COCA Call: HHS/CDC Update: 2010-11 Flu Season and Universal Vaccine Recommendations

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Speakers:

Dr. Howard Koh, Assistant Secretary for Health at the U.S. Department of Health and Human Services (HHS)

Dr. Garth Graham, Deputy Assistant Secretary for Minority Health in the Office of Minority Health at the U.S. Department of Health and Human Services (HHS)

Dr. Carolyn Bridges, Influenza Division Associate Director for Science (CDC)

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Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode. After the presentations, we will conduct a question and answer session. To ask a question at that time, you may press star 1. This conference is being recorded. If you have any objections, you may disconnect at this time.

I would now like to turn the conference over to Ms. Leshaundra Cordier. Ma'am, you may begin.

Leshaundra Cordier: Thank you (Marianne). Good afternoon. My name is Leshaundra Cordier and I'm representing the Clinician Outreach and Communication Activity -- COCA -- with the Emergency Communication System at the Centers for Disease and Control Prevention.

I'm excited to welcome you today to today's COCA conference call -- HHS CDC Update, 2010/2011 Flu Season and Universal Vaccine Recommendation. We are pleased to have Dr. Howard Koh, Assistant Secretary for Health with HHS, Dr. Garth Graham, Deputy Assistant Secretary for Minority Health and - with HHS, and Dr.

Carolyn Bridges, Influenza Division, Associate Director for Science with CDC -- all here with us today to provide influenza updates.

During today's call, you'll hear our third presenter referring to slides in her PowerPoint presentation. The PowerPoint slide set is now available on our COCA Web site at emergency.cdc.gov/coca. Click on Conference Calls. And the slide set can be found under the call-in number and call passcode.

Please note that continuing education credits are not being offered with this call. Following the presentation, you will have an opportunity to ask our presenters questions. Remember to dial star 1 and that will put you into the queue for questions.

Our first presenter today, Dr. Howard Koh, is the Assistant Secretary for Health at the U.S. Department of Health and Human Services. In this role, Dr. Koh oversees the HHS Office of Public Health and Science, the Commission Corps of the U.S. Public Health Service, and the Office of the Surgeon General.

He also serves as Senior Public Health Advisor to the Secretary, and leads an array of interdisciplinary programs, including the Department's 2010/2011 Seasonal Flu Effort. Dr. Koh previously served as the Harvey V. Fineberg Professor of the Practice of Public Health, Associate Dean for Public Health Practice, and the Director of Division of Public Health Practice at the Harvard School of Public Health.

He was also Director of the Harvard School of Public Health Center for Public Heath Preparedness, and graduated from Yale College at the Yale University School of Medicine.

He has earned Board Certification in four medical fields, including internal medicine, hematology, medical oncology and dermatology, as well as a Masters in Public Health Degree from Boston University. He has published over 200 articles in the medical and public health literature.

Our second presenter today, Dr. Garth Graham, is the Deputy Assistant Secretary for Minority Health in the Office of Minority Health at the U.S. Department of Health and Human Services. Dr. Graham earned an MD from the Yale School of Medicine, where he graduated Kum Laude. He was inducted into the Alpha Omega Alpha Medical Honor Society, and named a Yale President Public Service Fellow.

He also earned an MPH from the Yale School of Epidemiology and Public Health with a focus in Health Policy Administration. He was previously appointed a White House Fellow and Special Assistant to former Secretary Tommy D. Thompson at the Department of Health and Human Services.

Dr. Graham was the founding senior Editorial Board member of the Yale Journal of Health, Law, Policy and Ethics, served on the Editorial Board of the Yale Journal of Biology and Science, Public Health Reports and a number of other guest Editorial Boards.

He also served on the Public Health Executive Council at the Massachusetts Medical Society, the Board of Directors of Physicians for Human Rights, Chairman of the American Medical Association MSS National Minority Issues Committee, and on the Steering Committee at the Boston Men's Health Coalition.

Our third presenter, Dr. Carolyn Bridges, is the Influenza Division Associate Director for Science at CDC. Dr. Bridges graduated from the University of Washington, School of Medicine in Seattle. She completed residency in Internal Medicine at the University of Colorado. And after practicing general intern medicine, she joined the Epidemic Intelligent Service at the Centers for Disease Control and Prevention in 1996 working on influenza.

Dr. Bridges worked as the staff medical epidemiologist in the Influenza Branch in the National Center for Infectious Disease beginning in 1998, and joined the National Immunization Program at CDC in 2003.

In 2006, Dr. Bridges became the Associate Director of the Epidemiologic Science in the Influenza Division, National Center for Immunization of Respiratory Diseases. Her work is focused on influenza vaccine effectiveness, U.S. influenza prevention and control policy, influenza transmission and infection control, zoonotic transition of influenza between animals and people.

Dr. Bridges has authored and co-authored over 50 publications, including the Influenza Vaccine ACIP Recommendations for the last seven years.

At this time, we're going to welcome our first speaker, Dr. Howard Koh.

Dr. Howard Koh: Well thank you very much Leshaundra. And thank you to all my fellow clinicians who are on this call. It's really important to coordinate closely with you as this upcoming flu season arrives. And I first want to thank you all for being part of this information-sharing session. And thank you for your commitment to prevention and good patient care.

You heard from our moderator that I am a physician. I am a clinician. Cared for patients for over 30 years. And I'm also a former State Health Commissioner for Massachusetts, so I know what these vaccination efforts look like on the ground. So it's very, very important to have clinicians like yourselves being knowledgeable and familiar with the most up-to-date and reliable information. So we're very, very pleased to reach out with you and meet you through this call today.

We should thank you because last year through H1N1 -- through your efforts -- some 80 million Americans received flu vaccine against H1N1, and that was quite a Herculean effort.

We have another season coming upon us and know that the flu is unpredictable. And the CDC expects 2009 H1N1, as well as other seasonal viruses, possibly to spread this season. So we have to be ready for anything and everything. And fortunately, we have ample supply of flu vaccine that's already being disseminated as we speak; that will protect your patients and your communities against seasonal flu for this fall and beyond.

For this season, I'm very honored as the Assistant Secretary to be helping and coordinating the efforts across the Department of HHS. CDC has traditionally done so much of this work. But this year, we're trying to pull in the efforts across the Department, and so that's being coordinated through our office.

I also especially want to acknowledge our National Vaccine Program Office that's led by Dr. Bruce Gellin who is with us on this call today. What NVPO has done in the last several months to coordinate through the Department has been quite extraordinary. And we hope that the clinicians on this call will feel a difference and see better coordination at the federal level to help all of you at the local level take care of patients better.

On this call, I'm very pleased to make some opening remarks, and then hear from my colleague Dr. Garth Graham who will be addressing outreach to minority communities. And then my colleague Dr. Carolyn Bridges from the CDC who has great expertise and will be telling you more about the resources available from the CDC and the rest of government.

So just to begin, some basics that you all probably know. Each year on average some 5% to 20% of the population gets the flu. More than 200,000 are hospitalized. And estimates are that between 3000 and 49,000 people die from seasonal influenza-related causes. So that's the challenge.

The opportunity is that we have a number of ways to promote prevention through vaccination, through everyday preventative activities, and through proper use of antiviral medications if they're recommended by a clinician.

As we start another vaccination season, we should remember that flu viruses are always changing, that last year's flu vaccine may not protect against newer viruses. And annual vaccination is the only way to maintain protection.

We are very pleased that this year that we have a significant supply of vaccine for this upcoming season. It's being disseminated and distributed as we speak. So that's good news for this upcoming season. And it's fortunate that we are in that position, because we will have probably even greater demand, based on the recommendations of the CDC's Advisory Committee on Immunization Practices -- the ACIP.

Earlier this year, the ACIP voted to expand vaccination recommendation to include all people older than 6 months. So our first major message of this call is that everyone 6 months of age and older should be vaccinated against the flu as soon as possible and as soon as the 2010/2011 vaccine is available in your area.

The second major message is that all clinicians should encourage their patients to be vaccinated. You don't have to be a specialist or an expert to send this message and be involved in the vaccination efforts. You're - the sub populations particularly important for protection are those with chronic health conditions, like chronic lung disease, asthma and COPD, neurologic conditions, heart disease. These are the populations that suffered disproportionate burdens of illness and death last season.

We also know that children with chronic conditions, such as asthma, diabetes and neurologic diseases are also at risk, so they deserve special attention from all of us for this year.

In fact, we know that each year an average of 20,000 children younger than age 5 are hospitalized because of flu complications.

You will all know that last season we had a situation where young adults were particularly hit, those between the ages 19 and 24. We don't know what to expect for this upcoming season, but we should be ready.

And then traditionally, people 65 years and older are at the highest risk. This year we have two flu vaccines available to them -- the regular flu vaccine or a new vaccine with a higher dose, which is more immunogenic.

Last year we heard a lot about healthy pregnant women who came down with the flu. A number of them died, tragically. And in fact, although pregnant women make up about 1% of the U.S. population, they accounted for some 5% of the deaths last year, so we don't want that situation to be repeated this year.

And so these are some of the sub populations that we should be particularly careful with in terms of sending the vaccination message and make sure that we have good coverage.

The third major message is that we clinicians should be vaccinated as well. Sometimes we're so busy taking care of patients, we don't have time to stop and think about prevention for ourselves. But to state the obvious, if you're healthy, you can get sick and spread the flu to your patients. So vaccination is a first and very important step for all physicians and other clinicians. And this is one of our priority themes for this upcoming season.

We are very pleased that our commitment to vaccine safety and monitoring has increased. Last year, we had some excellent experience in making that monitoring system even stronger than before. I did mention some 80 million people received vaccination against H1N1.

We continue to have evidence that these vaccines are safe. And we need to communicate to the public that they are safe and really a foundation for prevention and public health. And each year the CDC, and the FDA and other parts of HHS work closely with providers, state and local health departments and other partners to ensure the highest safety standards are for these vaccines.

So these are some of the basic messages as we move into the season. It's a great honor for me as the Assistant Secretary for Health to help coordinate this this year in collaboration with our National Vaccine Program Office and Dr. Gellin.

And at this point, I'll turn it back over to our moderator Leshaundra.

Leshaundra Cordier: Thank you Dr. Koh for those opening remarks.

Please welcome our next presenter, Dr. Garth Graham.

Dr. Garth Graham: Thank you. According to recent Medicare data, the annual rate of uptake of seasonal flu in the general population is around 76%, compared to 57% in the Hispanic population and 59% in African-American population. Racial and ethnic minority populations were considerably lower rates of - for vaccination that the general population.

Close to 5000 African-Americans and 2000 Hispanics die each year due to influenza and pneumonia-related complications. And if healthy people 2010 immunization goals were to be achieved, there would be 60,000 fewer flu-related hospitalizations within minority communities, as well as over 1300 fewer deaths in African-American communities, and hundreds fewer deaths within the Hispanic communities overall.

The same study that calculated those estimates found that eliminating disparities in vaccination coverage would have an impact on mortality similar to the impact of

eliminating deaths attributable to kidney disease among African-Americans, or liver disease among Hispanics. Similar reductions and hospitalizations and death would be seen in other racial and ethnic groups, as well as those from lower socioeconomic standards, rural, hard-to-reach and at-risk populations.

While we don't have - well there is a scarcity of published data on national immunization rates of H1N1. Many reports have potentially linked lower vaccination rates and a high burden of chronic disease to higher death rates related to H1N1 in some minority communities.

For example, in California in 2009, non-Hispanic African-Americans, non-Hispanic whites and Native Americans had higher H1N1-related death rates of 50%, 80% and 10% respectively, compared to the general population. We saw similar types of data within Chicago, as well as some other places along the northeast coast.

Some preliminary focus group data done by CDC and others have shown that the role of physicians and healthcare workers in increasing immunization rates, particularly in minority and under-served communities, keep. And hence, why we thought it was important for you to understand the importance of your role as physicians and healthcare workers in improving the vaccination rates within minority and other under-served communities.

This year HHS has elimination of health disparities in vaccination rates in minority communities and other under-served communities a top priority. We realize it might take more than one year to reach this goal. But we're committed over the next couple of years to working hard to address a number of concerns.

We're going to be working to improve vaccine access and availability for the coming flu season.

We're going to address -- especially within minority communities -- general fear regarding safety, reluctance to accept vaccine, as well as misinformation and mistrust of (goal-mannered) administration of vaccines.

We're also going to address one key finding that has come out of some of the focus group data, that minority population perception that influenza is not a serious disease, and improve awareness regarding vaccine risks. We won't be able to do much of this without your help.

It's important, as Dr. Koh pointed out, that healthcare workers and clinicians get vaccinated but it's important that they stress to their patients. Particularly, we want to emphasize a role that physicians have in stressing this message to minority population; that influenza is a serious illness, especially for those who have chronic illnesses and those over the age of 65, but really for all populations. And make sure they stress the importance of getting vaccinated this particular year.

So as we work forward, we invite you to work with us in Minority Health, as well as the - or other partners across the Department of Health and Human Services, to engage minority communities in a very active outreach effort to increase the vaccination rates within minority and other under-served communities.

I'm going to stop there and turn it back over to the moderator.

Leshaundra Cordier: Thank you Dr. Graham.

Please welcome our final presenter, CDC's Dr. Carolyn Bridges.

Dr. Carolyn Bridges: Thank you Leshaundra. And thanks to everyone for joining us today. Just to start out as - with the disclaimer, I have way more slides than I can possibly cover. And so the extra information on the slides will be available to you, I understand, from Leshaundra. I won't cover all of that in the time that I have.

To start out though, my first slide titled Influenza. As you all know, influenza is contagious respiratory disease. We have our yearly winter epidemics. And then these unpredictable pandemics, as we had last year. And the hallmark of influenza viruses is their ability to undergo change. And that change occurs through two different ways.

One is through antigenic direct. And that occurs as the virus makes copies of itself as it replicates and makes errors in replication. So we have direct that goes on all the time.

And then shift, which is what happened last year when we had a new virus introduced to the human population from animal influenza viruses.

The complications with influenza are, I'm sure, well known to most of you. The symptoms of influenza can be quite variable though among many people.

The classic symptoms are really acute onset of fever, chills, body aches, with headache and fatigue, plus respiratory symptoms. Most predominantly cough, but also sore throat and runny nose are often reported. And particularly, children can have gastrointestinal symptoms. But we also saw more GI symptoms of nausea and vomiting last year with the new pandemic virus than typically seen with seasonal influenza, and then could also have sepsis-like syndrome.

And particularly older adults, it can be very difficult clinically to diagnose influenza because of the wide range of symptoms that they can have of where the primary complications can be worsening of underlying illnesses, such as congestive heart failure or COPD. And sometimes influenza is not often and apparent diagnosis when those patients with underlying illnesses come in.

Further complications -- again which we saw more of last year -- was primary viral pneumonia. And more typical with seasonal influenza, there are secondary bacterial pneumonia, as well as other secondary infections, like sinusitis and otitis media.

A definitive diagnosis for influenza really does require testing. Specific influenza testing -- the RGPCR test is the most sensitive and specific; viral culture, of course, is always a test that's available too. It take a little bit more time though -- several days. Though often, it's not as helpful clinically as a PCR test.

More often available are rapid influenza diagnostic tests. And these can be helpful, but many of the commercially available rapid tests are of sub-optimal sensitivity. And so we do not recommend that people use the rapid test to decide about specific treatment for antivirals for someone who presents with influenza, because many of those tests are likely to be false negatives.

And to remember that the clinical spectrum can vary somewhat with different influenza viruses. As I mentioned, more GI symptoms with pandemic virus than typically seen with seasonal influenza.

Or on influenza, the incubation period is generally 1 to 4 days, with the median of 2 days. And the duration of viral shedding is generally from about one day prior to symptom onset, through 5 to 7 days after symptom onset. The symptom - or the shedding can be longer, particularly in young children. And can go on ever for months in severely immune-compromised persons.

And a couple of more recent studies also show prolonged shedding of virus for people who are severely ill, such as those who are hospitalized or in the Intensive Care Unit.

The virus generally is not detective in stool, but there have been some more recent reports of the H1N1 virus in stool. And viremia is also thought to be uncommon.

Pathogenesis may differ somewhat for seasonal influenza, versus animal-origin influenza viruses. But hopefully this year, it's just seasonal that we're going to be seeing.

The impact, as Dr. Koh mentioned, for seasonal influenza is substantial in the United States. But it does vary markedly from year to year. And it's very difficult to predict what the severity will be or what the timing of the influenza season will be. And the timing of the peak influenza season can really range anywhere from November through April or May, and we think to be starting as early sometimes as October.

Also, as Dr. Koh mentioned, around 25% to 20% of the U.S. population can get infected in a given year. We see the highest rates of illness in children. But generally for seasonal influenza, the highest rates of complications occur among people 65 and older.

The number of influenza-related deaths also varies markedly from year to year, with the range over the last 30 years of around 3000 to almost 49,000 deaths.

We know when influenza A/H3N2 viruses are prominent. The number of deaths is about 2.7 times higher than years for H3N2 viruses are not prominent. And for seasonal influenza, around 90% of flu-related deaths occur among people 65 years and older. And these numbers were just recently updated in last week's Morbidity and Mortality Weekly Report.

We also have older studies that estimate about 220,000 influenza-related hospitalizations occur in the U.S. on average. And about 1/2 of those hospitalizations occur in people 65 and older.

The slide is a table showing the estimates of the impact of the 2009 H1N1 pandemic. And these are on the CDC Web site. But the epidemiology of the pandemic last year

really differed fairly markedly from seasonal influenza, with most of the severe illnesses and deaths occurring among people 65 and older. But substantial numbers of illnesses -- current estimate is about 61 million influenza illnesses.

And if you look at the next table, this is to show really what the relative comparisons are from the previous pandemics and to seasonal influenza, versus the most recent pandemic. And although these numbers are not directly comparable, because the methods used to make these estimates are different and the databases are somewhat different, but to get a sense of where we are for seasonal versus the 2009 pandemic for seasonal influenza, as I mentioned, about 90% of the deaths are in 65 and older, or 10% in those less than 65.

But for the pandemic last year, approximately 87% of those deaths occurred among people 65 and younger, so much greater impact last year among younger persons.

The groups that are increased risk are listed here in detail. It's children less than 5, but particularly, those less than 2 years of age. And adults and children who have certain chronic medical conditions, those are listed here, as well as pregnant women.

What we've learned from the pandemic last year is that the groups that we've traditionally termed to be high risk of flu-related complications are also were at higher risk of 2009 H1N1. Very high rates of hospitalization and death occurred among people with asthma, COPD, diabetes, chronic cardiovascular disease. And a very high risk of severe disease among people with neuromuscular, neurocognitive and other neurological disorders, and among pregnant women as was mentioned.

The one high-risk condition that previously hadn't been recognized was the risk - increased risk among persons who were morbidly obese.

A number of studies have been done which look at the risk of obesity - the presence of obesity as a risk factor for severe disease and death. I've listed one of these references by (Morgan Adel).

And this particular study, which was from the U.S., they found a higher disproportionate number of obese people among those severely ill with H1N1. Particularly, those who were morbidly obese with a body mass index of 40 or greater.

A number of other studies were looking at this as well, with larger sample sizes. And also, people are looking backwards at previous influenza seasons to see if this was a risk factor that maybe has been there for a while but was unrecognized.

Another issue that was highlighted during the pandemic was the racial and ethnic disparities in terms of influenza, lab-confirmed influenza hospitalizations. For both, the first wave of the pandemic, which was marked with 2009, and the second wave of the pandemic, the column label is 2009 to 2010, there were increased rates of laboratory-confirmed hospitalizations among Blacks who are not Hispanic, among Hispanics as well as among American Indian and Alaskan Native populations.

And as Dr. Graham mentioned, we know that Hispanics and African-Americans generally have substantially lower influenza vaccination rates. And so we really need to do a much better job at eliminating this health disparity and make sure we get adequate vaccination rates among people of all racial and ethnic groups.

Next, I just wanted to highlight a couple of very important studies about influenza vaccination and the benefits of influenza vaccine.

One of those studies was by Dr. Mark Loeb and colleagues in Canada. And they published their study in JAMA of this year. And they conducted a randomized trial of children in Hutterite colonies in Canada. This is a blinded study. And the objective of

the study was to assess the affect of influenza vaccination of children on influenza in the children themselves, and among unvaccinated contacts in their communities.

And they randomized Hutterite colonies to either receiving the influenza vaccine or hepatitis A vaccine. The children vaccinated were age 3 to 15, which is the age of school-age children in these colonies.

And then they had nurses make weekly visits to the colonies to collect swabs from male persons and do PCR testing for influenza. And they randomized 22 colonies to influenza vaccine and 24 to hepatitis.

They were able to get very high vaccination rates of study participants -- 83% of alible children received influenza vaccine. And what they found was a vaccine effectiveness of 61% among non-study vaccine participants. So 61% reduction in influenza among the unvaccinated people living in the colonies with the vaccinated children.

The children themselves also benefited with the vaccine effectiveness at 55%. That wasn't statistically significant. But the study really was not powered large enough to find the direct effects in the children. But very similar point estimates of both the communities and the children themselves.

The strengths and the importance of the study is that it really confirms the results of a study conducted in the 1968 pandemic by Dr. Arnold Montro and his colleagues in Tecumseh, where they found during a pandemic, if you vaccinate and you achieve high vaccination levels in children, you can decrease influenza and other people in the community.

Both of these studies achieved very high vaccination rates -- over 80%. And they had a comparison community with very low vaccination rates. They found similar

vaccine effectiveness in the vaccinated and the community unvaccinated persons, which just also lends support and strength to their results.

There are two additional years of data that are forthcoming from this study; so additional 2009 through '11 influenza seasons. They will not, however, have information on the 2009 H1N1 monovalent vaccines, because they didn't randomize that vaccine.

The second study I wanted to point out or mention is a study by Dr. (Vallman Entall) from Bangladesh. The study was published in the New England Journal in 2008.

And in this study, they randomized 340 pregnant women to receive either influenza vaccine or pneumococcal polysaccharide vaccine while the women were in their third trimester of pregnancy. And then they followed the women and their infants through the first six months after birth.

And their outcome was febrile illness in the infants. Laboratory-confirmed influenza in the infants. And febrile respiratory disease among the mothers. And what they found, which was consistent with when influenza viruses were circulating, is a substantial reduction in laboratory-proven influenza in the infants whose mothers received influenza vaccines.

This is really the first study that has been able to look at this. And doing it in Bangladesh, I think, was very helpful, because they have influenza year round, unlike the patterns that we have here in the temperate climate.

They also found not only benefits to the infants in terms of reducing all febrile illnesses and influenza, positive illnesses. But they also found 36% reduction in fevers in the mothers themselves. This again, brings a lot of support. Not only is it important to vaccinate the mothers for themselves, because they themselves are at

high risk, but also then it can help protect those infants less than 6 months during that vulnerable time where they are not eligible to receive influenza vaccines.

And then, well, I'll switch here a little bit and just talk about influenza vaccines. As you all know, the primary means to prevent influenza and its complications is influenza vaccine.

The ACIP now recommends vaccination of all persons age 6 months and older. It's also the primary means to protect those less than 6 months by vaccinating household members and out-of-home caregivers of children less than 6 months. And as I mentioned, vaccinating pregnant women can also help protect infants less than 6 months from influenza.

Vaccination is needed annually because the strains change on an annual basis. And we know that recommendation for vaccination by a healthcare provider is a key factor in a patient's decision to get vaccinated.

There are two main types of influenza vaccine.

The inactivated influenza vaccine. This one is an intramuscular - for intramuscular injection. It was first approved for use in the United States in 1945, so it's a very long history of use in this country. It's used in persons 6 months of age and older. And there are different manufacturers. Included one with a high dose vaccine for adults 65 and older, which I'll talk a little bit more about later.

The other type of influenza vaccine is a live attenuated influenza vaccine, or LAIV. This was licensed in the U.S. in 1999 and is approved for use among healthy, non-pregnant people, 2 to 49 years of age.

The people who have a medical condition that increases their risk of influenza complications are not recommended to receive LAIV, but other people of course may, including contacts of high-risk people.

Though healthcare personnel and contacts of high risk can take the FluMist. The only contraindication really is persons in terms of occupational contraindication are persons who work with people who are so immune suppressed that they require a protected environment. So just people in a bone marrow transplant unit, for example.

And again, both types of influenza vaccine are updated annually. And yearly vaccination is recommended.

In terms of safety, these vaccines have a very good safety record over many decades of use for the inactivated vaccine. And since 1999 with the live attenuated vaccine.

The primary reactions for the inactivated vaccine in randomized trials is really only redness and soreness at the injection site; although, other uncommon reactions can be body aches, mild fever. And in Canada a few years ago, ocular respiratory syndrome was also reported; that may occur occasionally outside of that year as well. But that is very uncommon.

The rare risk of seasonal flu vaccine may be an estimate of risk in some years of approximately 1 to 2 per million vaccinees of Guillain-Barré syndrome.

The live attenuated vaccine is also very well tolerated in children, particularly with the first dose of vaccine that they receive. They're more likely to have rhinitis, cough, low-grade temperature, headaches, and muscle aches. And particularly children who've had a history of wheezing before, they can have wheezing. All right. And so children who have - who are 2 through 4 years of age who have had a history of wheezing should not receive a live attenuated vaccine.

And again, this vaccine is indicated for people who otherwise are healthy and don't have a high-risk condition for fluenza.

In terms of adults, again, the live vaccine is very well tolerated, with minor and limited symptoms reported -- rhinitis, sore through, cough, chills and headache. And again, these are - generally last for maybe only 1 to 2 days. And the vaccine is very well tolerated.

All U.S. licensed vaccines are currently egg-derived. But they're contraindicated for people who have a severe egg allergy.

Severe allergic reactions to either vaccine are quite rare. But there is, of course, a system for monitoring as a - multiple systems for monitoring vaccine safety. One of those is a Vaccine Adverse Events Reporting System, or the VAER System. And anyone can report an adverse event to this system -- either a patient or clinician. And that's very helpful for identifying potential signals that - of any new safety concern that may arise. And influenza vaccines are also covered by the National Vaccine Injury Compensation Program.

For this year's 2010/2011 vaccine, there is only one vaccine this year, thank goodness, and not two. And for the first year, all persons 6 months and older are recommended for annual vaccination.

The vaccine strains include the H1N1 strain, which is the same strain that was included in the 2009 monovalent vaccine. There is also an influenza A/H3N2 component. This is a new strain for the northern hemisphere vaccine. And then the B/Brisbane/60/2008 strain. And this influenza B strain was included in last year's seasonal vaccine.

And during the summer, all three of these strains have been identified in the U.S., as well as internationally. Again, it's very difficult - or really impossible to predict at

this point which of these viruses may predominantly - predominate. And really, all three of them might circulate together or at different times during the season.

I just want to go back a little bit to the ACIP recommendations. The recommendations have changed considerably over the last several years. Starting in 2006, when the - it was the first time that children 6 months to 59 months were recommended for annual influenza vaccine, as well as vaccination of all caregivers and household members of children less than 5 years of age.

In 2008, all children age 6 months through 18 years were added to the group recommended for vaccination.

And then beginning this influenza season, the recommendation was further expanded to include all persons 6 months of age and older.

From last year to this year for seasonal influenza, it's a relatively small proportion of the population that's added, because prior to this -- because of the recommendations for healthcare personnel to be vaccinated and household contact of high-risk -- about 85% of the population was already recommended for vaccination.

Though some may ask -- what was the rationale for adding everyone 6 months and older, or having the universal recommendation? There are a number of reasons for this. Certainly, previous groups had been identified as being high risk of complications, including older adults and those with chronic conditions.

But we know that the vaccine program is safe. The vaccine has a very long track record. And it's effective in preventing substantial morbidity and mortality from influenza.

And we know that the morbidity and mortality occurs in all age groups, including adults 19 to 49. Most of whom already had a recommendation for an indication for a seasonal influenza vaccine.

Some people have influenza complications who have no previous identified risk factors. Or they have risk factors that they were not aware that they should be vaccinated. Or they might be at risk of flu-related complications for risk factors that may be newly identified, such as morbid obesity or potentially by race ethnicity.

A recommendation that all people 6 months and older receive vaccination eliminates the need to determine whether each person has a specific indication for vaccination. It also emphasizes the importance of preventing influenza across the population spectrum.

And it reduces potential barriers to increasing the number of persons vaccinated and protected from influenza, including barriers of lack of awareness about vaccine indications among people at higher risk of complications and their close contacts.

There are number of different brands of influenza vaccines that are available in the United States. The single live attenuated vaccine is the FluMist. And there are a number of other formulations and manufacturers' vaccines available for the inactivated vaccines.

It's estimated that there will be approximately 160 million doses available for the 2010/2011 season, which should be plenty of vaccine for anyone who wants to be vaccinated.

The next thing I wanted to mention was the vaccination of young children. There are a number of children who will be entering the season with a wide variety of immulogic profiles. The most children will be susceptible. Some of them will be

immune after natural infection. And some will be immune after having received two doses of monovalent vaccine.

The question really is -- what might have been the response - or what might be the immune level for children who received only one dose of monovalent vaccine?

And a number of studies have shown quite a wide range of antibody titers for children who are younger than 9 years of age who receive just one dose. But we know receipt of two doses, 73% to 100% of children should have a protective antibody titer.

So the ACIP currently recommends that children younger than 9 years of age whose vaccination status is unknown, or those who have never received seasonal flu vaccine before, as well as children who did not receive at least one dose of the monovalent, regardless of previous seasonal vaccine, all of those children should receive two doses of the 2010/2011 vaccine.

And I realize this is a somewhat confusing recommendation. But in the ACIP recommendation for flu vaccine, at the end of the document there is a diagram, which I'm showing here, which provides an algorithm to help providers make those recommendations about whether a child needs one or two doses of this 2010/2011 vaccine, based on their prior vaccine history.

I will just mention again that the Fluzone high-dose vaccine was approved in the U.S. by the FDA in December of 2009. And this high-dose vaccine is an option for you as adults 65 and older this year.

And the last thing that I will mention is about the Afluria brand of vaccine. So in April of 2010, vaccination of children younger than 5 years of age was suspended in Australia because of reports of febrile seizures during a mass vaccination campaign of children younger than 5.

They also noted high reports of fever in children 5 through 8 years of age. And they had had no prior years with similar kinds of reports.

They conducted several studies in Australia and New Zealand and found the increase risk; it was only associated with the Fluvax and Fluvax Junior brands of the CSL vaccine, but not with any other manufacturer's vaccines.

These febrile seizures occurred in median of 7 hours after vaccination. And the Australian study estimated that febrile seizures occurred at a rate of about 9-per-1000 vaccinees among children younger than 5.

The Fluvax Junior brand of vaccine is antigenically equivalent to the Trivalent vaccine approved in the U.S. for this fall.

A number of studies have been done to try and determine what the cause of these increased risk of febrile seizures are. And there has been - they have not been able to identify the cause. But the routine testing shows potency, antitoxin testing, or (genicity) testing -- all of that is - meets specifications and is appropriate.

So in August of 2010, earlier this month, the ACIP recommended that Afluria -- the brand of the CSL vaccine for the U.S. -- should not be used in children age 6 months through 8 years of age.

The ACIP also recommended that other age-appropriate licensed seasonal flu vaccines be used for this age group. However, if no other seasonal inactivated vaccine was available and the children couldn't use FluMist, then children 5 through 8 years of age who were high risk of flu-related complications may be considered for the use of Afluria, with physician consultation with the parents.

In addition, on the package insert for Afluria, there is additional information about the increased risk of febrile seizures, particularly in children younger than 5. And the Afluria vaccine -- only the single 0.5 mL dose, which is for 3 ages and older, will be market in the U.S.

Neither the pediatric 2.5 mL single dose preparation, nor the 5 mL multidose vials will be marketed in the United States. And, of course, vaccine safety monitoring will be continuing in the U.S.

And I have some additional slides on antiviral medications, which I will not go over. But they're there for your information. And I will stop and answer any questions that I can. Thank you Leshaundra.

Leshaundra Cordier: Thank you to all our presenters for providing our COCA audience with this great information. We're now going to open up the lines for the question and answer session.

Operator?

Coordinator: If you would like to ask a question, please press star 1. Be sure your phone is not muted and record your name clearly when prompted. Your name is required to introduce your question. To withdraw your request, you may press star 2.

Once again, to ask a question, press star 1 and clearly record your name. It will be one moment for the first question.

Our first question comes from (Robert Lowless).

(Robert Lowless): Hello. Thanks for taking my call. What kind of plans does the CDC have to promote greater rates of vaccination among minorities? What kind of plans do you have?

Dr. Carolyn Bridges: That's a great question. We're certainly working with a number of our partners. We've developed specific messaging and posters and outreach with, for example, the Indian Health Service. And Dr. Graham may have other specifics for other populations as well.

And we have for a number of years developed specific communications materials, which target different racial and ethnic groups.

Dr. Garth Graham: That's right, thank you.

Dr. Carolyn Bridges: All of those materials are available on the CDC Web site as well. Those are free resources.

Dr. Garth Graham: And let me actually add to some of those key points. We've been developing a number of key materials that we believe are going to be important for dealing with some of the challenges that I was articulating in terms of racial and ethnic minority communities.

And as I said before, if you go to the cdc.gov Web site and scroll through, you'll see some of the materials that have been developed there and some that will be coming as of next week and the following week. But that's just one of a many-pronged attack to make sure that we deal with this issue in a very comprehensive manner.

We do have specific plans to do a number of regional outreach events. Both - we'll be having some events here in D.C., as well as some at a local - at a state and local level to make sure that we connect folks and a variety of different partners around the key messages that I was articulating earlier.

But certainly, in terms of the individual who posted the question, we are trying to find as many partners as possible, and that's where your role is important. So if there are individuals here who would like to work with us to help make sure that we deal

with this at a variety of different levels, make sure that we connect with you at both the state and local level. Please feel free to connect with my office. We'll be leading the effort as along with the Partnership and Faith-Based Center here at the Department of Health and Human Services.

Coordinator: Our next question comes from (Amy). (Amy) your line is open.

(Amy): Oh, I'm sorry. I was just wondering like when we should start giving the vaccines this - for the season?

Dr. Carolyn Bridges: This is Carolyn Bridges. You can start giving vaccine as soon as vaccine is available in your community.

(Amy): Okay, okay.

Dr. Carolyn Bridges: So anytime. You can start today.

(Amy): Okay. All right, thank you.

Dr. Carolyn Bridges: You're welcome.

Coordinator: Our next question is from (Marie). (Marie)?

(Marie): Yes. I was wondering about the immune response of adults to the H1N1 and the pregnant women? Is there any evidence of immunity?

Dr. Carolyn Bridges: Yes. Yes. This is Carolyn Bridges. That's a great question. For adults, the immune response was very good to only one dose. So if anyone 9 years or 10 years of age and older, they responded well to one dose, including pregnant women.

It was really a question for the younger-than-9-year-old age group how many of those children responded to one dose, versus how many needed a second dose. Though we really think that children younger than 9 need two doses to make sure they have a good immune response and are protected from influenza.

So as I said, it can - the recommendation is a bit confusing. But basically, children need to have had - need to make sure they've had two doses of H1N1. Whether that's in the form of one of the monovalent doses if they only got one last year, then they just need one of the seasonal doses, assuming they've been vaccinated for seasonal flu before.

But if they didn't get any of the monovalent H1N1 vaccine, then they need to get two doses of the seasonal flu vaccine this year to be protected.

(Marie): And how long is that immuno response be - how long will it last?

Dr. Carolyn Bridges: Well the protection from the vaccine lasts - it starts to wane over the year. But it does last for the duration of the season.

We used to recommend holding off on vaccine a little bit, particularly for elderly and nursing home residents. But really, there is no evidence that waiting until October/November is beneficial at all in terms of effectiveness. So in the last few years we've changed the recommendations to recommend vaccinating as soon as vaccine's available. So there's no need to hold off on vaccine for your high-risk patients.

(Marie): Thank you.

Coordinator: Our next question comes from (Charlene Gallagher).

(Charlene Gallagher): I think my question has been answered already. I was concerned because commercial pharmacies are currently offering vaccines and hospitals have not received them yet. But it looks like that's been answered already. Thank you.

Coordinator: Our next question is from (Laurel Homer).

(Laurel Homer): Hello. Could you please provide guidance for influenza testing this season?

For instance, is H1N1 testing in addition to using rapid test until H1N1 is established in the community advised? Do you understand what I'm getting at?

Dr. Carolyn Bridges: I'm not sure I completely understand your question. But as you, I'm sure, remember from last year, that the biggest concern was that the rapid influenza diagnostic tests are not of optimal sensitivity.

(Laurel Homer): Right.

Dr. Carolyn Bridges: And so we had reports of many cases of patients who were tested, had a negative rapid flu test, and then treatment was delayed. And there were some bad outcomes.

So for seasonal influenza as well, these tests are not optimal. So really, the same recommendations apply.

The rapid test can be helpful to know when influenza is circulating in your community. Many of these tests can distinguish between influenza A and B. But for clinical decision making for an individual patient, it - if it's indicated for - if the patient has disease that's indicated for treatment you're concerned about, they should be treated regardless of the rapid influenza test results.

And as confirmatory testing is needed, then testing should be sent off, say, for PCR or culture testing.

(Laurel Homer): So it's…

Dr. Carolyn Bridges: But relying on the rapid test results to make treatment decisions, we've continued to advise against that.

(Laurel Homer): So until we know what's circulating in our community, is there an interest in knowing whether the influenza-presenting patient is H1N1, as opposed to non-H1N1 type A or B influenza? Because last year, what we would do is regardless of what the rapid showed, we would send off for H1N1. But then once we had established in our community that H1N1 was present, we didn't do that any longer.

But there was an interest for the in-patient, you know, if they were H1N1; know whether or not they were H1N1 versus another type of influenza. That was early in the season. So I'm trying to get the early season strategy down to advise the clinicians that are going to ask that question.

Dr. Carolyn Bridges: Right. Absolutely, it's helpful to know what's circulating and to get some early - some viruses from early in the season. So having some samples that are sent in for viral culture - because those samples for viral culture and PCR are very important for surveillance and monitoring. And as you say, alerting other clinicians in the area to when influenza viruses are circulating.

So yes. In general, that's a helpful practice. For our sentinal physicians that do surveillance in the community, we ask for them to send in some samples from the beginning, the middle and the end of the season for virus culture and/or PCR, so that we can monitor how the viruses may be changing over the season.

The antiviral medications that are recommended for use in the U.S. this year are the neuraminidase inhibitors. The Tamiflu, for example.

We're not recommending rimantadine or amantadine because of high levels of resistance. So the testing doesn't necessarily help with treatment options, because the only recommended treatment are the neuraminidase inhibitors.

(Laurel Homer): So whether it's influenza A, B or H1N1.

Dr. Carolyn Bridges: Exactly.

(Laurel Homer): Perfect.

Dr. Carolyn Bridges: H3, H1 or B; that those are the medications.

(Laurel Homer): Great. Thank you so much.

Dr. Carolyn Bridges: You know, the one point I might just make is that certainly if there is a concern about an unusually severe illness or exposure to animals that may be infected with influenza viruses, you know, those would be particularly helpful to send for viral culture and PCR testing if there's any concern about a novel influenza virus infection.

(Laurel Homer): Our clinician's practice last year, they would order more of the PCR, rather than the viral cultures. Are you recommending both?

Dr. Carolyn Bridges: No, they don't need to do both.

(Laurel Homer): Okay.

Dr. Carolyn Bridges: As I mentioned, more for sentinal physicians who are doing the surveillance.

(Laurel Homer): Sure.

Dr. Carolyn Bridges: It's helpful to have those viral - some viral cultures. We need some of those viruses for vaccine strain flu action purposes.

(Laurel Homer): Great, thank you.

Dr. Carolyn Bridges: Thank you.

Coordinator: Our next question comes from Lilyan Dayton.

Lilyan Dayton: Yes. Can you hear me?

Dr. Carolyn Bridges: Yes. Go ahead.

Lilyan Dayton: Yes. I work in an Outreach Program from the Pasco County Health Department in New Port Richey, Florida. And one of the big bugaboos of each season is, unfortunately, local physicians -- usually private physicians -- do not necessarily encourage any of their patients in many cases to get the flu shot. Some of their older patients who are on Medicare, they always encourage them because Medicare pays for it. But other age groups are not as seriously considered.

And when we talk to people at different venues, we can't get beyond what their doctor has not said to them - or what their doctor has told them. That - and also that the fact the season lasts much longer. And once you don't get it by December, they say - the physicians say then you don't need it. So this is what we fight every year.

Does the HHS talk to the physicians through mail, through email, or whatever means to encourage this to change? Thank you.

Dr. Howard Koh: Well this is Howard Koh. I can start off with this. I mean, that's one of the key messages for this upcoming season, so I want to thank you for raising that point.

And one of our top-line messages is that all clinicians should be involved now, encouraging their patients to be vaccinated. And that recommendation should be for all people 6 months and older.

This is where reaching out to professional societies, all clinicians who have contact with patients, to send that broad message about universal vaccination for flu is going to be a key effort for this upcoming season and beyond. So thank you for raising that point.
Maybe Dr. Bridges wants to say more.

Dr. Carolyn Bridges: Yes. Thank you Dr. Koh. There - we work with a number of partner organizations, including the Vaccine Summit, which represents a number of those organizations, of course, on the Advisory Committee on the immunization practices. A number of professional and medical organizations are represented. We work with the American Academy of Pediatrics, the ACP, the AMA and so forth to try and get those messages out. But, you know, again, as Dr. Koh said, it's really a team effort.

And we find that administrators have a very large role to play in healthcare settings to create an atmosphere where influenza vaccine is part of the norm and is really encouraged, well for the healthcare workers as well for their patients.

And certainly, we don't have optimal vaccination rates of healthcare workers. And so we do have a ways to go to get healthcare workers on board about the importance of vaccination. And hopefully that will help translate to them, making sure that they get their patients vaccinated as well.

Leshaundra Cordier: Operator, we have time for one more question.

Coordinator: Okay. Our final question will come from (Sandy Homen).

(Sandy Homen): Hello. I think my question has mostly been answered. But I live in the upper northwest - or north - Midwest, excuse me. And on the immunity response you said it does last for about a year, because typically, our season doesn't start until January or February -- in there. Flu season.

Dr. Carolyn Bridges: Right. Thank you. And I appreciate your asking and the question. As I mentioned, I think there's some carryover from prior ACIP recommendations, where there was this recommendation to kind of hold off, particularly on the frail, elderly, such as nursing home residents.

But more recent studies really find that there's no decrease over the course of the influenza seasons. There's no reason to wait until October/November.

The biggest reason to hold a lot of the larger vaccine clinics in October/November is because in some years that's when more of the reliable amounts of the vaccine supply has been available to be able to hold those larger clinics.

But if you didn't have vaccine, you can, you know, go ahead and vaccinate as soon as you have it.

(Sandy Homen): Okay, thank you.

Leshaundra Cordier: Well thank you. On behalf of COCA, I'd like to thank everyone for joining us today, with a special thank you to our presenters -- Dr. Koh and Dr. Graham from HHS, and Dr. Bridges from CDC.

If you have any additional question for today's presenters, please email us at coca@cdc.gov. Again, that email address is C-O-C-A-@-C-D-C-dot-G-O-V.

The recording of this call, the transcript and additional resources will be posted to the COCA Web site at emergency.cdc.gov/coca within the next few days. To receive

information about upcoming COCA calls, to subscribe to COCA, please send an email to coca@cdc.gov and write Subscribe in the subject line.

Thank you again for being a part of today's call and have - everyone has a great afternoon

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