

NATIONAL BIODEFENSE SCIENCE BOARD

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PUBLIC MEETING

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FRIDAY,

SEPTEMBER 25, 2009

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The meeting convened at 9:00 a.m.
in the Empire Room of the Omni Shoreham Hotel,
2500 Calvert Street, N.W., Washington, D.C.,
Patricia Quinlisk, M.D., Chair, presiding.

VOTING MEMBERS PRESENT:

PATRICIA QUINLISK, M.D., M.P.H., Chair
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.
JOHN D. GRABENSTEIN, R.Ph., Ph.D.
JAMES J. JAMES, M.D., Dr.PH., M.H.A.,
Brigadier General (Retired)
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):

TERRY ADIRIM, M.D., M.P.H., Associate Chief
Medical Officer for Medical Readiness,
Office of Health Affairs, U.S. Department
of Homeland Security (designated by Diane
Berry, Ph.D.)

MICHAEL AMOS, Ph.D., Scientific Advisor,
Chemical Science and Technology Laboratory,
National Institute of Standards and
Technology, U.S. Department of Commerce
(designated by Willie May, Ph.D.)

JOSEPH ANNELLI, D.V.M., Animal and Plant
Health Inspection Service (participating
via teleconference)

HUGH AUCHINCLOSS, M.D., Principal Deputy
Director, National Institute of Allergy
and Infectious Diseases, National
Institutes of Health, U.S. Department of
Health and Human Services

VICTORIA J. DAVEY, R.N., M.P.H., Deputy Chief,
Office of Public Health and Environmental
Hazards, U.S. Department of Veterans
Affairs

BRUCE GELLIN, M.D., M.P.H., Director, National
Vaccine Program Office, Office of the
Secretary, Office of Public Health and
Science, U.S. Department of Health and
Human Services

ROSEMARY HART, J.D., Special Counsel, Office
of Legal Counsel, Department of Justice

PETER JUTRO, Ph.D., Deputy Director, National
Homeland Security Research Center,
Environmental Protection Agency

CARTER MECHER, M.D., Director for Medical
Preparedness Policy, White House Homeland
Security Council (by phone)

EX OFFICIO MEMBERS PRESENT (or designee)
(Continued):

VINCENT MICHAUD, M.D., M.P.H., Director,
Medicine of Extreme Environments, Office of
the Chief Health and Medical Officer,
National Aeronautics and Space
Administration (designated by Richard
Williams, M.D.)

AUBREY MILLER, M.D., Office of
Counterterrorism and Emerging Threats,
Office of the Commissioner, Food
and Drug Administration, U.S. Department of
Health and Human Services (designated by
Boris Lushniak, M.D., M.P.H.)

BONNIE S. RICHTER, Ph.D., M.P.H., Director,
Office of Illness and Injury Prevention
Programs, Office of Health, Safety, and
Security, U.S. Department of Energy
(designated by Patricia R. Worthington,
Ph.D.)

JOHN P. SKVORAK, D.V.M., Ph.D., Commander,
U.S. Army Medical Research Institute for
Infectious Diseases

DANIEL M. SOSIN, M.D., M.P.H., F.A.C.P.,
Acting Director, Coordinating Office for
Terrorism Preparedness and Emergency
Response, Centers for Disease Control and
Prevention, U.S. Department of Health and
Human Services

DISASTER MENTAL HEALTH SUBCOMMITTEE:

DAN DODGEN, Ph.D., Executive Director
BETTY PFEFFERBAUM, M.D., J.D., Chair
ELIZABETH BOYD, Ph.D. (by phone)
LISA BROWN, Ph.D.
BRIAN FLYNN, M.A., Ed.D.
STEVAN HOBFOLL, M.A., Ph.D.
RACHEL E. KAUL, LCSW, CTS
ANN NORWOOD, M.D.
DORI REISSMAN, M.D., M.P.H.
DAVID SCHONFELD, M.D., FAAP

NBSB STAFF PRESENT:

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

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P-R-O-C-E-E-D-I-N-G-S

(9:03 a.m.)

ADMINISTRATIVE MATTERS

CALL TO ORDER AND CONFLICT OF INTEREST RULES

CAPTAIN SAWYER: I would like to welcome everyone here this morning to the National Biodefense Science Board meeting. I would like to welcome the voting members, the ex officios, and their designees, the Disaster Mental Health Subcommittee, presenters, members of the public, as well as individuals participating by phone.

I am Leigh Sawyer, the Executive Director of the National Biodefense Science Board. I also serve as the designated federal official for this Committee, this federal advisory committee.

The purpose of this public meeting is to present an opportunity for the National Biodefense Science Board to receive current H1N1 activity updates from representatives of the Department of Health and Human Services as

we build into the discussion topics that arise in the area. And we will also build into the discussion topics the areas of behavioral health.

I will begin with a roll call of the voting members. I would like to have you say "Present" if you are here. Patty Quinlisk?

CHAIR QUINLISK: Present.

CAPTAIN SAWYER: Ruth Berkelman?

MEMBER BERKELMAN: Present.

CAPTAIN SAWYER: Steve Cantrill?

MEMBER CANTRILL: Present.

CAPTAIN SAWYER: Roberta Carlin?

MEMBER CARLIN: Present.

CAPTAIN SAWYER: Al Di Rienzo?

MEMBER DI RIENZO: Present.

CAPTAIN SAWYER: Ken Dretchen?

MEMBER DRETCHEN: Present.

CAPTAIN SAWYER: John Grabenstein?

MEMBER GRABENSTEIN: Present.

CAPTAIN SAWYER: Jim James?

MEMBER JAMES: Present.

CAPTAIN SAWYER: Tom MacVittie?

(No response.)

CAPTAIN SAWYER: John Parker?

MEMBER PARKER: Present.

CAPTAIN SAWYER: Andy Pavia?

MEMBER PAVIA: Here.

CAPTAIN SAWYER: Eric Rose?

MEMBER ROSE: Present.

CAPTAIN SAWYER: Pat Scannon?

MEMBER SCANNON: Present.

CAPTAIN SAWYER: Thank you.

Now I would like to read the names
of the ex officio members. And if you are
representing an ex officio member, please
state so. Dan Fletcher?

(No response.)

CAPTAIN SAWYER: Carter Mecher?

(No response.)

CAPTAIN SAWYER: Larry Kerr?

(No response.)

CAPTAIN SAWYER: Richard Williams?

DR. MICHAUD: Vince Michaud for
Dr. Williams.

CAPTAIN SAWYER: Thank you.

Frank Scioli?

(No response.)

CAPTAIN SAWYER: Joseph Anelli?

DR. ANNELLI: Present.

CAPTAIN SAWYER: Thank you. Here
joining us by speaker phone. Thank you.

Willie May?

DR. AMOS: Present, Michael Amos
for Willie May.

CAPTAIN SAWYER: Thank you.

John Skvorak?

DR. SKVORAK: Present.

CAPTAIN SAWYER: Patty
Worthington?

DR. RICHTER: Bonnie Richter for
Pat Worthington.

CAPTAIN SAWYER: Thank you.

Hugh Auchincloss?

(No response.)

CAPTAIN SAWYER: Carol Linden?

(No response.)

CAPTAIN SAWYER: Bruce Gellin?

CAPTAIN SOSIN: Bruce is here. He
just stepped out for a moment.

CAPTAIN SAWYER: Thank you.

Boris Lushniak?

CAPTAIN MILLER: Aubrey Miller
here for Boris Lushniak.

CAPTAIN SAWYER: Thank you.

Diane Berry?

(No response.)

CAPTAIN SAWYER: Susan Haseltine?

(No response.)

CAPTAIN SAWYER: Rosemary Hart?

(No response.)

CAPTAIN SAWYER: Claudia McMurray?

(No response.)

CAPTAIN SAWYER: Victoria Davey?

MS. DAVEY: Present.

CHAIR QUINLISK: Peter Jutro?

DR. JUTRO: Present.

CAPTAIN SAWYER: Patricia

Milligan?

(No response.)

CAPTAIN SAWYER: Today we have asked our Disaster Mental Health Subcommittee to join us. And I would like to ask them to indicate their presence. Dan Dodgen is Executive Director.

DR. DODGEN: Present.

CAPTAIN SAWYER: Betty

Pfefferbaum?

DR. PFEFFERBAUM: Present.

CAPTAIN SAWYER: Jim James? I'm sorry. You're here as co-chair. Let me go to Marc Shepanek?

(No response.)

CAPTAIN SAWYER: Lisa Sayegh?

(No response.)

CAPTAIN SAWYER: Dori Reissman?

(No response.)

CAPTAIN SAWYER: Farris Tuma?

(No response.)

CAPTAIN SAWYER: Rachel Kaul?

MS. KAUL: Present.

CAPTAIN SAWYER: Terri Spear?

(No response.)

CAPTAIN SAWYER: Larry Raine?

(No response.)

CAPTAIN SAWYER: Larry Lehman?

(No response.)

CAPTAIN SAWYER: Elizabeth Boyd?

(No response.)

CAPTAIN SAWYER: Lisa Brown?

DR. BROWN: Present.

CAPTAIN SAWYER: Brian Flynn?

DR. FLYNN: Present.

CAPTAIN SAWYER: Jack Herrmann?

(No response.)

CAPTAIN SAWYER: Steve Hobfoll?

DR. HOBFOLL: Present.

CAPTAIN SAWYER: Gerard Jacobs?

(No response.)

CAPTAIN SAWYER: Russell Jones?

(No response.)

CAPTAIN SAWYER: Ann Norwood?

DR. NORWOOD: Present.

CAPTAIN SAWYER: Jose Ruzek?

(No response.)

CAPTAIN SAWYER: David Schonfeld?

DR. SCHONFELD: Present.

CAPTAIN SAWYER: Robert Ursano?

(No response.)

CAPTAIN SAWYER: Okay. Thank you.

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 at the federal government can establish or control committees or groups to obtain advisory recommendations when more than one members of the group are not federal employees.

The FACA imposes several procedural requirements on federal agencies that convene advisory committees. The majority of the work at 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 the subcommittee who, in turn, report directly to the Board.

The standards of ethical conduct for employees of the Executive Branch has been received by all Board members who, as special government employees, are subject to 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 apparent conflicts of interest that would compromise members' ability to be objective in giving advice during Board meetings.

Board members must also be attentive during the meeting to the possibility that then an issue may arise during the meeting that could affect or appear to affect their interests in a specific way.

Should this happen, the affected member will be asked to recuse himself or herself from the discussion by refraining from making comments and leaving the room.

The public will have several opportunities today to provide comments from 12:30 to 12:45, 2:45 to 3:00 o'clock, and 4:30 to 4:45.

If you are calling in, you will be given instructions by the operators as to how to signal that you have a comment. And you will be given a turn to present your comments.

If you are here in person, we would like to ask you to sign up in the sign-up sheet in the back that you would like to provide public comment.

We have not received any written comments for this meeting today.

I would like to remind everyone that this meeting is being transcribed. When you speak, please provide your name. The meeting transcription summary and any public

comments will be made available on our website.

Only four of the microphones can be used at any one time. So if you turn your mike on -- and there are already four on -- you will see a flashing light so that you will know to turn your microphone off.

Now I would like to turn this meeting over to our Chair, Patricia Quinlisk.

CHAIR'S REMARKS AND AGENDA OVERVIEW

CHAIR QUINLISK: Good morning, everyone. Thank you all for coming here today. I would like to thank the Board members for being here; our Mental Health Subcommittee; all the ex officio members; and, of course, the members of the audience and the speakers that will be speaking to us today.

If you look at the agenda, we do have a very full agenda. Obviously one of the major issues that is both facing this Board as well as the country is the H1N1.

So you'll see on our agenda that

that does take quite a substantial portion of our day to day. But, as Leigh said, at the end of the day, we will be hearing from the Disaster Mental Health Subcommittee and some of the great work that they have been doing also.

Just to remind people, this Board has been in existence for about 18 months now. And I would say that of all the committees and boards I have been on, this is the one that not only has been the most productive, but just personally it has been the most fun.

I have very much enjoyed working with all of the members of the Board and the Subcommittee, et cetera. I think that this is a great group of people. And we have been able to hopefully make some improvements and some suggestions to the Secretary that have been found to be useful.

Discussing that we do have a new administration, obviously, coming in and one of the things the Board is looking at is new

direction from Health and Human Services. And we will be having Dr. Lurie here in a few minutes to talk to us a little bit about what she sees our future being and some of the issues in which we can provide some assistance and some advice to HHS on.

Okay. While we are waiting for Dr. Lurie to arrive, we did go ahead and start some of our subcommittee meetings, and working group meetings occurred yesterday. We did have both the Pandemic Flu Working Group meeting as well as the Countermeasures meeting. Both of those have identified issues that we need to continue to meet on and to continue to address.

And there was a lot of discussion, too, about the meeting that this Board convened earlier this year on H1N1, where we brought in people from all different segments of both governmental agency advisory groups and outside of government groups to discuss issues surrounding H1N1 and its impact upon

this nation, very productive meeting, I believe.

Andy, do you want to say something about that meeting as long as we've got a minute?

MEMBER PAVIA: Well, I will comment briefly on two meetings. One was the one that occurred this July, which was the meeting on decision-making in pandemic influenza decisions.

I think what it did was it brought together people from many sectors of science from different parts of government and addressed some of the key issues that had to be considered in making decisions at the right time in the overall strategy.

And, as we heard yesterday and you will hear more this morning in terms of how vaccine development and vaccine planning has gone, I think, that some of the clarity that came out of that meeting has proved enormously useful. We have vaccine that is already

flowing, and we will have a robust supply as the month goes on.

I think that is the result both of some outstanding logistical planning and collaboration that went on directed by BARDA but also some key strategic decisions that were quite useful.

What we talked about yesterday and we will talk about morning this morning is the very, very large challenge that we as a nation face of trying to use that vaccine in a timely manner and to try to stay at least even with, if not a step ahead of, the virus.

We addressed a number of other issues which will come out today as well, including antiviral use, the availability of future antivirals, and new antivirals should resistance develop, and touched briefly on some of the major policy issues that will also come up in today's discussion.

I think I will leave it there unless there are specific questions.

CHAIR QUINLISK: And let me see if John Grabenstein wants to have a few comments about your working group meeting yesterday?

MEMBER GRABENSTEIN: Thank you, Dr. Quinlisk.

The Markets and Sustainability Workgroup has been focusing on the industrial base of the nation in terms of being able to discover, develop, and manufacture, procure, and store medical countermeasures for public health emergencies.

I believe it was August 11th we published in the Federal Register a call for comment about a document that the workgroup has been developing over the last several months.

And it is essentially an inventory of incentives and barriers to development of those countermeasures and the barriers being the frustrations that industry has confronted in terms of in several categories: financial, regulatory, legislative, and the like, and

then what had been proposed as incentives or means of overcoming those barriers.

And so there is a call for public comment on that document to turn it into a better thing so that the U.S. government, the Legislative and the Executive Branches, could address the barriers and get the nation on a better footing in that regard.

So, to anyone in the audience, I would simply repeat the call for comment. And we can provide details on the precise date and pages in the Federal Register so folks can give us back their input.

I will acknowledge my co-chair, John Parker, and see if he wanted to add anything.

CHAIR QUINLISK: Okay. Thank you very much.

I believe Dr. Nicole Lurie has joined us. And I am actually going to tell everybody a little bit more about her since this is the first time she has been with us.

Usually I give sort of a brief introduction. And I believe that most people do know Dr. Lurie, but I thought I would just go through a little bit so people know her background.

She is the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services. Prior to that, she was a senior natural scientist and a Paul O'Neill Alcoa Professor of Health Policy at the RAND Corporation. She directed RAND's public health and preparedness work as well as RAND's Center for Population Health and Health Disparities.

She has previously served in the federal government as principal Deputy Assistant Secretary of Health at HHS and in state government as a medical adviser to the Commissioner of the Minnesota Department of Health and in academia as a professor at the University of Minnesota's School of Medicine and Public Health.

She has a long history in the

health services research field, primarily in areas of access to and quality of care, managed care, mental health prevention, public health infrastructure, and preparedness and health disparities.

I think I won't go through all of the background, but I would just like to say that given the background and the issues that we are facing today, I think her background has hopefully uniquely prepared her to help us address some of these challenges.

So I would like everyone to join me in welcoming Dr. Lurie.

(Applause.)

DR. LURIE: Thanks.

OPENING REMARKS

DR. LURIE: Thanks, it's a pleasure to be here. I got to meet many members of the Board last night, which was terrific. And I just want to start by thanking all of you for your incredible efforts. You represent an amazing collection of very talented people who

give amazing amounts of time and service to our country. And, for that, I am really enormously grateful.

You know, I walked into ASPR in the middle of H1N1. I started, actually, as a consultant before I was confirmed in June. And since I have been here, I have had even more of an appreciation about for how important this group is. And I sort of feel like it's just an incredible gift to me to be able to take advantage of the talent and expertise and advice that all of you have.

You know, coming from RAND, I really very much value the sort of multidisciplinary perspective. And I sort of see it replicated here. And I think that that is terrific and very helpful.

As I think you know, the work that you have done on a lot of issues but particularly H1N1, has already really been game-changing. And, as you know through your workgroup meetings and our teleconferences, we

took your advice, particularly this advice not to wait, go ahead, fill and finish vaccine at 15 micrograms, take that risk. It turned out it took a lot longer to do that than anybody thought it would because of a whole lot of issues related to the development of the assays needed to know how much 15 micrograms actually was.

It is largely because of that and because of your urging us to very much jump the gun on this that we are going to be able to start this national vaccination effort early next month. And I think that that is really exciting.

I also have the benefit of coming to ASPR just after finishing in my other life, as we were talking about last night, doing an evaluation of another FACA committee and coming to a much more profound understanding of what the experiences of committee members are, how committees can actually help.

And I don't for a moment believe

that the issues that we identified for that FACA committee are unique there but I think probably apply to a number of the committees, at least, through HHS.

And so to start, I just want to say a couple of things about that. Again, people on all of these FACA committees -- and I have already said -- yourselves included, are people who give a huge amount of time and energy in public service. And I think in exchange for that, that we owe you a lot in terms of the way we at HHS take your advice and listen to it and behave.

And so I just want to say up front I very much want to engage with you in a robust process of collaborative agenda setting. Dr. Quinlisk and I have already talked about getting together to start a process for doing that in the future.

I also want to ask you guys to give me a head's up if you think I'm missing stuff, at least informally. And then Dr.

Quinlisk and I can decide together if the issues that you bring up to me are things that we think the Committee ought to address.

Okay?

And I think I anticipate that particularly when we are dealing with really active challenges, as we are now, that those communications will probably be pretty frequent.

I feel like I owe it to you, in return, to ask you clear questions that are focused, to convey your recommendations to the Secretary within two weeks of receiving them, and to communicate in a timely way exactly what it is that we plan to do with those recommendations. And by the time of the next public meeting, I feel like I owe it to you to come and explain to you in public exactly what was done.

I understand from our conversations that there are some things that you have actually not received feedback about

that have been lingering for a while. And so, as I commented last night, I would like to take a look at them.

I will make no commitments about how we might act in response to them, but I do want to take a look at them and think about as things have changed, what should we do with them, share with you my thoughts and reactions, and try to figure out if there are things that, even though they have been languishing, we should still take some action on. And so I will make also here publicly the commitment to do that.

Having said all of that, I wanted to take a little bit of time to lay out for you some of my kind of emerging priorities as I go forward because I think maybe that will help us all think about how to work more constructively together.

Before I do that, I just want to start with a quick story that has sort of helped me formulate more crisply some of my

own thinking. I know a couple of you have heard me talk about this before, and so I will forgive you for that.

But, you know, I think, like many other private citizens, I was very involved in the run up to the election. And on Election Day, I went to Philadelphia to help get out the vote.

I went to Philadelphia because when I had gone there four years ago, I had been in a precinct where there was so much voter intimidation that people didn't have an opportunity to vote unless they were escorted. And I felt like I needed to make sure that didn't happen again.

So I walked into a storefront in north Philadelphia. I actually went to college and medical school at Penn. So I know north Philadelphia pretty well.

And I spent my entire professional career working in inner cities, in fact, well before I became a doctor, working in inner

cities. And so I sort of know that scene pretty well.

I walked into a storefront in north Philadelphia. And it was like nothing I had ever seen before. I walked into a room, big, empty room. And there was a big table set up with lots of packets on it.

And there was somebody walking around with a name tag on that said, "In charge." And there was somebody else walking around with a name tag that said, "Operations" and another person who said, "Logistics" and another person whose name tag said, "Administration," another person whose name tag said, "Food," --

(Laughter.)

DR. LURIE: -- another person who directed me to an answer where there was just-in-time training for volunteers. And I went over to the area for just-in-time training for volunteers and joined many other people who were streaming off the streets.

Some were lawyers from New York. Some were doctors from Washington, like me. Some were just community volunteers who just wanted to come help out.

We all had our just-in-time training. We went over and picked up a packet and went in pairs out on the street to knock on doors to remind people that it was Election Day and that they should vote.

School was out that day. And there were roving bands of kids all over the street yelling, "Can I help you? Can I have your button? Can I have your" whatever?

And so I went up to some of them because I couldn't figure out how old they were. And I said, "So did you vote?"

And many of them gave me this really sheepish look and said, "I'm too young, but, you know, I took my granny to the polls" or "I took my auntie" or "my big sister. She's going to vote this afternoon." And it was kind of amazing to see these kids really

engaged.

Then I started knocking on doors.
And people opened the doors, which usually
doesn't happen when you walk up four flights
in a crummy old rundown apartment building.
And people said, "Yes, I voted."

And I would say, "Well, your
neighbor didn't answer the door. Does
somebody still live there?"

And they would say, "Well,
somebody lives here, but nobody lives up there
anymore. So you don't have to bother to go
up."

And I would say, "Well, when does
your neighbor get home?"

And they would say, "5:00
o'clock."

And I would say, "Do you think you
could take responsibility for being sure they
vote so I don't have to come back?"

"Oh, yes. I'll do that."

And as I knocked on doors

throughout the day and after my first shift, I understood that I was really safe out there by myself, including after dark, which may have been stupid, but it wasn't, I felt like all eyes had my back.

But what I got was, "You mean you have my name on a list? Somebody cares about me? Somebody knows where I live? Of course, I'll take responsibility for making sure my neighbor gets to the polls. When my husband gets home" or "my sister gets home" or "my aunt" or "uncle gets home, I'll be sure they voted."

And about 4:00 o'clock in the afternoon, I walked into a bar because I wanted to watch television and see what was going on. And the bartender gave me this really strange look.

And I tapped one guy on the shoulder who was sitting at the bar. And he pulled out my "I voted" sticker. And all the way down the line, everybody voted. Every

homeless drunk I met on the street voted.

And I called back to my colleagues at RAND. And I said, "You know, I've just been working in a pod all day, and we delivered something to every household in Philadelphia within eight hours."

That's pretty amazing because I think about that is one of our challenges in the SNS. And that is one of our challenges with countermeasure distribution. And I saw a community organized to get that done and actually much shorter than the time frame that we're given the CRI or the SNS to get it done. And I was really inspired by that.

Then I drove back that night. And on my way home, the thought that I was most left with was in public health, we say that the people that I talk to today are hard to reach. And, yet, we reached them. And they did something that they have never done before in their lives, which was that they voted. And, granted, it was just a single action

taken on a single day, but they did something they never did before.

And so the question I have been left with since is, how do we take what it is that we learned there in terms of how to organize and motivate people to take action that we take into the day-to-day work that we do in public health and that we take into the day-to-day work that we do in ASPR?

So I tell you that by way of telling you that my first priority is to really think seriously about how to build individual and community resilience. And to build community resilience, we have to really think about how we motivate and empower people to take action.

And, just as I think we have learned in public health, particularly over the last decade, come to this realization that individuals rarely act alone but they are very much shaped by the actions of their community by those around them, by the physical

environment in their community, if you look at obesity, we know that obesity is a contagious disease and that people get more obese if they are around other obese people.

And we also know that communities that have places to exercise and access to healthy food and all of those things are generally healthier and probably have something to do with reductions in obesity. I think the same thing comes for all of our work in preparedness.

So one of the questions and challenges and priorities for me is to really figure out, what does it take to build both individual and community resilience?

I don't think it's all up to the individual. I don't think it's all up to the community. But we also know that from health care, what creates health is this combination of individual and community, very much informed by a set of supportive public policies, which is one of the things that we

really need to think about in preparedness, and supported it very much by access to high-quality care. And so I think the same thing really is going to hold for the work it is that we do. This is going to involve some rebuilding, building and rebuilding, of our social fabric, obviously.

A second priority for me, not unrelated to the first, is to really think differently about this continuum from response to recovery. What it is that we do early on in response I think sets the conditions for how individuals and communities will recover. And, yet, when it gets to -- we have an organized system for response in this country. It's called SES. And we do that pretty well.

When it gets to recovery, our communities fall off a cliff. There is no organized system for recovery. There is no framework for dealing with the federal government for all the interagency and all of this stuff. And we need to really think about

that.

And we need to think about going into a response. What do we do as responders that sets the conditions for people to recover and hopefully to leave them at least as well off, if not better, than they were before the incident.

A lot of this, both individual and community resilience and recovery, means that there has to be a huge emphasis on mental health and behavioral health. And I know that your subcommittee worked very hard to identify a lot of activities and a lot of policies that very much relate to what I think you call disaster mental health.

And I think as we think about and talk about building community resilience, we really need to take to heart a number of your recommendations and probably even go further and think about what are the action steps that we need to put in place to operationalize some of those things, both for building community

resilience and for ensuring a really full and successful recovery.

A third priority for me is figuring out how it is that we leverage our health care non-system or system or whatever it is to engage them both in preparedness and response.

And I think walking in again to H1N1 in the era of trying to do health reform, it's never been clearer to me, number one, how these things are linked; and, number two, that we can't do effective public health, whether it's about preparedness and responses or whether it's about the rest of public health, without much more effectively leveraging the health care delivery system.

And so I think we need to think much more creatively about how to do it, whether it's using their data for surveillance, whether it's using them as the agents of behavior change, whether it's using the organized systems of delivery of care to

deal with reaching populations that we can't reach otherwise and really working in partnership.

Obviously for decades, medicine and public health have been on these parallel tracks, never to meet. And I believe that one of the responsibilities of my office is going to be to try to change that and model how that has changed. And so, again, we would appreciate your help and efforts in that.

I was sharing last night and I will just sort of provide a pretty up-to-date example of H1N1 in that we have enormous efforts, as you all know, going on to think about how it is that we are going to reach populations to get them vaccinated, to get them early treatment, to do all of these other things.

Well, it turns out that most of the health insurers have these really active programs for pregnant women. Whenever they recognize a pregnancy in claims data, they

call up the woman. They say, "We noticed you are pregnant," do some screening to figure out if she is at high risk, and enroll her in a high-risk pregnancy program if it's appropriate. They're all willing to call her up and say, "Noticed you're pregnant. You know, you are at high risk for getting H1N1. And we think you should get vaccinated."

They all have very active disease management programs where they manage complicated asthmatics and diabetics. They're all willing to do outreach to asthmatics and diabetics and other people with chronic disease and say, "You know, you've got a chronic disease. And we really recommend that you get vaccinated. And if you get sick, you need to get early treatment. And here is how to do it."

A number of the health plans have come together with us in a new vaccine safety monitoring system, which is linking immunization registries to their claims data

and basically functionally doubling the size of the denominator that we can monitor in a VSD-like system. It's not going to perform perfectly this time out, but it ought to provide the basis for efforts going forward.

And now almost all of the health insurers have said, "We will pay H1N1 administrative costs. We will pay pharmacists to vaccinate, regardless of whether there is a preexisting contract with a pharmacist." And over the last week, everybody has really come together to actively work out a mechanism.

Last night the AMA issued some emergency CPT codes to use for H1 administration. I want to thank Jim James for his help and leadership on the AMA side in getting that to happen.

So this weekend all the health plans are programming all of their billing systems so that the claims for H1N1 administration don't get rejected and so that

they will pay for both seasonal flu vaccine and H1 vaccine.

And so we have really worked in partnership, I think, between public health and the health care system to get a lot of that stuff done. That is the kind of leveraging the delivery system that we need to be doing day in and day out in public health, day in and day out in preparedness.

A number of them also said, really interestingly, so this whole experience has made us think about how we need to structure our policies around preparedness. Do we need to have first dollar coverage for some kinds of vaccinations?

We never thought we did before. We never thought that there was a reason for it before. We're going ahead and rethinking that, and some of our employers are going ahead and rethinking that.

When I said to them, "So if an emergency room opens up a tent in the parking

lot to triage patients, is that an alternative site of care? I mean, is that an out-of-network provider? And are you going to pay for that?" every single health plan director I've looked at has given me this unbelievable groan and said, "Oh, my God. Did we really invent this system?"

But they have also thought about, well, in an emergency, ought we to provide out-of-network coverage? And what does that look like? And how do we construct an insurance package so that there is out-of-network coverage if we have to evacuate people and they can still get care?

So there is so much opportunity here to really leverage the health care system and to work in partnership within one of the things that I really want to focus on.

Obviously something that you have all actively been talking about over the last day sort of gets me to this fourth focus area, which is thinking about the development and

delivery of countermeasures, both countermeasures for the threats that face us, countermeasures that have a profile of use that's acceptable and easy for the end user -- and I know that you talked about that yesterday -- that we have a really sustainable system for countermeasure development and that countermeasure development and acquisition has a return on investment to society that we're actually able to identify and quantify.

As I was sharing with some people last night, I actually believe that our program in BARDA is going to have a kind of return on investment that is akin to NASA in the space program. And I think we need to think about that at the front end, and I think we need to think about that at the back end. And I will very much look forward to all of your input in how to do that.

Well, how do we sort of achieve these and work on these priorities? I think we are going to have to do this in some old

ways, the old shoe leather epidemiology, going, knocking on doors, doing community building; and some new ways.

Part of the reason that all of these people were reached in Philadelphia had to do with knocking on doors and human contact. Part of it had to do with really creative use of new technologies.

I think there is a lot of new and emerging technology that can: a) link the public health and health care system much more closely together; b) think about how it is that we take care of affected populations more efficiently and remotely during an emergency; and c) help us be much better prepared.

Like there is not much of a market for countermeasures, there is not much of a market for the development of those kinds of public health IT tools and applications. And so I would look to you for some advice maybe about how to get those kinds of activities going.

Some of this is just about, as I said, basic community building and strengthening the bonds between people. And ultimately if we're successful, that kind of thing will be the norm for people to help each other, rather than the exception.

So I am looking forward to sort of sort of figuring out all of the stuff, to getting advice from you. As I lay all of this out, it is going to be rapidly very clear that we are going to have to prioritize the discrete activities that we take on in ASPR to achieve these goals.

But also, as I ask you for help in many of these areas, we are really going to have to prioritize our work together so that it's focused so that it can lead to some really actionable advice going forward.

And so I am looking forward to getting your input, to working with all of you, with Dr. Quinlisk, and others, to sort of prioritize those activities, and to work

together into the future to realize this vision for the American people.

Thank you.

(Applause.)

DR. LURIE: I am happy to take a few questions if you have them.

CHAIR QUINLISK: Let's go ahead and open it up to questions from Board members or ex officio members.

MEMBER GRABENSTEIN: John Grabenstein. Dr. Lurie, thank you very much for your comments. I've been reflecting last night and today on a phrase that has been in the newspaper a bit, "Let no crisis go to waste."

The first time I ever heard that I thought it was a bit crass a statement, but the wisdom in it I think is to use the energy in the system to climb the mountain, to get things done that haven't been done before.

And I think that is reflected in many of your comments about "We will be

attending to influenza vaccine, but let's think about all adult vaccinations." And we will be attending to various coding issues, but let's think beyond it and communication simplifications and the like.

I don't know if you have any comments along those lines.

DR. LURIE: Well, I know that Anne Schuchat is here. And she has also spent her whole life in immunization and I think has also actively been thinking about all of the things that we're doing for the H1N1 response that really inform our immunization efforts going forward but very much in that frame.

And so as I have been looking for the discrete foci of activity for dealing with responding to H1, I have been focused largely on thinking about, well, what are the systems that we have known need to be upgraded for a long time? And how do we upgrade them so that this response has a return on investment for the next 20 years?

A lot of those have to do with our surveillance systems, which are doing okay but many of which don't really leverage and harness new technologies, get us information that is as accurate, as focused as we want it to, that is as up-to-date as we want it to.

And there are now ways to achieve much greater information, much more timely and accurate information than we have now. And we are starting to use some of those things in this response, some of them in pilot form and some of them more fully to be able to achieve some of those goals.

Another example I think has been in this vaccine safety monitoring. What I think we're putting together, as I said, is about the 80 percent solution. I'm hoping it will become much more like the 98 percent solution going forward and will continuously improve and bring more partners into this as time goes on. That has involved a really active collaboration that is anchored in CDC

and NVPO but also involves the VA, DoD, private industry, et cetera.

Another example, all of the efforts that are going on to educate people about influenza, our larger efforts about educating people about vaccination, all of these payment things I just talked to you about in the benefit design issues I hope will have a much longer-lasting impact on how it is, at least that we do seasonal flu vaccine, if not for a vaccination in the long run.

I think one of the bigger challenges that we have in all of this is that we are trying to do all of this on the back of an incredibly fragile public health system. And it is a public health system that has been disinvested in for 25 or 30 years, as I think all of you know, that over the past year with the economic downturn has experienced unbelievable job loss.

So you call up people in an immunization program. And you find out

they've just been pink slipped. Some of them are still at work because they're just really committed to doing what they're doing, even though they're technically not working any more.

So, on the one hand, we're all hoping and working very actively with states and communities to help them be successful in these efforts. On the other hand, my big fear is everybody is going to say, "Oh, man. You did it with a quarter of as many people and far less resources. You don't need those resources."

And that is going to be I think a tension that we have to navigate going forward because it is very clear to me that we need to build a much more robust and sustainable public health system.

To do that, we need to come to some national agreement about what it is that public health is and does and be able to articulate that and help the taxpayer,

Congress, everybody else understand what the return on that is for the American public. That's a much longer-term challenge, but I am hoping that some of this response is going to help to build back some of that infrastructure.

It is very hard to do that, however, without sustainable funding. And, as I have come into this office and about a week after I started had to do my first budget presentation to the Secretary, I sort of looked at the funding history of my office. And it's flat and has this big blip for Katrina, and it has another big blip for Gustav and Ike. And it has another big blip for what we're dealing with now. And, in between, it's flat or sometimes even decreasing.

You can't build an infrastructure that way. And you can't be in a situation where somebody says, "Oh, we just gave you a bunch of money last year for this big

response. You don't need any this year."

Well, that was used to respond to an emergency, not to build any infrastructure.

And, just like communities need to be more resilient and people need to be more resilient and they will do better in an emergency if they are less vulnerable, our public health system is going to do better in an emergency if it is less vulnerable. And that is a long-term infrastructure-building challenge but a conversation that I think H1 gives us an opportunity to rekindle.

CHAIR QUINLISK: Are there any other questions? Andy?

MEMBER PAVIA: Again, thanks, Dr. Lurie, for your comments and your leadership and look forward to working with you.

You spoke about something that we have been thinking about probably since the inception of this Board, which is building community resiliency is one of the most important tools to defend against any sort of

disaster, be it a pandemic or a natural disaster. But I think we have all struggled with how do we do that.

That is not something that can be done from the top down, from government terribly well. It's certainly to something that can be done from one silo, be it public health or your office.

I am sure you have thought about this. And this may require too long an answer. But how do we move this forward such that you can do an activity that we are not really very skilled at? And who are the partners who need to be there?

DR. LURIE: That is a great question. It is not something that can happen from the federal government alone. It is not something that can happen from HHS alone, absolutely.

And some of it is going to have to happen by really a whole host of efforts that I think are real priorities for this

administration about sort of investment in some of the things that we will call social determinants of health or non-medical determinants, so a huge amount of energy and investment in early childhood education, in the education infrastructure in general, in the housing infrastructure, in the food infrastructure. So some of those things are happening to just generally raise the level of health and resilience of a community.

There is a huge amount of emphasis and interest now in really thinking about how it is that we harness new technologies. And I think a place where we could probably focus some of our energy and efforts is to think about how some of those new technologies can be used to reach; engage; and motivate people; and, interestingly, connect people to one another. And it's very interesting for all of us I think to watch the kind of social networking that happens over the Web and even for people who are pretty lonely and isolated.

A lot of people are starting to feel like they are part of a community that they have never been a part of before.

I don't think it is a phenomenon that we understand very well or at least those of us who sort of work in science and public health understand very well, but I think we need to understand that better. And I know that you spent some time thinking about it.

I also think we need to get much more concrete about defining what it is that we mean by community resilience and what the preparedness aspects of that are and then thinking about how would we know it when we saw it, you know. How would we measure it? How would we know if it was getting better? And I think doing that will help us probably to understand better the process of creating it.

I suspect a lot of it has to do with stuff that you have highlighted for us in the area of psychological first aid. I

suspect that a lot of it has to do with what we call people's individual preparedness plans.

But I might put it in terms of something like a goal of thinking that everybody in our society probably ought to have three people who know where they are and can go find them if something bad happened and help them out.

And everybody ought to know who they depend on for health and who depends on them and probably have a minimum -- I'll just pick a number out of the air -- of three such people, but maybe it's really five or ten. I don't really know, but the science is to inform that. And then think about how do you create that and how do you develop those things and measure them?

And I think you all -- and we are going to really need to turn to experts in this area to help us think about how to get really concrete about it in ways that are

really actionable and help us be more prepared and resilient. But I think that is some exciting work to do.

CHAIR QUINLISK: Any other questions, Board, ex officio, Mental Health Subcommittee members?

(No response.)

CAPTAIN SAWYER: Yes. That is open to the Disaster Mental Health Subcommittee members if you have a comment.

CHAIR QUINLISK: Well, seeing none, I would just like to again on behalf of myself and the Committee, to thank you very much for coming this morning. And we very much look forward to working with you. Thank you.

(Applause.)

CHAIR QUINLISK: Our next speaker is well-known to the Board. Anne Schuchat is the Director of the National Center for Immunization and Respiratory Diseases at CDC. She is going to be talking, giving us an

update on the H1N1 surveillance situation.

Thank you for being here today,
Anne.

DR. SCHUCHAT: Well, thanks,
Patty. It is a real pleasure to get to meet
with you in person. I have been on a couple
of the conference calls and, of course, really
value the work that your Committee has been
doing over the years and particularly this
year as we are facing this shared challenge
with the H1N1 virus.

It is also a privilege to follow
Dr. Lurie and think through the short-term and
long-term opportunities that we are facing
together.

H1N1 SURVEILLANCE SITUATIONAL UPDATE

DR. SCHUCHAT: I am going to now
provide you with a brief snapshot of what we
have learned and where we are with the H1N1
situation, mainly epidemiologically. And then
I will be back later as part of the vaccine
panel.

Of course, the spring outbreak did occur very late in our traditional flu season. And there was remarkable heterogeneity across the country, affecting largely younger people than we see with seasonal flu and causing widespread illness, some of which was severe or fatal. It was socially disruptive last spring with I think at one point more than half a million school children dismissed from classes.

And, of course, the public health and medical community around the world has really rallied and been deeply engaged in this, really, since April.

We have learned that certain people have a higher risk of being hospitalized or dying from the 2009 H1N1 strain.

Pregnancy is one of the more sobering features here, with six percent of the hospitalizations and deaths occurring in pregnant women, who make up just one percent

of the population.

The other factors are generally those associated with seasonal influenza that have always been recommendations for seasonal flu vaccine: asthma, chronic lung disease, diabetes, and so forth.

And in children, we have seen this very prominent role of the neuromuscular and neurocognitive conditions, not mild ADHD. These are things like cerebral palsy and muscular dystrophy, pretty severe neurologic conditions that have been, unfortunately, prominent among the deaths in children.

A very striking feature is this age difference. And you can see on the left side of the graph this age distribution of seasonal flu in terms of the more severe hospitalizations. And then on the right, you can see what we saw last spring.

The biggest difference is that green slice, which in seasonal flu is people 65 and over. And they have really been

remarkably spared to 2009 H1N1.

Then you see an expansion of the red, pink, and orange wedges, which are the children and young adults, school-aged children and young adults. And, of course, the recommendations for the H1N1 vaccine that the ACIP Committee came up with really follow this pattern here.

These data come from the state reporting. And we have done some changes recently in how state reporting is going to work. But primarily from the spring and summer, these are cumulative hospitalization rates of 2009 H1N1.

You can see that the highest rates of hospitalization are in the very young: children under five. But then the next highest is in 5 to 24-year-olds. And that is really, really different from what we see with seasonal flu.

People 65 and over, in pink, are way down at the bottom. And so this is just

one more way of saying that, I think, fortunately, seniors are being spared this while others are suffering from it.

These data again come from the surveillance from the states. I think this is something that, again, we have changed a bit how the states are reporting, but this is from the spring and summer. And you can see that the deaths really kept happening this summer.

H1N1 was less in the news, but we had continued to see lab-confirmed deaths caused by this virus without a huge variation over the summer months.

Going towards the fall, we are shifting much more to syndromic reporting and sampling of the virologic data, just because it won't be feasible, really, for the states to keep up and, as Dr. Lurie mentioned, trying to incorporate some new electronic systems and benefit from technology in things that may be ready to go pretty soon.

Traditionally and going forward,

we do track mortality. We have always used this 122 cities for P and I mortality, pneumonia and influenza mortality. And the H1N1 outbreak did not really show up on the P and I mortality graphs.

It turns out that the vast majority of this seasonal and sometimes epidemic pattern is driven by deaths in 65 and over. And when you have an epidemic or a pandemic that spares the elderly, we, fortunately, have not budged this general graph.

On the other hand, for the past several years, we have instituted reporting of influenza deaths in children as nationally notifiable.

And we began that after the 2003-4 season with those early deaths in Colorado. And, of course, it kicked in in the 2005-6 season.

And you can see in pick the 2009 H1N1 virus showing up on this graph really as

a whole second season of influenza deaths in children, really an out-of-season epi curve.

And I believe as of today, the number is up to 49 deaths in children so far confirmed to be from H1N1. And it's one of the sadder features of this pandemic that we're hoping to be able to mitigate.

Around the world, we have seen the H1N1 strain become the dominant strain in the Southern Hemisphere. And now as we get into fall and the Northern Hemisphere is back in play, interestingly, China hasn't yet seen the 2009 H1N1 dominate the strains that they are seeing, but pretty much everybody else is seeing that except for Kenya, where with basically relatively small numbers, they have definitely seen the introduction of H1N1, but they are also seeing seasonal strains.

Flipping now to what is going on today or recently, this morning on our website, CDC's website, our flu view surveillance is updated from this graph.

But you can see that in red, this season is already on the upswing. We're now at 4.6 or 4.7 percent of all outpatient visits being for influenza-like activity. That is higher than we ever got to last winter with the February, March peak. And it is approaching the level in 2007-2008 of the peak of that season.

We don't know how high this is going to go. We don't know how many peaks we will have. This, of course, is that national aggregated figure.

I want to show you a few graphs that present the regional variation that we are seeing. Breaking down regions, on top of the graph is region 4, the Southeastern states. And you can see they had this early rise that really kept on going. It is now as of this week starting to level out or even come down in some of the regions.

As of this week, nine of our ten regions are above the threshold, the national

baseline level. So certainly flu has arrived in most parts of the country. And the vast majority according to our virologic data is the 2009 H1N1 strain.

These are data from the influenza, the ILINet or the old Sentinel Provider Network. And in red, you can see dots where we are a couple of standard deviations above what you would expect for this time of year.

This map pulls out the 5 to 24-year-old age group. If you look at younger or older ages, they are not as red. And this is the reddest of all of the maps. You can see again that sort of Southeast prominence, which is changing week by week.

And, really, the key point is that influenza is unpredictable. And communities can be affected or unaffected over time. And what we have seen so far is this early increase in the southeast, probably because they began school earlier or possibly because they were relatively spared in the spring.

And it's way too soon for us to know what is going to happen for the rest of the fall and winter.

We are now monitoring with the Department of Education school dismissals. That was such a disruptive feature of the spring outbreak.

We have issued new guidance that we hope minimizes the disruption but maximizes the protection. Instead of closing schools as a first-line defense, it is really a rare circumstance that children will be dismissed from schools.

And as of last Monday, 41 schools were closed that day, affecting about 18,000 students. Most of these are very short dismissals. And often it's because they don't have enough healthy teachers to keep the classes in session. But, really, these are local decisions. But by tracking this, we can get a sense of those secondary impacts.

You have probably heard this, but

I just want to share that the government is really trying to be coordinated internally and then working outside with the private sector and using this national framework with four pillars.

I have just been sharing you the surveillance and situational awareness. Mitigation is a very important part of this. And I know you will be hearing about the antivirals later today, lots of work going on with the health care sector. You have a whole session on vaccination.

And, really, a key pillar that is sort of my 97 percent job right now is the communication pillar. And I think we have all learned from challenges, emergencies, and chronic health challenges, how important communication is.

I think, as Dr. Lurie said, there are a lot of new tools out there, but there are some old tools that are probably pretty good. And so communication will be a priority

across the government and I hope with strong partnership with the private sector.

So I don't know if there is time for questions or you want to move on to --

CHAIR QUINLISK: Why don't we go ahead and see if there are a couple of pressing questions on behalf of the Board, the Mental Health Subcommittee, or ex officio members. Again I am going to ask people to put their things up if they have questions. Jim, go ahead.

DISCUSSION

MEMBER JAMES: Dr. James, AMA. As we move along and as the vaccine starts to come on stream -- and I know how much work and thought has gone into the distribution mechanism, but when you are looking at an area like the Southeast, where peaking and probably aren't going to repeak, at least in the short term, is there any a) possibility or b) thought to being able to do vaccine redistribution so that the majority of the

vaccine goes into areas that are still at higher risk?

DR. SCHUCHAT: There are a couple of things I can say about that. Our plan going forward is the pro rata distribution of vaccine in terms of based on population for states.

You know, I think we need to be cautious about interpreting what is going on in the Southeast or, really, the general population protection.

In the Southeast, they didn't really have much disease last spring. And so whether there are more people who are already immune to this virus in some parts of the country than others is not clear.

We are doing some new things going into the fall that we hope will give us a better sense of community prevalence of influenza-like illness, not just relying on who comes to the doctor's office through the ILINet, but we are using the BRFSS system, the

Behavioral Risk Factor Surveillance System, to track weekly data about people who have had an influenza-like illness in the past month.

I think we are into our second week of doing that right now to try to understand what we are seeing over time and then as numbers build up state by state whether there are differences.

I think that, even with this first wave here in the Southeast or the first wave that some of the communities around the country had last spring, the vast majority of people are still susceptible to this virus.

We don't have a great quick serologic assay yet. So we can't tell you for sure how many people have been exposed, but the vast majority of people are still vulnerable. And we really don't know how many waves there are going to be.

So I think that there are still a lot of prevention opportunities. And our plan going forward is this pro rata distribution.

I can say, as you will hear later how the distribution is going to work, we hope that by having a central distributor have a little bit more flexibility because demand may differ in different places.

And if we have vaccine available and it is not being used some places and other places are really seeking it, we may be able to respond to that.

But for the time being, the states are allotted amounts of vaccine according to population. And they will be ordering according to that going forward.

CHAIR QUINLISK: Eric Rose?

MEMBER ROSE: Thanks for that very illuminating presentation. I get the sense that young adulthood seems to be a preexisting condition that predisposes to this illness.

In that regard, I am wondering whether or not you have done calculations, rather than mortality, calculation of life-years lost, because I suspect that would

skew this data to make it look, as it should, more severe than maybe we're giving it credit for.

DR. SCHUCHAT: Yes. I do think the age distribution is important. The issue of ultimate impact is difficult to say. We are doing some modeling. And there are a lot of other groups doing modeling to sort of understand how much illness and severe illness is occurring in different age groups.

So I would say that we don't have those kind of figures yet, but I can say that the ACIP Committee weighing in on really who ought to be first in line heavily weighted to younger people.

So healthy adults 25 to 64 are not in that first priority group. They are in the second batch. And then 65 and over folks are later on really reacting to local demand circumstances.

The issue with younger folks, you know, we do think this is a key priority to

get vaccine out to them. They're not just getting disease often, but they're probably spreading it pretty easily, too. So that is a big focus.

And it is not a group we vaccinate very well.

MEMBER ROSE: In that regard, is there a communication strategy that --

DR. SCHUCHAT: Yes, absolutely.

MEMBER ROSE: -- you are contemplating that is tailored to that?

DR. SCHUCHAT: Yes. I think we have a terrific communication team focusing on the vaccination effort. And the issue for teens and young adults, who really are not motivated by avoiding risk, their motivation is seeking risks. The issue is, how do you reach them and make them care about this?

So we're using a little bit more of the new media, the Twitter and social networking approaches, Facebook. There are some PSAs being developed trying to target

things that will appeal to that demographic.

And it's really less about fear of death or fear of hospitalization than just the stuff that you like to do that you are not going to get to do because you are laid out with several days of illness.

So I think whether that will work, I don't know, but I do know that we don't think we can reach them or motivate them in the same ways that we can reach or motivate other people.

CHAIR QUINLISK: Okay. I think there is one more question.

DR. HOBFOLL: Well, it is a question and a comment. Stevan Hobfoll from the Disaster Mental Health Subcommittee. You know, I think this data is actually underwhelming. And I think that is the problem.

We have a rather low-risk situation compared to many of the ones we might talk about, especially if we handle it

properly. That message is I think not getting across.

My guess is from that data, by bringing in all of those people to clinics, that you saved more lives by -- I know many people who personally found other illnesses that had to be treated, an early detection of cancer, for example, in a few cases, then died from this disease.

The problem actually is something that is quite preventable and, therefore, underwhelming. And that is a tricky business to get across in a communication.

I would also add that maybe in relation to what was mentioned earlier, the thing to do is inoculation plus. So every inoculation trip should include a check for something else, a check with something.

The advantage is we are bringing in lots of people who probably mentally could do a checklist for their health and be told that, hey, you really need to stop smoking,

lower your cola intake, and get some more sleep.

So I think we may be really missing a point by if we don't get that right message across.

DR. SCHUCHAT: I would like to make a comment about that that is a little bit more general than the H1N1 situation. There is I think a robust debate going on about the values and costs of integration. In the Childhood Immunization Program, one of the things we have very nice data about is that by raising preventive health visits for children for their vaccinations, we were able to increase lead screening.

We could deal with nutrition evaluations, mental health checks. As we promoted a preteen platform for vaccination, we brought in all of those other things that it is very important for providers and parents to talk about and providers and teens confidentially to talk about or preteens

before they get into the real difficult years.

I would say that in the emergency or preparedness response mode, you have to be pretty careful about what you integrate because of what you may or may not be able to achieve.

And one of our big fears right now is that the provider office health system is not going to be as reliable a place to vaccinate very large numbers of people in a short period of time, particularly older children.

We know that, even our routine seasonal flu vaccination recommendations that go into effect this year for children 5 to 18, the pediatric community let us know, you know, hey, we just can't handle this. This would triple the number of outpatient visits we see during those months. And we want to help, but we don't think we're the whole solution here. And that is where school-located vaccination has become a big topic.

So I think that as some of these affected communities have seen the challenges -- I know pediatricians in New York City had to cancel well child visits to deal with people who were ill with respiratory symptoms. You know, we have a tricky balance.

It will be fabulous if we can promote positive health messages in general as part of the outreach for this emergency, but I would be fearful of threatening the vaccination program. So it is just that balance of integration and vertical programs which we always have.

CHAIR QUINLISK: I think in the interest of the panel that we've got next, which Anne is part of, that we will go ahead and go on to our panel discussion. So I would like to ask that the panel members go ahead and come up to the front of the room: Robin Robinson, who is the Director of the Biomedical Advanced Research and Development Authority, or BARDA. We have Linda Lambert,

who is the Chief of the Respiratory Disease Branch at NIH. And Anne is back again and then Gus Birkhead, who is the Chair of the National Vaccine Advisory Committee. Could I ask all of them to please come forward?

CAPTAIN SAWYER: I might mention that you are getting very hot, new information. We have had changes in their presentations over the last 24 hours. So we're hoping we have the most recent. They have been trying to give you the most current information today.

CHAIR QUINLISK: And I believe we are starting with you, Robin. Thank you for being here.

PANEL DISCUSSION SESSION I:

HHS H1N1 VACCINE UPDATES

H1N1 VACCINES

DR. ROBINSON: Again thank you for the opportunity to come back and to update you on where we are with the H1N1 vaccine strategy that was actually implemented in early May of

this year, in which we have talked to many of you over the summer.

That vaccine strategy had three basic elements that were coordinated and integrated. And certainly it has been that way, not only the plan but actually the execution of it. And that was the vaccine development, vaccine manufacturing, and then vaccine administration.

So my colleagues here will be talking about different elements of that and the remarkable successes and challenges that we have experienced over the summer and going into this fall in the implementation of this strategy and how it actually has been informed by this group and others and that it's been a very interesting and useful collaboration and relationship with you and others.

So I think the first part of this is the vaccine development, where I think some of our most exciting news has come from. And so I want to turn it over to Linda Lambert.

And then we'll move over to the vaccine manufacturing. And then Anne will talk about the vaccine administration. And then, finally, you will hear from one of the other advisory groups of how we have been interacting with them.

DR. LAMBERT: Thank you, Robin.

It is a pleasure to be here and to be able to give the Board an update on the progress that the National Institutes have made over the last several months.

I am going to give you a quick update on our ongoing clinical trials and touch on some early results that we have, touch on the planned clinical trials that are in the works, and then end up with, as Robin alluded to already, an acknowledgment slide for the amount of effort that has gone into these.

So, as I updated this Board in June, our initial response to the H1N1 outbreak in relation to, as Robin said,

vaccine development really focused on the FDA moving forward immediately with discussions with companies on licensure; the CDC and other laboratories developing reference viruses; as Robin indicated, HHS taking the lead with industry on the development of vaccines, both for possible immunization programs and clinical trial material; the NIH through the National Institute of Allergy and Infectious Disease identifying clinical trials that the government should undertake; and then these groups meeting on a very regular basis to talk about the discussions on vaccine development and to refine study designs.

So for the clinical trials that the National Institutes of Health undertook, it was really not intended to do these trials to support licensure because of the amount of effort that was already underway between HHS and the company.

So the goal for the companies was to generate the data to support the product

from a regulatory standpoint. From the NIH's position, we were looking to help inform policy discussions and to fill gap areas.

So where we ended up with are several protocols that I'll briefly describe: a study looking at the rapid availability of immunogenicity data comparing one dose versus two doses across all age ranges; studies to look at the co-administration of seasonal influenza vaccine with the novel 2009 H1N1 vaccine; mixing vaccines and adjuvants from different companies; and, then, finally, a study in pregnant women. So these were the initial studies.

To do these, we turned to a network of contractors that we have had for many, many years. The Vaccine and Treatment Evaluation Units, these eight contracts, as well as a number of subcontracts have been established since the 1960s and certainly have taken on a tremendous amount of effort in the last several months to bring us to where we

are.

So I am going to touch very briefly. This study was the first study that we started in adults and the elderly. The age ranges were 18 and older to get 2 doses of either a Sanofi Pasteur vaccine or a CSL vaccine, 15 or 30 micrograms.

You can see there were 200 adults and 200 elderly in each of the trials. The trials both started on September 7th, and enrollment was completed on the 18th and the 21st of that month.

From a safety perspective overall, the vaccines were very well-tolerated. And recently -- I think it was September 11th -- the NIH put out a press statement with some very early, one-week post-first dose data, indicating that the vaccines at that time had generated a robust immune response so at least 96 individuals 18 years to 64 years of age had an antibody titer of 1 to 40 or greater. It was lower in those individuals in the older

age group.

And, similarly, CSL with a 15-microgram dose had an 80 percent response rate in the younger adults and a 60 percent response in those individuals 65 years of age and older.

These were very consistent findings to a paper that came out the day before by Greenberg, et al, with a CSL product. The study was conducted in Australia.

Again, this study was looking at antibody responses three weeks after vaccination. And very similar responses were seen here, which is very rapid responses in the age group. So the vaccine was safe and very immunogenic.

The second study that we started in adults and elderly is the co-administration study. That is to evaluate the safety and immunogenicity of the 2009 H1N1 vaccine given before, after, or at the same time as the H1N1

vaccine.

The immunogenicity time points are three weeks apart. The study enrolled 800 individuals stratified by age. The study also started on August 7th and completed enrollment later that month.

We do not have immunogenicity data from this group yet. We expect it in October. But we can say from a safety perspective, the vaccines are, as expected, very well-tolerated.

The trials that we started in pediatrics began about 12 to 13 days after we started the adult trials. The goal again same goals: assessment of the safety and rapid assessment of the immunogenicity data. We had an independent group who reviewed a safety assessment of all of the adult and elderly data within one week after the first dose.

We gave one dose of the Sanofi Pasteur vaccine at time zero and then 3 weeks later a second dose, either 15 or 30

micrograms.

The trial started on August 19th and completed enrollment on September 9th. Again safety profile overall well-tolerated. And just this past Monday, we issued a press statement about one week post-dose one data, again, in a subset of individuals and looked at their HAI responses by 1 to 40 or greater.

And, again, the 10 to 17-year-olds had a 76 percent response rate, the younger age group, 36 percent response rate. And the youngest age group was lower than that.

The pediatric version of the co-administration study was also started. That study, same design, again, 600 children 16 months to 17 years of age.

It started on August 20th. And enrollment completed this past Monday. And, again, we're expecting some preliminary data from that study late next month or early November.

Moving over to adjuvants, this is

what we have called the mix-and-match study. So as part of the DHHS pandemic preparedness strategy, a question that we were asking very, very early on is, can we assess the safety and immunogenicity of mixing vaccine antigens and adjuvants from different manufacturers?

And so the Sanofi Pasteur H1N1 vaccine and the CSL H1N1 vaccine were chosen for these studies. The vaccines are mixed at point of administration with 3.75, 7 and a half, or 15 with and without adjuvant. So the 3.75 group is only administered with the adjuvant. The Sanofi Pasteur study started yesterday. And the CSL study will start we hope late next month.

Moving into pregnant women, so, as you have heard, I'm sure, that there is an increased risk associated with pregnancy. The NIH identified very early on that there was a very significant interest in conducting studies in pregnant women.

We started a study with Sanofi

Pasteur's H1N1 vaccine on September 9th. And as of I think this morning, there were 58 or 59 women, who are enrolled in that study. Studies with Novartis' H1N1 vaccine as well as with CSL's are planned.

Again the study design is very similar to what I have previously described: 2 doses of the vaccine, 15 or 30 micrograms, given 21 days apart.

So planned clinical trials in other populations. So there are additional populations that we are developing protocols for. They include HIV-positive individuals, HIV-positive pregnant women and children, a study in asthmatics. And these studies, we all expect to use the Novartis H1 vaccine, again, up to 2 doses of the vaccine 21 days apart.

So, with that, I will conclude. It is very difficult to tell you how much work has gone into this, as Robin alluded to as well. Certainly throughout the U.S.

government, the Department, our colleagues, and industry have worked not just with us and with HHS for the clinical trials that I had the fortunate opportunity to tell you about but are also doing their own clinical trials and certainly all of our contractors, our VTEU units, our lead investigators I've highlighted for the clinical trials that I have talked to you about that are ongoing and certainly all the rest of our team, so our safety committees that have overseen the safety on a daily basis of these trials and our NIAID colleagues and team members for the other studies.

Thank you.

DR. ROBINSON: Thank you, Linda.

And I think we will just continue on and save the questions to the end if you don't mind.

I have just a few remarks that I want to remind you what our original goal was as we were looking at the vaccine strategy and the vaccine manufacturing is that we had the goal of being able to provide enough vaccine

for everyone in the country within six months.

Now, if you did the math early on, you would say, okay. If it's a pandemic, probably no one has much immunity. So that's two doses. There are about 300 million people in this country. So that's 600 million doses. And how do we galvanize a manufacturing consortia to be able to produce this amount?

And so what has happened is that we have good news, as Linda has pointed out. So we have had to change our strategies. The original plan was that we would have on ramps and off ramps so we could make decisions as we're going through.

And so, as you have seen through press releases over the summer starting back in May, then in August, then recently, we have bought different amounts of vaccine and adjuvants as a cautionary measure such that right now the U.S. government has bought about 250 million doses of vaccine. We have bought about 120 million doses of adjuvant. Those

are bulk form.

And, as we go through this, those are actually being fill finished as we need those to be, again because we want to have enough vaccine for everyone but also we don't want to be left in a state where we have got all of this vaccine sitting here and nobody is going to use it.

So our contracts actually have allowed us to be able to do that, but also as we have exit ramps, what will we do with the vaccine that is left over, either in bulk form or fill finished?

So one of the other things that we had projected going forward was that it would take about 20 to 23 weeks. And the Department with experts from industry and others has opined on this and honed it down if we actually had the clinical isolate in our hands and then actually have some vaccine that we can actually provide to the distribution system so it could go at it. That was the

time line.

What happened is that is about right. It has been about 21 to 24 weeks since late April, when the first clinical isolates were obtained. And then the CDC and others were able to make those virus reference strains, move them towards the manufacturers in late May.

Then the clinical investigation lots were made in early June for these clinical studies that Linda talked about and for the manufacturers.

And then the large-scale manufacturing of the vaccines was started in late June, continued into July, August, September, and is continuing onward.

At the same time one of the chief elements is to be able to tell you how much vaccine you actually have for development and creation of the potency assay reagents that are developed every year for seasonal influenza vaccine. And so we had to have

those for the SRID assay, which is our gold standard, to measure the product.

So in late May, early June, those reagents were started. It took the entire summer to get those. And we move forward. And I point this out because this is somewhat of a rate-limiting step. And it is something that I am going to address at the very end as what we will do going forward and to where we are going to focus our efforts.

So as we moved into July and August, we talked to you and the other Advisory Committees. And it became very clear to us that we should think seriously about moving forward with a dosage that would be the standard dosage and the fill finish as soon as were able to do so.

And so in August, we actually implemented those recommendations into action where we had fill finish manufacturing of the vaccine as a standard dosage, 15 micrograms for the adults and older children with the

inactivated vaccines and 107 focus-forming units for the live attenuated vaccine.

And we have moved forward with that. And, as it turns out, the clinical data supported that. And so that is very good. Had it not been, we actually then had a plan, actually, to how we were going to use adjuvant to come back with that.

And so that was one of the reasons why we actually started fill finishing some of the adjuvant, not the entire 120 million doses but about 30 million doses.

And so now we are at the precipice of now changing the spotlight from the development, then manufacturing, although the manufacturing will keep going on to vaccine administration. Anne will tell you more about that.

I bring this time line to you because there are places in which we can and we cannot change things in our present technologies.

We actually faced a number of challenges and surprises. Some of them were technological and had to do with manufacturing, but some of them had to do with very pragmatic bureaucratic things. And I just wanted to apprise you of some of those as we have gone through this.

First is there was the gold rush for obtaining vaccine back in May. So we got in there, and we fought with everybody else around the world supporting the U.S. efforts but also recognizing our global collaborations and responsibilities.

Part of that, though, was that we had contracts in place that would allow us to do. There were at least three of the manufacturers. And all we had to do was a strain change, just like the manufacturers had to do for the licensure of the product.

That helped us immensely because we could move forward. And we had a leveraged position with the manufacturers for a place in

line.

The other manufacturers, we were able to have those contracts because there were the other ones. We put those in place very quickly in May, and we actually executed those task orders off of that. So that was one of the things.

The second thing is that we had to obtain funding for this. And I point this out that the Department gave up all of its pandemic supplemental money that we had left for the H5N1 efforts and pre-pandemic planning. And so we all agreed it needs to go forward.

We have an effort here. And so then we had to convince Congress that we needed money. And Congress was gracious enough to provide that. And we have availed ourselves of that.

Because of the efforts and the fact that we will not need as much vaccine as the 600 million doses, then our tab for the

vaccine portion, at least the vaccine product, will be less than was anticipated. And that is good because we have other uses for that, as Anne will talk about.

The next one is a very big issue for us because it's not only the H1N1 pandemic that we are looking at but also how we balance this with seasonal influenza vaccination and going forward for this 2009-10 seasonal flu season.

And so our principle has always been that we would not interfere with seasonal influenza vaccine manufacturing. I can tell you today that we did not. Did we have ideas? And did we have discussions about it? Yes, we did.

We have to say that one of the issues that came up was that not all of the manufacturers were having success at being able to produce the seasonal influenza vaccine. They finally were able to, but it took for some of the manufacturers longer.

That had an impact on our H1N1 vaccine supply. But we worked through it.

And so I can safely say that the seasonal influenza vaccine manufacturing and the H1N1 vaccine manufacturing have been balanced such that both are moving along seamlessly but not without some challenges and struggles going forward.

The next issue is that we needed to report to our advisory committees, such as you, and to listen to what you had to say and then to take those recommendations and see if they were feasible and see if we could implement them.

And for many of the things that you and others have said, we have been able to do that but not everything. I think it has been a process in which we have benefitted. And it has shown that it does work and will be something that we can use going forward, not only for influenza or H1N1 but for other types of issues that we have coming forward.

The issue of the potency assays, the manufacturers had to determine how much vaccine they had, not in September or August. They had to do it in June.

Because they had clinical investigation licenses, they had to send out for the clinical studies that the NIH was going to do or they were going to do themselves.

So the FDA made a decision. There was quite a bit of data to show that the HPLC or alternative methods of determining the antigen concentration could be used. They were. And for the most part, they worked. And at the same time, the SRID reagents for that assay were moving along in production.

So, as we have seen, that was a good decision to move forward with. And so we kept our fingers crossed, but ultimately it was shown when the potency assays were done on the investigational lots with the commercial-scale lots, that there was a

reasonable amount of comparability there.

The other thing that we realized going into this before was that we needed not only the bulk manufacturers, the standard seasonal influenza vaccine manufacturers, to play a part but also fill finish manufacturers.

And this was part of this overall scheme that we talked about of having building infrastructure, building manufacturing and infrastructure in this country to be able to respond to this natural need year in and year out but also for preparedness needs.

And so we had to enlist fill finish manufacturers and do this marriage between the vaccine manufacturers and the fill finish manufacturers in order to open up the gates so that every amount of antigen we had as bulk could actually be moved into fill finish and to sprayers, vials, and syringes as soon as possible when these reagents were available to do so. And we have done that.

Fortunately, we had enough foresight and had plans in place that we can do this, but, as any business occurs, there were certainly struggles with actually making those marriages come together and then actually start working.

For the most part, we can say those are working and that we will have vaccine available using all the outlets we have. And so one of the issues is, can you have vaccine of this type or this type?

What we've done is had vaccine of everything we could have available made as soon as possible. And that is the principle that we have worked on.

One of the other things that you've heard quite a lot over the summer is about, "Oh, the virus doesn't grow well." The virus grows very well. The problem has been that for some vaccine manufacturers, their ability to purify that virus and then to make it into subunit vaccine has been a challenge

for them.

And so as we have gone through, we have had new strains of the vaccine, virus reference strains, come about. We have actually had improvements in the vaccine manufacturing without going outside of the license product manufacturing process.

And so that what we are seeing is that we are seeing that the yields of the vaccine are approaching what they see normally for H1N1 seasonal influenza.

But that has been a struggle all summer. And guess what? That is nothing new. That is what happens every year with seasonal influenza. They fight with each of the three strains for the different valences and move forward with it. We just don't ever hear about it.

The next issue is the logistics of actually bringing all of this together and then interfacing with our partners at CDC with their McKesson contract to move in this

distribution from the manufacturers to the distribution.

I can tell you I was out in the field last week. It is happening. Are there issues? None of them major at this point. I cross my fingers on that. But it is a distribution system and it is a manufacturing. And we should expect there are going to be bumps in the road. And so one day we have this much and then maybe a lot that has to go into quarantine, for whatever reason. But it will eventually. As we go through this, we will work through these things.

And the last thing is that I'll point out the challenges that we wanted to make the vaccine when it arrived at a provider's to be ready to use. And so in order to do that, you have to have syringes and needles and other ancillary supplies there. And so the Department took the principle of providing these together.

And so in order to do the

logistics of that, we're providing that as a challenge, but we have set into place where that can actually happen so that when it does get there, there are your syringes and needles. The vaccine is there. You pull it out of the refrigerator. You're ready to go.

Now, in closing, I have four things that I want to leave you with. One is that we really have to work really very diligently going forward as to how we can improve the potency assays and the reagents for them. And can we have vaccine sooner than we have had presently?

They're tied together. If we can have potency assays that are different and they can have those reagents available, then we can have vaccines sooner, regardless if it's egg-based, cell-based, or whatever. But we are supporting at the Department new types of vaccines, both at NIH and BARDA, with new technologies, recombinant vaccines.

Secondly is that we are about to

enter something that will be next week that will wake everyone up again. The seasonal influenza is coming. H1N1 has never left. It's still here. And we have vaccine programs that are going on. But next week the strain selection for the Southern Hemisphere for next year's vaccine is about to happen. And that should wake us up that we have vaccine manufacturing campaigns that are going to start this fall and then for the Northern Hemisphere in January.

So, again, we have just finished balancing the previous seasonal influenza vaccine manufacturing campaign with H1N1. And now we have to go forward with these.

So it will be a tightrope. And I am sure we can balance it. But it will be a challenge as we go forward. And we will have to see if there are other ways in which we can manage this as we learn from this pandemic.

And, lastly, what is our contribution, as the President said last week,

for being a leader in helping the entire world?

And so there will be efforts by the U.S. in not only vaccine donation but also helping other countries learn how to make influenza vaccine, both from CDC, NIH, and at BARDA's efforts.

So, with that, I will, then, turn it over to Anne. Thank you.

DR. SCHUCHAT: Okay. Well, hello again. I think Robin began this panel with a concept of coordination. And looking at my co-panelists and the institutions that they represent, I have to say I feel over the past few months I have been spending more time or talking more with them than with my husband. So I am really looking forward to the post-pandemic era.

(Laughter.)

DR. SCHUCHAT: So I am going to give you a sense of how the vaccination implementation effort works. And I have to

say that it is always humbling to listen to the NIH report because everything is working perfectly in terms of the clinical trials and the clean results and the great news. And, yet, we have to figure out how to actually administer these apparently very good vaccines to an awful lot of people in a very short period of time when we have disease already increasing.

July 29th the Advisory Committee for Immunization Practices on an emergent basis. This was Web-streamed all over the place. And it's archived on our website.

And their deliberation resulted in the following five groups being prioritized for vaccination initially: health care and emergency medical services personnel, pregnant women, people who live with or care for infants under six months, children and young adults up to the age of 24 years, and adults 25 to 64 with chronic medical conditions. This is 159 million people, more than half of

the U.S. population.

The ACIP learned from the lessons of the 2004-5 year, where we lost half the flu vaccine supply October 4th or 5th. They didn't want to over-prioritize. They were concerned that that year we told so many people to step aside that we actually had vaccine left at the end of the season.

They suggested these initial groups, but the local decision-making could quickly respond to demand. And if these groups were covered, pretty much turn on the tap for adults, healthy adults, and then for seniors relatively quickly.

I want to show you a little bit about how our vaccination distribution and administration effort will work. We are using a centralized distribution contractor. This is a contractor that we have been using for the childhood program, both the vaccine for children and section 317 program, and over the past several years had transitioned a public

health immunization program from depots in every state to a central distribution system.

It has been I think a very successful transition and has left us no longer so vulnerable with vaccine expiring in one state that needs to be shipped to some other state that can use it. When there is a power outage in one state's depot and we lose all of that vaccine, it's not insured.

We have a lot of safeguards in our centralized distribution system, but this is a big increase in how we use this centralized distribution. And it is in a short period of time that we have been implementing it.

So the vaccine and multiple formulations of vaccine will be coming from the five manufacturers that Robin spoke about, and then ancillary supplies will be coming from up to four manufacturers through that central distribution mechanism.

The state or large city public health agencies are placing orders. They are

enrolling providers throughout their jurisdictions, either pharmacies or doctors' offices or big box stores or school-located venues or local health departments, occupational health plans, hospitals.

You know, many, many different types of providers are enrolled by the state health agencies. And then, as orders get placed by the state into the system electronically transmitted to CDC and the contractor, the state is permitted, then, to sort of prioritize where will these initial allotments of vaccine go.

You know, if it's not a whole lot or it's certain kind of formulations, how do we roll the program out in our jurisdictions. The contractor ships the vaccine not to the state health department depot but directly to those provider sites. And our contract allows up to 90,000 sites that can be shipped to.

The vaccine for children program is really the basis of this. And that has

45,000 providers enrolled, a mix of public and private providers, that give out VFC vaccines.

These vaccine record cards with the lot numbers are going to be provided by CDC and included in that ancillary supply kit so that we'll be better able to track vaccine and that people will understand how to report adverse events and that kind of thing.

A vaccine information statement, actually, a draft one is on the website right now. It's being minorly tweaked since the vaccines are now licensed, but it's already buried someplace on our website. And it will become more visible shortly.

We are testing the distribution system with just a limited quantity of vaccine. The issue here is actually testing more the ordering system than the actual shipping part of it.

The provider enrollment is going pretty well in states. Many states are done with this. We provided a model provider

agreement out that includes the federal requirements of this, you know, you can't resell this vaccine, you will follow standard storage and handling procedures, the basics of being in because this is free vaccine.

But we're allowing the states to add requirements according to their own needs or preferences as long as it's not contradicting the federal necessities.

We have been working on this administration reimbursement issue. As Nicki said, we have had very good response from insurers. We do expect third party billing to be going on and the third party billers will reimburse or they may waive the administration fee altogether.

But a key concept is that no one should not get this vaccine because of financial barriers and not to slow down the mass clinics where they occur, where we know sometimes billing and charging and such can be turnoffs or slow things down.

And then we have worked on a lot of materials and guidance to help with implementation planning. In particular, I want to talk a little bit about the school-located venues. You know, why should we even think about these?

We do know that health care providers in some affected communities have already been relatively challenged with the sick visits. And we also know that the health system isn't so great for older kids and teens and so forth in terms of they don't have regular visits. They don't tend to -- you know, the system may not be able to expand to cover them. So in some places, anyway, a school-located program could address large populations relatively efficiently.

If they're done during school hours, it may be convenient for parents, school nurses where they still exist. And teachers may be able to help or at least we do know there is a huge amount of interest in the

education community in hosting these. And we know that public health is actively connecting with the school systems in many states.

When they are conducted during off hours, they could also permit a chance for others to come in, younger siblings, the larger community. Of course, we use schools as polling places. They're often a good place for gathering the community, well-recognized and trusted.

And, as I said before, the state and locals are really driving this and will be making decisions about whether they will offer some, many, or no school-located venues. I think the majority of states are planning these right now.

So at the national level, of course, there are some things that we do. Most of this is going to be a state and local-run program. And we're committed to be supportive through both financial resources and with technical assistance.

There are some responsibilities that we really have for the national monitoring, tracking, troubleshooting, and communication around what is going on.

We have some systems for understanding how many people have gotten vaccine. Our central distributor permits us to know on a daily basis how many doses have been shipped. So that is daily information we will be getting.

We have asked the states early in the system, really, the first 30 million doses worth, to be using something called the Countermeasures Response Administration reporting, where we will get weekly aggregate numbers of doses administered.

This will probably be incomplete. We suspect it to be very complete from the public venues and less complete or less timely from the private providers, but it will give us a sense of a minimum number of those ship-to doses that have already been

administered.

And that kind of information can be very important for interpreting how well the program is being taken up and also how to interpret any safety signals we see. It will serve as one form of denominator for how many doses have actually gone into people.

Actually, beginning in October, we have a national immunization survey module that will be on a weekly basis tracking immunization with the seasonal influenza as well as the H1N1 influenza.

And that will give us a national snapshot of where we are over time. And then the Behavioral Risk Factors Surveillance System will start to report state-specific data.

So these are both important ways to monitor the program and to also address the safety, to be incorporated into the safety, analyses.

We have several systems that we

will be using for evaluating vaccine effectiveness. And I think here we do benefit from our pre-pandemic efforts. We have been strengthening our ability to do in-season estimates of vaccine effectiveness against flu.

And these require a lot of logistics and also more lab testing than would routinely occur in regular care because, of course, efficacy is going to vary by strain. And not everything that syndromically looks like flu; in fact, much of what syndromically looks like flu, is not influenza, let alone a particular serotype.

So this year these vaccine effectiveness sites have been enhanced to continue year-round and to be strengthened so that they will be able to separately look at exposures to seasonal flu vaccine and the H1N1 flu vaccine and to enhance the lab testing. So we will be able to differentiate those.

We have what we affectionately

call the MMRV sites. Marshfield, Wisconsin; Michigan; Rochester, New York; and Vanderbilt in Tennessee are part of a multi-state common protocol laboratory-confirmed vaccine efficacy evaluation.

Then we are also using our emerging infection program network influenza sites to look at vaccine efficacy against hospitalization for influenza, including the H1N1. And we have been enhancing those facilities to have better laboratory characterization of the flu cases.

Okay. So I think on this slide, I don't actually go into the safety monitoring because I think I didn't update this and wasn't aware if you were going to get a safety presentation or not in this session.

I am happy to talk a lot about our plans for safety. I realize it is an omission. The other thing that we are doing, lots of safety work across the Department as well as with some new systems that Dr. Lurie

was talking about and then, additionally, a lot of national and state communication efforts, both to reach targeted populations, to reach provider groups, to reach trusted intermediaries, who can help communicate with the general public, and then several segments of the public; also a lot of outreach to the media.

We know that a vaccination program like this is large and perhaps unprecedented in recent decades in the U.S. and has lots of room for misunderstandings. And we have been trying to do substantial outreach to familiarize the media with what to expect, both with the disease and with the program.

Yesterday the Secretary spent several hours with three different groups of reporters in her second update to them about what is going on and what to expect looking forward. I was able to assist her in that.

And we have had a big workshop with the media in Atlanta for two days and a

tabletop with media here in D.C. And then we are having another tabletop with media next week in New York City, really trying to help enroll them as partners in this big program and allies and at least have them understand the basics because it can be a complex story to report.

So I think, with that, I will just stop and let us go to the last presentation.

DR. ROBINSON: Thank you, Anne.

Gus Birkhead, the Chairman of the NVAC, will now --

DR. BIRKHEAD: Thanks very much, Robin.

I think before I give the update on the National Vaccine Advisory Committee activities, I just wanted to respond a little bit from a state perspective to some of the comments that Dr. Schuchat was making.

In New York, we have two vaccine distribution areas. The New York City will be distributing its vaccine within the city.

And we at the State Health Department are distributing to the rest of the state.

Like many states, we have put up a preregistration process on our website and in 2 weeks had 2,400 preregistered. This includes a whole range of providers, from hospitals, federally qualified health centers, physician offices, pharmacies, local health departments. And our intention is to try and get vaccine to as many different kinds of venues as we are able to.

We are in the process of taking the CDC provider agreement. The only change to that in upstate New York will be the requirement that pediatric doses be reported to our statewide immunization registry, which is a requirement of our public health law for any vaccines for children.

Our hope, then, by next week and I am not sure if Anne mentioned but the first orders are anticipated to be opened up and received at CDC on the 30th, next Wednesday.

Our plan is to place orders for all of the hospitals, community health centers, and local health departments in upstate New York and push basically on an allocation system, push vaccine to all of those settings. So we are in the process of getting them on board. They need to sign on and validate the provider agreement form.

We are still waiting to know exactly how many doses we will be able to administer in which formulations but are anticipating FluMist as being the initial one.

I think many states are in the sort of position of being able to place orders starting next Wednesday. And I think our hope is not to be a barrier in getting vaccine out but to, as I say, push our entire allotment that is available out as quickly as we can while we are still in the process of further enrolling.

I will mention that we are allocated in the New York state outside of New

York City 3,700 direct ship-to sites from the federal warehouse. We are anticipating that we will probably exceed that number.

And so we are also making plans for our state depot and possibly county health department depots to distribute particularly to the smaller providers, who may not be able to handle a shipment, the minimum shipment, from the federal warehouse of 100 doses.

So that is a little bit of perspective. The activity out there, as Patty and others state and local representatives know, is we are furious at this point to get the vaccine out and not to have additional barriers to getting it in the hands of providers, who can start to administer it.

So, with that by way of a comment, I will update you on the activities of the National Vaccine Advisory Committee. NVAC is one of a number of committees, as you have heard, that are dealing with H1N1.

And NVAC is primarily focusing on

review of the implementation and giving recommendations. Our recommendations flow through the Assistant Secretary for Health at HHS on implementation issues.

To do this, we had a regularly scheduled in-person meeting in June, where we took up quite a bit of the agenda. And then over the summer, we held two public teleconferences, public meetings of NVAC by telephone, where we had presentations from Robin and Anne and others. So Anne is right. This is like the traveling road show all summer long and I guess still going on.

We focused particularly in the implementation on finance issues. And I will share with you a set of finance recommendations that we have come up with.

We also see it as NVAC's role to focus on getting stakeholder input. And so we have had a panel on each of our meetings from state and local health departments as well as the immunization managers to get that kind of

input as well as public comment.

We also, on NVAC, being the National Vaccine Advisory Committee, are trying to help with some of the coordination between all of the advisory committees. And so we have had presentations at each of our meetings from ACIP, VRPAC, and VSD, to name the main committees, and my role coming here today, really, to just share what the different committees are doing in the mode of coordination.

Vaccine safety is another key issue that NVAC has focused on, particularly the post-marketing vaccine safety. NVAC has just completed a year and a half process of commenting on CDC's Immunization Safety Office scientific agenda. And we are now embarking, with Andy Pavia on this Committee, as co-chair on a broader look at the vaccine safety activities around all vaccines.

And so this actually came, H1N1 came, at a time when we had a standing safety

committee. And so we were able to incorporate this with a few additional members into a smaller sub-working group and came up with some recommendations there.

And, finally, we have focused on communication efforts from the federal government, what is the communication plan with the public and with providers.

So I will very quickly share with you some of the recommendations from this group. I didn't mention that we just met a week or so ago for our September meeting and did have further discussion and discussion particularly of the vaccine safety monitoring plan.

And I will mention, didn't mention it yet, NVAC and the National Vaccine Program Office have undertaken the public engagement process around vaccines. Roger Bernier, CDC, particularly led that effort. And so we had an update on that as well.

So just quickly to cut to the

chase with the recommendations, in the area of safety, at our July meeting, we developed a series of recommendations to go to the Assistant Secretary for Health.

A primary recommendation was that there be the development of a clear federal plan, sort of write it all down. There has been a lot of discussion, but let's put it into the context of a clear plan for monitoring safety for the 2009 H1N1 influenza vaccine.

We also urge that there be development of methods to link vaccine exposure information to adverse event outcome information on as large a population level as possible.

I think this recommendation the National Vaccine Program Office has moved on. And Dr. Lurie mentioned the effort to enroll a number of major health insurance plans around the country to link with state immunization registries to try and enlarge the

population that could undergo VSD, Vaccine Safety Datalink, types of studies. And that is a very active area with a number of states beginning to participate. So that recommendation has definitely had legs.

We also recommended that there be the formation of an independent vaccine safety assessment committee to sort of oversee data on any signals that might arise to help advise the Assistant Secretary for Health and ASPR on sort of an independent view of whatever data might be coming through.

I think this recommendation is still being looked at, but this flows from I think a broader theme in our discussions of vaccine safety that it would be helpful to the vaccine safety enterprise to have some independent body overseeing or at least commenting on the conduct of vaccine safety science.

We have had a number of recommendations in the finance area, which I

mentioned. And there are some listed on this slide. Back at our July meeting, we recommended that the first dollar coverage for administration of vaccine, H1N1 vaccine, be the standard in both private and public health insurance program; that reimbursement rates for administration be adequate, in line with what Medicare would reimburse for, vaccine administration; and the issue that Dr. Lurie mentioned, that we have many community vaccinators and people in insurance plans, if their provider is not providing vaccine may need to go to a different location and how do you have insurance cover that if it is still in a private sector location; and, finally, the overall need back in July for funding to states for administration.

And so on a number of these, I think there has been a lot of progress. As Dr. Lurie mentioned, many insurers and, in fact, I think the America's Health Insurance Plans, the national trade organization, have

recommended that their members adopt and cover H1N1 vaccine administration.

And, in addition, there has been significant funding coming to the state health departments in phase one and two for planning and phase three for implementation of large-scale public vaccination programs. And so that has really enabled us and will enable us as the final, a large chunk of implementation funding gets to the states in the next few weeks to really begin to mount wide-scale efforts.

So, again, these recommendations I think have been very successful and I hope influential in trying to move the agenda along.

At our August meeting, we had some additional recommendations around vaccine safety. That is specifically to assemble the information on background rates in the general population of anticipated adverse events following immunization so that we have some

kind of an idea if we see a certain rate of miscarriage or heart attack or other complication, Guillain-Barre syndrome, that we have at hand some idea of what is expected in the population as a background. And I think that there is some effort going on around that, although that turns out to be more difficult sometimes than it sounds.

The second safety recommendation was a recommendation that there be organized drill or practice exercise for the federal government to work through how they would respond if a signal is detected around a vaccine and what the roles of the various parts of the federal government would be in assessing that and making a decision and then moving forward.

I believe there has actually been an exercise that has been conducted or is planned at CDC directly on this point. And I think that is great because this will be a complicated process of multiple federal

agencies interacting. And I think to get as much working out of the issues across jurisdiction and expertise will be very important.

And, then, finally, at the August meeting, we had a presentation on the communication plans. And again, similar to the safety arena, I think NVAC recommended that there be developed a clear and detailed federal plan to coordinate communications regarding H1N1, the pandemic as well as the vaccination, particularly the vaccination, campaign.

So to lay out what the roles of the various federal agencies would be and what the expectations will be for state and local health departments and professional organizations and others in communicating with providers as well as communicating with the general public.

So NVAC will continue through the fall. We don't have another scheduled meeting

until early next year. And I think we are looking at doing another telephone public meeting probably at the end of October or early November. And so there will be an announcement about that.

But we want to try and keep our sort of pulse, finger on the pulse, of what is going on with implementation, try to convene the stakeholders, as we have been doing, and hopefully provide some added value to the overall vaccine effort.

Thank you very much.

CHAIR QUINLISK: It is pretty obvious, I think, that the four of you have done an amazing amount of work and not just you but your staff members, your advisory committees, your collaborators, et cetera.

And I just would like to thank all of you for all of your efforts being done in the last several months and obviously into the future. It has served this country well all the work that you have done to get prepared

for this challenge.

I would like to now open it up to questions. Again, if you would put your name tags up if you have a question? And I will go ahead and start with you, Ruth.

DISCUSSION

MEMBER BERKELMAN: I want to echo that. I think you have done a tremendous amount in a short amount of time. And I've got one comment and two questions, actually, for Robin.

I was impressed this morning with Dr. Lurie talking about the need for -- well, she didn't call it a warm bed, but I'll call it a warm bed in this issue of a warm bed for production of vaccine and the fact that you have highlighted that you have several manufacturers you could actually go to. And it was easier.

I think, again, it just highlights the importance that we not just drop everything when the crisis is over and that

this need for fundamental funding of preparedness is there and that we have the infrastructure in place to be able to act and not wait for new funding. In fact, this came up several times with individuals on the Board.

Now, the questions I have are -- I was interested in the decision was made not to interfere with seasonal flu production this year and then to come in with the H1N1 production.

I wondered, in the future, how would you see that you would actually trigger that differently or not? What would be your thinking around that?

And the other thing is, how do you think the proportion of vaccine made in this country will change, when we're talking about, say, flu vaccine, will change over the next five years? I mean, we didn't have much five years ago made in this country. How do you see it forecast for the next five years?

DR. ROBINSON: Thank you, Ruth,
for both questions.

For the first one, this is
warm-based operations that we have been
involved in not only for influenza but also
for medical countermeasures against chemical,
biological, and radiological, nuclear threats.

And also we think about this in
terms of emergent infectious diseases because
when Congress passed the legislation to
establish the ASPR and also BARDA, these were
three of the mandates that were there and to
be able to have an infrastructure that would
serve the national needs.

We have done that for influenza
over the past three years in this five to
seven-year plan that we're in. I mean, we are
in year three now, which would be informative
of the answer to the next question.

One of those elements was, how do
we actually build this infrastructure for
manufacturing and not just for bulk but also

for fill finish but also the raw material supplies?

I will give you two examples. One is that -- and Bruce Gellin is here. So he remembers our early days, in 2004, where the very first contract, the very first money that we got from Congress, was "What will we do with that?" It was about \$50 million.

Well, we had a lot of ideas, but the one thing that kept coming back is that at that time, as is going on now, if we don't have the eggs to make the vaccine, then we won't have any vaccine.

So in 2004, the very first pandemic preparedness contract that we issued was for securing a year-round egg supply. Now, that paid dividends immediately because then we started preparing for H5N1, with H5N1 pre-pandemic vaccines that year, in fact. Had we not, we would actually not have been able to start that year and the next year and the next and the next until this year.

And, similarly for the vaccine that we have this year because the H1N1 is -- they were basically finishing, the manufacturer, what they needed for the seasonal influenza their manufacturers would have started slowing down and so forth.

But no. They're there year-round. And we have a part of the critical infrastructure. So that is the idea of looking at the one end of it, of the raw materials, and then also looking at the other end with the fill finish manufacturers. I think as we go forward, we can think of other ways that we can extend this outside of those things.

So how will we balance this? Well, we have been very fortunate. We have done this every year with the H5N1 with seasonal, this year with H1N1 with seasonal.

And I think, to be honest about it, we were given a lucky break about when it came. Had it been at a different time, we

would have had a really much more difficult decision.

Now, how can we avoid that? One of the ways is that we would have manufacturers available, a large enough manufacturing supply that they would actually have another facility that they could actually go to.

I will give you an example. This is a part of the public-private partnership. Right now at Sanofi Pasteur, they are producing the H1N1 vaccine in the new facility. The old facility, which both are licensed, is where they are finishing up seasonal influenza vaccine manufacturing. We will see more of that so that they can change and go from one to the other.

We awarded a contract to Novartis, to answer your second question, earlier this year for building a new state-of-the-art cell-based influenza vaccine manufacturing. That facility will have the ability to provide

150 million doses of vaccine at minimum for pandemic purposes.

But in that contract -- and this is a long contract, one of the longest contracts in the U.S. government -- it is 25 years.

That contract has that every year they are required to make vaccine, several commercial-scale lots for any influenza strain that we need, whether it be seasonal, pre-pandemic purposes, or for pandemic purposes to keep that facility and the personnel and the staff trained and licensed.

Also, it's not just for influenza. In that contract, it also says if there are other pressing threats that we need a vaccine or other biologicals that can use that facility, the technology in that facility, then we can use that.

You will see that we will go forward with other contracts like that going forward. And so that is the first part of

this was to build up and retrofit egg-based manufacturing to make sure that what we have is secure and can be maintained; secondly, build a cell-based influenza vaccine manufacturing.

I should say that the cell-based vaccines are licensed and will be given in other parts of the world. They were not ready yet this year to be licensed here.

And third is recombinant vaccines. Now the tricky part of this -- and I think everyone understands this -- is how are we going to balance this with the commercial markets and the needs for the manufacturers to survive. And that is what keeps me up when I'm not worried about the response to H1N1 quite a bit is, how do we sustain that?

And so we have some ideas about that. And we would be happy to share those another time.

CHAIR QUINLISK: Okay. Thank you.

I would like to remind people to

say their name before they ask a question. Since we have quite a few questions, I would like you to try to keep your question and answer brief if possible.

Roberta?

MEMBER CARLIN: Thank you, Patty.

Roberta Carlin. I have a quick question regarding the distribution and the guidance going down through the state health departments, then to the facilities.

I was thinking as Dr. Schuchat was doing her presentation about the five priority categories and specifically the last category. I am sure there has been thought given to what is the process for consumers coming to obtain their vaccines, having some kind of proof as to their medical status. Some, of course, will be very obvious, as with pregnant women and younger children.

But the piece that I was concerned about was the persons aged 25 to 64 with the medical high-risk conditions.

DR. SCHUCHAT: You know, I would say in general our strategy and the state and local strategy is more of a pull than a turn-away. These are groups that are not necessarily vaccinated very frequently.

The coverage is pretty low among everybody except for the seniors. And so we are working more actively with the provider groups that serve those people with the advocacy groups that connect with those people and with media and other public channels to try to let people be aware, "Hey, you know, you are in a group that ought to be thinking about this vaccine" and then had a lot of venues where you can go.

We really thought a lot about the 2004 or '5 season and turning people away. So it really backfired. And I think in a perfect world we find sort of that middle road or that sweet spot, where the people who really need it can get it and people who want it who aren't in those groups don't lose the

opportunity and we balance demand and supply. It is going to be very difficult.

We don't expect most of the local and state venues to be looking for any kind of proof. I think it is much more of a "How can we let those people think about seeking vaccine?"

Reality is that most people with chronic health conditions do not think about themselves as "I am a person with asthma" or "I am a person with diabetes."

MEMBER CARLIN: Exactly, yes.

DR. SCHUCHAT: You know, one of our hopes is that there will be a lot of occupational sites that want to offer vaccine and reach some of those people.

If you look at the non-elderly group, where do people get vaccinated? A lot of times it is at work. So I think it is going to be a big challenge, but it is one of those areas where we can have long-term benefits.

If we do successfully reach more people in those groups, the familiarity with getting a vaccine is pretty easy to tolerate. And just that awareness that, you know, "I think of myself as totally fine, but I should be thinking about flu vaccine on a regular basis."

MEMBER CARLIN: Thank you.

CHAIR QUINLISK: I think, Ken, you were next.

MEMBER DRETCHEN: Yes. Ken Dretchen. Again, as a follow-up to that comment, I was thinking about the other age bracket group below ten with the idea that, more likely than not, they will need a second inoculation.

And so the question is, one, from a communication; and, second, from an implementation vantage point, how are you going to be able to make that follow-up to make sure that, in fact, they get that second injection not too soon and not too late?

DR. SCHUCHAT: Right. So the trials are looking at a three-week interval. And so, you know, the idea of probably the immune system three weeks is as short as you can get and still have a good response because we always perceive that there be a race against time.

You know, I think that this will probably be a little bit easier in venues like a school-located clinic, where you can come back in three to four weeks with a second round of offering vaccine. There are meant to be both local and other approaches to communication for reminders.

Places with registries is another one of these short-term/long-term opportunities. States with good immunization information systems have these automatic ways to do reminder and recall so people can come back.

There is great data about use of registries to raise the return. And I think

it is exciting that New York State is linking the pediatric immunization to the registry because they will then be able to use those automated reminders.

There is also some innovative work going on at some private and public areas in terms of other technologies, you know, mobile phone kind of reminders and so forth.

I think we will probably have a lot of public messaging about "Did you get your second dose yet? Remember you need one if you are under ten."

And, of course, for seasonal flu, it's just depressing to see, even in children 6 months to 23 months of age, where we know the risk of hospitalization is higher and there have been efficacy studies suggesting one dose is zero efficacy, you need the second dose to get protected in that young age group, the very low rates of two-dose completion. So I do hope we will be able to get active targeted and then more general communication

about the second dose for those who do need it.

We're thrilled that adults and teens do not need a second dose. This is like the best news of the month. We don't know when Linda is going to give us our next best news of the month. It's usually not from CDC that you get the best news at this point.

CHAIR QUINLISK: Thank you.

I think I see David down at the end next. David is part of our mental health, Disaster Mental Health Subcommittee. Thank you.

DR. SCHONFELD: Thank you.

David Schonfeld. I just wanted to make one observation or bring up one point to be considered. And then I have a question. The first thing has to do with the labeling of this as a novel influenza strain.

And all of the emphasis on the experimental testing of the vaccine has I think led many individuals to consider this to

be an experimental and, therefore, potentially risky vaccine.

I say this also because I run a division that cares for pediatrics; we have had over 25,000 visits in the past year for children with developmental disabilities and a large percent of them with autism. And so it is something to think about.

And in the presentations where you talk about acceptable safety profile, it is probably not sufficient for the population that I serve or even for the general public.

And I will just say I had a relative call me yesterday about being advised not to take this experimental vaccine by a health care provider and spreading rumors about an increased risk of a rare complication.

I don't even want to repeat what the individual told me case I don't want to spread the rumor further, but I didn't have the answer to the question about the risk

profile of it. I just want to share that as part of the messaging that you will want to consider.

The question that I do have has to talk about the 18 to 24-year-olds that are at risk and whether it is perceived that their risk is because of their age or because of their placement in congregate settings, such as colleges.

If it is the latter, then I would question some of the concerns you would have about reaching that population and why you would not go through the infrastructures that are in places in educational settings, the actual places that place them at risk.

I tell you my own daughter already told me she got her seasonal vaccine through her health service at her college without my prompting. And so that, in fact, many of those students are in educational settings and are open, therefore, to health education messages and through health services.

So that is a question. Do we believe it is because of colleges or their living there that places them at risk or their age?

DR. SCHUCHAT: Thanks for both of those issues because I think we are completely in synch that those are two important areas. Our research shows the same thing about novel. We don't use that term or we keep trying to cross it out every place it is.

"Novel" and "new" in our focus testing as well as in our public engagement efforts make people worried. This idea that it's an experimental vaccine, no, it's actually a vaccine made exactly the way the seasonal flu vaccine is made.

A hundred million people get the seasonal flu vaccine every year. This vaccine is not cutting any corners in terms of how it is being evaluated and licensed and released.

And so we are really trying to thread the needle on communication. We are

not publicly calling this a swine flu vaccine and have gotten a lot of criticism that the media does use that term. It's offensive to many people and industries.

The 2009 H1N1 influenza is the official government name. And also that is the name for the vaccine, as opposed to "novel." So I think it is just a challenge.

And we do know that we are going to have to do a lot of outreach to parents and other members of the public to let them make good choices based on the available information.

You know, what is the risk of the disease? What do we know, and what do we not know about vaccines, influenza vaccines in general and this one? So I think your first point is really, really a good one.

The second thing about the 18 to 24-year-olds, this was an active discussion at our Advisory Committee for Immunization Practices. Can't we just recommend this for

college students or for adults in congregate settings?

Frankly, the 18 and over group wasn't even in the initial pediatric recommendation. They had a draft of 5-year-olds to 18-year-olds. And maybe after that, it would just be high-risk groups.

And one of the thoughts was, well, gosh, we know the university and college systems are dying to take this up and we'll really do a good job of promoting vaccine. And what do the data show?

I don't think there is sufficient data to say that only university attendees are at risk. I think there is probably more attention when there is illness or outbreaks in those settings, but we do know about illness in Riker's Island, for instance, and other young adult populations that in that case congregate.

The age, it seems like age is definitely a factor in this. As you go upward

in age, your risk decreases. So there were intentional discussions about the social consequences of singling out university/college types of populations versus others, how complex it would be for communication to focus on congregate young adults versus other young adults.

Do we really know that young adults in the workplace are at lower risk? No. So we went with the more broad recommendation. On the other hand, the college infrastructure is just actively engaged.

I know most of the states are finding tremendous interest in being provider sites from their college and universities, and I expect we will have real good uptake there.

American College Health Association has set up a nice surveillance system and is reporting weekly what is going on with disease.

So I think we will probably have

much more, you know, as a very targeted subset. I think they can take the pressure off the public health folks to make sure that they are able to vaccinate their populations.

CHAIR QUINLISK: Thank you.

Al?

MEMBER DI RIENZO: Thank you.

Al Di Rienzo. I would like to thank all of you for your excellent efforts and for being with us here today. Robin, while I really appreciate your forward-thinking in your answer to Ruth's question, I am wondering if the same applies to the back end of the problem. And so I will pick on one thing.

When you talked about the shipping -- and I know the contractor that you are talking about, and it is a central facility. I think you will get great efficiencies from that.

If there is a situation where you are dealing with maybe more than one front, so

we're talking about H1N1 now, but if there are maybe two or three fronts that you are dealing with, different problems, is there a secondary contractor or distribution center that can be leveraged?

DR. SCHUCHAT: The contract is actually through the CDC. So I will speak to that, and Robin can amplify. The contract has the ability to do subcontracting. And there was always an issue of scale here.

You know, the childhood program that goes through this contract, there are about 80 million doses a year. So this is a lot more than that going through this.

And they had to expand their activities in terms of subcontracts and new warehouses and so forth, but the basics of the software and communication and methods are there and the connection with the state health departments and the private individual sites was there.

So it was something that we felt

given how quickly we had to adapt that would be able to go to scale as effectively as alternatives and that would be preferable to multiple central contracts or to manufacturing the five companies directly shipping with some sort of complex way to consolidate where things go at any one moment.

I do think that this whole set of logistics and capacity is a good thing for your Committee to think about long-term.

DR. ROBINSON: Yes. Just one comment about that. And that is that we did talk to the other wholesale distributors that normally distribute influenza vaccine. And they were very interested.

As we go forward, I think how they can interdigitate with the CDC system for ordering, we will certainly entertain them.

CHAIR QUINLISK: Okay. We will take the last two questions. I believe, Eric, you're next. And then we'll do David.

MEMBER ROSE: Thank you.

Eric Rose. My question is for Dr. Lambert, and it's around the elderly response, the antibody response, which if I am reading it correctly, was about 65 percent. I assume there is a lower confidence limit around that that would be somewhat lower. Is that really good enough?

DR. LAMBERT: So when we look at the data from our studies -- and the average age in that population in that study was 72 years of age. So that is 65 years of age and older. We think that that is very consistent with what we see with seasonal influenza vaccines in that population.

And now that we have the very early blush on the pediatric data, we really can see what much lower responses look like.

So the assessment is that those responses in those populations, the adult and the elderly population, are very consistent with one dose falling seasonal influenza vaccines.

CHAIR QUINLISK: And our last question, Steve? Oh, I'm sorry. Eric, did you have another one?

MEMBER ROSE: I guess I would ask the question, but is that good enough in seasonal? And is that something that --

DR. LAMBERT: That is great. I love that question. So there has been a lot of interest and effort with the NIH, both through its R&D programs and collaborations with industry, to try to optimize influenza vaccines and a great interest at the concept of not one size fits all.

And we have done some studies in collaboration with industry that show higher doses. Not surprisingly, the higher the dose of the vaccine, the higher the antibody responses.

So I think it is a very actively engaged program, and there are a lot of different groups that are very interested in trying to understand if we can improve,

overall improve, seasonal influenza vaccines for various populations.

CHAIR QUINLISK: Thank you.

And Steve?

DR. HOBFOLL: Yes. Obviously a tremendous amount of work. And I just always worry that we get focused on the science, which is, of course, critical and miss a couple of major things.

So, for example, if you don't have good sleep before you get vaccinated, the vaccination doesn't take well. And that is probably one of the reasons why the college population was at risk. But we are not telling them, "During this season, let's really watch your sleep."

The other height, binge drinking, with binge drinking very high, it probably places these young people at risk. Probably more are going to die, by the way, because of binge drinking than because of H1N1.

The other is now moving towards,

as Dr. Schonfeld mentioned, dispelling major myths. So about 30 percent of nurses believe that the vaccine causes the illness and don't take it. And nurses are a highly educated group.

So we have to move now -- obviously I'm not advocating poor science -- keeping all of that great science but now moving to getting these other health messages out and dispelling major myths.

Most parents that are going to hold back on getting the children vaccinated, it's probably because they are worried that the vaccine causes illness. But I hear nothing out there of major messaging about that.

DR. SCHUCHAT: Yes. Thanks. I used to be a scientist. And now I live in this other world where I am dealing with the issues, the very issues, that you talk about. And I think they are just critical for our regular immunization program.

We know that attitudes and myths are massively important in understanding the concerns that people have and the way that we communicate about those concerns can really drive behavior in good or bad ways.

So it is absolutely fundamental to the success of our program that we're credible, that trusted people are talking, that we identify the common myths and deal with them in ways that people can be receptive to.

Again, it's a place where our short-term focus can have long-term benefits. We know that health care providers, not just nurses, have a lot of myths about the vaccine and they really those in the way they communicate with their patients and that they are very, very influential people for many in how you make your health care decisions.

So we are reaching out in old ways and new ways, not just to the health care community but the mommy bloggers, really

dealing with a lot of interest groups, and trying to find ways that we listen and that we can be heard.

I think that those issues will really be critical to our success.

DR. HOBFOLL: If I can just follow up? We just have to simplify the message, though. You know, I think of the Australian campaign on skin cancer, "Slip. Slap. Slop" because people can only get about three ideas across. And it's nice that they rhyme or all begin with "S."

Then you have to penetrate with that because I hear no clear messaging about this whatsoever, much more volume I hear on myths and chatter than I do on any concerted messaging. And it has to be simple of a few things that we need to get across.

DR. SCHUCHAT: Yes. Thanks. I just want to respond briefly. I think that we need simple messages, but we also have an important demographic that wants a lot of

information.

In our research into vaccine hesitancy, it is actually a more educated population. They want the references. They want to be able to read the papers themselves and come to their own conclusions. They don't necessarily trust their doctors.

So we have a lot of targeting to do. And certainly the simple, the better for a lot of people, but accuracy and credibility are also important. And when a simple message doesn't turn out to be a credible message, we lose ground.

So we are struggling with this like you can't believe, but I hope that we will be able to meet that challenge of the simple one.

We have been talking about the threes. Our campaign last year was "Take Three." You know, it was antivirals for care. It was vaccine for prevention. And it was simple steps in terms of covering your cough

and those types of things.

CHAIR QUINLISK: Okay. I would just like to thank you again for not only being here today but for all the work that you have done in the past and, unfortunately, all the work that I think you are going to be doing in the future. Thank you very much.

Okay. We are running just a little bit behind. What I would like to do is take a five-minute break and then come back, and we'll start with our last session of the morning. Thank you.

(Whereupon, the above-entitled matter went off the record at 11:33 a.m. and resumed at 11:43 a.m.)

CHAIR QUINLISK: We're going to go ahead and get started. Could I maybe go ahead and ask the panelists, go on up to the front of the room. We have noticed that there have been a few people on our Board or ex officio members who have come in a little late, so we are going to redo some of the roll

call to see if people have arrived.

CAPTAIN SAWYER: We're going to wait for a few more people to take their seats.

CHAIR QUINLISK: As we're waiting for people to come in I just would like to let people know that since we are running a little bit over, and we want to try to finish up this afternoon maybe a little bit early, we will be taking less time at lunch. So anybody who has plans there, I will give you forewarning.

DR. DODGEN: Earlier when I did the roll call there were a couple of people that were not at their seats and able to say they were here. I noticed Dori Reissman who is in our Disaster Mental Health S is here. This is for the record that I am making these notes. Also Dan Sosin, who is our ex officio from CDC, he's here, and I'm sorry I missed him earlier, and I apologize to Dan.

And Dr. Hugh Auchincloss was here earlier, and he may have stepped out, but I

want to make sure that he is recognized as being in attendance.

And for the Department of Homeland Security Terry Adrim is also here.

Now is there anyone else that I missed? Okay, thank you.

CHAIR QUINLISK: Okay, we are going to go ahead and get started with our late morning panel. And very quickly I'll introduce them. Robin, I guess you are not going to get away at all this morning. You are going to be on every single panel. So we have Robin Robinson back again. And we also have Anthony Fiore from the influenza division at the CDC and Debra Birnkrant, the director of the division of antiviral products at the FDA. Welcome.

PANEL DISCUSSION SESSION II: HHS H1N1

ANTIVIRAL UPDATES

H1N1 ANTIVIRALS

DR. ROBINSON: Good morning. I just want to give you a flavor of what we are

going to talk about. I'm going to talk about what was our goal for antivirals initially for pandemic preparedness; what was the chronology of events, what we did have and not have, as we entered the H1N1 events in April, and how that has transpired over the summer to the fall; and where we are with vaccine development with some new ideas, and maybe some new products.

Tony is actually going to talk about how do we use these, and what is really the policy guidance for these antivirals. And then Debra Birnkrant will talk about some of the efforts that we have in the department going on with some of the products from the licensure or EUA usage of these products.

So the National Strategy for Pandemic Influenza had as one of its goals for - in the area of antivirals, and that was simply that 25 percent of the population would have antivirals for treatment. That's what it said, and that's what we went for over the

last four years in providing a federal stockpile to meet that, and also helping states that for our overall national stockpile needs.

As we entered into April 2009, before the H1N1 the federal government had provided the necessary means to obtain 50 million treatment courses, both Tamiflu and Relenza, and stockpiled those at the SNS. The states had obtained 23.5 million treatment courses with federal subsidies, toward a goal of 31 million. So we had then about 73.5 million treatment courses. Our goal for treatment was about 75 million, and then 6 million more for containment.

As we went through May of this year, 11 million treatment courses were deployed by the CDC SNS to the states. That went out during the month of May. Some states used some of it. Some states didn't even unpackage it and distribute it. So there was a wide variability there, and Tony can talk a

little bit more about that.

We then said we have to replenish that. So the ratio of Tamiflu to Relenza in the stockpile, the federal stockpile, was 80 to 20; in state stockpiles it was 90 to 10. Again they could choose whatever they wanted, but they stayed pretty close to what the federal got.

Last spring HHS agencies talked very long about what our stockpile needs should be, and should we change that based on the H1N1 virus that was circulating last winter and its resistance to Oseltamivir or Tamiflu.

Because of that we moved to change the policy from an 80-20 ratio to a 50-50, because we had not seen significant resistance to the zanamivir product Relenza. However, when we bought antivirals, the first one was still an 80-20. As we've gone on through the summer that has been delivered. And so the federal stockpile has been replenished. And

so the states have also bought more antivirals, so that they have about 25 million they bought, 11 million that they had receipt from the federal government. So it's 36 million treatment courses of these antivirals there in the states. And then 50 million treatment courses back in the federal stockpile. So that is around 83-85 million treatment courses that we have today.

As we've gone forward the secretary signed a memo recommended by the agencies within the department to buy more based on the actions we had before. And that was that we needed to move forward with a more balanced or 50-50 ratio of these two drugs. So we will be going out soon with purchases of more zanamivir.

We also wanted address a need that we had in the stockpile for pediatric formulations. We have pediatric formulations of Tamivir, but we thought that we needed more. And zanamivir can be given down to

seven years old. So we will be adding more pediatric formulations to the stockpile as we go forward. I cannot give the numbers out because we are in procurement sensitivity right now. But just to say the least we are going forward with it.

However we are not going to move forward in a way that would destroy what would be available to communities under the commercial market. We want to make sure that if people want to buy it they have it there. And state stockpiles can backfill that as necessary.

So that's where we are basically right now. The manufacturers have been producing at full capacity, and have expanded that capacity throughout the summer, and will continue to produce these. There are swatch shortages going on, especially with some of the pediatric formulations we understand from some of the manufacturers, but they are still producing more, and actually moving from

producing the adult versions of the formulations to also address some of the pediatric formulation needs.

Relative to antiviral development, we have supported at BARDA, a drug that can be given intravenously, Peramivir, from BioCryst to individuals that are critically ill with influenza. They have completed their phase two studies, and we just have provided more funding to them to continue with their phase three studies. And they also have studies that have gone on outside the United States. So that is looking very, very promising, and there are other drugs which we are now considering funding as we go forward. We have a solicitation of received proposals to move forward with not only for new types of drugs but also combination therapies. And relative to that we have worked with the NIH and CDC to sponsor clinical studies of these drugs in combination both the older drugs and also some of the newer drugs. So Oseltamivir with a

product from Toyama which is a viral RNA polymerase inhibitor, and others like that.

So we are moving forward with that. And the last point is that some of these drugs that are given intravenously may be available sooner than several years from now under emergency uses authorization. And we'll have Deb talk more about that.

So these are what we have in our arsenal right now, and I'll turn it over to Tony now to talk about actually how this will be used for treatment.

DR. FIORE: Thank you, Dr. Robinson, and thanks to the Board for inviting me up here to speak to you.

My charge today is to describe the updates and the revisions that are on the antiviral guidance documents that are on the web from CDC. And to put that into context I also want to give you a little bit of information about antiviral resistance surveillance and sensitivities, and also a

little bit about safety monitoring.

So first I'll describe the surveillance data and then talk about the new treatment guidelines. We actually have another revision up there just in the past couple of days. And also talk a little bit about chemoprophylaxis, because this has been an issue that has bedeviled us over the past few months.

So antiviral resistance testing is really the province of specialty labs. There are three state health labs at this point that are able to do this. We are working at increasing capacity for getting more labs able to do it. There's a few references labs that can do it, and of course CDC does a lot of what goes on in this country.

You can do antiviral susceptibility testing in a couple of different ways. One is the usual way of sequencing the virus, which of course is quite laborious, but it does identify all the

potential sites on the virus that are known to confer resistance.

Another way if one has knowledge of what the most likely imitation is that is going to confer resistance you can do something called pyrosequencing, and that can be done directly on clinical specimens, and we do a lot of that know.

Our surveillance consists of isolates and clinical specimens that come in through our collaborating WHO nerves labs. These are labs that have been submitting specimens for antigenic characterization for many years; there's nearly 100 of them in the United States. We also get a lot of specimens from overseas in our function as a WHO collaborating center.

And of course we get calls a lot about looking at antiviral specimens from cases of particular interest, immunosuppressed patients that are not getting better despite treatment; outbreaks in the setting of

chemoprophylaxis, things like that. So we do sort of special studies to look at antiviral resistance in special specimens, and that's most of the places where we have picked up instances of resistance.

And these data were actually last week's data; they just updated the data in the past few hours. But the results are roughly the same. Thus far going back all the way to October, 2008, and counting the 2008-2009 season, of course last year was mostly a seasonal influenza A/H1N1 year, and last year was the season of resistance also to Tamivir and its isolates. So 970 out of 975 tested, that's pretty high.

All of those isolates, the seasonal influenza A isolates -- and I should have the word seasonal in there -- are sensitive to zanamivir, and interestingly enough those seasonal H1N1s were sensitive to the adamantanes, which are drugs that have fallen into disuse because of high resistance

levels, in the other influenza A subtypes.

All of the H3N2 viruses tested, we didn't test that many because it wasn't much of an H3N2 season, are sensitive to both the neuraminidase inhibitors, Oseltamivir and Zanamivir, but are uniformly resistant to adamantanes.

Now of course the predominant virus in the U.S. since April by far has been the 2009 H1N1 viruses. Those viruses are all sensitive to Zanamivir that we've tested. Of -- and that is going on 1,000 different specimens that are tested so far.

Over 99 percent of those 2009 H1N1s are susceptible to Oseltamivir. We have also seen Tamivir resistance in a few instances, as have some other countries. There have been 21 identified worldwide at least by my count. So it's a couple of handfuls across the world, and 10 of these have been in the United States.

And typically this has been in one

of two settings. One has been when there has been prolonged treatment of an immunocompromised person. Immunocompromised people often have trouble clearing influenza viruses, and can be on antiviral treatment for many weeks at a time. And it's not unusual even going back over the past several years and looking at seasonal influenza viruses to see resistance develop over time.

The second isolated instances of illness that occurred when someone was on post-exposure chemoprophylaxis. Typically that has been someone who has had an exposure, sometimes has either not fully taken the chemoprophylaxis dose or got started quite late on it. Probably was incubating the virus at the time they first began getting chemoprophylaxis, and shortly thereafter developed infection. And we have had a couple of instances of those viruses being resistant. You can read about them in several places. I have listed the two MMWRs most recently that

describe resistance just below -- at the bottom of the slide here.

Summary, here, this is your scorecard for resistance. You can see for Zanamivir, all of the viruses are susceptible. But Oseltamivir, seasonal H1s are resistant while the other strains are susceptible. Adamantanes, sort of the opposite pattern, susceptibility in the seasonal H1s, resistance across the other ones including the 2009 H1N1 viruses.

Of course this is important to put in the context of what viruses are currently circulating. As you can see here, this is the virus surveillance data that you have probably seen these sorts of slides before describing seasonal influenza. We are almost uniformly seeing 2009 H1N1 viruses right now over the last couple of months. So really the resistant pattern that you need to be concerned about if you are a clinician right now seeing a patient with suspected influenza

is that of the 2009 H1N1 virus. So this is the virus -- I'm sorry, antiviral susceptibility pattern that is of concern right now.

Susceptibility uniformly to Zanamivir, occasional resistance to Tamivir, uniformly resistant to the adamantane drugs.

So this is the most recent, just a screen shot of the most recent antiviral guidance that is up on the web. It was put up on the 22nd. We had also updated this in early September, a little bit of tweaking over the past few weeks to try to clarify some of the issues that came up after that original posting. And I'll go through some of the details of that guidance over the next several slides.

First it's emphasized right up front that most healthy persons who develop an illness that looks like influenza, and people who are already recovering from influenza don't need antiviral medications for treatment

or for chemoprophylaxis. But on the other hand we are continuing to see instances of people with severe cases of influenza who get fairly delayed treatment. So we want to emphasize empiric treatment of people who are particularly at risk or particularly sick with influenza should get prompt empiric antiviral treatment, and that is without regard to previous health or age. If you are really sick get treated, and get treated empirically. The empiric treatment of choice is Oseltamivir or Zanamivir, and it should be done as soon as possible after illness onset. I sometimes worry that this 48-hour treatment window is viewed as something that, it's open for 48 hours and then it closes. It's really sort of a continuum. Earlier treatment is better; it's probably better to get treated at 12 hours than it is to get treated at 36 hours after your onset.

Empiric treatment, we are really pushing for people who are quite ill. Because

of the problems I think we'll probably talk about this afternoon with laboratory confirmation of 2009 HN1N, of course that's the confirmation of it being that particular subtype appears in reference labs and state health labs, and doesn't often -- is not often able to inform treatment decisions. You have to make the treatment decisions before you get your lab results back. Don't wait and delay treatment initiation, especially for people with severe illness who don't have an alternative explanation for their respiratory symptoms.

And of course emphasizing again clinical evaluation and judgment are the key components. CDC doesn't want to get into the space between the provider and the person being treated; the provider needs to use judgment about who needs to be treated, and don't necessarily feel constrained by national guidelines that are meant to guide treatment. People don't fit into boxes necessarily and

"Treat sick people," I think, is sort of the bottom line on that.

So persons who we really want to push for empiric treatment include the pretty obvious persons: persons that are hospitalized; persons that appear to have viral pneumonia; persons who have influenza and what looks like a complicating bacterial pneumonia.

Now there are other groups of people who, regardless of health status, you should think about treating, so we put that into the consider box. These are people at high risk for influenza complications, and they include pregnant women, children that are less than two years old, people with chronic medical conditions, and persons who are 65 years or older.

And that last one is often a point of confusion. We've seen the surveillance data from earlier this year that shows that persons over 65 are less at risk of infection.

But of course if they get infected they get quite sick. They often have chronic underlying medical conditions, so we are trying to make that as clear as we can that there is a difference between risk of infection and risk of complications, because as it turns out, the highest case fatality ratios for infection are amongst that older age group, even though relatively few of them are infected.

A group that really caused a lot of consternation with the guidelines in early September, even though the guidelines really weren't changed since April was the group two to four years old. Those two to four year olds are at somewhat higher risk compared to older children, but it's important for clinicians -- here's a place especially where clinical judgment is necessary. Those who don't have high risk conditions don't necessarily require antiviral treatment. And this is a group of course that is getting a

lot of these influenza infections. Also a group that gets a lot of respiratory infections that could be influenza, and obviously empiric treatment of all two to four year olds is probably not feasible or desirable.

So because of our concerns about delays in treatment we offered some options up to clinicians to think about as they are going into the influenza season, or they are waiting for 2009 H1N1 to hit. The point of these is that we worried that clinicians while they might do quite well with being able to reel off the groups that are at risk or the groups that require empiric treatment, might not really think through from an office practice point of view the things they might need to do to try to get persons treated early.

So most of those things that are listed are sort of commonsense things, but we wanted to spell them out. And that is to have practices educate persons at higher risk for

influenza complications, about signs and symptoms, about the need for early treatment. Make sure that their patients have rapid access to telephone consultation and potentially clinical evaluation if it is warranted, especially for high risk patients; and to even consider phoning in a prescription if a patient who is at risk for influenza complications calls and reports that they have what sounds like suspected influenza, and it would be difficult to get that person in quickly to evaluate them, consider getting treatment started right away.

The testing issues I think will be talked about later this afternoon. Of course we have limited testing capacity, and many state labs are limited in how much testing they can actually do. We would prioritize testing for persons requiring hospitalization.

And finally something that we think gets missed, and something we saw in some of the chemoprophylaxis investigations

that we've done was that people who are undergoing treatment still shed virus. They might shed virus for a little bit less time. They might shed virus at a lower titer, but they are still shedding virus, and they need to continue the sorts of isolation precautions that they are taking, and continue hand washing, commonsense things like that. And of course the goal of this is to limit transmission of virus from persons on therapy, because that is the one place where you might see resistance.

For first exposure chemoprophylaxis, this again has really not changed that much since April, other than the fourth bullet. The idea of course is that prophylaxis should be started as soon as possible after exposure to the infectious person, preferably not later than 48 hours after exposure. It should be limited to persons who can actually take it, who look like they are going to adhere to the regimen;

those who have had a real convincing close contact exposure; and also persons to be considered for post-exposure prophylaxis are largely limited to those at higher risk for complications and also health care personnel who haven't had appropriate personal protective equipment during a close contact.

I think the major change since the May guidance is this idea that we expand on in the document to consider an alternative to post-exposure prophylaxis, and discuss with this worried person who has been exposed what the signs and symptoms are; assure them that they can get close follow up; that they can receive early treatment if they develop suspected influenza; and sort of a watchful waiting approach that would save on chemoprophylaxis doses and probably would be more efficient in our use of antivirals, and might even help with the resistance issue.

There is no group specifically recommended for pre-exposure chemoprophylaxis,

and by that I mean people at high risk for complications, usually it's people who are at very high risk for complications, who might be getting chemoprophylaxis for a fairly extended time during a peak influenza activity.

Now this is left in the realm of the judgment of the clinician. We think there are relatively few instances where this will be necessary, but we recognize this is a use of the drug that has been done in past influenza seasons, and probably not something that can be specifically banned.

We also in the guidance offer up some considerations for particular groups, especially for infants where of course the drug is not licensed in that group, and also for severely ill patients. Now the FDA moved very quickly in late April to develop an EUA that provided guidance on treatment of infants. There was some uncertainty I think amongst many practitioners about how well age-based treatment as recommended in the EUA

might apply to particular situations including under weight or premature infants.

And there is also a study, an NIH-sponsored study, that has been looking at a treatment of these infants, and we are working with FDA to discuss the possibility of updating this guidance to offer other potential alternatives to dosing including weight based dosing.

Now as far as severely ill patients go, it's become a fairly common practice now to give double dosing of Oseltamivir. This first was discussed in the H5N1 treatment guidance that came out a few years back, and has been somewhat more commonly used now for treatment of severe influenza for people in the ICU, because of concerns about absorption. There are really no studies to indicate that this is something that is a good idea to do, but it's discussed and references are provided for people who want to look into the possibility of doing

this.

Of course people who are severely ill might require more than five days of treatment. And finally it's noted that there are investigation or compassionate use medications that I think we will hear more about during the next presentation, and we also heard about Paramivir just a minute ago, medications that are not currently approved in the U.S. but might still be available in particular circumstances.

Just one slide about some of the ongoing studies we have about antiviral effectiveness. Some of these were set up pre-pandemic, some of them we are setting up now. We had arranged a year ago to begin an observational study in the United States among hospitalized patients, mostly in North Carolina, and Atlanta metropolitan area. That is we would look at patients who had been hospitalized; look at whether they had received antivirals and been hospitalized with

a lab confirmed infection, see if they received antivirals, and compare outcomes.

And this is sort of a duplication of a study done in Canada, which suggested that hospitalized patients could benefit from antiviral treatment, even if started more than 48 hours later.

We also have just beginning randomized controlled trials, the use of Oseltamivir for ill persons, and what that effect is on household contacts. There is one of these trials just getting started in Wisconsin, another going on in Bangladesh. And there is 2009 H1N1 in Bangladesh.

We also are proposing to do a randomized control trial of empiric antiviral therapy for community acquired pneumonia. And finally this just getting off the ground, and in fact the first investigators' meeting is today, of a pneumonia etiology study where persons with community acquired pneumonia who are hospitalized have a very complex package

with a diagnostics that really define the role of various different pathogens and the causes of pneumonia.

My last couple of slides will just describe adverse event monitoring, because I thought it might be of interest to the Board. Of course FDA runs MedWatch which is good for identifying new adverse events. Just as part of pandemic planning some of my colleagues in the division of health care quality promotion had developed a relationship with SAMHSA which runs things called the Drug Abuse Warning Network. And also the National Electronic Injury Surveillance System dash Cooperative Adverse Event Project, or NEISS-CADES, probably the longest acronym I've ever seen. And these networks have been used in the past mostly to look at overdoses of heroin and so on like that. But they also do look at illness related adverse events due to prescription drugs. And so now we are getting downloads from these two systems, we can use

them to compared to Oseltamivir prescription use that is collected in a biosense and look at some of the patient demographics of people that are describing adverse events, and look for signals. And none seen yet.

Just as an example of the kind of data they give, here you see charted with the purple line the antiviral prescriptions that have been filled through BioSense, seen through BioSense data, and then some of the antiviral reports that have come in over that time. And this pretty closely mimic the influenza season. We haven't seen anything extraordinary yet as I mentioned. This is three seasons worth of data. It is interesting how closely these follow influenza activity just even in terms of the severity of the season. We do see adverse events. They are quite rare as you can see, 40 or 50 in any given month, but they are a useful way to look for adverse events.

So just in summary, and this

summary is not meant so much for the Board as what the summary you see from the antiviral guidance that just went up. The focus is on use of antiviral medications in hospitalized or several ill patients, and those of high risk for complications. We want to limit the use of post-exposure prophylaxis as we can to those with risk factors for complications. And those who have a real good close contact exposure, and those are likely to actually take the drug.

And finally this idea of self monitoring and early treatment as an alternative to chemoprophylaxis is probably the largest new guidance that you see in the most recent antiviral guidance that CDC has put up on the web.

Thank you. Just an acknowledgment.

DR. ROBINSON: Thank you, Tony. Now Debra Birnkrant for the FDA will talk about some of these products that are licensed

and that may be available under EUA.

DR. BIRNKRANT: Thank you, and thank you for inviting me to participate at this meeting today. I'm not at liberty to disclose any predecisional actions at this point in time. So therefore I thought I would address the group by describing in general and briefly our EUA processes as well as comment on other means for accessing antivirals for influenza for serious and life threatening disease, as well as commenting on something that appeared recently this week with regard to medication errors and Tamiflu suspension in children.

So as background emergency use authorization, or EUAs, authorized use of unapproved products, or unapproved uses of approved products during a declared emergency only. And the EUA lapses at the end of the emergency. And what does that mean for the product under the EUA? It means that it reverts to the IND status if it's an

investigational product, or it reverts to the indications for the marketed product.

The EUA I'd like to stress does not replace clinical trials to support marketing. The goal of development for investigational antivirals is through an NDA or a BLA process. That is a marketing application.

Typically there are limited quantities of drugs used under EUA. That's because for the most part they may not be marketed products. FDA's review process of EUA requests depends on the information provided regarding the risks and the benefits of the proposed product in the setting of the nature of the disease and the emergency, as well as the availability of other approved products.

It's important to have pre-EUA discussions with the Agency, because as you can imagine during an emergency time is quite limited. Pre-EUA submissions allow for

specific discussions, and tracking the status of clinical trials and other supporting data; identifying gaps and proposals for filling them.

So we do recommend an early approach by government or any private entities that might request an EUA.

Here are some of the procedures in an abbreviated fashion. It's quite complex I can assure you. An emergency is determined either by the Department of Homeland Security, Department of Defense, or Department of Health and Human Services. And then the secretary of Health and Human Services declares an emergency to justify the use of these designated products under EUA.

Then the FDA consults, as time permits, and as appropriate, with NIH and CDC, to review the request, to be able to conclude that the agent, in this case the influenza virus, can cause serious or life threatening disease; that a product can reasonably be

believed to be effective; that the known and potential benefits outweigh the known and potential risks for the proposed use, and there is no adequate approved available alternative.

But the EUAs are not the answer to all questions for access. What we also need are adequate and well-controlled trials. They are extremely important to be able to acquire evidence for safety and efficacy which are the statutory requirements for marketing approval.

We are looking for proposals for efficient uses of clinical trial networks. We realize this is also a complex situation, that frequently these clinical trial networks are set up for chronic diseases, as opposed to acute diseases such as influenza.

The FDA staff are available to provide timely responses and feedback after our reviews are completed, and it's important to keep in mind that clinical trials can support and run in parallel with emergency use

authorizations.

There are other means to facilitate access to investigational agents, and that is through IND protocols, and single patient INDs, as well as emergency INDs, and I'll comment on that in a couple of slides.

I'd also like to emphasize that EUAs do not necessarily guarantee supply, and we have our FDA drug shortage team working with BARDA and CDC to monitor shortage issues.

What have we done to date that I can speak about? Well, we have authorized EUAs for approved influenza antivirals in April of 2009, following the secretary's declaration of an emergency. Specifically we authorized emergency use of zanamivir for inhalation and Oseltamivir products that were in the strategic national stockpile.

CDC was the EUA sponsor, and was granted these EUAs authorizing use of these two products in later courses of illness and in more severe illness than the labeled

indication. These EUAs also allowed for distribution with emergency use related fact sheets for health care providers, and authorized dispensers, and patients, without certain components of the usual prescription labeling because an emergency was declared.

In addition with regard to Oseltamivir an EUA also included dosing for infants less than one year of age, as well as expiry extension.

The Agency prioritizes reviews based on the criteria and the published guidance on EUAs. We assess the seriousness, incidence and urgency of the condition, the potential effect on addressing and unmet need and assuring national security, adequacy of data to support risk benefit, et cetera.

The Agency expects to work closely with the requester, and in the case of Zanamivir and Oseltamivir it was the CDC to provide timely feedback on fact sheets and conditions of use to be able to facilitate

availability and encourage additional data collection when feasible and appropriate.

Turning now to emergency INDs which are on a much smaller scale -- that is, they are basically for single patients in general -- they are also mechanisms to facilitate access to investigational products in the setting of a serious and life-threatening disease without adequate treatment alternatives.

And this has been used in the setting of viral diseases, including the 2009 H1N1 viral strain. The process, though simplified on this slide, is again complex. The IND sponsor, which is usually a physician, working in an intensive care unit, contacts the pharmaceutical company to secure the investigational product. The FDA is then notified by the sponsor, and we request additional clinical information.

The sponsor then submits an abbreviated protocol and data on the patient

on whom they would like to use the investigational agent.

The FDA allows the request, and provides an emergency IND number, if appropriate, to allow the sponsor to ship the product to the physician. However, the outcome data is not consistently received. It's not considered to be an adequate means to support a database to allow widespread use of a product. So as I mentioned even though we request that if a physician submit a protocol and information on the patient, at times it's very difficult to get follow up or outcome information, and to be able to use that type of information to support, let's say, a marketing application or an EUA, we have to get permission from the requesting physician. We would then have to get permission from the patient or the patient's family; and it becomes quite a complicated situation.

And in addition there is no template in order to be able to receive that

type of information and then put it into a database that can be utilized and manipulated for purposes of analysis.

With regard to the situation that was recently made public, with regard to Tamiflu, for oral suspension and medication errors, we were most recently made aware of this situation this week in the September 24th issue of the New England Journal of Medicine. And I will highlight for you the situation.

Tamiflu oral suspension is approved in the concentration of 12 milligrams per ml. And the approved dosing device is a syringe also labeled in milligrams. However it has become quite obvious at this point that U.S. physicians and parents are not used to delivering liquids in a syringe that is calibrated in milligrams. So there have been not many but some medication errors. In our errors database we have reports of 13 since 2000 when the product was approved.

Most recently this is what we

have. We have a prescription that states: give the child 3/4s of a teaspoon by mouth twice a day for five days, and this will dispense with the syringe calibrated in milligrams.

The parents of this patient were physicians, who are professionals with advanced scientific degrees. They were able to conduct the necessary calculations in order to be able to deliver the appropriate amount to their child. But it clearly raised questions for them in that how could other parents and child care workers dose Tamiflu oral suspension especially in the setting of an emergency as this pandemic has presented to us.

So we work with our partners at CDC and at Roche, the pharmaceutical company, to issue new and consistent messaging among the three parties. Specifically we have highlighted that dosing should be prescribed in milligrams according to the package insert,

and caregivers for children including parents and others should use the dosing dispenser packaged with the medication unless otherwise directed by a health care provider.

Prescribers should avoid prescribing Tamiflu suspension in teaspoons. This can lead to inaccurate dosing as we all know. If a prescription is written in teaspoons the pharmacist is asked to convert the volume to ml's and ensure that an appropriate measuring device is offered such as an oral syringe calibrated in ml's.

The dosing dispenser packaged with the product, that is the one I showed you, in milligrams should be discarded if the prescription is written in ml's.

And then if a dispenser that is packaged with Tamiflu is lost or damaged, or if the prescriber was just to use volume-based dosing, appropriate doses in ml's are also provided in the package insert, and again in such cases the syringe calibrated in ml's

should be used.

We have messaged this with our MedWatch partners as well as other groups. So has CDC, and Roche has posted a dear health care provider letter and will be doing additional education programs. We have also utilized the social networks that are out there. And apparently I was told we reached a million partners yesterday, or tweeters as they are referred to.

Be happy to take questions. Thank you.

CHAIR QUINLISK: Thank you so much for again all the work that you have been doing on this issue. What I'd like to do know is see if there are any questions on behalf of the Board members, the disaster mental health subcommittee or the ex officio members.

And Andy, I think you get to start.

MEMBER PAVIA: Well, thanks to everyone. And I've got a question really for

you, Tony. The 21 resistant isolates that have come in so far, two questions about them. One is, do we actually know what proportion are in the setting of prophylaxis? And we know of some. But actually of the 21 how many were in the setting of prophylaxis, or how close have you come to answering that question?

DR. FIORE: A number of them are still under investigation. It's surprisingly hard to track down what happened, because these isolates typically come in -- might come in as part of a routine viral surveillance, although only a few have come in that way. And then we have to try to backtrack about what has happened with them.

The 21 that I know about are worldwide. It's really just 10 in the U.S., two that were founded at a reference lab. So it's really just eight that we're looking at here.

I think no more than half of those

were in the setting of prophylaxis. There are at least two others that we are not really sure what was going on, but these could have been community acquired resistant isolates. And in fact one of the first ones that was identified actually was identified in Hong Kong, but in a U.S. citizen was an adolescent from California who was not known to have taken Oseltamivir nor were her family members known to have been taking it.

So it is, I think, as we have seen with seasonal 21, there certainly is -- we have a potential specter of community transmission of resistant isolates, yes.

MEMBER PAVIA: But we are getting into the area where it's the plural of anecdotes but not really data. But there seems to be a signal there that we need some way of detecting.

The other question has to do with our ability, our confidence, that we can detect clusters of transmission of resistant

virus around these anecdotes or these episodes. I know one or two have been investigated and have been reported, but how confident are we that we are able to screen at the site where resistance has popped up for ongoing transmission?

DR. FIORE: We are not very confident. I mean I think the North Carolina incident that is reported in MMWR is a good illustration of that. There were two resistant isolates there, and it was not clear where the children -- and these again, these were campers in a camp that had a lot of chemoprophylaxis going on. It was not clear where the children had acquired their virus. And when you are trying to look at these things after the fact, often a few weeks after the fact, all those viruses, and those people who were sick, are now gone. There's not a serologic test for infection with a resistant virus.

And so we are stuck with having to

rely upon getting as many isolates as we can from that time frame. So it is an imperfect system for surveillance. We get a lot of isolates from the U.S. We have scaled up our antiviral resistance testing. We get a systematic group of isolates from each of the state and public health labs each week now. But we are looking at a very small minority of the influenza viruses out there.

CHAIR QUINLISK: I believe you wanted to follow up?

CAPTAIN SOSIN: Just, I just wanted to follow up on the comment that there might be a signal here. And this is continually moving information, and we are all attending different meetings and hearing somewhat different things sometimes. But we happen to have Dr. Michael Shaw, who will speak later, who might be able to speak to this if I get it wrong.

But my understanding is we have two approaches to testing these specimens for

resistance. One is somewhat systematic sampling the nerves systems. Over 1,600 of those specimens have been tested, and actually none have shown antiviral resistance.

The second is the referrals of specimens coming from very specific clinical settings, and that's where we've seen resistance. So if you want to say it's some percentage of zero over 1,600, less than that, is what our signal looks like right now for antiviral resistance, as opposed to 10 out of that number.

MEMBER PAVIA: No, Dan, the signal that I'm concerned about is that we may be seeing a phenomena similar to what we did with the M2 inhibitors, which is that prophylaxis may be selecting for the emergence of spontaneous mutants who are allowing their propagation.

CHAIR QUINLISK: And that was Dan Sosin.

Steve.

MEMBER CANTRILL: Steve Cantrill,
question for Tony.

One of my concerns is
inappropriate use of antivirals in
chemoprophylaxis. And have you considered any
active educational measures to go after
conditions to impress upon them the
appropriate use. Because I am concerned about
depletion of the supply chain. I think we had
a hint of that in May.

DR. FIORE: We have reached out
to clinicians in a variety of different ways,
through Webinars, through clinician calls.
We've done a number of those. We did our best
to publicize the reposting of the antiviral
guidance, the revisions that we are working.
Some of the medical professional organizations
including IDSA, that is in the midst of
revising their antiviral guidance. That's
about where we stand.

We also have I think one of the
drivers of people receiving inappropriate

antivirals is just as it was for antibacterial agents, which is worried parents, worried adults, coming in who think they have had an exposure, or maybe you have a mild illness, who want antivirals, because they have heard that this is a very serious deadly disease. And so we are also reaching out trying to message the idea that most people who get this infection, including particularly most people who have no underlying medical conditions or are not pregnant, most of those folks are not going to require treatment.

CHAIR QUINLISK: Okay, seeing no other questions - Ruth, I'm sorry.

MEMBER BERKELMAN: Yes, Ruth Berkelman. I actually want to follow up on that and ask you if you have seen the flip side, the clinicians withholding antivirals inappropriately, particularly with misuse of the rapid influenza test.

DR. FIORE: Absolutely. That is the balance we are stuck with trying to strike

here. We certainly even before the pandemic were quite concerned about the fact that in our hospitalization surveillance, and this captures people with laboratory confirmed influenza who were actually tested by their clinicians, who obviously were suspecting influenza, that only about half of those hospitalized patients actually receive antivirals. In fact a lot more of them receive antibacterials than were receiving antivirals. And of course some of them probably had a complicating bacterial infection and it was appropriate.

But this is a problem that goes back. I think part of it has to do with sort of the 48 hour window shut sort of concept. I think people probably worry excessively about toxicity, or they may not be convinced the antivirals make a difference, or they sort - the way that the antivirals are licensed are that they save you a day or so of illness, and that doesn't sound like much, and hardly worth

the potential toxicity, or at least the perceived potential toxicity that is out there.

So yes, we definitely have an issue also with undertreatment.

CHAIR QUINLISK: Andy.

MEMBER PAVIA: Several things that have come up with this panel bring up the issue of communication with clinicians. And we talked this morning about messaging to the public. CDC and FDA have terrific ways of getting information onto their websites and pushing it out to some groups about new recommendations. But my sense, and I suspect many academic physicians' sense, is that that doesn't always reach clinicians very well, and isn't always translated into practice.

In the mess and the crisis mode that you have is there any effort to try and figure out what ways will get this information to clinicians better and change behavior more effectively than what we are doing?

DR. FIORE: I think working through the professional societies is one potential way. For example I participated in a Webinar sponsored by the AMA just the other day and there were 2,000 clinicians on the line. So we are reaching a fair number; that's a small proportion of the total.

But it was somewhat concerning listening to the questions after the Webinar. I think the baseline knowledge level is fairly low amongst some clinicians about use of antivirals, and about influenza in general to be honest.

And so yes, I think we need to work with our communications group to do a better job of getting that message out. And I think the professional societies also maybe need to help with that, because influenza is I think fairly - despite being such a common disease, is fairly misunderstood out there as always being a mild illness or perhaps not worth considering treatment. And for high

risk people I think that is a problem.

CHAIR QUINLISK: Ruth.

MEMBER BERKELMAN: Yes, Ruth

Berkelman. I just want to follow up on that and ask whether or not state health departments have tried to communicate. For example all physicians need medical licenses. And in some states they have ready access to emails. And I don't know how much that's been looked at - who does, who doesn't.

CHAIR QUINLISK: This is Patty Quinlisk. I can only speak for my state. But yes we have used a variety of ways of getting information out. But to be honest today we use the HAN more than just about any other message to get out to clinicians and to hospitals and to ERs, and infection control practitioners, et cetera, just because we can send it out on an emergency basis or whatever.

But we also do send out information via the regular channels, and to be honest it's been going on for years with

regular flu. But I still think the issue exists of - especially in Iowa - the rural private practitioner who is not part of the system getting the information still remains to me something of a challenge.

MEMBER JAMES: Yes, Dr. James. I would just like to make a comment on the email, both my experience in Florida which was a number of years ago, but when we tried during the anthrax outbreak to do the email distribution, lo and behold only 50 percent of physicians either recorded their email - they may have had email but they didn't allow its use.

Now being at the AMA after Katrina we also tried an email survey. And again I think there was about a 30 percent shortfall of physician email records.

CHAIR QUINLISK: I'll just say in Iowa we still have to use a lot of faxes to get hold of especially our rural doctors.

What I'd like to do now is open it

up for public comment. I would like to remind the public that if they do have a comment to please come up to the microphones, identify themselves. They can ask a comment of this panel or of any of the people who were here this morning who might still be here. So the whole morning session is fair game.

We are going to start out first with an email comment that we got. So Leigh is going to read that.

PUBLIC COMMENT

CAPTAIN SAWYER: Yes, and thank you panelists for staying there.

I would also like the operator to let those on the telephone know that they are available now to queue up for comments.

OPERATOR: At this time I would like to remind everyone, in order to ask a question, simply press star, followed by the number one on your telephone keypad. We will pause for just a moment to compile the Q&A roster.

CAPTAIN SAWYER: While they are compiling the roster I'd like to read a comment that we received this morning - well, actually it was received yesterday at 6:05 p.m. from Michael Murphy, CFA of the New World Investor.

This question is to be put to Debra Birnkrant. Since the FDA determined intravenous paramivirs to be safe and effective by granting an EIND in June, and since that process is so cumbersome, like getting the drug to the ICU, that less than 10 patients have been treated. Why has it taken so long for the FDA to issue an emergency use authorization and get this drug on hospital shelves? Hundreds of patients including dozens of children have suffocated to death without timely access to it.

DR. BIRNKRANT: As I mentioned, I can't speak about specific products that are investigational, but I can speak in more general terms. There is availability under

the emergency IND process for a single patient with a serious and life-threatening disease to be able to obtain a parenteral antiviral for treatment of influenza. There are limited quantities available of intravenous Relenza and intravenous Paramivir. So if there is an extremely ill patient who is hospitalized, then there are means to be able to get that drug to that patient.

The review process for an EUA is quite cumbersome, especially for an investigational product. It's cumbersome but less so for a product that is already approved but will be used in a somewhat different manner. The complexity surrounding the investigational product are such that it hasn't been determined based on our statutory requirements whether or not the product is safe and effective.

The level of effectiveness for an investigational product although is lower, it still requires intensive review of all of the

data that has been generated to date for the product. So in a way it's similar to a marketing application, but it has to be done in an abbreviated timeframe. And even though this is an emergency use authorization for an investigational product, we really want to make sure, since we have much more limited data than we would have in a marketing application, that the product is as safe as possible to be used in this extremely ill population.

So in addition to reviewing all the clinical data we have to review the nonclinical data, the manufacturing data. We go out to the manufacturing sites to make sure that it can be manufactured appropriately, especially for a parenteral antiviral there are concerns about sterility.

In addition we go to clinical trial sites as well to again ensure the best we can that this investigational product can be used and we have assuredness that it is

safe but not to the level that we would need to have for a product to be marketed.

So I just want to stress that if there are patients who require parenteral antivirals they are available but on a limited basis.

CHAIR QUINLISK: Thank you. I see nobody standing right there.

Okay, go ahead, identify yourself.

DR. MULLEN: Erin Mullen with Rx Response. Early on in the H1N1 outbreak the FDA put out a statement on their website asking for private sector companies that have stockpiled antivirals if they were at or near their expiration date to hold on to them.

There has been - that statement is still up; there has been no update on that. There has been some shelf life extension for product in the strategic national stockpile, but no word on private sector stockpiles. Can you speak to that please?

DR. BIRNKRANT: It's an important

situation that you've just mentioned, that is, the stockpiles that are outside of the strategic national stockpile. As you know over the years many large corporations have stockpiled antivirals and other products in preparation for a situation that we are dealing with today.

We need to be assured that these products have been stored at the appropriate conditions, because one thing we wouldn't want to have happen would be to distribute a product that was ineffective, because it had lost its potency, et cetera, or had become contaminated.

So although there are provisions for products in the strategic national stockpile to have their expiry dating extended, definitive statements and actions have not been carried over to private stockpiles. But we still recognize that it's an extremely important situation, because a lot of product is stored outside of the

strategic national stockpile, and outside of state and local stockpiles.

So it is something that is being - will be addressed, hopefully in the near future, and I can assure you that it is under discussion.

CHAIR QUINLISK: Thank you.

I believe that Dori Reissman has a question.

CAPTAIN REISSMAN: Good morning, and thank you for your presentations, and also to the panel that went earlier, although I'm not sure if anybody is still here from there.

I just wanted to raise one thing on behalf of the - on the disaster mental health aspects. In thinking about the syndromic confusion with flu, and presentation of flu, and to our health care providers, people don't know what kind of flu they have, and the fact that the virus tends to mutate or genetically shift in some way, and we could lose efficacy of the vaccine in the future, or

efficacy of the antivirals in the future, are we still trying to engage in a more pronounced way with the community mitigation strategies in and around the avoiding exposure to the virus, avoiding spread?

It's unfortunate that our agenda today does not address this at all, yet it's the missing piece of what we are talking about today. So I just wanted to put it out there to see if we are going to have any discussion in and around that.

CHAIR QUINLISK: Does anybody there want to try to -

I know that we have had conversations about community mitigation. I don't know if anybody here on the panel wants to deal with it. I can speak - there are huge campaigns going on in Iowa about --

CAPTAIN SOSIN: I think Patty should speak certainly afterwards because that is more practical - what's on the ground. Clearly, Dori - Dan Sosin - this is an area

that focuses on one of the pillars. HHS has taken it seriously. CDC has taken it seriously. We have a task force that continues to work on that side. But there is no question that visibility of that activity is dwarfed now by the vaccination campaign and all that it is going to take from public health to get that out and into arms. And obviously the antivirals are a measure that is out there, that is already out there that people are using.

So a lot more attention on clinical care and on getting vaccine. But we haven't forgotten about the community mitigation measures, and the need to better understand through the course of this no crisis goes un-used sort of setting to better understand how those community mitigation measures actually work, how effective they are.

DR. HATCHETT: Richard Hatchett, National Security staff. Just to Dori's

question, I think what we have seen over the last several months is if you think of non-pharmaceutical interventions as a spectrum ranging from personal actions through to population level type recommendations and interventions like closing schools or canceling public gatherings, the collective wisdom of really everybody at this point is that this particular event is one that warrants the continued attention to the personal recommendations which we have all heard until we are sick of them about you know covering your coughs and washing your hands and staying home if you are sick, but that it doesn't rise to the level of warranting the types of public interventions that were considered for more severe scenarios.

CHAIR QUINLISK: I'll just add that in Iowa we started doing our community mitigation messages, et cetera, months ago. Partly it was in preparation for school starting, so there has been a lot that has

gone out already. But you raise a very big point, in that we need to continue that message. Because all we have to do is have one parent refuse - you know forget to keep their kid home when he's got the flu and we'll have a school outbreak.

Does anybody else have a comment on that? Okay, at the microphone.

DR. FAGBUYI: Good morning, Dan Fagbuyi, Children's National Medical Center, also on my other hat, American Academy of Pediatrics. Earlier they mentioned issues with regard to reimbursement. I just want to reemphasize that it is important, and just give concrete examples.

An adult comes into the doctor's office, gets an IM shot of the influenza vaccine, they got charged \$21 approximately. A pediatrician who has to counsel a mom with four kids screaming in their room, has to hold the kid down after counseling the mom agreeing to get the vaccine, put two shots in this

child, and actually have them come back after that encounter for another set of two shots, it's \$2 - 4. There is a discrepancy there, and for a disease that is skewed to the left, affecting mainly the pediatric patients, it is paramount that we actually address those issues in terms of reimbursement, and to incentivize pediatricians.

I'm a pediatric emergency doc myself. I won't be giving this shot, but my other colleagues, as pediatricians, will be dealing with that.

Second, would be I know this is H1N1 focused, but I want to urge us to also start to consider issues with regard to bioterrorism. When we start to look at what we were talking about, the EUAs, and we met with the FDA before. But I think it's something to start to address, to look at other drugs that we would use as countermeasures when we get, say a nerve agent which may actually affect children a little

bit more different. And just as it's skewed to the left here, those kinds of events will be skewed to the left again, affect pediatric patients.

So we need to start considering that, i.e. Midazolam IM, pralidoxime, start thinking about those things, thank you.

CHAIR QUINLISK: That was not exactly a question. Does anybody have any comments?

Okay, let me just see, if there is anyone on the phone?

OPERATOR: Yes, you have a question from the line of Marlena Monroe.

MS. MONROE: Hello?

CHAIR QUINLISK: Go ahead.

MS. MONROE: Yes. My husband and I have been watching the stock quite closely, and reading up. And hearing just the travesty that is going on all over. As recent as just today on the message board regarding the 11-year-old child. And as a parent and - I'm

just wondering. I understand that there are procedures, and the FDA is involved, and the emergency use authorization is cumbersome. But is there any way to get this message across that this is another source? I don't think people are aware that this is a great source, that if their child is - or an adult, or a family member - is gravely ill, is there any other way to push this through, to get some sort of emergency use and make it publicly known so that it might be a solution to an urgent situation.

CHAIR QUINLISK: Okay, I'll see if our FDA representative would like to address that?

DR. BIRNKRANT: I'm not sure what case you are referring to with regard to an 11-year-old. And even if I were aware of it I couldn't really address that particular patient.

But again I can tell you that we do have procedures to allow for access to

drugs for serious and life-threatening diseases. One is through emergency IND usage, one is through single patient IND use, and we have EUAs as I mentioned.

Now with regard to influenza and children, or influenza and seriously hospitalized adults, we can make available parenteral antivirals for treatment. The two that are currently available under an emergency IND are IV zanamivir, and IV Peramivir. So if you would like, you can contact our division of antiviral products, speak with our chief project manager or a project manager in charge of influenza related activities, and we can put you or your physician in touch with the appropriate parties in order to be able to receive parenteral antivirals for influenza in hospitalized patients.

CHAIR QUINLISK: If I'm looking correctly, I do not see any other comments. Is there anybody else on the phone?

OPERATOR: There are no further
at this time.

CAPTAIN SAWYER: Looking at the
agenda, and where we are in time today, we are
hoping if it is possible for Dr. Shaw and Dr.
Hojvat who are here, we would like to move the
next presentation up a bit. Are they in the
audience, there? Okay, if you will be here,
and then also the Disaster Mental Health
Subcommittee, we would also like to move your
portion up as well, so that there is an
opportunity for everyone to hear your
presentations.

A couple of the Board members do
need to leave, so they wanted to ask if it was
possible and if you are amenable to this, they
are hoping to hear your full presentation.

So in order to accommodate this,
what do you suggest, Patty?

CHAIR QUINLISK: We'll try a 45-
minute break for lunch. If we could try to
move back here faster, do you want to do 30

minutes? I don't know, Dr. Dodgen, would you be able to be prepared? Okay, 30 is too close. Let's say 45 minutes for lunch.

CAPTAIN SAWYER: So let's say 45 minutes for lunch. We'll come back and we'll have the presentations on the diagnostics, if that is not an issue for our presenters. We will have discussion, the public comment period. We haven't had a lot of comments, so we will accommodate that as we get questions.

We may have a brief break then. We need to check with Dr. Dodgen if this is okay with your subcommittee, and then also start earlier the presentation of the subcommittee.

DR. DODGEN: I think that will be fine. We are all going to actually meet together at lunch so we can give you a more specific answer. But I think everyone is nodding, so it should be fine.

CAPTAIN SAWYER: Great. Well, thanks so much, and we will see everyone back

then at 1:45.

(Whereupon, the above-entitled matter went off the record at 12:59 p.m. and resumed at 2:02 p.m.)

CHAIR QUINLISK: We're going to get ready to start, if you could move to your seats, please.

Okay, we are going to go ahead and get started. And I'd like to thank the speakers for being here on time as we requested.

We are going to have another panel discussion, this time on the H1N1 Diagnostics, give you some updates on that. We have two speakers, Michael Shaw, who is the associate director of laboratory sciences at the CDC, and Sally Hojvat - is that it?

DR. HOJVAT: Hojvat.

CHAIR QUINLISK: Hojvat, sorry. As a person whose last name is Quinlisk I should be better at these names, but anyway, Sally is the director of the division of

microbiology devices at the Centers for
Devices and Radiological Health at the FDA.

Thank you very much for being here
today.

PANEL DISCUSSION SESSION III: HHS H1N1

DIAGNOSTIC UPDATES

H1N1 DIAGNOSTICS

DR. SHAW: I'm going to start off
with a presentation about the type of
diagnostics that we have been using so far,
and the situation as it has developed as the
pandemic has progressed.

We had done a fair amount in
preparation, just as part of the overall
pandemic preparedness, with several emphases.
One of them was to develop new tests to get
the capabilities out there, which turned out
to be fortunate, because it turned out that
some of the reagents we had been developing -
in this particular case, reagents for
detecting swine influenza - turned out to be
very useful.

But we also had in place plans and mechanisms for improving surge capacity, especially trying to get these plans rolled out to the states. And as you'll recall from the situation in the spring, that was one of the major efforts at the very beginning, is to try to get these new tests rolled out to everyone.

In the process of doing that sort of thing you have to have some sort of proficiency testing in place. You also have to work very closely with the regulatory authorities, which Sally will be talking about that later. But in that particular case I think it was an excellent example of what can be done. Because basically the EUA was put in place about a week after we had the first genomic sequence of the very first virus. So it was really an incredible speed to get this thing out.

And of course one of the other things you need to do is make sure that

everybody, not just researchers, but developers and manufacturers have access to the viruses and all of the reagents that they need to develop improved tests or develop their own tests, and of course, as we've been discussing earlier in this meeting the guidance to clinicians and just the overall surveillance to know what's out there.

This is sort of a summary of the types of tests that are out there right now, above this line, showing you which sort of setting they are used in. Over at the extreme left, immunoassays are the rapid tests that everybody is familiar with, the types that can be done actually in a physician's office.

Immunofluorescence, a little higher complexity, generally done in larger laboratories. Then you get into the more specialized tests, like the antigenic characterization serology. Those are generally done only at the very high complexity laboratories.

What made the big difference in this particular response was the real-time PCR, getting it out there. Because it was a fairly rapid test that was capable of differentiating the different subtypes, which was crucial in the beginning of this.

Down below that line I have also put some things that we would either like to see or are in development right now. Probably the most important ones are the improved point of care influenza test. We really need something better than is out there right now, something with higher sensitivity. And as you can see from the data that Dr. Fiore was presenting earlier, we are in desperate need of some more rapid way to determine antiviral resistance in the viruses that are out there.

The actual assay that has been used as essentially the gold standard for diagnosing the novel swine-like H1N1 influenza virus is the real-time PCR test that was developed at CDC basically is working on the

platform of the so-called five-target CDC assay that had been approved - cleared by FDA and rolled out to all of the LRM laboratories under a 510(k). The five targets in that case are Type A, Type B, seasonal H1, seasonal H3, and it also had a marker for the Eurasian lineage of H5. This was part of the overall pandemic preparedness, because the assumption was that that was going to be the one we had to worry about.

Well, in the process of developing this, as we had also developed reagents specific for other subtypes that might come along, H7, H9 for example. But we also had a very robust set of reagents for swine influenza, and that is what came into play in this particular instance. When we got that first Type A un-subtypable from the patient in California, it was run through our tests with these swine reagents, and we picked it up and we knew what we had.

At first we assumed it was just

one of these irregular sporadic cases of swine influenza infecting humans. It took the full genomic sequencing before we saw we had something different. But it did show us that we had reagents in place, and those are the ones that were put into the assay that was rolled out under the EUA, like I said in record time.

We've since updated the primers, as we've sort of made them a more optimal match to what is circulating out there. But basically the assay is the same, and it's currently trying to expand it to different platforms. But it was put into a kit, and it was made available, basically to any laboratory that had the trained personnel.

And a special way of validating the laboratories was put in place where basically they would use the assay in their own laboratory, send five specimens to us, we would verify and then we considered them good to go and they were able to do the diagnostics

themselves.

It took a tremendous burden off of us, because at the peak CDC was the only game in town, and we had to get this assay out to other laboratories. Our people just couldn't continue at that rate.

So this gives you an idea of what the timeline. You can see the very first case was confirmed in the laboratory at CDC on April 15th, and by the 29th we started getting these reagent kits going out to laboratories in the U.S. And a little later we started sending them out to international laboratories.

And also, I threw the other point in there that at the same time when we were doing the survey of trying to find a good vaccine candidate. So all of this was happening extremely quickly. It was really an amazing feat of work for all of the laboratory people at CDC to get this done as quickly as they did.

And at the peak of it the specimens coming in, we were getting up to 250 a day average and peaked at about 500. Right before the states started doing their own assays, and then immediately it dropped off and gave us some break on it.

But these kits have been sent out basically all over the world. You can see, this is an indication of all the different laboratories that have gotten it. Of course the green ones are the U.S. public health laboratories. The black ones that are scattered around, there are several Department of Defense laboratories also using it.

The blue ones are the ones that we have sent out to partner laboratories in WHO, and that is another aspect of the CDC response to this is that we have not just been supporting the U.S. effort, we have been sending out these reagents to other countries too.

Of course this is fine for

laboratories capable of running the high complexity tests. But the fact is that most of the patients out there are never going to get that. Number one it's expensive, and number two it takes awhile to get the results back. If you had the actual facilities on site, then maybe you could get the test result back in less than 12 hours. But a reasonable turn around even in an emergency is more like 24 to 48 hours, because you have to consider the time of actually getting the specimens sent off to the laboratory that is going to do it.

So essentially the test is most useful for surveillance purposes rather than for actual clinical treatment. It does continue to be necessary for us to know what's out there, because we want to know if for example seasonal influenza is still out there for reasons that I'll cover a little later. But that means that right now, aside from some of the laboratory-derived tests, some of the

commercial laboratories have started to develop their own commercial assays. But generally the type of test that a patient is going to get in a clinical situation are these rapid influenza tests. And they do have certain advantages, particularly speed, since you can do it while the patient is actually sitting there and get the result.

But the fact is that none of them subtype. The best you can hope for is a differentiation between Type A and Type B. You won't know if it's an H1 or an H3, much less whether it's a seasonal H1 or a pandemic H1 that the patient has. So the major advantage and the reason they are used so much is that they are very low complexity. As a matter of fact, the two most widely used ones are actually CLIA-waived, which is probably has something to do with why they are the two most widely used.

Also they don't require any special equipment. You just basically just

read a line on the test cartridge to see if you have got a positive result or not. I think everybody in this room is probably aware of the inherent disadvantages of these tests, which is why it's very difficult to write guidance as to how they should be used in a national clinical situation.

As I mentioned they don't give any subtype information. If you know that one strain is pretty much dominant in your area, then that is not so much a consideration. Back when the adamantanes were still being used for therapy that could make a difference, because the Type B influenzas were insensitive. They were all resistant to adamantanes. It only worked on the Type As.

The major drawback, however, is, their very low sensitivity. One of the first questions that came up when this new virus appeared was, would these tests even pick it up at all. And of course the reasoning was, there was no reason why they shouldn't,

because the antigen they are picking up was a nuclear protein antigen which is very highly conserved across all type A influenzas. And the testing bore this out. They will pick up this novel strain.

But the fact is that they pick it up at maybe a little less sensitivity than they do for seasonal strains, which isn't very good at all. And the range in best cases is 70 to 75 percent, and in most cases, basically you could make an equally accurate prediction, maybe more accurate, by flipping a coin rather than running these tests.

So one of the things we had to get out in the guidance early on was that if you are going to use these rapid tests, you could trust a positive result, but you couldn't necessarily trust a negative result, and you shouldn't use that negative result to determine how you were going to treat the patient, especially if it was a question of whether to initiate antiviral therapy or not.

Unfortunately there apparently were a lot of cases where physicians were assuming that a negative really meant that they weren't infected with influenza, so they would start giving antibiotics or some other sort of treatment. But, we are trying to get that information out there.

The other big drawback is one that we worried about at the beginning, which was that they are not easily modified. If this virus had changed sufficiently that that common antigen wasn't picked up by these any more, then essentially the tests would have been totally useless.

Fortunately that wasn't the case. But you could easily imagine a situation where the virus changed enough that that antibody that they are using in the test that they manufacture no longer pick it up.

One of the other things that gets back to what Tony Fiore was talking about earlier was the necessity for antiviral

resistance testing. This is something that at CDC we have gotten more and more requests for. We have in addition to just requesting specimens to come in as part of our regular surveillance for testing, we are getting requests from labs to specifically test a particular specimens to see if that one is resistant to antivirals. In a lot of cases they have a reasonable suspicion because of treatment failure or other reasons.

This pointed out very clearly that there is a gap in what is available for testing for antiviral agents. As I mentioned there are two major classes, the adamantanes are only effective against Type A. The ones that are obvious of concern right now, the neuraminidase inhibitors, because that is what's in not just our national stockpile, but virtually every other country that has established a pandemic stockpile, those are the agents that they have in them.

But the fact is that there is no

FDA-cleared or even any recognized as standard test for checking antiviral resistance for either class of drug. All of the testing so far has been done in reference laboratories. And we have to make special allowances for cases that are high priority to even think about doing something that might be relevant with clinical treatment.

So we need to try to change that. Because it's become clear - cases have become more common that we do need to determine, if for example a patient has become resistant, has a strain that is resistant to Oseltamivir, so they could switch the therapy to zanamivir, and also to get an idea if there is any overall change in resistance patterns. For that we will need to get the test out more broadly available instead of just the reference laboratories.

But right now about the only ones you are able to do, the most widely available rely on genetic sequencing. And that assumes

that you know what the mutation is that confers resistance. In the case of the pandemic influenza they have all been the same mutation, what we call the H275Y. It's a histidine changing to a tyrosine at position 275, which is in the enzymatic site. That confers resistance to Oseltamivir, but not resistance to zanamivir. So you can do sequencing of a sample fairly quickly looking at just that marker. And if you see the marker is there you know the patient is resistant.

So that is one of the things we are going to try to roll out first. There are a couple of other big laboratories that can do it, the New York State Health Lab will do it, Wisconsin State Health Lab. I think California is also getting it up and running. But one of our priorities is to try to get that out to more states.

The real gold standard assay however is a functional assay where you actually look at the drug inhibiting the

neuraminidase enzyme. That's probably something that is never going to get out of the reference laboratories, because it's just too high complexity an assay; the equipment is too expensive; and it requires highly trained personnel.

But the fact that there are only these two approaches right now means that there is a very obvious gap for something that needs to be done to improve our surveillance to get an idea of what is out there, not to mention for individual patient care.

You can imagine that there are several uses for this. To draw an example of what happened in 2006, that was when the adamantane resistance became so prominent, so common in the circulating H3s that a HAN was put out in January of that year basically recommending that you not use them anymore, and basically ever since then people have just stopped using them.

We don't want to see something

like that happen with Oseltamivir, but that did happen with the seasonal H1 influenza, so it is possible. We need to keep an eye out for that. And obviously as I mentioned, in exceptional cases you may want to do specific testing on a particular patient's specimens.

This is a summary of what we have done at CDC. This is just the specimens that have come into our laboratory as of last week. Tamivir, but that did happen with the seasonal H1 influenza, so it is possible. We need to keep an eye out for it. And obviously as I mentioned in exceptional cases you may want to do specific testing on a particular patient's specimens.

This is a summary of what we have done at CDC. This is just the specimens that have come into our laboratory as of last week. You can see that for the novel influenza at the bottom, we have tested almost 1,700 now, as of that date, found that nine of them have been resistant to Oseltamivir. None to

zanamivir, 100 percent resistant to adamantanes - that was not unexpected, we knew that.

But you can also see just a couple of rows above that the influenza H3 and 2s are still 100 percent resistant to the adamantanes, and almost 100 percent of the seasonal H1s are still resistant to Oseltamivir. Now you can imagine if all of those are circulating at once, if you had a test that would tell you the subtype, you would have a good idea of what sort of therapy to use. So right now we are caught in a position where there is not a rapid test that will tell you subtype, and there is also not a quick test that will tell you antiviral resistance. That is where the surveillance becomes more and more important, and why we'd like to encourage developers to get more assays out there.

So one of the ways we have tried to stimulate that is over - cause some

consternation in our tech transfer office, but we put our protocols up on a public website, WHO, for anybody to look at to develop their own tests. This is particularly important in international situations where it was difficult to get the CDC assay out there. At least they would be able to look at the protocol, the primer probe sequences, and try to develop it themselves. And a lot of the laboratories here in the U.S. could use it to make their own laboratory derived tests. That is exactly what we intended.

At the same time we put up our protocol for pyrosequencing, for looking for antiviral resistance. So far there has been less interest in trying to adapt that, but there are a few laboratories that are trying to do it. And of course we put our protocols up for the whole genome sequencing for any researchers who wanted to look at this.

So we are trying to get the information out there so developers have what

they need, because when you combine that with the influenza reagent resource where we make viruses available to them for testing, and we are also going to include standard resistant and sensitive strains of the virus, we would hope that they have everything they need to get started, and encourage them to do so.

So I guess in conclusion I'd like to reemphasize those gaps that have become extremely obvious since the pandemic effort first started back in April for us, for the rest of the country I guess in May is when it started rapidly expanding. The primary one is the lack of a rapid test that could be used in a physician's setting, in small clinics, or emergency rooms, some sort of situation like that.

It would be nice - well, not nice, in a situation like this it's mandatory that it is going to be able to differentiate subtype, because while it appears that the seasonal H1s have virtually disappeared

worldwide, so much so that the WHO recommendation for southern hemisphere vaccine doesn't have that component in it anymore, H3s are still hanging on in certain parts of the world. So that's still a possibility that you will see a patient with an H3. So subtyping information is desirable.

And we'd also like the type of test that when something new comes along you could adapt it fairly easily to include a new marker for this new strain if it comes up. And of course what I consider right now to be the most glaring gap is antiviral resistance. Because right now it's the only weapon we have. I mean, the vaccine is rolling out very soon, but there are a lot of people that won't be getting vaccinated, so that leaves antiviral agents. So we really need a good test for those.

So I'd like to leave it with the acknowledgments for all of the people at CDC that have been working on this, and turn it

over to Dr. Hojvat.

DR. HOJVAT: Well, thank you very much for inviting us again to give you an update on what the FDA is doing in terms of diagnostics for 2009 H1N1.

We also had a pandemic influenza preparedness, and you will some things are very common to the other sister agencies like CDC, we have common goals. We also try to promote the appropriate product development where we can by making it least burdensome for developers to send their assays to us to review. And we also have a component where we are watching those assays after they are out there. We have a surveillance system if things go wrong, and then we call up the companies and make sure that they either recall those products, or they work with us to put it into a safe position again.

The labeling that we have put together in these kits is also - we consider user education. Some of the problems with the

rapid tests for example are that they are not being run at an appropriate time frame, not within the first 48 hours of signs and symptoms, when the viral load is high, or with adults there is less virus being shed. So some of this variability that you see, especially with the rapid test, is because people who are using them are not using them at the appropriate times over the appropriate individuals.

It is true, though, that overall the sensitivity is certainly not as good as the later assays that have been coming on, the nucleic acid tests. But the 20 percent sort of level that you see in some of these papers is not what we cleared those assays for. The data that came in wasn't 20 percent or we wouldn't have cleared them. But we think some of it is because of inappropriate use of, and sampling as well. And even actually getting the samples, they are not getting the samples appropriately, and getting enough virus in

there to get those lines to come up.

So we try to do that in the labeling, but unfortunately people don't read the labeling, so that is a problem too.

There were shortages in April and May, especially of the rapid tests, and normally that is a time when the companies have slowed down; they don't expect to get orders for rapid flu tests in April-May, and their production cycle is usually, well, we've gone down now for the summer and we'll ramp up ready for the fall. So there were big shortages of these rapid tests, and even shortages of the ancillary reagents that are used to make these nucleic acid tests. So very much we tried to - well, we did contact all of the companies making this on an almost daily basis, and we were helping them in some ways go into sort of an allocation mode where they weren't providing 75 percent of their inventory to one individual customer, which at the beginning was happening when people

realized there were going to be shortages.

We also helped in terms of making it easier for them to get their shipments. Some of these kits are made in China. They were being held up at their ports of entry, and we were able to facilitate entry of new lots coming in, and continue to do that.

We do know that they are all ready for the surge. We don't know what that surge will be, but all of the companies at this point including the ancillary reagents for nucleic acid tests have certainly upped their inventories, and hopefully will be able to cover any surge that we might have this fall.

And we work very closely, as Michael said, with other federal agencies and stakeholders.

What are the pathways to clearing or authorizing diagnostics through the FDA? Well, the classic one of course, this is a Class 1 device, it's 510(k) clearance. They have to demonstrate safe and effectiveness,

and substantial equivalence, actually, under that particular section, 510(k) of the Food Drug and Cosmetic Act.

At the moment all through the summer in parallel to encouraging people to submit their assays for emergency use authorization, we have also been encouraging them to be doing clinical trials, to have 510(k) cleared assays, because if the emergency is taken down, the EUA is taken away and we might be left with the fact of having no cleared assays out there to pick up the H1N1 virus.

So we have been encouraging them, and we know that several of the companies are in clinical evaluations at the moment, and will be submitting in the next couple of months assays for us to clear under the 510(k).

Emergency use authorization, at the moment we have authorized a total of four different tests, two of them are from the CDC;

but we have had multiple requests. We are dealing with almost 24 different companies right now, helping them through towards potential EUA authorization.

We also have rejected some; that was an interesting point my colleague from FDA mentioned. There were some things that needed to be worked out in this EUA process. There was nothing at all written down on what you would do if you actually rejected a product for emergency use authorization. So this has been a very interesting learning process for us. Because I think it's the first time this has actually been put into place, and we have learned a tremendous amount. I think this is important because we would have to do this in the case of - someone mentioned - biothreat. These are the kinds of processes that we will have to go through very quickly. And it's been an excellent learning process for us over the summer, for everybody.

This has been gone through before,

but of course this is the status of influenza testing. As of April 24th this year, Michael has gone through that. What we had cleared are of course those rapid tests for A and B, and the DFA antigen test. And over the last two years we've begun to get in and cleared nucleic acid based tests for flu A and B, and also flu A and B and subtypes such as was mentioned before the CDC, and there are other assays that can actually subtype H1, H3 and H5, but of course not H1N1. There was not a cleared test available, either a nucleic acid test or a rapid test, to definitively detect and differentiate the influenza A subtype 2009 from the seasonal influenza A, H1N1.

And of course you heard, the CDC requested as to review and authorize their new device. And we have worked with them solidly over one weekend, a special weekend. And the emergency was actually declared on the 26th, and by the 27th we had already given an authorization, because they had anticipated

that there would be an emergency declared. So that was the path we took over that weekend.

This has been gone through before, so I'm not going to spend too much time. Again, we have been working under the same parts of the Emergency Use Authorization statute. That was the process. The HHS secretary declared the emergency and the FDA issues an EUA, that would be what we have done four days later for the CDC, and at the bottom you can see eventually - it could be a year, like April 26th of 2010 - the EUA would be taken down if the emergency is over, or it could be earlier; nobody knows.

Again one of the main points of an EUA - and I think my colleague was trying to stress that - is that we do have to base our decision on scientific evidence. And in the case of the drug trials, of course, and the vaccine trials, they have had to do some actually well controlled smaller clinical trials. In the case of the in vitro

diagnostic assays we have based all of our data on analytical data, some specimens that have been obtained. But we haven't asked people to go out and do actual clinical trials at sites, like we would for a 510(k). There is a lot of emphasis on - especially with the nucleic acid test - looking at what they have selected for their primers and probes, and we are seeing quite a variety of those. And that does take some time to make sure they are picking the right targets, and to be able to pick up the 2009 H1N1.

They don't all take the advice of the CDC. Some of them are picking their own primers and probes.

I think we have mentioned that, the duration of the emergency. And I can talk a little bit about the EUAs that already have been issued, two of them from CDC as I said.

And in the beginning there was an effort to save the 2009 H1N1 reagents, because they were in short supply. So the CDC initially adopted

a two-tier approach to this. The first tier assay in other words, the first test that was being done, was this cleared panel that we had cleared a year ago, and which was able to detect flu A and B and the seasonal subtypes, H1 and H3, as well as H5. And that EUA was issued on May 2nd.

The second tier assay was what you would run if in the first tier assay you got influenza A positive, and unsubtypeable, in other words, none of those subtypes for seasonal flu came up positive. That was the indication of course as Michael described on the identification of the first tests, is when those kinds of first tier assays, in clinical trials or public health labs, were coming up as only flu A positive, and unsubtypeable.

So that was the reason for the development very quickly the CDC of the second tier assay, and this one does pick up in those flu A positive, unsubtypeable specimens, they will come up as positive for this particular

assay for the 2009 H1N1 virus. And that EUA was issued April the 27th.

Since then we have been trying to expand the testing to be able to help the public health labs. Everybody knows the horror stories of the public health labs being totally overwhelmed; we talked about this the last time. We had this conversation, and it was realized there are actually two different kinds of testing, the kinds of testing which the public health labs do, which is more for surveillance, and then the other kind of testing which is diagnostic. That was what was asked to be done by the public health labs, and really it was not their mandate to be doing that kind of testing.

So we have tried to bring into place EUAs on a test which would expand the possibilities. And one that was sent into us was by Quest, the big laboratory, reference laboratory. They have worked in conjunction with Focus Diagnostics. And we were able to

give an EUA to them on July 23rd. And that assay does detect the flu A 2009 H1N1 in multiple respiratory specimen types.

Then we also received a request for EUA authorization from the Department of Defense. They have field hospitals and were experiencing in Iraq and Afghanistan some outbreaks of H1N1 in the troops. On this particular assay the reagents are those, the same ones manufactured by the CDC. And I think the CDC worked with the Department of Defense on this particular assay. It's actually run on an instrument that is very rugged; it's a very rugged that can be used in the field called a JBAIDS instrument. And this detects flu A 2009 H1N1 in nasopharyngeal swabs. They didn't ask for other specimen types. And we issued that authorization on August the 24th.

And I know immediately they - DOD, was training their field hospitals on how to use this. So that was a very productive

collaboration, too.

As I said we have many in the pipeline. You will see several others popping out with EUA marking on them over the next few weeks, and many of them who are asking questions. And where are they coming from? From everywhere. Commercial companies, from other big reference labs, from academia - it's quite remarkable the number of people who are asking us to look at their tests under this EUA paradigm.

Most of them are nucleic acid based tests. Some of them are very complex, multiplex tests. We are only really looking at the part that is going to be differentiating the H1N1, and there are the regular RT PCR systems.

The time to results ranges from 40 minutes, some of the nucleic acid tests are getting very sophisticated now, and are almost to a point where they could be used in a doctor's office. Very little preparation.

They are not quite there yet, but that's obviously where these kinds of tests will be in the next year or two.

Some of them take much longer.

And of course there is - I think it was stressed earlier on that the best assay is one that can be done and have results in that window period when you can give the appropriate antiviral therapy. So something that is four days may not be that useful to a physician and the patient.

Again it's unfortunate we have not seen rapid tests for us to even review yet, so that is something that we need to encourage developers of these kinds of tests to have something out there to replace the rapid tests that are available.

We have very interactive reviews with the sponsors as we call them, and depending of course on how good the data is, and the data that we require is what we feel is no more no less than what they should have

done to validate internally their test in the laboratory.

So we are trying to be as least burdensome as we can and do a very thorough more of a risk-benefit type of review, but on the other hand still trying to make sure that the safety involved as well.

So it's a very good submission we can turn it around in several days. Some of them if we feel it's very important we will hang in there and work very closely with the sponsor, because we feel it's the kind of assay that should be out there. And that can be maybe up to four weeks. It took us about four weeks to get the DOD assay from start to finish out the door. But in the end it turned out to be a well worthwhile process.

So again, how do we prioritize? We have - like I said, sort of flooded with all these requests. What is the practice or the process in terms of the public health need?

We do consult with our colleagues on what they think is the need out there at the time. And at the moment the big question is, do you test or don't you test? We know that probably 99 percent of the positive influenza tests out there are the 2009 H1N1. There is a philosophy that says that if you find three students in a school and they all have that particular, they come up positive on the H1N1 assay, you don't need to test the rest. And that is probably a very practical way of doing that.

But unfortunately the mother of the third, fourth, fifth, sixth, seventh and eighth person probably still wants to know if that's what their child has. So it's going to be very interesting over the next month or two to see if we really do have a surge of testing like there was in the beginning, or whether we've gone back to the status of a normal seasonal flu where you wouldn't see that kind of a surge.

Nobody knows, but it's going to be very interesting to see what happens.

Again, we prioritize on how we review the tests. We do as many as we can of course. But obviously if we get a request from the CDC for something that they feel is important, we will prioritize that. This week for example we have had a request to look at different specimen types, and what we have already approved or cleared under the EUA.

It appears now from some cases that have come out in publications that some of the hospitalized patients, they are showing up as having negative on the H1N1 tests, for example in nasal swab, the upper respiratory type of specimens, the disease has sort of gone down into the lower respiratory areas, and there are reports that if you take a BAL specimen, then that comes up positive. That wasn't one of the specimen types that we had looked at. We are going to look at some data on that, and as quick as we can get that into

the package inserts of the CDC assays so that the public health labs can test those kinds of specimens.

So that is something that comes up, and we will jump on it as soon as we can, because that does seem to be a very important request.

Again, what do we look in the diagnostic testing area, not the public health surveillance? Well, we will look at a company, for example, that we feel can come up to speed in manufacturing if there was a big surge; if they have instruments in the laboratories. Many of the labs have lots of a particular kind of instrument; that would be very useful to have assays out on those kinds of instruments. And again, the complexity issue, if there was a good rapid test that came in we obviously would be pushing that too.

And I mentioned that.

So what is the FDA's short and

long term strategy at this point? Obviously I told you we are tracking at the moment any potential shortages of any of the diagnostic devices or ancillary reagents. We have had to track and act on a lot of false claims for diagnosis as well. On a daily basis. And of course we are going to try to make it even easier for people to send in the information for us to review.

We have put together a standard sort of template, fill in the gaps, what information we would need to look at for these assays. And we have put together a guidance, which hopefully will contain that template, and that will go in and out as quickly as we can through the FDA system.

And again I mentioned we have to continue to balance that need versus the safety and effectiveness that was mentioned in terms of how FDA is looking at the antivirals and the vaccines.

Just a few things. Prioritizing,

we would have to prioritize, obviously, if there was a virus reassortment that occurred. We are looking at, we have had several companies who are interested in talking to us about devices that look at antiviral resistance, and I mentioned we are encouraging submission of 510(k)s for the H1 assays.

This is something we usually put forward. This is the last slide, but this is why we feel it's of use for people to submit their assays through the FDA. There is a certain consistency in the way that we are looking at these assays, so the assays can be compared. We spent a lot of time on the information and the interpretation of results, and the limitations of those assays are put into product inserts so that's a transparency.

And of course we do consistently monitor the manufacturing of these so that every lot that comes out is hopefully the same as every other lot, because they have in place their quality systems.

We have reporting of adverse events, and if there are problems we do have enforcement tools.

And our motto is actually transparency and due process.

Thank you.

CHAIR QUINLISK: Okay, thank you very much. Appreciate obviously all the work you've been doing to try to ensure that we have laboratory diagnostics available to us during this thing.

I'm going to go ahead and open it up for comments from the Board and ex-officio members as well as the Disaster Mental Health Subcommittee. And I guess we'll just start with you, Ruth.

MEMBER BERKELMAN: Thank you very much for the presentation.

One thing I am concerned with is, I don't - and you did not actually address this, so it's us as a body, I don't think we should minimize the effect that severe

restrictions of testing like limiting to the LRN has on when we do these severe restrictions for any new pathogen including the H1N1 influenza virus, its impact on surveillance statistics.

And these surveillance statistics do form the cornerstone for many of our policy decisions such as the vaccine priority groups. And I'm wondering if anyone has actually assessed the testing bias, that they have to go through this hurdle then to get things tested, whether they are more likely to test the young than the old, for example.

And my second question is whether there is any effort to revive what used to be - and I'm talking decades ago -- a relatively robust relationship that CDC had with the clinical labs, the academic labs, often around the country, almost like sentinel clinical labs as well as the public health labs, which I think you have done a fantastic job of revitalizing in recent years.

DR. SHAW: I will address the last one first because it's the easiest one to remember.

We still have quite close relationships with several of the largest clinical laboratories around the country. Probably not as many as we had say 15 years ago, because the thrust has become more toward working closely with the state public health laboratories. Of course the whole LRN system was set up for a lot of those same purposes.

But there are several in particular, and one of the things that probably isn't as high visibility is increasing interaction with veterinary schools because of the need to keep track of possible zoonotic infections. So those interactions are still there; they are just different, for different purposes.

I remember there were some fairly close interactions with several large academic centers when for example the preclinical

trials for the live attenuated influenza virus vaccines were being conducted under NIH auspices, CDC was very heavily involved in that.

It hasn't gone away.

MEMBER BERKELMAN: I'm actually thinking even back to the '70s. And I think that the LRN is extremely important, but also we ought to really look at having good relationships with those medical school academic centers and clinical labs.

The other question was about the testing bias.

DR. SHAW: Yes, the testing bias, I'm really not even sure how to go about finding out about that. I don't know if anybody has looked at that. You mean a bias that is inherent in their catchment area or the type of specimen that they take in?

MEMBER BERKELMAN: Some providers or hospitals just don't want to go through the hoops to get specimens in, that they may be

more likely to do it for a child than an adult.

We can talk about it later.

CHAIR QUINLISK: Steve.

MEMBER CANTRILL: Thank you both for your presentations.

I share your concern about the use and misuse of the rapid flu tests. And I am very concerned about inappropriate clinical behavior based on results. And as you mentioned, very often it's not even better than a coin flip.

And I applaud your efforts to continue to try to educate clinicians about their limitations.

A couple of suggestions. One, I would suggest maybe bifurcating your comments about labs. When the clinician starts to read about PCR his eyes glaze over and he becomes irresuscitable, as opposed to the rapid test, the one that he clinically is going to use.

And two, I think the comments

about timing and specimen collection are very cogent, and that is not solved by having the information sheet in with the test. Because the guy that decides to order the test, and the person that collects the specimen never see it.

So I would encourage you to incorporate aspects about that, appropriate timing and specimen collection, in terms of further education. And thank you for all the work that you have done on this difficult problem.

CHAIR QUINLISK: Okay, Andy.

MEMBER PAVIA: So Steve, actually my eyes start to glow and I salivate when you talk about PCR; it's rapid tests that leave me cold. And actually I think that the lateral flow immunoassay probably may have been pushed as far it can go in this area, and it's time to move on.

But thank you both for all the work you've done, and thank you in particular,

Michael, for putting the protocols out there, because I think that was an enormous service.

I think some things didn't work quite as well, and you know, take it the right way, but I think it's important to point out some limitations. The platform restriction probably prevented wider use in the fall and now in the spring. I mean the ABI-7800, 7900 are perfectly appropriate platforms and they should have been used.

The specimen type restriction, I understand the reasons and the lack of data to support that, but it certainly created a lot of confusion and difficulty, particularly when the nasal washes were not considered acceptable specimens.

So by way of a question, I wondered what have we learned from that, and how can we modify the EUA process? And I agree very, very strongly with Ruth that public health is well served by having robust sophisticated diagnostics at the bedside, and

that is how we detect emerging infections; it's where we get unbiased samples of what's going on. And I think the change we need to make in the near future is to allow some more sophisticated platforms to get out to the reference lab, to the busy university center, to unburden public health labs, but also to widen the surveillance net.

DR. HOJVAT: And that's exactly what we are trying to do in terms of the prioritization. We are trying to get ones in the different platforms, a platform that maybe 1,000 labs have. Or more reference labs, or even the medical centers seem to be close to the public health labs are also interested in getting that stamp of authorization. It's kind of interesting, we didn't think they would be doing that. But they also see I think the value of having one group looking at all of the assays. I'm not saying that that is what we can manage to do for every single lab developed test out there. It's been

interesting to see that big academic centers who obviously have been supporting the public health labs also would like some sort of stamp of approval for their validation which they - hopefully most of them have done a very good validation, and it's a very quick process just putting it through.

But the idea is to expand the possibilities as much as we can. It's gone slower than we thought, but that wasn't for the lack of our review time. It's for the lack of those kinds of systems coming in to us. We were hoping we'd have a lot more out by this time.

MEMBER PAVIA: Do you foresee though that if we were to do this again that you could for instance expand the indications to specimens for which other data suggests that it's a good or perhaps a pure specimen, without having platform-specific data on that specimen? So in the case of NP wash samples, for example.

DR. HOJVAT: It's always a tricky question. I mean as a scientist you want to see data. It's not - in vitro diagnostic tests are not just, it works on this, therefore it will work on that. There are differences between an ABI and a light cycler. They don't quite work the same way. They have to be tweaked a little bit. So that tweaking is - looks good, then we can show that, that's fine.

We're only been asking for people to show that they can pick up between about 20 positive specimens, for positive by the CDC assay, and 100 negatives, and then some LOD studies and some - and a lot of thorough examination of the primers and probes. It hasn't been an extensive evaluation, and for each specimen type to at least have more than one specimen, just a few specimens to make us feel comfortable.

CHAIR QUINLISK: Okay, what I'd like to do now is go ahead and open it up for

public questions. If you are a member of the audience and have a question, please come up to the microphone and state your name.

And operator, if I could ask you to see if there is anybody on the line that has a question.

OPERATOR: Ladies and gentlemen, at this time if you would like to ask a question, please press star one.

CHAIR QUINLISK: Operator, is there anyone on the line?

OPERATOR: At this time we have no questions.

CHAIR QUINLISK: Okay, then, in the interests of time since I see no questions here either, I would like to thank the panel again for being here today and giving us that wonderful update. Thank you.

(Applause.)

CHAIR QUINLISK: What I'd like to do now, since we do have a very important piece that we want to make sure we have time

on, and we do have people who have to leave a little early, I'd like to go right into our next session.

Those of you who need a break or would like to get a cup of coffee, please just go ahead and do so as we go on with the next session.

Our next session is going to be on the Disaster Mental Health Subcommittee, some behavior health considerations for H1N1. And two members of that committee, or actually multiple members of that committee are going to give us some updates.

Dan, you are going to go ahead and - I'll let you go ahead and do the organization and introductions.

DISASTER MENTAL HEALTH SUBCOMMITTEE:

BEHAVIORAL HEALTH CONSIDERATIONS FOR H1N1

DR. DODGEN: All right, then.

Okay, we were just having a minute of not technical difficult, more just confusion. But we are all settled now, so we are ready to

roll.

I think you all know me. I'm Dan Dodgen, I'm the executive director for the Disaster Mental Health Subcommittee, and also the director of the office within ASPR that coordinates both mental health, behavioral health, as well as the at-risk or special needs populations.

And really I'm just here to introduce our chair, Betty Pfefferbaum. Before I do that, though, I do just want to thank the Board again for the opportunity for us to come and speak with you, for the incredible inclusiveness not just of this day, but of course Dr. Lurie and her remarks this morning as well, we'll make sure to thank her separately.

We really appreciate this opportunity, and I think just the whole discussion today has pointed out that there are a lot of behavioral health concerns, and mental health concerns, that I think are

germane. So I hope it will be for everybody a nice switch. We've had some incredibly interesting but also very detailed and very precise scientific information today. And now we are going to switch, it will be equally scientific, but now we are going to move into some other ways of thinking about flu that I hope will be of interest to the Board and will foster continued thinking and continued collaboration.

So I'm going to introduce our chair, Betty Pfefferbaum. I think you all know Dr. Pfefferbaum who is also at the University of Oklahoma Health Science Center in addition to chairing our subcommittee.

DR. PFEFFERBAUM: I want to echo Dan's appreciation for your having invited us here and for your consistent attention to the mental health and behavioral health issues. Obviously in the face of a threat like H1N1, mental health and behavioral factors will influence health and safety outcomes for both

individuals and communities. The government response must contend with a number of psychosocial issues. For example one issue is coping with multiple uncertainties. We've heard a lot today about the limited availability of the antiviral medications, and also the vaccine. We are also concerned about things like the fact that individuals may have to make alternative arrangements for child care, or there may be loss of income when people are forced to stay home from work, or when they are simply adhering to some of the community mitigation strategies that Dori reminded us of this morning.

A second challenge will be in clarifying conflicting information, to promote protective action which would include things like adherence to a community mitigation strategy, public health recommendations, and public directives.

At a systemic level we are concerned about threats to the continuity of

essential services, and to the appropriate use of health services. We would expect a number of emotional reactions to the threat of this virus, things like confusion as I've mentioned, anxiety and depression, and the potential for an increase in adverse or health risk behaviors, things like drinking, smoking, et cetera.

Unchecked, health anxiety can have a number of repercussions that themselves can be quite serious. For example, noncompliance with some of these public health directives. But at a more systemic level a surge in demand for health services and complications in the triaging across health services. We haven't spent much time today addressing issues related to the workforce, except for some mention this morning about the importance of communication to providers.

If Steven Hobfoll's numbers are correct, and 30 percent of nurses believe that the vaccine can lead to the illness, I

maintain that we have a very serious problem in terms of workforce issues that will demand your attention and the attention of those of us in the behavioral health sciences.

You've talked quite a bit about the various risk groups. We are concerned about risk groups as well. Our concern tends to focus on issues that make people at greater risk for other reasons. Of course we are also concerned about those individuals in risk groups that have greater medical comorbidity. But we are also concerned about things like limited access to health care services and health care systems, and things like difficulty that some individuals or groups will have in simply comprehending what public health recommendations are and the directives that they are given. This may be due to things like their disabilities or impairment in their cognitive functioning. Or it may be due to simple things like limited proficiency in a language.

And again we have identified risk groups. Many of these are on the list that you have prepared. But I would point out concern for psychosocial reasons as well in, for example, people with disabilities, people living in institutional settings, those individuals from diverse cultures who have language problems and individuals with chronic behavioral disorders or those individuals who have substance abuse disorders or who are dependent on pharmacologic agents.

Our committee is particularly concerned about those people who are receiving mental health and substance abuse services. We highlight these individuals most basically because they are within our charge, and because they are typically a neglected population. But there are other reasons as well. First, many of them have comorbid medical conditions. Many of the mental health and substance abuse services and programs are delivered with services delivered in

congregate settings, settings which will increase the risk for rapid transfer of the virus if it lands in one of these settings.

And third, because it is unclear the extent to which these mental health and substance abuse programs are fully integrated into local and state health programs, and thus the degree to which the clients and staff in these systems will have access to appropriate assessment, vaccination and treatment.

We have identified three areas for presentation to you today, of various recommendations. They parallel the three working groups of our subcommittee. First is the delivery of appropriate individual community and systems interventions that include both infrastructure development and program guidance and assistance.

Second is in the area of education, training and consultation, to providers, decision makers, leaders and the public.

And third is in the area of risk communication.

So first with respect to mental health interventions, we've identified three areas, around which we have developed a set of recommendations to share with you. First, we recommend a focus on interventions that address uncertainty, that enhanced resilience and coping, and that foster adaptive behavior, so that people will respond appropriately to the recommendations that are put forth.

Second we recommend that the needs of these vulnerable populations be carefully considered, keeping in mind that many of the vulnerable populations do not self identify and they may not be obvious. These vulnerable populations live in heterogeneous settings, and they may require support for other functions if there is a disruption in various services.

And third, we strongly urge you to include disaster mental health in all of the

activities at state and federal levels, because an integrated mental health program and approach will be most effective. For example, we suggest that you establish a real time reach-back capacity to mental health experts who can serve as an advisory panel for you, and for various state efforts.

Our committee is currently compiling a list of potential partners who can function in this regard.

Second, we recommend that you create a priority advisory team that can assist through ongoing activities with you, a team, a smaller team that can be kept apprised of the evolving situation, and provide assistance and advice as you make important decisions in how to address and manage this crisis.

Again, I think members of our subcommittee may actually be available and appropriate as members of this advisory team, and we also can make other suggestions to you

about who else might serve.

Third, we recommend conducting field tests that would examine health behavior and unmet needs. This is not dissimilar to studies that are conducted in other emergency management situations or in other public health situations. The studies of course will differ in terms of content, and in terms of the interpretation of assessments, and in interventions, and they might require mental health expertise; again, I think our committee can be useful to you in identifying individuals and approaches for some of these studies.

We recommend that you facilitate collaboration across government entities and levels of government with state and local providers, and with professional guilds. This would have the advantage of expanding both the knowledge base and provider capacity, and again I think we can help. We certainly can help connect you with the professional guilds

and perhaps with some of these other entities as well.

We urge you to prompt the federal agencies that work with local and state mental health authorities to ensure that community mental health programs develop continuity of operations plans, and that you provide technical assistance and guidance in developing those plans.

And I echo Dr. Lurie's suggestion this morning about the importance of community resilience. A number of professional groups across the country have begun some rather exciting examination of what community resilience is, how we measure it and how we develop it. So again, I think we can help identify some of those resources for you.

Obviously we need to use the short time available wisely to create and capitalize on a sense of urgency that is clearly felt in this room but is not so obvious in the community or public at large, and there is a

very important need to counter the existing apathy and complacency but also the potential skepticism that we are likely to encounter.

We have talked about the ways in which hopefully this pandemic will be less serious than we are preparing for; that's our hope. It's certainly not a certainty.

But even if it is less serious than we had planned for, this represents for all of us an excellent opportunity for us to have a rehearsal for the more serious all hazards preparedness activities for which we already have some infrastructure, and you certainly are adding to that infrastructure very nicely through the activities of the Board and various other federal and state partners.

We should also seize this as an opportunity to study the broader human consequences of this pandemic, and also the effectiveness of the various community mitigation strategies that are put in place.

I want to note that a critical piece of mental health intervention for many of us at least as providers is the use of education and training. And education and training requires careful consideration of messages, strategies, and risk communication principles. So I turn first to Dr. David Schonfeld who will address education and training, and then Dr. Ann Norwood will speak to the issue of risk communication.

DR. SCHONFELD: Thank you. I'm going to begin by thanking Jerry Jacobs and Beth Boyd and other members of the Mental Health Subcommittee that helped me compile these recommendations that I'm going to be addressing. And my goal here is to outline just briefly some of the major recommendations related to training and education. And I've chosen to do this by structuring it for four target audiences: mental health professionals, health care providers, schools, and the general population. And I will concentrate on

10 actionable recommendations, some of which we can complete readily, and some are going to take a bit more time to complete, but we feel should be initiated now in preparation for future events.

Let me start with mental health professionals, and there are four recommendations to this group. The first is to prepare and make available disaster mental health educational materials that would be suited for all hazards, and could at least in the short term be applied in the context of a pandemic. A subgroup of the mental health subcommittee would be formed to either identify preexisting documents and/or assist in drafting a brief document for this purpose.

In reality many mental health professionals have not received training in disaster mental health, or even traumatic stress, as part of their professional graduate education. A large scale or worsening pandemic will likely require significant

involvement by more mental health professionals that are currently not yet trained in disaster mental health.

While there won't be enough time to educate these mental professionals fully in disaster mental health, during the outbreak, some guidance could be provided to these professionals to help them use related knowledge that they have so they could apply it in the setting of a pandemic. And these materials would cover issues around traumatic stress reactions, crisis intervention, bereavement support, and potential long term effects of traumatic events.

The second recommendation is to begin work on disaster mental health educational materials that would be specific to a biologic natural disaster such as but not solely a pandemic, and this likely would not be completed within the next couple of weeks. For this purpose we would want to include not only members of the mental health

subcommittee, but also representations from the guild associations so that we can be sure that we have contributions toward the development and then the subsequent use of the materials.

The third recommendation has to do with disseminating a handout or handouts for mental health professionals about addressing the needs of individuals with preexisting mental health problems during the pandemic. A crisis situation of any nature often uncovers past crisis events or losses that were not completely resolved and/or concurrent stressors which may for individuals become the primary focus of their concerns.

Let me tell you a brief experience I had with one school. A field trip of children had been accidentally exposed to a chemical agent, and it was unknown initially what this was, and it required the decontamination of a busload of children at a hospital. This was handled particularly well

and smoothly. But there were two students who continued to have ongoing mental health needs, panic attacks and inability to return to school. When I talked to them, it was discovered that one of the students was not that well known to the school. She had moved there one week prior. The reason for her move was not known until that point, but it was because her mother had been murdered.

The second child, in ongoing work with that child it became clear that she was being sexually assaulted by a family member, and that was the reason for her panic attacks.

The reason I mentioned this is that invariably I tell people that when it seems like a disaster is overwhelming and everyone is having trouble dealing with it, it actually gets worse. You have to help them deal with everything else that has ever bothered them or is bothering them.

As a result individuals with preexisting mental health problems that appear

to have been resolved are very likely to have a recurrence of some of their symptoms during a pandemic. Individuals with ongoing mental health problems may experience as well an exacerbation of their problems.

In the context of a worsening pandemic we have to realize that there will also be limited personnel availability within the context of an already overburdened mental health system. As mental health providers themselves become ill or need to care for their family members that are ill.

So continuity of operations as was already alluded to becomes a challenge.

But when you add to this that they need to serve more patients with mental health concern and a population of patients with worsening symptoms, the likely stress on the mental health system becomes obvious.

So guidance that helps mental health providers anticipate such issues, and offers practical advice on how to triage more

effectively in the context of the pandemic would become important supplemental materials.

So the members of the mental health subcommittee remain prepared to offer technical assistance and support to others in the development and dissemination of such resources.

The last recommendation for mental health providers has to do with the importance of developing and disseminating guidance materials on bereavement support that is suitable for use by mental health professionals directly and/or via distribution to other care providers or to the general population itself.

We need to realize that what distinguishes H1N1 or any pandemic is not really the nature of the virus, but the concerns that the public has about the potential for high fatality rates. Bereavement therefore is not an incidental or just - it is the main reason why people are

concerned. So it's critical that we prepare mental health professionals, health care professionals, and other professional audiences to provide compassionate death notification, and effective bereavement support services.

Although bereavement is a normative experience, it can have a profound and lasting impact on an individuals' adjustment and coping. There are actually few life stressors that even approach that of the death of a close family member, in terms of broad and sustained impact. Despite this there is very little discussion going on about bereavement in this setting.

And most mental health care professionals receive little structured training on bereavement support during their graduate education. If the pandemic should worsen and the number of those dying increases to a significant extent, it will be critical that all mental health professionals be ready

to identify and treat complicated mourning and provide assistant and/or referral for bereavement support to those experiencing losses.

Let me now turn to health care providers, and with this I include pediatric and adult medical providers, physicians, nurses, paramedics, emergency medical technicians, and quite frankly, anyone that provides direct care to patients and/or delivers related services.

And there are two recommendations for each of the three remaining groups. The first is to disseminate guidelines for health care providers on providing psychological support to patients in the context of a disaster, performing rapid and effective mental health triage and facilitating referrals for services.

For pediatricians and other pediatric health care providers, one example would be the AHRQ funded pediatric terrorism

and disaster preparedness resource, which has a large section on mental health needs which several people in this room contributed to.

We want to enlist the medical professional organizations in the development and/or dissemination of these guidelines to ensure their relevance to health care providers and facilitate their use.

The primary medical care has become in our country the de facto mental health care system, due in large part to the longstanding inadequacy of resources within the mental health system, the stigma associated with seeking mental health care, and the formidable barriers to access and reimbursement within our current health care system.

Our primary care providers are the first responders in this pandemic, and they will likely serve that role in most disasters related to the mental health needs of a population. So we need to make sure that

primary care providers can effectively detect somatization, screen for adjustment problems, perform timely and effective triage for mental health needs, provide brief support of interventions, and make effective referrals for mental health support and counseling.

Yet again the training of providers in these important areas has traditionally been limited. In health care providers, when surveyed after major disasters, consistently report their lack of knowledge and comfort in these vital areas.

In the long term it's important that we remedy these gaps through professional training and continuing medical education. But in the short term we can offer guidelines and educational materials. And I would emphasize, many of these already have been developed and can be made readily accessible.

The second recommendation is disseminating educational material for health care providers on bereavement support, and

patient education materials for their use with families after a death has occurred. We can enlist the medical professional organizations in the identification and development of materials for health care provider training and education, and in the dissemination of these materials as well as relevant patient education materials.

And I will say just as an aside the American Academy of Pediatrics has already identified many suitable resources and placed it on a disaster webpage.

During a pandemic it's highly likely - and I hope this is self evident - that most deaths will occur in a health care setting. Health care providers will therefore be intimately involved in death notification, and will be in the optimal position to ensure that the needs of grieving adults and children are anticipated and hopefully addressed.

So educational materials for health care providers that relate to death

notification and bereavement support for families should be disseminated, and again, they are already available, as is information suitable for health care providers to share directly with the families that they care for, so they can provide support to family members.

The third area has to do with recommendations for schools, teachers, and teacher mental health systems.

The first recommendation is to disseminate guidelines for school professionals, whether they be in the mental health area or members of the teaching staff, on how to provide psychological support to children in the context of a disaster, with information on performing rapid and effective mental health triage and facilitating appropriate referrals.

We recommend that schools partner with local and regional experts in disaster mental health in order to begin to provide local in-service training to their staff.

Most mental health support after a disaster that is delivered to children at least occurs within school settings. We know this from a number of disasters. It's therefore important that we prepare school mental health professionals, teaching staff and other school personnel so they are prepared to support children and the school staff in the context of the current pandemic.

Educational and training options already exist. And training materials are already available, but collectively - I'm just saying we're not placing the blame in any one area - the educational system has not generally placed this as a priority to date. And the resources are generally unknown and underutilized. Children who are having adjustment difficulties in the aftermath of a disaster or crisis are not accessible to education or capable of learning effectively while they are dealing with these issues. So attending to these emotional needs is the only

way that they will be able to attend to their education. So this should not be seen as competing with educational coursework or educational goals; it is rather the only way to meet them.

The second recommendation has to do with disseminating educational material for school professionals on bereavement support as well as parent educational materials that can be used with families after a death has occurred, but that they may not receive if they don't go to a health care setting.

I have already underscored the importance of attending to bereavement needs and the roles schools can play in supporting children. As director of the National Center for School Crisis and Bereavement, I have to say I'm particularly concerned about the current state of readiness for our schools to meet these critical needs of our country's children. I can actually think of no better time when this is more critical. And I think

I echo what everyone else is feeling, I hope there never is a more suitable time where this is more timely.

Again materials are already available, but unknown and underutilized.

The last group is the general population. The first recommendation is to establish a working group to include representation of different guild associations in disaster mental health and other interested mental health professional organizations to reach a consensus on a common model for community-based psychological first aid, or what I will refer to as PFA.

Professional organizations representing mental health fields can encourage their members to help communities develop culturally responsive programs of psychological support that is provided by members of the community to one another, to build the community resilience we've heard about.

Such an endeavor likely will take several years to bring to fruition, and require a concerted national effort. But the current pandemic underscores the need to start that process now, as soon as possible.

Psychological first aid as used in this context refers to psychological support that is both used to improve one's own resilience, and it's provided by non-mental health professionals to family, friends, neighbors, coworkers, and to students.

PFA focuses on education regarding traumatic stress on active listening. The term also incorporates more sophisticated psychological support that might be delivered by primary care providers to their own patients.

Properly executed psychological first aid is adapted to the needs of each group or community implementing it, and sharing the PFA that is introduced in the community doesn't conflict with the

community's world views, but instead includes effective strategies that may be specific to the group. This is often done in concert with the representative community committee which helps to ensure that what is being developed is responsive to that specific community.

The second recommendation is to disseminate information for how families and other caregivers can support children who are grieving, as well as information for grieving adults to support friends, relatives and themselves.

So lastly we should ensure that members of the public are optimally prepared to provide bereavement support to those who are grieving, whether that be family members or friends.

These materials as well as others already recommended should be readily disseminated such as through electronic formats, which we feel should preferably be housed at a central government site for ease

of action. There are times to Google, and a disaster is not necessarily the best time to do that. It would be better if it was centrally located.

As well these should be available in audiovisual and print formats to reach different audiences. Although it is not particularly relevant to a flu pandemic, these materials should also be made available as well at any facility that serve as a shelter or a go-to facility in the aftermath of a disaster, and is something else to consider for future planning efforts.

Thank you.

DR. NORWOOD: My name is Ann Norwood, and I first wanted to acknowledge Brian Flynn, Lisa Brown and Steven Hobfoll on the Disaster Mental Health Subcommittee, who helped me put this together, and also other members who chimed in.

Today we wanted to begin by just recognizing a lot of the really great work

that has gone on already in this pandemic. And specifically, I think we heard today from a number of speakers about important efforts to do good communications from all levels of the Health and Human Services, from CDC, from ASPER, and so forth; and that indeed communication is one of the four pillars that we are looking at as a nation in terms of responding to this event.

Similarly we want to thank NBSB for inviting us and for their recognition of the importance of communication. My first slide is not really intended to be death by acronym for those of you in the back, but rather just to show that this has been a crisis, a chance to exercise what might be needed in other crises. And there is a document called the National Response Framework that again in the aftermath of 2001 a lot of work has gone into preparing our nation for a variety of bad things that might befall us. And one aspect of this is a

communications plan, and during the H1N1 spring outbreak several of these different components were used.

And there's a series of incidence communication conference lines. Some targeted at the federal partners, so that everyone knows what's going on so you don't get different information. Another is partnership with state participation, and others with the private sector. So again this is an effort to make sure that everybody is up to date about what's going on, and one of the efforts to ensure that we speak with one voice, or at least not with a lot of conflicting information.

And that seemed to work well. Not only that, but they have taken lessons learned from the spring experience to make this process go better for the fall and the winter.

Another thing that we really, for those of you outside the federal government who have never worked there, it's really hard

to get outside your agency and be aware of what's going on in other agencies. And we have just been very impressed by the high level of interagency cooperation, especially around communications. There have been a lot of very hard working people tackling many of the issues we have heard alluded to today in the context of a rapidly evolving event. So again, kudos to those folks.

And then finally, I think we have heard alluded to as well, HHS and CDC efforts to engage both traditional media and new social media in trying to tee up what the issues they might expect to cover are in full, and the common goal of trying to get out accurate information in a timely fashion. So again these are things that we just wanted to acknowledge, and think worked really well.

Going forward we wanted to encourage several things. First of all the integration of behavioral health factors into all health messaging. And what we know is that

communication plays a central role in influencing individual and group behaviors, feelings and thoughts. As someone said before you can have a great vaccine but if no one takes it, you haven't gotten very much from that.

We feel that mental health experts can play a valuable role in developing messages that are compassionate, respectful, understandable and effective. Behavioral health practitioners may be especially helpful in times of high level of stress and anxiety to help particular populations, for example those caring for very ill individuals at home.

We also believe in the expanded use of nontraditional communication, the old adage a picture is worth a thousand words, leading by example. And understandably most messaging relies upon the written and spoken word. But nonverbal communication is also valuable, especially when you think of the relatively low literacy level in terms of science in the

U.S. And the example of say a photograph of a mayor or a faith-based organization leader standing in line to receive a vaccination sends a very powerful message, I think a lot more than someone else standing up there telling you all the reasons you need to get your flu vaccination.

Similarly, we also find in terms of issues such as stigmatization, that the images of influential people interacting with those at risk of stigmatization can also promote healthy behaviors. We saw this especially with SARS when it was first the Asian influenza, or Asian whatever it was called. And then also with the H1N1 in the spring.

Also again the use of comics, such as those laminated cards in airline seats, and pictograms to enrich and simplify messaging we think is very important. And actually it's very difficult to do that well. It takes a lot of work to go into that.

As we've heard other speakers mention, special populations must be acknowledged and addressed -- their needs addressed in messaging. All members of our society, taking into account such factors as culture, ethnicity, age, potential handicap and other medical conditions.

So again, different modalities may be needed, and other venues to make sure that all people here get the important message.

In particular from a mental health perspective we think that we need to anticipate issues that have high psychosocial impact, and I think today's caller asking about - I don't know what the story is with the 11-year-old, but clearly we've seen across a number of incidents that sick and dying children have a very powerful saliency to our humans, especially in the U.S. And we can go disaster by disaster and show you how that feeling of helplessness, if you see that you can't help kids, is really a very profound

thing that you want to try to make sure doesn't happen.

And some of the things that we also want to anticipate is, hopefully, things will not evolve in a bad way, but that in the current social climate in - and there is a fair amount of sensitivity around a number of issues shall I say? - and if you think that things should evolve where there is a scarcity of resources, we think there are some things that need to be taken into account. For example things like a services to undocumented populations, potential interruptions of commerce and supply chain, and perceived fairness and equity of services are a few of the sort of hot button issues that I think would happen.

And again these already underlying potential social divides would take on added psychological weight in the context of scarcity. And one of the things we have to remember about the United States is that,

because of our Constitution, we have federal level guidance, but ultimately the states will do what they think is in the best interest of their population, their citizens. So that we saw again in the spring where people may have the same goal in mind, but they may have different ways of going about it. So if things get bad, and different jurisdictions are doing different things, it's not really so much speaking with one voice, but how to explain all these different options.

So while we don't take a position on these issues, we just think that understanding the context in which we live is important in preparing our messages. And the impact and credibility of messages.

Finally we think it's important to maintain sensitivity to language and terminology. And again, as NBSB has been out in the forefront of, what do we call this thing, and I think the naming convention is kind of, that ship has sailed. But perhaps

going forward internationally there could some consensus about a way to come up with names for these things that are not - that work better.

Specifically we wanted to discourage the use of the term, "worried well." It's often used in the context of expected surge on emergency departments. One of the things we don't like about it is, it's very imprecise. When you say, well, we are expecting 80 percent of worried well. What does that mean?

And the other thing is, in this particular situation, you probably wouldn't get worried well, you'd get sick people who are afraid that they might have a lethal form of pandemic influenza.

So we think it's a lot more helpful if you tell people what it is you want them to do, and why, and especially to point out that - and this is a departure from what we normally tell them. In other words, we

kind of speak out of both sides of our mouth, I think. We say use an abundance of caution. Be pro-active. Do this and do that. But we are saying, well, not so fast on this particular case maybe.

So that again I think we need to be very good about understanding what motivates people to do certain things, and then seeing are there other ways we can meet their needs rather than lumping them all into worried well.

And again I just want to thank you all for all the hard work you are doing, and thank my team.

DR. DODGEN: All right, I just want to thank everybody for their comments, and thank everyone for your attention.

We want to move in a minute into a time of discussion with the subcommittee and the full Board. But before we do that, just two quick things.

One, I did want to acknowledge Dr.

Beth Boyd who is ill but who has joined us by telephone. So hi Beth, if you can hear us we're sorry you couldn't be here, but I did want to acknowledge that we do have a subcommittee member on the line.

And then I just wanted to turn it over to Dr. Quinlisk who wanted to make a few remarks regarding the subcommittee.

CHAIR QUINLISK: I think the first thing I'd like to say is just thank you and the subcommittee members for all of your hard work, to be honest not just on the H1N1 but on all of the issues. I think this is an area that we tend to know about but maybe not take as much action in as we should.

Two, the Board members, we have been given quite a few good recommendations from the Disaster Mental Health Subcommittee. What I'd like the Board members to do is look at them, digest them. I've also asked Leigh - I notice a lot of you had notes underneath the recommendations, and I think that I fully

supported those recommendations. So I'm going to ask if maybe we could get your notes as well as the slides. I think that would be very helpful, and then we will distribute that.

And then at our next meeting we will further discuss this, and perhaps at that point take a vote. So if the Board members could do that.

The next thing I wanted to do was just to bring to the attention of the Board and the public, in that we did receive a letter from Dr. Lurie, and there was some information about the Mental Health Subcommittee that I thought I would just read to you. There are just pieces of this.

But she said in her letter: "I know that mental health is a critical component to emergency preparedness and response. It is my intention to maintain a focus on the emotional and behavioral aspects of the work we do here at HHS."

She also said she would like us to do two things. "First I would like the NBSB to utilize members of the subcommittee to act as an ad hoc body of experts that could be called upon during events of significance. And then second, I would like the NBSB to convene the Disaster Mental Health Subcommittee in the next fiscal year to assess the department's progress in its efforts to better integrate behavioral health into emergency preparedness and emergency response."

So those are two things we specifically were asked to do with the Disaster Mental Health Subcommittee by Dr. Lurie. So I think that is something, too, I would like to discuss further at our next conference call at our next meeting.

Okay, I think now what we would like to do is to go on to the discussion for the members of the Board or other subcommittee members or ex-officio members, to go ahead and

ask questions.

And John, I think at this point I'm going to ask you to run the meeting. And I apologize, but I have to go.

Thank you, John.

MEMBER GRABENSTEIN: Planes won't wait.

So are there any questions or comments from members here at the table? And I see Aubrey here behind me. Captain Miller?

CAPTAIN MILLER: Yes, thank you, and thank you for the fine presentations.

One thing I wanted to mention, too, you talked a little bit about special populations with respect to mental health. And I've worked on disasters myself for a number of years. And one of the populations I find is actually the health care providers and the public health community too with respect to these. And I've seen it not only in others, colleagues working with me on situations, but even in myself, and that might

be - it certainly is an important group to be considered to have that support as well. And we tend to neglect ourselves.

And so I think it would behoove the department to also set the tone by encouraging its own mental health programs to support people working on disasters from both the public health and the health care provider perspective.

DR. SCHONFELD: First off I want to thank you for bringing up that point. I will tell you that I have that in an earlier draft, and then I ended up deleting it for time, and that was not a good decision, so thank you for bringing it up.

What I find often works well is to incorporate that into some of the educational material that is provided to providers about how to help your patients. And then add in how then also to help yourself and extend the same type of care. So that was the reason I didn't include it because I find if it's seen

as just mental health needs for health care providers, many of them will not access that in the same way. But it definitely needs to be a conscious part of what's rolled in, and also provided in specific services for the health care providers as well. So thank you for mentioning it.

DR. NORWOOD: Dori Reissman isn't up here right now. But I know she has been very active in conceptualizing it as part of an occupational health structure, and that within HHS, the public health service and so forth, that these kinds of issues haven't addressed and thought about. I don't know if Dori -

CAPTAIN REISSMAN: Well, thank you for that little plug, but that's true. We have been trying to address that through HHS and within ASPER itself in dealing with the federal responders. But it's been an upward battle as I'm sure you are aware.

MEMBER GRABENSTEIN: Jim James.

MEMBER JAMES: Yes, thank you for a great presentation. And this can go to the whole committee, any of the people up there. It's really not a question. It's kind of an observation, and a request, going forward. Because I think what you all need is more work so you can make more recommendations.

But this has to do with the worried well. And when - and I thank Anne for using that term; now I don't feel that it's pejorative.

But my son who is a child psychiatrist, when I used that term with him, said, well, you know dad, if you are worried you are not well. So. But one of the things that seems to be getting a lot of push over actually the past three to four weeks is the use of algorithms. Algorithms that are aimed at the general population for self triage, what the different motivations are behind those algorithms we won't go into, but certainly one of them is to relieve the stress

on the health care system by individuals who don't need to access that system. They don't use the term, worried well, but that is certainly I think a subset of that group.

And I would really like to see your subcommittee come up with some opinion, recommendation, input, on the use of algorithms in this kind of a situation, and the potential mental health implications.

DR. NORWOOD: I'm not going to address algorithms per se, but I just want - Lisa Brown shared a story - I think it was Lisa at lunch - about - or maybe it was Rachael - anyway long story short, people access health care for lots of reasons, and one of the things that has been seen on some university campus where lots and lots of students are sick is, parents can't get hold of their children, so they call the health clinic. Well, for those of you can remember back to your college days, there is usually like a skeleton crew there at all times. So

this is an example where worried well are calling. But if you say, put out information like telling the college kids, let your parents know you are okay or not okay. But also other ways people can get that information, you remove that burden from the service. So again I think it's helpful to think of what is it you are trying to accomplish. Now whether or not algorithms are part of it, I think they may play a role, but it depends I guess on - well --

DR. SCHONFELD: Let me respond to the issue about algorithms. Because through the American Academy of Pediatrics, I'm actually chairing a workgroup between the CDC and the AAP to develop guidelines or recommendations or clarification on, first off, those children with special health care needs who are most at risk, and actually what that means. Because people keep saying with -

I won't tell you the amount of time I've spent on calls where they say, well, they are

medically fragile, and I'm like, well, what does that mean. And then I get very long definitions of what medically fragile is, which don't always relate to H1N1.

So we've actually worked to develop a clearer sense of what those are, and I hope those will be released any day now. But in addition to that those are now being incorporated into the development of algorithms, both for health care providers as well as hopefully for the general public.

But part of the problem was, with algorithms you really need to know what you are recommending. There is one thing about how you communicate that to families. But we weren't even at the point yet where we had clear recommendations for providers, because we weren't clear what we should be telling them.

So I think we are moving along in that process, and now have a clearer sense of what to recommend. And then the next step

will be to communicate it in a format that health care providers can follow as well as families.

And I agree, there is a tendency to say, if your child has special health care needs, or if they are seriously ill, call your doctor. And then they call the doctor, and the doctor doesn't know how to ascertain over the phone, because usually the doctor is seeing patients. So then you have someone staffing the phone who says, well, come in or go to the emergency department. Then we have surge in the emergency department of everyone being sent in.

My own hospital is now opening up a flu clinic which will be staffed seven days a week until midnight, and all the faculty have to take mandatory shifts to staff this just because of the surge that we anticipate in the emergency department, which then has implications for closing other clinics, and for the health care delivery in the system,

even if it isn't a more serious pandemic, simply because we haven't communicated clearly about what families can do to take care of themselves, and what are the reasons for coming in, and then how they should access that care.

So it's an excellent point, and I know that at least from the pediatric setting there is some effort on that.

MEMBER JAMES: And one of the reasons I bring it up, and this goes directly to Dan, as different protocols come on the table, I really don't feel they have been well enough informed by mental health and behavioral input in terms of defining what you are trying to achieve, and then how do you best achieve it, from a behavioral health perspective.

DR. DODGEN: I guess I am supposed to respond to that, and then I know Betty wants to say something as well. So I'll do my best.

I think that - first off I think that there is a - what Anne's response and David's response I really think do fit together, which is, if we want to decrease the medical surge and the number of people presenting at various health care settings, we have to give people who are concerned things that they can do, steps that they can take, that will help them to make a better assessment.

We have to do the same for providers. And some of the work that David mentioned, there is a lot of work going on we know in the various - not just at CDC, but with many of the CDC partners and stakeholders, on ways that we can get providers better algorithms for making determinations about who needs to be brought in, who needs to be hospitalized versus you know treated and released, et cetera.

So we know that all of that is happening. I think though that you are

suggesting that there is a further step involved here, Dr. James, which is that we also need to do a better job of assessing the degree to which people are psychologically distressed and how do we measure whether or not we are addressing those concerns, and how do we also measure whether or not those concerns are impacting their other health care behaviors.

I think that those are issues that people are talking about. I don't think that we are there yet, but I certainly think that some of the recommendations and some of the activities that this group has already done can begin to speak to that. There are certainly other - there are tools, and there are papers out there who are also looking at these issues. But I'm going to defer to Betty, because I know she wanted to respond as well.

DR. PFEFFERBAUM: I think at this point it's probably just a summary of what my

colleagues have said. But I think in addition to having the effect of decreasing stress and load on the health service systems these kinds of materials have several advantages for individuals and families as well in terms of their educational potential, in terms of their ability to encourage individuals and families to take responsibility for themselves and their health care. And as Dan mentioned in terms of relieving anxiety.

MEMBER GRABENSTEIN: One of the -
I'm sorry, Ruth.

MEMBER BERKELMAN: Yes, Ruth
Berkelman, thank you. I was thinking about why people go to emergency rooms. And you mentioned that many times they are referred by the doctors. You have the clinic now all hours to man it, and you may know the answer to it. But I've heard from some that they are going there because they want to know. They are sick, and it may or may not be that they are worried about the illness, but they want

to know, do they have H1N1 or not. And they often just take the rapid flu test as the standard.

But this issue of knowing is one piece of this I think.

DR. SCHONFELD: I will say since this comes up a lot in the division that I run, it's developmental and behavioral pediatrics, and a lot of testing is done for children who have disabilities, when often you don't have any specific recommendation, but you can at least tell them what part of what gene has some difference. And you know we've had conversations about that. It's thousands of dollars with a fairly low yield in some cases. But what repeatedly is said is that at least then they know.

Well, part of it is, depends on why they want - they want to know it, because we as the medical field bring it to their attention as something that is knowable. And so that if we were able to translate - to see

their child or to see themselves as an adult and said, what's really important is this, and if they understood that, then that's what they'd want to know. But what we are saying is, there is this novel H1N1, and it's very serious, so of course they want to know, do I have that.

If we communicated instead, which might be a more difficult message, although I think it could be simplified, is that the virus that causes flu changes over time, and sometimes it changes quickly, and therefore we are not always - there might be less immunity to it, or we might not be as prepared to have it in the vaccine. So this one came more quickly, and we are working now to get a vaccine ready for it.

But once we start calling it something else, and stressing that it is highly different, then of course I would think anybody would want to know if they have it. But we defined it, and so we called it swine

flu, and then everyone wanted to know about pigs. So now we call it novel H1N1, and they see it as different.

So I think part of it is actually we are not thinking through what information we are delivering that is behaviorally relevant to the individuals, and then we expect their behavior to be guided by something other than that.

So I guess we've seen the enemy and it is us.

MEMBER GRABENSTEIN: I always thought that the Mexicans were very happy the virus is called California.

(Laughter.)

MEMBER GRABENSTEIN: Roberta, did you have a question?

MEMBER CARLIN: Yes, I really had more of a comment. I just want to thank all of you. I am aware that you put this presentation together in a very short amount of time and a lot of hours went into it. And

thank you for that.

I just had a comment regarding just the whole mental health piece, and controlling the anxiety that I think the typical consumer, citizen is facing right now with all these confusing messages. And as we were sitting here I just received an email from one of the many news services which says, CBS News: seasonal flu shot raises H1N1 risk.

Now you can just imagine the anxiety when you see this on CBS News tonight, and presuming people of authority are making these statements. So I think there is a clear role for the Disaster Mental Health Subcommittee to continue to work with NBSB on so many issues. And we look forward to working with you and your expertise.

DR. DODGEN: If I could just respond to that. Roberta sent me that email. If you see me looking down at the email, it's only because I'm reading stuff that Board members send me during a meeting; otherwise I

never would look.

But I think it really does speak to, I think, a very critical issue around communication, which I think we are trying to address here. And I know all the members of the Board have already read the report that you approved and submitted to the secretary down in December.

But I really want to emphasize that there is actually a lot of very good information, and particularly for the public members who are listening and people who are on the phone, there is a lot of good information and thinking about that, and really in that report, and everything that you've heard today, all the recommendations, they feel a little new because of course we've talked about what is relevant for H1N1. But they all grow out of what was in the report that you forwarded to the Board.

So in response to what Roberta is saying I guess I would just underscore that I

think we have now built a little bit of a baseline with what's in our report, and I think from that we can actually build and begin to talk about specific scenarios and specific ways to respond to some of these unique situations.

But I really wanted to emphasize that we've got a lot of information already at our disposal that we can now I think build from to respond to some of these kinds of issues.

MEMBER GRABENSTEIN: Here, and then down at the far end of the table.

DR. JUTRO: Well, I sort of did what you did. I just looked at my e-mail because I thought it was from a Board member. And it turned out to be directly relevant to the question that Ruth just asked. And it provided what I find to be a perspective that I had never heard before.

It's just a little announcement saying that the Medical Center of The Rockies

Emergency Room is preparing a swine flu drive thru. If more than 20 influenza patients are present, they are going to provide antiviral medication to patients without entering the ER, and if more than 40 are present they are going to move influenza treatment to another site completely independent of the emergency room.

So in essence it's a countervailing argument to the I think semi-rhetorical question that Ruth asked, and I thought it was very interesting. I'm curious about your thoughts.

DR. DODGEN: Well, first off, we'll see what the EMTALA says about that, although we know that that - the EMTALA has come a long way, and I think that it has been clarified a lot, what you can and can't do, and you can do more than perhaps we thought. But I won't speak on behalf of other agencies in that regard.

But I think again it underscores

the basic communication messages and principles that we keep coming back to over and over again, which is to make sure that we are providing information that is clear, that has specific actions that people can take, that helps them manage their anxiety by giving them actionable steps as opposed to increasing their anxiety by just raising more questions than you can answer.

I'll turn I think to Dr. Norwood or Dr. Flynn if you want to say more, or any others, because I think what you are saying sort of underscores the basic tenets or principles of communication.

MEMBER GRABENSTEIN: There is a placard up down there.

DR. HOBFOLL: Yes, Stevan Hobfoll. Great work by the Science Board, and our committee, great work. Great presentations.

I'm convinced that this is about the lowest level through out this kind of

level effort has to consider, and I hope that that's true. I've been in the military, and I've raised teenagers, so I know things can go very wrong that look okay. But for that reason we have to really use it as a template. And I think one of the major things is to get the information across. I use the example of USA Today or someone else mentioned the weather thing that you get online, that the information comes with a red banner at the top which tells you what is the temperature rating of how serious the threat is; then next in green what are you supposed to do. Next might be, what are the major obstacles; and then maybe if you do those things what are the likely outcomes. Because we could have a cry-wolf effect here of actually succeeding and then the public says, oh, why did we bother. It's because we succeeded in this case.

Now it sounds simple, but it means you have to take some risk. Because as soon as you say it is low level relatively, well,

that can come back and hit you if you turn out to be wrong. But you still have got to go with that. You can't - again back to the army analogy - you can't commit all your troops on stand up every time 12 soldiers on the other side come towards the border.

And we don't do that, and a lot of the messaging is very confusing, overwhelming, over-threatening. And then there is a general cry-wolf effect.

I think all of the work of the Board is critical, but behavioral enactment has to be a member of the Board, because no matter whether you are an individual clinician or in public health or have teenagers, getting them to behave that way - not just having answers, but then getting the behavior across - is the critical step and the one that we are typically missing; not the one, two percent of the variance of some very what happens to be a minute scientific question.

MEMBER GRABENSTEIN: Any response

or comment to that?

DR. SCHONFELD: Well, actually I just wanted to add a comment. A lot of what we talked about is really how individuals respond in disaster situations, but systems also have ways they respond in disaster situations. And I think the example of when hospitals plan is probably an example of what happens when a system panics is that with limited information, with a sense of impending doom, and not knowing better what to do, you come up with a plan. And systems often don't act well in disaster situations.

So I think to the degree we have talked about individual response, we need to think about how groups of people or communities respond. But we also have to think about how systems respond. And those could be health care systems; it also can be government systems.

So one of the things that we had talked about more broadly in the work of

Disaster Mental Health Subcommittee is to think about information about how systems and governments respond in disaster situations should be part of the training of government leaders as well.

But I think health care providers, and health care system leaders, should probably also be thinking about the impact of impending disasters on their decision making as well, not to be necessarily critical of that one decision.

DR. PFEFFERBAUM: And I would add that I think - well I hope that in light of recent news reports about failed terrorist plots that our public is sensitized enough again to the need for all hazards preparedness, and that the exercises that we are going through with respect to H1N1, and hopefully they will simply be exercises, serve as a rehearsal and as an infrastructure development to address other hazards.

And I think the public would

understand if we told them that, that while this may not be - we hope this won't be as bad as we are planning for, it will serve us well in the future.

MEMBER GRABENSTEIN: Thank you.

Captain Sawyer?

CAPTAIN SAWYER: I just wanted to give Beth Boyd an opportunity to say something, since she is on the line and she is not here in person. I know you are on the speaker line. I hope you're still there.

MEMBER GRABENSTEIN: Check if she is on mute.

CAPTAIN SAWYER: This might be a good time, do you think, John, to have the public comment?

MEMBER GRABENSTEIN: One more comment from me, and then we will go to the public comment. So operator, we are almost ready to call on you.

But Dan to you, I wanted to, as we begin to wrap up, what to do next. Every now

and again the Board members get transported up and dropped into a room together, or get connected by telephone together, and we do things, but we aren't everyday in the Humphrey Building or somewhere in downtown D.C. And so time is a wasting and it would be a shame to waste a month or two or three to do some of the things you have done. Because it's obvious in this work you have found some existing resources. You alluded to it in your slides.

And so if there is anything in existing resources that really ought to get blended into HHS action or U.S. government action in the next few weeks, I would hope you and Captain Sawyer and the others in the appropriate places would act on that, and get it - if it isn't already moving towards a website, or those sorts of things, to get it moving in that direction.

DR. DODGEN: That's, I think, a great question. I think David and others have

alluded to the fact that there are a lot of great materials out there already. I have to say, I actually said this on a phone call. I'm sure many of you know that the guidance this week came out from the White House Office of Faith Based and Community Neighborhood Partnerships on working with faith-based and community-based organizations in responding to the H1N1 influenza. It's actually a great guidance; it just came out this week.

And I was on a call as we released it where I said, oh, there is all kinds of great mental health stuff on the CDC website and the SAMHSA site or whatever at H1N1 and then when we looked it up we discovered that although there had been many good things, some of those links were no longer live.

So I think the first thing we probably need to do is make sure that the information that we already have is still accessible to the public. And those are often just oversight things. So I think that is a

first step that is relatively straightforward.

I think there are some other steps, which is, how do we figure out - and this may be something that the Board would want to make a recommendation about, I don't know, you can deliberate that yourselves, but how do we simplify the process of getting all the good information that is already out there, but that's in a million different places, how do we simplify the process of getting that either on a government site or on a professional association site where it will have a kind of credibility and easy accessibility that it may not currently have.

And I think it would be relatively easy for the members of the subcommittee to pull together a list of some good informational materials that are already out there that are either available through the Internet or available in other places. But I think there would still remain that additional step which the subcommittee couldn't

undertake, but which perhaps the Board could make a recommendation about, to say, okay, we know where the information is, but we've still got to come up with a strategy for how we are going to make it all if not on one site at least linked on to one site to make it more accessible to the public.

I think that is the next step, and then after that then we still of course would have to assess where are the gaps and what information isn't there.

But I think those would be the steps, and I would certainly defer to the Board in thinking about what recommendations you might want to make, or actions you might want to make. But certainly if you were to come back to us and say, can you give us a list of the 10 best sites we should be pushing out there, I think we could do that.

MEMBER GRABENSTEIN: So give us a list of the 10 best sites. But don't wait, I mean don't wait for us to say, oh wait a

minute, there is an 11th. I mean figure it out, and through your HHS processes get it out there.

DR. DODGEN: That's fine. I'm just trying to follow protocol and make sure that do this in order.

MEMBER GRABENSTEIN: And so we will conquer the pandemic or the pandemic will pass us over. I guess one or the other. But then there are all the other hazards, and we will continue to work with you to follow up on all the other good ideas you have provided to us.

So again, thank you very, very much. Did we have a joint round of applause for them all? We should.

Operator, would you give the phone-in instructions, please?

OPERATOR: And at this time, ladies and gentlemen, if you would like to ask a question, please press star one on your telephone key pad.

MEMBER GRABENSTEIN: And are there any questions, public comment, in the room? Yes, sir, would you please come up and tell you who you are.

DR. NG: Hi, good afternoon. My name is Tony Ng. I'm a psychiatrist. I'm the current president of the American Association of Emergency Psychiatry, and I want to first thank the subcommittee, I know many of them, and you guys are doing a great job with this, and I appreciate that.

I just have three quick comments. The first comment was, I think one of the Board members mentioned how do people use the emergency rooms, and emergency services. I think oftentimes, everyone has a different interpretation of where emergency is, and I think that is one of our problems that we see in the emergency service, that just feeling not well for some person may be really like dropping dead, whereas another person just having a headache. So I think in terms of

flu, people need better guidance in terms of what defines a trip to the ER. Example: You need to have all these symptoms, not just the fact that you don't feel well.

And then certainly - I'm glad Dan mentioned EMTALA, because if EMTALA is still in place - someone mentioned, I have - I just feel a headache, and I call the ambulance, they have to take you to the ER, they can't really say no. So that is an important point.

The other thing also is just in terms of risk communication we talked a lot about crafting the right message. I think what is also important is delivery of that message. And I think the problem is if Mozart had all the great music but couldn't play the piano you won't remember him. And I think certainly we need to have some communication with the media who can really help working together give us the right delivery. Because if CDC has a great message, but all you see from Associated Press is that one paragraph,

and then at the bottom 10 top reasons not to believe CDC, no one is going to remember what the CDC message is except the negative stuff. So it's important that we work on that.

Thirdly, unlike SARS when we didn't have the kind of Internet availability like we do now, I got - I wonder what kind of ways do we have to counter the almost instant time in terms of Facebook, Twitter, blog, all those things that basically go viral for lack of a better word about information that someone may pass out, and up top may not get to hear those messages until very late.

So we need to have a mechanism to really say like how do we respond quickly to those things.

MEMBER GRABENSTEIN: Thank you.

Operator, do we have any questions on the phone line?

OPERATOR: At this time there are no questions, sir.

MEMBER GRABENSTEIN: Okay, good.

Any other comments from the floor?

MR. SHRIVER: Good afternoon,
thanks to the committee.

Chip Shriver. I'm with the
command surgeons office at NORAD USNORTHCOM.
I just wanted to suggest, when you approach a
very timely issue of information, and
information management especially in a complex
unfolding health event, that there is some
science base out there. In fact, I would just
for example point you to a study that the
Defense Threat Reduction Agency did a few
years ago about a novel biological agent in a
sort of real-world scenario in Louisiana that
actually got data on who the public will go to
in complex health emergencies. And sometimes
it's not necessarily who we might think it is.

And there is some science out
there that I think can be kind of recruited
towards this end, to really inform the
information packaging and make the best
information drilled down to the common

denominators.

Thank you.

MEMBER GRABENSTEIN: Any other comments?

All right, Dan, I will give you the last word.

DR. DODGEN: I was just asking if there was anyone else on the phone line. I was hoping perhaps Dr. Boyd might be able to make a comment. But hearing nothing we will assume that there aren't anybody - isn't anyone calling in.

So I just want to thank again the Board for giving us this opportunity to be here, and thank all the members of the subcommittee for the incredible hard work that they have put in, not just in the last few weeks preparing for this meeting, but throughout the time that they have been in existence.

And we just want to reiterate what we said earlier, which is that we certainly

want to continue to work with the Board and be responsive to the needs and to requests that you might put to us. So we are here, and we are ready, and we certainly look forward to continued work and collaboration, and unless Dr. Pfefferbaum wants to say anything else, I think that is it for us. Thank you.

MEMBER GRABENSTEIN: Thank you very much.

(Applause.)

So we'll begin the wrap up.

Captain Sawyer, will you remind us of when the next public meeting is? Do we know the date?

CAPTAIN SAWYER: The next public meeting is October 14th, from 12:00 to 2:00 p.m. Eastern time. It's a public teleconference.

MEMBER GRABENSTEIN: And also each time the Board meets the Board realizes the skills of the NBSB staff. So I'd like to ask you to introduce the staff members to the public, and so that we can acknowledge them

and say thank you for all their hard work.

CAPTAIN SAWYER: Well, thank you. I'd like the staff of the NBSB to stand. And so everyone can recognize who you are.

(Applause.)

There's Don Malinowski, MacKenzie Robertson, Brook Stone, and over here on the right, Jomana Musmar and Erin Fults.

(Applause.)

MEMBER GRABENSTEIN: Thank you all very much. Do we have other administrative announcements.

CAPTAIN SAWYER: I will also acknowledge Carolyn Stevens who is not here today, but she helps us with the travel and other administrative issues.

MEMBER GRABENSTEIN: Very well. I don't have the gavel. You have the gavel. Are there other --

CAPTAIN SAWYER: So did you want to propose a plan for our next steps forward? It sounded to me like Dr. Quinlisk was

proposing that the Board take up the recommendations from the Disaster Mental Health Subcommittee for consideration, and would consider those possibly at our October meeting.

MEMBER GRABENSTEIN: Any comments from the Board members on that line of action? Good idea? Heads going up and down.

MEMBER JAMES: I think that was the plan.

MEMBER GRABENSTEIN: Right, I think it's unanimous.

CAPTAIN SAWYER: All right, you are looking to me to close the meeting. The meeting is adjourned, and we'll see you in October.

(Whereupon at 4:21 p.m. the proceeding in the above-entitled matter was adjourned.)