

September 29, 2009

Howard K. Koh, M.D., M.P.H  
Assistant Secretary for Health  
Department of Health and Human Services  
200 Independent Avenue, SW, Rm. 701-H  
Washington DC 20201

**RE: NVAC – September 15-16, 2009 Meeting**

Dear Dr. Koh:

This letter summarizes the National Vaccine Advisory Committee (NVAC) meeting held on September 15-16, 2009. This was a regularly scheduled, in-person meeting of the NVAC. The agenda for this meeting is enclosed.

It was a pleasure to have you join the meeting and offer your perspectives and provide updates on the vaccine and immunization activities occurring in the Department of Health and Human Services (HHS), particularly in the response to the H1N1 influenza situation. You also conducted the swearing in of the new members of the NVAC. While there were no new recommendations approved by the NVAC at this meeting to transmit to you, there were many updates on the implementation activities of prior recommendations on vaccine finance, adolescent immunization, adult immunization, and H1N1 influenza vaccine safety, finance and communications.

**Report of the Chair**

The focus of this Report was to review efforts underway to improve the effectiveness of the NVAC. These efforts include development of the 2009 annual report on the State of the National Vaccine Program, clearer identification and tracking of action items by the NVAC and the National Vaccine Program Office (NVPO), development and tracking of implementation plans for prior NVAC recommendations, and incorporating recommendations from the RAND Corporation's evaluation of the effectiveness of the NVAC into NVAC's operating procedures.

**Vaccine Finance Implementation plan**

CDR Angela Shen, NVPO, presented the implementation plan developed by NVPO for the vaccine finance recommendations approved by the NVAC in September 2008. This implementation plan identifies the agencies or partners responsible for implementing the recommendations and summarized their efforts to date towards addressing them. Efforts are underway to further refine this implementation plan, including development of action steps for recommendations that may require legislative action. To increase the visibility of these

recommendations, and the research that informed many of them, a special supplement to the journal *Pediatrics* focused on vaccine finance will be published in December 2009.

### **Adult Immunization Implementation Plan and Finance Considerations for Adult Immunization Recommendations**

CAPT Raymond Strikas, NVPO, presented the draft implementation plan developed for the adult immunization recommendations approved by the NVAC in June 2009. Following NVAC discussion, the implementation plan will be revised and due dates added for specific recommendations. A key discussion point was the need to look for lessons about adult immunization barriers and their solutions during the novel H1N1 influenza vaccination campaign.

Following the discussion of the adult immunization recommendations implementation plan, CAPT Strikas presented a draft charge to the NVAC Adult Immunization Working Group. This new charge moves beyond the first charge to the Adult Immunization Working Group - assessing Federal adult immunization programs - to a broader assessment of adult immunization programs with the explicit inclusion of finance-related issues as a barrier to adult immunization. The membership of this working group was also discussed, with the need for broader partner engagement, as was done with the Vaccine finance Working Group. The revised charge was discussed and refined, with further discussion at an Adult Immunization Working Group planning meeting held during the evening of September 15.

### **Vaccine Safety Working Group**

Dr. Marie McCormick updated the NVAC on the work of the Vaccine Safety Working Group (VSWG), following completion of its first charge in June. Dr. McCormick reviewed the Working Group's second charge, and provided an overview of the VSWG information gathering meeting held on July 15-16 that is helping guide the future direction of the group. The VSWG is currently developing a work plan that currently involves five subgroups (structure and governance; epidemiology; basic and laboratory science and genomics; implementation of developed white papers; and stakeholder engagement) that will collectively generate an estimated four reports, with an anticipated completion date of September 2010. These reports include a general report describing characteristics of an ideal vaccine safety system, and several reports related to specific subgroups.

### **National Vaccine Plan**

CAPT Strikas updated the NVAC on the review of public comments received about the draft National Vaccine Plan, and future steps towards the completion of the Plan. There were a large number of public comment received. NVPO staff, along with staff from other agencies or departments, have been categorizing, reviewing and addressing the comments. Additionally, the Institute of Medicine (IOM) has gathered stakeholder input on the draft Plan at five stakeholder engagement workshops held around the country. A final report of the IOM findings will be presented to NVPO by November, 2009. This report from the IOM will be reviewed by Federal agencies and Departments, and by the NVAC. Comments by the NVAC will be reviewed and discussed at an NVAC meeting, possibly held off-schedule through tele-conference or at the regularly scheduled February committee meeting. Following NVAC review of the IOM report, additional public and stakeholder comment will be obtained on the final draft version of the Plan.

RAND Corporation has been retained to help with the public and stakeholder comment process. Their efforts were described by Dr. Kristy Morganti, RAND Corporation. Public comment will be solicited through a written request for comment, while stakeholder input will occur through interviews with key stakeholders.

### **Adolescent Immunization Implementation Plan**

CAPT Abigail Shefer, Centers for Disease Control and Prevention (CDC), presented an update of the efforts CDC has been making to implement the Adolescent Immunization Recommendations approved by the NVAC in June 2008. These activities reach across many Centers at CDC, and gaps in implementation are being consistently tracked.

Additionally, CAPT Shefer presented preliminary National Immunization Survey – Teen Module (NIS-Teen) results that were subsequently published in the Morbidity and Mortality Weekly Report. These NIS-Teen results documented steady immunization rates for most adolescent vaccination indicators (i.e., combined measles, mumps and rubella vaccine; hepatitis B vaccine; varicella vaccine or history of varicella disease; and tetanus and diphtheria toxoids or tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine) with significant increases noted for other indicators (i.e., varicella vaccine; Tdap vaccine, quadrivalent meningococcal conjugate vaccine; and quadrivalent human papillomavirus vaccine).

### **Influenza**

#### *2009 National Influenza Vaccine Summit*

Dr. L. J. Tan, NVAC member and co-chair of the National Influenza Vaccine Summit, briefed the NVAC on the 2009 National Influenza Vaccine Summit. This year's Summit focused on a number of key issues: new methods for real-time influenza vaccination monitoring, which the RAND Corporation updated the NVAC on in June 2009; influenza immunization among health-care workers; influenza immunization in individuals aged 18 and younger; and the H1N1 influenza pandemic and vaccination issues, including responsive communication messages around multiple influenza vaccination campaigns this fall.

#### *Influenza Communication Plan*

Dr. Kristine Sheedy, CDC, and Ms. Stephanie Marshall, NVPO, provided an overview of the vaccination communication plans for the current influenza season, focusing on the complexity and challenges of addressing the H1N1 influenza pandemic while also encouraging seasonal influenza vaccination. Differences in the identified priority groups for each vaccine have made this particularly challenging. A number of overarching messages were presented and the means for outreach to both recommended high-risk populations and providers were discussed. A main focus of NVPO is the communication around H1N1 influenza vaccine safety, with an emphasis on the overall track record of influenza vaccine safety as well as the methods being put into place to ensure adequate vaccine safety monitoring for the upcoming vaccination campaigns.

#### *2009 H1N1 Influenza Update*

As was done in the July and August 2009 NVAC tele-conference meetings on H1N1 influenza, a broad range of partners and stakeholders were given an opportunity to update the NVAC on the status of their H1N1 influenza vaccine planning and systems development.

Dr. James Lawler, Director for Medical Preparedness Policy on the National Security Staff, spoke of the national framework to the influenza pandemic response, highlighting the findings in the President's Council of Advisors on Science and Technology (PCAST) Report to the President on U.S. Preparations for 2009 H1N1 Influenza. This framework involves a four-pillar approach of surveillance and situational awareness, mitigation, vaccination, and communications, and was explained with a warning not to attempt to predict everything that will happen, but to maintain flexibility in planning efforts.

An updated briefing on H1N1 influenza epidemiology was provided by RADM Anne Schuchat, CDC, with information related to both the current situation in the United States as well as globally. Discussion focused on modes of surveillance, with emphasis on the use of the US Outpatient Influenza-like Illness Surveillance Network (ILINet) and the National Respiratory and Enteric Virus Surveillance System (NREVSS) as opposed to direct case counting.

Dr. Robin Robinson, Biomedical Advanced Research and Development Authority (BARDA) provided an overview of H1N1 influenza vaccine development, highlighting that prior planning estimates for the time between clinical isolation of a new virus to vaccine distribution of 20 to 23 weeks held well, with approximately 21 to 24 weeks for the current H1N1 influenza vaccine development. Currently there are 36 planned or in progress clinical trials for H1N1 influenza vaccine worldwide, with a total sample size enrollment of approximately 20,000.

Dr. Matthew Fenton, National Institutes of Health (NIH), presented the outline of clinical trials on H1N1 influenza vaccine in three sets of special populations – 1) asthmatics, 2) HIV-infected pregnant women, and 3) perinatally HIV-infected children and adolescents. Dr. Linda Lambert, NIH, presented the outline of a series of H1N1 influenza vaccine clinical trials underway at NIH in addition to manufacturer's trials, to assess immunogenicity, safety, dosing intervals, co-administration with seasonal influenza vaccine, uses of different adjuvanted products and mixing of vaccines and adjuvants from different manufacturers.

CAPT Jay Butler, CDC, gave an overview of the H1N1 influenza vaccine distribution plan and activities, focusing on the centralized distribution of vaccine and ancillary supplies and methods to monitor and assess vaccine distribution, administration, coverage and effectiveness.

Dr. Roger Bernier, CDC, and Ms. Heather Bergman, The Keystone Center, briefed the NVAC on the CDC-sponsored public engagement sessions that occurred in 10 cities around the U.S. in addition to a stakeholder meeting held in Washington DC. The purpose of this public engagement was to learn about preferences of the public related to the question "Should the US take a 'full-throttle' or a 'go-easy' approach to vaccination against novel H1N1 or an approach somewhere in between?" Most public participants preferred a moderate approach overall and if the pandemic is less severe than expected, while if the pandemic was more severe, there was a stronger inclination towards a full-throttle approach. Most stakeholders were in favor of a full-throttle approach. A number of cross-cutting themes were identified through these sessions, and this information is being used to help inform the vaccination implementation plan.

Concerns from state and local partners were communicated by Ms. Claire Hannan, Association of Immunization Managers, Dr. Paul Jarris, Association of State and Territorial Health Officials,

and Dr. Anne Bailowitz, National Association of County and City Health Officials. Key themes of this discussion involved communication between all partners and stakeholders to ensure consistent messages, the need to communicate accurate information on vaccine availability for planning purposes as well as to properly inform the public about where they can get vaccinated, the need for adequate funding to maintain the vaccination effort and prevent financial barriers to vaccination, and supply issues for both seasonal and H1N1 influenza.

CDR Angela Shen, NVPO, addressed the implementation of the H1N1 vaccine finance recommendations approved by the NVAC in July 2009 and Dr. Daniel Salmon, NVPO, addressed the implementation of the H1N1 vaccine safety recommendations approved by the NVAC in July and August 2009. The NVAC appreciates your responsiveness to these recommendations and is strongly encouraged by the rapid development of implementation plans and mechanisms related to these recommendations.

Dr. Vito Caserta, Health Resources and Services Administration briefed the NVAC on the Countermeasure Injury Compensation Program (CICP). Following Secretary Sebelius' declaration of a Public Health Emergency for H1N1 influenza, the CICP will cover injuries sustained following the use of pandemic influenza countermeasures, including vaccines, anti-viral drugs, diagnostics, personal respiratory protection devices and respiratory support devices. While the NVAC is very aware of the National Vaccine Injury Compensation Program, there was less knowledge of the CICP, and the NVAC was happy to receive this briefing.

A final request for public comment yielded one comment, from James Moody, SafeMinds. Mr. Moody pointed out the need to be aware of the new trends in social media, where it has gotten easier for pop culture to mock the H1N1 influenza "doom and gloom" predictions, while also indicating the opinion that the government has missed an opportunity to ensure safety by not ordering all H1N1 influenza as mercury-free formulations, thus providing no guarantee that mercury-free vaccine will be available to all who want it.

Please feel free to contact me with any questions or concerns you may have in regard to any of the Committee's activities. I would also like to invite you to attend our next regularly scheduled NVAC meeting, which is scheduled for February 3-4, 2010, as well as any off-schedule meetings that will be held to address the H1N1 influenza situation or the revision of the National Vaccine Plan. Of course, I am available at any time to speak to you by telephone or to meet in person.

Sincerely,

/ Guthrie S. Birkhead/

Guthrie S. Birkhead, M.D., M.P.H.  
Chair, National Vaccine Advisory Committee