



**Arizona Department of Health Services
Fall 2009 New H1N1 Strain Response
Vaccine and Antiviral Prioritization Policy Committee (VAPPC)**

**Wednesday, August 12, 2009
9 to 11 a.m.
ADHS
150 N. 18th Avenue, Room 415B**

<i>Welcome and Introductions</i> Will Humble, Interim Director	9:00 to 9:10 a.m.
<i>Current H1N1 Summary and State Activities</i> Ken Komatsu, State Epidemiologist	9:10 to 9:30 a.m.
<i>Advisory Committee on Immunization Practices (ACIP) Priority Tiers</i> Teresa Ehnert, Bureau of Public Health Emergency Preparedness Chief	9:30 to 10:00 a.m.
<i>Statewide Strategy for Priority Vaccinations</i> Discussion, All	10:00 to 10:45 a.m.
<i>Next Steps</i>	10:45 to 11:00 a.m.



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Attendees:

Shoana Anderson, Arizona Department of Health Services
Ed Armijo, Arizona Department of Health Services
Sue Braga, Arizona Chapter of the American Academy of Pediatrics
Andrew Carroll, Arizona Chapter of the American Academy of Pediatrics
Cara Christ, Arizona Department of Health Services
Teresa Ehnert, Arizona Department of Health Services
Bob England, Maricopa County Department of Public Health
Don Herrington, Arizona Department of Health Services
Will Humble, Arizona Department of Health Services
Debbie Johnston, Arizona Hospital and Healthcare Association
Peter Kelly, Arizona Department of Health Services
Beth Kohler Lazare, Governor's Office
Ken Komatsu, Arizona Department of Health Services
Karen Lewis, Arizona Department of Health Services
Dan Marino, Arizona Medical Association
Janet Mullen, Arizona Department of Health Services
Alan Oppenheim, Arizona Department of Health Services
Mindy Rasmussen, Arizona Pharmacy Alliance
Rebecca Sunenshine, Arizona Department of Health Services
Carol Vack, Arizona Department of Health Services
Mary Wiley, Arizona Department of Health Services
Minutes: Tina Wesoloskie, Arizona Department of Health Services

Welcome and Introductions, Will Humble, Interim Director

Will Humble provided a brief introduction to the Vaccine and Antiviral Prioritization Policy Committee (VAPPC) (Committee). Mr. Humble explained that the previous prioritization guidance was geared toward a Category 4 or 5 pandemic. The Committee's main function is to develop a strategy for vaccine prioritization and to determine how Arizona will implement federal guidelines. Meanwhile the Advisory Committee on Immunization Practices (ACIP) developed recommendations, and ADHS appears to be on target with those recommendations. The ADHS Influenza Pandemic Response Plan, dated June 2006, identifies which stakeholders are to be included on the Committee. Moving forward, it will be critical to identify more stakeholders that may not have been represented at this meeting.

Current H1N1 Summary and State Activities, Ken Komatsu, State Epidemiologist

Ken Komatsu, State Epidemiologist, provided a summary of the current H1N1 status and response (PowerPoint: *Status of Novel A H1N1 Influenza in Arizona* attached for reference).

Slide 2

From April 15 to April 17, there were two cases of swine influenza A (H1N1) from residents of adjacent counties in Southern California. The viruses were genetically related to each other and contain a unique genetic sequence not previously identified in human and swine influenza viruses. These residents had no exposure to swine. Novel influenza A virus is different from currently seasonal influenza subtypes A H1N1 and A H3N2.

Slide 3

The symptoms of novel H1N1 flu in people are similar to those associated with seasonal flu. These include: fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills, and fatigue. Mr. Komatsu explained that this virus was demonstrating a higher rate of vomiting and diarrhea than seasonal flu (25% and 25%, respectively).

Slide 4

Mr. Komatsu explained that the virus is thought to spread the same way as the seasonal flu spreads. This is through respiratory droplets resulting from coughing, sneezing, and touching respiratory droplets and then touching mucus membranes without washing hands.

Slide 5

This graph demonstrates the Number of Lab-Confirmed Influenza Cases Reported by Week of Report, During 2006 to 2009. This shows a typical influenza season starting in October and ending in late May. The seasonal surveillance system picked up the additional H1N1 cases (spike in graph). These data are based on laboratory reports; laboratories are required to report positive results for any tests run. Therefore, the data are a reflection of who is getting tested (and not necessarily all of the cases).

Slide 6

This graph demonstrates the percentage of influenza-like illness (ILI) patients seen in doctor's offices. ILI is fever over 100°F and cough or sore throat. The graph shows a peak with Arizona's first case. ADHS needed to limit laboratory testing to hospitalized cases (otherwise data would have been inflated).

Slide 7

This graph demonstrates the Arizona Influenza Activity Levels, During 2006 to 2009 as defined by no activity, sporadic, local, regional, and widespread. March and April showed a spike in the 2008-2009 influenza season.

Slide 8

This graph demonstrates the Number of Lab-Confirmed Influenza Cases Reported by Week of Report, During 2006 to 2009. Again, the number of cases peaked in May 2009.

Slide 9

This graph demonstrates the Number of Confirmed H1N1 Cases by Date of Diagnosis from April to August 2009. The highest number of cases occurred during the Morbidity and Mortality Weekly Report (MMWR) for the week of May 2, 2009.

Slide 10

This map demonstrates the Novel Influenza A (H1N1) Rate per 100,000 by County. To date, Greenlee County has been the only county not affected.

Slide 11

This graph demonstrates the Confirmed Novel A (H1N1) by Age Group as of July 22, 2009 (total number of cases is 947). The most number of cases occurred in the 5 to 24 years of age group. This is different from seasonal influenza in where older age groups are primarily affected. The data are capturing the most severe cases, but we believe we are getting equal representation across all age groups. The data show more cases in the 5 to 24 age group with people over 65 seeing some immunity. Those under 24 have zero immunity.

Slide 12

This graph demonstrates Confirmed Novel A (H1N1) by Race as of July 22, 2009 (total number of cases is 947). Proportionally, more Hispanics and Native Americans are affected than whites. Although there are no national data to support this, Dr. Sunenshine noted that this may be a result of a higher rate of co-morbidities within the Native American population (diabetes, obesity, etc.). ADHS is working closely with the Navajo Area Indian Health Service (IHS) to obtain more data.

Slide 13

This table demonstrates by seasonal and pandemic strain type the laboratory data based on date received by the Arizona Public Health Laboratory. This shows that there is always other seasonal flu circulating in the community. The increase in results may be due to an increase in testing. Discussion ensued regarding if there was an increase in seasonal flu during the H1N1 outbreak. Others agreed that likely not, however, there was an increase in testing because more people thought they were ill. Early in the outbreak, we were seeing a 60/40 proportion but quickly into May or June it appeared to be 95% H1N1.

Slide 14

This table shows general H1N1 statistics including numbers of confirmed cases, deaths, median age overall, median age of those hospitalized, and median age of deaths.

Slide 15

This graph demonstrates the Confirmed Novel A (H1N1) Hospitalized Cases by Age Group, as of July 22, 2009 with a total number of 157 cases. The highest age group hospitalized was the 5 to 24 age group.

Slide 16

This graph shows the Confirmed Novel A (H1N1) Hospitalized Cases by Race, as of July 22, 2009 with a total number of 157 cases. Again, proportionally, Hispanic/Latino and Native American populations have a higher number of cases.

Slide 17

This graph demonstrates the Confirmed Novel A (H1N1) Associated Deaths by Age Group, as of July 22, 2009 with a total number of 15 deaths. Arizona has the top death rate in the country. However, this may be a result of the efficiency and quality of our surveillance system. With the deaths, it is important to remember that almost everyone who died had an underlying medical condition (often more than one). Although there were more deaths in the older population compared to the other age groups, it is difficult to determine if this is just a result of a small numerator in the data.

Slide 18

Mr. Komatsu provided an overview of the ADHS H1N1 activities during the spring response. ADHS continually involves all stakeholders in collaborative planning activities such as surveillance, vaccination, antiviral distribution, public messaging, and health alerts. Other key response activities included state laboratory testing, HHS funding, and on-going coordination including the Community Mitigation Task Force, statewide skills survey, the ADHS Public Health Incident Management System (PHIMS), planning scenarios, and triggers for control measures. Mr. Komatsu and others provided an overview of the surveillance systems in Arizona including various functions of the state's EMS system for bed polling and emergency department data.

Slide 19

Mr. Komatsu briefly reviewed a decision algorithm based on the severity of the illness, the vaccine availability, and whether public demand for the vaccine would be high or low.

Slide 20

ADHS is also revising the ADHS website so that our stakeholders and the general public can more readily access information.

Slide 21

Mr. Komatsu provided a brief summary of the current H1N1 activity. As of August 5, 2009, there is regional activity, continued community spread, 1,044 cases, 167 hospitalized, and 17 deaths.

Advisory Committee on Immunization Practices (ACIP) Priority Tiers, Ken Komatsu, State Epidemiologist

Ken Komatsu, State Epidemiologist, provided a summary of the ACIP priority tier recommendations. (PowerPoint: *Novel A H1N1 Influenza Vaccine and Recommendations of the Advisory Committee on Immunization Practices* attached for reference).

In general, goals of the Novel A H1N1 vaccine administration are to minimize deaths, maintain critical infrastructure, minimize the spread of the virus, and balance the socioeconomic impact with public health interventions.

Mr. Komatsu reviewed a set of planning assumptions for this discussion. We are currently at the regional level of Novel Influenza activity, and there will be deaths from Novel H1N1, including children. The current risk groups will not change significantly. The H1N1 vaccine will not be available when the season starts, therefore, herd immunity will not be achievable prior to the season. Lastly, we assume the vaccine will be safe and efficacious for this season.

The Novel A H1N1 influenza vaccine (vaccine) will be produced from five manufacturers, and both live attenuated (Flumist®) and inactivated vaccines will be produced. This vaccine is currently undergoing clinical trials. Clinical trials are looking at testing with and without an adjuvant to boost immune response (may minimize the doses needed). There was some discussion about the vaccine being developed so quickly and safety issues. Many of the questions focused on Guillain-Barré Syndrome (GBS). In 1976, vaccination with the swine flu vaccine was associated with getting GBS. However, as noted in the July 31, 2009 Morbidity and Mortality Weekly Report (MMWR), “The estimated frequency of influenza-related GBS was four to seven times higher than the frequency that has been estimated for influenza-vaccine-associated GBS” (MMWR July 31, 2009, p. 17 <http://www.cdc.gov/mmwr/PDF/rr/rr5808.pdf>). Dr. Lewis noted that ADHS will ensure specific messaging about GBS will go out to the public. In addition, other safety measures in place will include the Vaccine Adverse Events Response System (VAERS), national active surveillance for GBS, and others.

Discussion ensued regarding the safety of the vaccine and its perceived safety from the public. It was noted that the only different component is the timeline and multiple doses. Public health will never be able to ensure it is a perfectly safe vaccine. Mr. Humble reiterated the importance of accurate messaging .

This accelerated clinical process is outside the normal process for seasonal flu. There is not typically a clinical trial for the seasonal vaccine. The Food and Drug Administration (FDA) will license this as a strain change. The process is the same as the strain change done every year on the seasonal vaccine from the previous year’s strain. So, the H1N1 vaccine trials are conducted to ensure an extra layer of safety and to test for efficacy (one dose or two). Additionally, clinical trials are needed to determine if the vaccine will include an adjuvant.

The vaccine will be purchased by HHS and will include syringes, needles, alcohol swabs, and sharps containers. Vaccine distribution will likely be a combination of public health activities and private providers. National estimates currently have been 796,000 to 3.1 million doses initially followed by 200,000 to 597,000 doses weekly thereafter. Dr. England noted that a recent CDC call stated 20 million doses may come by the end of September, 100 million in October, and 80 million doses every month thereafter. Discussion ensued regarding the ability to cover Arizona’s population based on one dose or two doses needed. If one dose, everyone should be able to receive the vaccine who wants it. If two doses, the most we could ever cover would be half. However, the group anticipated we could cover at least the priority groups.

The vaccine will come in five milliliter vials with 10 doses per vial. One carton will contain 100 vials or 1,000 doses. ADHS is currently arranging to pre-register providers. This process will require screening by priority groups. Doses administered will be reported by age (aggregately) via the Arizona Statewide Immunization Information System (ASIS).

The vaccine is assumed to have efficacy similar to seasonal influenza vaccine (50 to 80%). Data have shown that it will likely require two doses, a minimum of 28 days apart. The H1N1 vaccine can be administered concomitantly as the seasonal vaccine. Dr. Lewis noted that approximately 20% of the LAIV and pre-filled vaccine will be thimerisol-free. The multi dose vials all contain thimerisol.

Statewide Strategy for Priority Vaccinations, Discussion All

Ken Komatsu reviewed the ACIP Recommendations. The recommendations were based on current disease patterns and those most at-risk for severe illness based on current trends in illness, hospitalizations, and deaths. Unknowns include how much vaccine is expected to be available and when.

ACIP Recommendations for the broader tier (if more vaccine is available) (*Numbers estimated from Arizona's population from the national population*):

- Pregnant Women (113,756)
- Household contacts and caregivers for children younger than six months of age (86,000)
- Healthcare and emergency medical services personnel (214,000)
- All people from six months through 24 years of age (2.3 million)
 - Children from six months through 18 years of age (1.78 million)
 - Young adults 19 through 24 years of age (520,000)
- Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza

ACIP Recommendations for the narrower tier (if less vaccine is available):

- Pregnant Women
- Healthcare and EMS workers who have direct contact with patients or infectious substances
- Household contacts of infants less than six months of age
- Children aged six months through four years
- Children and adolescents from five through 18 years of age at risk of complications from flu

Discussion

Dr. England noted that while providers may have better access to pre-school aged children through pediatricians' offices, they cannot reasonably use a large amount of doses in a short amount of time. There are limits on the numbers of patients they can see on a daily basis. Dr. England suggested a broader vaccination strategy with school-based vaccinations. For example (theoretically), if Maricopa County receives an initial 250,000 doses and there are 250,000 children from six months to four years of age, all of the vaccine could go to providers. However,

those providers cannot administer it all right away. Dr. England's proposal with this scenario would be to give 100,000 doses to the providers and 150,000 doses for public health school-based clinics. This way, more doses are administered in a quicker amount of time. There was some discussion about those parents who have children in multiple age groups and having to make appointments and trips to different avenues of vaccine administration. Discussion ensued regarding if pediatricians would really prioritize (i.e., "turn away" those not in the priority age group) patients. Andrew Carroll responded that his practice does keep a list of those children he cannot vaccinate at the time. This is likely not the practice of all providers, though. Dr. Carroll also noted that the demand for the vaccine may be low due to many factors including previous misperceptions about the severity of the H1N1 virus.

Mr. Humble asked if the advisory committee, in general, agreed on the broader set of ACIP priority group recommendations. In general, everyone agreed with these recommendations. There was lengthy discussion about excluding senior age groups (over 65) and critical infrastructure personnel from the priority tiers. The previous priority tier guidance was based on a more severe virus, and therefore placed more burden on the critical infrastructure sectors. The group agreed to re-evaluate the priority groups in the event the virus became more severe.

Teresa Ehnert urged the advisory committee to think about a set of alternate recommendations for critical infrastructure groups if they are not going to be considered for priority vaccination. There was also some discussion that these groups are already pushing to receive antivirals for prophylaxis (which is antithetical to current guidelines that antivirals are to be used for treatment only).

The group discussed at what point do we deviate from priority groups and expand if we receive enough vaccine? The group also questioned how long we leave that window open for the priority groups to be vaccinated. Dr. Sunenshine replied that the CDC does not want us to prioritize after the priority groups (within the general population group). It was noted that if we have administered enough of the priority vaccine, the VAPPC should reconvene and open it back up to the general, non-priority population.

There was some discussion regarding excluding people over the age of 64 from receiving the vaccine. Dan Marino noted that we run the risk of creating additional hospital surge capacity issues if the hospitals are overrun by ill elderly (increased use of ventilators, etc.). Others explained that is why vaccinating the elderly with the seasonal influenza vaccine is so critical (to minimize the resources needed for the seasonal influenza). There appears to be some immunity to the H1N1 virus with the 65 and older community.

Dr. Carroll suggested creating a titer to test of immunity (and can then target those without immunity). Dr. Sunenshine noted that only the CDC can do this and does not appear feasible nor are there resources available for this.

There was some discussion on whether it is worth the political battle to cut off the priority at 64 years old. Dr. England noted that it is worth it to reserve the vaccine for those who are at most risk. From a cost/benefit standpoint and use of resources, it is necessary to cut off at 64. This is because those in that age group have a lower infection rate due to some immunity to H1N1. Dr.

England further explained that there will always be outliers. Some people over 65 will likely die who may have been denied their novel flu shot. Beth Kohler Lazare noted that accurate messaging is key; the elderly believe they are always the priority for the seasonal influenza vaccine. Therefore, distinguishing these two vaccines is critical.

Teresa Ehnert urged the committee to consider Arizona's tribal populations needs in priority recommendations. The tribal elders are considered the priority group in tribal populations. Discussion ensued regarding tribal vaccine administration. The Indian Health Services (IHS) will pre-register and order the vaccine similar to a provider.

There was some discussion on laboratory surge capacity issues. Some sentinel sites are testing outpatients. It is likely that the laboratory will not even be able to maintain testing with even the hospitalized cases, depending on the severity of H1N1 in the fall. The rapid flu tests are 20 to 70% sensitive, and a negative test doesn't mean you don't have influenza. It is important to monitor the surveillance data. Dr. Sunenshine explained that if there appears to be mostly H1N1 circulating and there is a case that looks like flu, statistically it is more likely H1N1 than seasonal. Dr. Sunenshine noted that at this point in the season you have an influenza case (particularly if our seasonal influenza doesn't really begin to increase until December/January), it is likely H1N1. She also stated those cases should be treated as if they have H1N1.

Will Humble asked the committee for consensus with the narrower tier of priority groups. Dr. England again explained the rationale of not allocating all of the initial bolus to the provider community (reserving some for public health clinics). He further explained that if the strategy is to vaccinate all children, the priority is to vaccinate six months to four years old first (which the first bolus should cover). Children in school are easy to vaccinate because they are all co-located. However, if we wait until the first five priority groups are vaccinated, we will need to rely on school-based clinics to capture the priority children. By this time, the pandemic will be over until the rest of the school children are vaccinated. Discussion ensued regarding adding healthy children (outside of the ACIP recommendations) into the priority tier. Dr. England described his collaboration with Dr. Art Mullen. Dr. Mullen could operate 36 clinics a day and vaccinate every public school in Maricopa County in 23 days. He would be at financial risk for the billing information and other fiduciary issues. Dr. England's main concern is that the initial bolus will all be allocated to the other priority groups who may not be able to administer it fast enough. It is important to match the allocation of the vaccine to how much administration flow they can handle.

Debbie Johnston remarked that the priority tiers appear to be grouped into three categories: the spreaders, the at-risk (medically vulnerable), and those who take care of them.

Dr. England noted that it is critical to allow the counties to determine where McKesson will distribute within each county. Some smaller counties are prepared for school-based clinics. Public Health has to keep control over the distribution to McKesson. This is to ensure not all of the vaccine goes to the provider community.

Will Humble remarked that it is most reasonable to look at the priority groups collectively (i.e., sending out the vaccine to those who vaccinate in all of the priority groups at the same time and

not to just one priority group over another). With input and guidance from the counties, ADHS will be directing McKesson where to ship the allocations. Mr. Humble further noted that the committee needs to determine a blend for the narrower tier of priority groups where enough of the initial vaccine will go out without one group dominating over another. It is obvious that everyone will be short. A hybrid approach is necessary; each of these groups is equal in priority. The next step is for each county to determine its strategy (not specifics yet on how many doses to whom). It is clear that some will go to providers, some to community vaccinators, and some to public health. Discussion ensued on setting up conference calls with the Local Health Officers to discuss this.

There was some discussion on how Arizona will define healthcare workers and emergency medical services personnel? There were no significant conclusions regarding this and will need to be discussed at a later time.

Cherry Boardman noted that ADHS can broker the vaccines if provider offices are not using their allocation in a timely manner. In 2004, providers could send back doses they were not using.

Mr. Humble remarked that once the overall strategy by county has been determined, the committee and others will need to meet to discuss the actual numbers breakdown between public health, community vaccinators, and providers.

Dr. Karen Lewis spoke briefly about the ADHS pre-registration form. Although there are many unknowns, ADHS felt it was important to pre-register providers now. Once providers are pre-registered, they will receive a packet on how to order, safety and handling procedures, and the CDC Agreement form. The forms are due back to ADHS by September 15th.

Mr. Humble concluded the meeting by suggesting the committee re-assemble after September 15th to discuss statewide and county-specific strategies, actual numbers allocated to each vaccinator group, and to assess the provider pre-registration outcome.

Meeting adjourned.