

National Grand Rounds: 2009 H1N1 Influenza and Asthma

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Coordinator: Welcome, and thank you for standing by. At this time all participants are on a listen-on mode until the Question and Answer session - today's conference. At that time you may press star 1 on your touchtone phone, ask a question.

I would also like to remind parties that this call is being recorded. If you have any objections you may disconnect at this time. I would now like to turn the call over to Ms. Alycia Downs. Thank you, you may begin.

Alycia Downs: Hello, and welcome to today's COCA conference call, "National Grand Rounds: 2009 H1N1 Influenza and Asthma." We are very excited to have some CDC and NIH subject matter experts present on this call.

With us today we have Dr. David Callahan from the National Center for Environmental Health at the Centers for Disease Control and Prevention, Dr. Alkis Togias from the National Institute of Allergy and Infectious Diseases at the National Institutes of Health, and Dr. Gail Weinmann with the National Heart, Lung and Blood Institute at the National Institutes of Health.

We are using a PowerPoint presentation that you should be able to access from our COCA website. If you have not already downloaded the presentation, please go to emergency.cdc.gov/COCA. Again, that's

emergency.cdc.gov/COCA. Click on Conference Call Information, Summaries, & Slide Sets.

The PowerPoint can be found under the call in number and pass code. If you have any issues locating the PowerPoint, please send an email to coca@cdc.gov and we can help you locating.

After this activity the participants will be able to understand the risk that 2009 H1N1 Influenza poses to persons with asthma, understand the underlying pathophysiology that predisposes persons with asthma to serious outcomes, know the experience so far with 2009 H1N1 Influenza among persons with asthma, know how to reduce risks through achieving better asthma control, vaccination, early treatment and other clinical interventions, and know that persons with other chronic lung diseases such as Chronic Obstructive Lung Disease, COPD, are at risk as well.

In compliance with continuing In compliance with continuing education requirements, all presenters must disclose any financial or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters as well as any use of unlabeled products or products under investigational use.

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

I will now turn the call over to Dr. David Callahan.

Dr. David Callahan: Thank you, Alycia, and good morning, everyone. Thanks for joining us today. As you already know, persons with asthma have been hit very hard by this 2009 H1N1 pandemic.

Just to get us all on the same page I want to answer the question, “What is asthma?” Asthma is primarily an inflammatory disease. It involves chronic inflammation of the airways. Over the short-term that inflammation is cytokine mediated and over the long-term there is airway remodeling where the airway actually changes structure.

What makes asthma different from other chronic lung diseases is the reversible bronchospasm. And the symptoms when one gets bronchospasm is wheezing, breathlessness and coughing.

Now, let me give you an overview of what we’re going to talk about today. First, the public health significance of asthma, then inflammation and immune response in asthma by Dr. Togias, clinical management of asthma, also by Dr. Togias.

I’ll talk about the 2009 H1N1 influenza and asthma, data from the 2009 influenza surveillance, and the clinical guidelines related to influenza. Then Dr. Weinmann will talk about COPD as a high risk group, and then I’ll come back on for a conclusion.

After that we’ll have Questions and Answers, and joining us for Questions and Answers will be Dr. (Lorrick) and Dr. (Fiori) from our CDC Vaccines Group and our Influenza Division, respectively.

So let me talk about the public health - next slide. This one is entitled Asthma, Public Health Significance, just to make sure we’re all on the same slide.

Here is why we're so concerned about asthma. It's an incredibly common disease, prevalence is about 7.9% overall. That means 23 million people in the U.S., 7 million of whom are children. Healthcare utilization in 2006, the most recent numbers we have, asthma accounted for 10.6 million office based visits, 1.8 million Emergency Room visits, nearly a half million hospitalizations, and 3613 persons died in 2006 from asthma.

Now, on the next slide, Child and Adult Asthma Prevalence, you'll see that over the past - over 20 years, we've seen a steady increase in the prevalence of asthma.

On the far right of this slide you'll see current asthma, meaning symptoms within the past 12 months, and lifetime. Probably the thing to notice also is that asthma is more prevalent in children than adults.

The next slide, Current Asthma Prevalence for Youth by Race and Ethnicity, now I'm focusing on the school-aged children for part of this because we know that they've been particularly hit hard, unlike with seasonal flu where we see much more prevalence of flu in the older age groups.

As you'll see on the slide asthma is substantially more prevalent in non-Hispanic blacks. Interestingly, the Hispanic number is right around 10% which is right around the mean. However, that varies substantially by which Hispanic group you're looking at. Puerto Ricans have much higher rates of asthma and Mexicans have a much lower rate.

Now, asthma is a disease of striking disparities. Among U.S. children, and actually these apply much to adults as well, we can identify characteristics that put people at risk of Emergency Room visits, hospitalizations and deaths.

Some of these higher risk factors include low-income, minorities, particular non-Hispanic blacks and American Indians and Alaska natives. And as I mentioned before, some Hispanics such as Puerto Ricans.

Also, persons living in inner cities are at higher risk of severe asthma outcomes, although overall the prevalence of asthma in urban areas and rural areas is approximately the same.

Next slide. I want to talk a bit about population disparities in asthma. Interestingly, although asthma affects all age groups, it most often starts in childhood, affecting more boys than girls. However, by adulthood we see a switch with more women than men having asthma.

Although asthma affects people of all races, African-American's are more likely than Caucasians to be hospitalized for an asthma attack and to die from asthma.

Identifying populations with high asthma prevalence helps us focus resources to reduce the burden. Some of the extrinsic factors associated with high prevalence, morbidity and mortality include poverty, urban air quality, indoor allergen and inadequate disease management.

I'd now like to turn the presentation over to Dr. Togias who will talk more about inflammation's role and the clinical management of asthma. Dr. Togias?

Alkis Togias: Thank you, Dr. Callahan. It's a pleasure and what I'll try to do is discuss with you the role of viral infections in terms of causing asthma exacerbations. So if you move to the next slide which is the first slide entitled, Asthma and Viral

Respiratory Infection, I want to bring up some concepts that I think are very important in understanding asthma.

The first one is that there's lots of data coming from the U.S. and Europe and other countries around the world supporting the concept that most exacerbations in asthma are caused, or are associated at least, with viral respiratory infection, and that's the truth for both children and adults with asthma.

And many people believe that the exacerbation peaks that we see, at least in this country, in the fall and mid-winter are for sure associated with those viral infections.

However, there is a very interesting, and not very well understood, association between viral infections and allergy in that it is believed that the two together play a synergistic role in causing these exacerbations. For example, individuals who have a lot of allergy are more prone to these exacerbations which however are caused by respiratory viral infections.

Of course, one very important concept is that we all need to understand that these exacerbations that we see in asthma patients can be reduced significantly if asthma management is correct. So it is of central importance that the management of the disease is such, and follows the guidelines, so that it reduces those exacerbations.

If you move to the next slide, which is termed Airway Inflammation and Hyper reactivity, and it's just a cartoon. It's there to allow me to say a few things about the underlying pathophysiology.

And all I want to say is that there are these two components that Dr. Callahan already mentioned, the inflammatory component and then the hyper reactivity component.

The inflammatory component in the airways of people with asthma is such that at baseline you see an increased thickness of the airway wall, potentially increased production infiltrate by inflammatory cells. And that, per se, especially more severe disease, causes an obstructive element that renders those airways more likely to close down when an additional trigger comes on, and in this case would be our viral infection.

And then we have the hyper reactivity component which relates more to the smooth muscle element of the airways. As you know the airways have smooth muscles surrounding them, and there appears to be an increased propensity for those airways to close down with a bronchoconstrictive response when exposed to a stimulus.

Sometimes to an intrinsic stimulus and also force to extrinsic stimuli. So for a signal of an extrinsic irritant of magnitude X will cause an obstruction in a person with asthma whereas it will cause very little, if any, obstruction in a person who does not have asthma.

So if you think about somebody who now, on top of his baseline inflammatory condition, which is asthma, develops a viral infection which adds to the inflammation in the airways, then you can understand why a viral infection can have such a detrimental affect in the airways of people with asthma.

Now, if you move to the next slide you will also note that there are some points that are quite debatable. Some people would propose that perhaps

people with asthma are more likely to get infected by respiratory viruses, including influenza.

But I can assure you there's really no good evidence that that is the case. In other words, neither epidemiologically nor on the basis of some pathophysiologic studies do we have good evidence that people with asthma have more susceptibility to become infected with influenza or other respiratory viruses.

And there's also controversy whether there is increase viral replication in the airways of people with asthma. These are ideas that you will hear about, but they're all controversial and we don't have a definitive proof. So at this point what we believe is happening is the background is the back - it's the baseline inflammation and hyper reactivity in asthma that I explained to you a moment ago that is responsible for increasing the chance of a viral infection leading to an asthma exacerbation.

Now, move to the next slide which is, again, entitled Asthma and Viral Respiratory Infections, and in that slide some statements are made. The first, perhaps most important, statement is that most of these asthma virus induced exacerbations are secondary to rhinovirus infections, not to influenza.

And so rhinovirus is what we have, from the perspective of research, concentrated on over the past few years trying to understand the role of rhinovirus in asthma exacerbations.

And everybody still believes, of course, that influenza also causes asthma exacerbations, but the impact of influenza on asthma truly was not very well appreciated, and it's only now with the current pandemic of the 2009 H1N1

virus that we appreciate the impact of influenza on asthma, and of course, Dr. Callahan will give you much more inflammation on that in a moment.

Nevertheless, that old guideline, national and international, do recommend seasonal influenza vaccination for patients with asthma, and of course, as you will hear in a moment there is a strong recommendation that all patients with asthma do get vaccinated with the H1N1 vaccine.

The next slide you see a - some concepts related to the management of asthma. So I'm going to spend a couple of minutes on that slide and on the next slide, which is truly a quick summary of management - of the management of asthma.

As you all know, the so-called National Asthma Education and Prevention Program which was funded and supported, and has been funded and supported, by the National Heart, Lung and Blood Institute, has come up with a series of updates on the original guidelines on the management of asthma.

The most recent one being the one published in 2007, also known as the Expert Panel Report III. And for those of you who are interested in asthma, it is, I think, imperative to be aware of these guidelines and the concepts that they present.

In this particular slide I want to bring up some concepts that are important in understanding those guidelines, but I think also quite important in managing the diseases.

The concept of severity as is presented in the guidelines is a concept that deals with the intrinsic intensity of the disease process. Simply speaking it is a concept that refers to a person that has not been receiving treatment for

asthma and presents to you in a way that you are seeing the natural history of the diseases, and that's where you can categorize a person in terms of the severity.

But, of course, most individuals who come to you with asthma are people who have had long history of asthma treatment. And in those individuals it is more difficult to assess severity. What you're really assessing is the control of the disease.

So you concentrate on the level of control that these individuals have and that is a degree to which manifestations of asthma are minimized and, of course, the goals of therapy are met in terms of control. So you're managing the asthma based on control. And there's a third concept, it's a concept of responsiveness being the concept of how well your management improves the control of these individuals.

Will you please move to the next slide? This is a slide entitled Stepwise Approach for Managing Asthma in Children 5-11 Years of Age. Again, we chose to only show you this particular stepwise approach as opposed to the younger children or to adults.

The only reason being that first of all these are quite similar, second, as Dr. Callahan mentioned, this is a group that has been especially hit by the current situation with influenza.

The concepts here are that you need to, of course, realize what is the control or understand the level of control of a particular patient that you see. And on the basis of that control decide whether you're going to go up or down on the treatment.

But if you were to see a patient for the first time and you just wanted to assess what kind of management you're going to begin a patient with, you think about severity, and if you have what we call intermittent asthma, meaning somebody who only has symptoms less than twice a week or equal to or less than twice a week, then you start your management with step 1 with a preferred management is a short acting beta agonist that is using as need - that is being used as needed.

The moment you have symptoms that are persistent, meaning that they occur more than twice per week, you then are looking into the various other steps of the management and the first and important concept is that you need a controller medication. In other words, a medication that will be used on a daily basis.

The control - the preferred control medication for asthma at every step is inhaled cortical steroids, and at step 2 you're looking at low doses, whereas at step 3, 4, you're looking either at a low dose inhaled cortical steroid with an additional controller such as a long acting beta agonist, a leukotriene receptor antagonist or even theophylline, or you're looking at a medium dose inhaled cortical steroid.

And as you're moving to more severe disease at step 5 and 6, you need to use high doses of inhaled cortical steroids, again, with a combination with another controller. The recommended one would be the long acting beta agonist.

And if you reach step 6 where despite the usage of this combination of high dose inhaled cortical steroids and long acting beta agonists, you cannot control your patient, you then have obviously the option of using oral systemic cortical steroids.

There are alternative approaches that you see on this slide, but I don't think that I have enough time to go through them at this point.

It is important to understand that at each step you want to educate your patient, you want to look into helping your patient with environmental control, and most importantly to management comorbidities, one of them being very important, and that is the upper airways disease, in other words, rhinitis or sinus disease.

And again, every time you see your patient you want to assess control and you want to decide whether you want to step up, if needed, or step down, if possible, your therapy. And for the step down you want to always think about three months of a patient being under control before you decide to go one step down.

If you move to the next slide we're talking about asthma treatment and the H1N1 vaccine. As I just mentioned, inhaled steroids are the mainstay treatment for asthma control. Every asthmatic who has persistent disease needs to be on inhaled corticosteroids.

And again, based on the previous slide you realize that there will be quite a few patients with asthma who will require high doses of inhaled corticosteroids and some even will require oral steroids.

On the basis, therefore, of the need to provide vaccination for the H1N1 virus in people with asthma, and on the basis of the fact that some people with asthma do use very high doses of inhaled corticosteroids, or even oral steroids, we do have a question, and that is the question whether the influenza vaccine for the 2009 H1N1 virus will be adequately immunogenic in patients on high doses of inhaled steroids or oral steroids. We do not have the answer

to this question, and that is why the National Institute of Allergy and Infectious Diseases in collaboration with the National Heart, Lung and Blood Institute are conducting a study.

And you will see in the next slide the design of this study that is - it's already initiated about three weeks ago and it's moving very fast, and this is a study to look at the Immunogenicity as well as the safety of the 2009 H1N1 influenza vaccines in patients with asthma.

We have two cohorts, one with severe asthma and one with mild/moderate asthma, and these are the two groups that are going to be compared in this study. And each group is randomized to receive either a low dose vaccine, or a high dose vaccine. Low dose being the 15 micrograms of the vaccine, high dose 30 micrograms. In other words, double the dose of the recommended.

Plus, in this trial we are going to deliver two doses, two vaccinations, on each participant because we want to have all possible combinations to assess what would be the optimal dosing of this vaccine to generate adequate Immunogenicity in this trial.

So I'm going to stop here and Dr. Callahan will take over.

Dr. David Callahan: Thank you, Dr. Togias. On the next slide it just introduces myself, and I will point out the Captain before my name, I should mention that I'm a commissioned officer in the U.S. Public Health Service, America's Health Responds.

On to the next slide. Mild asthma and hospitalization risks. This is interesting in that we know that somewhere between half and three-quarters of persons with asthma have mild asthma, using the usual criteria.

However, 30% of asthma hospitalizations are among persons with mild asthma. It's not just the folks with severe disease who we're seeing in the hospital.

Thirty to 40% of Emergency Room visits are severe exacerbations in mild asthma. And one thing that makes this somewhat hard to assess is severity is often poorly documented in the chart when we go back and do retrospective studies.

Importantly, the main point of this slide is we need to make sure that your persons with mild asthma also get the preventative measures such as vaccination and early treatment should they become ill.

Now, focusing on those who are at greatest risk, there are some risk factors that are associated with death from asthma. A previous serious exacerbation, having had two or more hospitalizations or more than three Emergency Room visits in the past year.

If your patient is poorly controlled and remains that way despite your best efforts. If your patient has difficulty perceiving symptoms of exacerbations. Certainly comorbidities play a large role, cardiovascular and psychiatric in particular we see high rates of mortality, and also mortalities associated with poverty, with low SES.

Next slide. With regards to influenza, persons with asthma are at risk for severe disease. Interestingly, there's no evidence that they're more susceptible, they're not more likely to get influenza, however, influenza infection is associated with very severe asthma exacerbations leading to ICU

admission and refractory exacerbations that do not respond well to usual treatment.

Vaccination reduces the risk of these severe outcomes, not exacerbations overall. That's why we target persons with asthma for influenza vaccinations, to reduce the risk of severe outcomes.

We know quite a bit about influenza vaccination rates among persons with asthma. Next slide. We know that they're low. They should be 90% if we go by the Health People 2010 goals. In fact, we're only seeing about 36% of children and adults getting their seasonal flu vaccine, and in that 2-17 age group only about 29% are getting the seasonal flu vaccine.

Interestingly, the rates in adults are highest in non-Hispanic whites, and it's lowest in persons who don't have a medical home or a primary doctor.

Next slide. 2009 H1N1 and Asthma Hospitalizations. These are data that you may have seen in the recent New England Journal article, 32% of hospitalized patients with 2009 H1N1 had asthma, 20% with influenza 2009 H1N1 and asthma were admitted to the ICU. Interestingly, that's the same rate that we see in other person.

The risk, once you're hospitalized the risk of ending up in the ICU is the same for persons with asthma and not with asthma. However, since so many persons with asthma come to the hospital in the first place, the ICU admission, asthma is still the number one co morbidity associated with ICU admissions.

Now briefly I want to go over the ACIP recommendations. These have been reviewed on several recent calls. But for your persons with asthma, they should receive the seasonal flu vaccine, and for the 2009 H1N1 flu vaccine,

well, first of all everybody 6 months through 24 years has been a priority group, and then above 24 years persons with lung disease are a priority.

So in other words, persons 6 months to 64 years with underlying lung disease should be a priority for the 2009 H1N1 flu vaccine. I also want to remind you that your persons with asthma should have a pneumococcal vaccine, that is a new recommendation of ACIP. And the recommendations for asthma are similar as the recommendations for COPD which you'll hear about in a few moments from Dr. Weinmann.

Now, briefly I want to mention the influenza vaccine - next slide - influenza vaccine dosing in children. Children do not have any preexisting cross-reactive antibodies with the H1N1 2009 virus.

The preliminary results of an NIAID study shows that children 6 to 35 months, 3 to 9 years and 10 to 17 years immunized with the 15 microgram dose of the inactivated 2009 H1N1 vaccine, 25% among the 6 to 35 months, 36% among the 3 to 9 years, and 76% among those 10 to 17 years develop seroprotection after a single dose.

When a second dose was added children aged 3 to 9 years, 94% of them had a robust response compared with only 55% three weeks after the first dose. So anyway, the bottom-line is children need two doses of 15 micrograms of inactivated H1N1 vaccine for your children six months through nine years old given at least 21 days apart. Next slide.

I want to discuss the CDC guidance for persons with asthma. First let me direct you to the two links at the top of the slide, www.cdc.gov/h1n1flu/asthma_clinicians and cdc.gov/h1n1flu/asthma.htm. These have all the information that I'm about to go over.

First and foremost for your patients with asthma, they need to have an updated asthma action plan. This also provides you the opportunity to have your patients come in, assess their control, and get them under very good control; and in that asthma action plan, you can address what they should do when they get sick, if they get sick with influenza-like illness.

We want them to go into the season well-controlled, and we - also I want to reemphasize what Dr. (Toya) said, inhaled corticosteroids are really the mainstay and they are protective against severe illness. Next slide. I -- reiterating a little bit of what I said, persons with asthma should get the 2009 H1N1 and seasonal influenza vaccines. Importantly, they should get the inactivated, injectable vaccine only -- the flu shot. Don't use the nasal spray vaccine because that is associated with bronchospasm in persons with asthma.

Also, once again, persons with asthma should get the pneumococcal vaccine. Also, we know that people with asthma go downhill very rapidly once they develop H1N1 flu, so we're encouraging prompt treatment. Plan for early contact - for the patient to contact you early, and plan for empiric treatment if your persons - patient with asthma comes in with flu-like symptoms. We want the oseltamivir, the Tamiflu started as early as possible. Next slide.

Okay. Sorry, my slides weren't advancing. Regarding oseltamivir, the dosing is simple; it's 75 mg twice a day for five days for treatment of the flu. There is weight-based dosing for children, and I would refer you to our CDC Web site on asthma and antivirals for the simple chart of the weight-based dosing. It's important - it's best to start it within 48 hours of symptom onset, but if you saw the health alert that was sent out yesterday, even if it's beyond 48 hours, if you have a sick patient, particularly for hospitalized, they should be getting oseltamivir even if beyond 48 hours.

I want to point out that zanamivir Relenza is not recommended because of risk for adverse events such as bronchospasm in persons with asthma. We want persons with asthma to have rapid access to antiviral medications. We defer to your clinical judgment about how you may want to get them on oseltamivir quickly. When they come in to review their asthma action plan, review the signs and symptoms of influenza and the need for early treatment. Consider ensuring rapid access to you by telephone, eye consultation and clinical evaluation, and consider empiric treatment of patients based on telephone contact if in your clinical judgment that is appropriate for that patient.

Next slide. So far we've been talking about asthma, but I want you to remember other chronic lung diseases, persons with COPD face similar risks of severe outcomes. The recommendations for COPD are really quite similar as those for asthma, and remember that asthma and COPD can be comorbidities particularly in older age groups. To talk more about COPD, I'd like to turn the presentation over to Dr. Gail Weinmann from NHLBI. Dr. Weinmann.

Dr. Gail Weinmann: Thank you Dr. Callahan. And good morning to everyone. If you could advance to the next slide. This is primarily a session on asthma, but as Dr. Callahan said, other chronic lung diseases are at risk for the seasonal flu and H1N1 and this is just to serve you as a re - to serve as a reminder. Next slide, please.

So COPD is a very common lung disease which is why we're talking about it today. It is primarily a disease of smokers and ex-smokers, but there are some never smokers who develop the disease. The symptoms are primarily difficulty breathing either at rest or on exertion, and the patients may or may not have a chronic cough with sputum.

Like asthma, it's an inflammatory lung disease characterized by airflow limitation. The difference between COPD and asthma is that the airflow limitation is not fully reversible. Even though it's an inflammatory lung disease, the kind of inflammation is different than asthma, it has different cells and different cytokines involved. There is also remodeling, some of which is shown in that picture there, but the sources of that are different.

COPD is the term that is currently favored to encompass the chronic lung diseases of emphysema, chronic bronchitis and chronic obstructive bronchitis. Next slide, please. This slide is just to show you why COPD is such a big problem and we're talking about it today. Based on the (N Haynes) data, the estimates are that there are 24 million people in the United States who are affected by COPD. And about half of them do not know they have it.

That makes it very hard to do statistics on people since they aren't carrying the diagnosis even though they have characteristics of the syndrome. It is an older age group and this is also a little different than asthma, most are going to be over the age of 60. It - most have multiple comorbidities. Many of them are smoking related, but it's - they can be common diseases of aging. Some of them are called comorbidities, but they may actually be part of the COPD syndrome.

So this is just a high-risk group for everything in general. And it's important to think of the disease even in people who've never smoked because about 15% of people with COPD are never smokers. COPD is responsible for about 120,000 deaths per year. It is the fourth leading cause of death in the United States and it's rising. It's estimated to be 1/3 in the year 2020.

The rates are rising fastest in women. And at this time, the rate of death is about equal in men and women. COPD is also responsible for a lot of disability, people in - working age adults. So it is a high source of morbidity and it is a high source of healthcare costs particularly in those with CO - with severe COPD.

A lot of the healthcare costs are related to exacerbation. COPD, like asthma, has periods of worsening, the difference is that the disease exists in between and then is chronic and so that is responsible for a lot of the healthcare costs. Next slide, please.

This slide shows trends in lung disease mortality. So on the y-axis this is the percent of total U.S. deaths. And on the x-axis is the year. You can see that death from other lung disease, including lung cancer, have been pretty flat. But COPD is continuing to rise, and is now responsible for over 5% of the lung-related deaths in the United States. Next slide, please.

COPD patients are going to be high risk for flu complications. Some of it just has to do with the population and some of it is because of the lung disease. So they are going to have an aging immune system which makes it harder for them to fight the complications of the influenza. Many patients with COPD are on inhaled and oral corticosteroids which can affect their immune system.

We've already talked about the fact that they have multiple comorbidities. They have impaired airway defense and all - a lot of them, so the cilia as well as the mucus and lung destruction, and they also have reduced lung reserves - reserves. So they have an impaired ability to cope. Next slide, please.

So these are the recommendations for patients with COPD and the flu. Everyone with COPD should be getting the annual seasonal flu vaccine as a -

just as a general recommendation. They should have an updated pneumococcal vaccination every five years as recommended by CDC. And people with COPD, like people with asthma, should be getting the shot when they get the H1N1 Influenza Vaccination.

Next slide, please. So the - just to reiterate that patients with COPD should not get the nasal spray vaccine and the other recommendations is that the H1N1 can be administered at the same time as any other vaccine, including the pneumococcal.

Next slide, please. This is just to give you some resources that are on the NHLBI Web site. The first is the disease and condition index. This is written for the public and is written to be easily understandable to describe COPD, so it's a place to refer your patients if they ask questions about what is COPD and what can they expect.

The second reference is an awareness campaign that NHLBI is running on COPD. This Web site has materials for physicians to help you talk to patients about COPD. It also has materials for patients who carry the diagnosis of COPD and materials for patients who are at risk for COPD. So it's a good source for helping physicians talk to their patients.

And...

Dr. David Callahan: And I can...

Dr. Gail Weinmann: Yes, if you could take over David, thank you.

Dr. David Callahan: I'll wrap us up, then get us on to the Q&A. But just to - some of the high points of today's session. Persons with asthma or COPD are at higher risk of

complications from both seasonal flu and based on the data that we know so far, higher risk of complications from 2000 H1N1 Influenza. Next slide.

To help reduce risk among persons with chronic lung disease, maximize control; with your persons with asthma, maximize asthma control including use of inhaled corticosteroids. Vaccinate for primary prevention with the seasonal flu, the 2009 H1N1 Vaccine and the Pneumococcal Vaccine. Let your patients know about the signs and symptoms of influenza so that they can get in touch with you promptly so they can get early treatment.

And treat empirically with antivirals. Don't wait for that test result to come back and in fact, if you want to investigate this on the CDC Web site, the rapid tests are not reliable for picking up H1N1 influenza anyway, so just treat based on signs and symptoms. And the last slide has our interim guidelines and updates. These are updated continuously. And that is it. I'll -- we can now open it up for questions. Thank you for your attention.

Coordinator: Thank you. We will now begin the question and answer session. If you would like to ask a question, please press star 1. Please unmute your phone and record your name clearly when prompted. Your name is required to introduce your question. To withdraw your request, press star, 2. One moment please while we wait for the first question.

Janet Staley, your line is now open.

Janet Staley: Hi, thank you very much for taking my call. I do have - I am an allergist and but - and retired and helping with the flu clinics. And my question is what - the nature of the bronchospasm in asthmatics who were given the nasal application of H1N1 or is that borrowing from the seasonal flu vaccine? And in people who have some history, it sounds a little bit like asthma but aren't on

any medications and haven't been symptomatic for quite a while, how are you recommending making that call on giving the nasal, especially in terrified young children? Thank you.

Dr. David Callahan: This is Dr. Callahan. I - the - essentially the - we're seeing the response or the reactions with the 2009 H1N1 are very similar to what we've seen with the seasonal flu mist vaccine. In fact the wording on the FDA labeling is virtually identical.

The - we do not specifically address what you should do if you've got somebody with quiescent asthma or somebody who had been a wheezy kid that never quite got the diagnosis. From a practical standpoint, I would recommend proceed with caution. I - and if the benefits outweigh the risks of, you know, getting the kid vaccinated, I - that would be - that may well be a good clinician's decision.

Janet Staley: Thank you.

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

Lillian Dayton: (Unintelligible) thank you. I have a question about whether people with COPD getting a second dose or, excuse me, a dose every five years of the pneumococcal vaccine, the VIS form does not say anything about that and Dr. Atkins in the CDC recommends that no one get more than two PPVs in their lifetime. Can they explain the differences to me now?

Alycia Downs: You know, Dr. Callahan, do you have information on that?

Dr. David Callahan: I - not on the COPD though that is something that we can talk with our COPD folks here and get back to you on.

Alycia Downs: Yes, so if you send an email to coca@cdc.gov...

((Crosstalk))

Alycia Downs: ...again that email address is C-O-C-A@cdc.gov. We'll try to get that information to you.

Lillian Dayton: Thank you very much.

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

Pamela Johnson: Thank you. This question's in - question is in reference to Dr. Weinmann's discussion of COPD and H1N1. Dr. Weinmann, if I understood correctly, you were recommending COPD patients of all ages receive the H1N1, or just those in the high risk category of less than 64?

Dr. Gail Weinmann: The CDC recommendation which Dr. Callahan gave would be the people that are less than 64.

Pamela Johnson: Okay, thank you.

Dr. Gail Weinmann: Dr. Callahan, would you agree with that?

Dr. David Callahan: Yeah, that's the recommendation. I do want to point out that the - I - over time we will have adequate doses of vaccine for everybody who needs and wants one. So don't get - don't give up on it.

Pamela Johnson: Okay. Thank you, sir.

Dr. Gail Weinmann: Yeah, it is a high risk group and some of the older ones with aging immune systems may be at risk again. We really just don't have information on that yet.

Pamela Johnson: Okay, thanks.

Coordinator: Dr. (Shariff), your line is now open.

Dr. (Shariff): Hi, yeah, my question is regarding the patient with asthma/COPD who presents with the symptoms of flu and with exacerbation and do you recommend that the - everyone should be tested for H1N1, given that the rapid test for influenza is not really reliable. What would be your recommendation about that? About testing?

Dr. David Callahan: I'm - I'll see if our influenza - if Dr. (Fiori) has anything to say about that, but no. I - routine testing is not a CDC recommendation and particularly given the poor sensitivity and specificity of the clinical tests that you have, it's not recommended. If you do need to confirm a diagnosis, a real time PCR is the most definitive test for H1N1 flu. Dr. (Fiori) or Dr. (Lorrick), do you have anything to add to that?

Dr. (Tony Fiori): This is (Tony Fiori) at - I agree with that. The rapid tests, the ones that are most available to clinicians are useful when they're positive, but they are far too often negative when the PCR is later shown to be positive. So when you're making a treatment decision, they are often not useful and they are definitely not useful if they are negative, so don't hesitate to treat someone.

If you do a rapid test and find it negative, don't hesitate to treat someone even if it's negative. You're treating that - your clinical diagnosis of influenza not the result on that test. And testing - and for that reason many people use

testing pretty judiciously because it often doesn't end up changing their treatment decision.

Dr. (Shariff): Okay. Thank you.

Coordinator: Susan Sharpe, your line is now open.

Susan Sharpe: Yes, my question is about the time to protective antibody response in normal individuals to the H1N1 vaccine and then does this timeframe for protective antibody differ in the asthmatic patient?

(Al Castorias): Well I can take that question. This is (Al Castorias). We did not expect that the time is going to differ in the asthmatic patients. Of course, we're doing a study to look into that. What we are questioning right now and we want to have an answer, and hopefully we'll have that answer very soon, is whether there is - whether this is the case or not in the people who are on very high doses of inhaled corticosteroids that do have theoretically the possibility of causing some immune suppression.

At this point, the recommendation is that people with asthma have to be vaccinated with the same doses as everybody else and the expectation is that the response will be there at the same time point - time points and within a few days actually.

Susan Sharpe: Thank you.

Dr. (Tony Fiori): This is (Tony Fiori) and just to add to that, the NIH is doing studies in asthmatics, we should have those results out pretty soon, but there's every expectation that folks will respond in a similar way to people who don't have asthma.

Susan Sharpe: Thank you.

Coordinator: (Betsy Rameri), your line is now open.

(Betsy Rameri): Thank you. I just need to clarify something. People that have mild to moderate asthma happen to be over 64 years of age currently are not candidates to get the H1N1 vaccine, is that a correct statement?

Dr. (Tony Fiori): This is (Tony Fiori), yes, that's correct. I think Dr. Callahan had answered that earlier and I agreed with him. And the reasoning behind that is that even folks who are older than 65 who have chronic medical conditions appear to have some degree of protection based upon antibody responses they made in their youth and therefore good antibody responses when they first encountered influenza viruses that were more similar to the current pandemic virus than viruses that have circulated in more recent years. And so there's - that's one half of what I wanted to say.

The other half was that when someone who's over 65 with COPD or really just anyone does get H1N1 influenza, which has been surprisingly a - surprisingly much less than other age groups but it does happen, they are at higher risk for getting a severe outcome so those people should be aggressively treated.

(Betsy Rameri): Thank you.

Coordinator: Nancy Crooks, your line is now open.

Nancy Crooks: Good morning, I'm an asthma case manager, asthma educator. I was one of the nurses this year that was at American Lung Association SCAMP Camp for

children with asthma and by the end of the vacation about 50 to 60% of our children had the flu or flu symptoms. So my question to you, is there any - well, in looking back if we'd have - it seemed that we could have done some screening, we could have prevented this outcome. Are there any screening tools that are available that we could use to ask family members, you know, whether they're sick at home, are there any validated tools that we could use? Any that you know of?

Dr. (Tony Fiori): This is (Tony Fiori). None, none that I know of. A flu is very challenging because of the fact that the viruses are often shed including in pretty high amounts very early in the course of illness and even before illness starts, so it's hard to exclude people based upon any particular symptom. Once illness does start, you do want to try to reduce their exposure to others, but that in itself is not going to be fully successful in preventing transmission. It's an explosive disease in young persons who are highly susceptible and that's the situation we face with this pandemic.

Nancy Crooks: Thank you.

Coordinator: Dr. Elizabeth Conch, your line is now open.

Dr. Elizabeth Conch: Yes, referring to the 64 year age cut off limit, can you actually draw a demarcation line between 64 and 65 and beyond? If I understand correctly, you're saying don't give the vaccine - the H1N1 vaccine to people 65 and older but if they get sick with H1N1 and do have a very severe reaction, which you say they do, you wait until they get sick to treat them instead of trying to prevent it? I'm confused about this.

Dr. (Tony Fiori): This is (Tony Fiori). The situation we face right now is there's not enough vaccine for everyone who should receive it. We hope to be able to offer

vaccine who - to whoever wants it, including persons over the age of 65. You are right that there is a continuum of susceptibility to the virus that - it - that 64 is not so much more susceptible than 65 and 65 not so much more than 66 and so on, there's a - but 65 is an easily understood number.

It's a reasonable line to draw because a line does have to be drawn in order to get vaccine to those who are most vulnerable. And it probably would have been defensible to draw it at 60 or 68, but 65 is sort of a traditional line that's easily understood. It's similar to the recommendations that have existed for years to vaccinate those over 65 and it just made it seem like a reasonable age group. But we do hope and in the near future if possible to be able to offer vaccine to persons over 65.

For the moment, the best thing that we - that ACIP thought they could do for older folks to avoid getting them exposed is to reduce community transmission and this pandemic is very clearly driven by transmission in younger age groups. So if we can reduce transmission in kids, chances of an older person's coming into contact with the influenza virus would be greatly reduced.

Dr. Elizabeth Conch: Well, I can only say what's obvious. This looks like discrimination by age. There's some people older than 64 who are quite susceptible and obviously so to their physician. Would you recommend going ahead with H1N1 vaccine for them?

Dr. (Tony Fiori): ACIP issues guidance and recommendations, it's - they're not regulations. Physicians have the ability to vaccinate, once the vaccines in their clinic, who they want. We think, and ACIP thinks that it makes the most sense to focus on persons who are most prone to being infected, who respond best to

vaccination, and in a time of limited vaccine supply, I don't think that's going to last forever. I don't think it'll actually last all that much longer.

And we hope that older persons who have been patiently waiting for their chance to get vaccinated will quickly step forward when that vaccine becomes available more widely. At the moment, nearly all of our severe infections and nearly all of our hospitalizations are in younger age groups and this is quite different from seasonal flu in that respect.

((Crosstalk))

Dr. David Callahan: And this is Dr. Callahan. I'll just add something. In my own clinic, in my own clinic patients, I do follow the guidelines, but I also tell my older patients please give me a call when you get symptoms of flu. And early treatment with Oseltamivir or Tamiflu can make a difference. So it - there is an intervention.

Alycia Downs: Okay. I would really like to thank all of our presenters for providing our listeners with this information. I think this has been a very informative call and I'd also like to thank our participants for joining us today.

If you were unable to ask a question, please send an email to coca@cdc.gov, and we'll work with the presenters to get a response back to you in a timely manner. As a reminder, the audio file from this call and the transcript will be posted to the COCA Web site within the next week.

And I would like to thank everyone again for their presentation and everyone for participating. I hope everyone has a wonderful day.

Coordinator: That concludes today's conference. Thank you for participating. You may disconnect at this time.

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