

Update: CDC's Immunization Safety Office Scientific Agenda Development

Advisory Committee on Immunization Practices (ACIP)

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



In February 2005, 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 research plan... the group should meet publicly and allow interested persons to observe the process and provide input through established mechanisms.”

*Vaccine Safety Research, Data Access, and Public Trust, available at <http://www.nap.edu/catalog/11234.html>, accessed on March 15, 2008



Overview of Scientific Agenda Development

- ISO/CDC developed a draft ISO Scientific Agenda
 - Three input meetings with external consultants, federal scientists and vaccine manufacturers' representatives
 - Input from day-to-day partners, literature and other sources
- **NVAC is facilitating a scientific review of draft ISO Scientific Agenda**
 - **First meeting with NVAC Vaccine Safety Working Group was on April 11, 2008; open to the public***
- ISO/CDC will respond to feedback from NVAC review process and finalize the ISO Scientific Agenda



*NVAC Vaccine Safety Working Group Chair is Dr. Pavia

Objective and Scope of ISO Agenda

- Objective: to develop a comprehensive 5-year ISO Scientific Agenda with extensive expert input
- Scope: vaccine safety research, selected surveillance, and selected clinical guidance activities that
 - Are part of ISO's mission
 - Are in ISO's realm to lead
 - Could be implemented during the next 5 years with infrastructure generally accessible to CDC



Summary of ISO Scientific Agenda Draft Recommendations

1. Respond to emerging issues and conduct core, required scientific activities
2. Enhance vaccine safety public health and clinical guidance capacity in 7 areas
3. Address 5-Year research needs



ISO Agenda Draft Recommendations

#2: Enhance Vaccine Safety Public Health and Clinical Guidance Capacity in 7 Areas

Item	Capacity Area
A	Infrastructure for Vaccine Safety Surveillance: Vaccine Adverse Event Reporting System (VAERS)
B	Infrastructure for Vaccine Safety Surveillance and Research: Vaccine Safety Datalink (VSD) Project
C	Epidemiologic and Statistical Methods for Vaccine Safety
D	Laboratory Methods for Vaccine Safety
E	Genomics and Vaccine Safety
F	Case Definitions, Data Collection, and Data Presentation for Adverse Events Following Immunization
G	Vaccine Safety Clinical Practice Guidance



ISO Agenda Draft Recommendations

#3 5-Year Research Needs (30 items)

Item	5-Year Research Needs (30 items)
A	Specific Vaccine Safety Questions (7 items)
B	Thematic Area: Vaccines and Vaccination Practices (8 items)
C	Thematic Area: Special Populations (7 items)
D	Thematic Area: Clinical Outcomes (8 items)



ISO Agenda Draft Recommendations

#3 5-Year Priority Research Needs:

A. Specific Vaccine Safety Questions (Hypotheses)

Item	A. Specific Vaccine Safety Questions
A-I	Are vaccines (e.g., influenza vaccines, meningococcal conjugate vaccine [MCV4]) associated with increased risk for Guillain-Barré Syndrome (GBS)?
A-II	Is live, attenuated influenza vaccine (LAIV) associated with increased risk for asthma and/or wheezing, particularly in young children or persons with history of wheezing?
A-III	Is exposure to thimerosal associated with increased risk for clinically important tics and/or Tourette syndrome?
A-IV	Are acellular pertussis vaccines associated with increased risk for acute neurological events, particularly hypotonic-hyporesponsive episodes (HHE)?



ISO Agenda Draft Recommendations

#3 5-Year Priority Research Needs

A. Specific Vaccine Safety Questions (Hypotheses) (cont.)

Item	A. Specific Vaccine Safety Questions (Hypotheses)
A-V	Is immunization associated with increased risk for neurological deterioration in children with mitochondrial disorders?
A-VI	Is combination measles, mumps, rubella, and varicella (MMRV) vaccine associated with increased risk for febrile seizure and, if so, are there sequelae?
A-VII	Are varicella vaccines (varicella and MMRV) associated with increased risk for clinically important events related to varicella vaccine virus reactivation?



ISO Agenda Draft Recommendations

#3 5-Year Priority Research Needs

Item	B. Thematic Area: Vaccines and Vaccination Practices
B-1	Bivalent human papillomavirus (bivalent HPV) vaccine (Cervarix™)
B-II	Zoster vaccine (Zostavax®)
B-III	Annual influenza vaccination in children and adolescents (trivalent inactivated influenza vaccine [TIV] and LAIV)
B-IV	Non-antigen components of vaccines (other than thimerosal and ASO4 adjuvant HPV vaccine)
B-V	Simultaneous vaccination
B-VI	Safety of different products within the same vaccine category
B-VII	Off label use of vaccines
B-VIII	Vaccine-drug interactions



ISO Agenda Draft Recommendations

#3 5-Year Priority Research Needs

Item	C. Thematic Area: Special Populations
C-I	Premature and low birth weight infants
C-II	Pregnant women
C-III	Adults aged ≥ 65 years
C-IV	Persons with primary immunodeficiency
C-V	Persons with secondary immunodeficiency
C-VI	Persons with autoimmune disorders
C-VII	Children with inborn errors of metabolism



ISO Agenda Draft Recommendations

#3 5-Year Priority Research Needs

Item	D. Thematic Area: Clinical Outcomes
D-I	Autoimmune diseases
D-II	Central nervous system demyelinating disorders
D-III	Encephalitis/ Encephalopathy
D-IV	Neurodevelopmental disorders, including autism spectrum disorder (ASD)
D-V	Vasculitis syndromes
D-VI	Myopericarditis (not associated with smallpox vaccine)
D-VII	Clinically important outcomes related to postimmunization fever
D-VIII	Postvaccination syncope and sequeale



Acknowledgements

- External, expert vaccine safety consultants
- Interagency Vaccine Group federal scientists
- Vaccine manufacturers' representatives
- National Vaccine Program Office
- National Vaccine Advisory Committee (NVAC) and NVAC Vaccine Safety Working Group
- Advisory Committee on Immunization Practices
- Centers for Disease Control and Prevention (CDC) immunization experts and stakeholders
- Advisory Commission on Childhood Vaccines
- CDC's Immunization Safety Office (ISO) research and surveillance partner scientists
- CDC/ISO Agenda Writing and Reviewing Group
- CDC/ISO and Office of the Chief Science Officer scientists and staff



Resources

- Immunization Safety Office Scientific Agenda
<http://www.cdc.gov/vaccinesafety/agenda.htm>
- CDC, Vaccine Safety
<http://www.cdc.gov/vaccinesafety/>
- National Vaccine Advisory Committee,
<http://www.hhs.gov/nvpo/nvac/index.html>
- Institute of Medicine, Vaccine Safety Research, Data Access, and Public Trust, available at
<http://www.nap.edu/catalog/11234.html>

