CDC Weekly H1N1 Briefing October 1, 2009

Glen Nowak: Thank you all for joining us today, whether you're on the phone or here in person. Today's update on the influenza situation in the United States will be conducted by Dr. Anne Schuchat. She's the Director of the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention. Dr. Schuchat will give us an update on the seasonal flu, H1N1flu, and vaccine supply. So I will turn the podium over to Dr. Anne Schuchat.

Anne Schuchat: Thanks for joining us for today's press conference. I want to talk about three main things today. Where are we with flu, where are we with the antivirals, and where are we with the vaccines, particularly the H1N1 vaccines.

In terms of the disease activity right now, we expect tomorrow in our weekly update of FluView that we'll be reporting substantial flu illness in most of the country, significant flu activity in virtually all states. Most states do have quite a lot of disease right now, and that's unusual for this time of year. We're able to give a little bit of an update about the H1N1 influenza disease in pregnant women. I know that's been an interest to a lot of people. We've updated our numbers, and through late august, we can report that about 100 women in the United States have required intensive care unit hospitalization for H1N1 flu. Sadly, 28 pregnant women in the U.S. have died so far from the H1N1 influenza. These are really upsetting numbers, I know. And I just want to remind women and doctors and nurse midwives that antiviral medicine can be a very important treatment for pregnant women who have respiratory illness.

Stay tuned, the vaccine is an important way to protect yourself from seasonal flu or from the H1N1 flu. And as vaccine becomes available in appropriate formulations, we hope pregnant women and their caregivers will be taking advantage of it, and vaccinate pregnant women or take them to a place where they can be vaccinated.

I want to mention briefly an MMWR report issued a couple of days ago, it's on fatalities from the H1N1 influenza, and the important role bacteria have in some of these fatal cases. Our scientists reviewed autopsy material from 77 fatal H1N1 influenza patients and found that bacteria were present in terms of bacterial pneumonia in about a third of those fatalities. The good news is the leading bacteria was streptococcus pneumonia, and we have a vaccine for that. Adults are recommended to receive the pneumococcal vaccine if they have chronic medical conditions, like asthma, diabetes, chronic heart disease, chronic lung disease, immunodepression and so forth. Sadly, only about one in five non-elderly adults take advantage of that vaccine. So when people are going in for their seasonal flu vaccines right now, those very same people, we urge them to consider the pneumococcal vaccine which is available right now.

I want to catch people up with the antiviral situation. That's been something we've been hearing a lot about recently. Secretary Sebelius released about 300,000 courses of liquid Tamiflu for children to be made available to the states who may need this. So far, basically each state that needs their proportion of that supply will receive this Tamiflu over the next week. Based on requests we've already received. Texas and Colorado received their proportions today. The amounts, there are about 22,000 pediatric liquid Tamiflu courses for Texas, and about 4,600 of those courses for Colorado. Now, some of the liquid formulations of Tamiflu will have an expiration date that may have passed, but we want people to know that the FDA has extended the expiration date of those courses, after careful testing. Everything that is being released has gone through that sort of testing. I do want to remind people about our guidance on antiviral medicine used. Because this is such an important tool we have to reduce illness complications of influenza, whether it's the H1N1or regular flu. People who have severe illness, who are hospitalized or who

have other warning signs can greatly benefit from antiviral medicine. People who have the influenza-like symptoms and have conditions that make it possible they would have a worse time with flu should also receive antiviral medicine. That includes pregnant women, people with asthma, diabetes, immunosuppression, and the very old and the very young. There are important warning signs that people should know about, in particular parents. These include fast breathing, or difficulty breathing, trouble taking fluids, difficulty being woken up or if our child looking a little blue or a little gray. And importantly, getting better and then getting worse. Those are warning signs that really it's time to seek care. And we know that parents are concerned about the flu, and we want them to know about those signs.

I also want to let you know that our website flu.gov has a new place called flu essentials, and those warning signs and more, and a lot more information that we hope will be useful for people is updated right now on that website. So we hope you'll take advantage of that, flu.gov.

Lastly, I want to briefly describe where we are with the H1N1 vaccination effort. We are transitioning from the planning phase to the implementation phase. States and the large cities that are part of our program began placing orders yesterday. I can report to you that 25 of these areas placed orders yesterday, and they placed orders for about 600,000 doses of H1N1 vaccine. I want to describe to you the process going forward about how we'll catch you up about where we are with the ordering, and the shipments and all of that. Every Friday we will be updating through either the media press conference or definitely always with our website a couple facts and figures for you. We're going to let you know how much vaccine was available for ordering, and then we're going to let you know how much was shipped to each of the states or large cities by that day. And it will basically be information gathered through Wednesday, and it will be coming out on every Friday. Important to say, we're at the beginning, and we'll be getting more vaccine regularly, and the states and large cities will be ordering regularly. So this is really just the beginning. We expect the vaccine that was ordered yesterday should be arriving out to the sites by Tuesday. And we're really pleased that this is starting. Of course, this is a little bit earlier than we were planning to get started. And as we said last week, we're starting a little bit slow, but we wanted to start as soon as possible. More and more doses will be becoming available out to the sites, and this is the beginning. The first doses that are going to be available out there on Tuesday will be the nasal spray for inhalation. It's a good vaccine, but it's one that it can't be used in absolutely everyone. It's indicated for people 2 years of age through 49 who do not have conditions like pregnancy or chronic medical conditions. It's safe and effective. And we think it's important to get that vaccine out as soon as we've -- as soon as it has become available. The state and large cities have been making plans about how to use the vaccines as they come available in the communities. And they -- with the doses that we have right now, what they're doing is making practical targeted plans for the best use of the doses that we have. We believe that a lot of the states will be directing these early doses to health care workers. There's a bit of a myth out there that the workers shouldn't get the live vaccine, but that's a myth. Most health care workers who are under 50 and don't have those chronic conditions can receive the nasal spray. I want to make sure that you know that this is just the beginning. We're all in this together. We do expect some bumps in the road over the course as we begin this process together. We're working really closely with the states and large cities to make things go as smoothly and as effectively as possible. So I'd like to begin with the questions. We can start with one in the room.

Michelle Merrill: Michelle Merrill with Hospital Employee Health Newsletter. There was a case of a nurse who died in California who was co-infected with MRSA and I wanted to ask you if health care workers are at greater risk because of the prevalence of MRSA in hospitals and their potential exposure. And I also wanted to find out if you know anything about health care worker infection with H1N1, whether it's community based or hospital acquired.

Anne Schuchat: Thank you. There have been some investigations into the H1N1 infection in health care workers, and we did publish one MMWR a couple of months ago about that. Some of the acquisition was clearly from the community. Some of it may have been from co-workers in the hospital. It's really unclear how much of that transmission there was. We know MRSA is a big problem. I don't know whether health care workers are at greater risk of a MRSA complicating their influenza. But I do know there are a lot health care workers can do. There are priorities for the seasonal flu and H1N1 vaccine. We strongly urge health care workers to be vaccinated. Could we take a question from the phone, please?

Operator: thank you. As a reminder, today's conference is being recorded. Please press star 1 on your touch tone phone. As a reminder, if you're on a speakerphone, please pick up the handset before registering your question. Our first question is from Elizabeth Weise of USA Today.

Elizabeth Weise: Hi. Thanks so much for taking my call. In talking to parents and pediatricians, I'm hearing a lot of concern that the H1N1 vaccine is not sufficiently tested. I'm wondering, were any corners cut on clinical trials? Is there any reason that people should be worried? Or is that -- is there any basis for that is this.

Anne Schuchat: You know, safety is a top priority to us. And what i want people to know is that no corners have been cut at all. The H1N1 vaccine is being produced exactly the same way that the seasonal flu vaccines are produced, with exactly the same careful oversight. We've gone a further step to that, and the clinical trials have not found any red flags in terms of safety. Safety is just extremely important to all of us. And it's something we take very seriously. Next question from the room?

Mike Stobbe: Hi, doctor. Mike Stobbe from the AP, you gave an update on the swine flu situation. In how many states is it widespread? And also, when you're giving the update on pediatric Tamiflu, when did Secretary Sebelius release those, and how far past due expiration were those dates?

Anne Schuchat: okay. The update on the state activity will be coming out tomorrow in flu views, though the numbers that I would have would be from last week. Last week, 47 states were either at widespread or regional activity. We haven't quite gotten all of the reports in from the states today, so I'm not able to give you that update. But tomorrow at 11:00 you'll get he new state map and the new state numbers. I don't actually have the details of what day the secretary approved that release, but we can get that for you. What I need to say is that everyone that was past expiration, the extension is based on testing. So this isn't a matter of, okay, let's just change the label. This is, the FDA goes through a very careful process of determining that the vaccine is still potent and that it's safe to use -- I'm sorry, that the antiviral medicines are still potent and safe to use. This is for the liquid Tamiflu. But I don't have those details right now. Okay? Another question from the phone?

Operator: Thank you, Daniel DeNoon from WebMD.

Dan DeNoon: Thank you very much for taking my question. Dr. Schuchat, there's a report out of the Netherlands that a gene of the H1N1 has come up. That seems to be a gene linked to more human adaption to better spread in the upper respiratory system. I wonder if that raises any red flags for you all and whether CDC has detected any similar kinds of changes in the virus?

Anne Schuchat: Thank you. The situation in the Netherlands was an interesting one, with the two patients with the mutation that was potentially one that could be linked with increased ability to spread, increased transmissibility. We didn't see that at all here. And there wasn't spread in those cases. This is something scientists around the world, including scientists here at the CDC, are on the lookout for. We'll update you when we find things here. The good news is we're not seeing that. There was clinical implication of those findings. And we also don't have that type of mutation evident in our strains here. Next question from the phone?

Operator: Our next question is from David Brown of the Washington Post.

David Brown: Thank you very much. I have two somewhat related questions. You say that 25 entities placed orders for these 600,000 doses of nasal vaccines. Is it 25 out of the 90,000 --

Anne Schuchat: Let me clarify: 25 entities means states, large cities. There is four large cities that are part of our project areas. They include -- they consist of Washington, D.C., New York City, Chicago and Los Angeles County. We also have territories in the project areas. So it's 25. But they're not all states. The 90,000 that you were referring to, ultimately we have the ability to ship vaccines to up to 90,000 sites around the country. Now, that provides a lot of flexibility for the states and cities as they're directing vaccine to go to places like retail chains, doctors' offices and hospitals, to school located venues, and of course, to the public health departments that might be putting on some mass clinics themselves. The early doses are likely going to a much, much smaller number of places. And we do think a lot of the states or cities will be directing them to hospitals where health care workers can be vaccinated early. The early use is a practical targeted approach based on the state and local's expertise about the best ways to use the formulations that are available, you know, at the beginning. But of course, they'll be continuing to order and continuing to direct vaccines to more sites. Do you have a second question?

David Brown: The 600,000 will arrive on Tuesday and all be disbursed next week, is that your expectation?

Anne Schuchat: they will arrive by Tuesday. The details of what the use will be, I can't give you. What i can say is that the states and cities are doing very careful planning. They're planning a lot of different ways for vaccine to be used. And some are planning -- many are planning school located venues. They're planning health plans to offer them up to their high-risk clinic patients. They're using a variety of means. And so what we're going to do each week is tell you how much was available for ordering, how much has been shipped out to each entity, state or large city, and what we'll have in a few weeks, we'll be tracking the coverage. So we'll be able to tell you what kind of uptake are we getting. Initially we'll be telling you about the national snapshot of update. And then later we'll be able to give you state specific immunization coverage. That will be both for influenza vaccine, the regular influenza vaccine and the H1N1 vaccine. So we've actually started that national snapshot this week. We expect the uptake should only be the seasonal flu vaccine. But in the next few weeks you'll start to see that really important measure of how many people have been able to be protected. Next question from the phone?

Operator: Thank you. Our next question is from Sheila poole of the Atlanta Journal Constitution.

>> yes, hi. How are you. Of the 25 entities that placed the orders yesterday, can you identify them? Or is there a place we can go ont he site?

Anne Schuchat: we'll be able to make that available to people after the call. I don't have that list with me. But we can do that.

>> okay. And when do you expect the shots to be available?

Anne Schuchat: there's a good chance that sometime later next week they'll be available out in the sites. I don't have the exact day, as things are in the cue here. But we are expecting them in the near future. And those will be important additions to our protection program.

>> okay. And just one last question. We had a death this week, a 7-year-old girl in Dalton. I don't know if you're familiar with that case. But do you know if bacteria was present?

Anne Schuchat: I am not familiar with that patient and would have to refer you to the health department. But I just have to say each one of these saddens me greatly. And, you know, fortunately most people who develop illness from the H1N1 influenza are able to stay home and be cared for at home and don't need medicines at all. But unfortunately, even some children, healthy pregnant women have died from the virus. And we are saddened by every single one of them.

>> okay. Thank you very much.

>> next question from the phone?

Operator: our next question is from stacey singer of the "palm beach post." your line is now open.

>> thank you for taking my call. I have two questions. One concerns the pediatric Tamiflu and whether you can tell me where Florida falls on the list where it gets the released liquid. My other question concerns adverse incident reporting. I understand from the call this week that there are 3.4 serious adverse events per 1 million flu vaccinations. That would -- I presume that's for 15 years of data. So I assume that is from the injectable vaccine. Do you have similar information for the FluMist? Is the serious adverse event rate the same? Thank you.

Anne Schuchat: Florida, like all of the states, is able to request the liquid form of Tamiflu to be shipped. So i don't know if Florida has already submitted a request. But I do know that we are expecting any state that wants this to be able to get the liquid Tamiflu for children shipped to them within the next week. So this is -- you know, based on the Secretary's decision, and our ability to respond. So certainly the courses that have been approved for release, all the states can get them. And the second question was about the adverse events. I can tell you that the nasal spray has different adverse events than the injected vaccine. Both contain small amounts of eggs. The flu viruses are grown up in eggs to produce those vaccines. Both vaccines are contraindicated in people who have egg allergies. The nasal spray as it was tested, it was found that in children who had asthma, it could cause problems. So it's not recommended for kids with asthma. And it's also not recommended for children under 2years of age, because there were adverse events related to that in the very young. In general, though, it's a very well tolerated vaccine in healthy adults and children over the age of 2. The next question from the phone?

Operator: our next question is from donna young. Your line is now open.

>> hi. Thank you for taking my question. I'm trying to find out, once the study participant has received the vaccine, and they are exposed to the H1N1 flu, is CDC aware of any patients that have actually come down with the virus after receiving the vaccine as part of the clinical trials?

Anne Schuchat: thank you for that question. In terms of the clinical trials, I'm not aware of that. Of course, clinical trials are being done around the country now. And flu is circulating now. So I don't have information about that happening. It wouldn't necessarily be a surprise if it were to happen. The good news about the clinical trials is that what we've seen in adults, and older children, is that a very good immunoresponse was evident eight to ten days after the vaccination was given. So now a couple days after the vaccination was given, it may not be enough to protect you against it. But really, pretty quickly people were making good immune responses. It's also good to know that no influenza vaccine will be 100% effective at preventing the type of influenza that it's targeted against. The H1N1 vaccines are targeted against H1N1 flu, but they won't be 100% effective at preventing that. We think they're going to be pretty good, though, based on the clinical trials that had very high immunoresponses. Another thing to remind people of is you cannot get flu from the flu vaccine a lot of people think that, but it's just not true. Can I take the next question from the phone?

Operator: Our next question is from Robert Bazell of NBC news. Your line is now open.

Robert Bazell: You went into this in the beginning, but I think it's something we've heard a lot about. And because of the stories we do and the e-mails we get. When should Tamiflu be administered to a sick child? Because there have been tragic deaths where the child's parent takes the child to the doctor, the child is not in the adverse category and the doctor does not give Tamiflu because of following your guidelines. And then the child has died. This has happened a few times. I'm not asking you to comment on individual cases, but is there any thought to changing the recommendations and is there anyway of making it an easier decision? I know that's a very, very tortured one for both the physician and the parent.

Anne Schuchat: you know, CDC has updated our antiviral guidance based on what we've learned from the H1N1influenza. And based on what we know about the antiviral medicines, and what we're seeing with the patterns of virus that are out there. We've only so far seen a handful of Tamiflu resistance, but we know that is a possibility. And we also know that it can be very helpful in many instances. Our recommendations are that people who have severe disease and people who have chronic conditions or are pregnant who have a risk of having a bad complication from flu, should all be promptly treated with antiviral medicines. We also want people to know the clinical judgment is very important, that each provider is making decisions all the time. And each parent really needs to make those decisions of, my child is just getting worse now, and time to go back and check in. These are such sad stories. And really may heart goes out to the families that are suffering, this week in particular. But i think that our guidance is trying to make sure that we get antiviral medicines where they can be of the most good, and always flexibility for the clinician and the parent in that challenging encounter. Next question, please? From the room, I'm sorry.

Mike Stobbe: Mike from the AP. Why just 25? Have the other states and cities -- I'm sorry, the 25 that placed the orders, have the others not placed orders and why not? Do you think it will be 6 million to 7 million doses you expect next week?

Anne Schuchat: I think in terms of the 25, you know, that's about what we expected, and we know that more will be ordering tomorrow, and the next day. You know, they'll be ordering based on where they're directing the product and when they want it to arrive. And they're really

making decisions based on those allocations that they've gotten about, it was about that many doses of this formulation, how do we best use it. We're expecting states to continue to be putting in orders, more orders from the ones that already did, and then other states or large cities to be putting in orders tomorrow --I'm sorry, today and tomorrow. And then again, as I said, the stuff that was ordered yesterday should be at the actual sites that was shipped to by Tuesday. You had a second question. I forgot, I'm sorry.

Mike Stobbe: Are you still there will be 6million to 7 million --

Anne Schuchat: I think so. What I want to say, though, about the numbers, is the best way to think about this is that more vaccine is being produced, and more vaccine is being ordered, and more vaccine will be shipped regularly. And that we are expecting a slow start. You know, we are happy that we're beginning earlier than we expected. We're disappointed we don't have more vaccine yet, you know, all the way out to where we want it to get to. So we do think that we have a good system. We'd like to make it even better. And we need a little bit of patience the first couple weeks. The key thing about the numbers, to repeat, is that every Friday, we're going to share with you two key types of numbers. One is how much vaccine was ordered by -- let me double-check what we're sharing with you, okay? How much vaccine was available for ordering, and the second category of numbers is how much was shipped out, and we'll give you that in total. And then we'll have access -- you'll have access to it by state or large city. And those are two key numbers tofocus on. You can think about this as a pipeline. And what we're trying to do is pick two places to talk about numbers that are hard and fast, that will have the same meaning each week. So you'll be able to see things going up. I think we're also going to give you the cumulative about what has been ordered. Next question, please? From the phone, sorry.

Operator: Thank you. Our next question is from Brian Hartman of ABC. Your line is now open.

Brian Hartman: Hi, doctor. Two quick questions. First, if you could put into context the pregnancy statistics you said at the top compared to the seasonal flu year, and what should we make of those numbers. The second question is, anecdotally, it seems like every medical professional I talk to says everybody should be getting a flu shot and every regular person I talk to either in my neighborhood or my office or in my family has serious questions about that. Do you have a sense of how widespread that is, and how difficult it is for your message to get through? And what can you do about it?

Anne Schuchat: Let me answer those two questions. But first, I want to update folks that the secretary released the Tamiflu yesterday. So that was the date that we were looking for. Okay. So, you know, the H1N1 influenza in pregnancy has really been striking. We have obstetricians here at CDC who are coordinating the outreach as well as the surveillance efforts around it. And they're talking to doctors around the country who have never seen this kind of thing before. We don't track seasonal flu. We haven't in the past tracked seasonal flu complications in pregnancy. But what we are seeing is quite striking. So that whether this is more common or people are just noticing it, because we're attending to this H1N1 virus, it's difficult to say. But i think the obstetric caregivers here and the ones that we're speaking with have rarely seen this kind of thing in practice. As I say, we have people talking to the -- essentially providing consultations on a regular basis. And it's been very unusual. The difference between attitudes, you know, experts and health care providers and people, I think these are going to be dynamic. I think they may be changing week to week. Debates on what's going on in your community. And hopefully we'll be getting good information out to you so that you can make good choices. Our highest priority is for people to have good information to be able to make choices for their selves and their families

and to have vaccine available. And accessible to those who can really benefit from it, and want to get it. We are planning to have enough vaccine for everybody who wants to be vaccinated. At the beginning, we'll have a little bit of a slow start. And as more comes available, we're going to really be focusing on those priority groups, which are more than half of the country. But we have ordered enough vaccine so everybody who wants to be vaccinated can be. So the way that we are trying to track those attitudes, we are doing a number of things. We've done focus groups with parents, with providers, with pregnant women. We've been doing some surveys, or working with other institutions that are doing surveys or polls. We have a lot of information that we'll be gathering over time. But one thing i would say, i would expect it to be different in one town or another in different times. I just hope that you can be talking to those around you, and convince them that this is a serious virus. And vaccine is the best way to protect yourself, or those you love. Next question from the phone?

Operator: Our next question is from Bob Roos. Your line is now open.

Bob Roos: Thank you for taking my question. Questions about the report, the bacterial -- second bacterial infections. Is this good news or bad news? It seems that with patients who have serious disease, but don't have a secondary infection, wouldn't they be less treatable? Or wouldn't the bacterial be more treatable with antibiotics? Than those with just viral pneumonia? That kind of sounds like bad news.

Anne Schuchat: I think the important news is that a third of the fatalities that we looked at had this bacterial component. And that just reminds us as clinicians, or as public health people that antibiotics that treat bacterial infections can be very important in some circumstances. And that vaccine, against the pneumococcal infections, which is very underused, is a very preventive tool. I think each one of these deaths is very difficult and the circumstances is difficult. Certainly those with infection, you know, had a very difficult course. Most of them did have underlying conditions that worsened their risk -- their ability to cope with the virus. But of course, we just think it's important for clinicians to be thinking about that bacterial super infection or that pneumonia that can follow influenza. Next question from the room?

Michelle Merril: Thank you. It's Michelle Merrill. I understood that there was going to be some kind of decision on this guidance, updating the guidance related to respirator use. And when can we expect that?

Anne Schuchat: thank you. Protecting health care workers is really important to us. And as you know, there's been a process to evaluate the scientific data, the supply, the feasibility, all of those issues, how to best protect health care workers against flu, in particular against the H1N1 influenza virus. We are in the pro receives of updating those guidances, and we expect them pretty soon. I don't have an exact date, though. Last question from the phone, please?

Operator: Thanks you, the next question is from Rob Stein with the Washington Post. Your line is now open.

Rob Stein: Yeah, hi. Thanks very much for taking our questions. Sort of following up on an earlier question. Are you -- I guess I'm wondering, are you concerned that not enough people are going to get vaccinated because of some of the concerns people have been voicing about safety and the misinformation that's out there?

Anne Schuchat: i think it's really important people have good information so they can make good choices for themselves. I hope that I can provide the information people are missing in their

concerns. I can tell you that H1N1 vaccine is made exactly the same way as the seasonal flu vaccine. 100 million doses of that are used every year, and has a really good safety track record. As a doctor and health expert, I would strongly recommend the H1N1 vaccine for those, you know, really for anyone who wants to reduce their risk of this virus. But at the beginning for those in the high-risk groups. I can tell you as a health care worker, I'm looking forward to getting that vaccine. And as a person who's related to some people in the high-risk groups, I'm urging them to get the vaccine. I know those people want to make those decisions themselves. At CDC we want to get the facts out to you. Flu.gov has a place on it now about myth busting. A lot of people have concerns about vaccines, and it's good for them to be making wise choices for their families of the we want them to be making the choices on the right information, the accurate, factual information. So I want to thank everybody and I think we can make that information about the states available after the calls.