

NVAC Vaccine Safety Working Group Update

NVAC Meeting
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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.

Working Group Members

- Robert Beck
- Guthrie Birkhead^{1,2}
- Tawny Buck^{1,3}
- Chris Carlson
- Vicky Debold
- Cornelia Dekker¹
- Mark Feinberg¹
- Lynn Goldman
- Steve Goodman
- Lance Gordon
- Lawrence Gostin
- Sean Hennessy
- Paul-Henri Lambert
- James Mason¹
- Marie McCormick^{1,3}
- Gerald Medoff
- Trish Parnell¹
- Andrew Pavia^{1,3}
- William Raub
- Bennett Shaywitz

July 15-16 Kick Off Meeting

- Information Gathering Meeting
- 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

Invited Panelists

- Peter Bell
- Sallie Bernard
- Steven Black
- Mark Blaxill
- Michael Cohen
- Louis Z. Cooper
- Robert Davis
- Geraldine Dawson
- Robert Dodd
- Kathryn Edwards
- Neal A. Halsey
- Samuel L. Katz
- Paul Kim
- Thomas May
- Diane Osgood
- Richard Platt
- Stanley A. Plotkin
- Gerald V. Poje
- Gregory Poland
- Lisa Randall
- Anthony Robbins
- David N. Sundwall
- David Tayloe, Jr.
- Thomas M. Vernon
- Marguerite Evans Willner
- Collette Young

Major Topics of Discussion (1)

- Characteristics of an ideal vaccine safety system
 - Transparency
 - Reduce conflicts of interest
 - Public participation
 - Coordination
 - Effective
 - Timely
 - Evidence-based
 - Focus of prevention of adverse events
 - Responsibility
 - Respectful engagement with all parties

Major Topics of Discussion (2)

- Independent Safety Board
- Need for more basic research
- Need for more funding
- New data sources
- Improving active and passive surveillance
- Value of genomics?
- Need for risk perception/ communication research

Major Topics of Discussion (3)

- Resources
 - The VSWG considered an immediate recommendation for reprogramming of funds to the Vaccine Safety Datalink (VSD) and the Clinical Immunization Safety Assessment (CISA) Network, as well as an increase in funding for vaccine safety to the President's 2011 budget request
 - The VSWG ultimately decided it was premature to make a recommendation for targeted funding, but there was strong consensus that the vaccine safety enterprise is under-funded and needs additional resources

Moving Forward

- VSWG is developing a work plan that outlines the process forward
 - 5 Subgroups
 1. Structure and governance
 2. Epidemiology to detect, quantify, and examine causality of vaccine adverse events
 3. Basic and laboratory science and genomics to understand biological mechanisms and risk factors for adverse events
 4. Implementation of the white paper(s)
 5. Stakeholder engagement

Process and Products

- Subgroups will do additional information gathering, outline the issues, and propose recommendations for NVAC's consideration
- Reports will likely be phased throughout the upcoming year, with a goal of completing Charge 2 by September 2010

Process and Products

- The VSWG will issue ~4 reports
 - (1) Characteristics of an ideal vaccine safety system
 - Three reports with recommendations from the three content-focused subgroups
 - (2) Structure and governance
 - (3) Epidemiology to detect, quantify, and examine causality of vaccine adverse events
 - (4) Basic and laboratory science and genomics
- The Implementation and Stakeholder Engagement Subgroups will be process oriented