SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD (NBSB)
PUBLIC TELECONFERENCE
October 14, 2009

NBSB VOTING MEMBERS PRESENT
Patricia Quinlisk, M.D., M.P.H, Chair
Ruth L. Berkelman, M.D.
Kenneth L. Dretchen, Ph.D.
John D. Grabenstein, R.Ph., Ph.D.
James J. James, Brigadier General (Retired), M.D., Dr.P.H., M.H.A.
Thomas J. MacVittie, Ph.D.
John S. Parker, Major General (Retired), M.D.
Eric A. Rose, M.D.

NBSB VOTING MEMBERS NOT PRESENT
Stephen V. Cantrill, M.D.
Roberta Carlin, M.S., J.D.
Albert J. Di Rienzo
Andrew T. Pavia, M.D.
Patrick J. Scannon, M.D., Ph.D.

EX OFFICIO MEMBERS PRESENT (or designee)
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.)*
Joseph Annelli, D.V.M., Animal and Plant Health Inspection Service, U.S. Department of Agriculture
John Skvorak, D.V.M., Ph.D., COL, Commander, U.S. Army Medical Research Institute for Infectious Diseases, U.S. Department of Defense
Boris D. Lushniak, M.D., M.P.H., Rear Admiral/Assistant Surgeon General, Assistant Commissioner, Office of Counterterrorism and Emerging Threats, Office of the Commissioner, Food and Drug Administration, U.S. Department of Health and Human Services
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.)*

NBSB Staff
Leigh Sawyer, D.V.M., M.P.H., CAPT, USPHS, Executive Director
Erin Fults, Contractor, Scientific/Technical Writer
Donald Malinowski, M.S., Program Analyst
Brook Stone, M.F.S., LT, USPHS, Program Analyst

CALL TO ORDER AND CONFLICT OF INTEREST RULES

Leigh Sawyer, D.V.M., M.P.H., Executive Director, National Biodefense Science Board (NBSB), Office of the Assistant Secretary for Preparedness and Response (ASPR), Captain, U.S. Public Health Service (USPHS), U.S. Department of Health and Human Services (HHS)

CAPT Sawyer called the public teleconference to order at 12:03 p.m., welcomed the participants, and said the reason for the teleconference was for Board members to discuss recommendations presented to the NBSB on September 25 from the Disaster Mental Health (DMH) Subcommittee and for the Board to receive an update on H1N1. She then called the roll, provided a brief overview of the NBSB, and reviewed conflict of interest rules.

OPENING REMARKS

Nicole Lurie, M.D., M.S.P.H., Assistant Secretary for Preparedness and Response (ASPR), Rear Admiral, USPHS, HHS

Dr. Lurie thanked the members for continuing to meet as the H1N1 situation has developed. She said it has been very helpful to hear what the Board has to say. She noted that the first part of this call will focus on behavioral health considerations for H1N1.

Dr. Lurie said the meeting on September 25 provided a good exchange of information. Although formal recommendations have not yet been submitted, there was significant discussion in a number of areas, including interventions, education and training, risk communications, and vulnerable populations. There were a number of items that were discussed including: 1) identifying experts in behavioral health aspects of public health messaging and risk communications, which has been accomplished; 2) identifying experts with particular subject matter expertise in the vulnerable populations, which has been accomplished and a roster has been prepared of people to call on for additional advice; 3) pulling together behavioral health material to post on the Web site; this material is being vetted prior to posting on the Web site (www.flu.gov), which is especially important in light of the number of pediatric deaths and the importance of meeting the needs of people on the ground; 4) mobilizing existing guidance and materials for behavioral mental health providers.

Dr. Lurie noted that later in the call Dr. Jay Butler, who leads the H1N1 Vaccine Task Force at the Centers for Disease Control (CDC), will provide an update with the current status of the roll-out. She noted that last week vaccine started being distributed to states, beginning with a live attenuated virus; this week injectable vaccines will start to become available. There will be a slow roll-out over the first couple weeks but more will be available each week.

Following Dr. Butler, Dr. Clare Helminiak will provide a status report on medical surge capacity, Dr. Lurie concluded.

AGENDA OVERVIEW AND GOALS

Patricia Quinlisk, M.D., M.P.H., Chair, NBSB

Chair Patty Quinlisk reviewed the agenda, noting that Dr. Daniel Dodgen and Dr. Betty Pfefferbaum will discuss behavioral health considerations, followed by a discussion of the H1N1 vaccine issues. There will also be a discussion of the NBSB draft letter to Secretary Sebelius, HHS.

BEHAVIORAL HEALTH CONSIDERATIONS FOR H1NI

Daniel Dodgen, Ph.D., Executive Director, Disaster Mental Health (DMH) Subcommittee, Director, Office for At Risk Individuals, Behavioral Health, and Human Services Coordination, ASPR, HHS

Dr. Dodgen thanked Dr. Quinlisk and Dr. Lurie for their remarks and the continued support of the DMH Subcommittee. The Subcommittee appreciates the opportunity it had at the September 25 public meeting to provide its recommendations, which offered a framework for the work that ASPR and others are doing to respond to the H1N1 pandemic. There is a synergy between the NBSB DMH recommendations and the recommendations on mental health in the interim report of the National Commission on Children and Disasters, due to be released today, he said. Dr. Dodgen thanked Dr. David Schonfeld, a member of the National Commission and the Subcommittee, for assuring the two documents were synergistic.

Dr. Dodgen said that Dr. Pfefferbaum will next review the recommendations presented to the Board on September 25 Following Dr. Pfefferbaum, Dr. Dodgen will highlight some immediate activities that ASPR, with other agencies, have begun to implement.

Dr. Betty Pfefferbaum, M.D., J.D., Chair, DMH Subcommittee

Dr. Pfefferbaum summarized the Subcommittee's recommendations from the September 25 meeting, including actionable steps. The Subcommittee focused on three areas: interventions, training and education, and risk communications and its concerns about vulnerable populations. The Subcommittee recommended a focus on interventions that resolves uncertainty, enhances resilience and coping, and fosters adaptive behavior. It recommended attention to vulnerable populations and urged the integration of disaster mental health issues and approaches into the large public health response to the crisis.

Regarding actionable steps, the Subcommittee recommended using the Subcommittee and other professionals as well as regional and local experts as an ad hoc advisory team of experts to provide reach-back capacity and guidance and to help address specific issues. The Subcommittee recommended reaching out to mental and behavioral service providers through state public health, and mental health authorities, to promote attention to the continuity of operations, and to ensure access to information and materials. The Subcommittee also recommended identifying existing best practice community resilience materials for H1N1, and making them available to public health and community leaders working in the area.

Regarding training and education, the Subcommittee recommended identifying, developing, and disseminating existing best practice educational materials for mental health and medical providers and for school personnel. The Subcommittee recommended working with behavioral health and professional guild associations to reach a consensus

on the status of psychological first aid. The Subcommittee also recommended disseminating information on coping and grief, including dissemination of information to the public.

For actionable next steps in training and education, the Subcommittee recommended identifying and disseminating behavioral health materials relevant to the pandemic and linking them to appropriate Web sites. The Subcommittee also urged federal and state health officials to identify, and prepare to disseminate educational material and messaging on grief, and the stressors associated with the illness and death of children.

Regarding communication and messaging, the Subcommittee recommended integrating behavioral health factors into all health messages, expanding the use of non-traditional communication, and addressing the needs of special populations in messaging and sensitivity to terminology.

For actionable steps on communications, the Subcommittee has identified mental and behavioral health experts to assist in developing messages. The Subcommittee also recommends reaching out to federal planners, risk communicators, and NGOs representing state and local public and mental health to inform them of the importance of anticipating and preparing for issues with high psychological impact, e.g., child deaths, perceived fairness and equity in cases of scarce resources, and potential mistrust of government. The Subcommittee recommends identifying existing actionable guidance and education materials, and ensuring those are available on appropriate Web sites and elsewhere. The Subcommittee recommends that federal and state health officials promote the message that good health is good mental health, emphasizing that practical health activities reduce exposure and spread of the virus and can reduce public anxiety and foster adaptive behavior. The Subcommittee recommends providing guidance to public health risk communicators to ensure unchecked health anxiety is addressed by not using terms such as “unique” and “novel” when referring to H1N1, and to continue reassuring the public about the safety of vaccination. The Subcommittee suggests that federal and state health officials encourage the media to use images of community or national leaders as they are vaccinated to provide public reassurance. Also, that Federal and state health officials be directed to work with public health risk communicators to discourage the use of terms such as “worried well,” which has an imprecise meaning. The Subcommittee can focus on what is meant by this phrase and might be able to find new terminology.

Finally, the Subcommittee recommended that attention be given to special populations, particularly those at risk due to pro-morbid medical conditions, and those with limited access to health care or trouble understanding public health messages. There should also be attention to continuity of operations planning for individuals who receive mental health and substance abuse services.

Actionable steps concerning vulnerable populations include compiling a roster of subject matter experts for these populations; which the Subcommittee is doing. The Subcommittee also recommends encouraging Federal and state health officials to reach out to traditional vulnerable populations, in addition to those identified as at-risk, specifically for H1N1.

Daniel Dodgen, Ph.D.
Following Dr. Pfefferbaum's summary, Dr. Dodgen thanked Dr. Pfefferbaum and proceeded to give an overview of ASPR's Office for At-Risk Individuals, Behavioral Health, and Human Services Coordination (ABC). ABC is partnering with the Subcommittee to advance its recommendations. He described two cross-cutting themes in the recommendations: 1) the need to identify and mobilize behavioral health expertise to inform the response and 2) the need to identify and mobilize behavioral health educational materials and specific guidance for important audiences and vulnerable populations.

For the first theme, ABC has begun working with the Subcommittee to identify experts in the behavioral health aspects of public health messaging and risk communication. It can then work with HHS' risk communication and public information offices to ensure the experts are available. To meet the needs of vulnerable, at-risk populations ABC has been working with the Subcommittee to compile an additional roster of subject matter experts in vulnerable or at-risk populations that can also be called upon to inform the Board if they have specific questions for these groups.

For the second theme, ABC has been working with the Subcommittee and other HHS agencies to identify pertinent behavioral health materials and link them to www.flu.gov. The public affairs office is currently completing this task. ABC is also working with the Subcommittee and HHS agencies to identify guidance materials and reach out to behavioral health stakeholder groups to disseminate the material.

Dr. Quinlisk thanked Dr. Dodgen and asked for questions from Board members.

DISCUSSION
Dr. Kenneth Dretchen asked if there was any initiative underway to go directly to boards of education and state- and county-level bodies to disseminate information that is grade-level appropriate.

Dr. Dodgen answered that one of the things that has been hallmark of the H1N1 response has been the integration of the Department of Education at the Federal level and at local and state levels. The H1N1 summit that Secretary Kathleen Sebelius hosted in August included the Secretary of Education and the Secretary of Homeland Security as a sign to everyone that the response would focus on educational settings because of the pandemic's high impact on children. The message from the Federal level is the inclusion of departments of education; Tennessee, for example, is very much including its department of education in its H1N1 outreach efforts.

Dr. Dretchen followed up by asking if there was feedback from the state level to know what is happening on the ground with educational materials getting to children and their families.

Dr. Quinlisk responded that there has been a lot coming out at the Federal level and many states are working with their state boards of education. The real question is how much of it is filtering down to individual schools and going out to individual students. In Iowa, she said, there is a lot of that happening, but perhaps not as much as could be done. There is still a lot of parent concern about vaccine safety and the mildness of the flu.

Therefore, more education about the vaccine is appropriate. However, hygiene has been covered well.

Dr. Schonfeld added that material has been circulated on hygiene issues and preventing transmission but there has been very little information distributed about the behavioral health aspects and the implications to one's own health of peers being sick.

Dr. Dodgen said these comments show that the communication plans at the Federal and state levels are well thought out and comprehensive, but there is a gap at the local level, where implementation occurs. This is a question that is worth continued scrutiny, he added.

Dr. Russell Jones asked if there is a system in place to see the extent to which information is being used and the impact on behavior and outcomes.

Dr. Dodgen said this was a good question and noted that CDC was attending to this. He asked if anyone was on the call from CDC and, when no one responded, Dr. Dodgen noted that a CDC representative would be speaking later in the teleconference.

Dr. John Parker said he supported Dr. Dodgen's group and the recommendations. He went on to note that there have been years of inattention to the value of public health services across the country. In the states and local communities, public health departments are stretched just to get people to come and get the vaccine and stress its safety. The public needs support on the issues addressed by the Subcommittee, but the public health departments don't have the resources to do what is suggested. There are wonderful implementation ideas but they are very hard to implement because of manpower problems, he said.

Dr. Quinlisk agreed with Dr. Parker and noted that states are laying off public health workers, requiring them to do only what that have to do, not what they should do. For specific action at the state level it would be useful to say, "Here is the specific information, here is exactly what we want you to do with it, and this is the highest priority." That will make it more doable than trying to determine exactly what needs to be done to implement some of the action steps.

Dr. Jim James noted that as long as this is looked at as a public health responsibility, there will be no progress. Talking about mental health resilience means talking about a large, integrated system. Also, the kind of recommendations proposed are almost impossible to implement in the short term. The work of the DMH Subcommittee needs to be looked at from a strategic perspective, not in the context of H1N1.

Dr. Gerard Jacobs added that some of the recommendations made on September 25 were about establishing a work group to begin the process of moving forward with more community-based models of psychological first aid.

Dr. Pfefferbaum said this experience can and should be used to address the need in context of H1N1, but also to prepare for future events.

Dr. Quinlisk wondered if it was possible to have a prioritized list of things that state or local health departments can do, that identifies where the information is, and that

recommends what should be done with the information. Being in the middle of H1N1 now, we can't take action at the state level on preparing for other events because we're too overwhelmed with H1N1, she said. But there are lot of people who are concerned with some of these populations and risk communication and she wondered if something could be done for state and local health departments that was more immediate—steps that could be taken quickly and easily.

Dr. Dodgen agreed with Dr. James that in the middle of implementing the big-picture recommendations it is hard to develop quick-term solutions, without the overall integration of public health and mental health systems. But several comments speak to the importance of making information that is already out there available to a broad spectrum of providers and individual citizens, especially since there is a lot of good information available on helping people cope with grieving and what to do if a loved one is sick. It might merit further consideration to discuss how we improve our abilities to get existing information into the hands of the people who need it.

Dr. Parker suggested that a faster way to implement this would be to take into account the fact that public health departments are focused on getting vaccine out and getting people in. It might be encouraging if recommendations were forwarded to presidents of the professional medical societies and they could then help communicate these recommendations to their members so the providers become aware of what the Board is trying to do. As physicians see patients they could use parts of the NBSB's recommendations to bolster the mental resilience of the patient population. Dr. Parker also suggested that the Board could send a letter to the major health care organizations with the recommendations. In this instance, we are dealing with the entire provider community, not just public health, said Dr. Parker.

Dr. Quinlisk said the Subcommittee's action consists of developing recommendations that the NBSB could send to the Secretary. She asked if Dr. Dodgen's group and the Subcommittee had some defined steps that could be on what needs to be done and suggestions about how to get that information out to the public through professional organizations, etc. She added that this was the proper channel, rather than the Board going directly to professional organizations.

CAPT Sawyer said the Board could write a letter to the Secretary recommending the information be shared with professional organizations. She suggested that members think about the approach they would like to take. But she said the schedule required moving on to taking questions from the public and suggested returning to this question later in the teleconference.

Gretchen Michael, Communications Director, ASPR, said there are mechanisms the department and the CDC use to communicate directly with the medical professional associations and individual physicians, which include frequent communication vehicles. So, there are already mechanisms in place to get information out if the Board determines it wants to make recommendations and have those sent out. Also, in reference to communicating with schools and education departments, Ms. Michael noted that since the spring there has been a close working relationship with the Department of Education. There have been a number of conference calls with school superintendents and principals

and when the school guidance was issued, they were sent to all the school principals. There have also been public service announcements geared toward children. Others on H1N1 will follow, including one premiering on October 26.

Dr. Dodgen agreed and said all of the efforts mentioned include information about mental health and coping. Dr. Dodgen introduced Dr. Stephanie Zaza, M.D., M.P.H., Captain, USPHS Medical Officer, Coordinating Office for Terrorism Preparedness and Emergency Response, CDC.

Dr. Zaza introduced herself as the senior advisor to the director of CDC's Coordinating Office for Terrorism Preparedness and Emergency Response. Over the summer the CDC developed a number of guidance documents for community settings that focused on behavior change and actions organizations could take to facilitate that change, particularly in schools, colleges, universities, and child care settings. The CDC developed those in coordination with other Cabinet departments. There were major efforts, as Ms. Michael mentioned, to move that information out to organizations that could further spread the information and help people take action. She said the CDC was monitoring the success of its communications efforts. The Harvard School of Public Health uses polling methodology to look at behavior knowledge intent among a random sample. It has data on what people intend to do, what they are doing, and their beliefs. The CDC is then able to associate some of those responses with communication messages and Dr. Zaza said they are looking to see how those behaviors change over time. The CDC is also looking at vaccination intent and vaccination receipt. That will be ongoing through the flu season. Specifically regarding schools, the CDC set up a school dismissal monitoring system that looks at whether schools are closing. The CDC does not currently recommend schools close, except in rare cases. One way to determine if CDC's messages are working is to look at the number of school closures. Dr. Zaza noted seeing very small numbers of these. Those numbers and locations tend to follow the highest disease rates. These numbers were compared to the spring when we saw a very direct impact of our guidance. When CDC suggested schools close, it saw many close. As soon as the guidance was changed, to recommend against closure, schools opened again. There is evidence of a robust reaction to guidance documents.

Dr. Zaza suggested to the Subcommittee that if there are particular indicators of social-level determinants of stress in the system and behavioral impact, the CDC would be open to adding that to the survey.

Dr. Dodgen thanked Dr. Zaza for her offer.

PUBLIC COMMENT

The first public question was from Dr. Deborah Robinson, of Robinson Consulting, who asked about the next step to support communications. She suggested that in addition to Federal planners, risk communicators, and NGOs representing state and local public and mental health, that state and county level voluntary organizations active in disasters be added. These groups work daily with vulnerable, at-risk populations. And many of the members of these groups already do disaster mental health counseling. They only need the H1N1 take on this.

Dr. Robinson's second comment related to vulnerable populations. She said that if there is tracking of H1N1 hospitalization and death rates by racial and ethnic group, the reporting is not clear. The most significant finding of a Chicago study was that children age five to 14 were 14 times more susceptible to the virus than older adults and that African Americans, Hispanics, and Asian Pacific Islanders were four to five times more likely to be hospitalized than whites. In early September it was reported that children with neuro-developmental conditions are at an increased risk and that 50 percent of those pediatric deaths were African Americans and Hispanics. If this pattern is true it is extremely important for this to be communicated clearly as this would assist these populations to get the vaccine. Dr. Robinson said she works in the communities and finds reticence based on not seeing people dying. This information would be a very motivating factor, if it is found.

The next public comment was from Don Bennett, who identified himself as a teacher in Los Angeles. There have been rumors of an anti-viral called Peramivir that is effective in severe cases of H1N1. He wanted to know if the drug is a possibility that can be investigated to help with students who are severely ill.

The next public comment was from Paul Gordon, of San Francisco. In behavior communication there is an emphasis on front-end management, but it is frustrating that inside intensive care units that are being overwhelmed with acute influenza cases there is a need for an IV-administered anti-viral. There was a recent case of a doctor using, possibly, Relenza, with an inhalation administration, that caused death because it was a non-approved use. There is an anti-viral, called Peramivir which has shown tremendous results in treating acute influenza and it is available under an Emergency Investigational New Drug (EIND) process through BioCryst Pharmaceuticals. There is nothing on the CDC Web site that references this drug. Why has an emergency use authorization not been issued for this antiviral? Japan and other countries are moving faster than the U.S.

CAPT Sawyer said the last two questions would be addressed in the second hour of the teleconference since they relate to countermeasure interventions. There were no more public comments.

Dr. Ruth L. Berkelman said she would like to respond to the first public comment and encourage the CDC to put out death and hospitalization statistics frequently and in greater detail.

VOTE ON DMH SUBCOMMITTEE H1N1 RECOMMENDATIONS

Dr. Quinlisk opened the discussion up for input on the appropriate action to take at this time regarding the Subcommittee's recommendations.

Hearing no response, Dr. Quinlisk asked Dr. Dodgen and Dr. Pfefferbaum what kind of action they are requesting the Board take.

Dr. Dodgen said many of the recommendations could be included in broader recommendations that could go from the Board to the Secretary. The ones that fall in that category are contingent on further action the Board takes in terms of bigger-picture recommendations it may be sending to the Secretary. There are a couple of specific recommendations with which the Subcommittee could be tasked with by the Board. For

example, the term "worried well" has come up several times. The Board expressed the view at the September 25 meeting that it would be good to agree upon how to talk about this in the future. This could have a significant impact on future messaging activities.

Dr. Dodgen added that Dr. Zaza brought up an interesting issue of whether there are specific items related to behavioral health that might be added to some of the existing surveillance instruments. It would be worth the Subcommittee's time thinking about this because it would be something that could not only have an immediate impact but also a long-term impact. Activities that have a specific outcome and deliverable would also be appropriate for the Subcommittee.

The bigger picture is the list of recommendations the Subcommittee has come up with related to H1N1. Future steps for the Board might be to look at the Subcommittee's action steps and identify which ones could be acted upon immediately. While it isn't worth taking the time to vote on those now, the Board could review which action steps were handled, didn't get handled, or could be better handled in the future.

Dr. Quinlisk took time to applaud all the work that has been done. She added that, given today's discussion, there are two things the Board should pay attention to: 1) what the Board needs to start working on now so that it is better prepared to cope with situations like this in the future and 2) some very specific steps that could be done easily and immediately to deal with the situation being faced today. Dr. Quinlisk wondered if there were things that could be pulled from the Subcommittee's recommendations that could be sent as recommendations from the Board to the Secretary saying, "Here is what we think you need to do in the next week or two weeks, and here is the exact tool that we think is the best that can be used right now." She said if that could be done fast enough, it would be of practical use for the present situation.

Dr. James concurred with Dr. Quinlisk. Part of the trouble is pulling out what the Board can and should do in the short term in addition to the much more difficult strategic issue. If the Subcommittee can take the time to focus on the short-term H1N1 impact possibilities and get that to the Board and the Secretary, something good could be achieved.

Dr. Dretchen agreed.

Dr. Zaza added that there has been a lot of information generated during the response by various epidemiological investigation teams working with the CDC. The CDC is learning about what could be measured during the different implications of school closures in South America, the United States, and Japan. If there is a way to share some of that data with the Subcommittee it might yield a more formative recommendation in the near future.

CAPT Sawyer said that since there is not a specific list of items to be put forth to the Secretary now, the issue could be revisited later in the teleconference as scheduled speakers Dr. Butler and Dr. Helminiak have a limited window of availability for the call. Dr. Quinlisk agreed and postponed the present discussion. She introduced Dr. Butler and Dr. Helminiak.

H1N1 STATUS UPDATE; H1N1 VACCINE LOGISTICS
Jay Butler, M.D., CAPT USPHS, Program Director, H1N1 Vaccine Task Force, CDC, HHS

Dr. Butler was joined by Susan Cooper, the Commissioner of the Tennessee Department of Health and Mary Selecky, Secretary of Health for Washington State.

Dr. Butler provided a brief update on the H1N1 pandemic. During the past six weeks there has been a continuing increase nationally in the amount of influenza-like illness (ILI); for only one week was there a brief decline. The level of ILI measured as a proportion of all visits to central healthcare providers due to ILI are very similar to what they were at the peak of the 2007–2008 seasonal flu outbreak at just over 5 percent and greater than the rate at the peak of the 2008–2009 seasonal outbreak. Looking across the country, 37 states or jurisdictions have the highest level of influenza activity (widespread) and 47 have either regional or widespread activity.

Dr. Butler said the epidemiology of the disease has not changed from what it was during the outbreak last spring. The virus continues to disproportionately impact children, younger adults with underlying illnesses, and pregnant women. The elderly have lower attack rates, but when they become infected they are at higher risk of complications. Seventy-six deaths in children related to H1N1 have been reported and additional deaths have been reported in the last few days. The risk groups in the southern hemisphere during the austral winter were very similar to what was seen in the U.S. during the initial outbreak last May and during the increase in the past month. The virus has not undergone any major changes in terms of increases in antiviral resistance or changes in antigenic characterization. There is a good match between the virus that is circulating and the vaccine.

Providing a vaccine update, Dr. Butler said that as of October 13 more than 11 million doses have been allocated to the states for ordering. A little more than half that amount has been ordered, some of it has been delivered, and orders continue. Of the vaccine available for ordering, a little more than half is injectable and that became available a little more than a week ago. Most of it is in multi-dose vials. A little over five million doses are available as live attenuated vaccine.

Dr. Butler said the CDC is continuing to monitor coverage. The CDC started a weekly survey using the 2009 H1N1 flu survey. It started this past week to be able to assess seasonal flu coverage and coverage with H1N1 vaccine and intent to be vaccinated. Sixty-one percent of participants reported they will probably or definitely get the H1N1 vaccine, if it is available to them.

Susan Cooper, M.S.N., RN, Commissioner, Tennessee Department of Health

Commissioner Cooper said there was both challenging news and good news from the front lines. The good news is that the investment made in preparedness for all types of disasters has paid off. Had those investments not been made, the states would not have been able to respond as effectively as they have. In Tennessee the plan is working. The state has a model program of provider pre-registration for countermeasure distribution. The vaccine for children program was used as a base, which had 500 provider sites. More than 1,200 sites pre-registered with the state health department to give the vaccine.

This number does not include chain stores, which have multiple provider sites, and also does not include hospitals. Orders vary in size, and there is concern that some of the provider input was unrealistic; such as ordering a dose for every patient in the practice. There are also allocation issues. The majority of the vaccine received is mist, which is not appropriate for pregnant women, children, or adults with chronic disease. There were also challenges with delivery. The state could not deliver to every site because of limitations by the shipper on the number of places where the vaccine could be sent. But the CDC supported the state's request to add sites, which has been modestly helpful.

Dr. Butler added that there has been an increase from 90,000 to 150,000 ship-to sites nationally.

Commissioner Cooper noted that the state had ordered everything available and it is reaching providers in a timely fashion without shipments sitting on docks. She added that there has been very good coordination with the CDC and with the shippers to ensure that once the vaccine arrives, it can be quickly administered.

Regarding other high-level concerns, she described the problem of managing expectations on multiple levels: communities, counties, states, administrative and executive levels, and the Federal level.

Commissioner Cooper also raised the issue of mitigating misinformation. At the state level, media communication has not included fear mongering, and the media have been included as partners. That has worked well, she said, yet national news media still convey misinformation.

She said her state had managed well with its public health infrastructure, but as public health funding has diminished, the public health system has been weakened. Still, the state is handling the current situation without trouble. But she said it was important to look at what the funds in the past have prepared the state to do, and to consider that when making recommendations.

In closing, Commissioner Cooper described Tennessee's health administration, which she said is very different from Washington State's. Tennessee has 95 counties and eight contiguous states. In those counties, the state health department is the local health department. In six counties there are local boards of health. For the majority of residents, the state health department is a direct service provider.

Mary Selecky, Secretary of Health, Washington State Department of Health
Secretary Selecky picked up on Commissioner Cooper's description and compared it to Washington State, which has multiple international borders, including water, air, and the land border with Canada. The northwest area includes Alaska, Washington State, Oregon, Idaho, Montana, Alberta, and the Yukon Territories; which all work well together. An agreement was recently signed to ease epidemiological and communicable disease data transfer with Canada. In Washington State, the local public health authority has jurisdiction over its citizens in a way the state health department does not. There are 39 counties with 35 local health jurisdictions that report to elected boards of health. Counties range in population from 2,200 to more than 1 million. Yet she and Commissioner Cooper have the same responsibilities.

Secretary Selecky said one of the challenges is economics. She thanked federal officials for investing in vaccine production and the public health infrastructure to assure there could be the kind of response needed. But state and local health is faced with the biggest reductions in recent history. She told her state legislature she was worried about H1N1 because local health authorities have 330 fewer FTEs in 2009 than in 2008; many of which were public health nurses,. But she said she could absolutely meet the challenge because non-essential services will be discontinued, and employees will be moved around in the department. This is happening at the state and local level across the country. Public health needs the continued support from state, local, and federal action - including funding.

Secretary Selecky said schools face similar issues. H1N1 is extra work for most districts and they do not have the resources for it. Many schools don't have the money for extra cleaning supplies to comply with guidance to keep surfaces clean.

There is also the issue of overcoming fears associated with a new vaccine. She associated this partly to a frontier mentality and Glenn Beck, who is from Washington State, and has not supported vaccines. Calling the H1N1 vaccine a new vaccine has also created confusion; even though it is an accurate description and a lot of time is spent explaining this. She also cited a Harvard University study that said only 50 percent of parents intend to vaccinate their children. Furthermore, about 40 percent of adults say they will be vaccinated. Secretary Selecky noted that there are general vaccine safety concerns and we have to be prepared, as do providers, to explain that. The lack of availability of the seasonal flu vaccine adds to the confusion. Secretary Selecky said when she travels to her home community, which is very rural; she spends time with neighbors sorting out these issues.

Secretary Selecky said she appreciates the messages from the federal level. The state is complying with encouragement from HHS to post information on its Websites, except for the location of clinics. The locations are not being listed because the state wants to make sure that when the information is posted, that officials there are prepared. The vaccine that has arrived is being administered to healthcare workers and children, and she said she was proud of the work being done. The number of people who are hospitalized in Washington State continues to increase. Last week there were 42 hospitalized for flu; more than half for H1N1, and they were very sick and very young.

DISCUSSION

Dr. Jones asked Commissioner Cooper to clarify her point about misinformation.

Commissioner Cooper said her state is spending an inordinate amount of time talking about the similarity between the H1N1 vaccine and the seasonal flu vaccine, explaining that the risks are the same. There is a misperception that is heightened in the media that this vaccine was rushed to market, that corners were cut, that there's some special way this vaccine was made different from the seasonal flu vaccine, and that there are more safety studies yet to be completed. Also, a number of national media appear not to be supportive of vaccines in general. Their message is different from the message the state is delivering as the trusted communicator about the health of the public. States take their job seriously to protect the public.

It was noted by CAPT Sawyer that the briefing on Medical Surge would have to be rescheduled for the next meeting since CAPT Helminiak had to drop off the line.

Hearing no further questions for the previous speakers, Dr. Quinlisk asked for any discussion on any issues related to H1N1 discussed so far.

DISCUSSION (H1N1)

Dr. Quinlisk opened the discussion by agreeing with the points about misinformation, adding that anything that can be done at the national level or with non-governmental speakers would be very helpful. She said she has spent much of her time in the last several weeks addressing misinformation rather than getting out the right message.

Commissioner Cooper responded by referring to the presentation she made to the Board in June 2008 on the work the Association of State and Territorial Health Officials (ASTHO) had done around vulnerable populations, and on reaching people who are at risk for downstream effects. The idea of a trusted messenger needs to be revisited, she said. There is a need to be as crisp as possible with messaging without setting unrealistic expectations. For example, there are great plans for the clinics but the state can't say when it will operate because officials don't know when the vaccine will be available.

If information is not delivered soon, Secretary Selecky added, no one will show up when it is delivered.

Gretchen Michael said some states have put information on the Websites saying this is where the information will be posted and encouraging people to keep checking back.

She added that the best way to fight misinformation is to continue to put out good, factual information using credible messengers. There is a section on myths and facts on www.flu.gov where some of this misinformation is addressed. Ms. Michael said the national networks, for the most part, have done an excellent job trying to counter the misinformation. They have been our partners, she said, and we have done exercises with them with high-level Federal representation, which has been helpful for both sides to understand how each can help the other.

NBSB DRAFT LETTER TO SECRETARY, HHS

Dr. Quinlisk read the letter, which states:

"Dear Secretary Sebelius,

The members of the National Biodefense Science Board have been closely following the planning, production and testing of the vaccine for the 2009 H1N1 influenza pandemic, as well as national pandemic preparedness and response efforts in general. The Board members have expertise in a broad range of disciplines. We have had extensive briefings from experts in government, industry, academia, and other domains, providing opportunities to understand the preparedness and response process in detail.

We strongly support the national 2009 H1N1 immunization program based on the overwhelming evidence that the benefits of vaccination far outweigh any potential risks. We strongly encourage the early voluntary immunization of all high-risk Americans,

followed by the vaccination of all others who would like to be protected from this infection as the vaccine supply grows over the coming months.

The vaccines have been produced using the same processes, standards, facilities and manufacturers as seasonal influenza vaccines. Seasonal vaccine has an excellent safety profile and has been given to many hundreds of millions of Americans since the 1940s. We anticipate that the 2009 H1N1 vaccine will have a safety profile similar to the seasonal vaccine. In addition we are pleased with the systems being used to monitor safety.

We are concerned that many people have been confused by rumors, myths and unwarranted fears. We appreciate the work you are doing to dispel those myths.

Sincerely,

Patricia Quinlisk M.D., M.P.H.
Chair, National Biodefense Science Board."

Dr. Quinlisk noted that she had received written notice of support for the letter in its current form from two members not on the call, Dr. Andrew Pavia and Dr. Stephen Cantrill. Dr. Quinlisk then asked for further comments on the letter.

Dr. Berkelman voiced agreement with the letter but said the last paragraph may not be necessary because the "referred to" myths are not specified.

Dr. Quinlisk said continued Federal encouragement for dealing with rumors is helpful to the states and she suggested leaving the paragraph in the letter.

Dr. Berkelman then suggested omitting the word "those" in the final paragraph, since the myths were not specified.

Dr. Quinlisk supported removing the word "those".

Eric Rose approved keeping the paragraph with the modification.

Dr. Quinlisk called for a vote to approve the letter, amended so that the last sentence reads: "We appreciate the work you are doing to dispel these rumors, myths, and unwarranted fears."

Dr. Berkelman said the word "these" should be omitted.

Dr. Quinlisk then called for a vote to approve the letter so that the last sentence reads: "We appreciate the work you are doing to dispel rumors, myths, and unwarranted fears."

CAPT Sawyer called the roll. The vote was unanimously in favor.

Following the vote, Dr. Quinlisk called for continuing the earlier discussion on behavioral and mental health recommendations from Board members before further comments from the public.

DISCUSSION

Dr. Parker suggested the recommendations go forward with a cover letter saying that one, two, and three of the items be given a higher priority.

Dr. Quinlisk agreed, adding that they should specify action that could be taken immediately and easily.

Dr. Parker recommended that the committee be allowed to work on that and not vote today on delivery. We would have to see the cover letter first, he said.

Dr. Quinlisk agreed. Since most of the report discusses long-term issues, we should wait until we have specifics so those are the ones that can be acted upon quickly, she said. The others can be forwarded on at a later time.

Five members voiced their agreement.

Dr. Quinlisk asked if Drs. Dodgen and Pfefferbaum would ask the Subcommittee to pull off three to five specific pieces of targeted action that can be taken at whatever level they recommend. She asked for that in enough time for a vote at the next public teleconference in November.

Dr. Dodgen sought to clarify the issue by saying that the recommendations started with phone calls in June or July. The most recent document includes the actionable items. Dr. Dodgen's team, while working with the Subcommittee and its Chair, took the recommendations and turned them into actionable items. He said he was not sure what further work could be done. The next step would be at the December meeting when the Subcommittee looks at long-term strategies. Dr. Dodgen expressed his concern that continuing to focus on H1N1 responses may not be the best way to use the Subcommittee. He did not think his staff could keep doing additional immediate action steps, which could place an undue burden on them. He suggested looking at the big picture items that the December meeting can focus on, rather than just reacting to H1N1. Dr. Lurie has already articulated some of these in terms of overall progress on integrating behavioral health into the overall HHS public health emergency response, he said.

Dr. Quinlisk tried to clarify her point by referring to an actionable step that states, "HHS should identify and disseminate pertinent behavioral materials that are relevant." She said that is difficult to implement. She suggested saying that HHS should send every state health department in the country specific health information and this information should be provided to every doctor in the state to do X with their patients. As is, it is not clear what health materials are being referred to and the meaning of "disseminate" is unclear. Other questions left unanswered are: To whom? How?

Dr. Dodgen said that for some of the recommendations the best solution would be to go back to the concrete steps that have been taken. For example, he suggested pulling together all the Web sites that have been given to public affairs that cover children, special needs populations, general adults, and grief issues. Some of those things have been done. He suggested providing the Board, in writing, the steps that have been taken concretely to implement some of these recommendations by his team.

Dr. Quinlisk said she was not asking for what has already been done. She said she wanted the Subcommittee to say, "We are seeing that grief counseling, which is a high priority, is not being done, therefore we want this specific tool to be sent to every school in the United States for them to use during grief counseling when one of the children in their school dies." Saying information has already been put together on a Web site is not very useful in the midst of an emergency. The Subcommittee needs to help identify the highest priority steps that need to be taken in the next two weeks.

Dr. Pfefferbaum said the Subcommittee can get a couple people to identify the materials. She asked Dr. Quinlisk if the Subcommittee should provide materials or just references to them.

Dr. Quinlisk said what's needed is the specificity of identifying the best tools for the indicated action, rather than just to put a lot of general stuff on a Web site.

Dr. Pfefferbaum said there will be difficulty selecting a single best tool, but the group could provide a couple tools. She offered to work with Dr. Dodgen on this.

Dr. Dodgen agreed and said it was very doable. He reiterated that he wanted to avoid a pattern where the group is always behind the curve, forgetting some of the proactive activities that they want to be doing, placing them in a strictly reactive mode.

Dr. Quinlisk asked if any Board members would like to comment.

Dr. Parker said HHS should view people such as Dr. Quinlisk as their customer and have Uncle Sam come through for them.

Dr. David Schonfeld said that during his presentation on September 25 he talked about materials being available and heard from the group that it wanted access quickly, and that message is being repeated now. The American Academy of Pediatrics has already created a separate page on its disaster Web site around emotional adjustment to disasters, which lists those specific items he had mentioned were available. That link just came out last week, he added. The question is how to share that at a national level.

Dr. Quinlisk said to keep in mind that the recommendations need to be ones that HHS can then distribute. She also expressed her appreciation, saying she did not want to burden the staff, and agreed on the need to look ahead. But right now something practical would be very helpful, she added.

PUBLIC COMMENT

Paul Gordon, of the San Francisco area, said he had heard comments about grief counseling and managing perceptions and the number of hospitalized children being at an all time high. In the management and communication of the pandemic, there are an unprecedented number of young people in intensive care who are dying, he said. He asked, "How do you manage the people who make it into intensive care?" ICUs, he said, are overwhelmed with acute influenza and they do not have the resources, including respirators. He said his question was about making accessible all available resources to address this. Furthermore, the country needs a different form of treatment for those in intensive care. There are only two forms of antiviral treatments. The problem is they do

not help someone on a ventilator because there is no meaningful way to administer the drug. Peramivir has been through Phase Three trials in Japan and Secretary Sebelius has made a declaration to set the stage for an emergency use authorization of that drug. He asked for the status of the authorization. He also asked why information about Peramivir is not published on the CDC Web site when it is available to attending physicians today through EIND and has saved multiple lives. This can save the very people being talked about provided grief counseling to, he said.

CAPT Aubrey Miller, M.D., Office of Counterterrorism and Emerging Threats, Office of the Commissioner, FDA, HHS, answered that Peramivir is under review along with other antivirals for intravenous use. There should be decisions being made soon, but because the drug is under review, he could not discuss it. He said he did not have a timeframe.

Another member of public, Deborah Robinson, suggested that in response to rumors and unwarranted fears regarding mercury in thimerosal for multi-dose vials of H1N1 vaccine, comparing the mercury content to that of canned tuna could be informative. If this is an accurate comparison she suggested it could be used to calm fears.

CAPT Miller answered that he did not have specific information to answer the question about thimerosal but could follow up. [Response added below]

Dr. Quinlisk added that the difference between ethyl and methyl mercury is relevant and needs to be made clear as well.

The final member of the public to speak was Robert Reyl. The caller described himself as a concerned parent and said his doctor has been out of seasonal flu vaccine for three weeks, without expectations of further deliveries, and does not yet have the H1N1 vaccine. Given stories about children in intensive care units, he said it is not acceptable that the FDA cannot comment on Peramivir. A public announcement should be made to explain why it has not been authorized.

CAPT Sawyer noted she had received a public comment in writing from Michael Murphy, editor of The New World Investor. [Written comment added below]

WRAP UP AND ADJOURN

CAPT Sawyer said that the NBSB public meeting is a teleconference scheduled for November 13, 2009 from 12:00 p.m.–2:00 p.m. The information for that teleconference will be posted online.

Dr. Quinlisk thanked CAPT Sawyer, her staff, and Dr. Dodgen and the DMH Subcommittee for their work. She adjourned the teleconference at 2:10 p.m.

Public Comment

From: Michael Murphy [mailto:techperson@gmail.com]
Sent: Tuesday, October 13, 2009 1:58 AM
To: OS NBSB
Subject: Teleconference

I am interested in participating in the teleconference on Wednesday, October 14. I am the editor of New World Investor. I also have an email question for the NBSB:

The FDA approved an Emergency IND for peramivir in June, showing they know it is safe and effective. This is the only intravenous antiviral available to treat A/H1N1 flu in the ICU. But FDA has never notified ICU doctors it is available, and has never amended their antiviral administration page to show it is available. FDA has prevented the manufacturer from informing ICU doctors that it is available. FDA is working on an Emergency Use Authorization, which they say "can be issued in a matter of days or even hours." But it has been four months since the E-IND, and hundreds of Americans including dozens of children have suffocated to death in the ICU because peramivir is not in the national stockpile, and ICU doctors have not been told about the E-IND process. People are now saying that what Katrina was to FEMA, this EUA is to the FDA and HHS. Why is peramivir not easily available to ICU doctors today? How long will it take to get the EUA approved and the drug into ICUs across the country? Why have all these children been allowed to die unnecessarily?

Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) - response to question from Deborah Robinson. Thimerosal is present in all multi-dose influenza vaccine vials as a preservative - this is required by our regulations as stated in 21 CFR 610.15. The H1N1 vaccines are licensed through the strain-change supplement process, and will therefore be in similar presentation (monovalent as opposed to trivalent WITH thimerosal) for the multi-dose vials; there will be thimerosal-free prefilled syringes (PFS) and single dose vials, as well as thimerosal-reduced or "trace thimerosal" in PFS. The licensed dosage forms and presentations are detailed in the manufacturers' package inserts which can be found on our website at the following link: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm.

[We] are not aware of the messaging that has taken place to make the public aware of the presence of thimerosal in the H1N1 vaccines - that said however, the licensed H1N1 vaccines are *no different in thimerosal content* than what one would find in a regular seasonal influenza vaccine. If there were any public messaging about thimerosal, it would be more likely that CDC has the lead on this. There are preservative-free presentations of the H1N1 vaccine available for children and pregnant women, if that is the concern. Specifically on the issue of the safety of thimerosal in vaccines, I can suggest that we refer those concerned to the various IOM safety evaluation reports: http://www.iom.edu/en/Reports/2004/Immunization-Safety-Review-Vaccines-and-Autism.aspx and http://www.iom.edu/Reports/2003/Immunization-Safety-Review-Thimerosal---Containing-Vaccines-and-Neurodevelopmental-Disorders.aspx