

NVAC Vaccine Safety Working Group Update

NVAC Meeting
February 5, 2009

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Working Group Charge

1. Undertake and coordinate a scientific review of the draft ISO research agenda. Advise on:
 - a. Content of ISO draft research agenda (e.g., are the topics on the agenda appropriate? Should other topics be included?)
 - b. Prioritization of research topics
 - c. Possible scientific barriers to implementing the research agenda and suggestions for addressing them
2. Review the current federal vaccine safety system and develop a White Paper describing the infrastructure needs for a federal vaccine safety system to fully characterize the safety profile of vaccines in a timely manner, reduce adverse events whenever possible, and maintain and improve public confidence in vaccine safety.

Working Group Members

Name	Discipline	Group Representation
Andy Pavia	Pediatric and Adult Infectious Diseases, NVAC Member	Academia
Bennett Shaywitz	Neurology	Academia
Chris Carlson	Genomics	Academia
Corry Dekker	Pediatrics, NVAC Member	Academia
Gerald Medoff	Immunology	Professional Organization
Gus Birkhead	Epidemiology, NVAC Member	State Health Department
Jim Mason	Public Health, NVAC Member	CDC Director/ASH
Lance Gordon	Immunology, NVAC Member	Industry

Working Group Members, cont.

Name	Discipline Used for Initial Selection	Group Representation
Lawrence Gostin	Ethics/Law	Academia
Lynn Goldman	Toxicology/Environmental Health	Academia
Marie McCormick	Maternal and Child Health, NVAC member	Academia
Mark Feinberg	Immunology, NVAC Member	Industry
Paul-Henri Lambert	Global aspects of vaccine safety	Professional Organization
Sean Hennessy	Pharmacoepidemiology	Academia
Steve Goodman	Biostatistics	Academia
Tawny Buck	Parent of a child injured by a vaccine	Consumer Groups
Trish Parnell	Parent of a child with an infectious disease, NVAC member	Consumer Groups

Working Group Ex-Officios

- Dan Salmon, NVPO/HHS
- Larry Pickering, NCIRD/CDC and ACIP
- John Iskander, ISO/CDC
- Karen Midthun, CBER/FDA
- Robert Ball, CBER/FDA
- Geoff Evans, VICP/HRSA
- Barbara Mulach, NIAID/NIH
- Jessica Bernstein, NIAID/NIH
- Florence Houn, FDA
- Carmen Collazo, FDA
- Alice Kau, NIH
- Peter Scheidt, NICHD
- Renata Engler, DoD

Summary of ISO Scientific Agenda Draft Recommendations

1. Respond to emerging issues and conduct core, required scientific activities
2. Enhance vaccine safety public health and clinical guidance capacity in 7 areas
3. Address 5-Year research needs

ISO Agenda Draft Recommendations

#3 5-Year Research Needs (30 items)

Item	5-Year Research Needs (30 items)
A	Specific Vaccine Safety Questions (7 items)
B	Thematic Area: Vaccines and Vaccination Practices (8 items)
C	Thematic Area: Special Populations (7 items)
D	Thematic Area: Clinical Outcomes (8 items)

ISO Agenda Draft Recommendations

#2: Enhance Vaccine Safety Public Health and Clinical Guidance Capacity in 7 Areas

Item	Capacity Area
A	Infrastructure for Vaccine Safety Surveillance: Vaccine Adverse Event Reporting System (VAERS)
B	Infrastructure for Vaccine Safety Surveillance and Research: Vaccine Safety Datalink (VSD) Project
C	Epidemiologic and Statistical Methods for Vaccine Safety
D	Laboratory Methods for Vaccine Safety
E	Genomics and Vaccine Safety
F	Case Definitions, Data Collection, and Data Presentation for Adverse Events Following Immunization
G	Vaccine Safety Clinical Practice Guidance

Progress since last update

- Vaccine Safety Working Group divided into 4 subgroups, each focusing on one research topic and 2 capacity topics
- Regular conference calls within subgroups and as a larger Working Group
- Briefings with ISO
 - Q & A
 - Supplemental background information
 - CISA

Subgroups

Group	Group Members	Research Topic	Capacity Topic (s)
1	<ol style="list-style-type: none">1. Corry Dekker2. Bennett Shaywitz3. Sean Hennessy4. Trish Parnell	<ol style="list-style-type: none">1. Specific Vaccine Questions	<ol style="list-style-type: none">1. VAERS Infrastructure2. VSD Infrastructure
2	<ol style="list-style-type: none">1. Gus Birkhead2. Steven Goodman3. Jim Mason	<ol style="list-style-type: none">1. Clinical Outcomes	<ol style="list-style-type: none">1. Epi/Statistical Methods2. Case Definitions
3	<ol style="list-style-type: none">1. Chris Carlson2. Marie McCormick3. Paul-Henri Lambert4. Tawny Buck	<ol style="list-style-type: none">1. Special Populations	<ol style="list-style-type: none">1. Lab Methods2. Genomics
4	<ol style="list-style-type: none">1. Mark Feinberg2. Lynn Goldman3. Gerald Medoff4. Lance Gordon	<ol style="list-style-type: none">1. Vaccines and Vaccinations	<ol style="list-style-type: none">1. Clinical Guidance2. CISA

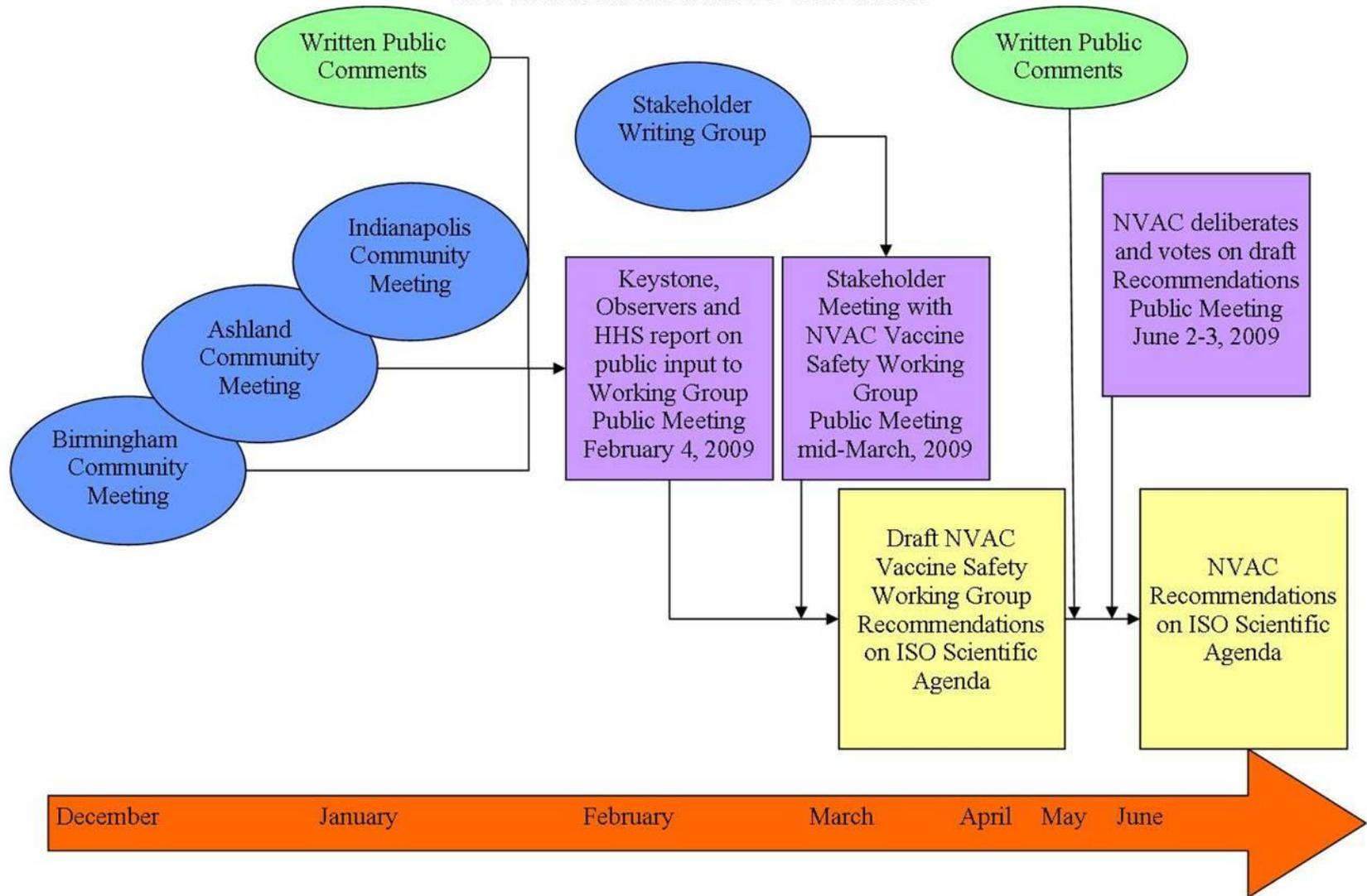
Public Engagement

- Meetings facilitated by the Keystone Center
- Planning Steering Committee includes NVAC Vaccine Safety Working Group members (Jim Mason, Tawny Buck, Trish Parnell), ASTHO, NACCHO, Keystone, NVPO, CDC

February 4 Meeting of NVAC Vaccine Safety Working Group

- To hear what was learned through the public engagement activities
- Heard reports from Keystone on community meetings and plans for stakeholder engagement, and NVPO on written comments received
- NVAC Working Group will consider this information in developing its recommendations

THE PROCESS FOR PUBLIC INPUT INTO THE NVAC RECOMMENDATIONS ON THE ISO DRAFT SCIENTIFIC AGENDA



Overarching Issues

- Constraints of looking at ISO agenda in isolation and need to include other partners
- Need for overarching framework
- Balancing scientific priorities with public priorities
- Emphasis on prevention, and when prevention not possible, amelioration of vaccine adverse events
- Need for greater specificity and hypothesis generation in the document

General Issues

- Risk Communication Research
- On-going review of the ISO Scientific Agenda
- Proposal for a retrospective study of decision making and the use of scientific data in decision making regarding vaccine safety issues, risk management, and risk perception
- Vaccine safety in the context of pandemic and biological preparedness
- Biologic mechanisms of adverse events

Capacity Issues Under Discussion

- Identify and evaluate ways to (1) increase the number of important events that are reported to VAERS, and to (2) improve the quality of the reports received.
- Evaluate approaches to follow up individuals from VAERS reports with rare adverse events for further study and for collection of biological specimens, when appropriate.

Capacity Issues Under Discussion continued

- Continue to facilitate collaboration between VSD statisticians and academic statisticians as the primary vehicle for new method development and monitoring existing methods that could be applied.
- Specify the laboratory capacity for research, and potential collaboration with other agencies or entities.

Capacity Issues Under Discussion continued

- A comprehensive study of innate responses to vaccinations, including common adverse events.
- Create an expert advisory group on genomics and vaccine safety to assist with developing a focused genomics research agenda and protocol development.

Capacity Issues Under Discussion continued

- Focus research efforts in this area on the adequacy of the case definitions and their usefulness in ongoing safety research conducted by VSD and other groups.
- Creation of a single resource dedicated only to comprehensive clinical guidance for vaccine adverse events.

Research Issues Under Discussion

- Include vaccinating children with mitochondrial disease, mitochondrial dysfunction, and other metabolic diseases as a priority scientific area.
- Question A-III (Thimerosal) be expanded to include speech and language delays
- Sponsor an external reanalysis of thimerosal and neurodevelopmental outcomes published in 2007 by Thompson et al.

Research Issues Under Discussion

continued

- Prepare a regular summary report on the safety of the expanded influenza vaccination program.
- Evaluate cumulative levels of non-antigen component exposure possible through the schedule of recommended vaccinations.
- Prioritization process for research of off-label vaccine use, based on the theoretical risk, the severity, and frequency of practice.
- Special populations category be extended to include adults aged > 60 years.

Research Issues Under Discussion continued

- Autism research should be focused and based on improved understanding of biology and phenotype: eg. regressive autism
- IOM review of the science, epidemiology and feasibility of studies of unvaccinated, vaccine delayed, and vaccinated children