H1N1 Influenza Preparedness Summit

July 9, 2009

Note: The Summit Agenda, H1N1Resource Kit, and News Release can be found at http://www.flu.gov/

Key Points

Call to Order/Opening Remarks

Raynard Kingston (Acting Director, NIH)

- Genetic analysis traced origins of H1N1 virus back to the virus that caused the 1918-1919 pandemic.
- Pandemics affect all aspects of society and collaboration between federal, state and local governments and public health as well as schools, businesses, etc, is crucial. This collaboration and communication also provides an opportunity to learn from each other and the past and bring the best knowledge to the current situation.

Situation Update

Thomas Frieden (Director, CDC)

- There is a level of unpredictability and remarkable heterogeneity with young people affected disproportionately. The H1N1 influenza has been socially disruptive, especially for schools.
- Tens of thousands of health workers responded and continue to respond worldwide.
- At this time in the US, we're seeing mostly cases of the pandemic strain of influenza. There are few cases among the elderly and more cases in young adults and children so the pandemic strain is a different pattern compared to seasonal influenza.
- Among patients hospitalized, an overwhelming proportion, more than 2/3 or ¾, have underlying conditions. These underlying conditions are important as they identify groups that need to be prioritized. Underlying conditions include asthma, which is the leading underlying condition in hospitalized patients, chronic lung disease, diabetes, morbid obesity (bmi 40 and above), neurocognitive disorders in children, and pregnancy. People with these underlying conditions are at higher risk and will be higher priority for prevention and treatment moving forward.
- There have been 50 outbreaks in summer camps; some communities continue to have high infection rates.
- In the Southern hemisphere, there is substantial disease in Argentina, Chile, and Australia; there is co-circulation with seasonal influenza strains in some areas and this is a strain on health care system in some locations.
- Antiviral resistance to Tamiflu (Oseltamivir) was detected in 3 patients (Denmark, Japan, and US traveler to Hong Kong).

- We're still trying to understand the transmissibility and monitor the antiviral resistance patterns over time. We'll need to continue to adjust our plans based on the data and to fit the situation.
- What can we do now: surveillance in our country and globally, planning at all levels as appropriate for each level in prevention and response, and effective communication.

Remarks and Introduction

Anthony Fauci (Director, NIAID/NIH)

- The NIH has a long history of studying seasonal influenza, which is a serious health problem year in and year out.
- Pandemics require well coordinated response and planning effort across HHS, including other components of the department, and interaction with leaders in federal and state government.
- As we prepare for a more serious pandemic, the NIH is conducting basic research to better understand the virus and how it causes disease, molecular analyses, patheogenesis transmissibility, etc.
- The NIH has been involved in the successful development and testing of vaccines and look forward to being part of the process to develop a H1N1 vaccine; it is an orderly process proceeding in a stepwise fashion. The NIH uses a long standing clinical trial process to quickly evaluate pilot lots to determine if a vaccine is safe, if it produces a protective immune response, and the appropriate dosing.
- We will start to evaluate the first vaccine candidate in early August, which will be critical in determining if, how, and when to start vaccine distribution.

HHS Activities and Priorities

Secretary Kathleen Sebelius (HHS)

- The pillars of preparedness include surveillance, community mitigation, vaccination, and communication.
- Surveillance: H1N1 has been identified in >100 countries around the world. The CDC estimates at least 1 million people in the US have already been affected. We don't know how the virus will present during seasonal flu season.
- Community mitigation: This includes everyone doing basic things to stop the spread of the virus. We need to remind all Americans to wash their hands, cough into their sleeve, stay at home if they're ill, and not to travel if ill. In addition, there may be limits on large gatherings and temporary school and workplace closures. Community mitigation also involves ensuring that medical providers are well prepared; an outbreak will bring the truly sick and the worried well to hospitals and clinics and providers need to plan now to deal with this influx of patients and have a plan for the strategic use of antivirals.
- Vaccination: The H1N1 virus presented new challenges and questions. Antivirals have proven effective, and we replenished own national stockpile as well as distributed antivirals to states. However, we need to prepare for the possibility of antiviral resistance and evaluate the plan in real time and adjust if the virus proves less severe.

- We're taking steps to prepare the nation and public health. Preparedness grants will be given to all 56 states and territories. $260 million will go directly to state health departments to for preparedness planning and vaccination clinics; $90 million will go to hospitals to prepare for the surge of patients.
- We're upgrading and expanding our website which is www.flu.gov, and includes guidance updated on a regular basis. This guidance is informed by science and public health best practices. We encourage every American to visit the website and also encourage you to link up this website from your websites. The information on the website is easy to use but worthless if it's not read.
- We're launching a new campaign to encourage more Americans to get prepared for the outbreak. We are offering a contest for the best public service announcement (PSA); the winning PSA will be aired live.
- It's important for every family and business to prepare their own family and business plans; it's a responsibility we all share as parents, co-workers, etc.
- We're asking you to return home and hold your own flu summits in your states, discuss the resources available and the steps you're taking to protect public health. We're also asking states to update their flu preparedness plan and mass vaccination plan; the President and Administration are dedicated to working with you.
- We need to learn how to better coordinate between federal, state, and local levels, identify weaknesses and strengths, and work together to fight the 2009 influenza virus.

President Obama

- It's clear that we were fortunate not to see a more serious situation in the spring when we first got news of this outbreak, but the potential for a significant outbreak in the fall is looming.
- Our entire team tried to engage in the most rigorous planning exercise to ensure we're prepared for anything that may occur in the fall.
- We want to make sure we're not prompting panic but prompting vigilance and preparedness.
- State and local officials need to prepare now to implement a vaccination program in the fall and work on an overall public communication campaign with the White House and work with schools that are affected. We looked at past cases in where it was properly and improperly handled and the most important difference was in well handled cases the state and local officials had complete ownership and provided ideas and situation updates to the federal government.
- We may end up averting a crisis, if we're all working together in a thoughtful and systematic way based on science. We can mitigate the damage and protect our neighbors, friends, co-workers.
- Any issues we have not brought up that affect the general approach or your specific situation/approach, please let us know; we want to make sure we're well prepared.
- In conversations with world leaders on this issue, it appears we're way ahead and may need to provide guidance to public health officials in other countries who have not done as excellent preparation as we have done.

DHS Activities and Priorities

Secretary Janet Napolitano (DHS)

- The work we do now on H1N1 is not wasted as there are applications to other scenarios as well.
- We cannot yet predict what kind of flu epidemic we will experience and how serious its lethality will be. HHS needs to lead the public health and science efforts of a flu epidemic, work on issues around vaccine distribution etc. However if it's a pandemic it affects many things including schools, the workplace, our ability to provide national security in a variety of ways, and continuation of government and operations in the private sector.
- We need to plan to do this under high rates of absenteeism, which is an issue the DHS is charged with coordinating. A flu pandemic crosses all sectors (public and private) and we need to ensure plans are in place and been exercised now so that operations can continue in spite of high rates of absenteeism, that back-up individuals are trained, that plans are in place so that functions of government, particularly public health and public safety, continue, including payroll.
- When you leave, we hope you plan flu summits in your states and plan for your area. It will be different for each area of the country. It's important to ensure tribes are included in the planning efforts.
- Businesses and private sector will be affected. Lessons learned in the spring reveal how important schools are, particularly for a strain like this one in which school-age children are disproportionately affected. Guidance for schools is difficult and not always uniform; if a school is closed there are ripple effects across a community. If children need to stay at home, at least one parent will need to stay home and we need to think and work this problem through. Lots of children receive lunch and breakfast at school through the Department of Agriculture: how will food be made available if a school needs to close? These are the practical issues that need to be considered and planned for. Another one is individuals in federal government that work with people all the time, including TSA and border control and customs. In addition to illness/absenteeism issues, there are personal protection issues. How do we distribute personal protective equipment? At what point do you require masks be worn? These practical questions are very difficult.
- Every state and locality has incarcerated populations: prisons, jails, juvenile populations. If an epidemic is transmitted in these populations, it's a public health issue that also affects guards and correction officers. What do you do with institutions? We need to refine plans that we have already made.
- The role of DHS is to work with you on these plans and encourage you not just to have plans but table top exercises that involve at least leadership working through a scenario over the summer.
- DHS will also provide regional coordination teams for state and local communities.
- Communication is a very key. We need to disseminate the preparation message; the more we are prepared, the less fear people have. There needs to be daily communication with state and local officials and communication with members of Congress. Over the coming weeks, the 3 Secretaries will brief the House and Hill on how we're preparing the nation. We all need to think about how we can prepare for particularly high rates of absentee rates. DHS is prepared and is preparing to coordinate among federal agencies and with state and locals.

Education Activities and Priorities

Secretary Arne Duncan (ED)

- The most important thing we can do now is think and plan.
- Schools are opening around the country in the next 2 months. Most school districts have developed good emergency management plans to address flu and other contagious diseases and we encourage them to review and update their plans.
- In addition to partnership and collaboration with scientists and public health, there needs to be partnership with schools and public health, mental health, faith-based organizations, etc.
- School closures have affected 500,000 children so far. Schools must develop plans to provide children with educational opportunities if they must close.
- School closure decisions must be made at the state and local level and not the federal level; we don't want bureaucratic issues getting in the way and we will work to ensure careful and quick consideration of waiver requests.

Panel Discussion: Q&A

Secretary Duncan

- It's important to disseminate clear guidance but ensure schools are closed on a case by case basis and school by school basis. We want to make sure everyone has the information they need. It's important to look at it on a school by school basis, especially as districts vary so dramatically across the country, with some districts having a couple schools and other having 1400.

Secretary Sebelius

- There will be a formal announcement tomorrow regarding the funding. $350M will be available immediately: $260M for states and territories and $90M for hospitals to prepare for surge capacity. The direct information will be posted on grants.gov. Applications will be due July 24th and the grant awards will be pushed out by July 31st.

Secretary Napolitano

- The Stafford Act is designed for natural disasters, like hurricanes or tornados, but if there is enough of an impact to wedge it into a possible Stafford Act declaration, we will. But the flu and Stafford act don't mesh really well.

Secretary Sebelius

- Experts tell us to prepare to be surprised; 1918 went very differently from 1976, etc. and we don't know what will happen with this virus strain when and if it mutates with the seasonal flu. We're seeing widespread transmission and know who is being affected right now. There is significant surveillance in the southern hemisphere now as they are in the seasonal flu season right now. We are advising to anticipate a serious/worst case scenario, and prepare all the preparedness and surge capacity we can. It's easier to walk back if doesn't reappear or is less severe than we anticipated. However, we cannot wait until October and decide we have a very serious situation on our hands. We need to assume it'll come back in a more severe form and plan for that.

Secretary Sebelius

- Antivirals are effective in treating the virus and pushing out antivirals to states is a critical component. However, the vaccination process is under way. We're developing and testing the safety and efficacy of the vaccine. We think a safe and effective vaccine will be ready by mid-October, but it will not all be available at the same time. The likely target population is younger people. We're working on a production time table and prioritizing within states. Should school-age and daycare populations be prioritized and if so, how do we best reach these populations? The Congress and President are working on this plan; funds have been appropriated to begin distribution with $1.0B for supplies and $7.5B for preparedness. This will be a federally funded vaccine program; we may have opportunities to recover some of the money from private insurance but overall it will be a public effort funded by the federal government.

Secretary Duncan

- We do not want to be a barrier.

School Preparedness

William Modzeleski (Associate Assistant Deputy Secretary- ED)

- At the height of the response in mid-May, over 700 schools closed affecting 468,000 students and 30,000 teachers; 200 million school days were missed, which illustrates how closing schools for a short time can have an incredible impact on the ability to teach.

Takeaways

- Planning is essential, particularly before a situation arises.
- We must plan for the uniqueness of schools – rural, urban, suburban areas, the resources available to them, etc.
- It's important to have strong and effective partnerships and that partnerships with non-traditional partners are formed.
- Open communication that is frequent, accurate, and meaningful is necessary, especially in updating parents and students about the situation.
- Have established communication plans, state plans, use a team approach and work with local health departments, etc.
- Also look to develop web-based technology to have continuing education in a period of prolonged school closure; need to look at other means besides online learning, since not everyone has access to high speed internet at home. Perhaps, television/video lectures, etc., and develop units of instruction explaining communicable diseases, etc. to young children.
- Many people have a say in whether a school closes.
- We need to identify what the triggers are for reopening schools.
- Child care and nutritional needs must be considered in the event of school closures.

Panel: H1N1 Flu Preparedness Lessons Learned From States and Localities

Takeaways

- States with the help of ASTHO and federal partners were able to effectively mitigate the effects of the H1N1 pandemic.
- There are studies underway on the economic impact of school closures and what kids did while they were off from school.
- There is a need to address multijurisdictional issues and establish formal agreements with other entities.

Q and A
Q: We need to deal with issues facing undocumented workers and how we are going to assist people that don't have benefits. What are steps that can be taken regarding this issue?
A: The vaccine will be available to everyone, however the access issue for this population does demand more thought and action. More guidance will be given out on this in the future.

Breakout: Vaccine and Antiviral Use and Distribution
Assume that the fall will be at least as bad as the spring. Coordinated, collaborative planning and response will be necessary.

Challenges
- Likely to be surge of illness before the vaccine is available
- Likely that seasonal and H1N1 vaccine campaigns will overlap
- Likely that different populations will be targeted for seasonal and H1N1 vaccine
- People will be vaccinated in different ways
- Need to be able to interpret adverse events

Q and A
Q: Where are we in the vaccine development process?
A: We are working with five manufacturers. Clinical studies beginning later this month will determine the dose, the number of doses and the interval between doses. We could have 100 million doses in October.

Q: What is the role of NVAC?
A: NVAC will focus on implementation and safety issues. ACIP will meet July 29 on tiering and recommended populations.

Q: What is the vaccine task force?
A: The H1N1 vaccine task force deals with implementation nationwide. The task force will coordinate with the advisory groups such as NVAC and ACIP as well as other agencies. The intent is to get vaccine to locals through the states while tracking vaccine, measuring effectiveness, measuring safety and coordinating communications. It will be essential to work with partners to be successful.

Q: How did antiviral distribution work?
A: It was heartening that all of the planning work paid off. We are in an excellent position to take the next step. One thing that needs further consideration is our view of the use of the antivirals from the Stockpile for emergencies – what about the uninsured?

Q: What ages will be vaccinated first?
A: This decision will come out of the ACIP recommendations. Current data suggest children, adults with underlying conditions, certain occupational groups, school staff, pregnant women and families with young children be considered.

Q: What is the role of FDA in the licensing of vaccines?
A: An unadjuvanted vaccine would be licenses by FDA just as seasonal flu vaccines are. If the vaccine uses an adjuvant, an EUA will be needed.

Q: What is the supply of antivirals?
A: Much of what was available has been bought. Manufacturers are working three shifts per day in two facilities and may open a third facility. HHS is looking to acquire additional supplies. Peramivir is in phase three trials this summer and may be available to seriously ill hospitalized patients in IV form. An IV form of zenamavir still needs clinical trials, but could possibly used under an EUA.

Q: Are there any plans to fast track the 13 valent pneumococcal vaccine?
A: ACIP is reviewing data. This is a good opportunity to remember that the pneumococcal saccharide vaccine is available and could be helpful for those with underlying medical conditions that have been heavily affected so far.

Q: What will we do for vaccine safety monitoring?
A: This will be a multimodal approach focusing on enhancing and using existing systems such as VAERS and Vaccine Safety Data Link.

Q: How are we dealing with public communications and reassurance?
A: Communications will be vital. This will be a voluntary vaccination program.

Q: What is the cost of administering vaccine?
A: The vaccine will be available in the private sector. The task force will work with CMS and insurers. NVAC is also working on recommendations for their July 27 meeting.

Breakout: Public and Private Sector Roles

Takeaways

- Regional Coordination teams (formerly PFO structure) will work out of Regional Response Coordination Center or JFO
- COOP planning is essential
- Need to consider the impacts of school and day care closures
- Technology will play an important role
- We need to focus on communications – both internal and external
- H1N1 is a people targeting event
- This is a shared responsibility of government and the private sector
- Look for influencers to carry the message forward

Breakout: Contuity Planning and Worker Protection

- Rex Wamsley, Director Continuity of Operations Division, National Continuity Programs, FEMA led the discussion of some of the elements of continuity of operations planning. These included how agencies and organizations should think about identifying essential and nonessential functions/skills, delegation of authority, communication and orders of sucession.
- Jordan Barab, Deputy Assistant Secretary and Acting Assistant Secretary for Occupational Safety and Health, US Department of Labor discussed issues of worker protection and how engineering and business processes are the most important ways to worker protection, while PPE is the protection of last resort. OSHA will be developing a web-based tool to help organizations to determine the risk of its workers.

Breakout: Community Mitigation

- Decisions about school closure should be made at the local level and on a case-by-case basis
- Decisions should also consider the social impact (ex: many schools in Chicago have greater than 80% of pupils on free or reduced lunch)
- Chicago closed a public school focus on special education because of the school's high number of pupils with developmental disabilities and the concern those pupils were at high risk
- Southern Texas had a very high rate of influenza which they attributed to a younger population and the early introduction of disease
- There is no uniform approach to dealing with day-care because state regulation varies from state to state.

Panel: Putting Principles of Risk Communication to Work – H1N1 Flu Outbreak Case Study

Common mistakes

- Mixed messages from multiple experts
- Information released late
- Paternalistic attitudes
- Not countering rumors and misinformation quickly

Important principles

- Be first
- Be right
- Be credible
- Express sympathy
- Promote action – give people things to do
- Show respect

Barbara Reynolds (Crisis Communications Advisor/CDC)

- It's important to maintain credibility despite uncertainty.
- It's important to anticipate questions, which doesn't mean you have to answer all questions at that time. It's ok to tell someone you don't have the answer.

- Good communication can help a good operational response but good communication cannot save a bad operational response.
- Invite the public into the process; let them know how we reached a conclusion by explaining to the public why that decision was made. This helps them to make the decision for themselves.
- Never turn down a single media request.
- Always be first, be right and be comfortable in giving out information in increments, be aware of what we do know with certainty, and show respect. Take into consideration how people want to be treated – honestly and with open communication.

Richard Besser (Director, COTPER/CDC)

- It's important to take risk communication very seriously and ensure it's something we actively do.
- You want to communicate what you know, what you don't know, and what you're doing to get the answers. Acknowledge the fear and the uncertainty and never tell people not to worry.
- Repetition of messaging is important and effective.

Q and A
Q: Given that people were really happy about the public health messaging and communication, why was NCHM funding cut? And how can we get Congress to recognize the importance of this?
A: Yes, the scope and importance of risk communication is often underestimated. However, we do the best with what we have.

Closing Remarks

Secretary Sebelius

- We're ensuring tools and resources to protect the public and hope this summit helped motivate your people to continue to prepare for an outbreak.
- We hope you return home and host a meeting like this one, with state and local governments, private business organizations, etc. Work with mayors and county officials and please reach out to tribal leaders if you live in Indian Country as well as the private sector.
- On the health provider side there is an unprecedented need for traditional medicine and public health to work together. All levels of government need to work closely together and update preparedness plans. An in-depth assessment of the response this spring is also important to determine who was missing from the puzzle and how well the response occurred.
- Please help us in driving people to the website www.flu.gov. We want people to start monitoring the site now to follow production of the vaccine and the outbreak and in getting information out.

Postscript: Earlier this week CDC released recommendations for State and Local planning for a Novel H1N1 Influenza Vaccination Program (planning assumptions) which can be found at http://sharing.govdelivery.com/bulletins/GD/USHHS-7ED23