State of SUDEP Guidelines Development and Other Opportunities to Advance Best Practices
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Partners Against Mortality in Epilepsy Conference - June 21-24, 2012
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<th>Name of Commercial Interest</th>
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Learning Objectives

- To understand the role of management guidelines in managing the risk of SUDEP
- To understand the strengths and drawbacks of evidence-based practice guidelines
Why have medical practice guidelines?

• Doctors and other healthcare providers often are faced with difficult decisions and considerable uncertainty. Decisions informed by:
  – Scientific literature
  – Their knowledge
  – Their experience
  – Patient preferences
Guidelines are not expert consensus

• Clinical practice guidelines are statements that include recommendations intended to optimize patient care, including:
  – systematic review of evidence
  – assessment of the benefits and harms of care options.

• The U.S. Congress, through the *Medicare Improvements for Patients and Providers Act of 2008*, asked the IOM to undertake a study on the best methods used in developing clinical practice guidelines.
The IOM developed eight standards for developing rigorous, trustworthy clinical practice guidelines

- Establish transparency
- Manage conflict of interest
- Guideline development group composition
- Clinical practice guideline-informed by a systematic review of the literature
- Establishing evidence foundations for and rating strength of recommendations
- Articulation of recommendations
- External review
- System for updating
Where are we now? National Institute for Clinical Excellence (NICE) Jan 2012

• “Information on SUDEP should be included in literature on epilepsy to show why preventing seizures is important. Tailored information on the person's relative risk of SUDEP should be part of the counseling checklist for children, young people and adults with epilepsy and their families and/or carers.

• The risk of SUDEP can be minimized by:
  – optimzing seizure control
  – being aware of the potential consequences of nocturnal seizures

• Tailored information and discussion between the child, young person or adult with epilepsy, their family and/or carers (as appropriate) and healthcare professionals should take account of the small but definite risk of SUDEP.”
“Tailored information on the person's relative risk of SUDEP should be part of the counseling”

• This is where the American Academy of Neurology Guidelines Development Subcommittee comes in!
AAN GDS SUDEP Guideline

• Questions addressed are:
  – Frequency of SUDEP in well-characterized epilepsy populations
  – Risk factors for SUDEP in specific populations

• Challenges in the scientific literature are:
  – Stating definition of SUDEP used in each report
  – Making sure that SUDEP cases are really SUDEP
    • Cannot rely on death certificates
    • Very low autopsy rate to prove “definite” SUDEP, most are “probable SUDEP”
Current status of AAN GDS SUDEP Guideline

• Most literature has been looked at for relevance to the questions and classified for the quality of evidence
• Conclusions with relative risks will be presented
• Recommendations regarding risks to be used for counseling patients will be presented
• Manuscript must be ready by end of summer
AAN GDS Guidelines: building blocks


Key Findings from these studies

• “In an analysis of four case-control studies of sudden unexpected death in epilepsy (SUDEP)” -All Class II studies-but this may be the best we will have
  – GTCS frequency, AED polytherapy, and number of AEDs were associated with an increased risk for SUDEP
  – Analysis of individual AEDs and of number of AEDs, adjusting for GTCS frequency, revealed no increased risk associated with AEDs as monotherapy, polytherapy, or total number
  – GTCS frequency remained strongly associated with an increased risk for SUDEP.
AAN GDS Guidelines

• Will hopefully find the same things for these two factors—seizure type and AEDs

• Will assess more factors
  – Cardiac status
  – AED drug levels
  – Planetary alignment

• Accurate frequency for populations

• Any preventative interventions will be assessed
AAN GDS Guidelines: How will they be used?

- SUDEP should be part of the discussion of the risks of epilepsy
- The AAN SUDEP Guidelines will provide some detailed information to be used for that discussion
Potential limitations and critiques of Clinical Practice Guidelines

• Biased guidelines from authors with conflicts of interest
• Data is limited
  – Study population is too narrow
  – Studies not of high quality
• Recommendations do not give individualized guidance, are overly simple or overly rigid
• Do not change practice
How can we make sure that the AAN SUDEP Guidelines change practice?

• Realistically, the overall goal is to facilitate the discussion about the existence of SUDEP and its risk factors with patients and their families

• Specific barriers for SUDEP discussion include:
  – Knowing what to discuss
  – Attitude as to whether it should be discussed
  – Implementation
  – Reinforcement to maintain this as a discussion point
Strategies to improve implementation of AAN SUDEP guidelines

• Authoritative source (AAN) with maximal dissemination upon publication

• Decision support tools (from AAN for each guideline)
  – Clinical Summary-one page table or paragraph

• Skill building for having the discussion, likely in purview of this group

• Developing automatic prompts in computerized reminder systems (not part of epilepsy PI measures)
  – Precedent for AAN creating a standardized checklist
Impact on Clinical Care and Practice

• Guidelines should help to prioritize treatment strategies to reduce the risk of SUDEP
• Guidelines should inform the discussion with patients and families about SUDEP by providing “true” (based on best evidence) information