

Subcommittee on Vaccine Safety

Subcommittee on Public Communication, Consultation and Participation

June 7, 2007

Agenda

- Update on ISO research agenda development and NVAC role in external review
 - Karen Broder
- Public input: Lessons learned -
 - Kristin Pope
- Research on public perception and input
 - Deb Gust
- Citizen and stakeholder engagement in research on vaccine safety

Institute of Medicine (IOM) Review and Recommendation for ISO Research Agenda

- In February 2005, IOM released its review and recommendations in the report, “Vaccine Safety Research, Data Access, and Public Trust”*
- IOM Recommended “a subcommittee of NVAC [National Vaccine Advisory Committee] that includes representatives of a wide variety of stakeholders review and provide advice...on the VSD [Vaccine Safety Datalink] research plan”
 - Meetings should be public

*Available at <http://www.nap.edu/catalog/11234.html>, accessed 4/1/07

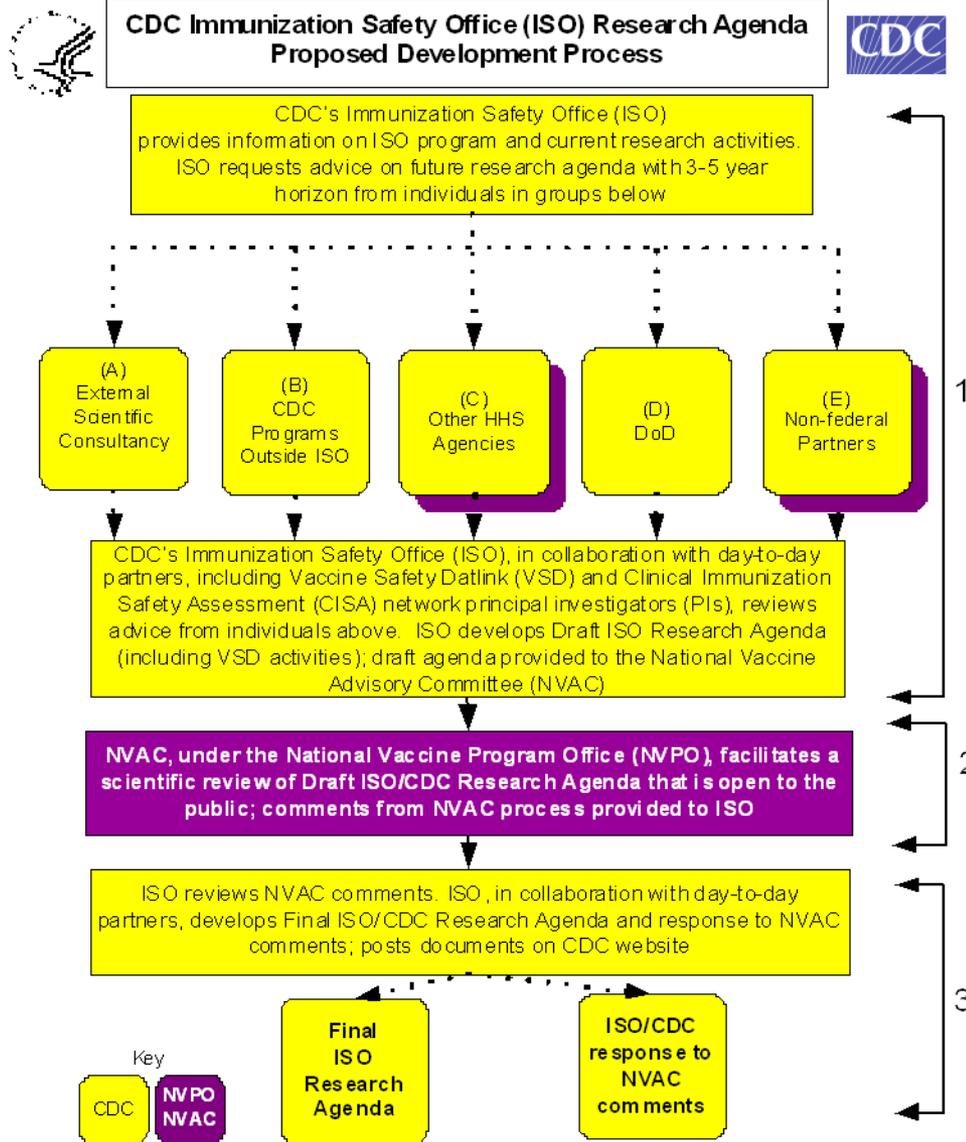
CDC's Response to IOM Recommendation for Research Agenda Development

- ISO seeks to develop a comprehensive scientifically robust ISO research agenda with extensive internal and external input
- Because of ISO's focus on integration of research across the office's components, the scope will include the full ISO research agenda, including VSD, as recommended by IOM
 - 3-to-5 year horizon

Overview of Research Agenda Development

- Coordinated **3-phase** development process with extensive internal and external input
 - ISO/CDC develops draft research agenda
 - NVAC facilitates scientific review
 - ISO/CDC responds to feedback from NVAC process and finalizes agenda
- Evaluate research agenda development process

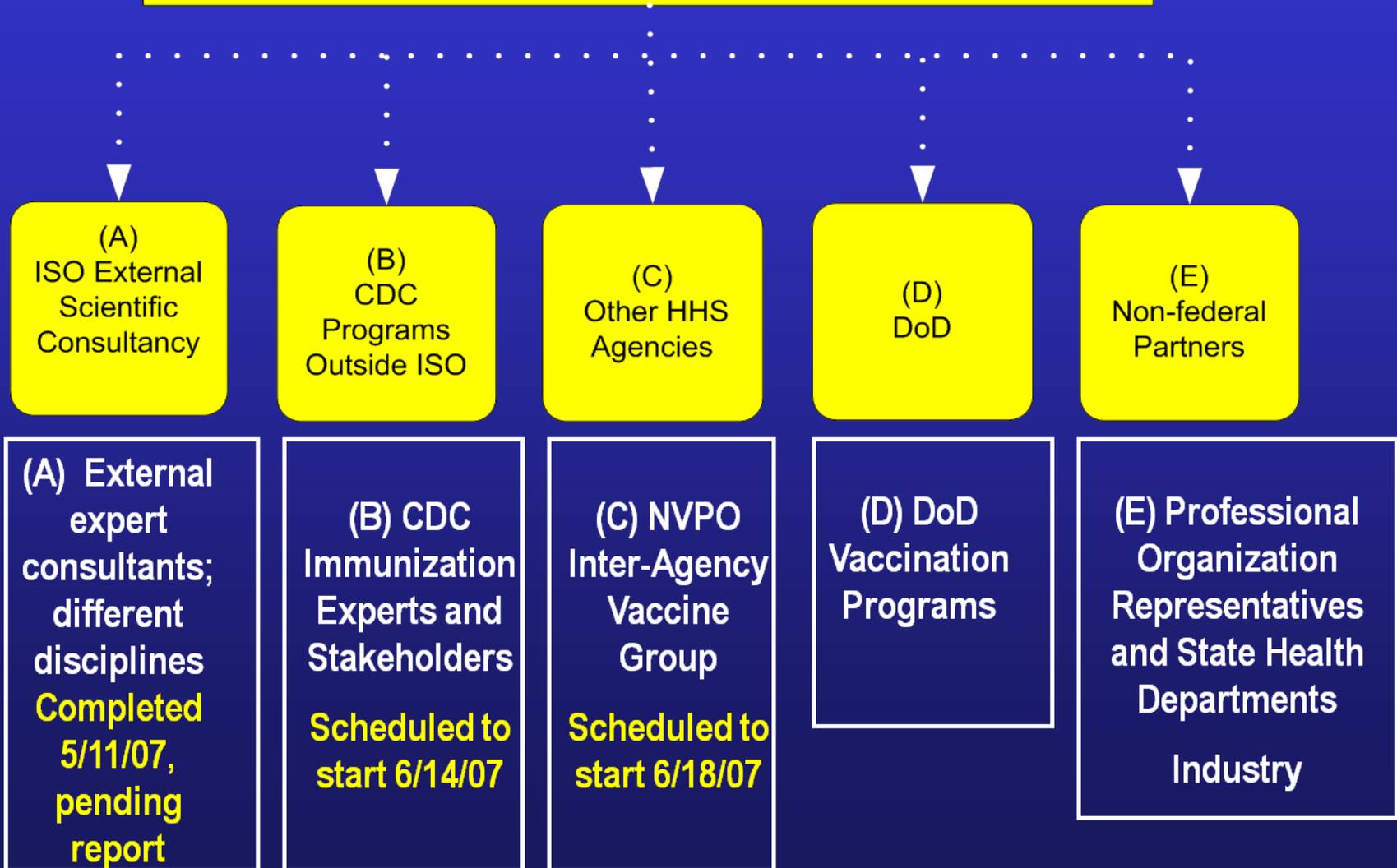
Proposed Development Process



DRAFT on 5/30/2007

Proposed Agenda Development Process

CDC's Immunization Safety Office (ISO)
provides information on ISO program and current research activities.
ISO requests advice on future research agenda with 3-5 year
horizon from individuals in groups below



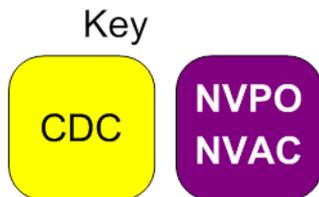
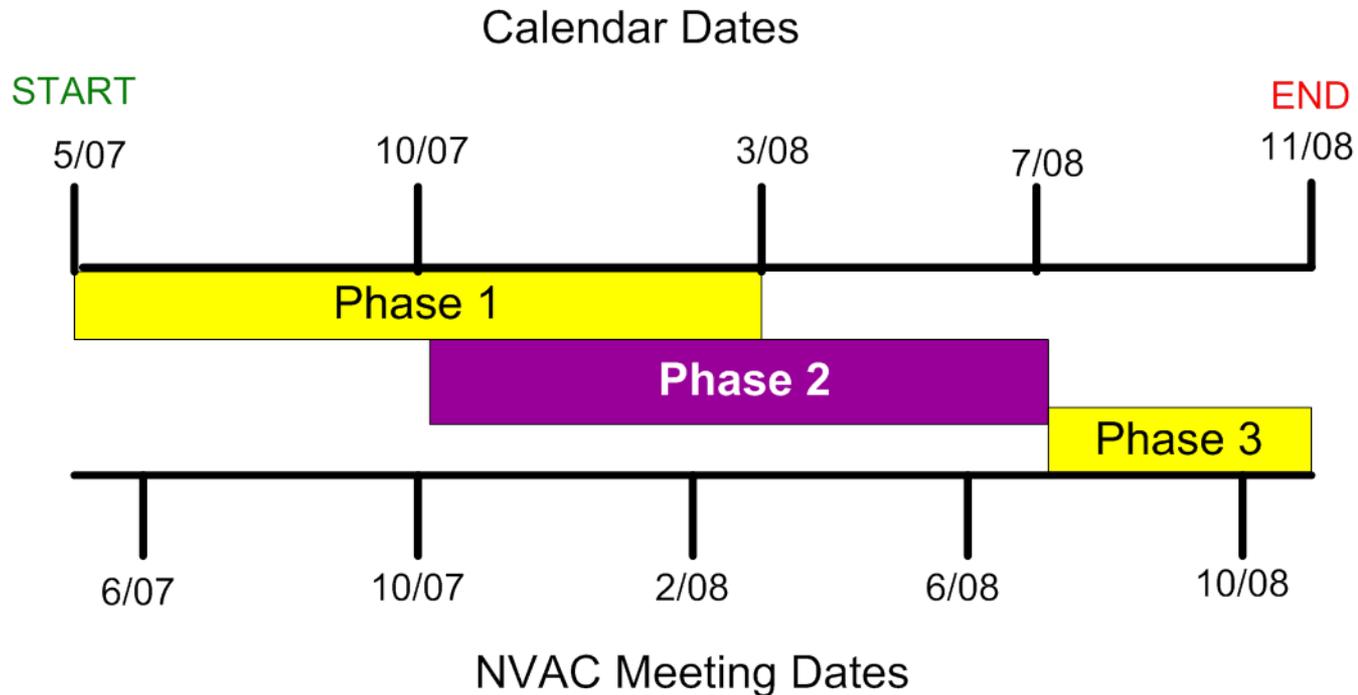
Task: NVAC Scientific Review Constituency

- What process should NVAC and NVPO use to implement a scientific review of the draft ISO research agenda in order to provide NVAC recommendations?
- Who should be invited to this review? Consider immunization safety experts, medical and scientific experts in related disciplines, and key immunization stakeholders

Task: NVAC Scientific Review Proposed Charge

- Is the proposed charge to the reviewers reasonable?
 - Content of the ISO draft research agenda (e.g., are the topics appropriate, what is missing, what topics should be studied by another agency or organization)
 - Prioritization of research topics
 - Possible barriers to implementing the research agenda and suggestions for addressing them
 - Process, e.g., future approach to ISO research agenda development and how often should the NVAC review be done

Draft Timeline Research Agenda Development: Estimated 18-month Process



New realities for immunization policy

“Because the powers granted to public health authorities are based on the public’s trust, and in democratic societies this trust is founded on broad participation in formulating policy, health care decision makers may well feel mounting pressure to include diverse perspectives not only of physicians and policy experts, but also of parent groups, politicians, special- interest advocates, economists and, perhaps, ethicists

Feudiner and Marcuse

Pediatrics, 1991

What are the goals of public participation?

- Enhance trust
- Ensure transparency
- Input on public values
- Improve quality of decisions

Next steps

- Develop composition, establish mechanism and nominate members for NVAC scientific review panel
 - Safety subcommittee
- Develop clear “terms of reference” - charge to NVAC for desired outcomes of review
 - ISO
- Continue to refine public role
 - ISO, Safety subcommittee, PCCP subcommittee
- Develop mechanism for industry consultation
 - ISO/NVPO

Additional information

ISO External Scientific Consultancy Process: Brainstorming Sessions

- Life Stage 1: Infants Aged 0–11 months
- Life Stage 2: Children Aged 1–10 years
- Life Stage 3: Adolescents Aged 11–18 years (non-pregnant)
- Life Stage 4: Adults Aged ≥ 19 years (non-pregnant)
- Life Stage 5: Pregnant Women – all ages
- Across the Life Stages A: Role of Public Perception in Shaping the Immunization Safety Research Agenda
- Across the Life Stages B: Considerations for Vaccine Safety Surveillance
- Across the Life Stages C: Safety of Non-antigen Vaccine Constituents and New Vaccine Technologies
- Across the Life Stages D: Adverse Events that Occur Years after Vaccination

ISO External Scientific Consultancy

Meeting Participants

Individual External Consultants

- Georges Peter, MD, Professor Emeritus, The Warren Alpert Medical School of Brown University: External Leader
- Kevin Ault, MD, Associate Professor, Emory University School of Medicine: Obstetrics and Gynecology
- Claire Broome, MD, MPH, Adjunct Professor, Rollins School of Public Health, Emory University: Epidemiology
- Penelope Dennehy, MD, Professor, The Warren Alpert Medical School of Brown University : Pediatric Infectious Diseases
- David Relman, MD, Associate Professor, Stanford University School of Medicine: Genomics
- William Schaffner, MD, Professor, Vanderbilt University School of Medicine: Adult Infectious Diseases
- Christopher Wilson, MD, Professor, University of Washington School of Medicine: Immunology

ISO External Scientific Consultancy

Meeting Participants

External Liaisons

- Kenneth Bart, MD, MPH, MSHPM, Consultant, National Vaccine Program Office, HHS
- Cornelia Dekker, MD, Clinical Immunization Safety Assessment (CISA) network, Principal Investigator (PI), Stanford University School of Medicine
- Jaime Deville, MD, Member, Advisory Commission on Childhood Vaccines, University of California, Los Angeles
- Geoffrey Evans, MD, Director, National Vaccine Injury Compensation Program (VICP), Health Resources and Services Administration (HRSA)
- Lisa Jackson, MD, MPH, Vaccine Safety Datalink (VSD) PI, Group Health Center for Health Statistics, Seattle
- Andrew Pavia, MD, Chair, Subcommittee on Vaccine Safety, National Vaccine Advisory Committee (NVAC), University of Utah School of Medicine
- Jean Clare Smith, MD, MPH, Assistant to the Director for Immunization Policy, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC

ISO External Scientific Consultancy

Meeting Participants

CDC ISO Research Agenda Development Team

Immunization Safety Office (ISO)

- John Iskander, MD, MPH, Acting Co-director, ISO
- Kristin Pope, Acting Co-director, ISO
- Karen Broder, MD, Senior Medical Advisor, ISO
- Jae Duncan, Program Coordinator
- Paul Gargiullo, PhD, Acting Team Leader VSD
- Jane Gidudu, Acting Team Leader Brighton Collaboration
- Laura Leidel, RN, FNP-C, MSN, MPH, Public Health Analyst
- Nancy Levine, PhD, Policy Analyst
- Linda Tierney, BA, Health Communications Specialist
- Claudia Vellozzi, MD, MPH, Acting Team Leader for CISA
- Bruce Weniger, MD, MPH, Vaccine Technology Unit Team Leader

Office of the Chief Science Officer

- Dixie Snider, MD, MPH, Senior Advisor to the Director CDC (consultant)
- Tanja Popovic, MD, PhD, F(AAM), AM(AAFS), Chief Science Officer, CDC
- James Stephens, PhD, Acting Associate Director for Science, CDC