

Pediatric Call: H1N1 Vaccine and School Guidance

Georgina Peacock, MD MPH

Pascale Wortley, MD MPH

Francisco Alvarado-ramy MD

August 26, 2009

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

Coordinator: Good afternoon and thank you for standing by. All participants will be able to listen-only until the question and answer session. This conference is being recorded. If you have any objections you may disconnect at this time. I would now like to turn the call over to Alycia Downs. You may begin.

Alycia Downs: Thank you. Good afternoon and welcome to today's COCA conference call focusing on Pediatrics, the H1N1 vaccine, and school guidance.

We are using a PowerPoint presentation for this call that you should be able to access from our Web site. If you have not already downloaded the presentation please go to 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.

There will be no Continuing Education credits contact hours for this call. I will now turn the call over to Dr. Peacock.

Georgina Peacock: Hello this is Dr. Peacock. I am the co-lead on the CDC H1N1 Children's Health Desk and also a Pediatrician here at CDC. And I wanted to thank you for joining us today on this Pediatric COCA call.

We do plan on having similar calls every month as the situation with 2009 H1N1 influenza continues. And these topics will focus on children and be focused on giving information to practicing clinicians.

These calls are being done as a collaboration between the CDC H1N1 Children's Health Desk and the Joint Information Center Clinician Team.

The Children's Desk is focused on coordinating activities related to children during this response through communication with external and internal partners and stakeholders.

The JIC Clinician Team is focused on outreach and communication with practicing clinicians. We are delighted today to feature two different groups involved in the CDC 2009 H1N1 influenza response.

Dr. Pascale Wortley will be providing an update on vaccine and Dr. Francisco Alvarado will be providing information on the recently released school guidance.

Following these two presentations there will be opportunities for questions. We ask that you keep questions to these two important topics as there will be opportunities on future calls to discuss other 2009 H1N1 influenza issues.

Before I turn this call over to these two speakers I would like to provide you with some current information on 2009 H1N1 influenza. Be aware that guidance and information is regularly updated at the CDC Web site and we encourage you to review this site regularly for updates. The Web site is www.cdc.gov/h1n1.

As of August 21, 2009 there are 7983 total hospitalizations due to 2009 H1N1 influenza and there have been 522 deaths reported to the CDC by state and local public health departments since mid April.

Thirty-seven influenza associated pediatric deaths have been reported to CDC due to 2009 H1N1 influenza virus infections. Influenza associated deaths are a reportable condition in the United States.

During the week of August 9 to the 15, 2009 a review of key indicators found that influenza activity has decreased slightly in the United States from the previous week. However there were still higher levels of influenza activity than is normal for this time of year.

Current visits to doctors for influenza-like illness are down from April but are higher than what is expected in the summer.

Visits to doctors for influenza-like illness were highest in February during the 2008-2009 flu season, but rose again in April of 2009 after the new 2009 H1N1 virus emerged.

Total influenza rates - hospitalization rates for adults and children remain low and are well below the seasonal winter time average for the last four years. Doctor's visits and hospitalizations are continuing to be monitored.

On August 5, the CDC revised its recommendation about how long people with flu-like illness should stay at home and away from other people to prevent spreading the flu.

CDC now recommends that those with flu-like illness stay home until at least 24 hours after their fever is gone, without fever reducing medicines like Tylenol or Ibuprofen or Acetaminophen.

The most important actions are to encourage and facilitate good hand washing and covering coughs and sneezes; to encourage flu vaccination for recommended groups when vaccine becomes available, and to separate sick people from well people as soon as possible.

CDC and its partners will continue to monitor the spread of flu, the severity of illness it is causing including hospitalizations and deaths, and whether the virus is changing. We will provide updates on what we learn about the flu and revise our guidance as needed.

Now I'm going to turn this over to Dr. Wortley who will speak to us about vaccines and vaccinations.

Following Dr. Wortley, Dr. Alvarado will discuss the current CDC full guidance.

Thanks for joining us today and we look forward to you joining us for future Pediatric COCA calls. Dr. Wortley.

Pascale Wortley: Thank you. Good afternoon, this is Pascale Wortley.

I realized after I had prepared this talk that it was a little longer than I could get through during the session but I left the slides in thinking that there would be - they would be useful reference.

So there are some slides that I won't cover that you'll get to keep as reference and actually the first one of those is going to be the summary of epidemiologic findings. So I'm going to move right along to the slide that's numbered Number 4, the ACIP recommendations.

These slides were actually prepared last week before they were published. So as you are probably aware, the ACIP recommendations were published this past Friday -- just a few days ago -- and I'll quickly walk through them.

Initially it is recommended that individuals in the five initial target groups be vaccinated.

These groups total to 159 million people and that includes pregnant women, household and caregiver contacts of children younger than six months, healthcare and emergency medical services personnel, children and young adults ranging from six months through 24 years of age, and then persons 25 to 64 with medical conditions associated with the high risk of influenza complications.

And as you may know, as far as seasonal influenza vaccination coverage, we don't really do a great job in these groups. And our coverage generally rate - is in the order of 20% to 50%. And in particular for younger children even though the recommendation has been out for a while we average something around 25%.

And then of course the recommendation for seasonal flu for older children is brand new so we don't really have data on that yet.

If vaccine supply were to be limited, the ACIP made recommendations for priority groups and that group of people totals 42 million.

So it's a subset of the 159 million which includes pregnant women, household and caregiver contacts of children younger than six months, the healthcare and EMS groups, children six months through 4 years of age, and then children five through 18 who have medical conditions associated with a higher risk of influenza complications.

Now once - whether assuming we start with the 159 million people group, once demand is met for those five initial target groups then we would move on to other adults 25 through 64 followed by persons 65 and older.

And decisions about when to transition from one phase to another will be made at the state and local level taking into account supply and demand.

I realize I've been forgetting to say to move to the next slide so we're now on Slide Number 7 which is the graphical representation of this - the ACIP recommendations and so I won't repeat that.

And then on Slide 8 I've listed a few things that were included in the recommendations that we frequently get questions about.

As you probably know it is extremely likely that patients - that persons will be requiring two doses of vaccine. And so the ACIP recommendations say that vaccines should not be held in reserve for patients who have already received one dose, assuming that they would receive a second dose.

So in other words we want providers to go ahead and vaccinate while they have vaccine and not be holding vaccine back for second dose administration because we anticipate they will continue to get vaccine and I'll talk more about that later.

Simultaneous administration of seasonal vaccine and H1N1 are permissible but on the other hand simultaneous administration of live, attenuated vaccines for example, live attenuated seasonal and pandemic would not be recommended.

And then finally all persons who are currently recommended for seasonal influenza vaccines should be receiving that as soon as it's available.

The next slide has to do with clinical trials. And I'm also going to skip over that in the interest of time but hopefully the information will be of interest to you.

The following slide makes the important point that manufacturers will be submitting a supplement to their seasonal influenza biologics license. Essentially what we have here is where this is being dealt with similarly to a strain change for seasonal vaccine which is essentially the process that occurs every year as new influenza vaccine is formulated.

We're on to Slide 11 now, and I wanted to talk a little bit about vaccine safety monitoring.

The objective of the safety monitoring response includes identifying clinically significant adverse events following the receipt of vaccine in a timely manner, and being able to rapidly evaluate serious events following the receipt of vaccine to determine their public health importance.

Of course there's a great emphasis on evaluating whether there's risk of Guillain-Barre syndrome associated with the receipt of vaccine. And then of

course, communicating vaccine safety information in a clear and a transparent manner to providers, public health officials, and the public.

On the next slide VAERS System is the backbone of safety surveillance and many of you I'm sure are familiar with that system. That will be the front-line monitoring system for collecting and analyzing reports of adverse events.

As you probably know, what VAERS is is a signal detection system but it's not a system that allows for determining whether there is in fact a causal relationship between vaccination and an outcome.

The next slide identifies ways that we have to determine whether there is in fact a relationship. One of the main ones will be something we refer to as the Vaccine Safety Datalink.

And what that is is a collaborative effort between CDC and several large managed care organizations. And administrative data are collected on an ongoing manner that allow for looking at the relationship between vaccination and certain outcomes.

And the administrative data are very often supplemented by additional chart reviews. But it can allow for a rapid cycle analysis to test some of these potential associations.

And then through the Department of Defense there is the Vaccine Analytic Unit which also allows for testing hypotheses.

In addition, through the Emerging Infections Program there is going to be activity around active surveillance for Guillain-Barre Syndrome in ten state

health departments. And additional states may be adopting that same protocol so that active surveillance maybe occurring more widely than that.

Also there's work being done with the American Academy of Neurologists for active GBS surveillance.

And then finally CDC has funded these six Clinical Immunization Safety Assessment centers - six academic centers who are also involved in evaluating potential adverse events.

So now I'd like to move on to Slide 14 and talk a little bit about what vaccine products are going to be available this season.

So as I'm sure you've heard in the news, many different manufacturers are making vaccine - CSL, GSK, MedImmune, Novartis, and Sanofi. Both inactivated vaccine and LAIV -- live intranasal - live attenuated vaccine are being manufactured.

Thimerosal-free vaccine should be available in sufficient quantities to cover pregnant women and young children. And storage will be identical of course, for the H1N1 vaccine as for the seasonal vaccine.

The federal government in addition to procuring the vaccine also is purchasing syringes, needles, sharps containers, and alcohol swabs.

So I guess that moves us on to Slide 15. So both vaccine and these ancillary supplies are being purchased by the US government -- procured and purchased -- and these supplies will be allocated across states proportional to population.

So now I'd like to say a few words about how does it, you know - how does it end up in a doctor's office?

Basically what we are talking about here is a blended vaccination model. In the past when we talk about pandemic planning there was always this image of vaccine being administered solely through public health.

One of the reasons for that was that it was assumed that supplies would be limited and it was important that it be controlled through this venue because it would be important to adhere very tightly to priority groups.

Now of course we have a situation where we will have a lot of vaccine and I'll get to that on the next slide. And it became clear early on that we really needed to think of a different model than the strict public health administration.

And so this blended model means that vaccine will be available for administration of course through the public health sector but also through the private sector.

And when we talk about private sector we are meaning it broadly. So in addition to pediatric offices, family physician offices, OB/GYN practices, internal medicine practices - it also will be available through the retail pharmacy sector and available to community vaccinators to use in different settings.

The states will be at the helm of this process. The state public health will direct where vaccine goes and they will be determining, of the vaccine that they get, their allocation, how much is going to be directed for public health clinics, how much is going to be directed to the clinical sector, and then the centralized - through a centralized distribution process they will place orders

and the distributor will fill those orders and send vaccine directly to those providers.

I'll talk a little bit more later about how one becomes an H1N1 vaccine provider.

So on Slide 17 we have a little bit of information about planning assumptions for vaccine. Our planning assumption is that vaccine will be available starting mid-October and the initial amount will be about 45 million doses mid-October followed on average by 20 million doses per week totaling close to 200 million doses by the end of the year.

There's been a fair amount in the press about the amount of vaccine decreasing which is true that these amounts are lower than what was projected earlier. But I think it's important to point out that 45 million doses is half of what we administer in a regular influenza season and this is just what we're getting in the first half of October so it's a substantial amount of vaccine to move.

As I mentioned earlier, two doses three to four weeks apart will likely be required and this will be determined on the basis of the clinical trials.

So what's going on on the public health side in terms of planning on Slide 18? Basically there are two major avenues of activity. One is planning large scale clinics which include but are not limited to school located clinics.

And of course school located clinics are important to reach the school aged children who wouldn't normally most of the time be visiting the pediatrician offices. And school clinics are a very convenient way to get these children

vaccinated. So many communities, though not necessarily all, will be planning such clinics.

In parallel public health is reaching out to providers to assess their interest and their capacity to administer the H1N1 vaccine. And among the first providers that they are reaching out to are pediatricians; and in large part because pediatricians of course do a lot of immunizing and because children are among this first target group.

As you know immunization programs already have ongoing relationships with pediatricians through the Vaccine for Children Program, so this in a way is the relatively easy part of it.

What's a little more challenging for the programs is to be reaching out to providers that don't deal with on as regular a basis such as OB/GYNs and Internists who are also seeing populations that we want to get vaccinated.

They are also working out arrangements with retail pharmacy chains and with community immunizers as I mentioned earlier because the idea is to have the vaccine as available as possible.

So moving on to Slide 19, state and local public health departments as I mentioned are then in the driver's seat in determining where vaccine will be directed. And there will be a process that some states have started to pre-register providers and then register them as providers of this vaccine.

And registering will mean entering into an agreement with the state or local public health to receive the vaccine and meet some requirements.

At the Federal level we will be putting out some minimum requirements. States will have the ability to modify these requirements to some extent as long as their requirements don't contradict the federal requirements.

States are in the process of getting the word out. I know that one of my colleagues recently received a letter from the State of Georgia inviting her to participate. Though this is an ongoing process, we've encouraged states to make it clear on their Health Department Web site how to get information.

And we're in the process of collating information from all the states that would be either a Web link or phone numbers so that we can also on our Web site have in one place the information that tells you if you are in any given state, who would you contact.

A few words on the next slide about vaccination financing issues. First of all providers will not be able to charge a fee for the vaccine or the syringes and needles because they are being provided at no cost to the provider.

Providers will be able to charge a fee for the administration of the vaccine to the patient or they'll be able to bill a health insurance plan or another third-party payer.

And providers will be encouraged to vaccinate their patients who are under or uninsured. However if they are unable to do that they should be referring them to a public health clinic or an affiliated public health provider.

On Slide 21 I included a statement that we have from Americas Health Insurance plans. And please note that this is mislabeled on the slide. So Americas Health Insurance Plan queried their members about plans for

covering H1N1 vaccine and their statement reads, every year health plans contribute to the seasonal flue vaccination campaign in several ways.

Health plans communicate directly with plan sponsors and members on the ACIP recommendations and encourage immunizations. They also provide information on where to get vaccinations and who to contact with any questions.

And just as health plans have provided extensive coverage for the administration of seasonal flu vaccine in the past, public health planners can make the assumption that health plans will provide reimbursement for the administration of H1N1 vaccine to their members by private sector providers in both traditional settings and in non-traditional settings where contracts with insurers have been established.

Though the non-traditional setting issue is a little more complicated because as you may know, whether a health plan covers or not - where an individual who is insured shows up at a retail pharmacy and can have that service covered depends on whether a pre-existing contract exists or not.

For children, probably not that many children would get vaccinated in that setting anyhow.

And lastly but not least, I just wanted to include a slide reminding people not to forget about seasonal influenza vaccinations.

The vaccines should be available somewhat earlier than the H1N1 vaccine. Although there have been some delays in its release. And people are encouraged to start utilizing it as soon as they get it.

The last slide includes some Web resources that we hope you'll find useful.

And at this point I am going to turn it over to the next speaker.

Francisco Alvarado: Well good afternoon. My name is Francisco Alvarado and I'm with the CDC H1N1 Response specialty, especially the group that deals with community measures.

My intention this afternoon is to summarize the CDC guidance for school based responses to influenza during the 2009-2010 school year. This guidance was released in early August.

If we move to the next slide -- CDC guidance for school responses -- this slide shows the purpose for the guidance, that is to provide recommendations on suggested means for reducing exposure of students and staff to influenza during the school year with the goals of decreasing the spread of influenza in the school and household while minimizing disruption of day-to-day social, educational, and economic activities.

As you can imagine these two goals could at times be in conflict with each other. So we are aiming to strike the proper balance to protect people in a manner that is proportional to the threat and recognizing that there are negative consequences, even risks of their own by dismissing a large number of students.

If we go to Slide Number 3 -- Background, U.S. Schools -- just to give you a sense of the magnitude of the school environment of 55 million students attend more than 130,000 public and private schools in the U.S. with approximately 7 million adults, teachers, and staff.

I think if you do the math, some way or another about a fifth or 20% of the U.S. population is linked to the school setting. And the school is not only a place where children go to participate in the education process, there are also feeding programs such as the reduced or free lunch program, breakfast program through USDA.

There is some child care services, there are healthcare services, and they also provide a stable routine for our children.

If we go to the next Slide -- Changes from Previous Guidance -- the new guidance recommends specific interventions for the school year. It as Dr. Peacock alluded includes the new exclusion period for ill persons and that is a change from the guidance that was given in the spring and the summer.

We also suggest interventions for use if the influenza conditions become more severe and I will go and provide an overview of those.

The guidance is accompanied by supplemental materials. There's a technical report that is more detailed and provides reasoning - the reasoning behind the recommendations. And there's also a communications toolkit and that toolkit provides models of Q&As about the guidance. It provides fact sheets for schools, teachers, and parents; posters that people could download and print and display in their schools.

And there's also a template - a template letter, a template email for schools to send to parents.

If we go to the next slide, Summary is the title of that slide. This is the main highlights of recommendations which are a first that we're currently thinking that the potential benefits of preventive or preemptive school dismissal is most

of the time outweighed by the negative consequences that such closure would bring.

But that school dismissal could be recommended in the future if severity were to increase - if disease severity were to increase.

The guidance also offers many strategic strategies based on the severity of the outbreak, based on the severity that we experienced in the Spring as well as additional interventions to consider if severity were to increase.

We're attempting to balance the goals of reducing illness and death with the goal of minimizing social disruption.

It provides an emphasis based - an emphasis on local goals, disease conditions, visibility, and acceptability.

We stated interventions should determine through collaborative decision-making that includes groups such as the education and public health agencies, parents, community, and healthcare providers and where pediatricians of course, feature prominently.

Next slide entitled - Recommended School Responses. So these are the recommendations for - to be implemented now given a similar severity scenario as in the Spring 2009.

And we are asking schools to request that staff and students who are sick stay home. That schools separate ill students and staff at the school and then send them home.

It stresses hand hygiene and respiratory etiquette. It promotes early treatment of high-risk students and staff. It asks that schools conduct routine cleaning and that there should be consideration of selective school dismissal.

That should be the exception more than the norm particularly for schools that deal with medically fragile children or a large proportion of medically fragile children or schools such as the ones that tend to pregnant women. Those would be a disproportionate amount of person at high risk.

Those would be the type of schools that even in the current severity setting would consider a preventive closure.

If we go to the next slide -- Recommended School Responses -- this outlines the measure that are recommended for consideration is there is increased severity and that would be active screening at school, allowing high-risk students and staff to stay home, asking students with ill household members to stay home so just basically quarantine, (unintelligible) home quarantine, increase social distance between people at school, extend the period for the exclusion of ill persons to stay home, and finally school dismissals are more of a preventive school dismissal recommendation.

If we go to the next slide -- Recommended Strategies -- stay home when sick. We're just going into a little bit more detail for the recommendations in the current scenario. So these are recommendations that are given for implementation now.

And the first one as Dr. Peacock stated, we're asking that persons with an influenza-like illness remain home for at least 24 hours after they are free of fever or subjective fever and that is without the use of any fever reducing medications like Ibuprofen or Acetaminophen.

We think that in most cases this would lead to a three to five day isolation. In most cases we found that outpatients have had an average of two to four days of fever so an additional day would lead to three to five days of exclusion from school or work. And of course to avoid contact with others during that period.

And there is specific guidance in the CDC Web site regarding home care of ill persons. And that's also updated as we learn about the epidemiology.

This isolation guidance, there's also a specific exclusion period guidance on the Web. I must share with you that there are some caveats that we recognize that people can shed virus before they are (unintelligible). They can shed virus more than 24 hours after the fever ends and even shed virus without any fever and while using antivirals.

So it's important to emphasize hand hygiene and respiratory etiquette despite the exclusion period or that the person is no longer ill and returns to school it is important to emphasize hand hygiene and respiratory etiquette.

We're also learning about a number of patients who are (unintelligible) but confirm with H1N1 infection. So basic infection control and hand hygiene and cough etiquette will remain as an important aspect of public health message.

A longer exclusion period may be appropriate for settings with high numbers of high risk persons such as the healthcare setting.

Next slide -- Recommended Strategies: Separate ill students and staff. Again in the current severity situation we recommend that schools move students

and staff with ILI or influenza-like illness symptoms to a separate room as soon as they're identified and until they can be sent home.

We're also asking that they wear a surgical mask when near others when available, and able to tolerate it.

We're asking schools to designate a staff person who is not part of a high risk group to mind the students while they are waiting to be taken home.

We're also asking that staff be provided with personal protective equipment if they're going to be caring or minding for this ill person at school.

Next slide -- Recommended Strategies: Hand Hygiene and Respiratory Etiquette; no surprise here. I think has been emphasized in many other messages from many groups including the AAP about, you know, hand washing after coughing or sneezing.

That staff and students should be provided with time, facilities, and materials needed to observe this hand hygiene recommendation. There's a recommendation that alcohol based hand cleaners are also effective when hand washing is not an option and that people, of course, cover their nose and mouth when coughing or sneezing.

Next slide -- Routine Cleaning. We do not advocate any special disinfection or cleaning measures at school. Regularly cleaning areas and items likely to have frequent hand contact and when visibly soiled is recommended.

We do not recommend any extraordinary cleaning agents; whatever is used in the school usually should suffice. And there's not any need to disinfect

beyond routine cleaning and that should be shared with custodians who take the brunt of this responsibility in the school setting but also with teachers.

Next slide -- Recommended Strategies: Early Treatments, Selective Dismissals. We are encouraging ill staff and students at high risk for complications to seek early treatment.

I think this will be an important consideration for the pediatricians in the country so that they - when they see their patients before and during the influenza season that they help patients identify where they're part of a high-risk group. And that these people should contact you -- the pediatrician -- whenever they have an ILI to discuss whether they should undergo further evaluation and possible antiviral treatment.

In terms of selective school dismissal that may be considered based on the population of the individual school. As schools are increasingly more inclusive in terms of special Ed and other special needs students being in the mainstream school.

But there are still some schools as I mentioned - pregnant women sometimes have their own school environment and that may be a situation where the school officials in consultation with the local health department may decide to selectively dismiss students. So we think this should be a rare event. It's a local decision; it's not going to be federal decision.

And with the goal there would be to protect students and staff at higher risk. This should not have any significant affect on community-wide transmission.

Next slide - If Severity Increases: Active Screening for Illness. So this would be in a scenario where we are seeing more severe disease, a higher proportion

of persons who are infected or ill with H1N1 are requiring hospitalization and ICU care or ventilation.

We would ask at that point that schools consider active screening in the school setting asking about fever and other symptoms, possibly considering a more sensitive definition of ILI.

Maybe nasal congestion and cough or sore throat without the presence of fever would be sufficient to dismiss someone or consider them ill for isolation purposes or exclusion purposes and send them home.

We ask that students and staff who appear ill be sent home or be sent to the school nurse or any other school-based healthcare worker for further screening and if possible - as I mentioned - for the baseline scenario, offer the person a facemask or surgical mask until they're sent home if they can tolerate it.

Next slide, again if severity increases, we would ask school and school boards to consider ways to allow people to stay home but that decision we're saying should be made in consultation with that person's healthcare provider and with any dismissal, we are asking schools to plan for continuing education for the student as technology and capacity allows. Next slide.

Again, if severity increases, we're asking students with ill household members to remain home for five days from the day the first household member got sick and that this is based on household transmission data where we have found that more than 90% of transmission in the household occurs within the first five days.

But again, I should emphasize that this is in a more severe scenario and next slide. Again, if severity increases, we would ask schools to consider creative

ways that they can increase the distance between people without dismissing students and that would include options such as rotating teachers rather than students, canceling classes that bring students together from multiple classrooms, outdoor classes where the weather allows, moving desks farther apart and other options.

Again, but these - there's very little data on these but these are just recommendations that schools can consider. Next slide, extend exclusion period for ill persons.

In a more severe setting, we would revert to what used to be the exclusion period for ill persons for at least seven days, even if they have no symptoms sooner than that.

And if ill persons are still sick after seven days that they should stay home until 24 hours after symptom resolution. Again, that would be in a more severe scenario. Next slide.

Finally, school dismissals, that preventive or pre-emptive school dismissals would be recommended nationwide based on a global and national risk assessment with the goal of reducing morbidity and mortality and partly be reducing demand or the peak demand on the healthcare system. This would be of course using early and in conjunction with other special distancing strategies.

This is pretty drastic so it could also come accompanied by cancellation of mass gatherings and other social distancing actions such as in the work setting having people altering work shifts or being able to work from home when possible, so this would be more of a community-wide combination of tools that would be implemented at this level of severity.

The preventive school dismissal mail should be considered as a time to vaccinate and inducing immunity is considered and so if you have more severe disease and you have vaccines starting to come down the pipeline - people starting to get vaccinated - you could perhaps dismiss students for a slightly longer time but a certain date that - or a fairly certain date - that you will have many of them immunized.

And then we're recommending that if you dismiss students for any reason, it could be a selective dismissal for school with the hyperportion of high-risk persons or a reactive dismissal where you have a high number of students or staff who are either being sent home or absent and the school cannot operate or if we are in a - or less so in a preventive scenario, more in a selective or reactive scenario - you would dismiss students for about five to seven days.

And a preventive or a pre-emptive school dismissal, you may be dismissing students for a longer period just because the reasons are different and that's another point we're making to schools that when they dismiss students, that they make it clear to the parents and the community the reasons why they're dismissing students and what are the objectives.

And part of the reason you hear me talk about dismissal and a closure and this has been debated over the last few years and during the pre-pandemic planning process, dismissal emphasizes that staff and teachers could go to school to support distance learning and perhaps support alternate means of feeding children.

Next slide, school dismissal monitoring. We are - we develop a system to report dismissals or school dismissals to CC the Department of Education and your state health and education agencies and people can go to that Web site or

schools go to that Web site to report when they are dismissing students and that generates real-time national summary data daily on the number of school dismissals and the number of impacted students.

As an example, we have one H1N1-related school dismissal today in Kentucky, about 342 students and so far this academic year we've had 11 schools close in four states for an average of 1.6 days and it affected over 4700 students.

Next slide, additional information assistance. You can go to www.cdc.gov/n1n1flu/schools to access the guidance, the technical report and the toolkit and you can either e-mail or call CDC info for any questions you have as a result of this talk or as new developments occur in your community and that impact your patients. I thank you and good afternoon.

Georgina Peacock: And this is Dr. Peacock. I'd now like to open it up for questions.

Coordinator: Thank you. At this time, we are ready to begin the question-and-answer session. If you would like to ask a question, please press star 1. You will be prompted to record your first and last name. To withdraw the question, you may press star 2. Once again, if you would like to ask a question, please press star 1. Our first question.

Question: Hello, how are you? I was wondering, I see that you've got your increasing severity kind of an algorithm of what the schools should do. What is going to be your trigger for letting the schools know that's the point at which they need to heighten it?

Because what we're experiencing now and I'll explain myself is that they've already gone past phase 1 and 2 and they're sending children to the hospital

who are sick, not even - they're bypassing their pediatrician's office, telling them that they have to go to the hospital and B, they have to be tested in order to return to school with a negative flu test and they can't return to school unless they are being treated with Tamiflu.

So what is the mechanism by which we're going to communicate or you guys are going to communicate that second severity level and just understand that there's some misunderstanding of the guidelines like when you say screening, in here what they're thinking is not taking temperatures and doing ILI screen but screening meaning testing - medical tests.

Francisco Alvarado: Okay, thank you. I think you raised a couple of key points and one of them and I don't know if you've discussed during the COCA calls and if you haven't, perhaps you can bring some of the SMEs on the call to talk about rapid testing.

But the sensitivity of the inflow of the rapid flu test has been suboptimal so I would not base a recommendation either to allow someone to return to school or to say that they have H1N1 or to determine whether I make a recommendation for anti-viral treatment to a high-risk person or persons who's hospitalized based on the flu test - on a rapid flu test.

Question cont'd: We realize that that's what we're saying is we don't like this rapid flu test either but when schools are telling parents that they cannot bring their child back to school until they have a negative test and that they must be tested and prove that they do not have H1N1, that is causing quite the stir.

Francisco Alvarado: I hear you and ..

Georgina Peacock: This is Dr. Peacock and I just wanted to let you know that we've been aware - we've been recently made aware that this is happening and we are looking at developing some materials to help people understand that the process is if children are sick, they should talk to their healthcare provider and as you say, not go to the emergency room, not get started immediately on Tamiflu.

And so we are aware of that and we will be developing things that will hopefully help you and help the schools understand this and I appreciate you bringing up this topic and we were also talking about it in quite a lot of detail this morning in one of our briefings.

Francisco Alvarado: And you also talk about Tamiflu and our solution period guidance which is also on the Web, explicitly talks about keeping the exclusion period regardless of whether you on Oseltamivir or not so even if you're on Oseltamivir but you are still (sebrile) or if the 24 hours have not passed, you still remain at home.

And finally we have colleagues in the influenza division working on the surveillance data from the spring and also the experience accumulated over the last several influenza seasons and they're going to try to come up with better triggers or benchmarks to sort of make a national determination if and when we determine that the - or we observe that the severity of the - or the virulence of the influenza illness is changing and that would be announced as (similar) mechanisms as the guidance and I'm sure it'll be a major message from CDC if that determination were to be made.

Question cont'd: Okay.

Georgina Peacock: We understand that there are hospitals and doctors' offices that are making different algorithms that help parents and help schools understand which children should go where and if you have examples of those that you would like to share, Alycia will come on at the end and give the COCA e-mail again.

If you could send those to us, we would be interested in seeing the different types of flowcharts and things that people are developing and seeing if we can adapt those for the national audience.

Question cont'd: Well, and we would be happy to share ours. The one last question that I have that you touched on and it's something that's also causing a lot of both anxiety and uncertainty is the two different kind of guidelines for return to work out there and there's a return to work in normal settings and then there's the return to work in healthcare settings.

And the healthcare one says seven days and it doesn't really say whether treatment or not treatment in the healthcare provider and then some things say 24 hours after the benefit of - or no fever - without the benefit of fever reducers.

And we're definitely trying to make a decision on that and balance the fact that we may not have enough Tamiflu and then what do you do with the employee that is continuously either exposed or ill and never has the opportunity to come off of Tamiflu, so if you can give us some guidance, we're trying to make that decision right now.

Georgina Peacock: Okay. That is a great question. What's I'm going to do is after this call, I'm going to go back to the people developing guidance for healthcare settings and make sure that we review that and we update that to be consistent with the other advice that is out there.

So as I said at the beginning, make sure that you look at the Web site regularly as we're updating things as we learn more and I'll make sure that we take a look at that very soon.

Question cont'd: Right. That one page, I look at it every day in hopes that it's going to be updated but it's May 3rd or May 6th I think...

Georgina Peacock: I will make sure - thank you for bringing that to our attention.

Question cont'd: Thank you. I'm done.

Georgina Peacock: Next question?

Coordinator: You may ask your question.

Question: I've had questions asked of me about housekeeping personnel and whether or not they need to stay home if they have family members that are sick or if they would be allowed to go in and do cleaning.

Man: They would be allowed to return or I mean, we don't have a recommendation for voluntary quarantine of staff even in an increased severity scenario, much less in the current scenario.

Question cont'd:: Okay. Thank you.

Coordinator: Our next question.

Question: Thank you. I have two question. The first one is about the administration of inactivated and activated and live attenuated flu vaccines. I understand that

you don't want to be squirting flu mist up one nostril and then squirting if there is a live attenuated intranasal version of the H1N1.

But so are you saying that you - it was not clear to me that you were only saying that, you don't want to be squirting the two things up two different nostrils at the same time or are you - what - the thing about if you're getting a injectibles vaccine, could you at the same time be getting an intranasal live attenuated or not and if not, what would be the time interval between the two?

Pascale Wortley: That's an answer that's going to be answered by the clinical - that's a question that will be answered by the clinical trials and mix and match so we will have to, you know, try out for that.

Question cont'd: Okay, and then the second thing is two kind of related things. One is we've seen with the central distribution of VFC flu vaccine a big delay between when the private sector, you know, when private flu vaccine is delivered and when VFC vaccines are delivered.

So it's kind of hard to believe that putting this on top of that system is really going to get it out very quickly. I mean there's been even a month to six weeks' difference between when providers get their private vaccine versus when they get their VFC vaccine.

And kind of related to that is who do you anticipate - who are people thinking is going to be giving all this flu vaccine in the schools? I mean, I'm assuming that physicians and nurses are going to be busy at their offices.

School nurses especially in urban areas can't possibly do this. Public health staff can't possibly do this. Is the idea that every community kind of figures it

out for themselves and tries to recruit like retired nurses and physicians and, you know?

Pascale Wortley: Let me clarify, one thing I did not mention and actually this matches up with another question that we received via e-mail and one thing that has already begun to happen and is going to happen more is that funding is going out through the preparedness program to the preparedness program project areas, what the money that has gone out to date has been for what we call accelerated planning and early implementation.

And then there is implementation funds that will go out and those are the funds that will be used to defray vaccination in the public health sector including school clinics.

And so we are not expecting - so, and I know that the funds are going to be needed to hire the additional personnel because we know that given a shrinking of the public health infrastructure, there probably isn't anywhere in the country that has on an ongoing basis sufficient staff to do this.

So additional staff will need to be hired to carry this out so that's how that will work. I think your question might have had another part. Oh, yes, you were asking about the delay between VFC vaccine and seasonal flu vaccine.

I'm not in the best position to tell you why that is but what I can tell you is that because of the way we have built this special system for H1N1, the system wouldn't even be able to distinguish between a provider who was VFC provider and another provider so there will not be a different.

What'll happen is that the states will be able to monitor on an ongoing basis how much of their allocation is available to them and they will then be allocating it amongst their providers that we have agreements with to...

Question cont'd: So it's not (McKesson) distributing it?

Pascale Wortley: Pardon me?

Question cont'd: So it's not (McKesson), it's not the same...

Pascale Wortley: It is, but the system is - you know, what happens for seasonal flu is that the VFC vaccine comes off of a federal contract.

Question cont'd: It's for all vaccines, you know, that it's - there are weeks of delays between when you order VFC...

Pascale Wortley: Right, but again, the point is that the VFC vaccine comes off of a federal contract and a provider orders vaccine for their non-VFC providers through a different process.

And so there's a lag there and as I said, I'm not in a good position to tell you why but with the way it'll work for H1N1 is that the system will not - it'll all be coming from the same place.

It's not like a provider who's getting one batch of vaccine off of the federal contract through (McKesson) and another batch of vaccine for example from (Sanifex) and how (Sanifex) distributes it.

Question cont'd: Thank you.

Pascale Wortley: Does that make sense?

Question cont'd: Yes. Thank you.

Coordinator: Your next question.

Question: Thank you. We're wondering what was the criteria that the Kentucky schools decided to make - have a dismissal, that you shared with earlier?

Francisco Alvarado: I do not have the specifics. I could get back to you if you send your information to the COCA e-mail account because I could look at their report. I don't think right now - because the system is very simple - I don't think we get the reason.

We've had, I mean, schools close for reasons for which there's really no legitimate reason such as cleaning the school, but in terms of if there's an outbreak in the school or what prompted them to close, I can find out but I don't have that information.

Question cont'd: That's fine. I'll e-mail you and we have an additional question.

Man: The other question is - as trying to make recommendations for clinicians, there's fairly straightforward recommendations for the use of Tamiflu or Relenza for those who are high-risk.

But the uncertainty I think that's going to be coming is trying to suggest how they approach a low-risk individual that comes in with an influenza-like illness within the 48-hour timeframe whom I would suspect that the pressure is going to be to utilize Tamiflu in that setting because they're going to have

no idea whether or not that person's illness is going to remain mild or actually get substantially more ill, you know, 48 hours or more later.

Well, how do we address that and how do - and concern then of course becomes the issue of Oseltamivir resistance.

Francisco Alvarado: All right, I mean, it's a challenge you're going to face undoubtedly during the fall and winter. Right now the recommendations are that anti-viral treatment be used for hospitalized patients and for patients who are at higher risk for seasonal flu complications but the final decision would be made by you and on the patient and their - or the patient's parents.

Georgina Peacock: There will also be updated anti-viral guidance that should be released next week.

Man: Okay. Thank you.

Francisco Alvarado: And again, it's - yes, I would just wait for that.

Coordinator: Our next question.

Question: No question at this time. Thank you.

Coordinator: Your line is open.

Question: Hi, thanks. We are already starting to see heavy influenza in a few of our schools around the state of New Mexico and what I was wondering is if we have these early outbreaks when the H1N1 vaccine becomes available, will there be any determination to self-select out from getting vaccine?

Pascale Wortley: You know, I believe that there's going to be a recommendation made around that because this question keeps coming up. In other words, somebody who's had H1N1 vaccine should they get vaccinated again and what I have heard (Tony Fiore) say who was the lead on the ACIP - the CDC lead on the ACIP recommendations - is that the general recommendation is that people should be vaccinated because we're often not sure if in fact they had H1N1.

Now if you are in a position where you are dealing with eight patients and you know in fact that they had lab-confirmed, well that - you might make a different decision on the individual basis.

But the general recommendation is that people should just go ahead and get vaccinated from a - through a, you know, from a population perspective. It's too hard to think about sorting out who needs it and who doesn't.

Question cont'd: Great. Thank you.

Coordinator: One moment for the next question. Our next question. Go ahead, sir. Your line is open.

Question: I was wondering if you're going to require the public health facilities or the school-based clinics - the sort of non-traditional physicians' office - to have some sort of certificate that they would give to the patients who are receiving vaccines so that we can make sure that it's fully documented the type of vaccine that they receive, the date, so that when they come back to the office, we can make sure that that's recorded in their medical records appropriately so kids don't get too many or not enough vaccines.

Pascale Wortley: Yes, first of all a lot of places do that automatically but we are going to be included and I forgot to mention this so I'm glad you bring it up and part of

the - with the ancillary supplies, the vaccination record cards that will include fields for the type of information you mentioned that would get filled-out at the time at the clinic and given to the patient.

So yes, I mean, that's a concern, to make sure the information gets back to the medical home and that also is making me think there's another question that came in by e-mail about shipping of ancillary supplies - will it be together or separate from the vaccine?

And it in fact will be separate but the - it'll be arranged in such a manner that the ancillary supplies arrive either before or the same day. Obviously what we want to avoid is having the ancillary supplies arrive after.

Coordinator: Our next question. Go ahead, ma'am. Your line is open.

Question: Yes. My question was in terms of how the H1N1 vaccine would be distributed, you mentioned that it'll be sent by the states to designated locations and that you also have a separate initiative reaching out to providers to assess their interest and then you're also going to have the school clinic initiative.

So am I correct in that no matter what the sites are that are going to be getting the vaccination, it'll all have to be designated by the state health department with an agreement between the health department and whichever one of these sites is going to be a provider or will it be different for each one of these sites?

Pascale Wortley: No, it'll be pretty much the same principle so again, the state is in the driver's seat in terms of deciding where the vaccine will go, who these vaccine receivings - what these vaccine receiving sites will be and then juggling the allocation as the vaccine comes available.

Sadly, as many of you on the line know of course, shortages of pediatric vaccine are not an unusual event and the immunization programs have a lot of experience with allocating vaccine.

Question cont'd: So our hospitals have been asking about the allocations and it'll be - everything will be decided then on a local level where the hospitals are in the allocation, right?

Pascale Wortley: Right. You know, I mean, some states are coordinating this at the state level. Others are delegating that coordination to the counties but so for example, if you were - your hospital is in a county where the county makes these decisions and then transmits the information to the state, then they would be deciding how that works.

Question cont'd: Thank you.

Pascale Wortley: You're welcome.

Coordinator: Our next question. Go ahead, ma'am. Your line is open.

Question: Thanks. I'm sorry. I did have one other question and it's regarding the H1N1 vaccine. I am in one of those states that also received from one of their districts and we comprise a large hospital or healthcare system with over three hospitals and 16 immediate care so we actually lay in five health districts within the state.

And we are going to be having ours I guess administered through the district. Now, I saw that the requirements that the CDC has put up as far as to receive the vaccine and then utilizing the (vayer) system and things like that.

Our particular state has also asserted that we have to enter each of one of the vaccines into the state immunization registry and that is a requirement evidently from what I've seen over and above what you are requiring.

And I just want to kind of give you the idea that that is going to be very impacting to a healthcare organization where we would possibly be vaccinating 9000 of our healthcare workers that take care of children every single day.

That is our business and that may be a deterrent for us accepting the H1N1 vaccine because that is a very resource-draining scenario where you have to get special training for the state immunization registration, has dedicated terminals, and people to be able to enter those things in.

So I just needed to kind of comment on that to say if you have any influence whatsoever that there may - and many of my peers feel the same way - that they will not perhaps be able to engage in the H1N1 vaccination strategy and perhaps have to send their employees - their healthcare employees - to the clinics because of that requirement.

Pascale Wortley: Well, you know, thanks for bringing that up and it is something we're concerned about because our objective is to have this agreement be as little of a barrier as possible and so it's something that we are in dialogues with the states on.

And I think it would be important for you and I'm sure you've already done this to mention to the state that this could potentially be a deterrent for your institution.

Question cont'd: We have. We appreciate it. We've talked to the state health officer and to the hospital association of this state because it is an absolute deterrent and in an already very strained healthcare system because we are experiencing over 100% surge in our emergency rooms right now due to influenza-like illness.

Pascale Wortley: Great. Understood.

Coordinator: Our next question. Go ahead. Your line is open.

Question: Hello. I represent Maryland - the non-public schools in the state, the Council of American Private Education - and when we met with the Maryland State Department of Education, we were informed that the school clinics would only be for public school students.

And I'm finding out that this is occurring not just within the State of Maryland and in Maryland, that's 138,000 K through 12 children and in the country, it's 12% of our school-age population.

Is there some assistance - guidance - that can be given to the states so that we're not directed to - what we were told was that our students would need to see their pediatricians or go to other flu clinics.

And for our low-income families, that's usually not a good scenario because they can't afford co-pays and so forth for doctors' visits.

Pascale Wortley: Well, I'm glad you brought that up because I was not aware of that so thanks for bringing that up and we will see what we can do.

Question cont'd: We were told that we could petition to get vaccines and do our own clinics but we'd have to find doctors and nurses and so forth and the schools the - you

know, schools of 200-300 students, there's 1200 of them in the state - do not have those resources.

Georgina Peacock: Right. It's interesting because in the past few years as you probably know, there's been a number of places that have done some seasonal flu school campaigns and like I can think of at least several that did include private schools but at any rate, I'm glad you brought this up.

It's not something I was aware of and we will, you know, see what we can do about it.

Question cont'd: Thank you.

Coordinator: Our next question. Go ahead. Your line is open.

Question cont'd: Yes. For the (thimerosal)-free vaccines, I wanted to know if there were one or more than one manufacturer, if there's going to be a list of all the ingredients, - not just the (thimerosal)-free - for people, you know, for when there might be other intolerance and sensitivities and so forth and whether that kind of scenario is also available in the seasonal flu vaccines.

Georgina Peacock: I am pretty sure - I unfortunately didn't have the detailed slides with the products by manufacturer. I'm pretty sure that there are two but I would have to double-check.

As far as the list of ingredients, whatever is in the package insert - the level of information that's in the package insert for seasonal influenza - will be the same level of information for this and the third question I've now forgotten.

Question cont'd: Well, yes, I wanted to know if there was going to be an ingredient list and if also for the seasonal flu because the seasonal flu ones that I've seen don't include an entire list of ingredients.

Georgina Peacock: Oh, I see. Well, you know, I have no idea if they - I haven't heard that they were planning on changing their level of information in their package inserts so, but...

Question cont'd: Is that available in some other fashion? I mean, if we are contacting the CDC and...

Georgina Peacock: I think the FDA might be the better place to contact.

Question cont'd: Somebody in particular?

Georgina Peacock: No, I really - I don't know. I mean, if you wanted to send an e-mail through to COCA and they would figure out the right place to send that.

Question cont'd: coca@cdc.gov?

Georgina Peacock: Yes, so if you - and I think that this is our last question and so I'm going to ask Alycia to come back on and give that e-mail address again. If you send that question, then we can get that question to our FDA liaison.

Question cont'd: Thank you.

Georgina Peacock: Thank you.

Alycia Downs: Yes, absolutely. I want to thank our presenters for joining us for this call and for our participants for being on as well. In case you didn't get the chance to

ask your question, please send an e-mail to coca@cdc.gov, C-O-C-A at cdc dot gov and we will do our very best to get you an answer.

The recording of this call and the transcript will be posted to the COCA Web site at emergency.cdc.gov/coca within the next week. Thank you again for participating and I hope everyone has a wonderful day.

I also wanted to give acknowledgement of a webcast tomorrow, Thursday, August 27th, from 1:00 to 2:00 pm Eastern that the Department of Health and Human Services is hosting and this is targeting pregnant women and new moms.

For more information and to get more guidance, please go to <http://www.cdc.gov/h1n1flu/guidance/pregnant.htm> and join the discussion tomorrow by sending questions or comments to hhsstudio@hhs.gov.

And if you have any questions about this webcast, please send an e-mail to coca@cdc.gov, so thank you very much.

Coordinator: This concludes today's conference. Thank you for your participation. You may now disconnect.

END