Rationale for Scientific & Policy session: What can we do to improve outcomes in the next five years?

Leveraging existing quality improvement & information sciences for greater application in epilepsy

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April 14, 2016
Disclosures

• No conflict of interests related to this presentation

• A very, very frustrated clinical pediatric epileptologist
Prevalence of Epilepsy in the USA

- The number of people with epilepsy, using prevalence numbers, ranges from **1.3 million to 2.8 million** (or 5 to 8.4 for every 1,000 people).

- The estimate currently thought to be most accurate is 2.2 million people or **7.1 for every 1,000 people**.

- However, higher numbers of people report that they have active epilepsy, **8.4 out of 1,000 people**. These numbers are even higher when people are asked if they have ever had epilepsy (called lifetime prevalence). 16.5 per 1,000 people reported that they had epilepsy at some point in their life.

IOM: Epilepsy Across the Spectrum, 2012; epilepsy.com
But let us return to the quotation that “80 to 85 per cent of all patients with epilepsy can be controlled.” Where did these figures originate? They are probably taken from a paper published in 1952 by Yahr et al. who stated in their summary that “The use of diphenyllyldantoin (Dilantin) sodium and phenobarbital in this group of 319 patients resulted in 79 per cent control or improvement of seizures regardless of causation. The addition of other anticonvulsants added 6 per cent, giving an overall rate of 85 per cent improvement or control.”
“In spite of medical therapy, seizures persist in approximately 20 percent of patients with primary generalized epilepsy and 35 percent of those with partial epilepsy.”

Devinksy, 1999; NEJM; 340(20), 1565

“Unfortunately, in 20–30% of patients, epilepsy cannot be controlled.”

Schmidt, 2009; Epilepsy & Behavior; (15) 56-65
Prognosis- 2016

- No change in the population-based estimates of control (20-35%)
- Recognition that *prognosis in individual groups* much worse
  - Dravet
  - Epileptic spasms
  - Lennox-Gastaut
  - Symptomatic causes with intellectual disability
Treatments- 2016

• Anti Seizure Drugs:
  – No significant improvement in efficacy
  – Improvements in tolerability
  – Limited added efficacy beyond first or second

• Surgery: under-utilized

• Dietary/metabolic:
  – Under-utilized
  – Under development

• Devices:
  – Efficacy equivalent to ASDs
  – Under development
Consequences of intractable seizures

- Accidents: falls, burns
- Aspiration
- Cognitive decline
- Psychiatric/behavioral co-morbidities: ADHD, depression, suicide
- Social isolation
- Unemployment
- Premature mortality including SUDEP (second largest cause of years of life lost#)
- Costs to society: costs of care ($12.5 B, 1995, intractable*) & lost human potential

#Thurman 2014
*Begley 2000
Response?

• Depression?

• Cynicism?

• Aggressive optimism
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Status of Epilepsy Research

undergradtutorialblog.blogspot.com

Miracles Just Ahead

cmtk.org

www.ifmelranthezoo.com

inactive, resting
active, non-desensitized
inactive, desensitized

pharmrev.aspetjournals.org

web.stanford.edu
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Status of Epilepsy Research

www.ifmelranthezoo.com
Potential Responses in the Near Term

• What about the patients who are suffering now? Dying now?
• Can we find strategies that have been demonstrated to improve outcomes in the short term?
• Can we supplement our research strategies to focus on meaningful outcomes for patients?
• Can we leverage existing resources for this purpose?
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What Can We Do Until Then?

• Adopt strategies known to reduce morbidity, mortality, and, when possible, reduce costs

• Implement meaningful, large scale data aggregation
  – Common definitions & data elements
  – Harmonize & Organize knowledge in a logical manner (ontologies)
  – Leverage the accumulated Big Data to inform personalized medicine

• Incentivize health system behavior that rewards active participation in improving outcomes for patients
What is the Evidence that “Organized” Care Makes a Difference

The 100 000 Lives Campaign: Setting a Goal and a Deadline for Improving Health Care Quality

More Evidence

- **N** = 15,000
- **2 yrs**
- Mortality reduced 6.2%
- 930 people

- 34/36 articles reduced morbidity or mortality
Get With the Guidelines—Stroke Is Associated With Sustained Improvement in Care for Patients Hospitalized With Acute Stroke or Transient Ischemic Attack

Lee H. Schwamm, MD; Gregg C. Fonarow, MD; Mathew J. Reeves, PhD; Wenqin Pan, PhD; Michael R. Frankel, MD; Eric E. Smith, MD, MPH; Gray Ellrodt, MD; Christopher P. Cannon, MD; Li Liang, PhD; Eric Peterson, MD, MPH; Kenneth A. LaBresh, MD

Background—Adherence to evidence-based guidelines for treatment of stroke or transient ischemic attack is suboptimal. We sought to establish whether participation in Get With the Guidelines—Stroke was associated with improvements in adherence.

Methods and Results—This prospective, nonrandomized, national quality improvement program measured adherence to guideline recommendations in 322,847 hospitalized patients discharged with a diagnosis of ischemic stroke or transient ischemic attack. A volunteer sample of 790 US academic and community hospitals participated from 2003 through 2007. The main outcome measures were change in adherence over time to 7 prespecified performance measures and a
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- Table of Contents
  - General Terms
  - Terms for describing epileptic seizure semiology
    - Motor
    - Non-Motor
    - Autonomic
    - Somatotopic modifiers
    - Modifiers & descriptors of seizure timing
    - Duration
    - Severity

Blume et al, Epilepsia 2001:42;1212-1218
Like the development of the Terminology Glossary, very thoughtful work has already been done for Common Data Elements. The challenge/opportunity is to take this work and adapt it to clinical epilepsy care.
Need to harmonized & organize terms & concepts

• ‘Harmonized’ implies taking multiple descriptions of the same thing & agreeing on a common meaning (e.g. convulsions & grand mal)

• Need to include the multiple levels of information available (e.g. report, observation, EEG, MRI, genetic testing)

• Need to show relationships between concepts (e.g. child, staring, EEG)

• Have rules and be ‘computable’
Past/Current classifications

- ILAE C & T- seizures 1981
- ILAE C & T- syndromes 1989
- Semiology (Luders)- 1999
- ILAE 2010
- ILAE Epidemiology 2010
- ICD-9, 10, (11)
- SNOMED CT
Ontologies

• = formal specification of **terms** in the domain (e.g. *epilepsy*) and **relations** among them (e.g. *complex partial* is a type of *partial seizure* which is a type of *seizure*)

• Why make one?
  – Share common understanding of information
  – Enable reuse of information
  – Make assumptions explicit
  – Analyze domain knowledge
Annotation Files and Enrichment Analysis: Gene Ontology Consortium

http://geneontology.org/

Perform Enrichment Analysis

Download Gene Association Files (GAFs)
GO- Relationships

(imagine same for seizure/epilepsy concepts & relationships)
Seizure/epilepsy Ontology

Demographics
- Symptoms
- Physical exam

EEGs
- Imagings
- Metabolics
- Genetic Testing

Physiological Pathways
- Neurochemical Pathways

Gene Ontology
- Epi4K
- EGI
Connecting the dots (nodes)

http://www.sciencedirect.com/science/journal/09521976/13/6
**PREDICTIVE ANALYTICS**

**Data mining neocortical high-frequency oscillations in epilepsy and controls**

Justin A. Blanco,1,2 Matt Stead,3 Abba Krieger,4 William Stacey,5,6 Douglas Maus,7 Eric Marsh,8,9 Jonathan Viventi,2 Kendall H. Lee,10 Richard Marsh,10 Brian Litt,2,9 and Gregory A. Worrell3

**ABSTRACT** The US health care system is rapidly adopting electronic health records, which will dramatically increase the quantity of clinical data that are available electronically. Simultaneously, rapid progress has been made in clinical analytics—techniques for analyzing large quantities of data and glean new insights from that analysis—which is part of what is known as big data. As a result, there are unprecedented opportunities to use big data to reduce the costs of health care in the US, six use cases—that is, key examples—where some opportunities exist to reduce costs through the patients, readmissions, triage, decompensation (condition worsens), adverse events, and treatment of diseases affecting multiple organ systems. We will discuss that are likely to emerge from clinical analytics to obtain such insights, and the infrastructure registries, assessment scores, monitoring devices that organizations will need to perform the necessary implementation changes that will improve care. These findings have policy implications for regulatory oversight, ways to address privacy concerns, and the support of research on analytics.

**Research and applications**

**Heart beats in the cloud: distributed analysis of electrophysiological ‘Big Data’ using cloud computing for epilepsy clinical research**

Satya S Sahoo,1 Catherine Jayapandian,1 Gaurav Garg,2 Farhad Kaffashi,3 Stephanie Chung,2 Alireza Bozorgi,2 Chien-Hun Chen,1 Kenneth Loparo,3 Samden D Lhatoo,2 Guo-Qiang Zhang1,3

Big Data from an EHR

Biomedical Informatics Insights

CASE REPORT

Personalizing Drug Selection Using Advanced Clinical Decision Support

John Pestian¹, Malik Spencer¹, Pawel Matykiewicz¹, Kejian Zhang², Sander Vinks³ and Tracy Glauser⁴

¹Clinical Linguistic Group, Division of Biomedical Informatics. ²Division of Human Genetics. ³Division of Clinical Pharmacology.
⁴Division of Neurology. Department of Pediatrics, Cincinnati Children's Hospital Medical Center, University of Cincinnati, Cincinnati, OH 45229. Email: john.pestian@cchmc.org.

Biomedical Informatics Insights 2009:2 19–29
Big Data from a claims database

- IMS Healthcare Surveillance Data Incorporated medical claims database
- ICD 9 codes for patient ascertainment
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Epilepsy Evidence Based Processes and Desired Outcomes

The Work Group identified the following evidence based processes and desired outcomes for patients with epilepsy prior to drafting the measurement set:

Desired Outcomes:
1. Freedom from seizures
2. Reduction of seizure frequency
3. Reduced risk of death associated with seizures (e.g., sudden unexpected death in epilepsy (SUDEP), accident, or suicide)
4. Reduce and address safety issues (e.g., falls, injury, etc.)
5. Increased independence
6. Reduction of mental health and behavioral health comorbidities
7. Recognition and reduction of cognitive morbidity
8. Increased patient engagement in care and self-management
9. Referral to appropriate testing and reduction of unnecessary testing (e.g., neuroimaging, EEG, etc.)
10. Reduction of Emergency Department visits and emergency services
11. Improved quality of life
12. Reduction of cost of care
13. Improved patient experience

N Fountain, P Van Ess
Evidence Based Processes:
1. Timely and appropriate referrals to an epilepsy specialist for patients with refractory epilepsy
2. Early and accurate diagnosis
3. Reduction of and monitoring of anti-seizure medication side effects
4. Improved coordination of care
5. Patient centered care provided
ICARE 2016

CMS Quality Strategy
2013 – Beyond

November 18, 2013

For Public Release
**ICARE 2016**

NQF #1953 Seizure type(s) and current seizure frequency(ies), Last Updated Date: Oct 21, 2015

**NATIONAL QUALITY FORUM**

<table>
<thead>
<tr>
<th><strong>BRIEF MEASURE INFORMATION</strong></th>
</tr>
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<tbody>
<tr>
<td><strong>De.1 Measure Title:</strong> Seizure type(s) and current seizure frequency(ies)</td>
</tr>
<tr>
<td><strong>Co.1.1 Measure Steward:</strong> American Academy of Neurology</td>
</tr>
<tr>
<td><strong>De.2 Brief Description of Measure:</strong> All visits for patients with a diagnosis of epilepsy who had the type(s) of seizure(s) and current seizure frequency for each seizure type documented in the medical record.</td>
</tr>
<tr>
<td><strong>2a1.1 Numerator Statement:</strong> Patient visits with seizure type(s) specified and current seizure frequency for each seizure type documented in the medical record.</td>
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Quality Measures for Neurologists

- Physician Quality Reporting System
- Started in 2007, eliminated going forward

Measure #268 (NQF 1814): Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy – National Quality Strategy Domain: Effective Clinical Care

2016 PQRS OPTIONS FOR INDIVIDUAL MEASURES: CLAIMS, REGISTRY

DESCRIPTION:
All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year.
In Summary

• There is clearly the need to be better soon
• There needs to be outcomes that are meaningful to patients, families, payers and society
• There is the strong suggestion from other areas of medicine that organized care can produce measure improvements in outcomes
• There is a requirement for consistent, detailed data collection & analysis