

HHS Update on Actions for NVAC H1N1 Vaccine Safety Monitoring Recommendations

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NVAC H1N1 Safety Recommendations

- (1) Federal Plans to Monitor 2009 H1N1 Vaccine Safety
- (2) Expanded Active Surveillance
- (3) Independent Vaccine Safety Assessment
- (4) Response to Scientific and Public Concerns on Vaccine Safety

(1) Federal Plans to Monitor 2009 H1N1 Vaccine Safety

A clear Federal plan to monitor 2009 H1N1 influenza vaccine safety is needed both for proper planning purposes in the Federal government and to provide information to the public and stakeholders (including states) about important vaccine safety activities. A comprehensive and detailed plan should be developed and disseminated that outlines the HHS plan for monitoring vaccine safety. This plan should include:

- Specific activities under development with acknowledgement of gaps and limitations. Specific studies planned to be carried out should also be included.
- An organization chart outlining who is involved, what their responsibilities are, the flow of information, how coordination will be achieved between different Federal office and agencies, who makes which decisions, who is responsible, and other relevant roles.
- A clear timeline of planning processes, completion of preparations, and execution of activities.
- Involvement and role of other Federal agencies such as Department of Defense and the Veterans Administration.

HHS Actions on Recommendation

Revising and Disseminating Plans

- Weekly Federal Immunization Safety Task Force calls
 - Include HHS, Agencies, DoD and VA
 - Chaired by ASH/ASPR
- Document updated and expanded by departments/agencies
- Final document “Federal Plans to Monitor Immunization Safety for a 2009 H1N1 Vaccination Campaign” in clearance process
- Will be distributed to Stakeholders (NVAC, State Health Departments, who else?)
- Article for journal supplement
- User-friendly version in development for distribution to wider audience

(2) Expanded Active Surveillance

The need to actively monitor vaccine recipients for vaccine adverse events is critical given that the vaccine candidates will all contain a new antigen and may be combined with adjuvants that are not part of licensed vaccines in the US. Relevant parties of HHS should develop appropriate procedures for linking exposure and outcome data in as large a population base as feasible, including consideration of subpopulations targeted for vaccine use. In order to do this, accurate exposure to vaccine and adjuvant type for each dose administered (with lot numbers, if possible) must be linked to outcome data. The current vaccine safety infrastructure is unlikely to be sufficient to accomplish this. Consideration should be given to the following strategies for active vaccine safety surveillance:

- Utilizing existing mechanisms that are used for vaccine adverse event surveillance but may need to be enhanced or refined.
- Exploring existing databases that have not yet been used for vaccine adverse event monitoring but could be.
- Developing novel strategies, although a process for collecting and vetting is needed given the short timeframe anticipated.

A clear timeline should be developed for finalizing necessary arrangements.

HHS Actions on Recommendation

Post-Licensure Rapid Immunization Safety Monitoring (PRISM)

- Active surveillance program based on the VSD & Menactra/GBS study
 - Collaboration with HHS, State HDs, America's Health Insurance Plans, Rich Platt (Harvard Pilgrim), and Public Health Informatics Institute
- Which states and health plans will be included is pending
- Link State registry vaccination data to health plans to capture vaccinations given in both public & private settings (exposure)
- Will Cover ~15% of US population

(3) Independent Vaccine Safety Assessment

Consideration should be given to a transparent and independent review of vaccine safety data as it accumulates. This Vaccine Safety Assessment Committee (VSAC) would be an independent group of outside experts with a charge to advise the ASH and/or ASPR on the presence, investigation, interpretation, and implications of possible side effects of H1N1 vaccines. The committee should be reviewing pre- and post-licensure vaccine safety data accumulated in a timely way and not await activation when a specific signal is declared. The VSAC should advise on distinguishing spurious from genuine side effects; anticipating and responding to coincident (non-causal) events; evaluating the occurrence, frequency, and seriousness of possible side effects associated with vaccine; programmatic and policy steps to take in response to purported or demonstrated safety concerns; strategies and content of communication about vaccine safety; and such other matters related to vaccine safety that the ASH/ASPR would find useful.

(3) Independent Vaccine Safety Assessment (continued)

Such an external review would involve an independent group of experts with no professional or commercial stake in the vaccines or conduct of an immunization program, to speed and improve response to possible vaccine side effects, to enhance public confidence, and to provide focused advice on what can become a scientifically and politically contentious issue. The VSAC may be made up of members of an existing Federal advisory committee, such as NVAC, and supplemented by other vaccine safety experts. The committee would only assess risks (not consider vaccine benefits) and the committee would be only advisory and not decision making. The ASH/ASPR would be responsible for assuring programmatic response to the assessment of risk.

HHS Actions on Recommendation Risk Assessment

- HHS sees the value in independent risk assessment for H1N1 vaccine
- Options being considered

(4) Response to Scientific and Public Concerns on Vaccine Safety

NVAC recommends that the Assistant Secretary for Health and the Department of Health and Human Services (HHS) develop, and where possible test in advance, a strong and organized response to scientific and public concerns about vaccine safety that may emerge during the 2009 H1N1 vaccination campaign. The challenge will be to communicate effectively and to differentiate rapidly between adverse events that may be causally related to the vaccine and those which would be expected by chance alone. Such a response could involve:

- Assembling information on background rates in the general population of anticipated events that, when occurring after immunization, might represent an adverse event including stratification by age group if possible.

(4) Response to Scientific and Public Concerns on Vaccine Safety (continued)

- Organizing drills or practice scenarios for how the government will respond to concerns about adverse events temporally related to H1N1 vaccination, including identifying data resources and strategies for communications. Events reported among pregnant women are especially likely to generate concern. There are special challenges around identifying possible adverse events, determining background rates, determining causality and effectively communicating in this population. Therefore, NVAC suggests that practicing a scenario of possible pregnancy associated events would be particularly valuable.
- These activities will allow agencies to plan responses in advance so that they are able to promptly and effectively investigate and make policy decisions and communicate about H1N1 vaccine safety to the media and the public.

HHS Actions on Recommendation

Responding to Safety Concerns

- DoD, VA, VSD, CMS, and PRISM calculating background rates for Tier 1 & Tier 2 Outcomes developed by FDA
- Developing vaccine safety communications plan
 - Message & materials development
 - Stakeholder outreach
 - Trainings
- Held tabletop session with media to discuss vaccine campaign and vaccine communications challenges including safety issues
- CDC holding a tabletop exercise with HHS agencies to walk through the steps of signal detection, signal evaluation, decision making, and communications