



Press Briefing Transcripts

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- [Audio recording \(MPEG\)](#) 

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Operator: At this time, I would like to remind parties that your lines are in a listen-only mode until the question and answer session at which time you may press star one to ask a question. Today's call is being recorded, if you have any objections, you may disconnect at this time. I will now turn the meeting over to Glen Nowak. Thank you, sir, you may begin.

Glen Nowak: Thank you and thank you all for joining us this afternoon for an update on the 2009 H1N1 flu. I have with us today three people who will be providing brief introductory remarks, Mr. Jay Butler, Director of CDC's H1N1 Vaccine Task Force, will begin by providing the brief overview of the current situation, as well as talk a little bit about what we know about H1N1 vaccine distribution and some of the planning taking place there. Dr. Butler will be followed by Dr. Jesse Goodman. Jesse is the Acting Chief Scientist and Deputy Commissioner at the Food and Drug Administration, and then after Dr. Goodman's opening remarks, we will turn to Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases at the National Institutes for Health and give an update on the vaccine clinical trials with respect to the 2009 H1N1 influenza vaccine. So at this point, I will turn to Dr. Jay Butler from the Centers for Disease Control and prevention.

Jay Butler: Thank you, Glen. Good afternoon and good morning to everyone. I want to touch on three topics at this time, cover -- provide an update on novel H1N1 activity in the U.S., activity in the southern hemisphere, and also talk about where we stand right now in regards to influenza vaccination planning. Here in the United States, we're seeing low levels of flu activity, although almost all that we're seeing is primarily novel H1N1 virus disease. It's important to remember that this time of year, we don't normally have influenza, so even a low level is an unusual event. To date, there have been 7,963 hospitalizations and 522 deaths that have been laboratory confirmed as caused by novel H1N1 vaccine. It's important to keep in mind that these numbers radically underestimate the number of cases that actually occur, because many cases go without testing, and in many areas, there is not routine testing of people who are not sick enough to require hospitalization. The novel H1N1 continues to disproportionately affect younger persons, so it behaves very differently from seasonal influenza, where we see much of the severe influenza among the elderly. 75% of the hospitalizations are in those aged under 49 and 60% of the deaths are in those under age 49. Most state health officials are reporting local or sporadic influenza activities. Two states, Alaska and Maine, are reporting widespread influenza activity at this time. Reports of widespread influenza activity in August are very unusual, as I mentioned earlier. Most of the influenza viruses typed are novel 2009 influenza AH1N1. These viruses remain similar to the ones that were chosen for the vaccine that's in development, and vast majority remain susceptible to anti-viral drugs, also Tamiflu and Zanamivir. Flu is unpredictable and it's hard to say what our season will look like, but preparation is important. Moving on to our southern hemisphere update, the activity from the 2009 H1N1 virus appears to be decreasing. The virus remains a predominant influenza virus circulating worldwide. Decreases in disease due to the 2009 H1N1 continue to be reported from South America and parts of Australia. The epidemiology of the disease caused by the virus in the southern hemisphere is very similar to that described in the United States this past spring. There have been no significant changes detected in the influenza virus, isolated from persons in the southern hemisphere as compared to viruses isolated from persons in the northern hemisphere. As you're aware, we've been watching the southern hemisphere very closely for any changes in the behavior, the epidemiology of the virus or in the virus itself, and we have not seen those events. In other parts of the world, the United Kingdom is reporting national decreases in disease due to H1N1 and Japan is experiencing an increase in cases. I'd like to move on to talk about vaccine for the 2009 H1N1. We're making progress in developing the plans for distribution, once the vaccine becomes available. This is what we currently know and are planning. We're expecting somewhere between 45 million and 52 million doses of vaccine to be available by mid-October. This will be followed by weekly availability of vaccine up to about 195 million doses by the end of the year. Keep in mind, these numbers are driven by a number of variables in the manufacturing process. There are five manufacturers working, so and everybody's doing the best they can to get as much virus available -- as much vaccine available as soon as possible, and so those numbers can be subject to change. Initially, the number of vaccine doses that will be available to each state will be based on the state's population. The distribution of the vaccine will be very similar to what's done currently for the vaccine for children program, so this will be a program that will be enhanced to enroll a larger number of providers rather than a completely new program that's developed. The states will receive orders from providers for the number of doses of vaccine needed, and will coordinate with CDC. These orders will be transmitted to a central distributor, who will be receiving vaccine from the five manufacturers and subsequently shipping those to the states, along with ancillary supplies for administration of vaccine. Today, the advisory committee on immunization practices recommendations for use of the H1N1 influenza vaccine were published in the "MMWR" and posted online. These final recommendations include target groups for vaccination, including those which according to the epidemiology that's been observed in the United States and indeed globally, focuses on the persons at highest risk of infection and severe disease, this includes pregnant women, children, and young adults aged 6 months through 24 years, as well as persons aged 25 through 64, who have medical conditions that put them at higher risk for influenza-related complications. Two other risk groups are those who are at higher risk of exposure or transmitting the virus to those who may be at high risk such as health care workers and emergency medical service workers, and persons who live with or care for infants younger than 6 months of age, that is, who are too young to be vaccinated.

In closing, let me make a couple key points. Influenza is unpredictable and while we're working to get -- working to make sense of much of the information as possible, we don't know what lies ahead in the coming weeks and months. We may see lots of flu activity in September and October. On the other hand, we may not. Second, it's best that we plan and prepare for lots of flu activity, and that's a good assumption, given that we expect to see both the 2009 H1N1 virus and the seasonal influenza viruses, causing illness this fall. I've talked mostly about vaccine but it's important to remember that we have to continue to do the other important things to control the spread of influenza, including hand washing, respiratory etiquette, that is, cover your cough and to protect others, stay home if you're sick. And finally, we can't stop the tide of flu any more than we can turn a hurricane in its course or stop the earth shaking during an earthquake, but we can mitigate the effects and question help prevent people from becoming severely ill by preparing well and acting effectively. At this point I'll turn it over to Dr. Jesse Goodman from the FDA and I look forward to taking your questions later.

Jesse Goodman: Thanks very much, Jay. I'll just provide a very brief update from FDA. We continue to work closely with colleagues at CDC, the National Institutes of Health, as well as in the entire Department of Health and Human Services. Our focuses are as follows. First, we are conducting continuing oversight on the quality and safety of the vaccine being produced, and the production process itself. That's going well so far, but our oversight is continuing. Second, we're taking a number of steps, and have taken steps to do everything we can to foster the availability of this vaccine against novel H1N1. For example, we and our other public health and international partners have provided new vaccine strains, which we believe may have improved growth and yield characteristics that can help the continuing production process. We have worked with our international counterparts and have provided the reagents to all of the vaccine manufacturers that are needed for them to assess the potency and quality of vaccines, and we're working also with HHS to do everything we can to increase capacity and various backup capacities in terms of production, for example, last week, we approved a new vaccine filling line, this is a facility that puts manufactured vaccine into its final form, so that it's ready to be administered to people, and we're continuing steps like that to increase our capacity, both in the U.S. and globally. We want to do this to stay and be prepared for the fact that there are, through vaccine production, is a complex process, and there are always uncertainties, so we're being forward-leaning in doing everything we can to have as many backups and be as prepared as possible. Then finally, of interest right now, we have worked with and are continuing to work with NIH. Again, our colleagues at Health and Human Services and also with the vaccine manufacturers, in assuring sound design, oversight, and analysis of the clinical studies, multiple clinical studies are ongoing already, both by the manufacturers themselves, and by our colleagues at NIH, so I think at this point, I will turn it over to Dr. Fauci, who will provide an update on the status of the studies that NIH is supporting.

Anthony Fauci: Thank you very much. Welcome to you all on the phone. With regard to the clinical trial process, that really is a step-wise process that began essentially when the CDC first isolated the virus in April, made seed lots of virus that was grown up and made into pilot lots by a number of the five companies that Jesse alluded to, for which we have long-time contractual relationships to produce vaccine for us for implementation of vaccine program. The pilot lots were made available to our clinical trial sites that are throughout the country, a total of eight clinical trial sites, and a number of clinical trials were designed and have begun to be implemented to ask some fundamental questions that would inform how we would use the virus, the proper dose, early safety data, as well as use of the vaccine, and the vaccine in certain populations. So we have five fundamental, basic trials, and I'm just going to very, very briefly outline them for you. With two separate companies, we're asking the question of 15 versus 30 micrograms, one dose versus two dose. Those trials were scheduled to begin in the first or second week in August, and I'm happy to report that we did begin those trials on August the 7th. Also, some good news there, that less than two weeks later, those trials are now, one is fully enrolled and another is, will be fully enrolled by the end of today. We expect first dose data somewhere around mid-September, if all goes well, and things seem to be going well and second dose data somewhere around mid-October. In addition, there are trials again in adults and the elderly, the ones I just referred to, that are asking what we call sequential administration questions, namely, what is the best time to administer the H1N1 novel flu vaccine, either prior to, simultaneous with, or following the administration of the seasonal vaccine? We had mentioned during the announcement of those trials that we wanted to wait at least a week or so following the adult elderly trial to begin similar trials in children, and in fact, about 10 to 14 days later, in this case, August 19th and 20th, we began similar comparable trials that I just mentioned, for the adults and the elderly, in children 6 months to 17 years, and in fact, if you do the extrapolation, we would expect some single dose data in late September and then the second dose data somewhere around late October. Those trials would comprise approximately 2,800 individuals. Very briefly and finally on the upcoming trials, we're going to be doing trials in pregnant women, on three separate products, and they will be the typical one versus two doses of 15 versus 30 micrograms, approximately 120 pregnant women in each trial, that is scheduled to begin in early September, and then finally, we are planning trials using adjuvants in what we call a mix and match, where we take the antigen from one company, Sinofia CFL and use the adjuvant from another company. Those studies are scheduled to start somewhere in mid to late September. The overall total number of individuals and trials will be approximately 4,500 to 4,600 individuals. I'll close there and be happy to answer any questions we said.

Glen Nowak: Thank you, operator, we will open the lines to questions. We'll take the first question.

Operator: Thank you, at this time, if you'd like to ask a question, please press star one and record your name. Our first question is from Betsy McKay, "Wall Street Journal," your line is open.

Betsy McKay: Hi, thanks very much. I had a couple of questions. First for Dr. Butler. Given the changed projections for the moment, for the amount of vaccine to be received in mid-October, are you going to have to narrow or change the prioritization list for who gets the vaccine first? And secondly, I wanted to ask Dr. Fauci, you mentioned that the trials are going well, so I wondered if you could talk to us about -- I know there aren't results yet, but have there been any events, what events have there been that tell you they're going well, alternatively, have there been any adverse events? And I understand it's very early in the process, so thanks.

Operator: Thanks, Betsy. I'll turn to Dr. Butler to ask you about the recommendations.

Jay Butler: Based upon the positions right now there's no changes in the recommendations from ACIP or changes in the prioritization, but we are continuing to monitor the amount of vaccine very closely, as well as the demand for the vaccine. Dr. Fauci?

Anthony Fauci: To answer to the question that was asked about the early results that we have, as I mentioned about the first dose and second dose immunogenicity data we're certainly not there yet but we do know in the adult and the elderly a couple of things. One, there are no red flags regarding safety. In fact, the trigger to go ahead with the pediatric trial about 10 to 14 days after the adult elderly trial was our data and safety monitoring board looking at the adverse events which were essentially none, so swollen arm that you would expect, a little bit hurt at the site, which you see with almost every vaccine, that allowed us to move ahead with regard to the pediatric trials, so safety issues at least in the short term, there were no red flags there. The other important issue when I said are going well is that the completion of enrollment in two of the major trials in such a relatively short period of time, that's a relevant question, because if you don't have a large enough end, namely number of people vaccinated at the time you get your first dose data, you may not be able to get a good feel for whether or not that first versus second dose immunogenic. The fact they're fully enrolled is a good news. I'll let Dr. Goodman speak to the second question, too.

Jesse Goodman: I just wanted to mention again with respect to safety, these are the studies of licensed vaccines from licensed manufacturers, where what's been changed is just the use of this particular H1 strain as opposed to other H1 strains we use in seasonal vaccines so there is a long, accumulated safety database about these products, but also, to reemphasize what Dr. Fauci said, we're monitoring these studies and the ones of manufacturers closely. I also want to congratulate Dr. Fauci on enrolling these studies quickly, and mention that one of my sons tried to sign up, and the study was already full.

Glen Nowak: Thank you. Operator, we'll take the next question.

Operator: The next is from Elizabeth Weiss, "USA Today," your line is open.

Elizabeth Weiss: Hi, thanks for taking my call. One of the morbidity factors reported earlier was obesity. Are you doing any special testing or looking at obese, given the obesity problem in the United States?

Jay Butler: Yes, this is Jay Butler again. The surveillance data to date has been analyzed very closely to determine whether or not obesity should be considered a special indication for vaccination. The conclusion to date is that those data don't suggest that that is going to be indicated, and that's been also reviewed by the ACIP. There are more data coming in, and there are also studies planned to be able to assess that more in detail but based on the data that we have so far, there is no plan for a specific recommendation to vaccinate people who are obese or morbidly obese. I should also emphasize that the risk appears to be primarily in those who are morbidly obese, that is, a body mass increase above 40. Many of those people have underlying illnesses, which already put them into the category where the vaccine is recommended for them, but we continue to look at that issue very closely.

Glen Nowak: Thank you. Operator, next question.

Operator: The next is from Helen Branswell of the Canadian press, your line is open.

Helen Branswell: If I could ask two questions, the first for Dr. Goodman and the second, Dr. Goodman or Dr. Fauci. Dr. Goodman, you were talking about the fact new seed strains have gone out to the manufacturers. I was speaking yesterday to one of them, and was told that they have concerns about maybe changing over, because with seasonal vaccine, if the seed strain is used they have to wait to get new reagents and said that could add time to the production process, so unless there was some sort of waiver of that requirement, they aren't certain that moving to another seed strain would be realistic. Is there something afoot there in terms of sort of bending that rule in that circumstance? And my second question relates to adjuvants. Given the yield problem and the fact that vaccine is going to becoming in slower than the U.S. had first anticipated, is the U.S. looking more strongly at the use of adjuvants?

Jesse Goodman: Your first question is really highly technical but I would say, and the question was if we have newer strains provided for manufacturing, that grow better and produce better yields, would we be able to use the current reagents that I mentioned, we provided the manufacturers, and really, Helen, that's not -- that's a scientific question, and if those reagents will provide a scientifically sound calibration of the vaccine, we would allow that, so it's not a matter of anything and I think right now our expectation is that they would but that will be under study but that's a good question. So it's not like there's some normal requirement, but it's that it has to be a scientifically sound validated assay of potency, at least that's my understanding. With respect to adjuvants, I want to reiterate as Dr. Fauci said, NIH is planning a study to be prepared to use adjuvants if needed. We have asked all of the manufacturers in part of the inactivated vaccines and part of their plans and planning and some studies are ongoing already expect to adjuvanted vaccines, so we're leaning forward and trying to be as prepared as possible in case adjuvants are needed and there are many possible reasons why that could come into play, if supply became a very severe or limiting problem, that would be one situation, if the virus dramatically changed and we found that an adjuvant could produce a more effective immune response that might protect more people, that would be another such situation. So I always like to say we're keeping that on the table. We'll have the studies that will help inform what they do, including safety, but right now, our major initial focus is on the licensed products and vaccines.

Glen Nowak: Dr. Fauci, anything you'd like to add?

Anthony Fauci: No, Jesse summarized it very well and it's important to point out that if things go the way we hope they will go, namely that we'll have enough product to be able to make the distribution outlined by Jay and Jesse, and that we don't have an overwhelming explosion of cases of a virus that's a bit different in the sense it's veering away from what we would expect because of the good match that we have now between the virus and the vaccine, then the plan is to go ahead with the licensed product that Jesse outlined.

Jesse Goodman: Yeah, and I'd like to add that there are many uncertainties here and I think this is very important for everyone to understand, the behavior of this virus is still uncertain. Dr. Butler mentioned the data from South America that shows it's continuing to behave as it has. That is somehow reassuring but it is still a virus that can be disruptive and cause very serious disease, including in healthy people. The vaccine production, as you've seen, and as we've always emphasized, has a number of uncertainties. What we see in these clinical trials, although we expect the normal licensed vaccine to be immunogenic, we don't know that yet so what we're trying here is to do everything possible to help our country and, in fact, our partners throughout the world be as prepared as possible. Operator, next question?

Operator: Thank you, the next is from Mike Stobbe from Associated Press, your line is open.

Mike Stobbe: Hi, thank you for taking the question. I need to ask about a report out of Chile today about the discovery, the confirmation of swine flu, human swine flu in Turkey. I needed comment about the significance of that. I know there was a concern voiced earlier this year about the potential mixing of the novel H1N1 with bird flu. I was wondering about the significance of this discovery, and have we been checking birds and other animals for swine flu, and virus mixing?

Glen Nowak: I will start by asking Dr. Butler to address that.

Jay Butler: Okay. Well, as mentioned earlier, influenza viruses are always doing unpredictable and surprising things, although isolation of this virus from Turkey may not be that surprising, because there are --because the swine characteristics of this virus, this may sound funny to say, it can have the capacity to infect turkeys. The reassortment type event you mentioned between the H1N1 and avian viruses has not been documented but that's certainly a concern, if a bird is co-infected between, with both strains. However, I stress again, that's a theoretical possibility that we've known existed, and it hasn't been documented to date. My understanding is that these isolets were obtained because of a drop in egg production, that this was a clinically a characteristic that was very different from the H5N1 avian influenza which is among poultry flocks. I cannot address the question about monitoring but oftentimes various levels of government, monitor something done and in this particular instance, this was an assessment, the cause of the decline in egg production and much of this work is done by USDA. I don't believe that we have anybody from USDA on the line.

Glen Nowak: Dr. Fauci, do you have anything to add to that question?

Anthony Fauci: No, but just underscore what Jay said, the ideas of recombinations of viruses, it's not that we want to pooh-pooh it as being insignificant. It's not surprising we see this infecting turkey because the bird, swine, human access with influenza is well-established. There's all possibilities of recombination that we haven't seen, the recombination between the seasonal and H1N1 and pandemic H1N1 is always of interest and concern because of the resistance to Tamiflu in the seasonal but those are things you keep an eye on, so the report of turkeys being affected in Chile, although it's of interest, did not raise any great concerns among us.

Glen Nowak: Dr. Goodman?

Jesse Goodman: Yes, I would just like to add, again, this is really a very telling example or report of why we also have to keep our eye on other kinds of influenza, besides H1N1. Avian influenza, why these efforts to be prepared for H5N1, the much more virulent avian influenza, are imported not to drop here, so while we're facing this current influenza challenge, influenza is always with us. We need to be prepared for unexpected events, just like this H1N1 was unexpected, and in the long run, we would all love to have technologies such as vaccines that could be protective against not just a single strain at a time.

Glen Nowak: Operator, the next question.

Operator: The next is from Bryan Hartman, ABC your line is open.

Brian Hartman: Thank you. Whenever there's a death of a child it gains outside attention to folks of other age groups for better or worse, and so I tend to see my mailbox fill up with newspaper articles whenever somebody in their early teens dies from this flu virus. I wonder if you could talk about pediatric deaths and what the stats are now, and put that in historical context? Thank you.

Glen Nowak: We'll start with Dr. Butler to answer that question.

Jay Butler: I think you're exactly right. Whenever a child dies, it's a crisis, and it's something that is a personal tragedy and also of a public health concern. As I was mentioning earlier, more than half of the deaths have occurred in younger people, and including children, and younger adults. The rate of infection in children is very high. The actual death rate among those who are infected is comparable to what it is in younger adults, but there is no level of immunity that we're aware of in children, so that is the group that is getting, that is being heavily impacted by disease, and also by death.

Glen Nowak: Operator, next question.

Operator: The next question is from Tom Mah from "Los Angeles Times." Your line is open.

Tom Mah: A world health organization official has been quoted as predicting a "explosion" of flu this fall, of this new pandemic flu. Do you have

any thoughts on this?

Glen Nowak: I will probably let each person take a crack at answering that question. I will start with Dr. Butler.

Jay Butler: Okay, well, to return to the recurring theme, influenza certainly is a virus that behaves in sometimes unexpected and surprising ways. An explosion of influenza activity would certainly be one of the worst case scenarios, and it's part of what we prepare for. We don't want to make assumptions that this is going to be mild. That's, you know, that kind of description is, I would say, a, projecting a worst case scenario, whether or not that occurs or not, I don't think any of us know. Dr. Goodman?

Jesse Goodman: No, I don't have anything to add.

Anthony Fauci: No, not really, except to say that we should expect that there will be particularly as we get to see children come back into school and congregate in places where they're in close contact with each other, you know, if you want to call that an explosion, you know, I think sometimes words that are used in an innocent way create alarm. I think in a realistic setting, we should expect that there clearly is going to be an upsurge of cases when you get into the fall. It might not be, as Jay said, early on, but we certainly need to expect that, as we have the confluence of kids going back to school, and the weather going into an influenza season. So that would not be surprising. Hopefully it's not going to be bad, but we'll be prepared for it.

Jay Butler: Certainly we see more influenza in the fall and winter in the northern hemisphere, so whether or not that's an explosion or not, depends on your definition. We now have a new influenza virus which the population has very little immunity to, so I think it's absolutely right that we need to expect that the level of disease is going to increase as we get into our expected influenza season. How bad that will be, whether or not it will be an explosion, we really can't say. Jesse?

Jesse Goodman: Yes, I think, again, this is part of the reason we're all here and we're all working very hard to do everything we can to be prepared. You know, we, again, as Dr. Butler said, most younger people do not have much or any cross-reacting immunity to this virus, so even though the infections, the overwhelming majority have been mild, a lot of people are getting infected, and some of them have severe disease, and as people come together, that's a factor that increases infection. As the weather turns cold, that appears to be a factor that increases infection, so I think we can expect an increase in infection, and we need to be prepared for the fact that it could be more severe for some reason. It could be the same. Also, other countries, as Dr. Butler mentioned, have been recently going through this, and have shown that, you know, for example, in South America and Australia, this can have a significant effect on the population. However, it can also be managed through public health measures, and as Dr. Butler said, we should be prepared to do everything we can do, but this is an epidemic of an infectious disease.

Glen Nowak: Thank you. Operator, next question?

Operator: The next is from Jane Dorenowsky from NBC News your line is open.

Jane Dorenowsky: Good afternoon. I have two short questions. Do the rules requiring health care workers to get vaccinated?

Glen Nowak: Dr. Butler will take that.

Jay Butler: I'm not quite sure what you mean by rules but it's an ACIP recommendation for health care workers to be vaccinated. The whole vaccination program is voluntary, whether or not a person receives vaccine and at the national level, there are no mandates for vaccination.

Jesse Goodman: Yeah, and we think it's very important for health care workers to get vaccinated. They are very -- one of the biggest stressors of an upcoming epidemic is going to be on health care systems so by being immunized they can both protect themselves but also help, have an effective health system that can deal with those who might be hospitalized or need medical care, so this is very important, but as Dr. Butler said, it's very important also that we are all emphasizing that this is a voluntary matter, when vaccine becomes available.

Anthony Fauci: As a health care provider, I would encourage my fellow health care workers to be vaccinated, that it's an important part of providing good quality of care and protecting your patients.

Glen Nowak: Did you have a second question?

Jane Dorenowsky: Yes, do the numbers of the vaccine that mentioned include the flu mist doses that are expected?

Jay Butler: Yes, those numbers include that, but as you may have heard, we're also taking measures to do what we can to potentially increase production and availability of that vaccine, and FDA and HHS and the company are working together on some additional approaches, and the good news there is that the producer, as they have stated, has actually had excellent yields of production of that vaccine and that's another vaccine that currently is in clinical trials being performed by the sponsor.

Glen Nowak: Operator, we have time for two more questions.

Operator: The next is from Donald McNeal, the "New York Times" your line is open.

Donald McNeal: Hi, I have two questions, please. The one is, is there any new CDC official estimate of how many total cases have been in the United States? I think we've been at 1 million for quite awhile now. Is it two, three, four, five, ten, anything like that? And the second do any of you have thoughts on why we're seeing the disparities we're seeing in increase or decrease of cases? For instance, any thought about why Alaska and Maine have seen widespread activity, and any thoughts UK is decreasing while Japan is increasing?

Glen Nowak: I will turn first to Dr. Butler.

Jay Butler: Okay, in the first question, actually an easy one. No, there are no new estimates. I think the last estimates were on the order of as many as 1 million cases, so I can say if that's accurate, it's more than 1 million cases now. The other question is a very good one, and it's one of the mysteries about influenza that why some communities seem to be affected early in the epidemic and others later, so that we see a very heterogeneous level of activity, as we look across the country, so just why, for instance, right now, Alaska is seeing more activity than some of the other states, same with Maine, I really can't say. Alaska was one of the last states to actually have laboratory confirmed H1N1 activity, so it's possible that they're later in the overall epidemic curve. That said, within a given state, sometimes some communities are impacted earlier than others.

Anthony Fauci: Yes, Donald, this is Tony. You know, we get asked this question all the time. If you look at the regular seasonal flu plottings that the CDC gives in their MMWR, not reported, sporadic, local, regional, widespread, we see this in seasonal flu so this isn't something that's characteristic of this novel H1N1. It's very interesting, when you go through the fall and winter seasons, if you do, like I and many of my colleagues do, follow regularly the map that the CDC puts out, you do see that disparity among different sections of the country, so this isn't something that's novel to the pandemic flu.

Glen Nowak: Absolutely. Operator, we'll take one last question.

Operator: The next question is from Bob Roos, CIDRAP News your line is open.

Bob Roos: Thank you, this question will be forever, I guess, actually two questions. Wondering if a definite decision has been made yet as to the number of doses per person, one or two doses, and also, have manufacturers actually started the fill and finish part of production, started finishing production of the vaccine at this point?

Glen Nowak: I will ask Dr. Goodman to address those two questions.

Jesse Goodman: Okay, on the first question, which, again, just to introduce it for people who may not have dived deep into the science up to now, usually people who have had no previous exposure to an influenza virus family, let's say, such as children under 9, who may not normally have been broadly exposed to influenza in normal circumstances or don't have cumulative amounts of antibody against it, normally young children require two doses of the inactivated vaccine to get, to develop immunity. The answer is, we will not know until we see the results of the clinical studies whether - because this vaccine is so new, and because of our observation of how it's behaving that so many people are susceptible, whether, in this case older individuals will also need two doses. I think we all feel that that is a distinct possibility that we need to be prepared for, but it is also possible that they will have enough cumulative immunity to other H1N1 strains that we may see in effect after one dose, so the clinical studies and the results that Tony mentioned should begin to accumulate through later September and into October will help in form that. Your second question was, what was it again?

Bob Roos: Fill and finish.

Jesse Goodman: Oh, about fill and finish. What I want to say about that, I am in the unique position of having, you know, both public and non-public information that is in the same mind, but what I would say is that it has been the intent of the government, as part of our response, to move forward to fill and finish vaccine as it becomes available, to have it initially available, and it is that planning that is allowing us potentially to plan to begin immunization in mid-October. So the basic answer is, yes, we are moving in that direction, and working with manufacturers to do that, as vaccine becomes available for filling and finishing, and again, that simply means actually taking the bulk vaccine that they've produced and putting it into vials at the standard concentration, so that is moving forward.

Glen Nowak: Dr. Fauci, is there anything you wanted to say with respect to the first question?

Anthony Fauci: Yes, with the first question, it's a very important question, so you just really need to stay tuned, because as Jesse said, we often see we need two doses in children who haven't had much experience, but even though there doesn't appear to be a lot of cross-reacting antibodies in younger people, we see some suggestion of that in the older individuals, we're going to know pretty soon as we get into mid to late September whether or not we have a pretty good response to that first dose of 15 or 30. That will inform us much better and be able to answer that question with a little bit more scientific knowledge, as to what the situation is going to be in the adults, the healthy, young adults.

Jesse Goodman: This is Jesse Goodman again. I wanted to add one thing, given the opportunity, and is that is that even with a single dose, the protective effects of influenza vaccine or for the most part, almost any vaccine, are not immediate. The body has to take its time to generate some antibody, that usually occurs over a couple week period. So even with a very effective vaccine and even where only one dose is required, people

should not presume that the minute they're immunized they're protected. Also, again, in the viewpoint of being very clear about influenza vaccines they are generally not like the other vaccines, polio or measles vaccine, many which are 95% plus effective in preventing disease if you're exposed to it, and influenza vaccines in healthy, young adults are not quite that protective. There's various estimates of protection, depending on the match of the strain, but, for example, with a well-matched strain in healthy, young adults, protection level is in the area of 70%, 80%, might be typical so again I think it's very important to understand what a vaccine can and can't do, and how quickly it can do it.

Anthony Fauci: That has important implications, even if you're vaccinated, wash those hands, cover those coughs, stay home if you're sick.

Glen Nowak: Well, I thank you all for participating in afternoon. A transcript of this will be on the CDC website sometime later this afternoon. If you still have questions on the media side, do contact CDC's Office of Media Relations at 404-639-3286 and again I thank the speakers and I thank those who called in today. Thank you

END

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