The Public Health Dimensions of the Epilepsies

NIH Perspectives and Priorities

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The National Institutes of Health (NIH)

**Mission:** To seek fundamental knowledge about the nature and behavior of living systems and apply that knowledge to enhance health, extend life and reduce the burdens of illness and disability.

- The 27 Institutes and Centers of the NIH annually invest over $28 billion in medical research.
  - 85% funds research at universities, medical schools, and other institutions in all states and around the world.
  - 10% supports projects conducted in NIH intramural laboratories, mostly on the NIH campus in Bethesda, MD.
The National Institute of Neurological Disorders and Stroke (NINDS)

**Mission:** to reduce the burden of neurological disease - a burden borne by every age group, by every segment of society, and by people all over the world.

• Primary NIH Institute for epilepsy research
  – $107M invested in FY2009
  – Several new initiatives announced in 2010

• Major epilepsy research areas include:
  – Understanding the causes of epilepsy
  – Epileptogenesis and epilepsy prevention
  – Seizure initiation, localization, and prediction
  – Developing, testing, and optimizing treatments
  – Comorbidities of epilepsy
The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

**Mission:** to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation.
The *Eunice Kennedy Shriver National Institute of Child Health and Human Development* (NICHD)

- Epilepsy-related activities include:
  - Neonatal Research Network, which studies infant hypoxic ischemic encephalopathy and includes seizures as an outcome
  - Implementation of the Best Pharmaceuticals for Children Act (BPCA), including trials on the efficacy and safety of anti-epileptics in the pediatric population
  - Epilepsy-related research at the Intellectual and Developmental Disabilities Research Centers
  - New research initiatives on intellectual and developmental disabilities, including epilepsy, infantile spasms, pediatric seizures, and related conditions
The National Institute on Aging (NIA)

**Mission:** to understand the nature of aging and to extend the healthy, active years of life; to support and conduct genetic, biological, clinical, behavioral, social, and economic research related to the aging process, diseases and conditions associated with aging, and other special problems and needs of older Americans

- Epilepsy-related research includes:
  - Clinical impact of the use of antiepileptic drugs in elderly nursing home residents
  - Development of a wireless home video system for ambulatory EEG monitoring of seizures
  - Genetic regulation of seizure-induced neurogenesis and its link to epilepsy
  - Role of epileptiform activity in cognitive impairment in animal models of Alzheimer’s disease
The National Institute of Mental Health (NIMH)

**Mission:** to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure.

- Epilepsy-related activities include:
  - Many existing mood disorder treatments are also effective anticonvulsants. Research to identify their mechanisms and find new treatments could point to common and unique targets.
  - Basic research on neurotransmitter receptors, ion channels, and signaling relevant to both cognitive function and epilepsies
  - Along with other Institutes, supports research on autism, which can be associated with epilepsy
  - Major participant in the NIH Common Fund’s Molecular Libraries Program, which could identify new compounds for reducing seizures while sparing cognition
Other epilepsy-related research across NIH

• At least 16 other NIH Institutes and Centers support research on or related to the epilepsies, including:
  – NIAID: infections of the central nervous system
  – NIAMS: bone and hormonal health in women with epilepsy
  – NCI: paraneoplastic neurological disorders
  – NIDA: basic neuroscience; endocannabinoid-based therapies
  – NIDCD: channelopathies that lead to deafness and epilepsy
  – NIBIB: seizure localization and prediction devices
  – NIEHS: effects of toxins in the central nervous system
  – NHLBI: respiratory ion channels; sudden unexpected death
  – NINR: family caregiver interventions
Epilepsy Research Benchmarks

• NINDS has sponsored two *Curing Epilepsy* conferences, leading to a biomedical epilepsy research agenda.
  – March 2000: “Curing Epilepsy: Focus on the Future”
    • White House-initiated conference
    • Scientists, health care providers, and leaders of voluntary health organizations developed the first Epilepsy Research Benchmarks
    • No seizures, no side effects, and the prevention of epilepsy in those at risk
    • Follow up to the 2000 conference
    • Reviewed progress along the 2000 Benchmarks
    • Updated 2007 Benchmarks focus on epileptogenesis, new and improved treatments, comorbidities of epilepsy, and Sudden Unexpected Death in Epilepsy (SUDEP)
Epilepsy Research Benchmarks

• The entire epilepsy research community shares responsibility for achieving the Benchmarks.
  – including NIH and other research funders, scientists, and patient and provider organizations

• The goals and overall Benchmarks process have been well accepted by and integrated into this community.

• NINDS works with epilepsy researchers who serve as Benchmarks Stewards to track and promote progress.

• Plans underway for a third Curing Epilepsy Conference in 2013.
Interagency Collaborative to Advance Research in Epilepsy (ICARE)

- Interagency committee formed in 2003

- Recently expanded by NINDS to achieve broader representation across NIH, other Federal agencies, and the research and patient advocacy communities

- Serves as a forum to share information on epilepsy research activities, discuss research needs, and build collaborations

- The expanded ICARE first met in March 2010 and plans to meet next in June 2011
NIH Priorities for “The Public Health Dimensions of the Epilepsies”

• Better population and public health data will inform research directions.
  – Surveillance and epidemiology
  – Areas of interest include:
    • SUDEP and comorbidities of epilepsy
    • Risk factors for developing epilepsy
    • Factors affecting health and/or treatment outcomes
    • Pediatric epilepsy in neurodevelopmental disorders
    • Epilepsy in aging and age-related disorders
    • Comparative effectiveness of different treatments

• NIH research can draw on such data to better target needs and develop new hypotheses for investigation.
NIH Priorities for “The Public Health Dimensions of the Epilepsies”

• Putting Science to Work
  – NIH research can provide evidence for what works.
  – Challenges remain in moving treatment advances and practice guidelines into clinical practice.
  – Additional steps and partners will be critical to achieve real improvements in clinical care.
  – Important needs and roles for:
    • Healthcare systems research
    • Improved regulatory processes
    • Patient education
    • Provider education
Opportunities for addressing priorities

Comparative effectiveness research (CER)
• NIH has long supported CER to assess the relative benefits of treatments.
• The new Patient-Centered Outcomes Research Institute (PCORI) will provide additional opportunities for CER.

NIH Program Announcement: Dissemination and Implementation Research in Health
• To identify and develop ways to move evidence-based interventions into public health and clinical practice settings
• Includes treatments, health behavior change, quality of life improvement services, and methods for prevention, early detection, and diagnosis
Opportunities for addressing priorities

- The HMORN provides a geographically diverse sample of over 13 million people receiving health care in the US.
Opportunities for addressing priorities

HMO Collaboratory (NIH Common Fund)

• The HMORN and its federated patient databases are ideally positioned to lead research in cross-cutting NIH interest areas, including:
  – Large-scale epidemiology studies
  – Pragmatic clinical trials
  – Health care delivery

• One-year NIH “start-up” supplement to assess the overall inventory, capacity, and structure of the HMORN
  – Shared understanding by NIH and HMORN of current investments, products, and how infrastructure would need to be bolstered to support “signature” projects in NIH interest areas
Opportunities for addressing priorities

*Strengthened collaboration between the NIH and FDA*

- Joint Leadership Council to ensure
  - regulatory considerations are integral components of biomedical research planning
  - latest science is integrated into the regulatory review process

- Joint Request for Applications: Advancing Regulatory Science through Novel Research and Science-Based Technologies

- Opportunities for faster, more adaptive clinical trials
Thank you

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