NATIONAL BIODEFENSE SCIENCE BOARD

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PUBLIC TELECONFERENCE

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FRIDAY,
AUGUST 14, 2009

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The meeting convened telephonically at 12:00 p.m., Chair Patricia Quinlisk, presiding.

VOTING MEMBERS PRESENT:

PATRICIA QUINLISK, Chair, M.D., M.P.H.
RUTH L. BERKELMAN, M.D.
STEPHEN V. CANTRILL, M.D.
ROBERTA CARLIN, M.S., J.D.
ALBERT J. DI RIENZO
KENNETH L. DRETCHEN, Ph.D.
JAMES J. JAMES, Brigadier General (Retired), M.D., Dr.PH., M.H.A.
JOHN S. PARKER, M.D., Major General (Retired)
ANDREW T. PAVIA, M.D.
ERIC A. ROSE, M.D.
PATRICK J. SCANNON, M.D., Ph.D.

EX OFFICIO MEMBERS PRESENT (or designee):

JOSEPH ANNELLI, D.V.M., Animal and Plant Health Inspection Service
DIANE BERRY, Ph.D., Chief Scientist, Director, Threat Characterization and Countermeasures, Office of Health Affairs, Department of Homeland Security
BRUCE GELLIN, M.D., M.P.H., Director, National Vaccine Program Office
ROSEMARY HART, Special Counsel, Office of Legal Counsel, Department of Justice
PETER JUTRO, Ph.D., Deputy Director, National Homeland Security Research Center, Environmental Protection Agency
CAROL D. LINDEN, Ph.D., Principal Deputy Director, Biomedical Advanced Research and Development Authority
AUBREY MILLER, M.D., Office of Counterterrorism and Emerging Threats, Office of the Commissioner, U.S. Food and Drug Administration (designated by Boris Lushniak)
COL. JOHN P. SKVORAK, D.V.M., Ph.D., Commander, U.S. Army Medical Research Institute for Infectious Diseases

NBSB STAFF PRESENT:

LEIGH SAWYER, D.V.M., M.P.H., CAPT., U.S.P.H.S., Executive Director
ERIN FULTS, Scientific/Technical Writer
DON MALINOWSKI, M.S., Program Analyst
JOMANA MUSMAR, M.S., Policy Analyst
BROOK STONE, M.F.S., LTJG, U.S.P.H.S., Program Analyst

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P R O C E E D I N G S

12:03 P.M.

CAPT. SAWYER: Thank you and I also would like to welcome the National Biodefense Science Board members to this public teleconference. We do have a particular session devoted to the public. And I'd like to begin by welcoming, as I said, the voting members, ex officios, and we have here today members of our Disaster Mental Health Subcommittee. I'd also like to welcome the public to this teleconference.

I am Leigh Sawyer, the Executive Director of the National Biodefense Science Board. I serve as the Designated Federal Official for this Federal Advisory Committee.

The purpose of the public teleconference today is to allow the Board to receive current activity updates from the representatives of the Department of Health and Human Services on preparation for H1N1.

The public teleconference is being

convened to assure that the public is given the opportunity to hear the deliberations and to provide comments.

I will begin first with a roll call of the voting members.

DR. PICKERING: Larry Pickering here.

CAPT. SAWYER: Thank you, Larry.

DR. PICKERING: Is this Leigh?

CAPT. SAWYER: Yes.

DR. PICKERING: Hi.

CAPT. SAWYER: Hold on one minute. Okay. Let's begin the roll call. First, please say here if you're on the line.

Patty Quinlisk?

DR. QUINLISK: Here.

CAPT. SAWYER: Ruth Berkelman. Steve Cantrill.

DR. CANTRILL: Here.

CAPT. SAWYER: Roberta Carlin.

DR. CARLIN: Here.

CAPT. SAWYER: Al Di Rienzo.

MR. DI RIENZO: Here.

CAPT. SAWYER: Ken Dretchen.

DR. DRETCHEN: Here.

CAPT. SAWYER: John Grabenstein. Jim James. Tom MacVittie. John Parker.

DR. PARKER: Here.

CAPT. SAWYER: Andy Pavia. Eric Rose.

DR. ROSE: Here.

CAPT. SAWYER: Pat Scannon. Okay.

MS. BERKELMAN: This is Ruth Berkelman. We had trouble getting on the line.

DR. JERNIGAN: This is Dan Jernigan. I'm just now joining.

CAPT. SAWYER: Okay. I can see from the list here that there are people -- we may give you just a couple more minutes here to get on to the line.

DR. JUTRO: Leigh, this is Peter Jutro. They're incredibly slow. It took about 12 minutes before they answered the

phone and then after you give your name it took several more minutes to look us up.

CAPT. SAWYER: Okay, so let's pause then just for a few minutes to give everyone an opportunity to join the call.

(Whereupon, the above-entitled matter went off the record at 12:06 p.m. and resumed at 12:07 p.m.)

CAPT. SAWYER: Let's try this roll call again.

I know Patty Quinlisk is here.

Ruth Berkelman.

DR. BERKELMAN: Here.

CAPT. SAWYER: We have Steve Cantrill, Roberta Carlin, Al Di Rienzo, Ken Dretchen. Has John Grabenstein joined?

Okay, Jim James? Tom MacVittie. John Parker is here. Andy Pavia, have you joined? Eric Rose? Pat Scannon.

DR. ROSE: Here.

CAPT. SAWYER: Oh, Eric Rose. That's right. You had already said so. And

Pat Scannon? Okay, let's go with ex officio representatives.

Dan Fletcher? If you are an alternate, please say your name. Carter Mecher. Larry Kerr. Richard Williams. Frank Scioli. Joseph Annelli.

DR. ANNELLI: Here.

CAPT. SAWYER: Willie May. John Skvorak.

DR. SKVORAK: Here.

CAPT. SAWYER: Patricia Worthington. Hugh Auchincloss. Carol Linden.

DR. LINDEN: Here.

CAPT. SAWYER: Bruce Gellin.

DR. GELLIN: Here.

CAPT. SAWYER: Boris Lushniak.

DR. MILLER: Aubrey Miller for Boris Lushniak.

CAPT. SAWYER: Thank you, Aubrey. Diane Berry?

DR. BERRY: Here.

CAPT. SAWYER: Sue Haseltine?

Rosemary Hart.

MS. HART: Present.

CAPT. SAWYER: Claudia McMurray. Lawrence Deyton. Peter Jutro.

DR. JUTRO: Here.

CAPT. SAWYER: Patricia Milligan. And are there any voting members that have joined that I have not named -- you were not available for the phone call, for the phone roll?

Okay, let me proceed then. There are members of the Disaster Mental Health Subcommittee in attendance on today's call. I'd like to welcome them and thank them for joining.

I'd like to provide now a review of the FACA requirements. The NBSB is an advisory board that is governed by the Federal Advisory Committee Act. The FACA is a statute that controls the circumstances by which the agencies or officers of the Federal Government can establish or control committees or groups

to obtain advice or recommendations for one or more members of their group are not federal employees.

The majority of the work of the NBSB including information gathering, drafting of reports and the development of recommendations is being performed not only by the full Board but by working groups or subcommittees who in turn report directly to the Board.

With regard to conflict of interest rules, the standards of ethical conduct from employees of the Executive Branch document has been received by all Board Members who, as special Government employees, are subject to the conflict of interest laws and regulations therein.

Board Members provide information about their personal, professional, and financial interests. This information is used to assess real, potential, or other apparent conflicts of interest that would compromise a

member's ability to be objective in giving advice during the Board meetings. Board Members must be attentive during the meetings to the possibility that an issue may arise that could affect or appear to affect their interest in a specific way. Should this happen, it would be asked that the affected member recuse himself or herself from the discussion by refraining from making comments and leaving the telecon.

The public comment period is scheduled from 1:40 to 2 o'clock p.m. You will be given instructions by the operator as to how to queue up so that your phone line will be open for you to speak.

The Federal Register notice announcing the August 14 public teleconference, stated that public comments could be addressed to the Board and sent to the NBSB email prior to the meeting. We have received public comments. The public comments received by June 12th have been shared with

the Board Members and all the others will be read during the public comment period.

All public comments will be included in the August 14 NBSB public meeting summary and available on our website shortly after the meeting.

If you would like a copy of the public comments received to date, please email now, nbsb@hhs.gov.

I'd like to remind you that this meeting is being transcribed, so when you speak please provide your name.

Now I would like to introduce our Assistant Secretary for Preparedness and Response, Dr. Nicole Lurie as she would like to welcome the Board. She was introduced for the first time at our July 17 meeting and we're so pleased that she's able to be here today.

DR. LURIE: Great. Well, thank you so much for joining again today and stepping up the frequency of your meetings to coincide

with I think the urgency of the event.

Let me start by thanking Patty Quinlisk for her leadership as Chairman of NBSB and to all of you for your very active participation.

What I wanted to do today was give you an update since our last meeting. You will recall that at our last meeting I committed to come back at every meeting, if I could, give you an update on what we did with your recommendations and I want to take the opportunity to do that now.

Since we last met, we have within my office established a very robust H1N1 Task Force with the goal of coordinating issues that touch on H1N1 across all of the HHS agencies. And I think that's going very well.

Captain Clare Helminiak is chairing that Task Force and it's organized now, according to the four pillars, the National Security Council, Homeland Security Council have established for the whole H1N1 event and

they are broken down into surveillance, which includes both situational awareness about virology and epidemiology of the disease, as well as situational awareness about the medical care system capacity and functioning.

Mitigation measures, which obviously relate to antivirals, community mitigation measures, and all of medical care is really in that category. Vaccination and communication and education.

Today, I know that you're going to hear updates from BARDA and from CDC and from the three other Advisory Committees working on H1N1 issues. And I'll let all of those people update you on those.

I want to say, first of all, that as I commented before, your work group meeting and then the subsequent meeting of the entire Board I think for all of us, we really took this as a call to get much more aggressive, I think, than we had been being about our preparations, particularly on the vaccine end.

We took your recommendations. We took them to the Secretary and more importantly we've been acting directly on them.

We heard you loud and clearly that we ought to be prepared to have vaccine available for distribution at the earliest possible time and that you thought that we ought to go ahead, for example, and fill and finish vaccine without having the clinical data available. And so we've gone ahead and done that. The task orders to get that done were issued at the end of last week and early this week.

In terms of the timing of that, I think a number of you probably read in the press and others that there was an initial challenge with the potency of reagents that were necessary to go ahead and actually formulate vaccine for fill and finish. You know, fortunately, we weren't again reliant on a single set of reagents or a single manufacturer of those and had backup plans in

place in a variety of places including with FDA. And that has really enabled now all of the manufacturers to go ahead. They now all have potency reagents in their hands. We're working actively with them and we believe by next week we'll be able to go ahead and begin formulating, filling and finishing their vaccine.

So this, I think, accelerated action is really a very direct consequence of your debate and advice to us.

We also previously told you that clinical trials were planned to begin August 1st and we are pleased to be able to tell you that those have begun on time and on schedule. Recruitment on participation in those trials has been really quite robust.

Regarding the discussion about antivirals and I know you'll get an update of this later, I've been really pleased with how FDA, BARDA, CDC and NIH have been working together to think about the EUA process and to

enhance access to investigational antivirals while we're in the process of assessing the appropriate risks and benefits. And so I think again we heard you and we're moving forward on that front.

We've also been really pleased with the advice that we've gotten from the Mental Health Subcommittee. And you'll hear from Dan Dodgen later, but I've really asked Dan and his team to really start to think very proactively about mental health issues that are likely to arise as children, parents, teachers, coworkers may die after severe illness from H1N1. And so again, we're sort of doing really proactive planning in that regard.

I'm really looking forward to hearing the results of your discussion today and to the reactions to all of the updates we provide and again, you know, as before, look forward to the formal recommendation as well as your very thoughtful discussion and thought

process as we go on.

So with that, I'll conclude my opening remarks, say thank you again, and turn this back to Leigh so we can get on with the business at hand.

CAPT. SAWYER: Thank you very much. Dr. Quinlisk, are you ready to open the meeting?

CHAIR QUINLISK: Yes, go ahead and open it. I'd just like to add my welcome to Dr. Lurie. And I'm very gratified to hear that our advice has been useful to you and is being acted on. Hopefully, that will continue into the future. I think there's been a lot of good work done by people on this panel, both on the Subcommittees and the working groups as well as the general board and hopefully we can continue to be useful to you and just wanted to welcome you to come and talk to us any time and certainly, if there's anything that we can assist or give advice on or consider, please don't hesitate to let us

know immediately and we'll do our best to get whatever advice or information back to you.

DR. LURIE: Thanks, Patty. I really appreciate it and just appreciate and if you should hear on both sides open call for frequent communications, feel free to call or email, whatever, as the need arises.

CHAIR QUINLISK: Okay, thank you, Nicki.

I think what we'll do then is we'll just go right ahead and go to our updates for HHS on the H1N1. I think we're ready to do that, right, Leigh.

CAPT. SAWYER: Yes, we are.

CHAIR QUINLISK: Okay, I'll go ahead and introduce our first person. Daniel Jernigan is going to go ahead and talk to us about H1N1 situational update and he is the Deputy Director with the National Center for Immunization and Respiratory Diseases at CDC.

DR. JERNIGAN: Thanks a lot, Patty. So, just very briefly, in terms of some of

the domestic surveillance issues, the CDC is no longer presenting on its website the case counts, the laboratory confirmed case counts. However, we still are working with state health departments in collecting and reporting the numbers of laboratory-confirmed hospitalizations and deaths.

Before this week on the website you can see that the numbers of cases were increased from last week of around 6500 hospitalized cases that were laboratory confirmed, 7,511. The numbers of deaths increased from 436 to 477. So these numbers in terms of the cumulative numbers are continuing to increase, but the overall trend is not rising as it had been in the past. It's consistent with amount of disease that we're seeing overall in communities.

In terms of our key influenza surveillance indicators for outpatient ILI illness, looking at the ILI net, we see that the percent of influenza-like illness that are

among those that are going to the doctor in the outpatient setting is below the national baseline, but that percent, that is the numbers of people that are going to the clinic with influenza-like illness over the total number of people that are going to the clinic, it's still above what we would see normally at this time of year. So early on in the season we saw that blip that was likely related to a lot of media interest, but what we've seen is a consistent increase in the amount of people going to the doctors through the summer above what we would expect.

Some areas where there have been more recent increases that are notable, according to their syndromic surveillance, as well as ours, is in Florida and in North Carolina. And so those are areas that we'll be following up on to see what the subtype is of that and if there are other causes of influenza-like illness that might be driving those increases there.

Overall, if you look at it nationally, the percent of outpatient visits for ILI decreased slightly, but it is still above what we would expect at this time of year.

In terms of hospitalizations through the emerging infections program and through some other sites, we are monitoring the rate for adults and children that are being hospitalized with influenza and those remain low so far. They are not anywhere near where we would expect during an influenza season. So that's something that we are monitoring now and as the season goes forward, we'll continue to see whether or not there are age-specific increases, that is, seeing if children are increasing in their hospitalizations for influenza.

In terms of monitoring deaths, the proportion of deaths that are attributed to pneumonia influenza was low and it's within the bounds of what is expected in summer. For

those of you that monitor the curve closely, you could see that it looks like a slight increase above the seasonal baseline, but that's within the bounds of what we would expect and we've seen that not continue to increase.

In terms of the virus itself, the subtype surveillance demonstrates in the United States that almost 100 percent specimens characterized at CDC and at state public health labs are the pandemic H1N1 virus. If the antigenic changes, there's no significant drift that we have seen in the pandemic H1N1 away from what's in the vaccine and for those viruses in the United States.

In terms of antiviral resistance, so far we are not finding -- we have not reported any resistant cases in the United States. There are two cases in Washington State that we are working with them on to verify and that those two cases of resistance that is pandemically resistant, pandemic H1N1,

are in persons who are receiving therapy and so those have not been reported yet, I don't believe, publicly.

Internationally, there are nine reports of resistance that have come out, four in Japan, one in Denmark, one in China, one in Hong Kong, one in Canada, and one in Singapore.

So far there are no zanamivir resistant to H1N1 viruses yet.

In terms of geographic spread, there are four states that are reporting widespread activity, but most states are reporting only sporadic or local activity.

Let me just very briefly give a comment on international surveillance. As of August 12th, the WHO was reporting 177,457 lab-confirmed cases and 1,462 deaths coming out of at least 168 countries that are reporting.

In terms of the sub-type testing internationally, looking at it from a Northern

and Southern Hemisphere, what we see globally is around 66 percent of influenza viruses that are being collected are the pandemic H1N1 and about 89 percent of influenza viruses in the Southern Hemisphere are the pandemic H1N1. So it is the predominant strain now of both in the Northern and Southern Hemispheres in terms of what is said to be.

Overall, in Argentina, an area where we were looking for it closely, there appears to be a decline in illness there, as well as in parts of Australia. In South Africa, the novel H1N1 continues though to increase there.

The epidemiologic and clinical characteristics of infections that have been evaluated in the Southern Hemisphere appear to be similar to what we're seeing in the United States so far and we've not identified any changes in the virus in any of those sites that have reported information to us at this point.

So with that, I'll hand it back to Patty.

CHAIR QUINLISK: Okay, thank you very much, Dan.

I think what we'll do is go on now to our second presentation on the H1N1 vaccine, Robin Robinson who is the Director of the Biomedical Advance Research and Development Authority, BARDA, is going to give us an update.

DR. ROBINSON: Thank you, Patty, and thank you, panelists and members of the NBSB. I want to give you an idea of where we were since my third performance with the group this summer.

The vaccine strategy has three elements, as you recall: the vaccine development, vaccine manufacture, and vaccine administration. And I'll talk about two of those right now, but overall, things are where we had planned. Jay Butler will talk about the vaccine administration and planning that's

going on.

With the vaccine development, as Dr. Lurie said earlier, the manufacturers have started their clinical trials and NIH just started its. They're running as expected and we should have data coming back in September to inform us as to what the number of doses, the amount of antigen in the vaccine and any other aspects of antigen sparing with some of the manufacturers using their adjuvants. So those are moving forward as we had hoped.

With the vaccine manufacturing, all five manufacturers have received their seed. They're making vaccine at all five sites, across the world for the U.S. The licensed vaccine manufacturers received influenza vaccine. They have just received their potency assay reagents so that now they can start to determine over the next week how much vaccine they've already produced and then that will inform them to start the fill finish manufacturing of the inactivated subunit

vaccines. So that will proceed over the next week and a half and so we will have a better update as to how much vaccine has already been made at this point.

On the live attenuated vaccine, we have news that the virus grew well, but they were manufactured at a higher amount than we had anticipated for the bulk vaccines, so where we are right now, as we go forward, is we're still looking around a mid-October campaign, preparing for that and as you recall, we actually had bought 109 million doses of vaccine from the five manufacturers. And if we needed 120 million doses of adjuvants, if we had conditions that warranted us to go forward with those adjuvants.

If you remember from our last meeting, our initial estimates we were about 120 million doses in the middle of October. We now have gone through and were able to revise those to less than that. So we're looking around at least 45 million with 20

million doses each week coming up after that.

As we go forward, we will be able to see some of the optimization at the manufacturers, increasing the yield to the product, and also the fill finish lines becoming more available. That's very important.

There are several reasons why we have less than we had anticipated from the very beginning and the first, as you read, and we talked about this is that the manufacturing of the subunit vaccine that's been activated is the -- the virus' production yields are less than we would see with seasonal flu, so that the overall amount would be a little less than before. The second is there is a limited number of fill finish sites and as we go forward, we will be expanding those to maximize what we have had in the past in the United States so that we would have more than the anticipated amount right now.

Also, we saw that one of the

manufacturers had obligations in its home country of manufacture, CSL in Australia, to produce vaccine for Australia ahead of others. That has now happened and they are certainly working with the Southern Hemisphere influenza that's going on there right now and so there is quite a bit of interest in getting back as soon as possible. We're working with them to make sure that Australia has theirs when they needed them and U.S. will have them, get them and go forward.

The other thing is you're probably aware that some of the seasonal influenza vaccine manufacturers have been making their vaccine, completing their orders and started to send those out, but one of the manufacturers has had problems with one of the strains, finishing it up, and has impacted our time lines by four to six weeks. And so that we are trying to work with them to see how we can manage that and be able to raise our production on that.

So those are some of the reasons we're going on. We do note, should know there's a new seed strain that has been worked on in the laboratory. Looks like it's going to give yields that are similar to seasonal influenza, H1N1, and so the manufacturers are starting to receive those seeds and will be working with those over the next two weeks to see if they truly on a commercial scale, do see the increase in yields. So we'll watch very carefully on that and keep you updated.

So I think just to let you know that HHS is working with the states and local health departments as much as possible to keep them updated and at this point I think it would probably be good for me to turn it over to Jay Butler at CDC so he can talk about the vaccine planning.

DR. BUTLER: Okay, thank you, Robin, and good day, Patty, and everyone else.

Before I start, just an audio check. Am I coming through okay?

CHAIR QUINLISK: You are doing fine, Jay. Thank you.

DR. BUTLER: Okay, great. Well, to address the issue of the administration phase of the big three that Robin highlighted, I wanted to highlight four components of that area: vaccine distribution, assessment of the number of doses administered and coverage, safety monitoring, and communications. Of course, the overarching goal of this voluntary vaccination program is to provide vaccines to as many people who wish to be vaccinated.

So starting with vaccine distribution, the vaccine will be distributed in a manner similar to federally-purchased vaccines provided through the Vaccines for Children Program or VFC. Vaccines from the five manufacturers will be shipped to a central distributor who will fill the orders for vaccines. The orders will be sent to the distributor under the direction of state and territorial health departments. The vaccine

will be shipped to the healthcare providers, retail pharmacies, or to the state and local public health facilities for administration, either through the public health clinics or special mass vaccination clinics. So this system really is designed to provide maximum flexibility to fit with state planning efforts.

Ancillary supplies, including needles, syringes, alcohol swabs, sharps containers will also be provided and will be shipped by the distributor in a way such that they will arrive either the day before or the day of arrival of the vaccine.

Additionally, vaccine record cards will be provided for each recipient by CDC, and the Vaccine Information Sheet, or VIS will be available for download from the Internet.

Moving on to tracking of doses and the coverage assessment. The number of doses administered will be tracked for two reasons, one, to provide a rough estimate of a

denominator of persons who are vaccinated to evaluate any early reports of adverse events and also to determine the performance of vaccine delivery to specific age groups for whom the vaccine is recommended and later in the agenda, Dr. Tony Fiore will be providing a description of the Advisory Committee on Immunization Practices and Recommendations for Vaccine Use.

The Countermeasures Response Administration, or CRA system will be used to track the number of doses administered. This is a web-based aggregate data reporting system that will accept data on the number of doses administered to people in various age groups and providers and health agencies. The CRA is designed also to allow states to download data from their existing immunization registries.

Additionally, coverage as we continue along and the number of doses increases will be assessed by two mechanism. Both are existing mechanisms that are being

modified for this purpose. One is the National Immunization Survey. This system was previously used to assess vaccination coverage can begin collecting data as early as the week of October 10th and provide weekly national coverage estimates.

Additionally, the Behavioral Risk Factor Surveillance System, or BRFSS, will be used, as it has been used recently to assess coverage of seasonal influenza vaccine. This will provide a more complete picture, although somewhat less timely of vaccine coverage that will allow state-by-state assessment of coverage, as well as measure of coverage of specific risk groups.

It appears that the updated BRFSS data will be available as frequently as twice monthly.

The third topic I wanted to touch on is a critically important one and one that is given a very high-level view of is safety monitoring. Certainly, we want to do

everything to provide a safe vaccine and the public expects this. Data from clinical trials will provide data on reactogenicity, but will not provide data on any rare adverse events.

So there's a number of mechanisms that will be used to monitor vaccine safety. The first two I'd like to describe are existing systems that will be enhanced in various ways. The first is the Vaccine Adverse Events Reporting System or VAERS. This existing surveillance system will function primarily as a method of signal detection, that is a way to collect numerator data on moderate or severe reactions after vaccination. The number of signals detected will be compared with background rates as well as the number of doses administered and investigated further, as indicated.

Even now, before we are into a vaccination program, the VAERS receives 150 to 200 reports daily. These are processed and

the system is in the process of being staffed up to be able to receive more reports. We anticipate a capacity of up to a thousand reports a day.

The second system that I wanted to highlight is the Vaccine Safety Datalink. This existing system will be used to assess the prevalence of any signals detected in vaccinated and unvaccinated persons and compare these rates with expected background rates. VSD is a population-based surveillance using eight participating managed care organizations that represent just shy of three percent of the U.S. population. This system incorporates a system of rapid cycle analysis which is intended to arguably achieve the goal of near real-time surveillance for adverse events.

There are a number of other methods in the works, ones that some of you may be familiar with is the Defense Medical Surveillance system of collaboration between

DOD and FDA which links back to ancient history and interaction with the military health system for slightly over one million active duty personnel.

Additionally, there are special projects specifically focused on Guillain-Barré syndrome, using the Emerging Infectious Disease Program sites. These will combine with laboratory and clinician-based surveillance to detect any increases in rates of Guillain-Barré syndrome.

And then there's a number of special projects that are being planned with collaborations. Those are very much in development at this time and protocols are being reviewed and revised even as I speak.

A drill of the adverse events detection investigations scenario is in development and will be executed. The plan right now is for early September.

And the last area I wanted to touch on was communications. The overarching goals

of the H1N1 communication included providing situational awareness, transparency and needed information to public healthcare providers and public health professionals, as well as to the media. Additional goals include engaging partners, setting realistic expectations, enlisting public participation and discussion about implementation and addressing concerns.

Certainly some of the challenges around vaccine communication include coordination with messages on community mitigation and seasonal flu vaccine. We want to make it clear which vaccine does what, that just because you've been vaccinated doesn't mean you can stop washing your hands, that kind of coordination.

Methods of communication will include print, broadcast and web-based media. Additional activities include developing professional education materials to encourage pneumococcal vaccination of adults for whom the vaccine is currently recommended by ACIP

to reduce the risk of this life-threatening bacterial infection which is a complication of H1N1 pneumonia.

Also planned is a journalist workshop on influenza to provide an opportunity for detailed answers to questions from the media from influenza subject matter experts. And I'll stop at this time and I look forward to what follows and I think next on the agenda is back to Robin Robinson to discuss antivirals. Thank you.

CHAIR QUINLISK: Yes, Robin, could you go ahead and just give us the antiviral update?

DR. ROBINSON: Yes. Thank you, Jay, and thank you, Patty.

Three topics I want to discuss with you, the first is as Dr. Lurie said that we have taken your recommendations to look at some of the investigational antiviral drugs such as peramivir by IV presentation; zanamivir IV; and also oseltamivir. And so

we're supporting the clinical studies for the latter two and the first one we have been supporting for the last several years for the development of peramivir and the Department is actively discussing and meeting to talk about whether these products could be available and how much we would need at least initially for procurement. And so I think very soon we will be -- have a final decision in going forward with that under emergency usage authorization for critically ill individuals with influenza, seasonal or the H1N1 virus. So we took your advice on that and thank you for that.

Secondly, just to give you a little update on where we are with the stockpile, both at the federal and state level, total right now in the states' and at the federal's own hands about 84 billion antiviral treatment courses and there are 3 million that have been ordered by the SNS that should be arriving very soon, so it brings up to a pool rated 7. And then taking advice for bringing up our

level of pediatric formulations of oseltamivir to be in the strategic national stockpile for deployment if needed, and also looking at the possible resistance to oseltamivir, acquiring more zanamivir, and so those, with a contingency fund appropriations, may be available a little bit later in the end of the summer or early fall as we move forward with the procurement on that.

So we think with all of those we would be able to have a little over 100 million treatment courses by this fall of the antivirals and we've actually seen the states pick up and buy more the last time we've talked. We've seen a little more than 2 million treatment courses bought by the states in addition to the 11 million that were deployed to them in early May. And what's left for the United States as far as being able to buy it. There's a small amount that would be available through the rest of the

year for the commercial market. The manufacturers are working three shifts a day, seven days a week to provide more that would be available as we go into the new year.

Thank you.

CHAIR QUINLISK: Okay, thank you, Robin.

I think, Dan, we're going back to you for an update on diagnostics.

DR. JERNIGAN: Sure. There were three or four major issues just to follow up on. One was regarding the public health laboratories and their ability to meet clinical diagnostic needs that were posed by the present pandemic. And so we had a number of discussions with the Association of Public Health Laboratories and with representatives from the Public Health Laboratory community. It's clear that we are trying to focus their testing on the surveillance testing rather than providing clinical testing capacity. So I think in looking through the overall search

capability within the broad laboratory community, we also recognize that clinical hospital laboratories are not going to be able to provide the testing that might be asked of them as well.

So there are a number of different lanes that essentially have -- that are open in order for there to be the availability of better testing. I'll just touch on a couple of those. There are at least three other FDA 510(k) cleared assays that are out there that companies have been marketing their use and the dose. Those tests will provide a higher sensitivity and specificity for influenza and some of them can also tell if it's an influenza A, but not an influenza seasonal H1 or seasonable H3 and therefore they're able to indirectly detect the pandemic H1.

We understand that there are other assays that are coming forward to FDA and asking for the emergency use authorization and I don't know if our colleagues from FDA wanted

to comment on that in a second, but in addition to those that are either FDA 510(k) cleared or that are under an EUA, there are also, we understand, development of these laboratory-developed tests or, quote, home brews that we think are likely to be available out there that are validated under the CREAB regulations.

One thing to point out that Focus Technologies which is a subsidiary of Quest Diagnostics applied for and was given an emergency use authorization for their H1N1 pandemic PCR, so at this point that increases the access to H1N1 specific testing from a number of non-hospital settings as well as hospital settings. And so the way this would work is that a doctor can take a specimen, put it into the box that Quest picks up every day and then get the result back in 24 hours in an outpatient setting and then there may be a more rapid turnaround in some clinical settings for those clinical laboratories that

utilize Quest for their reference testing.

The CDC is completing validation of the H1N1 pandemic PCR as well as the five target PCR on the Roche light cycler and plan to submit that to FDA and we're also working with the Department of Defense on their JBEDS platform as well as increasing the number of laboratories that are qualified to use the existing CDC five target and H1N1 tests. So overall, we're trying to increase the numbers of places that can do surveillance testing, but also those that can do clinical testing.

At the point of care, with regard to rapid tests, there was a statement last time about the fact that the existing lab diagnostic tests had unacceptably low sensitivity to rule out H1N1 infection. And since that presentation, the CDC has published an MMWR in a report about three of the FDA approved rapid influenza diagnostic tests and I would just direct you to the CDC website where the MMWR can be found at the MMWR

website.

Where we found the sensitivity of these three -- three of the largest and most distributed tests ranged from 40 to around 70 percent and so it's not great, but for some of the tests it's at a level that was higher than what had been reported for seasonal influenza in some other peer-reviewed literature.

The overall outcome of that MMWR and a subsequent meeting that we had with representatives from the laboratory and clinical community was guidance from CDC that was posted on the website about two weeks ago where we walked through the -- what we considered the acceptable interpretation of rapid tests where essentially if a person gets a positive test, it is something that you can act on, but if you have a negative result, we do not recommend that one, make decisions about cohorting or make decisions about returning persons into areas where there might be increased risk of transmission based on the

test results alone. And that information and an algorithm is presented on the CDC website.

Let's see, finally, in terms of some better diagnostic tests, there was a request for us to discuss that. We are working with this one company, Mesoscale, that has the diagnostic tests that can determine with a higher sensitivity and specificity in the outpatient setting about having that device in strategic locations in the U.S. so that we can use it this fall for better surveillance for influenza, but also putting it in areas where they may not have access to PCR easily like in some of the island territories or in remote areas that IHS facilities maintain.

And then finally, our Influenza Reagent Resource is available still and at this point we are continuing to provide reagents, both the PCR primers, but also the support reagents to all of the public health laboratories and to a number of other

qualified laboratories and a number of those reagents are also available from the Influenza Reagent Resource website.

And with that, I'll hand back over to you, Patty.

CHAIR QUINLISK: Okay, thank you very much, Dan.

What I'd like to do now is open it up for discussion from members of the Board. Remember, when you ask your question, would you please identify yourself and if your question is directed to a certain person just make that obvious too.

So let's go ahead and open it up for discussion.

DR. PAVIA: Hi, this is Andy Pavia. I have two questions for Dan. The first, I think I know the answer to, but it might be helpful if we knew the names of the three platforms that were cleared under 510(k).

The second question is a little more complicated and that is can you fill us

in on how you will be able to do rapid granule surveillance for resistance and get that information out in a quicker manner than last year.

DR. JERNIGAN: And again, if folks at FDA want to chime in, that would be fine, but the three are Luminex, Perdessa, and Verigene which I believe is a Nanosphere company, the last one. Those are the three that I was referring to.

The second question was about antiviral resistance, and so we have in the U.S. through the Biologics Surveillance Network which is about 95 public health laboratories, they are continuing to receive specimens from sentinel provides and that information, excuse me, those specimens are tested by target as well as with the H1N1 primer set and then those that are either specimens or viruses are sent to the CDC where we do further characterization or resistance testing both sequencing, but also functional

testing.

Right now, the sequencing capabilities that we have at CDC and a few other public health laboratories and there are some academic institutions that do the same I think, but the functional testing does not occur at very many places at all and we are one of the few that does that.

So in terms of the sequencing, we have the initiative through APHL and through the Public Health Emergency Response Grants. There was the ability for the states to apply for funding to improve their capability to do antiviral resistance testing. And so we're planning to engage with APHL and public health laboratories to increase the capability to detect new antiviruses through functional testing, but also the known sequences with genetic sequencing, power sequencing at selected sites.

We have done calculations to try to determine how many viruses we would need in

order to detect a certain percentage of change and so I have some of that information. I don't have it with me now though, but at this point we could be doing better in terms of having more places with it, but we do have a system where through sampling we think we can adequately detect when there is emerging resistance.

CHAIR QUINLISK: Dan, this is Patty. Could you about getting that information out and how fast it's going to take after identification of resistance?

DR. JERNIGAN: At this point we have a weekly report of our antiviral resistance and that information is, of course, in the FluView distributed by email and also on our website each Friday. And so if you go to the FluView site today, you can actually see what the most up to date information is there.

WHO also reports the resistance globally on their website. But at this point

if we do detect meaningful resistance that is, we're seeing this is not in an individual that was say a bone marrow transplant patient who had been taking lots of Tamiflu for a period of time, if we're seeing that there is what really looks like emerging antiviral resistance, that's something that we would put out through HAN and not wait for the weekly cycle.

We will be moving into daily reporting for certain things once influenza activity increases and so at that point we would probably be putting out the results that we have from virologic surveillance on it at least weekly and much more likely bi-weekly or even more frequently, depending on the influenza activity.

CHAIR QUINLISK: Okay, thank you, Dan.

Other questions?

DR. ROSE: This is Eric Rose.

CHAIR QUINLISK: Go ahead, Eric.

DR. ROSE: We also discussed the possibility of using antivirals for post-exposure prophylaxis, particularly in the window of time that it sounds like we may be faced with in which we're seeing not a robust supply of vaccine. Is there formal consideration of using the antiviral stockpile at least in that gap?

DR. GELLIN: Eric, this is Bruce Gellin. So two things about that. One is that CDC is in the process of revising antiviral guidelines. So I don't know the specifics of the timing, but we'll all look to that.

The second is that as we've discussed before, that would then, depending on the specific guidance and to which populations and how long that prophylaxis might be in place, it could be a serious drain on the available antivirals that we have. So I think that we all recognize that there is going to be this potential period in which

vaccine won't be available and antivirals might, but that's really the current thinking. And I don't know if Robin or others or folks from CDC want to add to that.

CAPT. FIORE: Bruce, this is Tony Fiore from Influenza Division at CDC. You're correct. We're in the process of revising our guidance. Our major emphasis will be on identifying ways that people at high risk for complications or the severely ill can get more ready access to early antiviral treatment. We see a large opportunity for improvement in how quickly people get their antivirals.

So our major emphasis has been early treatment. There is some guidance about use of antiviral prophylaxis and in certain circumstances unprotected healthcare workers that get exposure, that sort of thing. But due to what we've heard about constraints about overall supply what we are focusing largely on antiviral treatment, we'll continue to take this up in the ACIP Influenza Work

Group as time goes on. We meet again next week and we'll be talking about these things as time goes on.

I don't foresee any major, in the near future, change in the relatively limited use of prophylaxis.

DR. ROSE: This is Eric Rose again. I understand the issue of a potential drain, but has that been well modeled with different scenarios especially as we're hearing vaccines are really not going to be available and even then only partially available in mid-October.

DR. GELLIN: This is Bruce again. Let me respond and I think Robin may have some comments. And some of this, as we highlighted in the presentations from ACIP that talk about when vaccine is available and where it's going, so I think that's related as well. Because the latter, to give a sneak preview is healthcare workers are high on that list. So I think particularly for that population it's

going to be relevant. Robin may have some comments about the modeling.

DR. ROBINSON: Yes, Eric, thanks for the question. The MIDAS modeling group and several others that are in CDC and in BARDA have embarked on this for a while now, in fact, since early July. And looking at the different scenarios of different amounts of vaccine being available and then what will we do with the antivirals. So they are coming out hopefully this month with some results and will be able to inform us going forward.

CHAIR QUINLISK: Thank you. I'm going to ask a question. One of the concerns that I have is that we have the school children going back to school now and the vaccine is not available until October and obviously this is the new vaccine; the old method of producing that there's some concerns about the risk.

Has there been modeling done on risk benefits, especially if we have, say, the

peak of H1N1 occurring as early as September and maybe even going down by the time the vaccine is available? And how do we make the decisions at that point that how you use the vaccine that does become available? I know there's not an answer to it, but I wonder if they've been looking at it or there's been any modeling done on that?

DR. ROBINSON: Patty, this is Robin Robinson again. The CDC and the MIDAS groups are looking at that as one of the specific questions to come back with you and these targeted groups from ACIP and what will we do with schools and other mitigation measures more than just antivirals, that to me, affected here.

CHAIR QUINLISK: Absolutely. Are there other questions?

DR. JAMES: Dr. James. I just had a quick question for whomever has the best answer.

Where are we, especially the health

care facilities, on supply versus demand of N95s?

DR. ROBINSON: Jim, Robin Robinson again. We have members of our staff and also at CDC that are working on this and we will get you an answer back to your question. I would not want to comment other than the manufacturers are working at full capacity right now and there have been efforts in the business community to buy these products and also by the Department.

DR. JAMES: Thank you.

DR. GELLIN: Just related to that, just so you know that the IOM has been holding a workshop on personal protective equipment for healthcare workers. There's a report due out in early September. So that's essentially, I think, was the last couple of days, a report on that topic and healthcare workers.

DR. PAVIA: This is Andy Pavia. To add to that, HICPAC, the advisor to CDC on

hostile infections has recommended modification of the guidelines for personal protective equipment that if adopted would lead to a much decreased demand for N95s. IOM discussion to date is moving in the same direction so there are further discussions that have to happen, but there might be some balance between supply and demand to get things moving in the direction that the science points.

CHAIR QUINLISK: This is Patty. Maybe we could ask Leigh to keep an eye on that IOM report when it becomes available, to let us know, and forward a copy of that. I think that would be very useful for the board.

CAPT. SAWYER: I'll do that.

CHAIR QUINLISK: Thank you. Any other questions or comments on updates that we got from HHS?

Okay, I think what we'll go do is go on to getting our updates from the Advisory Committee and I believe the first one is the

Vaccines and Related Biological Products Advisory Committee which I believe is VRBPAC. And I believe Dr. Modlin is going to give us the update. Is that correct?

CAPT. SAWYER: Is Dr. Modlin on the line?

DR. BAYLOR: If not, this is Norman Baylor from the Office of Vaccines, Food and Drug Administration. If he's not on the line, I will do it.

CAPT. SAWYER: I guess he is not on the line, Norman.

DR. BAYLOR: Okay, I will give you the VRBPAC update.

We at the FDA have held its Vaccines and Related Biological Products Advisory Committee in July, July 23. And really the purpose of that meeting was to present to our Advisory Committee the pathway for licensure of the 2009 H1N1.

We've been collaborating with a number of the Government agencies, DCNIH,

BARDA, the Department and others and we presented to the Committee that our determination was that the monovalent vaccine against pandemic H1N1 2009 could be licensed as a strain-change supplement and this strain-change supplement would be to the existing BLA. This is consistent with our licensure of new seasonal vaccines every year. It's also consistent with past regulatory activities and we communicated to the Committee that this would also facilitate the availability of vaccines, if recommended. If we've -- in the past, with the supplemental H1 vaccine A-Taiwan, probably the most recent time that we used this procedure for a monovalent vaccine.

We had a number of discussion items for the Committee. We had CDC present the epidemiology of the emerging H1N1. We had an overview of the procurement process by Dr. Robinson of BARDA. CDC's presentations were presented by Dr. Fiore and Dr. Nancy Cox at CDC. And we also discussed manufacturing

considerations, where we were with preparation of the Agency. We've heard some of those updates today that preparations are on track.

We also presented our approaches and activities as far as clinical trials to support the H1N1 and as you've heard earlier today many of these clinical trials have started by the manufacturers as well as by the National Institutes of Health.

These clinical trials will be done to get an idea of the dose, the proper dose for the H1N1.

NIH also presented an overview of their clinical trials at this meeting and we lastly presented data, some data on tools that could be used as far as looking at surveillance and post-marketing safety monitoring. The manufacturers presented comments on their clinical trials as far as how they modified some of the recommendations that we gave them. And lastly, the Committee did concur, the VRBPAC Committee did concur

with our recommendations to license the 2009 H1N1 monovalent vaccine, absent a strain-change supplement and they also agreed that pregnant women should be immunized with these vaccines.

I will stop -- there were a number of other discussions at the meeting as far as the use of adjuvanted products, delivery, the use of effective delivery of situations of the delivery methods for the vaccines and what have you. So I think I'll stop there and if there are any questions, I'd be glad to take them.

CHAIR QUINLISK: Okay, do people on the Board want to hear him talk a little bit more about the adjuvant. I know that's an issue that's come up at previous meetings.

DR. BERKELMAN: Yes, we would.

CHAIR QUINLISK: Could you just go ahead, Norman, and say just a little bit more about the discussion with the adjuvant?

DR. BAYLOR: We didn't get into a

lot of detail on the adjuvants, but we did say, since the focus of this particular meeting was the pathway, but we did indicate to the Committee if adjuvants were used, since we have limited experience with the adjuvants in the United States and we don't have any of the novel adjuvants used in vaccines, most likely if adjuvants were needed. These would be used under an activated influence, the vaccines would be used under an EUA. We also, and the Committee, they concurred with that approach. They made some comments on the safety evaluations of these adjuvants. We did not present any data on the adjuvants at this particular meeting. This is probably something that we will be doing in the future, but I think it's fair to say that the Advisory Committee had no objections to the use of these adjuvants under emergency use authorization, if the need arose.

CHAIR QUINLISK: Okay, thank you. Let's go ahead and finish two updates before

we open it up for questions.

The next update is going to be on the National Vaccine Advisory Committee or NVAC and Bruce, I believe you may be doing that one.

DR. GELLIN: It's actually a two-part performance with me and Andy.

CHAIR QUINLISK: Okay. Why don't you go ahead first and Andy, just go when he's done. Go ahead.

DR. GELLIN: Gus Birkhead couldn't be with us today, otherwise he would do this as well. Just to remind you, this section is about -- so NBSB is informed of what the other federal advisory committees dealing with in vaccines, particularly what H1N1 are doing.

NVAC essentially has two large charges here. One is to look at financing issues and the second is to look at safety issues. We will take advantage of Andy's many hats since he's the chair of the Safety Program, so he'll talk about that as well, but

I briefly wanted to give you a sense of what was happening and the recommendations that came from NVAC about financing.

Remember, that the Federal Government is going to be purchasing all of the doses so this is about the administration fee primarily and maybe for the sake of time we can send around the recommendations as they were forwarded to the Assistant Secretary for Health, the NVAC reports. But again, it's all about the administration fee. And you also recognize that NVAC's recommendation, though reported to the Assistant Secretary for Health, the Assistant Secretary doesn't necessarily have the ability to act on them other than to follow their recommendation in the sense that one of the recommendations is about all public and private health insurance plans should voluntarily provide first dollar coverage.

Again, you can recognize that the ASH doesn't necessarily have the ability to

make that happen, but is in the process of outreach to these groups to notify them of the recommendations and the rationale for them.

Another, again, all related to reimbursement rates. There was one directed to CMS, again, others to different health plans. One relevant to community vaccinators to facilitate their participation and also to ensure that the Federal Government was doing what it could to support the vaccination effort for the vaccination campaigns. As you know, part of the funding that's already gone out to the states is not only for their planning, but also beginning to cover some of these fees as well.

So I think that's the broad stroke and I'm happy to get into more details, but I think that it may be better just to read these and recognize that this, like the recommendations that Andy will talk about, are works in progress and the NVAC like you, as a formal meeting via teleconference on the 24th

of August. So that will be a time when we too will be reporting back about the actions on these recommendations to date.

Andy?

DR. PAVIA: Thank you, Bruce. Let me just briefly tell you about the H1N1 safety recommendations. The group includes Gus Birkhead, as Rich already mentioned; Steve Black, vaccine safety expert; Corry Dekker, another vaccine safety expert and NVAC member; Harvey Feinberg from the Institute of Medicine; Clare Hannan, Executive Director of the Association of Immunization Managers; Marie McCormick; William Rawlins from the American Health Insurance Plans; David Sundwall, who is a state health officer representing the Association of Safety and Health Officers. I just tell you that to give you a sense of the breadth of experience and the kind of expertise we brought to the group.

There are many types of discussions we've been having on an on-going basis with

CDC, in particular, but also involving the VA, DoD, and NIH who all have a role in vaccine safety. To date, we've issued one set of recommendations which were voted on by the full NVAC on July 24th and these are on the NVAC website, but I think we can probably send these around as well. I won't read them, but let me just give you the gist of the content.

There were three recommendations. All were approved by the full NVAC and have been forwarded to the ASH and shared with the Secretary as well.

The first recommendation was really an organizational one that there is a need for developing in writing a comprehensive and detailed plan that outlines the agency-wide and the Government-wide plan for vaccine safety monitoring. As you can imagine, this is difficult because there are many people contributing vital data to this. It's not all happening within CDC or FDA and the decision making process based on this data also needed

to be thought through. And there were four specific components of this including developing timelines, involvement of other agencies, and developing a visible roadmap or organizational chart as to how this would proceed.

My understanding is that that's well underway and Bruce can comment on that.

The second recommendation had to do with the capacity of the existing systems to get rapid answers not on whether a signal was occurring, but whether or not there appeared to be causal relationship between that signal about some event that was temporally related with vaccine and the concern there was one that I think was shared by everyone involved that the existing systems were at a disadvantage because of the novel way that this vaccine is going to be administered with much of it in the public sector and the need to link data on who got what vaccine.

So the recommendation was to

strengthen the existing systems and to look toward novel systems to be able to evaluate potential vaccine risk and there are three specific bullets under there, to utilize existing mechanisms that are used for vaccine adverse events, but to enhance them or refine them as needed, to explore other existing data bases that are not yet routinely used for vaccine adverse events, but could be in the setting and to develop novel strategies for doing such things as active surveillance of specific populations. And activities are underway for all three of these according to my understanding.

The last recommendation has to do with how data will be analyzed and decisions made and this has both scientific and transparency in public trust issues because this is, in many ways, much like the situation with political trials that information that comes back in real time will be complex, confusing, and require very good scientific

review.

The Safety Working Group suggests a consideration of the development of something resembling the Data Safety and Monitoring Board that would provide a second look at vaccine safety data as it came in. Unlike the Data Safety and Monitoring Board, this Board would not be expected to stop trials, to make policy decisions, but would really provide the epidemiologic, statistical, and vaccine safety expertise to give a second expert unbiased view of the data that was coming in that could be used to corroborate or disagree with the Government's internal evaluation of data as it came in. And however, it turned out would add to the scientific validity and the general trust.

So you can read these recommendations in full, but I think I'll stop there.

CHAIR QUINLISK: Thank you both very much, Andy. And again, maybe we can ask

the staff, if you're interested, to pull those up and send them out to us.

CAPT. SAWYER: Yes, we'll do that.

CHAIR QUINLISK: Thank you, Leigh. Let's go on to the ACIP, the Advisory Committee on Immunization Practices and I believe that we'll have two speakers here also, Larry Pickering, the Executive Secretary of the ACIP and Tony Fiore, who will talk about the priority recommendation who is in the Influenza Division at CDC.

Why don't you go ahead, Larry?

DR. PICKERING: Thank you very much. An emergency meeting of the ACIP was held on July 29th. We had 14 of the 15 members attended, about 60 or 70 percent of the liaison organizations of which we had 26, all the ex officio members. And there were probably 300 or so public members that -- public people who were there and a large news media interest also.

So it ensured for a very good and

vigorous discussion of the information that was presented. And Tony will talk in a moment about the results of the recommendation.

Pre-meeting material was distributed to all ACIP members so they had background knowledge of what was going to be discussed with uniform and the meeting agenda and the slides were posted on the ACIP website two days after the meeting, and they're still on the website if anyone wants to look at those.

There were four meeting goals that were presented. One was to review the epidemiology and virology of H1N1; secondly was to use scientific data to support guidance on which groups should be focused on the initial vaccine efforts. The third one is to provide recommendations on which groups should be prioritized for vaccination first, if vaccine is produced and distributed in phases and we've heard a little bit about that from Robin. And then lastly is to provide

recommendations that would allow the overall vaccine program, both seasonal and pandemic, to be most successful. The seasonal recommendations were published by Tony and his group I think several weeks ago at MMWR.

So with that, I think I'll stop and let Tony provide information and fill us in on the recommendations of the ACIP with regard to vaccine usage.

CAPT. FIORE: Thanks, Larry. This is Tony Fiore. And thanks for requesting my very brief summary of what was a long and fruitful and complex meeting on July 29th.

Just leading up to that meeting, the Influenza Work Group which consisted of a couple of ACIP members and a number of members from the liaison organizations and some outside experts have been meeting at least, I guess about once a week and sometimes a lot more often by emails and phone and so on, to develop work group recommendations the ACIP could look at. When we were doing that we

were, of course, concerned that the recommendations be evidence based.

We also thought there should be an emphasis on local decision making because based on the experience in 2004 when there was a vaccine shortage and we ended up still throwing away vaccine at the end of the year, we didn't want to over prioritize. We didn't want to have people stepping back and waiting for their turn and having everybody step back at the same time and nobody getting the vaccine.

So the intent was to develop a quite large group, one that not only exceeded the size of the initial vaccine supply, sort of a big tent approach, to try to get the programs up and geared for running back ACIP programs aimed at large groups.

So the initial groups that were picked and ended up getting voted in by the full ACIP at that July 29th meeting, you probably have read already, but it's pregnant

women, households that have contact with children less than six months of age because those young infants can't be vaccinated themselves; healthcare and emergency medical services personnel; persons aged six months through the 24 years of age and that's based upon the highest incidence being in those age groups; and then persons aged 25 to 64 and medical conditions that confer a higher risk of complications based upon the hospitalization data showing that 70 percent of adults hospitalized had underlying medical conditions.

We were also concerned that there might be at least initially very tight supply of vaccine in some places. It's really hard to predict demand and how distribution will play out. And so we wanted to give sort of a fall-back position that had a much narrower focus group in situations where the vaccine supply was really tight. And if things go well, if lots of vaccine doses come out fairly

quickly, we may never need to use these narrow prioritization groups. But just so you know, this consists of pregnant women and household caregiver contacts of children of less than six months of age so that group stays, gets complete transfer to that smaller prioritization group.

Then the healthcare and emergency medical services personnel were narrowed down to those who just had contact with patients or infectious material. The child group was just narrowed down to children six months to four years old. And also children older than that who had medical conditions associated with higher risk of influenza complications. So that first big group is about 160 million. That smaller prioritization group is about 42 million.

The ACIP voted those in and that information will be published in the MMWR, the final set of recommendations perhaps as early as next week.

The Work Group also looked at what should we done once the programs are up and going and meeting the demand of that 160 million big group, big target group. At that point, vaccination will be recommended for all adults up through age 64 years and then as supply increase and demand is being met the next, the third stage would be adults 55 and older, and the last group would be reexamined as needed, according to new epidemiologic data or clinical trials data, immunologic data, and also the context of global needs for H1N1 vaccine. But even in the best case scenario, it certainly will be weeks to months before we get to that second, that third group of older folks.

Finally, the Work Group is also assuming that two doses are going to be needed, and didn't want people to keep in reserve a second dose once they gave dose one to a person, because the assumption is that supply will increase over time. They also

wanted to emphasize the use of seasonal vaccines as soon as it's available for all the people for whom seasonal vaccine is recommendation, including older folks.

I think that's about the gist of what the recommendations are. As I said, you'll see this published very soon and obviously, there's a communications campaign that will be going with this that Kris Sheedy outlined at the meeting, Kris from CDC. We will no doubt be revisiting this at the October ACIP meeting which sounds like it's going to occur just as vaccines start becoming available, so we'll have a chance to look these over again, if we get new epidemiologic information or there's a new supply or demand issues that we need to deal with. That's it. I'll turn it back over.

CHAIR QUINLISK: Okay, thank you very much, Tony. Again, we know that these recommendations, as you said, might be coming up pretty quickly could we ask the staff to

watch for those and when they are available to send them on to the members.

CAPT. SAWYER: Sure. We'll do that.

CHAIR QUINLISK: Let's go ahead then and open this up for discussion. Just remember to say who you are and if you have a question targeted for somebody let them know.

Let's go ahead and I'll put it up for the members of the Board.

DR. SCANNON: Yes, this is Pat Scannon. Are there any recommendations or discussions relative to the timing of seasonal vaccine versus the H1N1 vaccine?

CAPT. FIORE: This is Tony Fiore. I'll field that. There were recommendations that the two vaccines could be given simultaneously, if needed, that is the two, when they're inactivated vaccines, you're not likely -- depending on final licensure, it's not likely you would be able to get up to two LAIV vaccines at the same time.

It's our hope that a lot of people will be getting those seasonal vaccines which even now are becoming available in clinics, will be getting those early and actually will get lots of that. Seasonable vaccine campaign underway before, novel H1 vaccines show up, but at this point pending the information from the clinical trials and they are looking at this, we're assuming that the two vaccines, two inactivated vaccines could be given at the same time.

DR. SCANNON: Thank you.

CHAIR QUINLISK: This is Patty. I've got a question. I don't know if this is happening nationwide, but certainly in Iowa there seems to be a campaign with misinformation about the Government going to force people to accept the vaccine and misinformation about what the vaccine contains and things of that sort.

I don't know whether that's happened nationally, too, and I guess it

brings up the whole question about how to communicate not only what we're recommending and who to give the vaccine, but information about the way we're watching for safety issues, etcetera.

I don't know that that's particularly targeted to somebody, but maybe Andy could take a first whack at it.

DR. PAVIA: Okay, I'm not sure -- I think it's very clear that from all the discussions that have been had so far and given that this is public call that there is absolutely no intention of making vaccination mandatory for any group.

The communications efforts have been highlighted by I think everyone in the advisory groups and they're well recognized at HHS and CDC, but there's an attempt, I think, to coordinate those efforts and really get accurate information out. Beyond that, I'm not sure I have any terrific insights.

CHAIR QUINLISK: It was pretty

amazing, our Governor's office and legislators as well as handing out pamphlets at our Farmers' Markets, with all the same information, so that it appears that there's some kind of a very coordinated effort to tell people that they're going to be tied down and vaccinated.

DR. PAVIA: I've seen similar material as well and it really begins with that fiction. There are some concerns about adjuvants that again suggest that untested vaccines are going to be given to people without their consent, etcetera. I think the real danger is that this kind of misinformation has a way of spreading barley.

CHAIR QUINLISK: I saw one that said if you get this vaccine it will cause you to become homicidal and kill other people. Anyway, other questions?

DR. DRETCHEN: Ken Dretchen. When you look at the second priority group to the 25 to 64, that's a pretty wide group and it's

conceivable that people who are at the upper end of that group may actually be more akin to people who are in the third group, the 65 and older, who may only need one inoculation in order to be protected. So is there going to be data, do you think, coming out of the clinical trials that may help to elucidate if that second group may change in terms of the wide disparity of the age factor between 25 and 64 to some other higher members of that group maybe added to the third priority and may only need a single inoculation which would obviously cut down on the amount of dosages we need?

CAPT. FIORE: Yes, this is Tony. We are hoping that we will have some data available that might help us out with some of the issues about whether you really need two doses. It is quite plausible and I think there's some hope. I remember hearing some expressed in person NBSB meeting that some of the older folks might need one, but at this

point ACIP felt like it would be much easier to -- or much more from a communications point of view, easier to recommend two and if there are some subgroups that only need one, to pull back, then tell everybody -- leave people with the impression that one might be enough because at least for seasonal influenza vaccine, we know that one dose isn't really 50 percent as good as two doses for young children, for example. It really just gives you that initial priming and it's hard to show that there's any effects in the single dose in that group and that might be true of the larger population swapped with this situation.

DR. DRETCHEN: Yes, this is Ken Dretchen again. Yes, I was just thinking about the fact that even in the age bracket maybe from age 55 on, depending on potential prior exposures, we want to make sure that those numbers of 25 to 64, you know, were not written in stone.

CAPT. SAWYER: Patty, this is Leigh

Sawyer. I would like to encourage us to move on the agenda. We have over 250 people on the phone and I do not know how many public comments we'll have. So I don't want to cut the Disaster Mental Health discussion short.

CHAIR QUINLISK: That's a good point. Thank you. So I think what we'll do if people have other questions for this group we can just email them, but let's go ahead and get the Psychological Impact of H1N1. I believe Dan Dodgen is going to give us a bit of an update. He's Executive Director of the Disaster Mental Health Subcommittee.

Is that correct, Dan?

DR. DODGEN: Yes. I'm on the line and I just want to say quickly your question about risk communication, I think is particularly germane and one of our subcommittee members is actually on today, Brian Flynn. I'll introduce him in a second and he's going to talk a little bit about the psychological aspects of the way that we do

communication.

But first, I'm going to turn it over to our Disaster Mental Health Subcommittee Chair, Dr. Betty Pfefferbaum, to talk a little bit about the psychological impact of H1N1 more generally.

DR. PFEFFERBAUM: Thank you, Dan. I want to begin by thanking the Board for the opportunity to address some of the psychological issues associated with H1N1. One aspect of any planning or response to a severe outbreak of this disease or other epidemics is to address the emotional effects that this kind of emergency would have on children and families, communities and healthcare providers.

We know, for example, to expect an increase in anxiety and stress in the fall when people are exposed to more frequent information about this issue through the media and through public service messaging about the threat of flu and the healthcare precautions

that they should follow.

Parents are already concerned about their children and also worried that schools may have to close. This would create child care and financial challenges.

In the workplace, employees may become more concerned about the financial and health consequences of catching the disease while managers will have to consider the impact of employees needing time off when they're sick or to care for other people who are sick.

Thus, the illness and concern about it have the potential to affect school and workplace productivity and to raise psychological and social concerns.

In the event that the flu results in a significant increase in serious illness and death and especially if this occurs in children and younger people, stress and grief reactions will be widespread and require psychological and bereavement support.

Employees will need access to services at and through work and children and staff in schools will also require support services. If isolation and quarantine are widely used, vulnerable populations including, for example, people with substance addiction who rely on community support for recovery may be cut off from needed services and thus alternative means of providing people with opportunities to connect are an essential component of planning.

Hotlines and interactive websites are examples of strategies that could become important in delivering emotional support to these and other people in our communities. And we're particularly concerned about children who are especially vulnerable to stress and anxiety during a disaster like this. Professionals and caregivers need to prepare now to educate and reassure children and their families on how best to stay healthy and how to cope if they or friends become ill.

This is an important, actually an essential part of facilitating coping and resilience.

Dan, I'll turn the floor back to you.

DR. DODGEN: Thanks, Betty, and I think that's useful information for the Board to consider.

Let me just talk a little bit about some of the things that we've been doing here, particularly in ASPR. Obviously, there's a lot of other parts of HHS represented on the call and I don't want to represent what they're doing, but just a couple of the things that we've been up to lately that the Board may be interested in.

In May, we hosted a behavioral health symposium which is a lecture, discussion for ASPR staff on disaster mental health strategies to assist both responders and civilians with coping and remaining resilient in the base of distressing emergency

events such as natural disasters or pandemic influenza. And we were lucky enough to have Bob Ursano who many of you know because he's a member of the Disaster Mental Health Subcommittee in addition to being Director of the Study for -- the Center for the Study of Traumatic Stress, at USPHS, as the person delivering that symposium for us.

We also have done a number of other things as this outbreak has continued. We've been working with members of NDMS mental health specialty teams to develop recommendations for mental health force protection for federal responders, germ response to H1 influenza, H1N1 influenza and in particular, thinking about how such services might be delivered in a sheltering place or social distancing scenario.

We also participate in weekly multi-agency planning calls to ensure that behavioral health and at-risk populations are integrated into the Department's overall

planning and guidance strategies. And I'm not sure if Terry Spear from SAMHSA is on board or not, but SAMHSA has actually developed a number of guidance materials related to mental health and pandemic influenza and the National Child Traumatic Stress Network which is funded by SAMHSA has targeted materials designed for parents and caregivers, educators, mental health professionals, etcetera. So there have been a number of activities. I could give you more, but I think those are some highlights.

I also should say as an aside that while we've continued to work on the H1N1 scenario, my team has also been completing, compiling all the information that was gathered from across the federal family related to the NBSB's recommendations on disaster mental health. So we are continuing to work on those, apart from H1N1.

Just to let you know, too, besides the mental health and behavioral health piece of it, we've been also attending to the needs

of at-risk individuals which I think are highly related. I want to thank the Board again for working with us on our June 17th planning meeting that we held with national experts related to pediatric issues in emergency response for H1N1.

We are continuing to plan the larger meeting that will follow from that. We've been doing conference calls and outreach strategies related to migrant workers and immigrant populations and we also actually today, this very day I'm hosting another meeting, so I'm breaking away from it to be with you all on the needs of at-risk populations in H1N1 and other scenarios and we've actually got a roomful of people a couple floors above me right now, stakeholders from across the at-risk population sectors talking with us about special needs and at-risk populations in this kind of scenario and things we need to know for them.

So I've told you a little bit.

There's a lot more, but I want you to have a sense of the diversity of activities that we're undertaking. With that, I'm going to turn it over to Dr. Brian Flynn, also a member of our Disaster Mental Health Subcommittee and also with USPHS, to talk a little bit about risk communication issues that have been raised by several of the Board Members.

DR. FLYNN: Thank you, Dan. In the interest of our late agenda, I'll be very brief. I thought it might be helpful to make a couple of comments about why the Mental Health Subcommittee has an interest in communication and particularly risk communication here.

We really did take in our work and continue to take a very broad view of what constitutes disaster mental health and behavioral health. We're interested not just in what folks usually think about as almost a default setting of disaster mental health as the emotional issues, but we really feel that

there's an interconnected relationship among the psychological, emotional, cognitive, developmental and social influences that really help determine how people behave in all phases of disasters and emergencies including preparedness response and recovery and that these really do help chart whether interventions are effective or they're not.

The Committee, in its recommendations, just as a reminder, came up and we've divided our work into three major categories: intervention, education and training, and then communications and messaging. So we clearly felt that communications and messaging not only is an important part, but important enough to have its own section and have two recommendations.

The Committee really believes and stated in our report that we feel that communications is an essential part of mental and behavioral health interventions and that these kinds of communications are central

interventions in protecting all aspects of public -- of the public's health, including behavioral health.

Just as a quick reminder about what those two recommendations that came to the Board and were endorsed by the Board include, one was the development of a disaster mental health and behavioral health strategy that really talked about development of mass communication messages to deliver psycho-education and develop education and training programs regarding the integration of behavioral health and mental health and social principles and risk communication.

The second one talked about development of an internet-based tool kit.

I guess the last category of things I might mention is kind of where do these recommendations stand and what are some of our special concerns and what might be some potential priorities.

As the Board knows, you did

recommend and endorse these recommendations. Those were received and acknowledged by the Secretary in December, and now as Dan mentioned, a review and survey has been done of a lot of different agencies to see how those recommendations are and might be implemented.

It's the Committee's view or the Subcommittee's view that virtually all of our communication and messaging recommendations have some direct applicability to H1N1 issues. It's been very heartening to hear what's been going on. Certainly the report by Dr. Butler of some of the CDC activities and Dan's report are very reinforcing in this.

The Board may be familiar with the relatively recent Homeland Security publication on nuclear incident communication planning final report. While not germane to this topic, I think it does really speak to a very, very sound methodology of integrated and comprehensive communication strategy. So

there's a lot going on. I think we need to continue to make sure that whatever goes on within and among federal agencies and state agencies really assures that we have the state-of-the-art content, horizontal and vertical integration of the efforts and message content and strategies.

I think we also need to make sure that we continue to make sure that some of the general principles that were in our Subcommittee's report get reflected in our on-going activities, things like on-going, meaningful involvement of all stakeholders including vulnerable populations and the use of latest technology and communication methodologies.

With respect to some special concerns and priorities that we would like the Board to be interested in and we would welcome an opportunity to continue to contribute are things like what are some of the special communications challenges in the face of

uncertain and rapidly changing events. What's the impact of language? One of those things that we've discussed a lot is how important language is and what we call things, how we label things, has significant impact in how people understand them, the extent to which they accept our guidance and adhere to our suggestions.

In addition, the role of leadership and communications is important. As mentioned earlier, we believe that it's extremely important to have integration of messaging policy and planning with key stakeholders outside the health system, including the health system, things like schools and work places in addition to health care providers and public health authorities. And then as has been mentioned by Betty and some others, we need to make sure that we continue to address the specific communications issues for vulnerable and special needs populations.

DR. PFEFFERBAUM: Dan, this is

Betty Pfefferbaum again. I'd like to just note that the Mental Health Subcommittee has wide-ranging expertise and is willing and ready to help address these mental health issues associated with this potential disaster and of course with other disasters as well including issues related to the vulnerable populations like children and pregnant women and those with disabilities and underlying medical conditions.

To make the most effective use of our expertise, I would suggest that the Board direct us to focus on actions to protect at-risk people and vulnerable populations and actions to address the psychological impact of a more severe pandemic in schools and workplace settings where extensive morbidity and multiple deaths may occur. Thanks.

CHAIR QUINLISK: Okay, thank you very much. I appreciate you coming to our meeting today and giving us that information and suggestions. I think it's very

worthwhile. One of the things I've felt in my years in public health is communication often is the most important thing we do and to address people's concerns is just critical.

I think what I'll do in the interest of time and see if anybody has a pressing question right now, but I wanted to then go to the public comment period to make sure we give them enough time.

Does anybody have a pressing question?

DR. JAMES: It's not a question. This is Dr. James. I just wanted to recommend that we work with Dan and the Subcommittee and get some specific material to the Board to give further guidance to the Mental Health Subcommittee.

CHAIR QUINLISK: That sounds really good, Jim. And I think the other thing I'd like to do is make sure we go to Dr. Lurie and those people and see if there are specific issues that they are looking for advice on.

DR. JAMES: Absolutely.

CHAIR QUINLISK: Yes. Maybe if the Board is all right, I'll work with Leigh and the staff and we'll get back to the Disaster Mental Subcommittee on some suggestions and meanwhile people have specific issues, if you could just email myself or Leigh.

I think what we need -- if nobody has any other questions right this minute, is to give the public a few minutes to see if there's any questions there. If there's not, we can come back to our discussion on this.

CAPT. SAWYER: Yes, thank you, Patty. This is Leigh Sawyer. I'd like to ask the operator now to give the instructions for the public comment period.

OPERATOR: At this time, I would like to remind everyone in order to ask a question, please press star and then the number 1 on your telephone keypad. We'll pause for just a moment to compile the Q and A roster.

CAPT. SAWYER: Thank you. While we're doing that I would like to provide the public and the Board with just snapshots of the information that we have received in advance of the meeting as public comment.

On August 12th, the NBSB received public comments from Jim Capuccio addressing the emergency use authorization for peramivir. I am going to take one part of what he said. Mr. Capuccio stated, "I urged the members of this Committee to have peramivir made available and stockpiled to protect our families. If ever there was a time for an emergency use authorization, this is it. What possible harm could come from having a successful Phase 3 drug candidate available to protect us during a pandemic?"

We heard from Jared, a member of the public, emailed the NBSB today and asked that I quote -- or I will quote, "that the Board please discuss the options for parenteral antivirals. We now have Phase 3

data for peramivir, but would like to know more about the EUA process for this agent."

Our third public comment was received today, Moshe Sadofsky, Associate Professor of Pathology at Albert Einstein College of Medicine at Yeshiva University in New York, emailed the Board to ask the Board and I quote "address the issue of tamiflu resistance arising in influenza H1N1, a broader antiviral stockpile is needed in addition to a vaccine program."

All of these public comments will be made available to the public as part of the meeting summary.

Let's see how many we have in queue here. Operator, let's go ahead and start the questions.

OPERATOR: The first question is from Arlean Hardin with Central North Alabama Health Services.

MS. HARDIN: Yes, can you hear me?

CAPT. SAWYER: Yes.

MS. HARDIN: Okay. My question has kind of been answered in that last part, what she just finished on about the amount and the feasibility of the -- relating to the broad vaccine need.

CHAIR QUINLISK: Okay, I don't quite understand your question. Could you re-ask it?

MS. HARDIN: My question has already been answered.

CHAIR QUINLISK: I am sorry, okay.

OPERATOR: The next question is from Gabe Hoffman with Accipiter.

MR. HOFFMAN: Hi, thank you for taking the question, in two parts if you don't mind. Looking at a recent HHS report to Congress, it was a few months ago. It indicated that HHS has expended all the funds allocated for direct federal stockpile of antiviral drugs. I was just wondering if you could give a sense of what the procedures or processes would be to access additional funds.

And the second part is when HHS looks at doing EUAs for use as an agent, for example, we look at the EUA for zanamivir and we see that it's been approved for use at a later time frame. When you're thinking about IV antivirals, is it something, is it a factor that plays in your decision making whether we're talking about a different formulation of an already approved agent such as an IV zanamivir versus let's say an IV peramivir which is not currently in predation.

CHAIR QUINLISK: Is there anybody still on the phone from FDA who could maybe address that?

CAPT. SAWYER: Patty, we can get back to the questioner with a response to that. This is Leigh Sawyer.

MS. STYRT: And I think that you may also want to ask BARDA since they look at the EUAs overall and Dr. Robinson may actually want to take the first crack at responding to that.

CAPT. SAWYER: I am sorry, who was that that just spoke up?

MS. STYRT: This is Barbara Styrt from the FDA. We look at all the data that's proposed for EUAs, but as Dr. Lurie mentioned at the beginning of the meeting, this is very much a process that involves multiple different Government agencies working very closely together and so Dr. Robinson from BARDA might actually want to have some input on that question.

CAPT. SAWYER: Is Dr. Robinson on the line?

CHAIR QUINLISK: It sounds like we're just going to have to get back to the person. Sorry that we don't have an answer. Can we have the next question?

OPERATOR: Your next question is from Martin Shkreli with Elea Capital Management.

MR. SHKRELI: Thanks for taking my question. I guess it's going to have to be a

comment since Dr. Robinson is not on the call, but it's simply just having a hard time understanding the rationale for stockpiling an investigational intravenous agent or an neuraminidase inhibitor when we have 90 million oral doses stockpiled. So if anyone has an answer to that, I'd be curious, but specifically, this is for Dr. Robinson.

DR. PAVIA: If you like I can comment on that as an ID clinician and I've been involved in some of this discussion. It's Andrew Pavia.

There are patients with severe illness who end up in ICUs for whom we have difficulty administering oral drugs. That's one use for parenteral drugs. Another is the theoretical need for people with very severe illness trying to get higher doses in and then, of course, the resistance considerations. I hope that helps.

MR. SHKRELI: Thanks very much.

CHAIR QUINLISK: Okay, next

question.

OPERATOR: Your next question is from Michael Murphy with New World Investor.

MR. MURPHY: Yes. I have basically the same question and I think with Dr. Robinson not on the line it's hard to get an answer unless someone knows why it's taking so long to get through the emergency use authorization process when schools are just about to open and presumably there will be hospitalized children here within 15 or 20 days.

CHAIR QUINLISK: Again, I'm not sure we're going to be able to answer that, given that Dr. Robinson has left the line.

Leigh, let's just take that down and see if we can get some answers on it.

CAPT. SAWYER: Yes, we will do that.

CHAIR QUINLISK: Okay. Next question.

OPERATOR: The next question is

from Robert Rayl.

MR. RAYL: My question has been answered also.

CHAIR QUINLISK: Okay, thank you very much.

Next question?

OPERATION: Your next question is from William Rodriguez with the FDA.

MR. RODRIGUEZ: As a pediatrician, I have a question. We heard that the studies have started. The question is have any studies started in children, whether it's in Europe, whether it's here, whether it's at NIH? That's number one. Because I think that the most critical thing is going to be whether these kids are going to respond, particularly with unadjuvanted vaccines if we're doing them over here and whether we're going to -- when are we going to find whether we need to get a second dose, if it's adjuvanted?

CHAIR QUINLISK: Thank you.

DR. BAYLOR: This is Norman Baylor

for the FDA Office of Vaccines. Are you speaking of vaccines?

MR. RODRIGUEZ: Yes, I was talking about vaccines. That's right.

DR. BAYLOR: Those clinical trials will be starting shortly in pediatrics.

CHAIR QUINLISK: Do you have an idea of when some information will be available about the need for the second dose?

DR. BAYLOR: We won't have information until 21 days after the first dose.

CHAIR QUINLISK: Okay, thank you. Next question.

OPERATOR: Your next question is from Bob Koch.

MR. KOCH: Thank you very much for all the information. It's the first time I've listened in on this kind of conference. I just have an observation and that is that in spite of what would seem to be an obvious need, I see very little neighborhood planning

going on in communities and as to how neighbors can help neighbors if the worst case scenario should unfold. And given that the Government resources are going to be severely stretched and having their own impact and not availability, it would depend upon volunteerism, just old-fashioned helping out our neighbors and I'd like to see more activism on the part of the Government to raise awareness and to assist in neighborhood planning.

CHAIR QUINLISK: I think that's a very good comment. And I'll just say as somebody who works in a small state with a lot of rural people our county health departments have been working on some issues with churches, other groups, AARP, things like that in their communities and they're also working with the schools, particularly with the provision of meals to the children who are nutritionally challenged if the schools close. So I think some of it's being done, but I

would guess a lot of it's being done more at the local level than at the national level. I'll see if anybody else has any comments on that.

(No response.)

I do think that's important, so I appreciate your comment.

Could we have the next question?

OPERATOR: The next question is from Frederick Hayden with the University of Virginia.

MR. HAYDEN: Good afternoon. Thank you. I wanted to ask several antiviral questions, if I may. We've heard that there was a large deployment from the FNS and presumably also private sector use of also oseltamivir in response to the events over the summer.

I was wondering what lessons were learned because one of the common features of the fatal cases to date has been late presentation for care and presumably

initiation of therapy, so what have we learned in terms of the deployment side on the antivirals and treatment of individuals. And then, a second question again, back to -- timely susceptibility testing I think is going to be extremely important to make informed decisions particularly in hospitalized patients going forward.

So what are the plans to try to increase the capacity to do that in a much more rapid fashion than currently is available? Thank you.

CHAIR QUINLISK: Okay, maybe we could have somebody try to answer one of those questions? I know earlier we talked a little bit about the timing. I believe it was Dan Jernigan talking a little bit about the vaccine, excuse me, the antiviral testing.

(No response.)

I believe maybe Dan Jernigan is no longer on. Is there anyone could address either of the other questions or comments?

(No response.)

I think that we're going to have to take those comments and get back to you. Sorry about that.

Any other comments, any other questions from the public?

OPERATOR: Our next question is from Deborah Robinson with Robinson Consulting.

MS. ROBINSON: Will this meeting and the other teleconferences be archived so that the public can access them at a later time? I think it's really great that so many of the advisory committee meetings either have been web cast, those that are in person, or you could dial in as a member of the public and I just wanted to know if they're archived somewhere and where can you find them?

CAPT. SAWYER: Thank you for your interest. This is Leigh Sawyer. We do have a website. I can give you the long address or the shortest way to find it. The shortest way

is to Google NBSB and follow your lead there.

I will also give you the website. It's www.hhs.gov/aspr/omsph/nbsb. Also, the Department has a website, flu.gov, and they have -- the advisory committees are linked to that website so that it can take you to the various department, federal advisory committees providing guidance on H1N1 issues and other issues having to do with flu.

CHAIR QUINLISK: I think on that note, Leigh, we will need to wrap up because it is 2 o'clock. Is there anything else, Leigh, you need to say at this point?

CAPT. SAWYER: Patty, do you want to have a quick wrap up?

CHAIR QUINLISK: Yes, I think that today on the callers, obviously with several suggestions, particularly with the National Disaster Mental Health Subcommittee, so I would like to solicit comments or suggestions for that and Leigh and I will get back to Dr. Lurie and see if there's things that we can do

given the desire of that Subcommittee to help with some specific advice for going forward with H1N1 and groups like the children and other subgroups in our population.

We have obviously some questions that we'll need to get back on. Let me just see if there's any other comments from the Board members or any other actions that we need to take going forward?

(No response.)

Did you hear of anything else, Leigh, that you felt we needed to address before our next meeting in person?

CAPT. SAWYER: No. I wanted to just again thank the Board members and the Disaster Mental Health Subcommittee, as well as our guest speakers and those members of the public audience who participated today in the proceedings.

It's very encouraging to see interest in this area and we're all very anxious to work with the public and the

government to make a real impact on the pandemic or the H1N1 as we see it in the fall and through this next year.

I'd like to remind everyone, we have the next scheduled public meeting, that will be held as a full-day meeting on September 25th in the D.C. area and once again you can check our website for the location of that meeting and for the agenda and other documents that will be available in advance. So thank you very much, Patty. Those are my remarks.

CHAIR QUINLISK: Okay, well, thank you very much. I think you brought up some good points and I thank from my standpoint for all the people who participated, members of the Board, as well as the speakers and the public. Thank you again. I thank staff for putting together the agenda and arranging all the speakers. I'll just say that this meeting is now closed and I look forward to seeing everybody in about a month. Thank you.

OPERATOR: That concludes the conference, you may disconnect. (End- 2:03 PM)