

# **GUIDELINES FOR ESSENTIAL SERVICES, PERSONNEL, AND FACILITIES IN SPECIALIZED EPILEPSY CENTERS**

January 12, 2010

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**Committee to Revise the Guidelines for Services, Personnel and Facilities at Specialized Epilepsy Centers**

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This document was developed by the members of the Committee to Revise the Guidelines for Services, Personnel and Facilities at Specialized Epilepsy Centers. After discussions with the general membership they were adopted by the Board of the National Association of Epilepsy Centers. The Guidelines will be reviewed and updated when considered necessary by the Board.

Robert J. Gumnit, M.D.  
President

## **Introduction**

This is the third iteration of guidelines adopted by the National Association of Epilepsy Centers (NAEC). The initial document, published in 1990, established guidelines for services, personnel, and facilities that characterized specialized epilepsy centers<sup>1</sup>. The revised guidelines published in 2001<sup>2</sup> were a further step in the maturation of epilepsy centers.

The goal of epilepsy care since the initial guidelines were released has not fundamentally changed. The goal of treatment: no seizures and no side effects<sup>3</sup> is increasingly achievable *and* expected. At the same time, purchasers of health care expect this goal to be achieved more efficiently and at lower costs. Both consumers and purchasers of health care services have increasingly demanded that these treatments clearly and directly improve quality of life. The convergence of these forces continues to motivate NAEC to provide specialized epilepsy centers with a framework for a systematic, well-organized approach to subspecialty epilepsy care.

We define a specialized epilepsy center to be a program which not only provides routine care to individuals with seizures or epilepsy, but also specializes in providing comprehensive diagnostic and treatment services to individuals with uncontrolled seizures, (i.e. intractable or refractory epilepsy). Of the 2.7 million Americans estimated to have some form of epilepsy approximately 25-30% of these individuals do not attain adequate seizure control and suffer from intractable epilepsy<sup>4</sup>.

These guidelines summarize the essential services, personnel and facilities that Level 3 and 4 epilepsy centers should provide. The previous guidelines defined medical and surgical centers as separate entities. This committee has concluded that the evolution of epilepsy centers has progressed to a point where these distinctions are blurred and these guidelines remove this differentiator.

These guidelines are structured differently than previous versions. We present an overview of the essential elements of level 3 and 4 specialized epilepsy centers in the text and lay out specific recommended resource requirements and center capabilities in the appendices.

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<sup>1</sup> Recommended guidelines for diagnosis and treatment in Specialized Epilepsy Centers. *Epilepsia* 1990; 31 (Suppl1):S1-S12.

<sup>2</sup> Walczak TS and the Committee to Revise the Guidelines for Specialized Epilepsy Centers. Guidelines for essential services, personnel, and facilities in specialized epilepsy centers. *Epilepsia* **42**: 804-814, 2001.

<sup>3</sup> Living Well with Epilepsy. Report of the 1997 National Conference on Public Health and Epilepsy. Centers for Disease Control and Prevention. National Center for Chronic Disease Prevention and Health Promotion. Atlanta GA. 1997, 1-22.

<sup>4</sup> Kobau et al. Epilepsy Surveillance Among Adults – 19 States, Behavioral Risk Factor Surveillance System, 2005. *MMWR* August 8, 2008; Vol. 57(SS06); 1-20.

## **The Spectrum of Epilepsy Care and Referral Guidelines**

Typically, epilepsy care starts with an evaluation at an emergency room or a primary care physician's office. This is considered the first level of epilepsy care. It then most often proceeds to the second level of epilepsy care, which is a consultation with a general neurologist or possibly a specialized epilepsy center if considered necessary and is locally available. Many, and perhaps most, patients with seizures can be initially evaluated and managed at the first or second level of epilepsy care by a primary care physician or a general neurologist in their local community. If seizure control is obtained, no further specialized epilepsy evaluation may be warranted. If seizures persist and cannot be brought under control by the primary care provider within 3 months, further neurologic intervention is appropriate; the neurologist should assume full management of the patient's seizures at this point<sup>5</sup>. Recent evidence suggests that up to 70% of patients have seizures fully controlled with medication<sup>6</sup>. Once seizures are under control, care can be transferred back to the primary care provider.

Somewhat more difficult to define is the appropriate time for a general neurologist to refer a patient to a Level 3 or 4 specialized epilepsy center. Studies by Kwan et al have shown that only a small percentage of patients in whom the first antiepileptic drug was ineffective would ever become seizure free with additional anticonvulsant drug treatment alone. The authors concluded that patients with inadequate response to initial medical therapy likely had refractory epilepsy that would persist even when newer medications were tried<sup>7</sup>. At the same time with the availability of multiple new medications, some have argued that adequate medication trials may now take longer to achieve. In addition, the Agency for Healthcare Research and Quality (AHRQ) has published an evidence-based report that shows that non-pharmacologic treatments (read surgery) are desired strategies for epilepsy after initial medication treatment failure<sup>8</sup>. This being the case, patients would benefit from the comprehensive evaluation, in some cases a surgical work up in a level 3 or 4 center. For these reasons, NAEC recommends that referral to a Level 3 or 4 specialized epilepsy center should occur when a patient's seizures are not fully controlled with the resources available to the general neurologist after 1 year. This recommendation was included in a technical assistance document supported by a grant from the Centers for Disease Control and Prevention for state Medicaid programs in contracting with managed care plans for epilepsy services.<sup>9</sup>

If the diagnosis of epilepsy is in question or if psychogenic nonepileptic events are suspected, a referral to an epilepsy center is appropriate early in the evaluation process for diagnostic purposes. Accurate diagnosis of the epilepsy syndrome and rapid treatment with the best possible medication may minimize the number of seizures and anticonvulsant trials and

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<sup>5</sup> Scheuer ML, Pedley TA. The evaluation and treatment of seizures. *N Engl J Med* 1990 22;323:1468-74.

<sup>6</sup> Velis D, Plouin P, Gotman J, Lopes da Silva F. Recommendations Regarding the Requirements and Applications for Long-term Recordings in Epilepsy. *Epilepsia* 48: 379-384, 2007.

<sup>7</sup> Kwan P, Brodie MJ. Early identification of refractory epilepsy. [N Engl J Med](#). 2000 Feb 3;342(5):314-9

<sup>8</sup> Agency for Healthcare Research and Quality. "Management of Treatment-Resistant Epilepsy", Evidence Report/Technology Assessment: Number 77. AHRQ Publication number 03-E027, April 2003. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/clinic/epsums/epilsum.htm>.

<sup>9</sup> "Optional Purchasing Specifications For Services Related To Epilepsy: A Technical Assistance Document." *GWUMC School of Public Health and Health Services (CHSRP) June 2002*.

minimize impact of the seizures on quality of life. Early diagnosis of nonepileptic events is associated with improved outcome<sup>10</sup>.

Referrals to specialized epilepsy centers for acutely ill patients with uncontrolled seizures, status epilepticus, or patients with epileptic foci adjoining eloquent cortex should occur as early as possible. These patients are in need of an immediate thorough evaluation and aggressive treatment. As with all patient care, referrals for epilepsy patients should focus on what is in the best interest of the patient and emphasize treatment that is likely to improve the patient's health, safety, and quality of life.

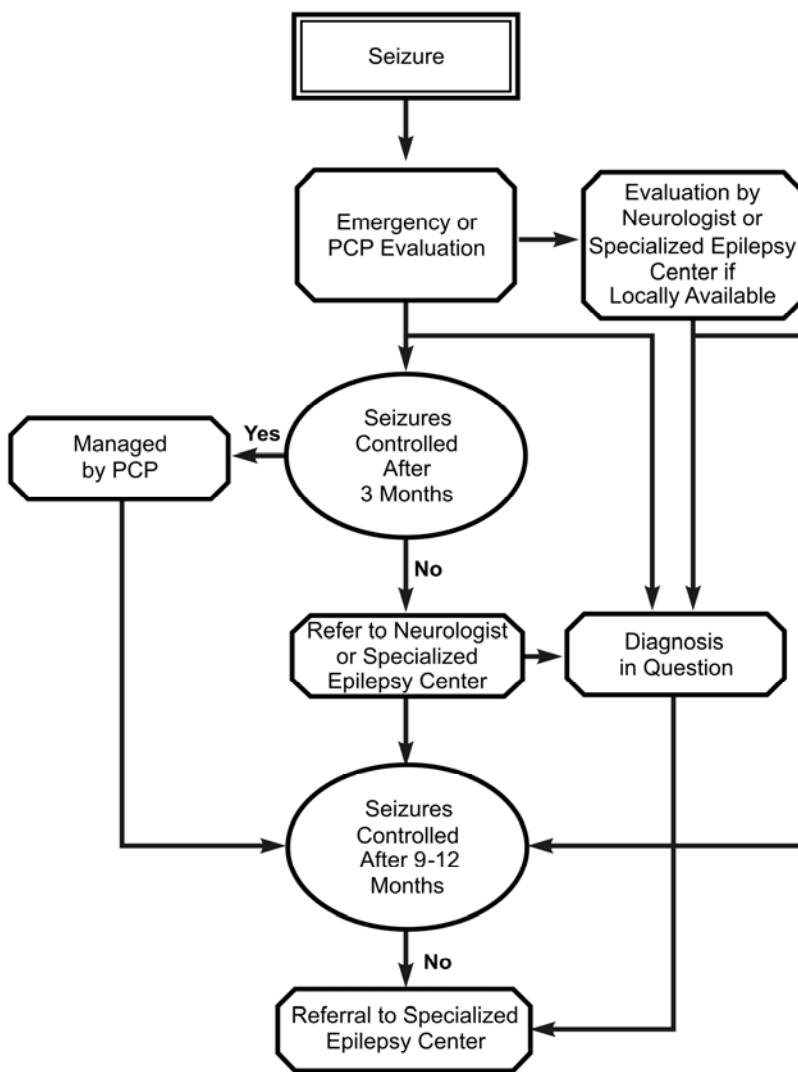
The NAEC believes very strongly that the needs of the patients with seizures can best be met through well-developed cooperative relationships between primary care physicians, general neurologists, and specialized epilepsy centers. It is the responsibility of the epilepsy center to develop a clear specific treatment plan that the center and primary care physician or general neurologist can together carry out. The flow diagram below suggests a strategy for having an adult patient with seizures or epilepsy appropriately evaluated for proper diagnosis and treatment and ultimate referral to specialized epilepsy center when appropriate<sup>11</sup>. ILAE recommendations exist for children that are similar to this paradigm for adults<sup>12</sup>. Specifically, they suggest a child be evaluated by pediatric epilepsy center when they have uncontrolled seizures (defined as failure of two or three appropriate medications), they are disabled by the seizures or medication side effects, or they are a possible candidate for surgical intervention. Additionally, the recommendations suggest that if childhood epilepsy requires syndromic classification then specialty evaluation is appropriate.

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<sup>10</sup> Walczak TS, Papacostas S, Williams DT, Scheuer ML, Lebowitz N, Notarfrancesco A: "Outcome after diagnosis of psychogenic non-epileptic seizures" *Epilepsia* 1995;36:1131-1137.

<sup>11</sup> Adapted from *Epilepsia* 42: 804-814, 2001

<sup>12</sup> Cross JH, Jayakar P, Nordli D, Delalande O, Duchowny M, Wieser HG, Guerrini R, Mathern GW. Proposed criteria for referral and evaluation of children for epilepsy surgery: Recommendations of the subcommission for pediatric epilepsy surgery. *Epilepsia*, **47**(6):952–959, 2006



### **Essential Elements of Care Provided By Specialized Epilepsy Centers**

As stated above most patients with epilepsy can be effectively treated by a primary care physician or general neurologist, which is considered the first and second levels of epilepsy care. However, as the now widely disseminated work of Kwan and Brodie<sup>13</sup> has suggested, it may be possible to identify patients who are not responding to standard medical therapy much earlier in their treatment paradigm. These patients who have either persistent seizures or side effects should be considered to have failed standard treatment and should be referred to a third or fourth level specialty epilepsy center. Level 3 and 4 epilepsy centers provide an interdisciplinary and comprehensive approach to the diagnosis and treatment of patients with epilepsy. The primary goal of the team is to achieve complete control or at least a reduction in the frequency of seizures and/or medical side effects in patients with intractable epilepsy. A discussion of the common elements of all level 3 and 4 epilepsy centers follows. These are:

<sup>13</sup> Kwan P., Brodie MJ, Early identification of refractory epilepsy. *N Engl J Med* 2000; 42; 314-9.

1. Interdisciplinary care team approach
2. Electrodiagnostic facilities
3. Safety Protocols and Quality Measures
4. Patient Education

### **Interdisciplinary Care Team**

The care of the epilepsy patient at specialized epilepsy centers is provided by a collaborative interdisciplinary team that is directed by a neurologist or neurosurgeon with special expertise in epilepsy. The team typically includes neurologists and neurosurgeons, neuropsychologists, nurse specialists, EEG technologists, and other personnel with special training and experience in the treatment of epilepsy. While every facility will have different personnel, the interdisciplinary team may include staff with special expertise in the areas below or have identified other centers for patient referrals.

- Epilepsy surgery
- Vagus nerve stimulator or other neuromodulatory devices
- Antiepileptic drugs
- Investigational drug and/or device trials
- Ketogenic diet
- Genetics
- Psychiatric comorbidities
- Management of women with epilepsy during pregnancy including pre-pregnancy counseling
- Neurophysiology
- Management of nonepileptic psychogenic events
- Management of status epilepticus and seizures in hospitalized patients
- Management of epilepsy in special populations (i.e., women, elderly, children, developmentally disabled, and individuals with multiple medical problems)
- Brain Imaging
- Cognitive comorbidities
- Alternative or complementary medicine

The primary task of the team is to accurately diagnose the patient's epilepsy and develop a treatment plan with the goal of controlling seizures with no side effects. This is accomplished through a comprehensive epilepsy evaluation, which provides epilepsy specialists with the necessary information to formulate a treatment plan, whether medical, surgical, or using an implanted stimulator. Video-EEG monitoring is the essential diagnostic tool used in Level 3 and 4 epilepsy centers. An even more intensive evaluation is a necessary prelude to selecting the 10% of intractable patients who would benefit from resective brain surgery or implanted brain stimulators.

A comprehensive epilepsy evaluation can include video-EEG monitoring, cognitive testing, other specialized brain imaging and procedures to determine the diagnosis and to prepare the most effective medical or surgical treatment plan. During hospitalization, anticonvulsant medication withdrawal is often necessary in order for the patient to experience seizures. In some cases, this may precipitate overt seizures (balancing the need to provoke seizures but not induce status epilepticus requires expertise and intensive care). Seizures are recorded with video and EEG and analyzed by an epileptologist. Large amounts of data are collected and evaluated by the members of the center team who collectively determine the patient's course of treatment.

In addition to video-EEG monitoring, cognitive testing and other specialized imaging the following additional components are assessed by the interdisciplinary team and used to develop a treatment plan:

Patient and family education needs
Injury and safety assessment
Medical comorbidities
Psychiatric comorbidities
Reproductive issues
Cognitive dysfunction
Social dysfunction
Occupational dysfunction
Educational dysfunction
Rehabilitation needs

The treatment plan is then developed in collaboration with the interdisciplinary team. While it is not this guidelines purpose to prescribe specific practice parameters to each institution, publications exist that outline minimal standards for treatment of epilepsy that should form the foundation from which specialized centers develop their own protocols.<sup>14,15</sup> A treatment plan is individualized to each patient, reflecting the patient's unique condition, identified clinical needs, and expectations and desires regarding treatment.

The comprehensive evaluation provided to candidates for epilepsy surgery requires formal interdisciplinary collaboration. This is usually accomplished in a weekly or bimonthly case management conference attended by the entire interdisciplinary team where all relevant data about the patient's evaluation is reviewed before the treatment plan is determined. Documentation of the interdisciplinary team meetings and care plan should be included in the patient's medical record.

### **Electrodiagnostic Facilities**

Inpatient and outpatient units evaluating and treating patients with epilepsy require features beyond those needed for routine patient care. Unit layout, unit furnishings, and personnel needs must be considered as well as the availability of emergency and intensive care services. The essential components of Level 3 and 4 epilepsy center facilities are fully described in Appendices 1 and 2. While requirements for epilepsy monitoring units vary by the level of the epilepsy center, all electrodiagnostic facilities should have certain common features including the presence and availability of qualified EEG technologists and medical staff at all times. Spike and seizure detection software can supplement but cannot replace the need for highly trained personnel. When the patient has intracranial electrodes in place, the continuous presence of well-trained nurses responsible for patient safety is mandatory; these nurses work in conjunction with monitoring technologists who are responsible for the integrity of the recording. The facility should be designed, whether in-patient or out-patient so that the staff has easy access to patients

<sup>14</sup> National Institute for Clinical Excellence. The diagnosis and care of children and adults with epilepsy. <http://www.nice.org.uk/nicemedia/pdf/CG020publicinfoenglish.pdf>, 2004.

<sup>15</sup> Caplin DA, Rao JK, Filloux F, Bale JF, Orman CV. Development of performance indicators for the primary management of pediatric epilepsy: Expert consensus recommendations based on the available evidence. *Epilepsia*, 47(12):2011–2019, 2006.

to facilitate examination and provision of first aid and medical care. Further, the layout must minimize the risk of injury due to falls.

Protocols for situations frequently encountered in the care of epilepsy patients are advisable. These could include, but are not limited to protocols for:

- Medication reduction to increase seizure yield (not recommended in the outpatient setting);
- Patient examination during seizures;
- The number or duration of seizures over a given period that requires physician notification;
- Designated provider of emergency services in the event of emergencies (if an outpatient facility), ;
- Measures to be taken if number, duration, or severity of seizures observed is excessive, Care of head-dressings in patients studied with intracranial electrodes; and
- Measures to prevent postoperative infections or other complications in patients studied with intracranial electrodes.

### **Safety Protocols and Quality Measures**

Seizures are potentially dangerous events that can lead to serious injury or death. It is often necessary to reduce a patient's medications or do other procedures to provoke seizures in an epilepsy monitoring unit. It is therefore absolutely incumbent on an epilepsy center to have safety protocols in place. This has been recommended by the International League Against Epilepsy<sup>16</sup> and at a recent American Epilepsy Society Symposium<sup>17</sup>.

While there is potentially no limit to protocols that can be put in place to manage patients treated in specialized epilepsy centers, nursing protocols regarding patient safety are a must. These should include, but are not limited to, guidelines for patients while in and out of bed in the event of a seizure. Because of the need for increased nursing care, inpatient epilepsy monitoring units often require a higher nurse to patient ratio than is standard for the institution. It is important that in addition to adequate levels of nursing to provide quality care, there should be a formal educational program at centers to assure nursing competency with regard to patient safety. This should include epilepsy specific training for nursing staff that will be responsible for the patients undergoing video-EEG monitoring and other diagnostic testing.

The management of seizure emergencies is an issue of fundamental importance. A protocol similar to cardiac arrest should be in place. While emergency resuscitative equipment is required in all medical facilities, access to additional care may be required. This may include arrangements with nearby hospitals to provide emergency services when needed, if an outpatient facility. For inpatient facilities, ready access to an intensive care unit and anesthesia services is necessary in the event of status epilepticus.

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<sup>16</sup> Velis D, Plouin P, Gotman J, Lopes da Silva F. Recommendations Regarding the Requirements and Applications for Long-term Recordings in Epilepsy. *Epilepsia* 48: 379-384, 2007.

<sup>17</sup> EMU Symposium: Expert Consensus Process on Patient Safety in the Epilepsy Monitoring Unit (accessed at <http://www.aesnet.org/go/professional-development/educational-opportunities/archived-aes-symposia?module=2008/emu/index.cfm>). American Epilepsy Society Annual Meeting, Seattle, Washington, 5 – 9 December 2008.

## Quality of Care

Diagnosing and treating epilepsy is a multi-step process that can involve complex testing and can be undertaken by different specialties. Medical professionals caring for epilepsy patients vary in their skill and approach to diagnosing epilepsy, determining seizure type, identifying causation, and administering appropriate therapy. For these reasons, the development of quality performance measures has been an important step to improving patient outcomes and quality of life.

Recommendations for performance or quality measures and practice guidelines exist from both national and international sources. These include: Scottish Intercollegiate Guideline Network<sup>18</sup>, National Institute for Health and Clinical Excellence<sup>19</sup>, Singapore Ministry of Health<sup>20</sup>, and American Academy of Neurology (AAN). The AAN, in collaboration with the NAEC and the American Epilepsy Society, are developing physician performance measures using the American Medical Association's Physician Consortium for Performance Improvement model. These measures are evidence-based and encompass multiple facets of epilepsy diagnosis and treatment including the use of diagnostic tests, documentation of etiology of seizure type and seizure frequency, and counseling about drug side-effects and safety issues. Further, they should be relatively easily monitored in an epilepsy center.

## Patient and Provider Education

A cornerstone of the comprehensive epilepsy center is education, directed to the patient, family and caretakers. Patient direct involvement and self-management of the epilepsy treatment plan is critical to good health and quality of life. Patient education methods can include formal courses, informational brochures, consultations with epilepsy nurse specialists, social workers, and other educators, and referrals to the local affiliate of the Epilepsy Foundation. Comprehensive epilepsy center personnel also participate in education of the larger health care community. Within the epilepsy center, continuing education can take the form of journal clubs, case management conferences, didactic lectures, development of care plans or clinical pathways, and quality assessment and improvement activities.

## **GUIDELINES FOR LEVEL THREE AND FOUR EPILEPSY CENTERS**

### Third Level Epilepsy Center

A third level epilepsy center should provide the basic range of medical, neuropsychological, and psychosocial diagnostic and treatment services needed to treat patients with refractory epilepsy. In addition, many level 3 centers offer noninvasive evaluation for epilepsy surgery, straightforward resective epilepsy surgery and implantation of devices, such as the vagus nerve

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<sup>18</sup> "Diagnosis and Management of Epilepsy in Adults: A National Clinical Guideline." Scottish Intercollegiate Network. 2003. Available at: <http://www.sign.ac.uk/pdf/sign70.pdf>.

<sup>19</sup> Stokes T, Shaw EJ, Juarez-Garcia A, Camosso-Stefinovic J, Baker R (2004). Clinical Guidelines and Evidence Review for the Epilepsies: diagnosis and management in adults and children in primary and secondary care. London: Royal College of General Practitioners.

<sup>20</sup> "MOH Clinical Practice Guidelines 1/2007: Epilepsy in Adults." Singapore Ministry of Health. 2007. Available at: [http://www.moh.gov.sg/mohcorp/uploadedFiles/Publications/Guidelines/Clinical\\_Practice\\_Guidelines/Diagnosis%20and%20Management%20of%20epilepsy%20in%20adults.pdf](http://www.moh.gov.sg/mohcorp/uploadedFiles/Publications/Guidelines/Clinical_Practice_Guidelines/Diagnosis%20and%20Management%20of%20epilepsy%20in%20adults.pdf).

stimulator. Knowledge and experience with epilepsy surgery has become sufficiently widespread that lesionectomy and anterior temporal lobectomy in the presence of clear-cut mesiotemporal sclerosis can be performed at level 3 epilepsy centers.

However, third level centers that offer such surgery should meet additional requirements, especially for an experienced neurosurgeon, neuropsychometric and neuroradiologic expertise. The physicians making health care decisions at such centers must be fully knowledgeable regarding all surgical options available and establish appropriate referral arrangements for more complex surgeries with fourth level centers. (See Appendix I.A.2.g.) If such surgery is to be considered, the best surgical procedure for the particular situation must be recommended and this may not necessarily be the procedure that can be provided by the Level 3 center.

Cooperating third and fourth level centers should attempt to standardize data collection and make data exchange portable so that diagnostic studies do not have to be repeated for referred patients. This might include uniform imaging protocols, uniform video-EEG monitoring protocols, easy access to referring physicians, and agreements to send all appropriate information with the patients.

### **Epilepsy Surgery at Level 3 Centers**

Knowledge and experience with resective epilepsy surgery have disseminated widely since the 1990 guidelines were published<sup>21, 22</sup>. We define resective epilepsy surgery as resection of cerebral cortex with the primary aim of treating epilepsy. Epilepsy training programs have increased the number of individuals capable of performing epilepsy surgery. Table 2 summarizes the services and personnel typically needed at a Level 3 center. With this capacity it is reasonable to perform straightforward lesionectomy and straightforward anterior temporal lobectomy at the third level of epilepsy care.

**Table 2. Third level epilepsy centers (adapted from *Epilepsia*, 42(6):804-814, 2001)**

<b>SERVICES PROVIDED</b>	<b>PERSONNEL</b>
Electrodiagnostic EEG services including long term monitoring	Neurologists (Adult and/or Pediatric) with special expertise in epilepsy EEG technologists and related personnel
Epilepsy Surgery including VNS (routine lesional surgeries and those not requiring invasive monitoring)	Neurosurgeon(s) with special expertise in epilepsy
Neuroimaging	Neuroradiologist
Neuropsychological and psychological services	Neuropsychologist/neuropsychometrist Psychosocial personnel including clinical

<sup>21</sup> Recommended guidelines for diagnosis and treatment in Specialized Epilepsy Centers. *Epilepsia* 1990; 31 (Suppl1):S1-S12.

<sup>22</sup> Surgery for Epilepsy. NIH Cons Dev Conf Consens Statement 1990 Mar 19-21; 8(2):1-20.

	psychologist, social worker, school services for children
Pharmacological expertise	Access to consultation with Clinical Pharmacist
Nursing support (specific to epilepsy)	Nurse specialist
Rehabilitation (in patient and outpatient) including physical, occupational and speech therapy	Rehabilitation service personnel
Consultative expertise in multiple fields: neurosurgery, psychiatry, internal medicine, pediatrics, general surgery, obstetrics/ gynecology	Interdisciplinary clinical services available
Other	Biomedical engineer and IT support

We define lesionectomy as resection of a structural epileptogenic lesion and surrounding tissue that is performed primarily to treat epileptic seizures. In excellent candidates for lesionectomy, a single epileptogenic lesion is present, the lesion is an appropriate distance from cerebral regions necessary for normal function, and noninvasive electrophysiologic evaluation indicates that the lesion and surrounding area is responsible for the patient's seizures. Straightforward lesionectomy, defined in this manner, can be performed at a third level center. If these criteria are not met, the situation is usually not straightforward and intracranial evaluation will probably be necessary. Such patients should generally be referred to a fourth level epilepsy center.

We define anterior temporal lobectomy as the removal of a small amount of lateral temporal cortex followed by aggressive amygdalar, parahippocampal and hippocampal resection. In excellent candidates for anterior temporal lobectomy, magnetic resonance imaging detects unilateral mesial temporal sclerosis, noninvasive electrophysiologic evaluation indicates that the same temporal lobe is responsible for the patient's seizures, and neuropsychometric evaluation including intracarotid amobarbital testing indicates that temporal lobectomy can be safely performed. Straightforward anterior temporal lobectomy, defined in this manner, can be performed at a third level center. If these criteria are not met, the situation is usually not straightforward. Further evaluation is necessary, often including intracranial recording. Such patients should generally be referred to a fourth level epilepsy center.

Current experience indicates that the vagus nerve stimulator rarely cures epilepsy. In contrast straightforward lesionectomy and straightforward anterior temporal lobectomy as defined above cure epilepsy in the large majority of cases. Patients with refractory epilepsy should therefore be evaluated for resective epilepsy surgery before the vagus nerve stimulator is considered.

There is no absolute number of surgeries that are required for designation as a third level center (see Appendix section I.A.2.e.). Rather, experienced medical personnel (epileptologist and epilepsy surgeon with at least two years experience each) AND adequate volume of video-monitoring patients annually (defined as at least 50 cases) should be the determinants.

### Fourth Level Epilepsy Center

Fourth level epilepsy centers serve as a regional or national referral facilities for intractable epilepsy patients. These centers should provide the more complex forms of intensive neurodiagnostic monitoring, as well as more extensive medical, neuropsychological and psychosocial treatment. Fourth level centers also offer a complete evaluation for epilepsy surgery including intracranial electrodes and provide a broad range of surgical procedures for epilepsy. Many level 4 centers are actively involved in clinical trials and are well aware of trials conducted in other level 4 centers to make patient referrals.

The major distinction between level 3 and 4 centers is the comprehensive nature of the services provided. Table 3 lists some of the additional capabilities that a level 4 center must have to distinguish itself from the level 3 centers.

**Table 3. Features distinguishing Level 4 centers**

Functional cortical mapping by stimulation of subdural electrodes either extra-operatively or intraoperatively.
Evoked potential recording capable of being used safely with intracranial electrodes.
Electrocorticography.
Placement of intracranial electrodes.
Resection of epileptogenic tissue in the absence of structural lesions.
Adequate clinical experience by both the neurosurgeon and neurologist/epileptologist.
Specialized neuroimaging either on site or by established arrangement including interictal positron emission tomography (PET) and/or ictal single photon emission computed tomography (SPECT)

### Epilepsy Surgery at Level 4 Centers

Sectioning the corpus callosum is being performed less frequently. Hemispherectomy is indicated infrequently in adults but still has a role in pediatric epilepsy surgery for specific clinical situations. Consequently, we do not recommend that fourth level centers must able to perform corpus callosum section or hemispherectomy. However, physicians making health care decisions at these centers should be aware of the indications for these procedures. They should establish referral arrangements with other fourth level centers performing these procedures and refer patients requiring these procedures when necessary.

There is no absolute number of surgeries that are required for a Level 4 center (see Appendix section II.A.2.h.). Rather, experienced medical personnel (epileptologist and epilepsy surgeon with at least five years experience each) AND adequate volume of video-monitoring patients annually, particularly surgical evaluations (defined as at least 100 cases) should be the determinants.

## **APPENDIX**

### **I. Third Level Epilepsy Center**

#### **A. SERVICES PROVIDED**

##### **1) Electrodiagnostic**

- a) 24-hour video-EEG with surface electrodes supplemented with sphenoidal or appropriate additional electrodes. Continuous supervision by EEG technologist or epilepsy staff nurse, supported when appropriate by monitoring technician or automated seizure and interictal activity detection program.
- b) Intracarotid amobarbital (Wada) testing or mechanism to obtain one
- c) Intraoperative Electrocorticography
- d) Adequate volume of video-EEG monitoring for seizure classification or localization annually (at least 50 cases)

##### **2) Epilepsy surgery**

- a) Emergency or elective neurosurgery, including biopsy and removal of incidental lesions and treatment of cerebral complications of epileptic seizures.
- b) Management of surgical complications.
- c) Surgical resection of epileptogenic structural lesions with the goal of treating seizures (“straightforward lesionectomy”).
- d) Standard anterior temporal lobectomy in the presence of mesial temporal sclerosis.
- e) Experience in resective epilepsy surgery
- f) Implantation and management of vagus nerve stimulators or other neuromodulatory devices.
- g) If the third level center does not actually perform surgery, it must have established referral procedures with one or more level 4 surgical centers.

##### **3) Imaging**

- a) Magnetic resonance imaging (in 2009, defined as a minimum of 1.5T) with appropriate magnet strength and sequences for the sensitive detection of mesial temporal sclerosis and common epileptogenic lesions.
- b) Computerized axial tomography
- c) Cerebral angiography

##### **4) Pharmacological expertise**

- a) Quality-assured anticonvulsant serum drug levels. Levels of newer anticonvulsant drugs and free drug levels should be readily available.
- b) 24-hour antiepileptic drug level service
- c) Pharmacokinetic expertise by at least one member of the team.

##### **5) Neuropsychological/psychosocial services**

- a) Comprehensive neuropsychological test batteries for
  - i) evaluation of cerebral dysfunction for vocational and rehabilitative purposes;
  - ii) localization of cerebral dysfunction in evaluation for epilepsy surgery
  - iii) basic assessment of characterological and psychopathological issues.
- b) An established referral arrangement for comprehensive management of psychogenic nonepileptic events.
- c) Clinical psychological services for assessment and basic treatment of emotional disorders associated with chronic epilepsy.
- d) Basic assessment of social and vocational needs.

**6) Rehabilitation (inpatient and outpatient)**

- a) Physical, occupational, and speech therapy for basic evaluation and treatment of multiply handicapped individuals.
- b) Sufficient physical, occupational, and speech therapy for managing complications of surgeries performed at the center.

**7) Consultative expertise**

- a) Psychiatrist, board-certified (ABPN), with special interest in treatment of people with epilepsy and psychiatric disorders
- b) Internal medicine
- c) Pediatrics
- d) General surgery
- e) Obstetrics/gynecology
- f) Neuropathology
- g) Neuroradiology

**B. PERSONNEL**

**1) Physicians**

- a) A neurologist or neurosurgeon with special expertise in epilepsy should serve as program director.
- b) At least two board certified neurologists with expertise in epilepsy, clinical neurophysiology, video-EEG monitoring, selection of patients for epilepsy surgery, and the pharmacology of anticonvulsant drugs. Generally neurologists would have undergone fellowship training in these topics. At least one of these individuals should be board certified in clinical neurophysiology by either the American Board of Clinical Neurophysiology or the American Board of Psychiatry and Neurology with added qualifications in clinical neurophysiology. Appropriate experience may substitute for clinical neurophysiology certification. At least one of these individuals should have experience in the selection of patients for and the adjustment of the vagus nerve stimulator.
- c) At least one board certified neurosurgeon with special interest in epilepsy, experience in resective epilepsy surgery, and in the implantation of the vagus nerve stimulator.

- d) Experienced epileptologist and epilepsy surgeon are defined as having at least two years experience each post fellowship and an adequate volume of video EEG monitoring annually (at least 50 cases).

## **2) Neuropsychologist/neuropsychometrist**

- a) Neuropsychologist – Ph.D. in clinical psychology with specialization in clinical neuropsychology as evidenced by pre- or postdoctoral training and/or work experience; or, a Ph.D. in psychology with postdoctoral training from an APA-approved clinical neuropsychology program. The neuropsychologist would supervise neuropsychological evaluations and assessments and may also supervise interventional psychologists. This individual should have specific experience
  - i) in use of neuropsychometric tests in evaluation for epilepsy surgery; and
  - ii) interpreting results of intracarotid amobarbital tests.
- b) Psychometrist – A bachelor’s degree in a behavioral science plus supervised experience in neuropsychometric instrument administration and scoring under the direction of a qualified neuropsychologist. This individual would administer and score the neuropsychological tests.

## **3) Psychosocial**

- a) Clinical psychologist/counseling psychologist – Ph.D. from an APA-approved clinical or counseling psychology program and a special interest in epilepsy.
- b) Social worker – ACSW preferred with experience coordinating case services for epilepsy patients in an outpatient setting

## **4) Nursing**

- a) Clinical nurse specialist/nurse clinician – qualifications include nursing degree with experience in epilepsy. Responsibilities include providing patient and family education and coordinate nursing services for epilepsy center
- b) Head nurse/staff nurse – Qualifications include R.N. with experience in epilepsy. Responsibilities include coordinate nursing functions for inpatient service

## **5) EEG Technologists and personnel**

- a) When intensive neurodiagnostic monitoring of patients is performed, an EEG technologist, monitoring technician, or epilepsy staff nurse must observe the patient and maintain recording integrity. An EEG technologist attaches electrodes, maintains integrity of the recording, is capable of observing for seizures and examining patients during seizures, and operates recording equipment. A monitoring technician is defined as an individual trained in seizure observation and capable of maintaining recording integrity in the temporary absence of an EEG technologist.
- b) All technologists and technicians should be certified in basic life support. All technologists preferably would be board-eligible or certified by the American Board of Registration for EEG Technology (ABRET). All technologists should meet American

EEG Society long-term monitoring qualifications<sup>23</sup>. The chief technologist should be ABRET-registered and have additional training in long-term monitoring.

- c) At least one technologist should have experience with the technical and safety issues encountered during electrocorticographic recordings in the operating room.

**6) Rehabilitation services**

- a) Registered occupational therapist
- b) Physical therapist supervised by physician
- c) Psychiatrist with special interest in neurological dysfunction
- d) Speech therapist and vocational counselor preferred

**7) Support services**

- a) Biomedical engineer and/or IT specialist.

**C. OUTPATIENT VIDEO-EEG MONITORING UNITS**

**1) Layout and furnishings** should

- a) Allow nursing or monitoring staff easy access to patients to facilitate examination and first aid
- b) Minimize risk of injury due to falls.

**2) Personnel**

- a) Continuous observation by qualified providers such as EEG technologists is mandatory. Additionally, physician or staff epilepsy nurse should be readily available.

**3) Useful Protocols** (modified as necessary to account for individual situations)

- a) Examination during seizures
- b) Number or duration of seizures over given period requiring physician notification
- c) Transportation and designated provider of emergency services in the event of emergencies.
- d) Medication reduction to increase seizure yield is not recommended in the outpatient setting. It should not be done without physician or extensively trained nurse clinician on premises.

**4) Access to additional care.**

- a) Ready access to emergency resuscitative equipment in the monitoring unit
- b) Arrangement with nearby hospital to provide emergency services when needed.

**D. INPATIENT UNITS AT THIRD LEVEL EPILEPSY CENTERS**

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<sup>23</sup> American Electroencephalographic Society Guidelines for Long Term Diagnostic Monitoring in Epilepsy. *J Clin Neurophysiol* 1994;11:88-110.

**1) Layout and furnishings should**

- a) Minimize risk due to injury and falls. Measures taken should be more thorough than in the outpatient setting because likelihood of seizures occurring is greater with medication reduction.
- b) Decrease risks for leaving unit or confused wandering in the postictal state.
- c) Allow continuous observation of patients for the purposes of safety and examination during video-EEG monitoring. Observation should be possible during wakefulness and sleep. Arrangements should assure privacy when appropriate, e.g. when patients use the bathroom but rapid access must be available at all times.

**2) Personnel**

- a) Continuous observation by EEG technologists or epilepsy staff nurses is highly recommended, supplemented as appropriate by frequently reviewed spike and seizure detection. Reliable and appropriately trained family members or nursing assistants may assist in some situations. A higher nurse to patient ratio than in standard care is necessary.
- b) Epilepsy staff nurses must be continuously present on site. EEG technologists must be continuously available.
- c) 24 hour physician on site. 24 hour availability of epileptologist.

**3) Mandatory Protocols** (modified as necessary to account for individual situations)

- a) Examination of speech, memory, level of consciousness and motor function during and following a seizure.
- b) Number or duration of seizures over given period requiring physician notification.
- c) Measures to be taken if number, duration, or severity of seizures observed is excessive.

**4) Access to additional care**

- a) Ready access to intensive care unit and anesthesia services in the event of status epilepticus.

## **II. Fourth Level Epilepsy Center**

### **A. SERVICES PROVIDED**

**1) Electrodiagnostic**

- a) 24-hour video-EEG with surface electrodes supplemented with sphenoidal or appropriate additional electrodes. Continuous supervision by EEG technologist or epilepsy staff nurse, supported when appropriate by monitoring technician or automated seizure and interictal activity detection program
- b) 24 hour video-EEG recording with intracranial electrodes (subdural, epidural or depth electrodes) under continuous supervision and observation as above. Level 4 centers should have an average of at least 6 cases with indwelling or intraoperative electrodes annually averaged over 4 years.

- c) Intracarotid amobarbital (Wada) testing
- d) Functional cortical mapping by stimulation of subdural electrodes either extraoperatively or intraoperatively.
- e) Evoked potential recording capable of being used safely with intracranial electrodes.
- f) Electrocorticography.
- g) Adequate volume of video-EEG monitoring for seizure classification or localization annually (at least 100 cases).

## **2) Epilepsy surgery**

- a) Emergency or elective neurosurgery, including biopsy and removal of incidental lesions and treatment of cerebral complications of epileptic seizures.
- b) Management of surgical complications.
- c) Open and stereotactic biopsy
- d) Surgical resection of epileptogenic structural lesions with the goal of treating seizures (“lesionectomy”).
- e) Anterior temporal lobectomy with or without mesial temporal sclerosis.
- f) Placement of intracranial electrodes.
- g) Resection of epileptogenic tissue in the absence of structural lesions.
- h) Implantation and management of the vagus nerve stimulator or other neuromodulatory devices.
- i) If the center does not offer corpus callosotomy and hemispherectomy, it should establish referral procedures with fourth level centers offering these services.

## **3) Imaging**

- a) Magnetic resonance imaging (in 2009, defined as 1.5T) with appropriate magnet strength and sequences for the sensitive detection of mesial temporal sclerosis and common epileptogenic lesions.
- b) Computerized axial tomography
- c) Cerebral angiography.
- d) Access to one or more of the following either on site or by established arrangement:
  - i) interictal positron emission tomography
  - ii) ictal single photon emission computed tomography
  - iii) functional magnetic resonance imaging (fMRI)
  - iv) MEG

## **4) Pharmacological expertise**

- a) Quality-assured anticonvulsant serum drug levels. Levels of newer anticonvulsant drugs and free drug levels should be readily available.
- b) 24-hour antiepileptic drug level service

- c) Pharmacokinetic expertise by at least one member of the team.

**5) Neuropsychological/psychosocial services**

- a) Comprehensive neuropsychological test batteries for:
  - i) evaluation of cerebral dysfunction for vocational and rehabilitative purposes
  - ii) localization of cerebral dysfunction for evaluation for epilepsy surgery
  - iii) complete assessment of characterological and psychopathological issues.
- b) Inpatient and outpatient psychological services for assessment and treatment of emotional disorders associated with chronic epilepsy.
- c) Assessment of social and vocational needs. Interventive social services.
- d) Comprehensive management of psychogenic nonepileptic events.

**6) Rehabilitation (inpatient and outpatient)**

- a) Physical, occupational, and speech therapy for evaluation and treatment of multiply handicapped individuals.
- b) Sufficient physical, occupational, and speech therapy for managing complications of surgeries performed at the center.

**7) Consultative expertise**

- a) Psychiatrist, board-certified (ABPN), with special interest in treatment of epileptic patients with psychiatric disorders
- b) Internal medicine
- c) Pediatrics
- d) General surgery
- e) Obstetrics/gynecology
- f) Neuropathology
- g) Neuroradiology

**B. PERSONNEL**

**1) Physicians**

- a) A neurologist or neurosurgeon with special expertise in epilepsy should serve as program director.
- b) At least two board certified neurologists with expertise in epilepsy, clinical neurophysiology, video-EEG monitoring, selection of patients for epilepsy surgery, and the pharmacology of anticonvulsant drugs. Generally neurologists would have undergone fellowship training in these areas. At least one of these individuals should be board certified in clinical neurophysiology by either the American Board of Clinical Neurophysiology or the American Board of Psychiatry and Neurology additional qualifications in clinical neurophysiology. Appropriate experience may substitute for clinical neurophysiology certification. At least one of these individuals should have

experience in the interpretation of intracranial EEG recordings and cortical stimulation studies. At least one of these individuals should have experience in the indications for and the adjustment of the vagus nerve stimulator.

- c) At least one board certified fellowship-trained neurosurgeon with special interest in epilepsy, experience in resective epilepsy surgery, placement of intracranial electrodes and insertion of the vagus nerve stimulator. Generally neurosurgeons would have undergone fellowship training or additional training beyond residency in these topics.
- d) Experienced epileptologist and epilepsy surgeon are defined as having at least two years experience each post fellowship and an adequate volume of video EEG monitoring annually (at least 100 cases).

**2) Pharmacologist or Pharm. D.**

- a) With special interest and training in epilepsy

**3) Neuropsychologist/neuropsychometrist**

- a) Neuropsychologist – Ph.D. in clinical psychology with specialization in clinical neuropsychology as evidenced by pre- or postdoctoral training and/or work experience; or, a Ph.D. in psychology with postdoctoral training from an APA-approved clinical neuropsychology program. The neuropsychologist would supervise neuropsychological evaluations and assessments and may also supervise interventional psychologists. This individual should have specific experience
  - i) in use of neuropsychometric tests in evaluation for epilepsy surgery; and
  - ii) interpreting results of intracarotid amobarbital tests.
- b) Psychometrist – A bachelor’s degree in a behavioral science plus supervised experience in neuropsychometric instrument administration and scoring under the direction of a qualified neuropsychologist. This individual would administer and score the neuropsychological tests.

**4) Psychosocial**

- a) Clinical psychologist/counseling psychologist – Ph.D. from an APA-approved clinical or counseling psychology program and a special interest in epilepsy
- b) Social worker – ACSW preferred with experience coordinating case services for epilepsy patients in an outpatient setting

**5) Nursing**

- a) Clinical nurse specialist/nurse clinician – qualifications to include nursing with experience in epilepsy. Responsibilities include providing patient and family education and coordinate nursing services for epilepsy center
- b) Head nurse/staff nurse – qualifications include R.N. with experience in epilepsy. Responsibilities include coordinating nursing functions for inpatient service

**6) EEG Technologist(s)**

- a) When intensive neurodiagnostic monitoring of patients is performed, an EEG technologist, monitoring technician, or epilepsy staff nurse must observe the patient and maintain recording integrity. An EEG technologist attaches electrodes, maintains integrity of the recording, is capable of observing for seizures and examining patients

during seizures, and operates recording equipment. A monitoring technician is defined as an individual trained in seizure observation and capable of maintaining recording integrity in the temporary absence of an EEG technologist.

- b) All technologists and technicians should be certified in basic life support. All technologists preferably would be board-eligible or certified by the American Board of Registration for EEG Technology (ABRET). All technologists should meet American EEG Society long-term monitoring qualifications<sup>24</sup>. The chief technologist should be ABRET-registered and have additional training in long-term monitoring.
  - c) At least one technologist should have experience with the technical and safety issues encountered during electrocorticographic recordings in the operating room.
  - d) Additionally, several technologists should have experience with long term monitoring with intracranial electrodes and the safety and recording issues occurring during cortical stimulation. At least one technician should have experience with electrocorticographic recordings in the operating room.
- 7) **Rehabilitation Services** (usually by consultation or referral)
- a) Registered occupational therapist
  - b) Physical therapist supervised by physician
  - c) Psychiatrist with special interest in neurological dysfunction
  - d) Speech therapist
  - e) Vocational counseling
- 8) **Support services**
- a) Biomedical engineer and/or IT specialist

### C. OUTPATIENT VIDEO-EEG MONITORING UNITS

- 1) **Layout and furnishings** should
  - a) Allow nursing or monitoring staff easy access to patients to facilitate examination and first aid
  - b) Minimize risk of injury due to falls.
- 2) **Personnel**
  - a) Continuous observation by qualified providers such as EEG technologists is mandatory. Additionally, physician or staff epilepsy nurse should be readily available.
- 3) **Useful Protocols** (modified as necessary to account for individual situations)
  - a) Examination during seizures
  - b) Number or duration of seizures over given period requiring physician notification

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<sup>24</sup> American Electroencephalographic Society Guidelines for Long Term Diagnostic Monitoring in Epilepsy. *J Clin Neurophysiol* 1994;11:88-110.

- c) Transportation and designated provider of emergency services in the event of emergencies.
- d) Medication reduction to increase seizure yield is not recommended in the outpatient setting. It should not be done without close supervision by a physician or extensively trained nurse clinician on premises.

**4. Access to additional care.**

- a) Ready access to emergency resuscitative equipment in the monitoring unit
- b) Arrangement with nearby hospital to provide emergency services when needed.

**D. INPATIENT UNITS AT FOURTH LEVEL EPILEPSY CENTERS**

**1) Layout and furnishings should**

- a) Minimize risk due to injury and falls. Measures taken should be more thorough than in the outpatient setting because likelihood of seizures occurring is greater with medication reduction.
- b) Decrease risks for leaving unit or confused wandering in the postictal state.
- c) Allow continuous observation of patients for the purposes of safety and examination during video-EEG monitoring. Observation should be possible during wakefulness and sleep. Arrangements should assure privacy when appropriate, e.g. when patients use the bathroom but rapid access must be available at all times.
- d) Additionally neurodiagnostic equipment and furnishings must meet electrical safety and other standard of the American EEG Society's Recommendations for Intensive Neurodiagnostic Monitoring<sup>25</sup>.

**2) Personnel**

- a) For scalp video-EEG monitoring, continuous observation by EEG technologists or epilepsy staff nurses is highly recommended, supplemented as appropriate by frequently reviewed spike and seizure detection. Reliable and appropriately trained family members or nursing assistants may assist in some situations. A higher nurse to patient ratio than in standard care is necessary. For video-intracranial EEG monitoring, continuous observation by EEG technologists or epilepsy staff nurses is mandatory
- b) Epilepsy staff nurses must be continuously present on site. EEG technologists must be continuously available.
- c) 24 hour physician on site. 24 hour availability of epileptologist.

**3) Mandatory Protocols** (modified as necessary to account for individual situations)

- a) Examination of speech, memory, level of consciousness and motor function during and following a seizure.
- b) Number or duration of seizures over given period requiring physician notification.

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<sup>25</sup> American Electroencephalographic Society Guidelines for Long Term Diagnostic Monitoring in Epilepsy. J Clin Neurophysiol 1994;11:88-110.

- c) Measures to be taken if number, duration, or severity of seizures observed is excessive.
  - d) Care of head-dressings in patients studied with intracranial electrodes
  - e) Measures to prevent postoperative infections or other complications in patients studied with intracranial electrodes.
- 4) **Access to additional care**
- a) Ready access to intensive care unit and anesthesia services in the event of status epilepticus.