

NVAC Vaccine Safety Working Group Update

NVAC Meeting
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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

Update

- Consideration of public engagement results
- Writing Group drafted consensus statement, prioritization criteria and gaps document
- Stakeholders meeting March 16, 2009
- WG draft report and prioritization criteria revised

Additional Feedback

- Draft Working Group report posted on the NVPO website (April 13, 2009)
- Special NVAC meeting (with liaisons and ex-officios) to discuss the draft report (May 7, 2009)
- Second formal written request for public comments on the draft Working Group report (April 13-May 13, 2009)
 - 43 public comments received
- Written comments from CDC

- NVAC Comment
 - Highlight in the executive summary that just because Specific Vaccine Safety Questions were prioritized, those are not the only high priority items.
- Working Group Revision
 - “Importantly, although only Specific Vaccine Safety Questions were formally prioritized, those are not the only high priority items. It is likely there are many specific questions embedded in the topic areas that would also be high priority if they were specified in a manner appropriate for application of the prioritization criteria” (p9).

- NVAC Comment
 - Considering that the document will likely be read by individuals other than its main target audience, I favor expanding the background with a paragraph explaining the extensive safety requirements for vaccine licensure.

- Working Group Revision
 - Paragraph added summarizing NIH, FDA, and CDC roles in vaccine safety both pre- and post-licensure (p16).

- NVAC Comment

- Make the point that the results of vaccine safety studies are important, since they could lead to changes such as the withdrawal of a vaccine (RotaShield) or a change in recommendation (OPV to IPV), and they are important for informing providers and the public.

- Working Group Revision

- “The results of post-licensure safety studies have an important role in vaccine safety policy, such as the shift in the U.S. from Oral Polio Vaccine (OPV) to Inactivated Polio Vaccine (IPV) or the withdrawal of RotaShield from the U.S. market” (p16).

- NVAC Comment
 - Acronyms are used frequently without the first usage being coupled with the full series of words. Possibly it is because the Executive Summary was added after the body of the report was written.
- Working Group Revision
 - Revised and acronym list provided (p7).

- NVAC Comment
 - Recommendation #16: Consider an “on-line” product with updates continually (i.e., when appropriate) with the printed version updated annually. The “online guide” could be used to fill out a VAERS report by clinicians.

- Working Group Revision
 - “This report should be updated annually, with an online version that could be updated at the time new guidance is available and facilitate online submission of VAERS reports” (p53).

- NVAC Comment

- Through out the document and beginning with the introduction the document refers to “highly visible public concern” or “significant public concern” related to vaccine safety. In my opinion these statements should be changed, for example what does it means when the document refers to significant public concern? It could be interpreted as a majority of the population. In reality the document should note that there are small but vocal groups in several areas of the country and not that there is significant public concern. I am concerned that this language validates beyond a reasonable scientific level the issue vaccine adverse events, at a time when the majority of the children in most areas of the country are appropriately vaccinated.

- Working Group Revision

- Modified to only make statements about results from public engagement activities.
- Added a paragraph summarizing data on public concern (current understanding and trends in non-medical exemptions to school immunization requirements) (p15).

- NVAC Comment

- As an additional item for the research agenda I propose the study of the impact of well designed and executed scientific studies on the attitudes and beliefs of individuals who refuse vaccination for themselves or their children. Can we change their beliefs and behaviors based on any of the multiple proposed areas of research? Clearly the issue of vaccine safety is of paramount importance and needs to be studied carefully even in the absence of concerns from any particular group but it appears that at least some of the study recommendations are targeted to certain specific groups.

- Working Group Revision

- None; the Working Group did not feel it appropriate for ISO to conduct research on risk communications with the goal to change beliefs and behaviors; rather the emphasis for ISO should be effective risk communication.

- NVAC Comment
 - In relation to recommendation 10 on increasing the number of reports to VAERS I believe that we are interested specifically in increasing reports by healthcare providers only.
- Working Group Revision
 - None; the Working Group did not want to limit who may submit VAERS reports.

- NVAC Comment

- In relation of the study of adverse events in “Special Populations” the document should specify which populations and the rationale for the specific population. I am concerned that there could be an extremely large group of special populations and interest groups that would like their special populations studied that would make the design and execution of any study unfeasible.

- Working Group Revision

- None; paragraph in draft requesting that the ISO Scientific Agenda be more explicit in the linkage between the identification of special populations and the risk of AEFI, with important issues to consider with respect to heightened risk of AEFI, if any.

- NVAC Comment

- Despite the working group’s desire to have broad public engagement, the document should describe the number of individuals that participate in each meeting and the potential biases associated with their participation. I am concerned that the methodology of the public engagement process could have selected for a specific segment of the population. In particular it should be highlighted through the document that Ashland, OR was selected as it is an area with a large number of families who object to vaccination.

- Working Group Revision

- “The three communities were chosen based on desired geographical diversity and interest in the perspective of a community with a high rate of vaccine hesitancy and non-medical exemptions from school vaccination requirements (Ashland, OR). Between 47 and 70 community members participated at each meeting” (p22).

- Liaison Comment

- Page 10 - capacity recommendations:

- Conspicuous by its absence were bullets to address a couple of issues that have come up multiple times at ACIP meetings. Specifically the need to expand the VSD's capacity and add research studies for pregnant females as a special populations.
 - In regard to VSD expanding the denominator would allow rarer adverse outcomes to be discovered more quickly and accurately than currently done.
 - VSD has been shown to be so much better than VAERS, that it was sad to see 2 recommendations to improve the generically 'flawed' VAERS system and none to improve the far superior VSD one.

- Page 38

- This page talks a little about VSD infrastructure, but tables that discussion to a later date. However, it is too important a tool to not elaborate more on its importance, especially since the flawed VAERS is addressed.

- Working Group Revision

- “There are also issues for the VSD infrastructure (such as size and characteristics of study population, etc) which will be addressed in the second charge of the Working Group” (p43).

- Liaison Comment

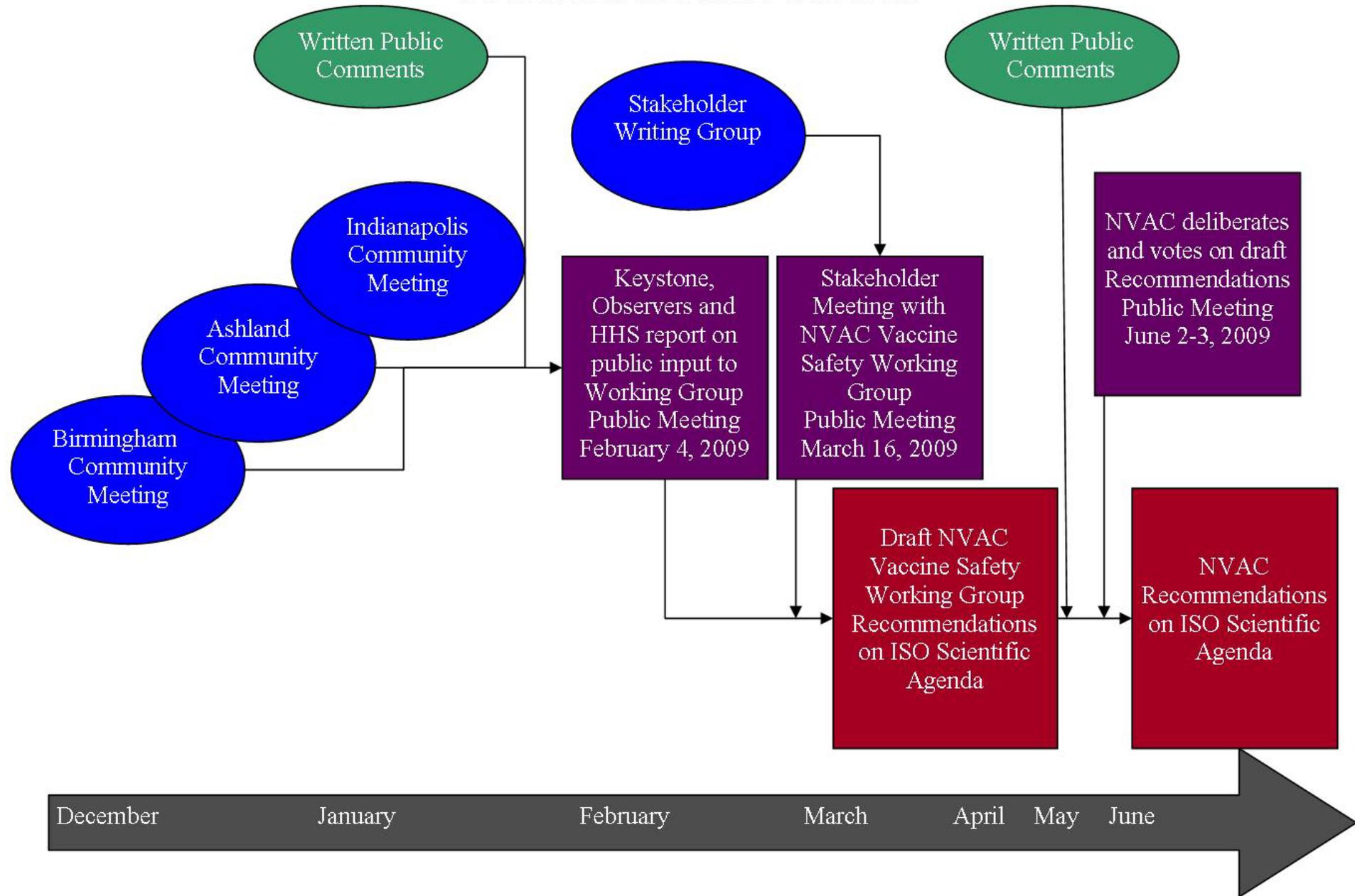
- In regard to studies of pregnant females, the need for better studies to determine risk , if any, for vaccination of pregnant females has come up as a major gap at a number of ACIP meetings and yet no resources seem to be applied to this important area. This absence of data leaves pregnant women out of most vaccine recommendations and could help explain their dismal immunization rates for flu vaccine (10-15%) which is recommended.
- Page 60: I agree with the comment that Special populations categories including pregnant females 'require further development'. However, this subcategory is so important that I would at least recommend a subcategory if possible to comment on like was done for 'Adults over 65 years if age', 'persons with autoimmune disorders', etc.

- Working Group Revision

- “The absence of data for pregnant women was identified as a glaring gap, especially as a recent study highlights the potential benefit to the infant by vaccinating pregnant women, but again specific hypotheses are necessary for the NVAC to provide further input” (p66).

- Ex-Officio Comment
 - Tables on pages 67-68 should be put in the Exec Summary and the column on the extreme right listing the final category of priority should be bolded.
- Working Group Revision
 - None; the Working Group did not want to give the impression that the prioritization of the Specific Vaccine Safety Questions insinuated that other vaccine safety questions were not also of high priority.

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



Vote
on NVAC Recommendations
on the
ISO Draft Scientific Agenda

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, Neal Halsey, Greg 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, Neal Halsey, Stan Plotkin, Kathy Edwards, Greg 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
 - David Tayloe, Sallie Bernard, Lisa Randall, 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
 - Bob Dodd, Michael Cohen, Richard Platt
- 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, Tony Robbins, Tom Vernon, Marguerite Willner, David Tayloe
- 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?