-party payers.

The second grouping of activities I mentioned were triage and clinical algorithms. The critical care collaborative, a coalition of professional societies representing more than 100,000 healthcare professionals were at an effort to develop consensus recommendations for definitive care for the critically ill

during a disaster including current capabilities and limitations, a framework for optimizing critical care surge capacity, medical resources for surge capacity and a framework for allocation of scarce resources in mass critical care.

This set of papers was published in the May 2008 edition of the Journal CHEST and can be viewed at www.chestjournal.org. We realize, however, that this effort was focused on adults and not specifically children; therefore, we have currently funded an expert working group that will identify a framework for the development of triage protocols and methods for prioritizing access to pediatric critical care resources such as ventilators during a mass casualty event such as a pandemic.

The working group, which we hope to convene in early summer 2009, includes representatives from a wide range of fields including bioethics, critical care, disaster preparedness and response, emergency medical services, infectious disease, hospital medicine, law, military medicine, nursing, pharmacy and respiratory care. The draft framework issued by the working group will be reviewed by an expanded group of stakeholders.

The last item I'm going to cover are triage tools for directing patients through appropriate healthcare venues. We are working currently with partners from the clinical public health state and local government sectors to develop a standardize suite of triage tools to ensure that influenza patients receive care in appropriate venues based on the patient's clinical status and on hospital and community resources.

During the pandemic, professional healthcare venues may include hospitals, long-term care facilities, walk-in clinics and urgent care centers. Successful coordination of care among these venues will prevent hospitals from being overwhelmed by huge surge in the patient population.

The triage tools will be tailored to the needs of specific healthcare groups including emergency departments, 911 call centers, emergency medical services, primary care physicians, outpatient, walk-in clinics, urgent care centers, alternate care facilities, and home healthcare agencies as well as public health department. The tools are going to be validated by a field evaluation during flu season as well as via discussion-based exercises.

- Beth Stevenson: Next we have Dr. Sue Gorman who is with the Division of Strategic National Stockpile.
- Susan Gorman: Thank you.

During this response the Strategic National Stockpile deployed the first 25% of the pro rata allocation of antiviral and personal protective equipment to the 62 project areas. The antiviral included dosage forms specifically for pediatric patients. These dosage forms included Tamiflu, Oseltamivir suspension in a 12 milligram per milliliter 25 milliliter bottle as well as Tamiflu, Oseltamivir capsules in 30 milligram and 45 milligram strength.

The Tamiflu, Oseltamivir 30 milligram capsules can also be used to make 60 milligram regimens. It may take 1 to 2 bottles of suspense to complete a 5-day treatment course depending on the weight of the child. 30 milligram capsules are generally used for children weighing less than or equal to 15 kilograms; 45 milligram capsules for children weighing between 15 kilograms to 23 kilograms; and 60 milligram regimens made up of 2, 30 gram capsules for children weighing greater than 23 kilograms up to 40 kilograms.

Tamiflu, Oseltamivir 75 milligram capsules were also part of the allocation and can be used in children over 40 kilograms. Tamiflu capsules can be opened and mixed with sweetened liquids such as regular or sugar-free chocolate syrup if suspension is not available.

Relenza, Zanamivir, was also sent out and can be used for treatment in children ages 7 years and older and for prophylaxis in children aged 5 years and older.

This information can be found in the package inserts for the drugs which are posted on the CDC H1N1 Web site under the emergency use authorization tab. The Strategic National Stockpile is responsible for stockpiling 50 million treatment courses of antiviral.

Six million courses were earmarked to support containment efforts and 44 million treatment courses were allocated pro rata distribution to the 62 project areas. Overall of the 44 million treatment courses allocated to project areas, about 12% were for cure for children age 12 years and under and about 9% of this was for children under 7 years of age.

The pediatric proportion of the stockpile regimen follows the most recent census data. The strategic national stockpile is responsible for replenishing its inventory of the 25% prorate allocation of antivirals that were deployed to the 62 project areas.

Efforts are currently underway to replace this inventory so that we are ready for the next wave should the assets be needed.

Thank you.

Beth Stevenson: Thanks, Sue.

And next we have Mr. Jeff Hageman, who is with the Division Healthcare Quality Promotion to briefly address infection control.

Jeff Hageman: Hi. The current infection control recommendations are posted on CDC's Web site for healthcare settings. They have not changed since the guidance that's Web dated May 3, 2009.

There is, however, on May 8 a supplement to this infection control guidance that addresses specific concerns in outpatient hemodialysis settings.

To determine if changes to the infection control guidance is warranted, we're working closely with the flu experts here at CDC as well as obtaining input from several partners including the Federal Advisory Committee, Healthcare Infection Control Practices Advisory Committee. We're looking at available information both at the neurological information that's coming in as well as information regarding a small number of healthcare personnel with confirmed or probably H1N1 influenza infection.

Currently the available data on ill healthcare personnel collected so far, although is not complete, indicates that most exposures in these individuals have been community exposures and not exposures in healthcare settings.

Beth Stevenson: Thanks.

We have actually two more quick speakers who will - Dr. Marshalyn Yeargin-Allsopp and you're also going to be - who will be addressing children with disabilities and chronic medical conditions. Marshalyn Yeargin-Allsopp: Okay, thank you, Beth.

Good afternoon.

We have provided guidance for children with developmental disabilities and chronic medical conditions on the CDC Web site. As already mentioned certain children such as those with developmental disabilities and chronic medical conditions are at higher risk for complications from influenza infection. It's important to note that a recent study on influenza associated deaths in children found that half of the child deaths were among children that had an underlying medical condition.

Those at higher risk include and it's a relatively long lists: infants less than 6 months of age and all children with chronic neurologic conditions such as those with intellectual and developmental disabilities, (unintelligible), kidney disease, (unintelligible), HIV/AIDS, diabetes, asthmas or other problems that affect lung function, double cell disease and those on long-term aspirin therapy for chronic disorders.

Another group of children with an increased risk for complications are those with poor nutrition, (unintelligible) because of prolong vomiting and diarrhea and children with an underlying metabolic disorder who are unable to tolerate prolong periods of fasting.

Because many children with neurologic or metabolic conditions may not have the ability to report the onset or the worsening of symptoms delay in identification of influenza infection can lead to additional complications; however, we must remember this may be true for all children. Parents and caregivers of children in these special populations that are at increase risk should remain vigilant for signs and symptoms of influenza.

If there is a suspicion of influenza infection or concern about an exposure to a known probably or suspected infection, parents should consult their healthcare providers to assess the needs for evaluation and for possible anti-influenza treatment or prevention.

Beth Stevenson: Thanks, Marshalyn.

And next we have Dr. Kat Shealy who's going to be talking about breastfeeding, infant feeding from the Division of Physical Activity and Obesity.

We may have missed her. She may be - she is still muted.

With that, since I'm not hearing Dr. Shealy, I think maybe we can open it up for questions and turn it back over to the operator.

Coordinator: Thank you, ma'am.

At this time if you would like to ask a question, please press star 1 and record your name. To withdraw your request you press star 2.

Once again if you'd like to ask a question at this time please press star 1 and record your name.

One moment.

And your first question - Your line is open.

Question: Yeah, (Rushek Cokarney).

Coordinator: Your line is open, ma'am.

Question cont'd: Hello. I'm a pediatric hematologist and I'm very interested in this H1N1 as it relates to children with disorders.

I have two questions. What is the duration of viral shedding that some of these children who are immunity suppressed as a result of, you know, chronic duct transfusion or being on steroids have and number 2 is the incident of bacterial infections that some of these children might experience, second bacterial infections.

Edwin Trevathan: Yeah, thank you very much, excellent questions.

So the first question, certainly when you talk about children with hematological disorders, certainly we know - certainly hematological disorders for among children for seasonal influenza are risk factors for complications that might result in hospitalization.

For this knew - this novel virus, we don't really know what the risk factors are. There are some indications that suggest that some of the high-risk groups for seasonal influenza are also high-risk groups for this viral infection, but it's really too early to tell because we clearly have had children hospitalized and adults hospitalized who had no underlying condition.

In terms of the duration of viral shedding, so you're quite right. For seasonal influenza clearly very - there are differences. For a very young infant, there is

clearly good data to suggest prolong viral shedding is possible, much longer for an older school-age child or adults.

For children that are immuno-suppressed or immuno-compromised, prolonged viral shedding could be even - of a longer duration. Now that period could range from many weeks to months.

With this new virus infection again we have no data to really guide and therefore we're really - until we have such data on viral shedding I think we can sort of use the guide.

We can sort of use data from seasonal influenza which would be to suggest that in your patient population, immuno-suppressed, immuno-compromised you may see very prolonged viral shedding.

And one way to assess that particularly in hospitalized patients would be to do serial swabbing certainly on a weekly basis or so forth.

And of note for seasonal influenza there are such patients who can shed for prolonged periods without any evidence - any symptoms.

Once they resolve sort of their active pulmonary disease they may still have prolonged shedding. That is clearly a risk for nosocomial transmission.

And we don't have good data right now but some anecdotal very preliminary data suggests that there may be very high viral shedding in the upper respiratory tract. And that is something that we would expect with a novel virus. And if there is very high concentrations of this virus in the upper respiratory track that may also facilitate greater spread, greater transmission among exposed.

And yet what we're seeing is fairly high attack rates among children. Now the issue of children who have diarrhea, there is the potential, unknown at this point, but there is the potential that there could be the presence of the virus in the gastro-intestinal tract.

And there could be potential for fecal shedding. We are investigating this and we don't have any data, but until we have such data I think that that route must be considered and has implications both for household transmission as well as a hospital based transmission.

Finally something to say that I did not completely go into which was not only should aspirin not be administered to any child with suspected probably or confirmed infection with this new virus, but aspirin containing products should also be avoided as well.

Question cont'd: What about bacterial infection?

Man: Oh yeah, thanks for that. We don't have good data on that, we're actively pursing this right now. What I can say preliminary data suggests that we're seeing more of a viral pneumonia picture in patients who are hospitalized.

We're very concerned about the potential for secondary invasive bacterial infections, particularly secondary bacterial pneumonia.

Something we observe with children with seasonal influenza, one of our concerns is that we may start seeing both some of the common community

acquired pathogens such as group A strep both methicillin sensitive as well as methicillin resistant staphylococcus aureus and pneumococcal infections.

But to date we haven't seen that. It's certainly something that we're very concerned about and we'll be actively looking. And this - as the data are available this will help inform some of our recommendations for management of particularly hospitalized children.

I think at this time we would view anti-viral treatment with oseltamivir, zanamivir, primary medical treatment as well as supportive care in the hospital setting.

But in addition bacterial infection is suspected then using guidance for community acquired pneumonia should be followed if bacteria infection is suspected.

I think in your patient population you have to consider other bacterial pathogens than just - I think for immuno-suppressed and immunocompromised you would obviously consider not just all community acquired pathogens as well. Thanks.

Coordinator: Your next question, your line is open.

Question:Thank you. Yeah, I'm a pediatrician in the Chicago area affiliated with Mercy<br/>Hospital. And my question is that I understand that the national stockpile<br/>supply of for example Tamiflu was sent to children's hospitals.

And my question was in a true emergency pandemic with you know where a lot of kids needed the medication, how would general hospitals be able to get the Tamiflu for the national stockpile?

Because you know patients will be going to all the hospitals in the area, not just the children's hospital.

Woman: Right, so the assets that were deployed from the strategic national stockpile were sent to receive stage and store areas in the states. And once they went to those central locations within the states, the states were responsible for further pushing them out into the clinics or treatment centers or hospitals.

> So that is an issue that we would have to take back to our program consultants that work directly with the states and express your concern that we would want to have (suspension) go to all locations and not just pediatric locations.

Question cont'd: Right. Okay.

Woman: We can take that back to them.

Question cont'd: All right, or just you know how it would need work. Thanks.

- Woman: Right.
- Coordinator: Your next question, your line is open.

Question:Hi, I'm a pediatrician in upstate New York covering primarily school districts.And two counties in which I work have had confirmed cases.

I understand that it was explained to me today by our local commissioner of health that we're no longer looking at containment which is part of the reason we're not doing school closure. But rather reducing transmission. Meantime your current recommendation for return to school is seven days or 24 hours after the last symptoms with the caveat whichever is longer.

And you know we're in the midst of final examinations, we're in the midst of senior prom. We have an economic crisis where parents are afraid of losing jobs for missed time at work.

And I honestly am struggling as a school physician to explain to superintendents and parents why children who are completely symptom free cannot return to school after 24 hours, why we need to follow that very conservative whichever is longer clause.

And I'm wondering whether you might be loosening that up in the near future and whether you might also tighten up your definition of acute respiratory illness as you have in the beginning of this outbreak where it required fever plus two symptoms instead of fever plus one symptoms.

Since so many kids fall under fever plus one symptom category. And thank you all for the phenomenal job you're doing. It's been a privilege being a physician in the United States with the kind of care you're providing.

Woman: Oh, thank you very much. Well thank you for that question and I can assure you that this is a question that's hotly debated here and has been over the last several days.

At the present time it's felt that we need to continue to stick with the conservative recommendations, primarily related to the question that Dr. Uyeki addressed earlier related to viral shedding.

We don't know at this time but with a new virus it's felt that it could be longer than it might be with seasonal flu so until we actually know a little more information or have additional epidemiologic information it's felt that we need to stick with this recommendation for now.

But you're right as we gain new information and we're trying to get this as quickly as we can, this in fact may be changed. But for the time being the decision has been to stick with that recommendation.

Question cont'd: Thank you.

Coordinator: Your next question, your line is open.

Question: Thank you. I'm a pediatrician in solo practice in New York City and I have many vulnerable patients in my practice. For example right now in my office I have a child with chronic lung disease and severe combined immuno deficiency.

> Now if she should become symptomatic I have no source of obtaining Tamiflu or Relenza except for eBay. So could you please guide me in how I can obtain Tamiflu or Relenza for these children who either are immune compromised, have chronic lung or heart conditions or serious developmental disabilities?

- Woman: Have you worked with your health department receive some of the allocated assets from the strategic national stockpile?
- Question cont'd: No, because they didn't feel I have a probable case that was diagnosed a week ago Monday, a child from Mexico who tested positive for Influenza A and the Department of Health did not want me to treat him.

Woman: Well all I can say from the stockpile's perspective is that we have sent the anti-virals to a centralized location in the state and they are responsible for allocating them out within the state.

I'm also informed by all the anti-viral manufacturers that there are no shortages and that they should be readily available through wholesale distributors and in the local pharmacies.

Have you checked there and had no luck either?

Question cont'd: We've had no luck either, either from all the distributors that we've worked with and I've been in practice for 16 years. The local pharmacies, they have told me that as soon as they get anything they will save some for me at a price.

> And they have referred me to eBay. So the family that is here right now, the only place I can refer them to is eBay because the Department of Health will not let me treat this child unless she either demonstrates influenza A or has recently been to Mexico.

This is the New York City Department of Health by the way.

Woman: Okay, well that's information that we can go back with our program consultants and check again with the New York State and see why they won't release them to you.

> But we provided those so they could be used, they shouldn't just be sitting there, so hopefully they can use those that are already there from the stockpile.

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

Edwin Trevathan: This is Ed Trevathan, that's a good question and a good point. If you don't mind at the end of the call I think Beth if you can provide the email address, if you could email us with that question at the pediatric help desk - health desk that would be helpful.

And we can then also share your questions and concerns, I know Sue Gorman well. Thanks.

Question cont'd: all right, thank you.

- Coordinator: Your next question, your line is open.
- Question: Good afternoon, thank you for taking my question. I'm a pediatrician at Columbia University Center for Disaster Preparedness and I have a synthesis question that's going to span a few questions that have already been asked.

Intended for the (woman) with the strategic national stockpile, I just wanted to see if we had a feel for how these drugs have been utilized after they've been pushed out to the states.

Because I've been hearing also that they're not having manufacturing shortages, so wasn't sure where people are sourcing their needs for oseltamivir if it's coming from FS or if it's coming from the normal supply chain. Thank you.

Susan Gorman: Right, I don't have good visibility right now on how the states are using their assets. That is something that our program consultants are currently working with the states to survey them and find out what they've done with the assets so far.

And as that information becomes available we can share it but I don't have good information for you right now.

Question cont'd: Okay thank you. Can I ask a follow up question? The assets that are pushed, do you intend to ever get those back if they're not used or is that a one way push?

Susan Gorman: Right now we don't intend to get them back, once we sign them over to the state it becomes the state's property.

So we are not intending to take them back.

- Question cont'd: Okay. Thank you.
- Coordinator: Your next question, your line is open.

Question: Yes, I was wondering if you could tell us about what safety information there is for the use of oseltamivir under 12 months of age?

Woman: As you can imagine we have a group, we're deciding who's - several people can answer.

Edwin Trevathan: This is Ed Trevathan, I'm not in the room but let me just mention that that question when it was brought up on a previous call, Dr. (Linda Lewis) with the FDA mentioned that the FDA did a detailed thorough review of the safety data and the pharmacokinetic data that they had available.

And felt comfortable that they had the available data to issue the emergency use authorization. And I believe there is - there are some data on the FDA

	Web site that you can access based on what Dr. (Lewis) said on a previous call.
	I do not believe she's on this call, but if she is, (Linda) please go ahead and chime in.
Woman:	I'm going to have Dr. (unintelligible) (Kim) speak to this.
(Kim):	First of all I have a disclaimer, I'm not a pediatrician. I just want to talk to you about the reason why Tamiflu is un (unintelligible) for children less than one. It's because it is not FDA approved for that age population.
	So you are correct, when a product is used under a new age there is a limited space in efficacy information. And from (unintelligible) Dr. (Linda Lewis) were on this call she would be able to elaborate on the NIH study that the PK modeling in children less than two years of age.
	So I think that's what the FDA's issuance of this product under one year of age was based on. And I guess the FDA made - I don't think it's a published data but I know that FDA has looked at the NIH PK modeling study for children less than two for treatment of influenza.
Question cont'd:	It might be useful to have FDA make that data available.
(Kim):	Yes, I will touch base with FDA and see if that NIH study can be - study results can be available. I will touch base with them.
Question cont'd:	Thank you.
Coordinator:	The next question, your line is open.

Question:	Thank you. I am the Director of a Center, bio terrorism (unintelligible)
	preparedness, in Nova Southeast University College of Osteopathic Medicine.

And my question is understandably each day that passes the media has become less vocal about H1N1.

And simultaneously complacency as we all know was a major enemy and we also are at risk for what I'll call the cry wolf situations as the current disease is relatively mild.

How do we maintain the vigilance of the population if a second phase occurs that is considerably more virulent, perhaps more lethal than phase one and do we have a plan in place, what is being considered to address that situation with and without a vaccine that possibly may be available then?

Man: Yeah, thanks for your comments and questions. And clearly this is something that CDC and many countries are now very concerned about. As you know winter is approaching in the southern hemisphere.

And how this virus transmits and what the impact is in the southern hemisphere is obviously of great interest. And also influenza viruses continue to evolve.

This virus is no different, it will drift and how this changes in terms of the impact of - in terms of the severity cannot be predicted. But we are clearly focusing on both the current situation and trying to prepare for what could happen in the early fall.

I think none of this is clearly unpredictable, that's the easiest - in terms of characterizing this current situation as very mild, I think we have to be very careful about that.

Although it does appear that a very high proportion of people have not required medical attention, have had self limited illness, there clearly have been adults and children who have been hospitalized with severe disease.

And although the number of deaths has been small, relatively small I think we're early in this epidemic right now.

And there have been comparisons made to seasonal influenza and clearly we should realize and I think you're well aware that during seasonal epidemics in the US, there is a substantial amount of morbidity and mortality.

So I think no one can predict what is going to happen over the next month or couple of months or certainly in the fall.

But it's something that CDC is intensely focused on and we will be preparing and working not only with states and our state and local health partners but with the clinician community including the pediatric community as the situation evolves.

Woman: I think I would also encourage you as I had mentioned to purchase more of a community health care delivery response. So among clinicians you should start preparing for a surge and how you would deal with that patient surge.

Start talking to your hospitals and do this more as a community approach to your planning with your public health department as well as with emergency management. Because in any kind of local crisis emergency management actually directs resources and helps coordinate a community with funds. And they do not necessarily always have conversations with the health care or the public health sector.

So we strongly encourage you to as a grouping health care public health and emergency management together start having dialogues at your local level as to how you would respond if you really had a tremendous surge in patients.

- Question cont'd: Thank you very much and your communications methods are extremely well appreciated.
- Woman: Thank you.
- Coordinator: Your next question, your line is open.
- Question: My question has been answered.
- Coordinator: Thank you, your next question, your line is open.

Question: Yes, I have a question about an infection control recommendation and that is for the use of the N95 respirator.

I'm uncomfortable with saying that the N95 respirator should be used for all contacts. I think it is appropriate for aerosol generating procedures.

Is there evidence to support the need for the N95?

Man: Thank you for that comment. I think you know that's one of the things that we're trying to gather that's additional data, especially the data on healthcare workers who have confirmed H1N1.

> To look at exposures, where those exposures occurred as well as the evolving epidemiologic data that the flu group is getting to, to get the data to determine if we can make a change based on that data.

So at this time with the available data, you know as of right now we don't have enough data right now to make a choice, to make a determination of whether or not a change from N95 is warranted.

Question cont'd: Is there evidence for seasonal flu?

Tim Uyeki: With seasonal influenza we believe that much of the transmission is through large droplet particles, but clearly the role of small particle droplet nuclei are thought to play a role. I think that this is a novel virus.

And there's so many - there's a ton of unanswered questions about this virus and we really do not know right now. As I mentioned, I alluded to the potential for higher viral shedding in the upper respiratory tract.

And how that influences potential transmissibility through small particle droplet nucleus, small you know aerosol transmission I think is unknown.

And given the absence of data right now I think it's very difficult to conclude anything right now.

And I think we have to consider all possibilities.

## Coordinator: Thank you, the next question, your line is open.

Question: Hi, thanks for taking questions. I'm the state school nurse consultant in South Carolina. In the guidance for schools and childcare there is an exclusion for influenza like illnesses which would be fever, cough or sore throat, fever with cough or sore throat.

> While in the definition, the case definition, it's based on acute febrile respiratory illnesses which includes fever with cough, sore throat or rhinorrhea or nasal congestion.

Can you help me understand the rationale for using the two different criteria?

Woman: Thank you for that question. We've had a discussion about this today and we are in the process of moving our guidance towards influenza like illness which would include fever and either cough or sore throat.

The case definition guidance that is up on the Web is being redone and we will be moving towards influenza like illness. So I'm sorry for the disconnect at the moment but there are a number of things that are rapidly evolving.

And we're trying to get our - all of our guidance is in line with the evolving situation. Just hasn't happened yet.

Question cont'd: Thank you. And I have one more comment just as you're thinking about healthcare workers, to be sure to think about those school nurses that are in the school health offices as healthcare workers.

And would they indeed need to have an N95 mask and also be fit tested.

Woman:	Absolutely and we've had that discussion and one of the specific recommendations that we discussed today that will probably be in the updated version would be that if a child for example became ill during the day with an influenza like illness and had to be isolated say in the nurses office or in a room.
	And had to have supervision so that a person would not normally need an N95 respirator but would be supervising a child in close proximity for a period of time until their parents could pick them up would need to probably consider using an N95 respirator.
Question cont'd:	Thank you. Any specific guidance you could be very clear on would be helpful.
Woman:	Thank you, we'll consider that.
Woman:	We'd like one more question from the operator in the interest of respecting everyone's time.
Coordinator:	Yes ma'am, thank you there is one other question, however they did not record their name. If you asked a question, your line is open.
Question:	Can you hear me?
Man:	Yes.
Question cont'd:	This is Nicole Alexander calling from Rhode Island. I'm an infectious disease adult and pediatric infectious disease fellow.

I've been working with the Department of Health and we've heard back from schools that have already bought gel for their students. A lot of the gels that they have are not alcohol based gels and they want some specific recommendations on which non-alcohol based gels would be appropriate.

And I know that our local prison and gel also cannot have alcohol based gels so they have one with benzalkonium chloride in it. And we've been trying to find any FDA or EPA approved information about acceptable non-alcohol based gels.

And was wondering if you had any further information where I can be referred to.

Man: I think if you can give us your contact information or email in addition the FDA Web site which is - I think it's ocep.fda.gov has some information about alcohol based versus non alcohol based hand gels.

But if you can - we'll provide the email address for - and we can have some of our specialists get back to you.

Question cont'd: That would be great. Thank you.

Justin Williams: Want to thank all the presenters today for providing our listeners with this information. We'd also like to thank our participants for joining us today.

As Dr. Trevathan and others mentioned earlier in the call, if you have any additional questions or comments, please send an email to <u>coca@cdc.gov</u>. That's C-O-C-A @cdc.gov.

We will be able to answer some individual inquires but please just you know make sure that you're succinct with your questions. And make sure to follow COCA for any upcoming guidance and information as it becomes available on the CDC Web site.

The recording of this call and the transcript will be posted to the COCA Web site, emergency.cdc.gov/coca as we get them and please remember to check the CDC H1N1 flu site regularly for any updated information or guidance.

That's cdc.gov/h1n1flu. Thanks again for participating and have a wonderful day.

Coordinator: And this does conclude today's conference, you may now disconnect.

## END