



INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

COMMITTEE TO REVIEW ADVERSE EFFECTS OF VACCINES

Ellen Wright Clayton, J.D., M.D. (Chair)

Rosalind E. Franklin Professor of Genetics and Health Policy
Director, Center for Biomedical Ethics and Society
Professor of Pediatrics and Law
Vanderbilt University Schools of Medicine and Law
Nashville, TN

Inmaculada B. Aban, M.S., Ph.D.

Associate Professor
Department of Biostatistics
University of Alabama, Birmingham
Birmingham, AL

Douglas J. Barrett, M.D.

Senior Vice President for Health Affairs
University of Florida
Gainesville, FL

Martina Bebin, M.D., M.P.A.

Associate Professor of Neurology and Pediatrics
University of Alabama at Birmingham
Birmingham, AL

Kirsten Bibbins-Domingo, Ph.D., M.D., M.A.S.

Associate Professor and Attending Physician
University of California, San Francisco
San Francisco, CA

Graham A. Colditz, M.D., Dr.P.H.

Niess-Gain Professor in Medicine
Associate Director for Prevention and Control
Alvin J. Siteman Cancer Center
Washington University School of Medicine
St. Louis, MO

Martha Constantine-Paton, Ph.D.

Investigator, McGovern Institute for Brain Research
Professor of Biology
Department of Biology
Department of Brain and Cognitive Sciences
Massachusetts Institute of Technology
Cambridge, MA

Deborah J. del Junco, Ph.D.

Senior Epidemiologist and Associate Professor
Biostatistics, Epidemiology, and Research Design
University of Texas Health Science Center
at Houston
Houston, TX

Betty A. Diamond, M.D.

Head, Center for Autoimmune and Musculoskeletal Disease
The Feinstein Institute for Medical Research
North Shore-LIJ Health System
Manhasset, NY

S. Claiborne Johnston, M.D., Ph.D.

Associate Vice Chancellor of Research
Director, Clinical and Translational Science Institute
Professor of Neurology and Epidemiology
Director, Neurovascular Disease and Stroke Center
University of California, San Francisco
San Francisco, CA

Anthony L. Komaroff, M.D.

Steven P. Simcox, Patrick A. Clifford, and James H. Higby Professor of Medicine
Senior Physician
Brigham and Women's Hospital
Harvard Medical School
Boston, MA

B. Paige Lawrence, Ph.D.

Associate Professor of Environmental Medicine
Associate Professor of Microbiology and Immunology
University of Rochester School of Medicine and Dentistry
Rochester, NY

COMMITTEE TO REVIEW ADVERSE EFFECTS OF VACCINES

M. Louise Markert, M.D., Ph.D.

Associate Professor of Pediatrics and Immunology
Division of Pediatric Allergy and Immunology
Department of Pediatrics
Duke University Medical Center
Durham, NC

Marc C. Patterson, M.D.

Chair, Division of Child and Adolescent Neurology
Professor of Neurology, Pediatrics, and Medical
Genetics
Director, Child Neurology Training Program
Mayo Clinic
Rochester, MN

Hugh A. Sampson, M.D.

Professor of Pediatrics and Immunology
Dean for Translational Biomedical Sciences
Director of the Jaffe Food Allergy Institute
Mount Sinai School of Medicine
New York, NY

Pauline A. Thomas, M.D.

Associate Professor
Department of Preventive Medicine and
Community Health
Department of OB/GYN and Women's Health
University of Medicine and Dentistry of
New Jersey
Newark, NJ

Leslie P. Weiner, M.D.

Richard Angus Grant, Sr. Chair in Neurology
Professor of Neurology and Molecular
Microbiology and Immunology
Keck School of Medicine
University of Southern California
Los Angeles, CA

IOM Staff

Kathleen Stratton, Ph.D.

Study Director
kstratton@nas.edu

Andrew Ford, Ph.D.

Program Officer
aford@nas.edu

Erin Rusch

Research Assistant
erusch@nas.edu

Trevonne Walford

Program Assistant
twalford@nas.edu

Rose Marie Martinez, Sc.D.

Board Director
rmartinez@nas.edu



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The Committee to Review Adverse Effects of Vaccines is posting a bibliography of citations it has reviewed. As a reminder, the committee is assessing epidemiological, clinical, and biological literature in order to make conclusions about the causal relationship between specific vaccines and specific adverse events.

The committee directed comprehensive searches of the published biomedical literature using MEDLINE (1950-present), EMBASE (1980-present), BIOSIS (1969-2005), and Web of Science consisting of Science Citation Index (1900-present) and Social Science Citation Index (1956-present). The searches retrieved over 12,000 unique citations. The bibliography contains three sections. Section I includes citations for the 1,487 papers that the committee is reviewing in depth. Section II includes the other 11,158 citations in the committee's bibliography. Section III contains the working list of adverse events.

The committee welcomes your review of these citations and asks that you alert us via email at vaccinesafety@nas.edu if you are aware of published scientific literature that has not surfaced in the extensive search undertaken under the committee's guidance. As per standard procedure, any comment you submit to the committee, including your name and identifying information will not be kept confidential and will be included in the Public Access File as the National Academy of Sciences complies with Section 15 of the Federal Advisory Committee Act (FACA). The National Academies shall be authorized to use any such comments or submissions in accordance with the National Academies' Terms of Use Statement. Please feel free to direct others to this announcement.

The committee will conduct an additional literature search at the end of the 2010 calendar year to identify relevant articles published since the initial searches were conducted. The committee report is expected to be released in mid-2011.

A link to the bibliography can be found at www.iom.edu/vaccineadverseeffects. Click on the link on the right-hand side of the page that says "Review Background Information". Click on link that says "Request for Input on Bibliography".



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COMMITTEE TO REVIEW ADVERSE EFFECTS OF VACCINES

DECEMBER 2009 WORKING LIST OF ADVERSE EVENTS TO BE CONSIDERED BY THE COMMITTEE

The Committee to Review Adverse Effects of Vaccines met for the first time on April 20-21, 2009. At the open session, staff from the National Vaccine Injury Compensation Program (VICP), which is operated out of the Health Resources and Services Administration, presented a working list of adverse events associated with the four vaccines under review by the Committee.

The presentation by VICP can be found here:

<http://www.iom.edu/~/media/Files/Activity%20Files/Research/VaccineAdvEffectReview/2009-APR-20/Charge-to-the-Institute-of-Medicine-Committee.ashx>.

The working list was updated to include adverse events for four new vaccines the Committee will also review. The working list can be found on the next pages of this announcement. The Committee reserves the right to add conditions to this working list and wishes to receive input.

It is most helpful for the committee to receive comments on the list by 4 January 2010. Please e-mail the committee at vaccinesafety@nas.edu with suggestions for additions. Please include "Input on Working List of Adverse Events" in the subject line of the e-mail. Feel free to submit a brief rationale and/or relevant bibliography in support of the suggested addition.

Please note: Any comments you submit to the committee, including your name and identifying information, will not be kept confidential and will be included in the Public Access File as the National Academy of Sciences complies with Section 15 of the Federal Advisory Committee Act (FACA). The National Academies shall be authorized to use any such comments or submissions in accordance with the National Academies' Terms of Use Statement.

The Committee has been advised that the VICP is seeking input through the Advisory Commission on Childhood Vaccines (ACCV) into this adverse events working list. The Committee will finalize the list of adverse events to be addressed upon review of any additions requested by VICP subsequent to the ACCV process, as well as suggestions submitted directly to the Committee to Review Adverse Effects of Vaccines.

COMMITTEE TO REVIEW ADVERSE EFFECTS OF VACCINES
DECEMBER 2009 WORKING LIST OF ADVERSE EVENTS TO BE CONSIDERED BY THE COMMITTEE

| DTaP/Tetanus Containing Vaccines | Hepatitis A Vaccine | Meningococcal Vaccine | MMR Vaccine |
|--|--|--|--|
| <ul style="list-style-type: none"> • Anaphylaxis or Anaphylactic Shock • Arthropathy (Arthritis, Arthralgia) • Autism* • Autism Spectrum Disorders (ASD)/Pervasive Developmental Disorders (PDD)* • Ataxia • Bell's Palsy • Chronic, Remitting Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Chronic Inflammatory Disseminated Polyneuropathy ▪ Multiple Sclerosis • Chronic Urticaria • Complex Regional Pain Syndrome • Convulsions: <ul style="list-style-type: none"> ▪ Febrile, Afebrile ▪ Infantile Spasms ▪ Myoclonic Epilepsy • Encephalopathy/Encephalitis • Fibromyalgia • Immune Thrombocytopenic Purpura • Insulin-dependent Diabetes Mellitus • Monophasic Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis • Myocarditis • Opsoclonus Myoclonus Syndrome • Optic Neuritis • Serum Sickness • Sudden Infant Death Syndrome (SIDS) | <ul style="list-style-type: none"> • Anaphylaxis or Anaphylactic Shock • Bell's Palsy • Chronic, Remitting Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Chronic Inflammatory Disseminated Polyneuropathy ▪ Multiple Sclerosis • Hepatitis (autoimmune) • Monophasic Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis | <ul style="list-style-type: none"> • Anaphylaxis or Anaphylactic Shock • Chronic Headaches • Chronic, Remitting Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Chronic Inflammatory Disseminated Polyneuropathy ▪ Multiple Sclerosis • Encephalopathy/Encephalitis • Monophasic Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis | <ul style="list-style-type: none"> • Anaphylaxis or Anaphylactic Shock • Arthropathy (Arthritis, Arthralgia) • Autism* • Autism Spectrum Disorders (ASD)/Pervasive Developmental Disorders (PDD)* • Ataxia • Brachial Neuritis • Chronic Fatigue Syndrome • Chronic, Remitting Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Chronic Inflammatory Disseminated Polyneuropathy ▪ Multiple Sclerosis • Complex Regional Pain Syndrome • Convulsions: <ul style="list-style-type: none"> ▪ Febrile, Afebrile ▪ Infantile Spasms ▪ Myoclonic Epilepsy • Encephalopathy/Encephalitis • Fibromyalgia • Hearing Loss • Hepatitis • Insulin-dependent Diabetes Mellitus • Monophasic Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis • Opsoclonus Myoclonus Syndrome |

Also see General Considerations on page 4.

* "Secondary" autism or autistic features arising from chronic encephalopathy, mitochondrial disorders and/or other underlying disorders will be considered by the Committee. For "Primary" autism, VICP has asked the IOM to consider the review of the medical literature post *Immunization Safety Review: Vaccines and Autism (2004)* report. In particular, VICP is interested in the Committee's review on more recent theories of "neuroinflammation" and "hyperarousal/overexcitation of the immune system via multiple simultaneous antigenic stimulation."

COMMITTEE TO REVIEW ADVERSE EFFECTS OF VACCINES
DECEMBER 2009 WORKING LIST OF ADVERSE EVENTS TO BE CONSIDERED BY THE COMMITTEE

| Hepatitis B Vaccine | Human Papilloma Virus Vaccine | Influenza Vaccine | Varicella Vaccine |
|---|---|---|--|
| <ul style="list-style-type: none"> • Anaphylaxis or Anaphylactic Shock • Arthropathy (Arthritis, Arthralgia) • Brachial Neuritis • Chronic, Remitting Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Chronic Inflammatory Disseminated Polyneuropathy ▪ Multiple Sclerosis ▪ Neuromyelitis Optica • Complex Regional Pain Syndrome • Convulsions: <ul style="list-style-type: none"> ▪ Febrile, Afebrile ▪ Infantile Spasms ▪ Myoclonic Epilepsy • Encephalopathy/Encephalitis • Fibromyalgia • Insulin-dependent Diabetes Mellitus • Monophasic Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis • Polyarteritis Nodosa • Systemic Lupus Erythematosus • Vasculitis | <ul style="list-style-type: none"> • Amyotrophic Lateral Sclerosis • Anaphylaxis or Anaphylactic Shock • Arthropathy (Arthritis, Arthralgia) • Brachial Neuritis • Chronic, Remitting Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Chronic Inflammatory Disseminated Polyneuropathy ▪ Multiple Sclerosis ▪ Neuromyelitis Optica • Hypercoagulable States • Monophasic Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis • Pancreatitis • Syncope • Thromboembolic Events | <ul style="list-style-type: none"> • Anaphylaxis or Anaphylactic Shock • Arthropathy (Arthritis, Arthralgia) • Asthma • Bell's Palsy • Brachial Neuritis • Cardiac: <ul style="list-style-type: none"> ▪ Myocardial Infarction ▪ Stroke ▪ Sudden Death • Chronic, Remitting Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Chronic Inflammatory Disseminated Polyneuropathy ▪ Multiple Sclerosis ▪ Neuromyelitis Optica • Complex Regional Pain Syndrome • Encephalopathy/Encephalitis • Fibromyalgia • Monophasic Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis • Oculorespiratory Syndrome • Polyarteritis Nodosa • Small Fiber Neuropathy • Systemic Lupus Erythematosus • Vasculitis | <ul style="list-style-type: none"> • Anaphylaxis or Anaphylactic Shock • Arthropathy (Arthritis, Arthralgia) • Cerebellar Ataxia • Convulsions: <ul style="list-style-type: none"> ▪ Febrile, Afebrile ▪ Infantile Spasms ▪ Myoclonic Epilepsy • Disseminating Oka VZV Infection (in the immunocompromised) • Encephalopathy/Encephalitis • Hepatitis • Meningitis • Monophasic Demyelinating Diseases: <ul style="list-style-type: none"> ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis • Oka VZV Zoster • Pneumonia • Thrombocytopenia |

Also see General Considerations on page 4.

COMMITTEE TO REVIEW ADVERSE EFFECTS OF VACCINES
DECEMBER 2009 WORKING LIST OF ADVERSE EVENTS TO BE CONSIDERED BY THE COMMITTEE

General Considerations

In addition to the specific adverse events, the committee will review general considerations for the eight vaccines. General considerations include underlying (susceptible) populations, "immune dysfunction", vaccine administration issues, anaphylaxis and autoimmune diseases (time interval), and sequential vaccination issues.