NVAC Vaccine Safety Working Group

IACC Meeting
July 15, 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

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 Review of ISO Agenda

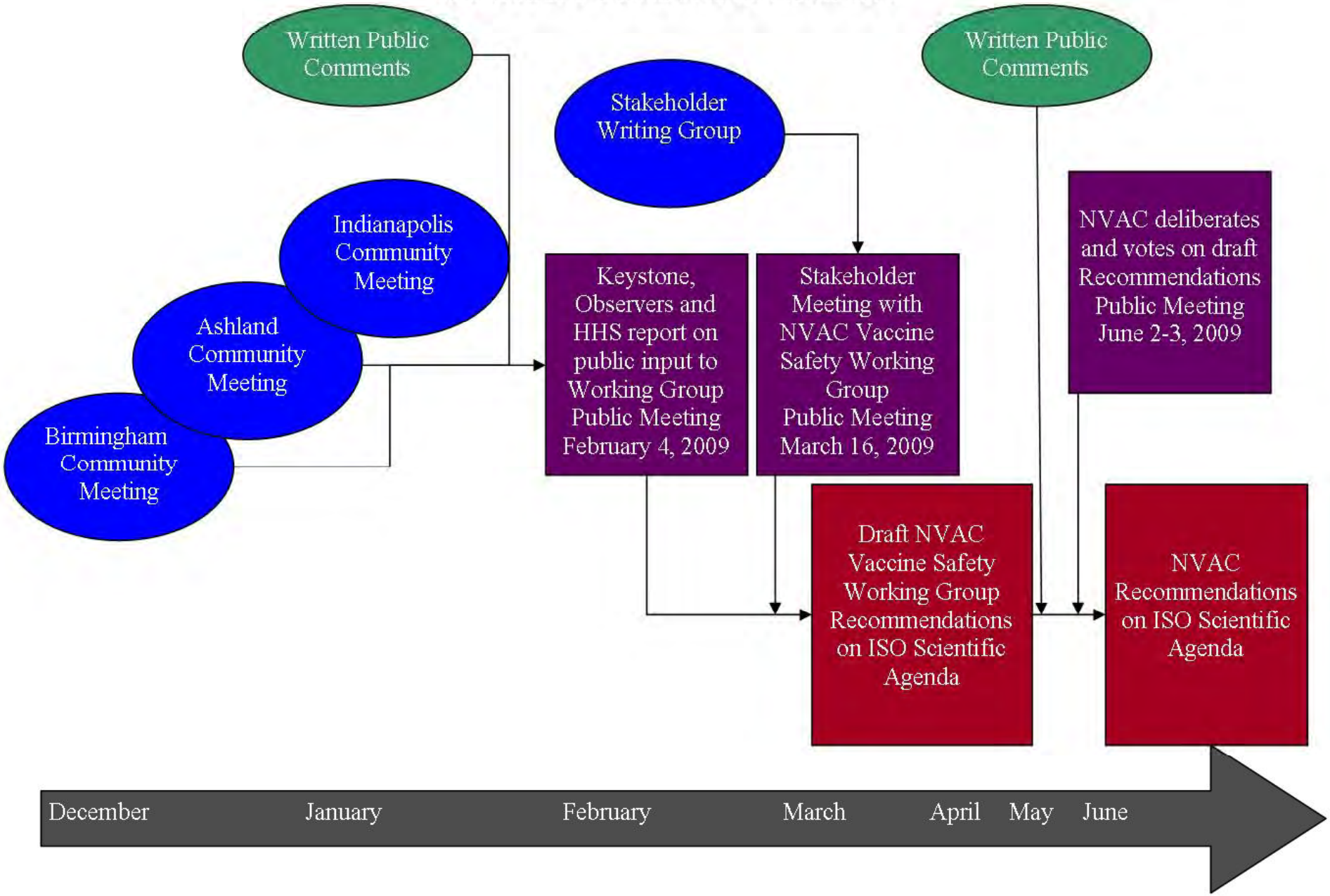
- Subgroup review of agenda and drafting of recommendations
- Internal peer review
- Writing Group drafted consensus statement, prioritization criteria and gaps document
- WG draft report and prioritization criteria revised
- NVAC and public review of draft report

Public Engagement Activities

- Three meetings facilitated by the Keystone Center
  - Birmingham AL (December 13 2008)
  - Ashland OR (January 10 2009)*
  - Indianapolis IN (January 17 2009)
- Writing group meeting
  - Salt Lake City (February 20-21, 2009)
- One stakeholder meeting
  - Washington DC (March 16, 2009)
- Two requests for written comments
  - Input on draft ISO Scientific Agenda
  - Input on Working Group draft report
- Public comment period at NVAC Vaccine Safety Working Group meetings

*Ashland was chosen for its high rate of vaccine exemptions

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



On June 2, 2009, NVAC unanimously adopted the Vaccine Safety Working Group's recommendations

Elements of the NVAC report related to Autism Spectrum Disorders (ASD)

“The NVAC also notes the public engagement process identified public concern (Appendix 2) related to thimerosal, particularly with respect to autism/ASD. The NVAC is assured by the many epidemiological studies of the effects of mercury exposure done in a variety of populations, which have demonstrated that thimerosal in vaccines is not associated with autism spectrum disorders in the general population.” (57)

“…a small and specific subset of the general population (such as those with mitochondrial dysfunction) may be at elevated risk of reduced neurological functioning, possibly including developing ASD, subsequent to vaccination. ” (69)

“In the context of vaccination research, the ASD clinical subset of particular interest is regressive autism” (70)

“Vaccination almost certainly does not account for the recent rise in ASD diagnoses; however, public concern regarding vaccines and autism coupled with the prevalence and severity of ASD warrant additional study in well defined subpopulations.” (71)

Feasibility Study

- An ad hoc committee will be established with broad methodological, design, and ethical expertise to consider strengths and weaknesses, ethical issues and feasibility including timelines and cost of various study designs to examine outcomes in unvaccinated, vaccine delayed and appropriately vaccinated children. The process should be open and transparent, engaging individuals from a broad range of sectors. The committee will:

Feasibility Study

- Consider strengths and weaknesses, ethical issues and feasibility including timelines and cost of various study designs

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- Consider broad biomedical research including laboratory studies and animal studies
- Assess study designs comparing children vaccinated by the standard immunization schedule with unvaccinated children (by parental intention), and possibly partially vaccinated children or children vaccinated by alternative immunization schedules

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  Consider broad biomedical research including laboratory studies and animal studies

  Assess study designs comparing children vaccinated by the standard immunization schedule with unvaccinated children (by parental intention), and possibly partially vaccinated children or children vaccinated by alternative immunization schedules

  Assess the ability to include biomarkers of immunity and metabolic dysfunction, and outcomes including but not limited to neurodevelopmental outcomes (including autism), allergies, asthma, immune-mediated diseases, and other developmental disabilities such as epilepsy, intellectual disability and learning disabilities.

Charge 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.

Changes to the Working Group

- Three co-chairs
  - Andy Pavia
  - Marie McCormick
  - Tawny Buck
- Three new members
  - Vicky Debold, PhD, RN
    - Health Administration and Policy Dept
      George Mason University
      VRBPAC Public Representative
  - Robert Beck, JD
    - ACIP Member Public Representative
  - Bill Raub, PhD
    - Former Deputy Director of the National Institutes of Health and Science Advisor to the Secretary, Department of Health and Human Services

Current Plans

- Kick-off Working Group meeting scheduled for July 15-16: Information gathering only
- Five panel discussions
  1. Principles and policy alternatives for a robust vaccine safety system
  2. Identifying innovative ways of overcoming gaps in vaccine safety science infrastructure
  3. The ideal system to meet the needs of the public, public health, and healthcare professionals for confidence in vaccine safety
  4. Lessons from other safety arenas
  5. Enhancing the adoption and implementation of the NVAC white paper

1. Principles and policy alternatives for a robust vaccine safety system

- Confirmed Panelists
  - Mark Blaxill, Lou Cooper, Robert Davis, Neal Halsey, Gregory Poland
- Topics of Discussion
  - What are the basic principles that should guide the vaccine safety system?
  - What aspects of the current vaccine safety system are important and/or insufficient to meet these principles?
  - What policy approaches could be considered, and what are the strengths and weaknesses of these approaches?
  - How can we bring together stakeholders to improve the vaccine safety system?
  - How can coordination, integration, and/or organizational structure be enhanced?

2. Identifying innovative ways of overcoming gaps in vaccine safety science infrastructure

- Confirmed Panelists
  - Steve Black, Geri Dawson, Kathryn Edwards, Neal Halsey, Samuel Katz, Stanley Plotkin, Gregory Poland
- Topics of Discussion
  - What are important strengths and/or deficiencies in the current vaccine safety infrastructure?
  - What strengths are critical to preserve?
  - What new ways, technologies, or data sources are available to address some of these deficiencies?
  - What agencies/organizations could play a different or enhanced role to address these science gaps?

3. The ideal system to meet the needs of the public, public health, and healthcare professionals for confidence in vaccine safety

- Confirmed Panelists
  - Sallie Bernard, Thomas May, Lisa Randall, David Sundwall, David Tayloe, Collette Young
- Topics of Discussion
  - What are the basic principles that should guide the vaccine safety system?
  - What aspects of the current vaccine safety system are important and/or insufficient to meet these principles?
  - What mechanisms could meet public expectations for funding and conducting vaccine safety research?
  - What information does the public need to make informed decisions?

4. Lessons from other safety arenas

- Confirmed Panelists
  - Michael Cohen, Robert Dodd, Diane Osgood, Richard Platt, Gerald Poje
- Topics of Discussion
  - What principles are important in your safety arena that may be important to vaccine safety?
  - How does your safety arena effectively address uncertainty, gaps in knowledge, competing interests, and maintaining public confidence?
  - How does your arena garner resources and support to prevent (rather than respond) to crises?
  - What elements of infrastructure and organizational structure are important for achieving your principles and objectives?
  - How are coordination and integration achieved in your safety arena?
  - In your arena, how do you work effectively with stakeholders and the public?

5. Enhancing the adoption and implementation of the NVAC white paper

- Confirmed Panelists
  - Peter Bell, Paul Kim, Anthony Robbins, David Tayloe, Thomas Vernon, Marguerite Willner
- Topics of Discussion
  - What stakeholders are important to the success or failure of the NVAC white paper?
  - How can the process of developing the white paper enhance its implementation?
  - How does one balance the pros and cons of incrementalism with broader vision?

Next Steps

- Additional information gathering
- Public/stakeholder engagement
- Drafting of white paper

Additional Slides

Elements of the NVAC report related to vaccine ingredients

“The NVAC is assured by the many epidemiological studies of the effects of mercury exposure done in a variety of populations, which have demonstrated that thimerosal in vaccines is not associated with autism spectrum disorders in the general population.” (57)

“The NVAC recommends question A-III (Is exposure to thimerosal associated with increased risk for clinically important tics and/or Tourette syndrome?) be expanded to include speech and language delays as potential outcomes of interest.” (55)

“The NVAC recommends ISO sponsor external and multidisciplinary additional analysis of data published in 2007 by Thompson et al.” (56)

“The NVAC recommends ISO evaluate cumulative levels of non-antigen component exposure possible through the schedule of recommended vaccinations.” (61)