National Vaccine Advisory Committee (NVAC) February 6, 2009 Meeting on the draft strategic National Vaccine Plan: Goal 2 – Enhance the safety of vaccines and vaccination practices

Participants:

Andrew Pavia	NVAC member and Moderator
Daniel Salmon	National Vaccine Program Office (NVPO)
Kirsten Vannice	NVPO
Anna Buchanan	Association of State and Territorial Health Officials
David Salisbury	NVAC liaison – United Kingdom
Trish Parnell	NVAC member
Nicole Lurie	RAND
Thomas Vernon	Consultant, Novartis Vaccines
Melinda Wharton	Centers for Disease Control and Prevention (CDC)
Nancy Levine	CDC
Jim Moody	Safe Minds
Natalie Bolea	PhRMa
Jennifer Zolot	
Janice Fajarito	
Alina Baciu	Institute of Medicine
Amy Pisani	Every Child by Two
Geoffrey Evans	Health Resources and Services Administration

Telephone Participants:

Leigh Ann Murdock
Sally Bernard
John Best
Tim Booton
Gina Caradonna
Threesa Cedillo
Allison Chapman
Aaron Chetan
Mimi Dawes
Carmen Denis
Sara Difucci
Steve Dionne
Rebecca Estep
Maggie Fetsuga
Cammie Fisher
Rachel Ford
Wendy Fournier
Erin Hale
Carmi Hazen
Rolf Haslehurst
Kren Hendricks
Doreen Johns

Robert Krakow
Alison Macneil
John Martin
Holly Masclans
Terry Poling
Lisa Randall
Jeanna Reed
John Ruch
Jason Schwartz
Rita Shreffler
Nicole Simon
Kim Stagliano
James Strickland
Ginger Taylor
Theresa Watkins-Bryant HRSA
Katherine Walker
Katie Wright
Maureen York
Kathy Young

Summary of Discussion:

There were many callers into the meeting, making for a dynamic conversation. One area of prolonged discussion was the 4th indicator *(Conduct research to explore host factors and biological mechanisms associated with serious [adverse events following immunization] AEFIs and annually report results to the Assistant Secretary for Health, vaccine advisory committees, vaccine policy makers and other stakeholders)* and associated objectives/goals concerning genetic risk factors and biological mechanisms. There was consensus among the group that it was a very important new field of science, although there was caution against being unrealistic or over-promising. There was also support shown for reducing administration errors. The group did not propose values for Xs in the indicators.

Summary points:

- The issue of individual risk and elucidating individual risk factors received strong support from participants in the room and on the phone, despite acknowledgement that the science is challenging and time consuming.
- There was strong support for efforts to reduce administration errors, including better tracking/recording.
- Education in a multitude of ways is critical, particularly to make sure that everyone in the healthcare system knows how to use VAERS to facilitate better tracking/reporting of adverse events.
- New systems, such as electronic health records, may allow for better data transmission and integration

- Indicator 1- Dissemination is very important (*Conduct and disseminate the results of active and passive surveillance-based safety assessments for newly recommended vaccines or for vaccines with expanded recommendations:*

    - *Within 1 year of publication in CDC's Morbidity and Mortality Weekly Report of new or revised ACIP recommendations.*
    - *Within 1 year after X million doses have been distributed*)

- Indicator 4 - Strategies must be developed for how to deal with this topic, which garners enormous scientific and public interest, but scientifically poses challenges. The process should be transparent of what the studies are, what the methods are, and who is doing the research.