

SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD (NBSB)
PUBLIC TELECONFERENCE
November 13, 2009

NBSB 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, Brigadier General (Retired), M.D., Dr.P.H., M.H.A.
Thomas J. MacVittie, Ph.D.
Eric A. Rose, M.D.

NBSB VOTING MEMBERS NOT PRESENT

John S. Parker, Major General (Retired), M.D.
Andrew T. Pavia, M.D.
Patrick J. Scannon, M.D., Ph.D.

EX OFFICIO MEMBERS PRESENT (or designee)

Michael Amos, Ph.D., Scientific Advisor, Chemical Science and Technology Laboratory,
National Institute of Standards and Technology
Diane Berry, Ph.D., Chief Scientist, Director, Threat Characterization and
Countermeasures, Office of Health Affairs, U.S. Department of Homeland Security
Victoria 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, Special Counsel, Office of Legal Counsel, U.S. Department of Justice
Peter Jutro, Ph.D., Deputy Director, National Homeland Security Research Center,
U.S. Environmental Protection Agency
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
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.*)
Patricia A. Milligan, R.Ph., C.H.P., Senior Advisor for Emergency Preparedness, U.S.
Nuclear Regulatory Commission

NBSB Staff

Leigh Sawyer, D.V.M., M.P.H., CAPT, USPHS, Executive Director
Don Malinowski, M.S. Program Analyst
Jomana Musmar, M.S. Policy Analyst
MacKenzie Robertson, Program Analyst
Carolyn Stevens, Executive Assistant
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 p.m. EST. She welcomed everyone and informed participants that the purpose of the teleconference was for the Board to discuss recommendations presented by the Disaster Mental Health (DMH) Subcommittee. The Board would also be updated on H1N1 and seasonal influenza activity as well as H1N1 vaccines, antivirals, and other personal preparedness issues. 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

Due to a conflict with Dr. Lurie's schedule, no opening remarks were provided.

AGENDA OVERVIEW AND GOALS

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

Chair Patricia Quinlisk reviewed the agenda, noting that Dr. Betty Pfefferbaum would be presenting the recommendations for H1N1 from the Disaster Mental Health Subcommittee. H1N1 updates would then follow.

DISASTER MENTAL HEALTH (DMH) SUBCOMMITTEE RECOMMENDATIONS FOR H1N1

Betty Pfefferbaum, M.D., J.D. Chair, DMH Subcommittee, National Biodefense Science Board

Dr. Pfefferbaum summarized the recommendations for H1N1 from the DMH Subcommittee.

The Subcommittee strongly recommended that state and local public health officials invite their behavioral health authorities (both mental health and substance abuse) to meet and discuss local efforts and plans; identify constituents (including high risk and vulnerable populations); and develop steps they can take together to address mental health concerns.

A current roster of state disaster mental health and substance abuse coordinators from the

HHS Substance Abuse and Mental Health Services Administration was forwarded to the Board.

The Subcommittee also recommended that state and local public health officials as well as behavioral health officials develop strategies to maintain calm at treatment sites such as flu vaccine clinics, primary care settings, and emergency departments – in order to minimize stress for providers working at these locations. The Subcommittee recommended ensuring sensitivity to emotional and behavioral health needs that may arise at vaccination sites. A strategy that has proven to be successful is to assign a mental health staff to monitor the waiting area/line in order to:

- Provide a reassuring presence and convey that everyone will be cared for throughout the entire process.
- Provide basic and accurate information about what to expect when they receive attention (simple handouts are helpful).
- Identify and intervene with persons experiencing severe psychological distress (the fact sheet “Maintaining Calm at the POD,” which offers further suggestions was provided to the Board).

In the interest of providing swift, accessible education about behavioral health considerations during this crisis, the DMH Subcommittee—with the assistance of the Office of the Assistant Secretary for Preparedness and Response—compiled a list of specific resources (including those related to death and bereavement) that pertain to behavioral health. The list was provided to the Board. The Subcommittee further recommended that the Board propose distribution of the list to state public health authorities.

The Subcommittee also recognized that significant expertise regarding public health messaging currently exists among individuals within the federal government, including HHS. The DMH Subcommittee is comprised of members who are willing to serve as subject matter experts for messaging and guidance as needed. Subcommittee members also have access, through their affiliations and associations, to additional experts in various specialty areas that can act as resources when gaps in messaging or communication challenges are identified.

DISCUSSION

Dr. Quinlisk asked whether there were any specific issues to be discussed by public health officials and behavioral health officials once they convened. Dr. Pfefferbaum responded that the idea was to foster the joint planning among various authorities. Topics for discussion could include efforts already underway, planning for future efforts (both near- and long-term), and identifying and addressing the needs of the high-risk and vulnerable populations, which may differ across systems and locales.

Dr. Berkelman asked whether maintaining calm at vaccination sites for H1N1 is currently

a problem. Dr. Quinlisk said that a recent article in the media reported threats of violence in a clinic somewhere in the Northeast. She added that – due to the variance in vaccine supply from place to place – there are clinics offering vaccines to different kinds of people at different times, which confuses the public and causes frustration, especially when taking into account that vaccine supply has not met the need.

Dr. Pfefferbaum underscored that the Subcommittee did not expect major mental illness or psychiatric issues to be a concern at vaccination sites. Rather, the application of good clinical skills and working with people in general should be sufficient to maintain calm in most locales. Dr. Grabenstein opined that the recommendations seemed to be good clinical, which provide suitable crowd control and queuing processes to help keep things calm in the first place.

Dr. Berkelman suggested identifying sites most at risk, as it might not be tenable to implement the Subcommittee’s recommendations at every site. Dr. James explained that the letter was meant to function as a checklist for states to consider. They could then operationalize it based on their specific conditions.

Dr. Quinlisk asked if there would be someone at the national level specifically examining mental health issues arising from vaccine shortages and distribution challenges for the purpose of compiling recommendations for future situations. Dr. Dodgen explained there are several efforts towards monitoring various factors at the point of distribution, including the psychological impact. However, it’s likely there isn’t a point-person specifically assigned at the federal level. He explained that Dr. Lurie has asked the DMH Subcommittee to begin thinking prospectively as to how HHS is performing with regards to integrating mental health into the department’s overall public health emergency preparedness activities.

Dr. Gellin added that the issue has come up in the past with the National Vaccine Advisory Committee (NVAC) and similarly NVAC has suggested capturing lessons learned. Perhaps there could be an effort to revisit the topic and also get a better sense as to where this might have a focal point within the Department. Dr. Quinlisk suggested examining the matter beyond just the federal level. In other words, to try to understand how the federal, state, and local levels influence each other.

Dr. James said that there is also a need to establish study protocols to obtain real-time data that could help answer the kinds of questions being raised. The challenge is that it takes 8 to 12 months to obtain funding for these types of studies, which is too long and results in investigators missing the window of opportunity to carry out the study. Dr. Berkelman added that there are a number of preparedness and emergency response research centers that might serve as a platform for this type of research.

Dr. Quinlisk suggested adding a recommendation to the Secretary’s letter that states the importance of mental health issues, and that given the present pandemic interventions are one of the largest responses of its kind, we should not lose the opportunity to learn more about mental health response and lessons learned in the mental health area. As people

evaluate the response to the H1N1 pandemic, there should also be assurance that mental health issues are examined and included in the report, and distributed to improve response in the future.

Dr. James agreed and suggested that the matter should be high on the DMH Subcommittee's priority list as it moves forward. He also suggested that outlining a plan that includes research (or a study base to start answering these questions) could be extremely helpful. Dr. Quinlisk agreed and asked the DMH Subcommittee to determine the main questions to be answered.

Dr. Cantrill made a minor suggestion to change the words "emergency room" to "emergency department" in the recommendation provided by the DMH Subcommittee.

Dr. Quinlisk opened the meeting for public comment.

PUBLIC COMMENT

CAPT Sawyer read a letter from Gladys Padro and Ashley Pearson, Acting Co-chairs of a newly formed consortium of 23 State Disaster Behavioral Health Program Coordinators. They had two requests. The first request was that the board recommend to DHHS direct funding of State Mental Health Authorities for all hazards planning and preparedness for disaster behavioral health activities. FEMA/Department of Homeland Security, through the Stafford Act has funded the Crisis Counseling Assistance and Training Program by providing funds directly to State Mental Health Authorities for disaster behavioral health response and recovery, which includes a significant training component. With such a long-standing track record at the Federal level, they that planning and preparedness funding should be directed to State Mental Health Departments.

The second request is that the Board appoint a minimum of two State Mental/Behavioral Health Disaster Coordinator members from the Multi-State Emergency Behavioral Health Consortium as full representatives on the Disaster Mental Health Subcommittee. One of their initial contributions could be to undertake a review of the important and significant work that has been accomplished by State Mental Health Authorities in disaster behavioral health planning, preparedness, response and recovery, including training.

Once the telephone-lines were opened, Paul Gordon from West Coast Health Alliance, made the first public comment. He said that in talking about behavioral and fear-related issues, one of the things that needs to be addressed and brought to public attention are some of the efforts taking place that have apparently resulted in some very positive, dramatic results, such as the results with regards to the intravenous (IV)-based peramivir antiviral. He suggested that this needs to be publicized more.

Jane Bishop, a State Behavioral Health Disaster Coordinator in Pennsylvania, applauded the recommendations being made to include state mental health authorities and their disaster coordinators along with drug and alcohol emergency responders. She described some of the efforts her state has undertaken, including working on issues related to the

H1N1 pandemic vaccination program. They receive funding from the state's Department of Health, but most states don't have direct funding from the federal government. She hopes that dialogue will continue with State Disaster Behavioral Health Coordinators.

Russell Jones, a member of the DMH Subcommittee, from Virginia Tech, said that having a mental-health professional onsite whenever possible is a good idea. It is something that was done following Hurricane Katrina as well the Virginia Tech shootings. He also supported Dr. James' suggestion of putting more science behind these types of efforts.

VOTE ON DMH SUBCOMMITTEE RECOMMENDATIONS FOR H1N1

Dr. Grabenstein and Dr. Berkelman suggested 'distilling' the DMH Subcommittee recommendations and including them in a separate letter which would be reviewed by the board members prior to forwarding to the Secretary.

Dr. Quinlisk said the board would take the three recommendations from the DMH Subcommittee and slightly modify the language, but not the intent of the recommendations. The board would also add a paragraph about the issues discussed today. The board agreed to move forward on this.

Dr. Grabenstein moved to transform the letter received from the DMH Subcommittee for the Board's transmission to the Secretary. He moved that the three recommendations be adopted along with capturing lessons learned. The letter would state that attachments were provided to the Board and are available, however the attachments themselves would not be included in the letter. Dr. Dretchen seconded that motion. Dr. Quinlisk called a vote, which was unanimously in favor of the motion.

H1N1 UPDATE: H1N1 AND SEASONAL FLU ACTIVITY, H1N1 VACCINES AND ANTIVIRALS, AND OTHER PERSONAL PREPAREDNESS METHODS **Sally Phillips, R.N., Ph.D., Immediate Office of the Assistant Secretary for Preparedness and Response, HHS**

The presentation by Dr. Phillips focused on the status of medical surge and the capabilities of the federal government to address it. Following the declaration of a public health emergency, five 1135 waivers have been issued thus far [under section 1135 of the Social Security Act [42 U.S.C. § 1320b-5], healthcare facilities may petition HHS for 1135 waivers to ensure that sufficient healthcare items and services are available to meet the needs of Medicare, Medicaid, and CHIP beneficiaries - by waiving certain legal requirements that could otherwise limit the ability of the nation's healthcare system to respond to the surge of patients with the 2009 H1N1 influenza virus]. These requests were handled by HHS within 24 hours.

The federal government has been aware of an increased number of hospitalizations and has taken steps to give as much authority and leeway for hospitals to be able to respond. Many of the challenges faced are related to the Emergency Medical Treatment & Labor Act (EMTLA), as well as, an increase in the number of patients with influenza like illness (ILI) seen in emergency departments. Another concern relates to very sick individuals, and

the surge issues at intensive care units (ICUs) related to that type of care. Statistics show that there have been 17, 838 hospitalizations confirmed by influenza laboratory tests.

Several resources, including financial resources from the Hospital Preparedness Program, have been provided to support health care systems in addressing this surge. Also, the last \$90 million in supplemental funds have been primarily geared towards H1N1 for various purposes, including getting health care workers vaccinated, and the purchasing of ventilators or respiratory equipment that may be necessary to address the cusp of the event.

There are several reporting systems currently in use to monitor events in the health care system, including the National Hospital Available Beds for Emergencies and Disasters (HAvBED) System. HAvBED has been enhanced, with new data elements now in place to identify system stress. This will help determine the need for federal augmentation and support.

Some hospital data received over the past two months show an increase in the number of patients, but the situation remains manageable and there have been no requests to augment patient care. The only augmentation has been in the form of a few requests to help support some vaccination programs.

Dr. Cantrill asked if the 1135 waivers can be retroactive for a couple days. He also asked if data analysis showed if the influenza cases are coming in “waves.” Dr. Phillips confirmed that waivers can be retroactive. She also added that there is no definite pattern, with some areas of the country having reached plateau, others being on the downturn and still others on the rise.

Dr. Quinlisk asked if a third wave is expected and whether or not the system is prepared for this. CAPT Butler responded that they don’t know if it will happen. A smaller peak occurred in January and February of the 1957-1958 pandemic, which was a third wave. After analyzing data from the 1918-1919 epidemic, some individuals also believe there was a third wave at that time. Dr. Quinlisk remarked that it’s important not to be complacent and stop vaccinations if there’s the possibility of a third wave.

Dr. Quinlisk asked if our hospital systems might be a massively overwhelmed. Dr. Phillips responded that the surge plans put in place by the emergency departments are working and are helping to accommodate the increased number of individuals. One of the areas of concern, however, is ICUs, which are not always expandable. They seem to be quite taxed but are holding up. Dr. Phillips believes that no major requests have been made to date.

Dr. Quinlisk asked if there was a need for respirators and other related equipment. Dr. Phillips responded that some hospitals have contracts where they can pull in additional ventilators as part of their regular surge plans. Also, many states have built-up caches that have been pre-deployed. There are no indicators at this time that hospitals have not been able to access ventilators.

Dr. Cantrill said that there are issues with regard to Personal Protective Equipment (PPE). Some locations have run out of N95 masks, and there is still much confusion – even in the literature – whether one should use surgical masks or a N95 masks. So, some hospitals have not done an adequate job of preparing for a PPE draw.

Jay Butler, M.D., CAPT. USPHS, Program Director, H1N1 Vaccine Task Force, CDC, HHS

CAPT Butler provided an update on the epidemiology of H1N1 and seasonal influenza. He also touched on H1N1 vaccine distribution.

The surveillance tool ILINet – which is based on the proportion of visits to physician offices for influenza-like illness in a network of single providers around the country – has shown a decline in the proportion of visits for ILIs from 7.9 two weeks ago to 6.7 this week. Nonetheless, 47 out of 50 states are reporting widespread influenza activity.

Pneumonia mortality rates are above normal for the normal range for this time of year and are within the range usually seen only during the peak of influenza season. Younger persons are disproportionately impacted by H1N1 as measured by rates of illness, hospitalization, and death. Current estimates based on mathematical modeling of surveillance data show that through mid-October 22 million Americans have been ill with H1N1 and approximately 4,000 have died.

The vaccine program currently has 43 million doses available for order through individual states. Orders can be placed by state health departments on a daily basis. These orders are transmitted to CDC for review, then a central distributor ships the vaccine overnight.

The biggest challenge in the vaccine program has been supply. The amount of vaccine entering into the pipeline has remained relatively low. In addition, weather issues on the East Coast have resulted in some states receiving a smaller allocation this week.

Dr. Berkelman asked CAPT Butler to comment on the finding that, given the estimates, the majority of children, maybe as many as three or four, as well as many young adults may have died from H1N1 with no laboratory test confirmation. CAPT Butler responded that this point estimate is arrived at by comparing the number of cases reported with an isolate for confirmation, to numbers obtained from modeling based on the best epidemiology. One should keep in mind that this is a point estimate.

Dr. Grabenstein asked Dr. Butler to consider a scenario where a location ordered more vaccine than it could use. In this scenario, would the surplus be redirected to a place where it's needed or would states (or big municipalities) quickly realize the error and transfer the doses to a place nearby where they could be used? Dr. Butler responded that this has actually happened at the state level but that there isn't enough regional variation to try to do this at the national level. Some states are making decisions on distribution based on local epidemiology. For example, a state ensured a larger allocation for tribal and Indian Health Service facilities due to the concern that American Indian populations, at least in that state, were disproportionately represented among hospitalized cases. At this point the wisest

course seems to be for the states to be able to have the ability to make local decisions based on local epidemiology.

Anita Patel, Pharm.D., M.S., Health Scientist, Division of Strategic National Stockpile, CDC, HHS

Dr. Patel's presentation touched on issues related to the Strategic National Stockpile (SNS). She reported that back in the spring – in April and May – the Stockpile had deployed 25 percent of all of its pandemic influenza countermeasures on hand (pro rata, based on population) to the 62 project areas. Approximately 11 million regimens of antiviral drugs, gloves, gowns, face shields, surgical mask and respirators were deployed. In October and November, an additional 58.6 million N95 respirators, as well as 535,000 regimens of antiviral suspension products, were deployed. The decision to deploy these products was based both on need as well as monitoring of the supply chain, to ensure there were enough products available for the U.S. population.

There has been follow-up with states to determine both the focus for the distribution of national stockpile assets received, as well as for the distribution of their state stockpile assets. States are reporting on a weekly basis through a voluntary survey mechanism. On average, about 41 out of 62 project areas are reporting a wide variety of information; including the locations where they're moving shipments of antiviral drugs and personal protective equipment (PPE).

There is also collaboration with manufacturers, distributors, and retailers to gain visibility on their inventory. This information is used to determine the supply of antivirals and PPE. The demand side is being monitored as well, specifically for antiviral drugs and prescription rates, to determine if prescription needs are being met with the current supply. All this information is used to ensure the Stockpile is released at the appropriate time.

Dr. Dretchen asked if there were any shortages in the distribution of pediatric oseltamivir (Tamiflu) formulations to the states. Dr. Patel responded that there have been limited-supply issues, especially with the suspension products. There are three antiviral formulations for pediatrics: 30 milligram Tamiflu capsules, 45 milligram Tamiflu capsules, and Tamiflu oral suspension. The oral suspension product has been in limited supply. This has resulted in a "push" of oral suspension product supplies to states, along with guidance to project areas for them to push it down further to the local level. There are no shortages of the capsules in the supply chain, and these can be an alternative to the oral suspension. For children that can't swallow capsules, capsules may be opened and the contents added to a sweetened liquid, such as Hershey's chocolate syrup, for administration. This method does not allow for as precise dosing as can be provided with formulations dispensed by a pharmacist.

Dr. Patel explained that CDC has also been focusing messaging towards pharmacists making them aware of compounding as an option. Compounding guidelines from the Tamiflu package insert have been posted on the FDA Web site. Additional guidance

including videos on compounding, and other communications have been targeted directly to community pharmacists, as well as professional pharmaceutical organizations.

CAPT Sawyer asked if there was any resistance to H1N1 antivirals. CAPT Butler responded that the amount of resistance seen was minimal.

Michael Bell, M.D., Associate Director for Infection Control Division of Healthcare Quality Promotion, CDC, HHS

Dr. Bell addressed issues related to personal preparedness.

Dr. Bell reported that the situation regarding personal protective equipment (PPE) supply is far from adequate to cover ‘the waterfront’ in terms of exposure risk for health care personnel. It has become clear that health care personnel diagnosed with H1N1 have a variety of sources of exposure, and that exposure to sick patients is actually the minority of those exposures, with the majority being split between household exposures, and exposures to other health care personnel who show up at work, despite being sick.

DISCUSSION

Dr. Quinlisk asked what kind of feedback Dr. Bell was obtaining from health care workers regarding masks, supplies, and use of the procedural masks vs. N95 masks. Dr. Bell responded that – fairly uniformly around the country – there are patches of areas having difficulty in supplying both masks and respirators. Despite the fact that distributors, or other sources, might say they're available, there's a challenge when it comes to the actual clinician opening a cabinet and finding them. He said that somewhere in the local supply chain there are challenges in maintaining supplies. Dr. Bell added that sometimes when a facility attempts to order more masks or respirators, they're being told they will get a proportion of the allocation based on annual purchasing, and that any extra order will take several months to fulfill. Dr. Cantrill said he was seeing the same situation - that N95s were on back order. Dr. Cantrill suggested that this be an area of focus for hospital preparedness in the future.

Dr. Quinlisk remarked that in Iowa, while the hospitals seem to be pretty good at using masks appropriately and using the appropriate mask, getting people to use masks in the clinic/outpatient settings is much harder. She said she's heard of many individuals who were being treated for the flu and remarked that health care providers didn't have a mask on.

Dr. Bell said this is not only seen in outpatient settings, but also in a range of settings where respiratory protection hasn't traditionally been used. The challenge is not only the willingness to use the equipment, but also the infrastructure needed to use it appropriately - in other words, training, fit-testing, etc. The respirator health programs that are supposed to underlie the respirators tend not to be in place in long-term facilities, clinic settings, ambulatory surgical facilities, etc. Therefore, it's important – when making recommendations to go beyond in-patient facilities because patients are seen in a variety of settings and standard recommendations for hospitals alone may not be adequate to guide behavior. Even if recommendations were made for other settings, the challenges still remain in terms of making sure that everyone is trained and fitted properly so they can adhere to the recommendations.

Dr. Cantrill added that another problem is that nominally only 30 to 50 percent of health care providers believe in influenza vaccinations (based on receiving one personally).

Dr. Bell also reported that the updated interim guidance shows an intentional focus towards solutions that will protect individuals more broadly, such as vaccine use, rather than masks and respirators, because having an immune population is the best possible solution. There's also the importance of source control and the dedication of some of the mask supply for use in coughing individuals. If one could ensure that sick individuals stay home, these two strategies alone may have a much bigger impact than protective equipment for routine patient care.

PUBLIC COMMENT

Mr. Robert Rayl, a private investor, asked about the emergency use authorization (EUA) given to IV peramivir on October 23. He asked if the board knew how many patients have received the drug and whether or not results were good enough to allow peramivir for use as a first-line treatment, instead of when patients are on ventilators and in serious conditions. He also said there's an H1N1 crisis in Ukraine. If the Ukraine requested peramivir, Mr. Rayl asked if it could come from our government or would the drug have to be purchased from BioCryst?

RADM Lushniak responded that he did not have the number of requests at hand, but could obtain that information. IV peramivir is a product that has been issued an emergency use authorization (EUA), for this specific emergency, and has not yet been fully approved. Certain conditions still need to be met to obtain access to the medication. So, at this point, even though there's more use of it, the data are not there to move it out of the EUA status at the moment.

Dr. Patel said that in October as well as the beginning of November 2009, HHS procured a total of 11,200 treatment courses of IV peramivir from BioCryst. The product was made available through CDC via the Strategic National Stockpile, and only for use under the EUA. Licensed clinicians may request this product through CDC's Web site. Clinicians requesting the product are required to review the scope, conditions, and criteria for an EUA. They must also agree to comply with the conditions of the authorization. Once the request is received and accepted, CDC can deliver the product directly to hospitals within 24 hours of the decision to ship. To date, there have been a total of 829 regimens deployed to 533 patient requests (some patients were given a 5-day regimen, others a 10-day regimen). Ninety-three percent of the supply still remains, which is sufficient to meet the demands seen thus far.

Dr. Rose asked if IV Tamiflu and Relenza have also been distributed through an EUA. CAPT 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 answered that those products are not under an EUA, although they are available through the Emergency Investigational New Drug (E-IND) process on a case-by-case basis. The peramivir intravenous formulation is not a first-line treatment and is

intended for very sick individuals. For all others, there are approved antiviral medications currently available for individuals to take through normal routes of administration.

Dr. Berkelman asked about the average time between request and shipment of IV peramivir. Dr. Patel said that at the moment the average time for a decision is 30 minutes. She added that the electronic system is set up in such a way that there's a small time frame between a request and a decision to deploy. This involves, in part, the Strategic National Stockpile having confirmed logistical information and assured that all conditions of the EUA have been fulfilled.

Ms. Grace Huang asked how many N95 respirators had been released from the Stockpile and how many still remain. Dr. Patel responded that 20.4 million respirators still remain in the Stockpile and a total of 27.6 were deployed in the spring with an additional 58.6 recently deployed.

In reference to liquid Tamiflu, Ms. Huang asked whether the quantity released from the Stockpile was for children. Dr. Patel confirmed that this was the case. An additional 540,000 bottles (one bottle equals one regimen) were deployed from the Stockpile for a pediatric oral suspension. That was deployed in the fall, and is in addition to the 59,000 courses deployed in April.

Ms. Huang also asked which five states received 1135 waivers. She also asked if there was a correlation between the states that received them and the severity of the disease at this point. Dr. Phillips said there were two requests approved for Ohio, one for North Dakota, one for Montana, and one for Washington state. Dr. Phillips said that she didn't know if the requests were correlated with disease severity.

Mr. Paul Gordon asked about issues relating to IV-based antivirals. He believes that neither the IV-based Relenza nor Tamiflu have been through clinical trials when used through IV-based administration. He also asked if the U.S. would be left at risk if BioCryst were to publicly sell its inventory of IV peramivir to other countries.

CAPT Miller said he could only respond to the first question. CAPT Miller said that IV formulations of Tamiflu and Relenza, were currently not approved for IV use. These can be obtained on a case-by-case basis through an emergency use Investigational New Drug request. There are no EUA requests at the moment, with respect to the IV formulations of these drugs.

Dr. Patel added that they are confident the Strategic National Stockpile's inventory will be able to meet current demand for a product. They have been working with BARDA, which has been engaging the manufacturer to ensure that product is available if additional amounts are needed.

Mr. Gordon said he heard about shortages of some Tamiflu formulations for pediatrics. He asked if there had been any discussions on the expanded use of IV peramivir. In particular,

he asked if there's any consideration for expanded use earlier in the protocol or for pediatric use.

Dr. Patel responded that, currently, IV peramivir is allowed for use in pediatrics. In terms of additional expansions for use under the EUA, CDC has no additional plans at this time to make a request to the FDA for changes on its currently requested EUA.

CAPT Sawyer read two written communications sent by other individuals to the Board. The first was from Anjelica Dortch of McKenna, Long and Aldridge LLP. She requested that information be made public on the number of H1N1 vaccine doses delivered to the distributor from each individual manufacturer. This would provide a better understanding of vaccine production and distribution logistics between HHS and the vaccine manufacturers.

The second communication came from Samuel Dixon who works in the Addictions and Mental Health Division of the Department of Homeland Security. He expressed concern about any language in the Board's recommendations that mandated how services should be delivered. He added that most H1N1 distribution centers do not need claims, as they have staff appropriately trained and are professional in their ability to provide intervention and referrals to clinical providers. Mr. Dixon underscored that mental health resources are already strained enough without asking them to provide monitoring services.

WRAP UP AND ADJOURN

CAPT Sawyer announced that another public meeting will be held on Wednesday, December 9th from 12-2 EST. More details will be posted online. Dr. Quinlisk thanked all participants and applauded all efforts being carried out at the national level. She adjourned the teleconference at 2:02 p.m. EST

Public Comment

From: Dortch, Anjelica [adortch@mckennalong.com]
Sent: Tuesday, November 10, 2009 7:25 PM
To: OS NBSB
Subject: Comment for Nov. 13t Meeting

Dear NBSB Committee Members,

Thank you for taking this opportunity to review this comment with regard to H1N1 vaccine production information.

On a weekly basis the public is updated on the available doses of the H1N1 vaccine for purchase by states. However, no information is publicly available with regard to the number of doses being delivered to the distributor from each individual manufacturer. This information needs to be made available to the public to provide a better understanding of vaccine production and distribution logistics between HHS and the vaccine manufacturers.

Once again thank you for your time and attention to this matter.

Sincerely,

Anjelica Dortch

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From: Samuel N DICKSON [samuel.n.dickson@state.or.us]
Sent: Friday, November 13, 2009 12:47 PM
To: OS NBSB
Subject: Teleconference input

Attachments: Samuel N DICKSON.vcf

I appreciate the boards work and recommendations. I am concerned that any language in the recommendations be careful not to mandate how services should be delivered. Most H1N1 distribution centers do not need clinical psychologist "monitoring for stress". Public Health, School and Health care staff appropriately trained and professional in their ability to provide intervention and referral to clinical providers.

Mental Health resources are already strained enough without asking them to provide "monitoring" services.

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State Disaster Behavioral Health Consortium

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Patricia Quinlisk, MD, MPH
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National Biodefense Science Board
US Department of Health & Human Services
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Dear Dr. Quinlisk:

We are a newly formed consortium of 23 State Disaster Behavioral Health Program Coordinators, representing states across the nation from California to Maine, Illinois to Georgia. The consortium has the endorsement of its respective State Mental Health Commissioners. Enclosed is the consortium mission statement. We respectfully request this letter become a part of the November 13, 2009 official meeting record concerning the Disaster Mental Health Subcommittee Report and Recommendations.

Today we submit for your consideration two requests, and provide our rationale in the discussion that follows:

1. that the Board recommend to DHHS direct funding of State Mental Health Authorities for all hazards planning and preparedness for disaster behavioral health activities. FEMA/DHS, through the Stafford Act, has funded the Crisis Counseling Assistance and Training Program by providing funds directly to State Mental Health Authorities for disaster behavioral health response and recovery, which includes a significant training component. With such a long-standing track record at the Federal level, we believe that planning and preparedness funding should be directed to State Mental Health Departments.
2. that the Board appoint a minimum of two State Mental Health Disaster Coordinator members from the State Disaster Behavioral Health Consortium as full representatives on the Disaster Mental Health Subcommittee. One of their initial contributions could be to undertake a review of the important and significant work that has been accomplished by State Mental Health Authorities in disaster behavioral health planning, preparedness, response and recovery, including training.

Mission: *The Mission of the State Disaster Behavioral Health Consortium is to ensure that State mental health authorities are represented in disaster and emergency response planning and preparedness activities at the national level as key partners in all Federal public health and medical preparedness and response activities.*



Since 1974, Section 416 of the Robert T. Stafford Disaster Assistance Act has provided funding to State Mental Health Authorities to address the psychological impacts of disasters on individuals and communities, through the Crisis Counseling Assistance and Training Program (CCP). This program is funded by FEMA and administered by DHHS/SAMHSA/CMHS through an interagency agreement between the two agencies. These Federal funds are the only legislatively mandated funds available for crisis counseling to serve both individuals and communities in Federally declared disaster areas. The State Mental Health Authority is the official grantee. This program has a long history of success and has increased the understanding of behavioral health consequences of disaster events, resulting in best practice interventions.

As a result of developing, managing and administering these programs over a period of more than 20 years, State Disaster Behavioral Health Coordinators have more hands-on experience in disaster behavioral health programs than any other state, university, or voluntary agencies. States have also become experts in developing creative and innovative interventions, training and education programs, outreach modalities and public information campaigns. State Disaster Behavioral Health Coordinators engage in a broad scope of roles in disasters: providing management of state disaster behavioral health services, technical assistance to State leadership, conducting needs assessments, and developing program evaluations; in addition to leading the program in partnership with local mental health providers. We also provide consultation to senior officials at all levels, regarding matters concerning disaster behavioral health.

We have led the way in creating strong networks of intergovernmental and interagency collaboration with all preparedness, response, and recovery partners in the states. These include: Emergency Management agencies, faith based communities, Departments of Health, Education, Justice, first responders, National Guard, Voluntary Organizations Active in Disasters (VOADs), leaders of non-English speaking communities and many others. Coordinators have been working for years to develop and provide guidance in accordance with SAMHSA, CDC, FEMA and others to champion disaster behavioral health. A major accomplishment is the intergovernmental coordination and partnership among States, as evidenced by this consortium, formed on our own initiative. As disasters do not respect State boundaries, we have spontaneously worked together across our governmental jurisdictions.

We are mindful of the significant documents and reports that have been produced in the last several years, either by Federal agencies or with Federal funding. We have thoughtfully considered those documents, their recommendations and guidance as we deliberated in voicing our concerns. Some of these documents include: The Institute of Medicine Report (2003) "Preparing for the Psychological Consequences of Terrorism" made several



recommendations regarding evidence-based techniques, training and education that the Federal government should lead. The interagency workshop of DHHS, Department of Defense, Department of Veterans Affairs, Department of Justice and the American Red Cross convened in November 2001 resulted in the report "Mental Health and Mass Violence – Evidence-Based Early Psychological Intervention for Victims/Survivors of Mass Violence". This report reached consensus on best practices, which supports the model of the Stafford Act Crisis Counseling Program, that States have successfully implemented since the program's inception. SAMHSA and NIMH provided partial support to a significant and important article published in *Psychiatry*, Winter 2007 "Five Essential Elements of Immediate and Mid-Term Mass Trauma Intervention Empirical Evidence." This article was co-authored by many credible experts in the field who have conducted research on disasters, and identifies five "evidence-informed" principles, which reinforce the very same principles that have guided the Crisis Counseling Program for more than two decades.

Most recently, we have reviewed the **DHHS Disaster Mental Health Subcommittee Report, which was presented to the DHHS National Biodefense Science Board (NBSB) on November 18, 2008.** As States, we have concerns and question some of these recommendations provided to the NBSB. We also believe the invited experts of the Disaster Mental Health Subcommittee did not adequately reflect the range of subject matter experts that should have been invited to participate on the Subcommittee and present their findings to the Subcommittee membership.

The lack of State Disaster Mental Health agency representation on the Subcommittee is a significant oversight. There is no reference in the report, background or discussion of the federally funded Stafford Act Crisis Counseling Assistance and Training Program or of the successes and best practices of this program. The Crisis Counseling Assistance and Training program lays the foundation in this country for disaster behavioral health services, continues to build upon that foundation, with 100 % major Federal response funding, develops best practices, and moves the field forward to advance the knowledge base of disaster behavioral health services.

The lack of acknowledgement and inclusion of the contributions of the State Disaster Behavioral Health Coordinators raises questions regarding the comprehensiveness of this report. It references the "existing disaster mental health model" but does not provide any background, history, description or context of this model. Since the Subcommittee recommends building upon this model, then it should, at a minimum, define, and describe the model and provide a rationale for its recommendation why it should serve as the foundation for the Subcommittee's future endeavors. Decisions made by the NBSB will have an impact on the way in which state and local jurisdictions implement services.



Although some of the recommendations suggest new initiatives, such as legislation, regulations and grants language inclusive of disaster behavioral health, some recommendations appear to contradict guidance from earlier federally funded reports, while others appear duplicative or redundant from previous reports. We question the focus on research; the university-based approach to training, the inclusion of national health associations, guilds and universities, and the exclusion of the State Mental Health Authorities. Much has been developed in the past twenty years with Federal funding for communication and messaging, and States are already underway identifying, educating and training their cadres of mental and behavioral health experts to serve as consultants. In fact, many states have developed networks among these groups for the provision of disaster behavioral health resources.

Finally, FEMA, through the Emergency Management Institute, has for years conducted a week-long Crisis Counseling Assistance and Training Program. Before moving to the development of another partnership with an academic military program at the Uniformed Services University of Health Sciences, it would seem more reasonable and appropriate to review the current annual course provided to State Mental Health Authorities, as well as to support the provision for states to develop their own networks. State Disaster Behavioral Health Coordinators have developed curricula on a range of disaster behavioral health topics, training local community mental health providers and other local social services providers to respond to the psychological impacts of natural and human-caused disasters. The National Center for Post Traumatic Stress Disorder (NCPTSD) has developed curricula and training that compliments what FEMA and the States have been doing for years. Given the severe budget constraints of the Federal and State governments and the difficult economic downturn, we suggest it would be more productive to husband those resources, not reinvent the wheel, but rather, refine it, since expertise and proven training curricula already exist.

Some current critical areas for the Board's consideration that we believe need attention:

1. Need for integrated Federal coordination and consistent Federal guidance to the States in disaster behavioral health planning, preparedness, evidence-based practice, services interventions and training.
2. Clarifying and defining the competing and conflicting roles of organizations which are identified as disaster behavioral health trauma stakeholders and experts: for example, the American Red Cross,



International Society for Traumatic Stress, National Association of City and County Health Officials, and other nonprofit organizations.

3. Support for the expanding mission for disaster behavioral health services (ESF-6 and ESF-8, ESF-15) in the context of declining resources. Federal emergency mandates are requiring states to demonstrate increased attention to planning requirements, without the resources. Other State agencies are requesting and requiring State Mental Health Authorities to provide training and guidance for new requirements in ESF-6.
4. Examination of the Post Katrina Reform Act mandate for a new case management services system that has significant implications for overlap and duplication with the existing Crisis Counseling and Assistance Training Program, ensuring the appropriate partnership in service provision.
5. The need for State Disaster Behavioral Health representation and inclusion in all key Federal planning initiatives on disaster behavioral health, such as the Disaster Mental Health Subcommittee.

We suggest that the Board, in partnership with States, should build upon the legacy of the Stafford Act Crisis Counseling Assistance and Training Program, where millions of Federal dollars have supported an excellent program that has resulted in best practices. State budgets are facing one of the most austere times in modern US history. We suggest a more effective use of resources would be to invest directly in State-to-State and local capacity building, which already exists, before implementing the Disaster Subcommittee's recommendations. Thank you for your time and attention.

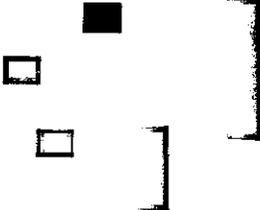
Sincerely,

Gladys Padro, MSW, LSW, Co-Chair

Ashley Pearson, MPA, Co-Chair

On behalf of the State Disaster Behavioral Health Consortium

cc: The Honorable Kathleen Sebelius



State Disaster Behavioral Health Consortium

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Mission Statement: The Mission of the *State Disaster Behavioral Health Consortium* is to ensure that State mental health authorities are represented in disaster and emergency response planning and preparedness activities at the national level as key partners in all Federal public health and medical preparedness and response activities. The Consortium will promote the equitable progression of policies, curricula and practices to support individuals and communities impacted by emergencies, disasters and other events that overwhelm local resources and potentially create traumatic reactions. The formation of a consortium will provide States with a forum for a collective and unified voice in national decision making toward the continual shaping of the nation's emergency behavioral health preparedness and response system.

The Consortium will build upon previous Federal and Congressional report recommendations, and the guidelines set forth by the Robert T. Stafford Disaster and Emergency Act to further develop a national behavioral health capability within the National Response Framework. In collaboration with its federal and state partners, the Consortium will endeavor to advocate for awareness of the psychosocial impact of disasters and other emergencies and the importance of offering behavioral health interventions and outreach services for both individuals and communities.

The goals of the *State Disaster Behavioral Health Consortium* are to promote:

- 1) State and local behavioral health representation in national disaster public policy decision-making with Federal partner agencies.
- 2) Dissemination and sharing of resources to advance consistent response and recovery planning processes.
- 3) Standardized training based on core curricula that will prepare a cadre of qualified, trained professional counselors and paraprofessional outreach workers to respond to the psychosocial needs of impacted individuals and communities.
- 4) Technical assistance for all-hazards emergency response plans that include provisions for providing both behavioral health and substance abuse services.
- 5) Integration of appropriate disaster behavioral health interventions and services into all phases of emergency management.
- 6) Collaboration with federal, state, and local disaster response agencies to work to prevent, respond to, recover from and mitigate the psychosocial effects of emergencies, disasters, and other incidents.