Presidential Symposium
IOM Report 2012: Epilepsy Across the Spectrum
Promoting Health and Understanding

Symposium Chair:
Frances E. Jensen, MD
Hospital of University of Pennsylvania
Philadelphia, PA

Saturday, December 1, 2012
Convention Center – Ballroom 6C, Upper Level
8:30 am – 11:30 am
OVERVIEW
This symposium will describe the process that led to the development of the 2012 IOM. There will be a report on the potential impact of the IOM report on both the AES community and the health care community in general. There will be a review of the major elements of the report and how it will be implemented to change professional education, certification of epilepsy centers and specialists, and patient access to care. Actionable elements of the IOM report that will require coordinated participation of federal and nonfederal entities will be addressed. The relationship of the IOM report to the expanded NINDS and inter-institute funding programs for epilepsy research as well as how the IOM report can support the NINDS Epilepsy Benchmarks will be described. Finally, the response of patient advocacy and nongovernmental organizations will be presented, including implementation of the report recommendations and coordination with the community of professionals in epilepsy care.

LEARNER OUTCOMES
- Recognize the impact of current gaps in diagnosis and treatment, as well as quality of life issues for patients with epilepsy
- Utilize information from emerging surveillance efforts to assess incidence and prevalence of epilepsy in the population across all age ranges to define clinical needs in their communities
- Understand significant areas of need for clinical, basic, and epidemiological research related to epilepsy and its comorbidities and their relationship to NINDS Epilepsy Benchmarks in order to define their research goals
- Identify and engage others devoted to provision of care in order to coordinate management of patients with epilepsy
- Manage care of patients based on established quality measures and desired improvement strategies in order to optimize patient outcomes.

TARGET AUDIENCE
Basic: Those new to epilepsy treatment or whose background is limited, e.g., students, residents, general physicians, general neurologists and neurosurgeons, other professionals in epilepsy care, administrators.

Intermediate: Epilepsy fellows, epileptologists, epilepsy neurosurgeons “mid-level” providers with experience in epilepsy care (e.g., advanced practice nurses, nurses, physician assistants), neuropsychologists, psychiatrists, basic and translational researchers.

Advanced: Symposium will address highly technical or complex topics (e.g., neurophysiology, advanced imaging techniques, advanced treatment modalities, including surgery)

AGENDA
8:30 – 8:45 am  Clinical and Basic Science Research Awards
8:45 – 9:00 am  Introduction and Overview
                  Frances E. Jensen, M.D.
9:00 – 9:35 am  The IOM Process and Committee Discussion
                  Joseph I. Sirven, M.D.
9:35 – 10:10 am  The Context of the IOM Report: A View from HHS Leadership
                  Howard Koh, M.D., MPH
10:10 – 10:45 am  What the IOM Report Means for Basic and Clinical Research
Story Landis, Ph.D.

10:45 – 11:20 am  How the IOM Report Will Impact the Lives of Patients with Epilepsy
Susan Axelrod

11:20 – 11:30 am  Conclusions
Frances Jensen, M.D.

ACCREDITATION
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ABPN Core Competencies
The American Board of Psychiatry and Neurology has reviewed the Presidential Symposium and has approved this program as part of a comprehensive lifelong learning program, which is mandated by the ABMS as a necessary component of maintenance of certification.
Core Competencies: Medical Knowledge, Professionalism, System-Based Practice, and Practice-Based Learning and Improvement

FACULTY/PLANNER DISCLOSURES
It is the policy of the AES to make disclosures of financial relationships of faculty, planners and staff involved in the development of educational content transparent to learners. All faculty participating in continuing medical education activities are expected to disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. AES carefully reviews reported conflicts of interest (COI) and resolves those conflicts by having an independent reviewer from the Council on Education validate the content of all presentations for fair balance, scientific objectivity, and the absence of commercial bias. The American Epilepsy Society adheres to the ACCME’s Essential Areas and Elements regarding industry support of continuing medical education; disclosure by faculty of commercial relationships, if any, and discussions of unlabeled or unapproved uses will be made.

FACULTY / PLANNER BIO AND DISCLOSURES
Frances Jensen, M.D. (Chair)
Dr. Jensen has recently been appointed as Chair of Neurology at the Perelman School of Medicine, University of Pennsylvania. She was formerly Professor of Neurology, Harvard Medical School and Director of Translational Neuroscience and Director of Epilepsy Research at Boston Children's Hospital and senior neurologist at Boston Children's Hospital and the Brigham and Women's Hospital. She is a graduate of Cornell Medical College and did her neurology residency training at the Harvard Longwood Neurology Residency Program. Her research focuses on mechanisms of epilepsy and stroke, with with specific emphasis on injury in the developing brain as well as age specific therapies for clinical trials development. She received a 2007 Director’s Pioneer Award from the NIH to explore the interaction between epileptogenesis and cognitive dysfunction. Dr. Jensen also is the recipient of the 2008 American Epilepsy Society Basic Science Research Award. Dr. Jensen is President of the American Epilepsy Society in 2012 and serves on a number of other leadership boards including the Council for the Society for Neuroscience, the nominating committee at the American Neurological Association, and is on Council at NICHD. In addition, she serves on the scientific advisory panel of a number of charitable foundations for medical research. Dr. Jensen has authored over 100 manuscripts on subjects related to her research, has been continuously funded by NIH since 1987, and has trained numerous clinical and basic research fellows who now hold independent faculty positions nationally and internationally. Dr. Jensen also is the sponsor of an FDA-approved IND for an ongoing multi-center clinical trial of a novel therapy for neonatal seizures, generated from basic research in her laboratory. She is also an advocate for awareness of the adolescent brain development, its unique strengths and vulnerabilities, as well as their impact on medical, social, and educational issues unique to teenagers and young adults.

Frances Jensen, M.D. discloses receiving support as Research Funding from For Profit Commercial Sources/Principal Investigator from Lundbeck A/S.

Susan Axelrod
Susan Axelrod is Chair and founder of CURE: Citizens United for Research in Epilepsy. In 1998, she and other mothers joined forces to find a cure. She has brought overdue exposure to epilepsy, appearing on TV news programs and featured in magazines such as PARADE and Newsweek. Axelrod has received numerous honors for leadership from Research!America, the American Epilepsy Society and others. She has spoken at international conferences focused on medical philanthropy and advances and has served on the NIH’s National Advisory Neurological Disorders & Stroke Council and as a reviewer for the Medical Research Program at the Department of Defense.

Susan Axelrod has nothing to disclose.
Howard Koh, M.D., M.P.H.
Dr. Howard K. Koh is the Assistant Secretary for Health for the U.S. Department of Health and Human Services. He oversees 14 core public health offices — including the Office of the Surgeon General and the US Public Health Service Corps — as well as 10 regional health offices across the nation and 10 Presidential and Secretarial advisory committees. As the Assistant Secretary for Health, he is dedicated to the mission of creating better public health systems for prevention and care so that all people can reach their highest attainable standard of health.

Howard Koh, M.D., M.P.H. has nothing to disclose.

Story Landis, Ph.D.
Story Landis, Ph.D. is Director of NINDS. She received her BA from Wellesley and PhD from Harvard. After postdoctoral work at Harvard, she served on the faculty of the Dept. of Neurobiology. In 1985 she moved to Case Western Reserve University where she created the Department of Neurosciences. Dr. Landis joined NINDS in 1995 as Scientific Director and re-engineered the Institute's intramural research programs. She has made fundamental contributions to the understanding of nervous system development and is an elected fellow of the Academy of Arts and Sciences, the American Association for the Advancement of Science and the Institute of Medicine.

Story Landis, Ph.D. has nothing to disclose.

Joseph Sirven, M.D.
Dr. Joseph Sirven is a Professor of Neurology and Chairman of the Department of Neurology at the Mayo Clinic in Arizona. He is currently Education chair for the Epilepsy Section of the American Academy of Neurology, Chair of the Annual Course Committee for the American Epilepsy Society and Chair of the Professional Advisory Board for the Epilepsy Foundation. In 2011, he served on the Institute of Medicine committee on the Epilepsies. He is editor-in-chief of Epilepsy.com. He has authored numerous publications in several journals and books. He is editor of four textbooks in epilepsy.

Joseph Sirven, M.D. discloses receiving support as Consulting/Advisory Board Activity from Neuropace Eisai UCB; as Research Funding from For Profit Commercial Sources/Principle Investigator from Eisai.

Paul Levisohn (Medical Content Specialist)
Dr. Levisohn is Associate Professor of Pediatrics and Neurology at the University of Colorado School of Medicine and Children’s Hospital Colorado. He is former medical director of the Epilepsy Monitoring Unit at The Children’s Hospital. He has served as chair of the AES Practice Committee, is co-chair of the advisory committee for the National Center for Project Access at the Epilepsy Foundation and is a member of the EF Professional Advisory Board. He currently serves as consultant to AES on medical content of AES continuing medical education activities.

Paul Levisohn, M.D. has nothing to disclose.

Kevin Graber, MD (Liaison Reviewer)
Kevin Graber is associate professor of neurology and neurological sciences at Stanford University. In addition to clinical efforts at the Stanford Comprehensive Epilepsy Center, he studies the cellular neurophysiology of posttraumatic epilepsy in model systems, with emphasis on strategies for prevention.

Kevin Graber, M.D. has nothing to disclose.
DISCLAIMER
Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the American Epilepsy Society or any manufacturers of pharmaceuticals.

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The Medical Education Evaluator® is an online system allows any attendee to self-manage the process of completing course evaluations, tracking credits and printing out the appropriate certificate for either AMA PRA Category 1 Credits™, CE or ACPE pharmacy statement of credits.

Log on to the Evaluator via the AES website at www.aesnet.org. Once you are on the Evaluator, you will be asked to enter your MyAES ID # and password. The certificate(s) are saved to your personal account page which is cumulative. You may print the certificate(s) in PDF format at any time.

To help support this process, AES members who want CME will be asked to pay $35 before January 18 and $50 between January 19 and February 28. Non-AES attendees who want CME will be asked to pay $50 before January 18 and $75 between January 19 and February 28.

The online Evaluator will be left open through February 28, 2013. You must complete the evaluations and credit tracking by that date.

By completing this information online, attendees greatly assist the Council on Education and Annual Meeting Committee with important needs assessment data whereby the AES can further plan and address educational gaps to meet the needs of our learners.

A meeting attendance certificate will be available for international meeting attendees at the registration desk.

SYLLABUS
Syllabi for the educational symposia are available to print in the AES Virtual Tote Bag. Paper handouts will not be provided on site.
Epilepsy Across the Spectrum: Institute of Medicine Process and Recommendations

Joseph I. Sirven, MD
Professor and Chairman
Department of Neurology
Mayo Clinic
Phoenix, Arizona USA

Learning Objectives

• Review IOM Process for the Epilepsy Report
• Outline Epilepsy Report Recommendations

The IOM serves as adviser to the nation to improve health.

- Unbiased, authoritative advice
- Evidence-based recommendations
- Committees composed to avoid conflicts of interest
- Neutral venue for open dialogue and discussion
- Honorific organization

The Institute of Medicine asks and answers the nation’s most pressing questions about health and health care.

- The IOM is an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public.
- Established in 1970, the IOM is the health arm of the National Academy of Sciences, which was chartered under President Abraham Lincoln in 1863.

The IOM’s Unique Study Process

UCB, MAP, Vertex, Eisai, Neupace, NIH, Upsher-Smith

Epilepsy therapy Project

Research Support

Time Support
Statement of Task Highlights
The IOM committee was asked to conduct a study and prepare a report to recommend priorities in public health, health care and human services, and health literacy and public awareness for the epilepsies and to propose strategies to address these priorities. The study focused on the following four topic areas:

- public health surveillance, collection, and data integration;
- population and public health research;
- health policy, health care, and human services; and
- patient, provider, and public education.

Study Sponsors

Department of Health and Human Services (HHS) sponsors:
- Administration on Developmental Disabilities
- Center for Devices and Radiological Health (CDRH)
- Center for Drug Evaluation and Research (CDER)
- National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
- National Center on Birth Defects and Developmental Disabilities (NCBDDD)
- Susan Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
- National Institute of Mental Health (NIMH)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Institute on Aging (NIA)
- Office of the Assistant Secretary for Health
- Office of the Assistant Secretary for Planning and Evaluation
- Office on Women's Health

- Various 50-50 nonprofit organization sponsors:
  - American Epilepsy Society (AES)
  - Citizens United for Research in Epilepsy (CURE)
  - Dravet.org
  - Epilepsy Foundation
  - Epilepsy Therapy Project (ETP)
  - Finding a Cure for Epilepsy and Seizures (FCES)
  - Huntington’s Disease Foundation
  - International League Against Epilepsy (ILAE)
  - National Association of Epilepsy Centers (NAEC)
  - Preventing Teen Tragedy
  - Reunions’ UnDecembered (UD) Children’s Project
  - Tuberous Sclerosis Alliance (TSA)

Timeline

- January 2011 – First committee meeting
- March 2011 – Committee meeting and public workshop on public health surveillance, population health research, and data collection
- June 2011 – Committee meeting and public workshop on health care quality and access and education of patients, families, and providers
- September and November 2011 – Committee meetings
- January to March 2012 – National Academies’ Report Review
- March 30, 2012 - Report release

Epilepsy – Definition

- Seizure – disturbances in the electrical activity of the brain
- Epilepsy – two or more unprovoked seizures separated by at least 24 hours
- Epilepsy is a spectrum of disorders:
  - Many different types of seizures
  - Many causes
  - Many syndromes and types of epilepsy

Terminology

- The committee believes the term “epileptic” should be discontinued because it has negative connotations.
- The committee suggests using terms such as:
  - “seizure medications” (to replace “anti-epileptic drugs”)
  - “epilepsy seizures” (to replace “epileptic seizures”)
Magnitude

- 2.2 million people in the United States and more than 65 million people worldwide have epilepsy;
- 150,000 new cases of epilepsy are diagnosed in the United States annually;
- 1 in 26 people in the United States will develop epilepsy at some point in their lifetime;
- Children and older adults are the fastest-growing segments of the population with new cases of epilepsy;
- Epilepsy is the fourth most common neurological disorder in the United States after migraine, stroke, and Alzheimer’s disease.

Cross-Cutting Themes

- A common and complex neurological disorder
- Often affects quality of life
- Whole-patient perspective needed
- Effective treatments available but access falls short
- Data needed to improve epilepsy knowledge and care and to inform policy
- Strengthen health professionals’ education
- Bolster education efforts for people with epilepsy and their families
- Eliminate stigma

Recommendations

- **Increase surveillance**
  - At present, public health researchers, policy makers, and advocates are “flying blind” due to the lack of adequate epilepsy surveillance data.

- **Prevent epilepsy**
  - Gaps in knowledge about epilepsy’s risk factors, comorbidities, and outcomes limit the ability of programs to prevent epilepsy and its consequences.

Recommendation 1

- Validate and Implement Standard Definitions and Criteria for Epilepsy Case Ascertainment, Health Care and Community Services Use and Costs, and Quality-of-Life Measurement
  - CDC, in collaboration with professional organizations and other federal entities should fund demonstration projects to validate and implement standard definitions for epilepsy case ascertainment, health care and community services use and costs, and measures of quality of life for use in different data collection systems and for different specific objectives.
  - Once validated, these definitions and criteria should be adopted by funding agencies and used in surveillance and research that is the basis for planning and policy making.

Recommendation 2

- **Continue and Expand Collaborative Surveillance and Data Collection Efforts**
  - CDC should continue and expand its leadership in epilepsy surveillance and work with relevant stakeholders. Surveillance should be funded that uses large, representative samples to determine the overall incidence and prevalence of epilepsy—and mortality—over time as well as in specific populations. Data collection efforts should:
    - Expand epilepsy questions in population health surveys.
    - Include epilepsy data in existing registries for comorbid conditions.
    - Standardize the practices of coroners and medical examiners and work toward a national epilepsy-related death registry.
    - Explore the linkage and use of emerging data collection and sharing partnerships using electronic repositories.
    - Include epilepsy data in future longitudinal studies.

Recommendation 3

- **Develop and Evaluate Prevention Efforts for Epilepsy and Its Consequences**
  - CDC should partner with other stakeholders to develop and evaluate culturally appropriate and health literate prevention efforts that focus on:
    - preventing neurocysticercosis in high-risk populations;
    - continuing prevention efforts for established risk factors of epilepsy (e.g., traumatic brain injury, stroke, brain infections such as meningitis);
    - preventing continued seizures in people with epilepsy and depression;
    - reducing felt stigma; and
    - preventing epilepsy-related causes of death, including accidents and injuries, SUDEP, and suicide.
**Improve Health Care**

- Problems with quality, access, and value of health care for people with epilepsy.
- Delays in diagnosis and referral, disparities in access to care, and challenges in co-management between primary care and specialty providers.

**Recommendation 4**

- **Improve the Early Identification of Epilepsy and Its Comorbid Health Conditions**
  - AES and AAN should lead a collaborative effort with the wide range of relevant federal agencies and professional organizations to:
    - Develop and validate screening tests for early identification of epilepsy in at-risk populations.
    - Establish and disseminate a standard screening protocol for comorbidities with currently approved screening tests.
    - Establish and disseminate a screening tool for early identification of patients with persistent seizures to lead to earlier referrals to an epileptologist.

**Recommendation 5**

- **National Quality Measurement and Improvement Strategy**
  - AES, in conjunction with other professional organizations, should initiate the development of a national quality measurement and improvement strategy for epilepsy care.
  - The strategy should:
    - Develop and implement a plan to disseminate existing clinical guidelines;
    - Define performance metrics for epilepsy care;
    - Continue the implementation of a set of performance metrics that includes patient-generated measures; and
    - Conduct demonstration projects to validate performance metrics.

**Recommendation 6**

- **Establish Accreditation of Epilepsy Centers and an Epilepsy Care Network**
  - NAEC and the AES should collaborate with relevant organizations to establish accreditation criteria and processes with independent external review mechanisms for accreditation of epilepsy centers.
  - Accredited epilepsy centers should work together to form an Epilepsy Care Network that includes data sharing, clinical trial and other research networking, professional education, and other collaborative activities.

**Improve Health Professional Education**

- Gaps were found in the education of health care professionals related to epilepsy

**Recommendation 7**

- **Improve Health Professional Education About the Epilepsies**
  - AES and AAN should collaborate with relevant organizations to ensure that health professionals are sufficiently knowledgeable and skilled. These organizations should:
    - Define essential epilepsy knowledge and skills.
    - Conduct surveys to identify knowledge gaps.
    - Evaluate existing materials and learning opportunities.
    - Develop interactive materials and tools for integration into existing curricula and programs.
    - Ensure that materials and programs reflect current research, clinical guidelines, and best practices.
    - Explore and promote the use of innovative interdisciplinary approaches.
    - Disseminate educational materials and tools widely.
Improve Quality of Life

• Living with epilepsy is about much more than seizures. Children have challenges in school, adults face uncertainties about social and employment situations. Others have limitations on driving a car, and questions about living independently.

• Health care and community services are often fragmented, uncoordinated, and difficult to obtain.

Improve Education for People with Epilepsy and Their Families

• People with epilepsy and their families have significant information needs about epilepsy and its management.

• Access to resources and programs that are accurate, up-to-date, easy to understand, and linguistically and culturally appropriate is inconsistent.

Raise Public Awareness

• Public misperceptions and misinformation about epilepsy continue to exist

• Stigma and internalized fears of discrimination and prejudice affect the quality of life of people with epilepsy.

Recommendation 8

• Improve the Delivery and Coordination of Community Services

CDC and other epilepsy organizations should partner with community service providers and epilepsy centers to enhance and widely disseminate educational and community services for people with epilepsy. Specific attention should be given to identifying needs and improving community services for underserved populations. These efforts should:

• Link people to local and regional resources.
• Develop innovative partnerships with organizations working with related diseases or disorders.
• Conduct pilot studies of academic achievement interventions.
• Maintain effective transportation, employment, and housing programs.
• Identify evidence-based best practices in employment programs.
• Develop best practices for coordination of health care and community services.
• Provide a 24/7 nonmedical help line.
• Develop educational opportunities for community service providers.

Recommendation 9

• Improve and Expand Educational Opportunities for Patients and Families

• To ensure that people with epilepsy and their families have access to accurate, clearly communicated educational materials and information, epilepsy organizations should:

• Evaluate epilepsy websites and their educational resources.
• Develop a central website with links to other online resources.
• Ensure resources are up-to-date, effective, and reflect current science.
• Engage people with epilepsy in the development of online resources.
• Support the development and use of self-management and educational programs.
• Engage EF affiliates, epilepsy centers, and health care systems and providers to disseminate resources and self-management tools.
• Explore the development of a certificate program for epilepsy educators.

Recommendation 10

• Inform Media to Improve Awareness and Eliminate Stigma

CDC and other Vision 20/20 organizations should support and bolster programs that provide information to the media to improve public knowledge and combat stigma. Efforts should:

• Promote frequent, accurate, and positive story lines about characters with epilepsy.
• Encourage high-profile individuals with epilepsy to speak openly.
• Establish partnerships with stakeholders that represent related conditions associated with stigma.
• Continue to work with media on news and human interest stories about epilepsy.
• Disseminate regular updates on research and medical advances to journalists and policy makers.
Recommendation 11
• Coordinate Public Awareness Efforts
  • EF and CDC should lead a collaborative effort with relevant organizations to
    educate the public through awareness efforts, promotional events, and
    educational materials and should:
    • Establish an advisory council.
    • Develop shared messaging that emphasizes the common and
      complex nature of the epilepsies.
    • Explore the feasibility of an ongoing, coordinated, large-scale,
      multimedia, multiplatform, sustainable public awareness campaign.
    • Ensure that all awareness campaigns include:
      • consideration of health literacy, cultural appropriateness, and
        demographics of target audiences;
      • rigorous formative research and testing throughout the
        campaign; and
      • appropriate evaluation and follow-up.

Strengthen Stakeholder Collaboration
• Epilepsy advocacy and research organizations and
  government agencies should work together to
  create a strong, united voice for change.
• People with epilepsy and their families who are
  willing to speak out can be persuasive advocates for
  better services.

Recommendation 12
• Continue and Expand Vision 20-20 Working Groups and
  Collaborative Partnerships
  • The members of Vision 20-20 should continue their efforts and
    expand ongoing working groups that communicate regularly, identify
    common goals, develop strategic plans, and, when possible, carry out
    joint activities. The working groups should focus on:
    • health policy, health reform, and advocacy;
    • surveillance and epidemiologic and health services research;
    • health care and community resources and services;
    • education of health professionals;
    • education of people with epilepsy and their families; and
    • public education and awareness.

Engage People with Epilepsy and
Their Families
• Among the most persuasive advocates and educators are
  people with epilepsy and their families who are willing to
  speak out to provide a more complete picture of the disorder
  and its impact.

Recommendation 13
• Engage in Education, Dissemination, and Advocacy for
  Improved Epilepsy Care and Services
  • People with epilepsy and their families should, to the extent possible:
    • become informed about epilepsy and actively participate in and
      advocate for quality health care and community services;
    • discuss best options for care with health care providers;
    • consider participation in research;
    • engage with community professionals to educate them about epilepsy
      and ensure that needed services and accommodations are provided;
    • talk openly, when possible, about epilepsy and its impact on life;
    • actively participate in support networks; and
    • work with nonprofit organizations to raise awareness and participate in
      advocacy efforts.

Research Priority Areas
1. Increase the power of data & prevent epilepsy
2. Improve health care
3. Improve health professional education
4. Improve quality of life
5. Improve education for patients & families
6. Raise public awareness
Welcome

- Free PDFs of the report are available: [www.iom.edu/epilepsy](http://www.iom.edu/epilepsy)
- Twitter hashtag: #IOMepilepsy
The Context of the IOM Report: A View from HHS Leadership

Howard Koh, MD

Slides not available
What the IOM Report Means for Basic and Clinical Research
December 1, 2012

Story C. Landis, PhD
Director, National Institute of Neurological Disorders and Stroke

Learning Objectives

• Identify the recommendations and priorities in the IOM report that relate to biomedical research

• Understand ongoing and new NIH activities relevant to IOM report priorities, and identify future research opportunities

• Learn about other NIH epilepsy research activities

The IOM Report and NIH

NINDS contributed to funding the IOM report, along with
• National Institute on Aging (NIA)
• Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
• National Institute of Mental Health (NIMH)

The IOM committee’s charge focused on public health dimensions beyond biomedical research

• NINDS coordinates the Epilepsy Research Benchmarks
  – Community-wide priorities for basic, translational, and clinical research
• NIH shares the IOM report’s vision for reducing burden of epilepsy
• Opportunities for NIH to contribute directly and as a partner

Epilepsy Research Benchmarks

• “Curing Epilepsy 2000: Focus on the Future”
  – White House-initiated conference
  – Developed the first Epilepsy Research Benchmarks
  – No seizures, no side effects, and the prevention of epilepsy

• “Curing Epilepsy 2007: Translating Discoveries into Therapies”
  – Reviewed progress of the 2000 Benchmarks
  – Updated the Benchmarks: epileptogenesis, new and improved treatments, comorbidities and Sudden Unexpected Death in Epilepsy (SUDEP)

• “Curing the Epilepsies 2013: Pathways Forward”
  – April 17-19, 2013

The Benchmarks make a difference

• Raise awareness of research needs across community
  – Comorbidities of epilepsy and SUDEP
    – Growth in research since added to the Benchmarks

• Inform priority-setting for NINDS investments
  – Epilepsy Centers without Walls program
    – Genetic causes, epileptogenesis, SUDEP

• Provide a framework for tracking progress
  – How far have we come?
  – What needs and challenges remain?
  – Have new opportunities emerged?
Epilepsy Benchmarks and IOM Recommendations: separate, but complementary

**Prevent epilepsy and its consequences**
- **IOM report**: prevention of epilepsy due to established risk factors
- **Benchmarks**: understand the causes of epilepsy, identify biomarkers, develop strategies to prevent epileptogenesis

**Improve healthcare**
- **IOM report**: early identification and referral, guidelines and quality measures, improving access to care
- **Benchmarks**: optimize existing therapies and develop new therapies and technologies

**Comorbidities**
- **IOM report**: emphasizes the early identification of comorbidities and more effective and coordinated care
- **Benchmarks**: identify predictors and underlying mechanisms that contribute to comorbidities, determine optimal treatments

IOM report priorities and relevant NIH/NINDS activities

- **Recommendation 1**: Validate and implement standard definitions and criteria for epilepsy case ascertainment, health care and services use and costs, and quality of life measures.
- **Recommendation 2**: Continue and expand collaborative surveillance and data collection efforts.
- **Recommendation 3**: Develop and Evaluate Prevention Efforts for Epilepsy and its Consequences

Standard Definitions and Criteria

**NINDS Epilepsy Centers without Walls program**
Planning grants toward potential Centers include

- **SUDEP**
  - Prevention and Risk Identification of SUDEP Mortality (PRISM)
    - Sam Lhatoo, Case Western Reserve University CTSA (lead)
    - Surveillance register of SUDEP by monitoring a multicenter cohort of epilepsy patients undergoing seizure monitoring
    - Capacity for comparative studies of SUDEP/near-SUDEP cases vs. cohort survivors to identify risk factors (with a focus on brainstem and serotoninergic dysfunction)
  - SUDEP Center Research Pipeline
    - Jeff Noebels, Baylor College of Medicine (lead)
      - Basic science, human genetics, and clinical physiology approaches to validate a combined genetic and clinical SUDEP risk profile for screening and treating individuals with epilepsy

Preventing epilepsy and its consequences

**NINDS Epilepsy Centers without Walls program**
Planning grants toward potential Centers include

- **Anti-epileptogenesis and disease modification**
  - Potential EEG biomarkers and anti-epileptogenic strategies for epilepsy in Tuberous Sclerosis Complex (TSC)
    - Martina Bebin, Univ. of Alabama at Birmingham (lead)
    - Develop biomarker to identify TSC patients at risk for epilepsy and establish parameters for anti-epileptogenic drug trial
  - Epilepsy Bioinformatics Study (EpiBioS)
    - Pete Engel, UCLA (lead)
    - bioinformatics approach to develop biomarkers for epilepsy risk and epileptogenesis after an insult to the brain
  - Prevention of Temporal Lobe Epilepsy
    - Jim McNamara, Duke University (lead)
    - Identify biomarkers for development of TLE after febrile status epileptics in childhood, leveraging FEBSTAT cohort and data

Preventing epilepsy and its consequences

**Translational research**
- **NINDS Anticonvulsant Screening Program**
  - Increased emphasis on epileptogenesis/disease modification and treatment-resistant epilepsies
- **NINDS Cooperative Program in Translational Research for Resistant Epilepsy and Epileptogenesis**
  - Targeted initiative supports preclinical research toward preparing IND/IDE application
  - One project to develop a seizure prediction (drug delivery device that will administer medication at times of high seizure likelihood
    - Greg Warren, Mayo Clinic (lead)
      - Validation of NeuroVista Seizure Advisory System, coupled with responsive drug delivery in a naturally occurring form of canine epilepsy
Preventing epilepsy and its consequences

Targeting known risk factors

- NIH research on the prevention and treatment of established risk factors for epilepsy, such as stroke, perinatal hypoxia-ischemia, TBI, brain tumor, and infections, should aid in the prevention of epilepsy
- Need to incorporate epilepsy as an outcome in studies of these conditions

Highlights and opportunities

TBI

- $30 million donation from the NFL for research on medical conditions in athletes and relevant to the general population, including TBI
- NINDS/NIH and Department of Defense building a research database for TBI, to promote data sharing and comparative effectiveness research

Stroke

- Recent NINDS effort to identify potential high priority initiatives to advance stroke research, in terms of prevention, treatment, and recovery

Additional NIH Research Activities

Risk factors for epilepsy of unknown and genetic/presumed genetic cause

- Epilepsy Phenome/Genome Project; Dan Lowenstein, UCSF
- Epilepsy Center without Walls: Ep4K project;
  - International collaboration to identify genetic causes of epilepsy by analyzing at least 4000 patient genomes
  - FY2013 NINDS funding opportunity for additional collaborations to analyze existing DNA samples from patient cohorts (heritable epilepsy or differential responses to anti-epileptic drugs)

Comparative effectiveness studies

- Ethosuximide, valproic acid, and lamotrigine in childhood absence epilepsy; Tracy Glauze, Cincinnati Children’s Hospital
  - Ethosuximide provided best combination of seizure control and fewest attentional side effects after 16 weeks; NEJM 2010; 362 (9)
  - Continuation to determine relative benefits over longer term
- NIA-funded study of elderly nursing home residents treated with phenytoin, lamotrigine, and levetiracetam; Angela Brindavan, Univ. Minnesota Twin Cities

Additional NIH Research Activities

Comorbidities of epilepsy

- Longitudinal studies to understand contributing factors and outcomes
- Basic and clinical research on mechanisms:
  - Autism-Epilepsy Workshop (May 2012; NINDS, Autism Speaks, NICHD)
- Research on these conditions more generally may be applicable to their occurrence in people with epilepsy

Seizure medications and birth outcomes

- The Neurodevelopmental Effects of Antiepileptic Drugs (NEAD) Study
  - Pregnant women with epilepsy on AED monotherapy from 1999 to 2004 to determine long-term neurodevelopmental effects across four common AEDs (carbamazepine, lamotrigine, phenytoin, valproate)
  - Results associating adverse cognitive and other outcomes with valproate are already contributing to changes in clinical practice
  - NINDS and NICHD are supporting a continuation of the study to include maternal outcomes, more drugs, and polytherapies

NIH and the broader epilepsy community

- ICARE: Interagency Collaborative to Advance Research in Epilepsy
  - NIH, other Federal agencies, and the research and patient advocacy communities
  - Annual meetings provide forum for sharing information, highlighting advances, discussing needs and opportunities, and promoting collaboration
- NINDS/NIH participation in:
  - Vision 2020
  - HHS-wide epilepsy working group

“Curing the Epilepsies 2013: Pathways Forward”

April 17-19, 2013

Send us your best ideas!

www.ninds.nih.gov/2013epilepsiesRFI
How the IOM Report Will Impact the Lives of Patients with Epilepsy

Susan Axelrod

Slides not available