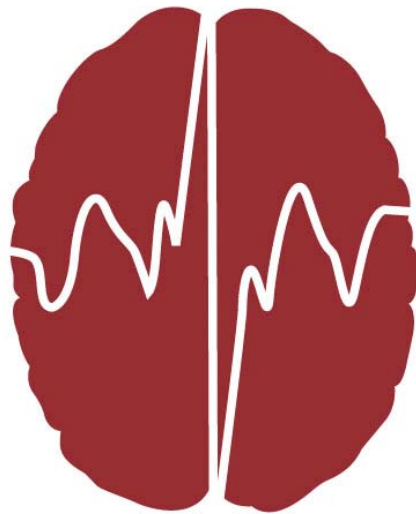


Clinical and Economic Workshop

May 2009

Salt Lake City



ACMEGS

AMERICAN CLINICAL MEG SOCIETY

Clinical Neurosciences Center

University of Utah

Welcome to Salt Lake City! On the behalf of the Organizing Committee, I hope that you enjoy your visit to Salt Lake City and the University of Utah.

This is the 3rd annual meeting of the ACMEGS. We intend that the 2 day program can be used as a forum to discuss the clinical utility and the economics of creating and maintaining a successful clinical MEG service in the United States.

During the afternoon sessions we will be presenting a proposed public statement for the ACMEGS. Please take some time to think about what the Society can do for its members and share your thoughts during this time. Remember that this is also a social event, so introduce your self to other members.

The meeting provides an informal and friendly atmosphere for discussing and exchanging recent studies that might lead to new clinical indications for MEG and increase the economic success of MEG. There are both short-term and long-term strategies to achieve acceptance of clinical MEG. In the short term we can help our member hospitals to promote the appropriate use of the technology. It is important to work closely with the local payors and governmental regulatory bodies to ensure accurate and successful reimbursement.

In the long run, it is important to have well-designed, peer-reviewed studies of the clinical effectiveness of MEG. We also should strive to publish the effectiveness of MEG in new applications such as evaluation of minimal cognitive deficit, head trauma, schizophrenia diagnosis and stratification, and motor mapping in Parkinson's disease. Dr. Jeff Lewine will expand on these topics on the first morning.

We also welcome Robert Knowlton again for the second John Gates Memorial Lecture.

Since this is a national conference involving many clinical sites, under no circumstances should anyone divulge their institutional billing rates or other actual billing rates. If they attempt to do so, they will be asked to leave.

Please enjoy the conference and dinner.

Sincerely,

Michael E Funke, M.D.

President, American Clinical Magnetoencephalography Society

Organizing Committee:

Anto Bagic, University of Pittsburgh Medical Center, Pittsburgh PA

Greg Barkley, Henry Ford Hospital, Detroit MI

Michael Funke, University of Utah, Salt Lake City UT

Robert Knowlton, University of Birmingham, Birmingham AL

Roland Lee, University of California San Diego, San Diego CA

Steven Stufflebeam, Mass. General Hospital, Boston MA

PROGRAM

Friday, May 15, 2009

- 8:30 am **Arrival / Breakfast Reception (Provided)**
- 9:30 am **ACMEGS Presidential Address (Michael Funke)**
Welcome and Introduction
- 9:40 am **Update Clinical Research (Michael Funke)**
a) Jeffrey Lewine: Beyond presurgical mapping and epilepsy – What do we need to do to develop new, reimbursable clinical applications
b) Sylvain Baillet: Data, methods, software, and reports: The kitchen sink of a MEG program
- 10:40 am **ACMEGS Practice Guidelines Committee - Reports (Anto Bagic)**
a) Epilepsy (Anto Bagic)
b) Language (Susan Bowyer)
c) Evoked Fields Minus Language (Richard Burgess)
- 12:15 pm **Lunch / ACMEGS Photo shooting**
- 1:45 pm **Business Meeting**
a) Financial Report (Anto Bagic)
b) Mission Statement (Michael Funke)
c) Position Statement (Anto Bagic)
d) New Business
- 2:45 pm **Coffee Break**
- 3:00 pm **Overcoming Coverage Denials & Strategies to Maximize Reimbursement (Andy Dean)**
a) Presentation (Andy Dean)
b) Comprehensive Appeals Documentation (Charmaine Keck)
[All members will be approached prior to the meeting to contribute information regarding insurance policies and appeals strategies, compiled into useful document]
- 4:15 am **MEG Economic Environment (Michael Longacre)**
a) Progress on the Medicare Project 2009 (Michael Longacre)
b) Dialogue with National Payers (Michael Longacre)
c) Update on AAN activities (Greg Barkley)
d) Discussion of the new projects and priorities
- 6:00 pm **John-Gates-Lecture 2009 and Dinner at the Commanders House**
MSI and Epilepsy Surgery: A Clinical Decision Analysis (Robert Knowlton)

Saturday, May 16, 2009

- 8:30 am **Board meeting at the Guest House, Breakfast will be served**

Michael Funke

ACMEGS Presidential Address

Michael Funke, M.D., Ph.D.

Assistant Professor of Neurology, Director of Clinical Magnetoencephalography
Clinical Neurosciences Center, University of Utah, Salt Lake City UT



Annual Society Meeting
Salt Lake City, Utah, May 15, 2009

The Times . . .

- CMS HOPPS lowered MEG reimbursement 2009
- 4D-Neuroimaging went out of business
- The Recession!
- BCBS Tech Assessment acknowledges difficulty in fairly assessing MEG
- Class I evidence paper published
- New clinical MEG startup operations
- Centers upgrade MEG systems
- Epilepsy big topic in Newsweek!



History of ACMEGS

- APC Panel Meeting 8/05, transition from New Technologies APC to Clinical APC
- Follow-up Meeting with CMS 9/05 on proposed clinical MEG reimbursements values for 2006
- Clear need for professional medical organization to convey interest of clinical MEG community
- Founding ACMEGS 4/06, trade organization with 510c(6) tax status to allow for political activity

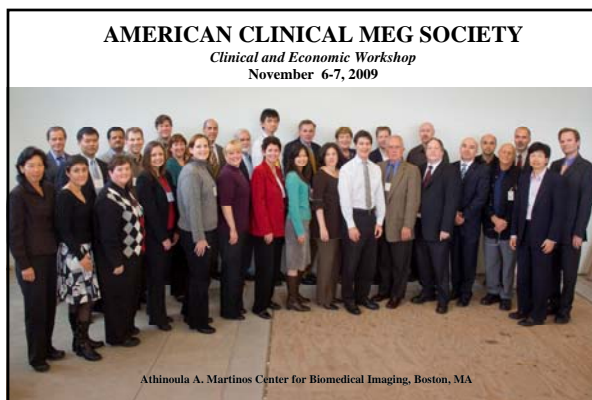


History of ACMEGS

- First annual ACMEGS meeting in Pittsburgh 9/07
- Second annual ACMEGS meeting in Boston 11/08
 - Announcing the “Six Steps Program” to capture and report cost appropriately to CMS
 - Initiating development of clinical practice guidelines
 - Creating Executive Director position
 - Adopting new membership fee schedule



19



31



Clinical MEG & ACMEGS

- *Present MEG Economics:*
 - CMS has recently reduced reimbursement values for 2009
 - Private insurance reimbursement is uneven
- *Goal:*
 - Achieve fair reimbursement from federally funded and private insurance carriers
- *Strategy:*
 - Organize through ACMEGS



Current Mission Statement

- ACMEGS will educate clinical MEG sites as well as private and US government policymakers about reimbursement issues and appropriate patient care standards.
- ACMEGS works with and complements other national and international organizations, such as the AES & International Society for the Advancement of Clinical MEG.



Membership Status

- Currently over 51 members from 21 sites in the United States
- Equal representation from all manufacturers
- Want at least one member from each site in the United States



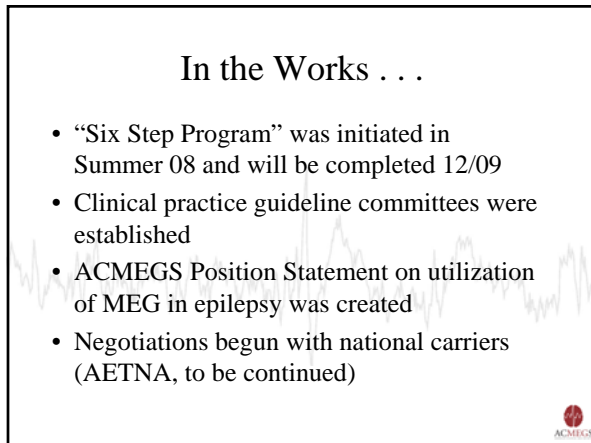
In the Works . . .

- New logo . . .



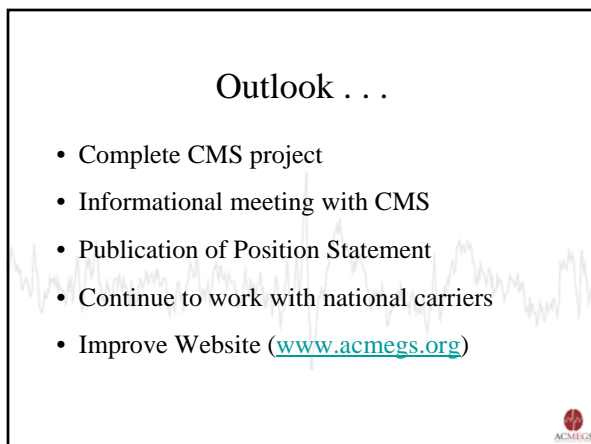
In the Works . . .

- “Six Step Program” was initiated in Summer 08 and will be completed 12/09
- Clinical practice guideline committees were established
- ACMEGS Position Statement on utilization of MEG in epilepsy was created
- Negotiations begun with national carriers (AETNA, to be continued)



Outlook . . .

- Complete CMS project
- Informational meeting with CMS
- Publication of Position Statement
- Continue to work with national carriers
- Improve Website (www.acmegs.org)



Outlook . . .

- Establish national payer analysis document
- Work toward practice guidelines and QC/QA parameters for clinical MEG
- Engage with advocacy groups
- Joint meetings with ACNS (?)
- Fund-Raising



Mark your Calendar . . .

ISACM 2009

September 3-5th

Athens, Greece

Thursday - Saturday Meeting

Roundtable Format

Sunday - optional cultural tours



Words of Caution

- Please do not share with each other your institutional reimbursement rates and your billing rates.
- Sharing such information could be considered collusion and could have legal ramifications for you and the society.



Acknowledgments

- Active participation of ACMEGS members
- Clinical Neurosciences administration for generous support
- Clinical Neurosciences staff
- Educational grants donors



Wireless Internet Access . . .

- Chose "HOTSPOT" network. . .
- Open your internet browser . . .
- Login with your personal e-mail address



Enjoy the Meeting!



Jeffrey Lewine

Beyond presurgical mapping and epilepsy – What do we need to do to develop new, reimbursable clinical applications


Jeffrey Lewine, Ph.D.

Executive Director

Alexian Brothers Center for Brain Research, Elk Grove Village, IL

ALEXIAN ADVANCED MEDICINE


Alexian Neurosciences Institute



Beyond Presurgical Mapping and Epilepsy

What do we need to do to design new, reimbursable clinical applications

Jeffrey David Lewine, Ph.D.
Director, Illinois MEG Center
Director, Alexian Brothers Center for Brain Research



ALEXIAN
HOSPITAL NETWORK

Alexian Brothers Medical Center
St. Alexius Medical Center
Alexian Brothers Renaissance Health Hospital
Alexian Federal/Quinton Hospital

Where are we now?

- At best, we have only two established applications that merit reimbursement by insurance companies, and many of the companies do not easily recognize these.
 - Presurgical Functional Mapping of Eloquent Cortical Regions
 - Localization of Epileptiform Activity
- There are a handful of emerging applications that may soon reach clinical fruition [documentation of mild traumatic brain injury, prediction of recovery from stroke, etc.], but as a community we must work together to identify the best prospects and figure out what is needed to bring these applications to fruition.
- We must remember that even the most elegant findings in a clinical population [e.g., identification of auditory processing abnormalities in autism, dyslexia, or schizophrenia] are irrelevant to an insurance company unless we can show that MEG alters patient care in a positive and cost-effective manner. Good and interesting science is great for NIH, but BCBS is not going to pay for good science.

What do insurance companies look for?

- Diagnostic or Prognostic
- Validation with respect to gold standard
- Positive clinical outcome with evidence that care is changed.
- Cost effectiveness

What do insurance companies want?

- Double-blind, placebo-controlled, multi-site studies showing positive patient outcomes!
- We must look at sensitivity, specificity and positive and negative predictive value.

Applications

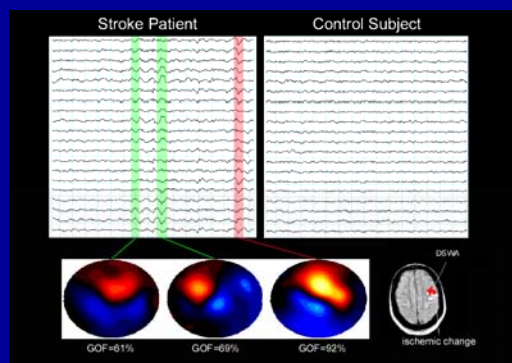
- Mild Traumatic Brain Injury:
 - two sites, similar but not identical strategies
- Autism:
 - two sites looking at similar auditory functions, two other sites doing unrelated work – we need to coordinate
- Schizophrenia / other psychiatric:
 - Multiple sites, not coordinated. More clinical research than clinical application
- Tinnitus:
 - Just one site
- Learning Disabilities:
 - Multiple sites doing unrelated work – we need to coordinate. Is there a clinical app or just research
- Stroke, Dementia, other?

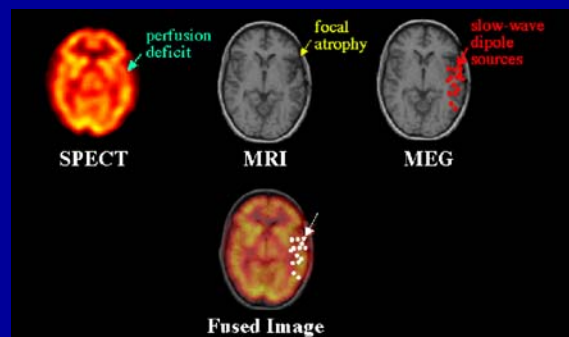
Mild TBI

- Furthest along pipeline, studies at ABMC and UCSD
- May get a free pass on some requirements because of military issues.
- Basic Approach – examine spontaneous data, possible supplement with evoked data
- Spontaneous – power spectra, coherence, slow wave activity
- Evoked: somatosensory and sensory gating.

Slow Waves

- Alexian – focus on dipolar slow waves: good sensitivity and good specificity
- UCSD- VESTAL analysis of slow waves: very high sensitivity, specificity uncertain
- Specificity is needed with respect to PTSD, Depression, and sleep problems





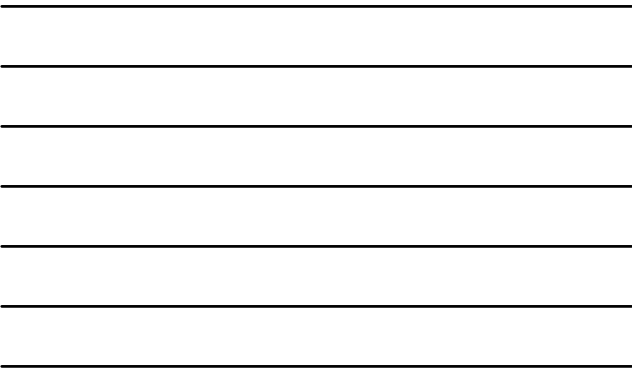
Type of Subject	N	% with DSWA
Un-injured Control Subjects	106	5.7 %
Mild Head Trauma without PCS	33	15.2 %
Mild Head Trauma with PCS	68	64.7 %
Moderate Head Trauma with PCS	30	80.0 %

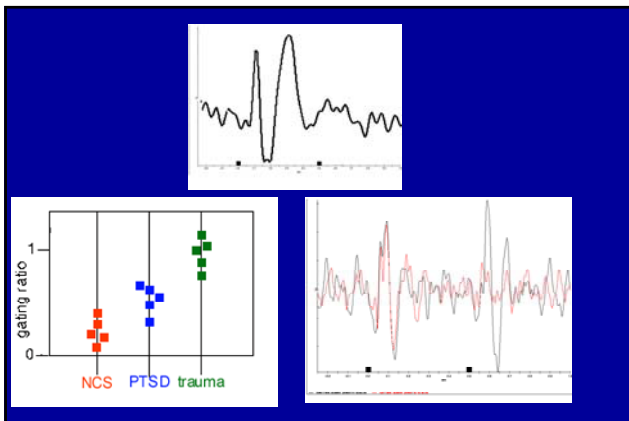
Type of Examination	N	% abnormal
MEG-DSWA	68	64.7%
Clinical MRI	68	13.3%
Clinical EEG	68	20.6%
Clinical SPECT	30	40.0%

Type of Subject	N	% with MEG-based Spectral Deviations	% with Abnormal MRI
Un-injured Control Subjects	20	10 %	0%
Mild Head Trauma without PCS	23	26 %	0%
Mild Head Trauma with PCS	48	55 %	8%
Moderate Head Trauma with PCS	30	80 %	47%

	S+	S-		P+	P-		C+	C-
M+	2	17		4	19		18	1
M-	3	6		3	6		4	7

[illegible]





Central Database

- Good for simple evokes

Distinguishing mTBI from PTSD

- No significant slowing in PTSD
- Reducing response in 50% of PTSD
- Augmented P3A in PTSD
- Normal Somato

Distinguishing mTBI from Depression

- Depression – reasonably normal gating
- Increased augmenting response
- Decreased frontal theta in depression

SUGGESTION

- Central Repository for Spontaneous Data with Normal Control Subjects and mTBI patients. Other patient data could also be maintained.
- Data sets could be distributed in a blinded manner

MEG in Autism

- Abnormal Auditory Processing ++
- Epileptiform Activity
- Abnormal Face Processing +
- Abnormal Somatosensory Organization +

Auditory Evoked Responses

- CHOPP
 - Delayed M100 responses
 - Abnormal temporal processing
 - Abnormal Laterality
 - Abnormal developmental trajectories
- Alexian
 - Delayed M100 responses
 - Abnormal temporal processing
 - Abnormal Laterality
 - Abnormal Intensity Dependence [may predict treatment response]

Epileptiform Activity in Autism Critical Observations

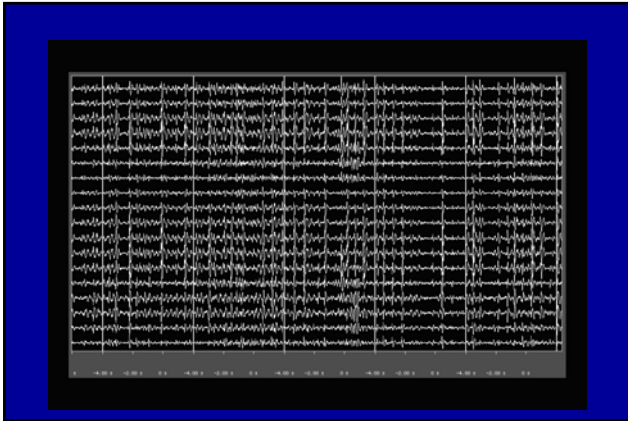
- By adolescence, 20-30% of children with an ASD are also diagnosed with epilepsy.
- Epileptiform abnormalities have been reported to be seen in 30-70% of children with ASDs, especially during sleep, and even in the absence of clinical seizures.
- The Autistic regression seen for about 20-25% of children is reminiscent of the language regression seen in Landau-Kleffner Syndrome, a rare condition associated with nearly continuous centro-temporal epileptiform activity during slow wave sleep.

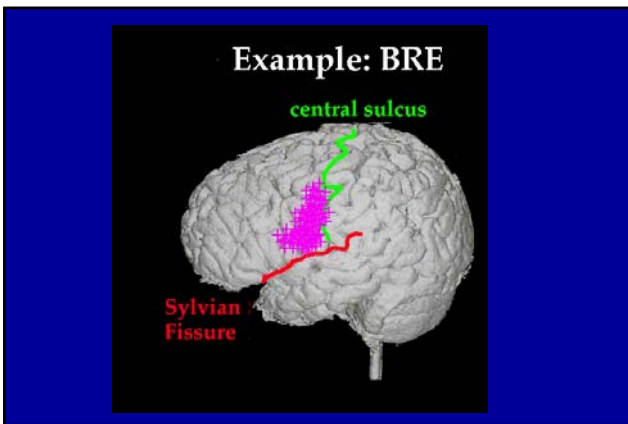
Question:

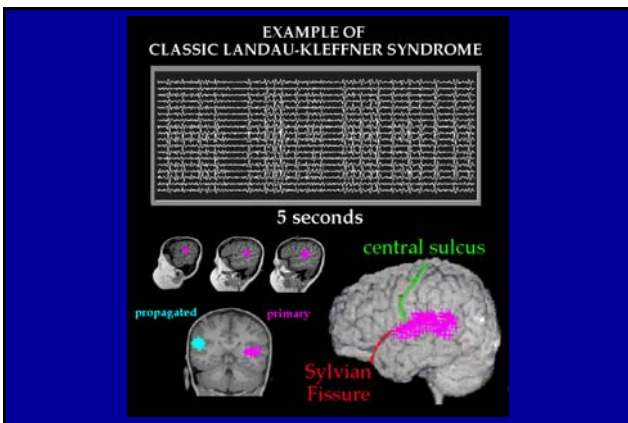
What are the similarities and differences in the patterns of epileptiform activity seen in LKS, its variants, and the ASDs.

Strategy:

Use combined MEG, EEG, and MRI to localize sites of origin of epileptiform activity and propagation pathways.







Definitions:

LKS, N=10:	domain specific language regression, CSWS
LKS-v, N=8:	domain specific language compromise, spikes but not CSWS
ASDs, N=50:	DSM-IV criteria for PDD-NOS or autistic disorder
Aut, N=66	DSM-IV criteria for autistic disorder, 33 DD, 33 R

Data were collected during sedation induced slow wave sleep using whole-head MEG and simultaneous EEG

LKS Profiles

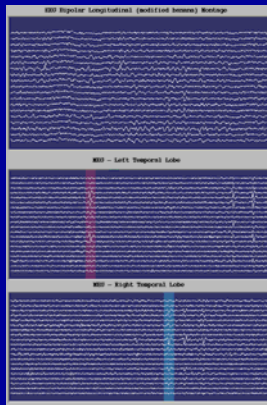
- 10 Children with classic LKS.
 - 9 had primary spike activity restricted to the peri-sylvian region.
 - 1 had peri-sylvian activity plus rare inferior frontal spikes
- 8 Children with LKS-variant
 - 6 with just peri-sylvian activity
 - 1 with just inferior frontal activity
 - 1 with peri-sylvian and inferior frontal activity
- When language cortex is compromised by epileptiform activity, language dysfunction is seen, even when the activity is not CSWS, and even when clinical seizures are controlled by medication.

ASDs Profiles - 50 Patients

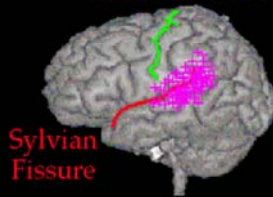
- 16 with Autistic Disorder, 34 with PDD-NOS
- Following relatively normal early development, all had language, cognitive, and social regression between 18-30 months
- 15 had clinical seizures

ASDs Results [Lewine et al., Pediatrics, 1999]

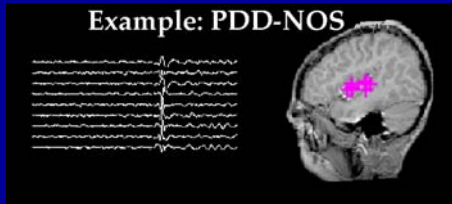
- 41 of 50 patients showed spikes.
- 2 patients with previous diagnoses of PDD-NOS showed almost continuous spiking in an LKS pattern
- For the other 39 subjects with spikes, spikes were frequent in 15 cases, intermittent in 10, bursty in 4, and rare in 10.
- In 7 cases, spikes were seen only in the MEG [all with an intra-sylvian pattern].



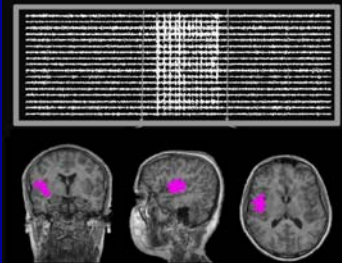
Example: PDD-NOS
with LKS profile
central sulcus



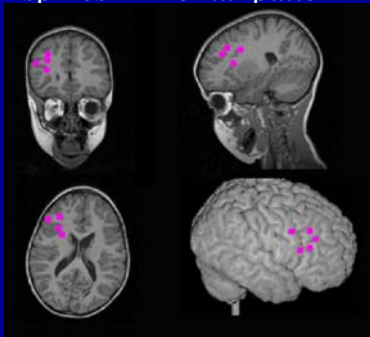
Some children with autism spectrum disorders show only rare spikes, but in an LKS pattern



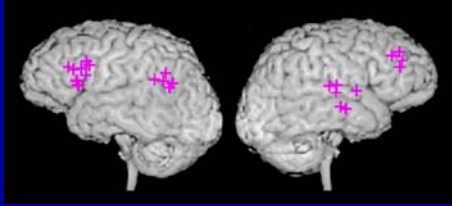
EXAMPLE OF
PATIENT WITH AUTISM
20 seconds

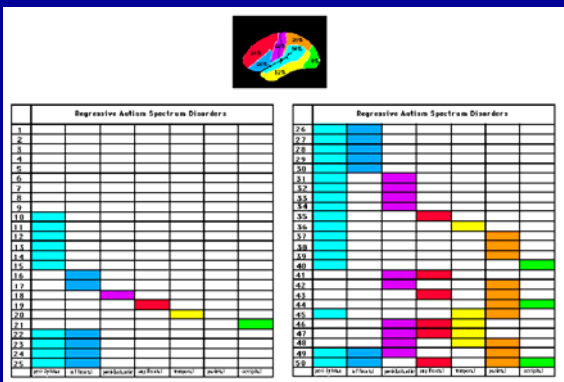


Example: PDD-NOS with rare
spikes in frontal pattern



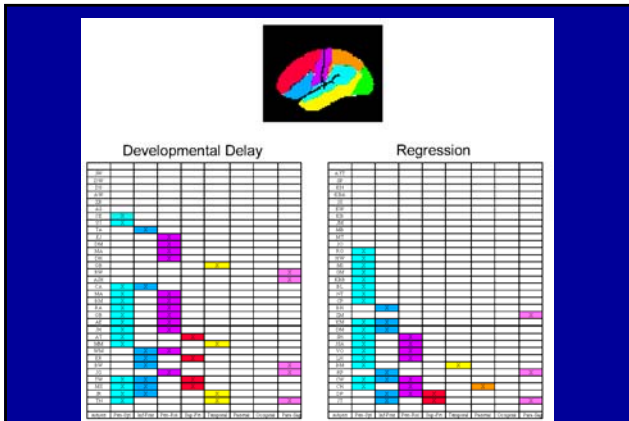
Many children with autism spectrum disorders show multi-lobar, bihemispheric activity.

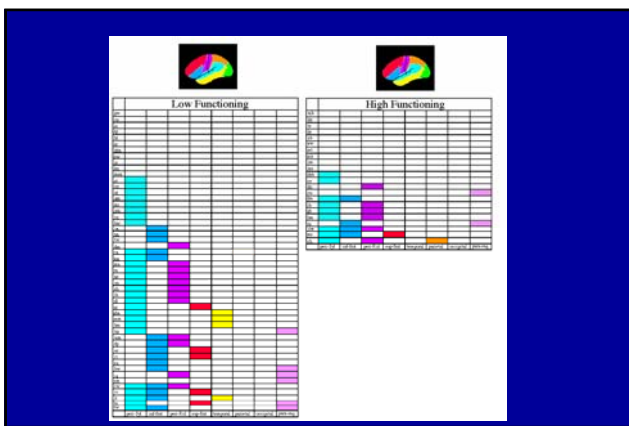


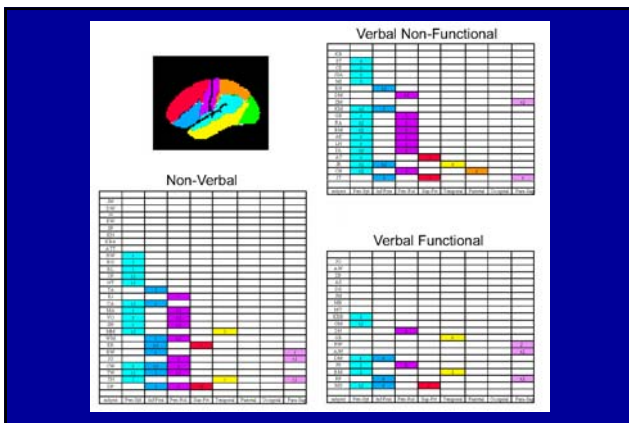


Patterns

- 28/41 children with spikes showed peri-sylvian activity in the same region implicated in LKS.
- Peri-sylvian activity is NOT common in traditional epilepsies.







Patterns

- Patterns are epileptiform activity are similar in developmental delay and regressive forms of autism.
- Peri-sylvian language areas are most commonly involved. There is an association between language dysfunction and epileptiform activity in language cortex.
- Of 47 kids with non-functional verbal language or no spoken language at all, 34 showed epileptiform involvement of language cortex [72%]. In contrast, of 19 kids with functional language, only 7 show epileptiform activity in language cortex [37%].

Treatment of Epileptiform Activity

- AEDs [Few studies, mostly open label. The majority of studies, but not all show some mild-moderate degree of efficacy].
- Steroids

Steroid Treatment

High Dose Prednisone, 2-3mg/kg/day

- Clinical and EEG data from 36 children with regressive autism and epileptiform EEG. Most were stable on depakote prior to addition of steroids.
- Objective language testing in 20.

Subject	Age	Tests	Receptive Pre-treat	Language During	Difference	Expressive Pre-treat	Language During	Difference
R2	9.5	C/EF	45	70	30	40	71	31
R3	7.1	P/E	40	63	23	49	69	20
R4	6.3	P/E	65	86	21	67	92	25
R5	6.6	P/E	50	66	16	49	68	19
R6	8.3	P/E	21	62	41	27	63	36
R8	7.3	C/EF	41	59	18	30	48	18
R9	5.1	C/ELF	78	93	15	60	81	21
R10	5.0	P/E	45	87	23	72	92	20
R11	6.6	P/E	49	82	33	49	78	29
R13	10.5	P/E	25	42	17	50	50	30
R15	6.11	P/E	58	75	17	57	89	32
R20	8.6	P/E	21	45	24	21	49	28
NR2	5.3	P/E	60	64	4	58	60	2
NR3	6.3	P/E	55	58	3	58	62	4
NR8	7.3	C/ELF	70	72	2	64	64	4
NR9	5.5	P/E	65	65	0	59	64	5
NR9	9.8	C/EF	30	30	0	23	25	2
NR12	7.4	P/E	45	47	2	36	39	3
NR15	8.1	C/ELF	41	45	4	41	45	4
NR16	4.8	P/E	80	84	4	81	83	2
Avg			50	65	15	48	65	17
T-Stat				5.5				6.1
P val				p<0.0001				P<0.0001

-
-
-
-
-
-

Multi-Site Studies

- Agree to share paradigms and data
- Establish repository for spontaneous and evoked data in control subject and patients.
- If you contribute, you can check data out.

Data, Methods, Software, and Reports: The Kitchen Sink of a MEG Program

Sylvain Baillet, Ph.D.

Associate Professor of Neurology, Scientific Director MEG Program
Department of Neurology, Medical College of Wisconsin, Milwaukee WI

ACMEGS Practice Guidelines Committee – Reports on Epilepsy

Anto Bagic, M.D., M.sc.

Assistant Professor of Neurology & Neurosurgery, Chief, Epilepsy Division, Director MEG
University of Pittsburgh Medical Center, Pittsburgh PA

American Clinical MEG Society (ACMEGS)
Guideline 1: Standards of Practice for the Conduct, Analysis and Reporting of
Clinical MEG-EEG Recording of Spontaneous Cerebral Activity

INTRODUCTION

The following are considered “minimum standards” for the routine clinical MEG-EEG recording of spontaneous cerebral activity in all age groups.

Recording at minimum standards should not be end goal of the MEG center, but starting level for improvement towards optimal clinical testing procedure, data analysis and reporting. Minimum standards provide only adequate fulfillment of essential responsibilities to the patient and the referring physician.

The minimum standards have been recommended to improve standardization of procedures and also facilitate interchange of recordings and reports among laboratories (centers) in the USA.

QUALIFICATIONS OF MEG-EEG PERSONNEL

[Should this be a separate guideline?]

1. Minimal Qualifications for a Clinical Magnetoencephalographer

These standards are proposed for individuals entering the MEG field after 2009. Many highly competent magnetoencephalographers who entered the field before 2009 and currently interpret MEGs do not meet the requirements listed below.

1.1 The clinical magnetoencephalographer should be a physician with board eligibility or certification in neurology, pediatric neurology, neurosurgery, or psychiatry.

1.2 Additional background training should meet the minimal requirements for examination by the American Board of Clinical Neurophysiology (www.abcn.org) or the American Board of Psychiatry and Neurology (ABPN) Subspecialty in Clinical Neurophysiology examination (“Added Qualifications”, www.abpn.com).

1.3 Specific MEG training should also include supervised learning and practice of clinical MEG of at least 6 months and independent interpretation and reporting of at least 50 valid MEG studies of epilepsy, and 25 valid MEG studies of each type of evoked fields: auditory evoked fields (AEF), language evoked fields (LEF), motor evoked fields (MEF), somatosensory evoked field (SEF) and visual evoked fields (VEF). Majority of epilepsy studies should be abnormal and include a mixture of clinical findings.

2. Minimal Qualifications of Magnetoneurodiagnostic Technologists

2.1 The background qualifications of magnetoneurodiagnostic technologists shall be those set forth for electroneurodiagnostic technologists by the ACNS and allied organizations. Registries in electroencephalographic or evoked potentials technology (R. EEG T., R. EP T.), administered by the American Board of Electroencephalographic and Evoked Potentials Technologists (ABRET), are required for entry-level technologists (www.abret.org).

2.2 In no case should a technologist with less than 6 months of supervised clinical experience, following formal training, operate independently or in an unsupervised capacity.

2.3 Additional specific supervised training for a minimum of 3 months should include principles of MEG technology, technical aspects of MEG systems with detailed familiarity with and competency in operational routines including helium filling, tuning procedures (as applicable), standard testing procedures, trouble shooting, artifact prevention and elimination, data storage, sufficient understanding of source localization and software approved with MEG system used that enables a technologist to preprocess routine clinical data competently, identify artifacts and abnormalities, perform basic source localization using FDA 510(k)-cleared software and prepare studies for magnetoencephalographer's analysis, interpretation and reporting.

3. Laboratory (Center) Organization

3.1 The laboratory (center) director shall have the primary responsibility for the overall operations and policies of the laboratory (center). The policies of the laboratory (center) should be documented in a policy and procedures manual. Under the supervision of the MEG laboratory (center) director, the chief MEG technologist shall be responsible for the daily operation of the laboratory (center). The chief technologist, together with the laboratory (center) director, shall maintain the highest standards of MEG-EEG technical practice.

3.2 All MEG-EEGs should be analyzed by, and official reports, including clinical interpretations, provided by, a qualified magnetoencephalographer/electroencephalographer. Under no circumstances should a technologist, however well-qualified and experienced, have primary responsibility for clinical interpretation of MEG-EEGs. Qualified technologists, however, should be able to give a descriptive technical report of the record.

3.3 Records should be maintained in an orderly manner and should be available for review by the patient's referring physician and other qualified persons.

LABORATORY (CENTER) ENVIRONMENT

1. General layout of the center

MEG center has to be laid out, overall designed and equipped to meet safety requirements of the Department of Health for neurodiagnostic laboratories while meeting all functional requirements necessary to obtain MEG-EEG recordings that meet the standards of adequate clinical quality.

1.1 Magnetically shielded room (MSR) conforming to the current functionality and safety standards should be used. Entire MSR, including and adjustable lighting system and audio-visual communication system has to be checked regularly and operational at all times during preparation, scanning and de-preparation of a subject.

1.2 Patient bed and/or chair have to be appropriately cleared with the MEG system and only use of such equipment is acceptable. Both have to meet appropriate safety standards, including assuring subject's safety in the case of an unexpected event such as an epileptic seizure or drug reaction via a safety belt, protective rails or other appropriate means.

1.3 Procedure preparation room designed and equipped according to the regulation of Department of Health and optimal procedural requirements of the center is recommended for protecting patient's privacy during preparation, providing instructions, explaining procedure, changing and storing subject's clothes, placing and removing EEG electrodes, etc. This room would particularly facilitate a patient flow when scanning becomes frequent.

2.0 Measurement System

An FDA 510(k)-cleared whole head system is necessary to record simultaneously from the entire head. Simultaneous recording of MEG and EEG is standard requirement for clinical epilepsy study. Thus, if an EEG module is not integrated within a whole head system, and therefore FDA 510(k) cleared simultaneously, only use of standard EEG equipment meeting existing FDA regulations and ACNS guidelines is acceptable. Technical standards recommended by the American Clinical Neurophysiology Society (ACNS) and the International Federation of Clinical Neurophysiology (IFCN) should form the basis for selection of clinical EEG equipment [Ref. ACNS Guidelines].

2.1 Head position:

Since the exact information about the relative position of the head with respect to the sensor array is necessary for source localization, an appropriate reliable digitization system has to be used to obtain the positions of fiducial points (usually, the nasion, left preauricular point and right preauricular point) for creating the Cartesian coordinate system of the head and exact locations of the head position indicator (HPI) coils and additional anatomical points facilitating coregistration of MEG data with MRI. Exact and fixed relationships and locations of HPI coils within the Cartesian head coordinate system enables reconstruction of the exact position of the head in the sensor space once their locations are detected based on transient electrical signals that create predefined dipoles coinciding with each coil's location.

Head position measurement is recommended before and after each recording segment (block) to quantify head movement and estimate the quality of the recorded data in the segment.

2.2 Head Digitization:

In preparation for an MEG-EEG study, an established standard digitization procedure commensurate with the MEG system has to be followed strictly as a prerequisite for accurate head localization in the sensor space, continuous head position tracking where available and co-registration of MEG data with subjects MRI for source localization.

2.3 Sampling frequency of the MEG system has to be set in advance in order to ensure adequate acquisition of the signals of interest. The frequency of a low pass filter (LPF) applied to the data prior to digital conversion less than one third of the sampling frequency is recommended to avoid aliasing. A high pass filter (HPF) is usually required to minimize effects of large low-frequency signals.

2.4 Real-time monitoring of data quality: The waveforms for an adequate number of MEG and EEG channels should be displayed for real-time monitoring during the measurement. It is recommended to have displays that also include EOG, ECG and EMG channels.

2.5 Temporal synchronization of data: The clock for all the recorded signals has to be exactly synchronized during recording.

2.6 Tuning and calibration routines: Appropriate tuning and calibration routines have to be followed regularly according to the particular MEG and EEG systems used for recording. A phantom calibration as part of the check out each morning before a clinical study may be most appropriate routine if feasible.

2.7 Acquisition of Anatomical Image

Volumetric MRI of a scanned subject of sufficient clinical quality should be used for integration of neurophysiologic data with anatomical images. The volumetric MRI field of view must include the “whole head” with the entire nose (including the tip), ears and vertex in order to allow optimal selection of cardinal points and overall coregistration MEG data with MRI.

The co-registration method of MEG and anatomical images will vary depending on the type of MEG system and software package used.

3.0 Safety precautions and subject comfort issues:

All provisions for subject safety including access, equipment, its regular and emergent operations, personnel qualifications and competencies and access to emergent medical care have to be implemented and have passed Department of Health inspection as appropriate.

Attention has to be paid to the patients' comfort that also may significantly affect the quality of recording. Standard approaches used for neurodiagnostic testing procedures should be implemented.

Suitable level of **sedation** including **general anesthesia** are considered appropriate when necessary to obtain an adequate clinical MEG-EEG recording. It is implied that these procedures are always performed by physically present specialized medical team that includes an anesthesiologist physician and/or other licensed provider capable of handling all possible outcomes of sedation according to the current standards of care and institutional policies. MEG-EEG team should not be a part of this team that has a complete autonomy in making clinical decisions deemed in patient's best interest and commensurate with the current standard of care.

4.0 Quality Control Of Localization Accuracy:

The localization accuracy of source modeling software must be regularly verified using a phantom signal.

Well-established physiological landmarks such as a short latency component of the SEFs (M20) may be provide additional information for interpreting clinical studies relative to functional localization,

5.0 Data storage and management:

Long term storage and management of MEG-EEG data has to comply with the current regulation pertaining protected health information (PHI), medical records, studies and tests.

Long-term storage of sufficient capacity commensurate with projected annual volume of data with appropriate IT security, back up and data recovery plan has to be available for successful operation. Storage capacity sufficient to immediately receive and store at least 60-minute long recording of spontaneous brain activity acquired at routinely used sampling frequency has to be available before each clinical scan. A scheduled automatic back up of recorded data is recommended.

PREPARATION FOR MEG-EEG RECORDINGS

1.0 Technologists:

Trained MEG-EEG technologists under the supervision of a trained clinical magnetoencephalographer with adequate experience and certification should perform the clinical MEG examination.

2.0 Preparation:

Standard accepted clinical procedure for neurodiagnostic studies has to be followed in preparation for a study. In this context, specific aspects of MEG scanning have to be addressed comprehensively and timely with particular attention to the issues pertaining

sources of artifacts that should be addressed through the standardized screening procedure. MEG-EEG technologist has to be familiar with procedures of preventing and eliminating sources of artifacts, including degaussing procedure and awareness of potential needs for advanced arrangements for turning a medical device off as would be the case with a vagus nerve stimulator (VNS).

3.0 Subject and data monitoring:

Spontaneous MEG-EEG signals change significantly according to the internal state of the patient. Thus, the standard procedures of monitoring the subject and corresponding signals and detailed annotation system analogous to one used in EEG have to be implemented. Unfortunately, current MEG systems do not allow routine real-time annotations as is a routine with EEG systems. This is a critical prerequisite for subsequent accurate analysis, interpretation and reporting by a clinical magnetoencephalographer.

4.0 Introduced magnetic noise and its prevention and removal:

The MEG-EEG technologist must make sure that all sources of magnetic noise are removed. This includes, but is not limited to: ferro-magnetic materials on the subject including clothes and jewelry, hair sprays, make up, etc. Changing routinely into a hospital gown is the best approach that does not preclude occasional needs for a hair wash or skin cleaning before an examination. In cases where sources of unacceptable magnetic noise cannot be removed, such as with dental prostheses, CSF shunts or surgical implants and devices, the MEG measurement may have to be cancelled if approved software for post-acquisition artifact removal is not available. Clinical magnetoencephalographer and MEG-EEG technologist have to be able to make decisions regarding the circumstances when ultimately useful data can be obtained in unavoidably suboptimal recording situations.

5.0 Head circumference measurement:

Due to a fixed head space in a MEG system helmet, it is necessary to measure subjects head using a replica helmet before a study. Alternatively, this can be accomplished during an initial noise screening run, before electrodes are applied. It must be kept in mind that EEG electrodes, particularly used with EEG caps may add to the head circumference and lead to a failure of a study due to inability to position the head appropriately.

6.0 Screening run:

Before the final preparation for a study, it is recommended that a subject gets placed into a recording position for a brief acquisition aimed at screening for sources of artifact.

EXAMINATION OF CHILDREN

1.0 Specifics of recording spontaneous activity in children:

Generally, school age and older children may be sufficiently cooperative to be scanned similarly as adults.

Younger children, uncooperative and/or developmentally delayed children require adjustment in scanning procedure commensurate with a particular clinical situation.

Spontaneous recording during natural **sleep** is a preferred option if attainable since routine MEG-EEG study of spontaneous activity optimally should include sleep and does not require medication.

Utilization of **hypnotics** is not universally accepted as a mean of sleep induction, and should be specifically annotated on the record and/or supporting documentation if used. In the above cases, the presence of a parent or a staff member within MSR may be necessary.

Suitable level of **sedation** including **general anesthesia** are considered appropriate when necessary to obtain an adequate clinical MEG-EEG recording. It is implied that these procedures are always performed by physically present specialized medical team that includes an anesthesiologist physician and/or other licensed provider capable of handling all possible outcomes of sedation according to the current standards of care and institutional policies. MEG-EEG team should not be a part of this team that has a complete autonomy in making clinical decisions deemed in patient's best interest and commensurate with the current standard of care.

2.0 Optimal head positioning:

Particular attention to the head positioning and fixation should be implemented to obtain adequate recordings from children since their small head size leaves a lot of space for significant movements within a conventional whole-head MEG systems developed for adults. Accordingly, the heads of smaller children should be carefully positioned and fixed using soft clothes, non-magnetic padding or non-magnetic jelly-filled padding. For older children it may be preferred to simply center the head in the helmet and fix it appropriately. Information regarding the head position must be appropriately recorded and documented at the time of recording, and this information must be incorporated into the data analysis. Real time head position tracking systems available with some advanced systems is expected to improve dealing with this issue. Currently, the head motion corrections may be required since the head movement can affect the accuracy of signal source estimation.

RECORDINGS OF SPONTANEOUS CEREBRAL MEG-EEG ACTIVITY FOR CLINICAL PURPOSE

1.0 Protocols:

Currently, clinically indicated and accepted MEG-EEG recordings of spontaneous cerebral activity are obtained to detect abnormalities in background cerebral activity and identify *interictal epileptiform discharges* (IIEDs) for the purpose of localization of epileptic foci. MEG recording is not currently indicated for diagnosing epilepsy.

2.0 Monitoring:

Spontaneous MEG-EEG signals change significantly according to the internal state of the patient. Thus, the standard procedures of monitoring the subject and corresponding signals and detailed annotation system used in EEG have to be implemented. Unfortunately, current MEG systems do not allow routine real-time annotations as is routine with EEG systems. This is a critical prerequisite for subsequent accurate analysis, interpretation and reporting by a clinical magnetoencephalographer. If real time annotation on the MEG recording is not available, then a log sheet should be kept of the studies done (spontaneous, evoked response) and any clinical events that occurred (seizure, excessive movement). For later analysis of the recordings it can be helpful to track time each study began, patient state during a spontaneous recording (awake, drowsy, asleep), whether epileptiform discharges occurred and if so their general head region location.

3.0 Simultaneous EEG recording:

It is considered necessary that MEG and EEG are recorded simultaneously as a standard approach when a patient with epilepsy is being evaluated since they provide complementary information and the highest yield when competently combined. It is recommended to record EEG data using a common reference electrode for maximal reviewing and secondary processing flexibility. MEG-compatible (i.e. non-magnetic or minimally-magnetic) EEG electrodes and lead wires should be used according to well-established EEG practice.

Any deviation from this practice should be stated explicitly in the report, including its ramification for clinical interpretation.

4.0 EEG identification of artifacts:

Simultaneous recording of EOG, ECG and at times EMG as established in the field of clinical EEG is recommended standard approach for identifying eye movements, muscle activity, magnetocardiographic (MCG) contamination and monitoring and assessing the subject's general state.

5.0 Video monitoring

Combination of simultaneously recorded video and EEG is the foundation of electro-clinical correlation as the gold standard in clinical epilepsy. Sufficient quality video

recording that includes an overview image and an enlarged head image of the patient synchronized with MEG-EEG is strongly recommended.

6.0 Recording time:

The MEG-EEG recording time of spontaneous cerebral activity should last at least 30 minutes and preferably include both wakefulness and sleep. Longer recording is recommended if IIEDs are insufficiently frequent to allow for reasonably clinical certainty. A repeated study with longer recording time, additional sleep deprivation, antiepileptic drug (AED) manipulation coordinated with patient's epileptologist, sedation, or other clinically acceptable accommodations aimed at increasing diagnostic yield may be necessary.

RECORDING STATES:

Overall, the standards established in clinical EEG field should be followed to the degree that they are compatible with adequate quality of MEG recording.

1.0 Sleep recording:

A sleep recording is an essential part of standard EEG because of activating effect of sleep on IIEDs. Sleep recording is recommended as a standard part of MEG-EEG recording. Although natural sleep is preferable, sleeping pills - with special care towards patient safety - can be used to obtain a sleep state within the limited time for measurement. Utilization of partial sleep deprivation, i.e. limiting amount of sleep to up to 4 hours a night before the MEG study, is recommended as preferred initial mean of attaining sleep.

2.0 Hyperventilation:

Hyperventilation is a standard activating procedure for clinical EEG and may be implemented during MEG-EEG study. However, during hyperventilation, the MEG can be contaminated by large artifacts caused by head movements. Thus, the MEG data immediately following hyperventilation may be most useful.

3.0 Drug activation:

Utilization of pharmacologic means for the purpose of activating IIEDs is not universally accepted. Thus, appropriate expertise, procedure and documentation have to be implemented in these situations.

SPONTANEOUS MEG-EEG DATA ANALYSIS

The standard elements of spontaneous MEG-EEG data analysis include examination of the time series data and the source analysis computations using accepted methods.

1.0 Visual Inspection of Time series:

Visual inspection of time series (“raw data”, original data as collected) is obligatory initial step in analysis of spontaneous MEG-EEG data aimed at identification of artifacts and evaluation of overall data quality and integrity.

2.0 Filters:

Use of appropriately selected filters is necessary to eliminate irrelevant biological signals and the inherent noise of MEG system and environment.

Particular selection of a high-pass, low-pass, band-pass and notch filters depend on specific analytical routine and utilized MEG system. Utilization of particular filter settings requires appropriate conceptual understanding of the filtering method and full competency in their practical use.

Most current analytical routines utilized for analysis of spontaneous MEG-EEG data for localization of epileptic foci may benefit from using HPF of 1-4 Hz and LPF of 40-60 Hz.

3.0 Artifact removal software:

Some modern MEG systems are delivered with proprietary **software for noise elimination** based on different methods and with variable capabilities. FDA 510(k) cleared software should be used exclusively. Appropriate understanding of the method and consequences of its use is necessary regardless of the method.

READING OF MEG-EEG RECORDING OF SPONTANEOUS CEREBRAL ACTIVITY:

1.0 Visual examination of spontaneous activity:

Initially, the waveforms for the entire MEG-EEG recording should be visually examined and the standard principles of reviewing clinical EEG, including vocabulary and waveform definitions should be applied in reporting.

When IIEDs are identified, their morphologic and temporal characteristics in MEG and EEG should be evaluated and reported.

2.0 Generator Source Analysis

2.1 Introduction:

Generator source analysis is used for estimating primarily the location of sources of neuromagnetic activity based on measured spontaneous cerebral activity.

Classically defined IIEDs are utilized for this purpose.

2.2 Assessment of Magnetic Isofield Map:

Evaluation of a magnetic isofield map at selected time point is necessary for estimating the number of generator sources and their spatial distributions. This evaluation should reflect the type of sensor coils in a particular MEG system.

When the magnetic isofield map at a selected time point has a dipolar pattern resembling the theoretical standard, including the central location of a dipole vector on the dipole contour map, a single ECD can be used as an estimate of a generator source. Otherwise, multiple ECD analysis has to be implemented.

It is useful to view maps sequentially over the time course of the spike. If during a single phase of the spike, its magnetic field rises and falls, but does not rotate or change shape, one can assume a stable MEG source. If the field rotates during a single spike phase, the MEG source may be propagating.

2.3 Head modeling for ECD source analysis:

Current accepted clinical standard for the head model is a simple sphere.

A head model is based on the subject's volumetric MRI and has to be defined according to established routine commensurate with competent understanding of FDA 510(k) cleared software package utilized with a MEG system.

To minimize fitting errors, the sphere definition should include as large portion of the area of interest as possible. It is legitimate to utilize different spheres for the same subject in order to model multifocal sources that are not confined to the same general region.

2.4 Single Equivalent Current Dipole Model Analysis:

The equivalent current dipole (ECD) model is currently accepted standard method for modeling sources of IIEDs when analyzing spontaneous MEG data acquired for the purpose of localization of epileptic foci. Software utilized for source localization has to be FDA 510(k) cleared.

2.5 Multiple ECD analysis:

When an isofield map suggests the presence of multiple ECD generator sources, ECD estimation should be performed by selecting subsets of channels associated with each ECD generator source, as long as their locations are sufficiently separated from each other. Software utilized for source localization has to be FDA 510(k) cleared.

2.6 Interpretation of ECD results:

When interpreting ECD results, it must be considered that an ECD is theoretical simplified representation of activity over an area that can't be inferred as can't be coexistence of multiple closely spaced sources that can't be resolved as separate sources.

Selecting specific channel groups for the purpose of modeling a particular individual source or a part of complex source is legitimate approach of biasing, but it must be considered that an inappropriate channel selection can lead to an incorrect source estimation

2.7 Analysis points in the IIED waveform:

Selection of analysis points in the IIED waveform has to be according to the defined standards: the initial peak, the onset of a peak or a time point between the two can be fitted. It is preferred to select large-amplitude peaks with a high S/N ratio since this minimizes the calculation errors.

If an assessment of sequential field maps over a single spike phase shows no rotation, one can assume a stable source and model only at the spike peak for greatest S/N. If field rotation is evident, it is useful to model time points before and after the peak to identify possible propagation. Note that modeling time points off the peak will mean lesser S/N and a larger confidence volume. This requires a more careful interpretation of the results.

2.8 Reliability of the single ECD assumption:

Parameters commensurate with source modeling software (goodness of fit, total error, coefficient of correlation, and confidence volume) provide additional measures of the appropriateness of applying the single ECD to model given MEG data. For example, goodness of fit (GOF) above 70% is one frequently used criterion. However, none of these parameters as a sole guarantee the appropriateness of the model. Only competent implementation of all indicated recommendations increases the likelihood of correctness of the entire analytical procedure.

2.9 Multiple dipole estimation:

When multiple dipolar patterns are recognized in a magnetic isofield map, multiple-dipole estimation methods such as the 2-dipole method should be implemented. Implementation of multiple dipole methods and interpretation of the results implies sufficient methodological and clinical competency.

2.10 Analysis methods other than the dipole model:

While widely validated in research setting, other methods for source localization, including dipole scan models, distributed dipole models, beamformer models and others are not widely clinically accepted. Thus, these methods can't be recommended as a current standard, and if used, it has to be in addition to competently implemented ECD method, regardless of software utilized that has to be FDA 510(k) cleared. A MEG-EEG report has to clearly reflect methods used in data analysis.

3.0 Coregistration of MEG findings with Brain MRI:

Referring physicians should receive the results presented in the form of magnetic source images (MSI) that contain accepted source localization co-registered with the subjects brain MRI.

Methods of co-registration depend on MEG system and additional software utilized for source localization. Any reliable, accurate and established method of co-registration may be implemented.

GENERAL RECOMMENDATIONS FOR ANALYSIS OF EPILEPTIFORM ACTIVITY

1.0 IIED analysis:

Source localization of all IIEDs that include epileptic spikes (20-70 ms) and sharps (70-200 ms) is recommended as standard approach for investigation of epileptogenic foci. Clinical significance of all IIEDs is equivalent, but many magnetoencephalographers may be relying only on “spikes”.

Morphology and temporal characteristics of visually identified IIEDs and particularly those with accepted ECD models should be reported.

2.0 Assessment of Magnetic Isofield Map:

Evaluation of a magnetic isofield map at selected time point is necessary for estimating the number of generator sources and their spatial distributions. This evaluation should reflect the type of sensor coils in a particular MEG system.

When the magnetic isofield map at a selected time point has a dipolar pattern resembling the theoretical standard, including the central location of a dipole vector on the dipole contour map, a single ECD can be used as an estimate of a generator source. Otherwise, multiple ECD analysis has to be implemented.

It is useful to view maps sequentially over the time course of the spike. If during a single phase of the spike, its magnetic field rises and falls, but does not rotate or change shape, one can assume a stable MEG source. If the field rotates during a single spike phase, the MEG source may be propagating.

If an assessment of sequential field maps over a single spike phase shows no rotation, one can assume a stable source and model only at the spike peak for greatest S/N. If field rotation is evident, it is useful to model time points before and after the peak to identify possible propagation. Note that modeling time points off the peak will mean lesser S/N and a larger confidence volume. This requires a more careful interpretation of the results.

PCA and ICA can be useful for verifying the visual inspection method in a more quantitative way.

3.0 Current Moment:

In analysis of the IIED, the current strength (a dipole moment) of the estimated single ECD may be helpful in determining the appropriateness of the model and not the specific properties of the source, if close adherence to using an equivalent current dipole model appropriate for the number of sources in the topographic map has been followed.

It is recommended that ECDs with an estimated current strength (a dipole moment) between 50 and 500 nAm get accepted as valid models of potentially clinically relevant sources, and those outside of this range rejected as indicative of an estimation error.

Clinical interpretation of accepted ECDs requires adequate competency and is not limited to any single parameter.

4.0 Anatomical and Physiologic plausibility of ECD model

The ECDs meeting the above requirements (1.0-3.0) have to meet the requirement of anatomical and physiologic plausibility in order to be ultimately accepted.

5.0 Number of spikes:

Number of IIEDs is a very important indicator of epileptic disease and may have a predictive value for surgical outcome in certain patient groups. However, methods of spike quantification are not established even in clinical epilepsy.

Currently, MEG-EEG is used to clarify and/or establish localization of epileptic foci. For this purpose, sources for at least 5 (10) spikes should be reported. There is no definitely established number of necessary spikes, but current practice of clinical MEG suggests that the number of data points should be increased according to the degree of distribution of epileptic foci (focus).

Absolute (if small) or relative (if large) number of spikes should be reported, along with relative reliability of focus definition and possible need for an additional study customized to increase the frequency of IIEDs using established methods that are indicated above.

Spike Averaging: Averaging a number of similar spikes will improve the S/N and reduce the confidence volume. Only spikes that are nearly identical with similar field maps and field map evolution should be averaged.

6.0 Spike clusters:

Various degrees of spike clustering may be a useful parameter for assessing number and relative activity of epileptogenic foci, but do not necessarily indicate their exact locations. The lack of clustering should not be interpreted as a quantitative indicator of source extent but rather the degree to what they can be specified.

Currently, there are no widely accepted standards for interpretation of spike clustering.

7.0 Spike orientation:

Consistent spike orientation may be suggestive of a specific source location. Spikes that are modeled with dipoles having a consistent orientation as well as location are likely to have a single cortical source. Dipole orientation is in general orthogonal to the net orientation of the source cortex. Dipole orientation can therefore be used to identify the most likely source cortex in the region of the dipole. If there is no cortex of appropriate orientation near a model dipole, the accuracy of the model should be questioned. Final interpretation of spike orientation must be considered in the context of particular clinical reality.

8.0 Comparative Analysis with EEG:

Simultaneously recorded EEG serves several purposes in MEG/EEG analysis. EEG can be more quickly reviewed for obvious IIEDs given the lesser number of channels. This can shorten the time necessary to find MEG spikes for modeling. However, because some MEG spikes do not have an EEG correlate, the MEG should be reviewed separately and completely. Conversely, some EEG spikes that have a radial field will not have an MEG correlate. EEG review can also identify epileptiform “normal variants” that should not be considered pathological. The relative timing of MEG versus EEG spikes can be useful in characterizing propagation. If an EEG spike or spike peak follows that of the MEG, propagation from a tangential source to a radial source is likely. If the MEG spike lags that of the EEG, propagation from a radial to a tangential source is likely.

9.0 Analysis of slow wave activity: Should this be addressed?

MEG-EEG REPORTING:

[Should this be a separate guideline?]

MEG-EEG reporting guidelines are not meant to represent rigid rules but only a general guide for reporting MEG-EEGs. They are intended to reflect standard MEG-EEG recordings rather than to special procedures. When reporting on more specialized types of records, description of technical details should be more complete than in the case of standard recordings.

The report of a MEG-EEG should consist of the following principal parts: 1. Patient information and history, 2. MEG-EEG acquisition, 3. Methods of analysis of spontaneous activity, 4. Description of the record with significant MEG and EEG findings, and 5. Interpretation, including (a) impression regarding its normality or degree of abnormality, and (b) correlation of the MEG-EEG findings with the clinical picture.

MEG-EEG report has to be evaluated, approved and signed by a credentialed clinical magnetoencephalographer with no exceptions.

Susan Bowyer

ACMEGS Practice Guidelines Committee – Reports on Language

Susan Bowyer, Ph.D.

Henry Ford Hospital, Neuromagnetism Laboratory, Detroit, MI

2.6. Language-Related Brain Magnetic Fields (LRFs)

Linguistic stimuli presented acoustically or visually result in language-related responses (late responses) in addition to primary auditory and visual responses (early responses). Language-related magnetic fields (LRFs) appear after the primary sensory components (Papanicolaou et al. 1999, Zouridakis et al. 1998) and are localized to language-related areas of the brain regardless of the modality of stimulus presentation (Papanicolaou et al. 1999). LRFs are repeatable (Breier et al. 2000, Papanicolaou et al. 1999). Laterality of the language areas, as measured by MEG, corresponds to results from the Wada procedure (Breier et al. 1999, Bowyer et al. 2005b, Hirata et al. 2004, Kober et al. 2001b, Maestu et al. 2002, Simos et al. 2000) and intracranial recordings (Papanicolaou et al. 1999, Simos et al. 1999b). Most studies of LRFs have focused on receptive language areas, while expressive language has been localized in frontal (Bowyer et al. 2004, Bowyer et al. 2005b, Castillo et al. 2001) and basal temporal areas (Bowyer et al. 2005a). The primary clinical application of LRFs is to determine the language-dominant hemisphere (Breier et al. 1999, 2000, Hirata et al. 2002, Kober et al. 2001a, Näätänen et al. 1997, Papanicolaou et al. 1999, Papanicolaou et al. 2003, Salmelin et al. 1994, Simos et al. 1998, Simos et al. 1999b), which is particularly important since significant changes can be induced by anatomical and functional disorders (Breier et al. 2005, Maestu et al. 2004, Papanicolaou et al. 2001, Pataraia 2004b, Simos et al. 1999a, 2000). Results from numerous studies suggest that LRF studies may replace the language portion of the semi-invasive Wada procedure (Papanicolaou et al. 2004, Bowyer et al. 2005b, Merrifield et al. 2007, Hirata et al. 2004).

Recordings of LRFs may be clinically indicated i) for determining the language dominant hemisphere in patients with either organic or functional brain diseases before surgical interventions such as craniotomy (Ganslandt et al. 2004, Simos et al. 1999a, 1999b), stereotactic (Grummich et al. 2006) or radiosurgical procedures (Aoyama et al. 2004), and/or ii) when objective functional evaluation of language fields is required (Breier et al. 2003, Heim et al. 2000, Helenius et al. 1999, Simos et al. 2002, Szymanski et al. 2001).

5.5. Recordings of Language-Related Magnetic Fields (LRFs)

5.5.1. LRF sources: Long latency responses (more than 200 ms) evoked by language stimulation contain activity arising from language areas, independent of the method of stimulation, auditory or visual. Such responses are enhanced when attention to the task is displayed. The signal sources are typically derived from Wernicke's language area (superior temporal gyrus [Brodmann's area \(BA\) 22](#), angular gyrus BA 39, supramarginal gyrus BA 40) and Broca's language area ([pars opercularis](#) and [pars triangularis](#) of the inferior frontal gyrus BA [44](#) and [45](#)). LRFs are useful for identifying the language dominant hemisphere.

5.5.2. Stimulation: Systems for presenting language stimulation are typically similar to those for eliciting AEFs and VEFs. Identification of the language dominant hemisphere can be easily accomplished by comparing results from language stimulation with non-language stimulation. Enhancement of LRFs can be obtained in a task requiring the subject to recognize or categorize linguistic stimuli. Word comprehension and picture or action naming are activation tasks frequently used.

5.5.3. State variables: Before study of LRFs, it is necessary to confirm that the subject had adequate sleep on the night before the examination, since the state of wakefulness is critical

for the study. The occipital alpha rhythm in spontaneous on-going MEG can be used to monitor wakefulness.

6. Data Analysis

The main parts of MEG analysis are examination of the time series data (spontaneous brain magnetic fields and evoked magnetic fields) and the source analysis computations.

6.1. Time series analysis: It is important to evaluate the MEG waveforms (continuously recorded data or averaged time series data). Observation of the waveforms of all channels makes it easy to detect artifact contamination and to evaluate the S/N ratio.

6.1.1 Use of Filters: Since recorded waveforms normally contain biological signals irrelevant to the analysis, in addition to the system and environmental noise, filters may be used in accordance with the target signals and the purpose of the analysis.

6.1.2 Filter types: In addition to filters such as high-pass, low-pass, band-pass and notch filters, filters specific to a certain system are used. A notch filter may be used when 50 Hz or 60 Hz noise caused by AC power sources cannot be eliminated during the recording. When a high pass filter is applied to filter out low frequency signals, sufficiently long time series data are required. It is preferable that any high pass filter be applied prior to off-line averaging. The pass band, stop band, and band characteristics of the filters should be appropriate for the target signals. Elimination of the direct current component by an offset filter is particularly important when generator sources are estimated based on signal amplitude. To eliminate biological noise such as ECG, noise elimination methods such as principal component analysis and independent component analysis can be used.

6.2. Averaging: When magnetic signals are small, continuously recording data can be averaged off-line to improve the S/N ratio. Averaging over the multiple time epochs is valid only when intracranial events are assumed to be identical (Abraham-Fuchs et al. 1990). Adequate S/N can be typically achieved with a numbers of trials between 50-100 (artifact free).

6.3. Reading of Spontaneous Magnetic and Evoked Magnetic Fields

6.3.1. Visual examination of spontaneous fields: The waveforms for the entire recording period should be visually examined. Similar to the reading of EEG waveforms, the presence or absence of abnormalities in the spontaneous magnetic fields, including the dominant rhythm in the occipital region and paroxysmal activities such as magnetic spikes, sharp waves and slow waves should be noted. When paroxysmal activities are observed, the waveform shapes and the timing relation between MEG and EEG activity should be evaluated.

6.3.2. Replicability of evoked fields: Similar to the standard for evoked potentials, recording of magnetic evoked fields should be repeated at least once to confirm the reproducibility of the response.

6.3.3. Grand averaging: When reproducible waveforms are observed, grand-averaged waveforms from multiple sets of recordings can be used for the generator source analysis. For grand averaging, it should be confirmed that the relative positions of the detection coils and the head are within an acceptable range across all the recording sets. In case of

sufficiently high S/N ratios in each set, the results of the generator source analysis can be used as a proof of reproducibility.

6.4 Spectral analysis of MEG data In parallel to the analysis of EFs/ERFs, the MEG data can be evaluated in the frequency domain in terms of power at single sensors or functional coupling between pairs of sensors (or pairs of sources).

6.4.1. Event-related desynchronization (ERD) and event-related synchronization (ERS):

Event-related desynchronization (ERD) and event-related synchronization (ERS) of EEG or MEG rhythms describe neuroelectric event preceding and following a task execution (Pfurtscheller and Aranibar, 1979; Klimesch, 1999; Pfurtscheller and Lopes da Silva, 1999). ERD/ERS means reduction/increase in EEG power during event (sensory, cognitive, motor) when compared to baseline at a certain frequency band.

6.4.2. Temporal Spectral Evolution (TSE): An alternative procedure frequently used from MEG data is the temporal spectral evolution (TSE) analysis, which provides an index of event-related changes in magnitude of magnetic fields in the physical unit of the recording (Hari et al., 1997).

6.4.3. Coherence: The functional coupling of brain rhythms, spectral coherence analysis indexes the temporal synchronization of two EEG or MEG time series (i.e. relative to two sensors or brain imaged locations) in frequency domain (i.e. frequency-by-frequency), and helps to assess linear functional cortico-cortical connectivity. In general, decreased coherence indexes reduced linear functional connections and information transfer (i.e., uncoupling) between cortical areas beneath the paired electrodes or a modulation of common areas by a third region. In contrast, coherence increase is interpreted as augmented linear functional connections and information transfer (i.e. coupling), which reflects a functional interaction of different cortical structures for a given task.

6.5. Generator Source Analysis

6.5.1. Data for Generator Source Analysis: Generator source analysis is defined as a method for estimating the sources of electrophysiological activity of the brain based on measured spontaneous and evoked magnetic fields. For assessment of spontaneous and evoked magnetic fields, background magnetic fields and the baseline activity before stimulation are used as a baseline, respectively. Source estimation is performed at time periods when there are significant deviations from the baseline activity.

6.5.2. Assessment of Magnetic Isofield Map: Assessment of a magnetic isofield map at any time point is useful for estimating the number of generator sources and their geometric distributions. The magnetic isofield map reflects the amplitudes of the signals across the detector array at a particular time slice. In determining the signal amplitudes, it is necessary to remove the direct current component and frequency components irrelevant for analysis.

6.5.2 Direct current component: For eliminating the direct current component, an averaged value can be used over a selected time period either before or after the target signal in which no effects from the target signal are present. When the entire spontaneous activity recording is long in comparison with the period to be analyzed, the entire recorded period can be used for elimination of the direct current component. Similarly, for an averaged steady-state

response, the entire averaged period can be used for calculation of the direct current component.

6.5.3. Number of maxima and minima: For data recorded with a magnetometer or an axial gradiometer, the number and the position of the outward and inward magnetic field maxima should be noted. For planar gradiometer data, the number of gradient maxima and the direction of the magnetic field vector at the maxima should be noted.

6.6 Single Equivalent Current Dipole Model Analysis: The equivalent current dipole (ECD) model assumes that a pair of positive and negative current charges exists in close proximity in the brain. The theoretical distribution of the magnetic fields produced by an ECD is called a dipolar pattern (Williamson and Kaufmann, 1981).

6.6.1. Indications for Single Equivalent Current Dipole Model: When the magnetic isofield map at a given time point shows a dipolar pattern similar to the theoretical one, a single ECD can be used as an estimate of a generator source (Brenner et al. 1978, Hari et al. 1988).

6.6.2. Multiple ECD analysis: When an isofield map suggests the presence of multiple ECD generator sources, ECD estimation can be performed by selecting subsets of channels associated with each ECD generator source, as long as their locations are sufficiently separated from each other.

6.6.3. Interpretation of ECD results: In interpreting ECD results, it must be kept in mind that a generator source actually represents activity over an area and that multiple generator sources too close to be resolved can be modeled as a single generator source (Hari, 1991, Mikuni et al. 1997, Oishi et al. 2002a). Even when the generator sources are sufficiently separated, with distinct dipolar patterns, ECD modeling can result in an incorrect estimation if an inappropriate channel group is selected.

6.6.4. Virtual sphere definition: Estimation of a generator source using the single ECD assumes either a realistic head model or a simple model that treats the brain as a sphere. For clinical MEG, the simple sphere model is normally used (Hamalainen et al. 1987, Sarvas, 1987, Yamamoto et al. 1988). The sphere is defined so that it contains a large portion of the area of interest in the brain obtained by anatomical measurements with a minimum fitting error.

6.6.5. Analysis points in the waveform: Analysis points in the waveform must to be selected in accordance with defined standards. In the case of evoked magnetic fields, the peak is normally used for assessment. In case of epileptiform discharges, the initial peak is normally used. The origin of abnormal waves can be estimated by selecting time points near the onset of a peak if there is a good S/N ratio. However to minimize the calculation error, a large-amplitude peak with a high S/N ratio should be selected.

6.6.6. Reliability of the single ECD assumption: Parameters such as goodness of fit, total error, coefficient of correlation, and confidence volume can be used to measure the appropriateness of applying the single ECD to the MEG data. It should be noted, however, that although assessment indexes can be used to indicate low reliability, high approximation parameters do not guarantee the appropriateness of the model.

6.7. Multiple dipole estimation: When multiple dipolar patterns are recognized in a magnetic isofield map, multiple-dipole estimation methods such as the 2-dipole method can be used (Scherg et al. 1996).

6.7.1. Risk of multiple dipole estimation: Increasing the number of estimated dipoles increases the risk of the ECDs being trapped to a local minimum. When multiple sources and analysis periods are spatiotemporally close, it is generally difficult to apply the multiple dipole estimation.

6.8. Analysis methods other than the dipole model: To estimate multiple generator sources, currently developed methods such as spatial filtering with Beamformers (Huang et al 2007), L1 norm (Uutela K et al. 1999), L2 norm Ilmoniemi et al. 1985) or MR-FOCUSS (Moran et al 2005) are available. To obtain a measure of localized cortical activity, spatiotemporal filtering techniques have also been implemented. When the estimation methods other than the dipole method are used for the analysis of clinical MEG, the results by the conventional dipole model should also be documented.

6.9. Coregistration with Anatomical Brain Images: Clinically useful information can be obtained by overlaying the estimated generator sources on various brain anatomical images. MRI is the most commonly used brain anatomical image for superimposition, but other images may be useful. Any method of superimposition with the brain anatomical images can be used if it results in precise superimposition.

ACMEGS Practice Guidelines Committee – Report on Evoked Fields

Richard Burgess, M.D., Ph.D.

Neurological Institute's Epilepsy Center, Cleveland Clinics, Cleveland OH

AMERICAN CLINICAL MEG SOCIETY --- DRAFT GUIDELINES
Evoked Fields, Excluding Language Evaluation
(Task Force: Richard Burgess, Michael Funke, Heide Kirsch)

Introduction and philosophy

It is indeed a propitious time for us to be promulgating guidelines for MEG evaluations -- and to practice according to them. The main reasons, of course, are the usual ones: a crying need to ensure that labs MEG labs are adhering to good practice, a desire for systematic comparison across labs and in multicenter studies that demand consistent practices, and some minimal standards that both lab directors and payors can point to. But this era in particular is especially demanding of bodies providing guidance about what constitutes good practice.

With health care reform high on the list of federal priorities and no money to spend on it, there will certainly be added scrutiny focused on new and expensive procedures. If there is a perception that the field does not quite have its act together or has not produced quality results, then there will be considerable risk of loss of clinical funding. The very existence of voluntarily-produced and expertly reviewed guidelines demonstrates a level of professionalism and maturity that establishes a baseline of clinical credibility.

There are some initial philosophical questions that our group attempted to grapple with in order to create some context for our guidelines. These questions, and some brief summaries of our answers, are included below:

1) Who is the target audience? Current practitioners of the MEG art? Trainees and those who educate them? Administrators and dept chairman at hospitals considering establishing a MEG lab? Payors?

The guidelines are not meant to be a how-to manual for magnetoencephalography. They are aimed at those already trained in MEG who are responsible for insuring that their laboratory is conducting high-quality studies that are considered standard-of-practice. Our guidelines do not address training or credentialing of personnel involved in acquisition or analysis of MEG evoked fields. The guidelines are meant to answer the specific questions that insure some level of uniformity across laboratories.

2) Are these guidelines meant to be "minimal standards" or "best practices"?

ACMEGS was formed, in part, to advocate for best practices in magnetoencephalography so that high-quality clinical answers are delivered, MEG testing becomes even more sought-after, and reimbursement is commensurate. Therefore, the guidelines are designed to recommend excellent standards of practice --- not minimal requirements. Not all laboratories are equipped the same, either in terms of their instrumentation or their operation, naturally, so not all laboratories can be expected to do things exactly the same way. We should assume that eventually these standards will evolve into "best practices."

3) Shall we include only CMS-approved clinical studies, or provide more general guidance that can be extrapolated to the conduct of research studies?

Educational endeavors, by ACMEGS as well as by other organizations and universities, will provide the foundation for extending MEG studies into many realms of investigation. The guidelines, however, should focus on established areas where it is known that MEG works well. MEG's strength, and the primary reason for referral of patients to the MEG lab, is in *localization*. It is on the capability for localization of the evoked activity that the guidelines focus, rather than on typical normal/abnormal decisions that depend on a normative database (not available for MEG data) for latencies and amplitudes (as in traditional EP studies).

4) What are the assumed technical standards for the equipment that we expect to be employed in this application? Do we need to specify, or leave to others?

As everyone is aware, shake-ups have recently occurred in the MEG industry. MEG recording systems are not commodities, and MEG analysis packages are not uniform. We chose to restrict ourselves to whole-head systems, as these certainly are the standard for clinical use, but we expect that more advanced specifications, such as acceptable noise performance or adequate ADC resolution, will continue to evolve. Given the enormous capital costs of MEG apparatus, it is not reasonable to expect replacement or upgrade frequently.

Most of the philosophical ramblings contained in these guidelines are inappropriate and too lengthy to be included in published documentation. For the members of the Guidelines Working Group, however, we felt it important to include this contextual material in the initial draft.

Background and Prior Art

It is our group's opinion that version #6 of the ISACM guidelines, based mainly on the 2004 paper from the Hashimoto group at the Kanazawa Institute, set recommendations at a very low level. Due to the lack of detail, newcomers attempting to establish clinical services for their MEG laboratory would most likely find these recommendations inadequate. The recent announcement of the Papanicolaou book indicates that the published guidelines might be slightly different in structure than version #6.

A stark contrast to those are the ACNS guidelines which are very detailed and precise. Indeed in the traditional areas of clinical neurophysiology (EEG, EMU, EP, etc) some of the ACNS guidelines are employed for credentialing, certification, or are cited in malpractice cases. There are preliminary efforts underway to form a closer cooperation between the ACMEGS and ACNS. While it is early in MEG's introduction into clinical practice, there is considerable merit to strive towards eventual guidelines of the caliber of the ACNS's.

Practice Recommendations for MEG Evoked Fields

General Indications for MEG Evoked Fields

Like other laboratory tests, it is important that clinicians involved in MEG acquisition and interpretation have clear ideas about the indications for the various modalities of testing. If it is not clear what clinical question is to be answered by the MEG EF, or if the referral does not seem to have an adequate purpose, the MEG clinician or laboratory director should telephone the requesting physician to obtain additional information and to ascertain that MEG is being appropriately employed.

Somatosensory evoked fields

Indications

- Localization of somatosensory cortex (in situations with rather large abnormalities, such as cystic encephalomalacia, polymicrogyria etc., or smaller caliber abnormalities in vicinity of the expected central region).
- Localization of the central sulcus (in conjunction with motor evoked fields).
- Biological quality check of coordinate transformation.

Stimulation

- Sites of electrical stimulation frequently used in clinical SEF examination include the median nerve and tibial nerve, mechanical stimuli can be used for fingers, lips, tongue and other regions of the body
- Electrical stimulation
 - Active electrical devices need to be FDA approved, optical isolators
 - Stimulus parameters (constant current 6-10 mA, constant voltage, durations 100 μ s, monophasic rectangular pulse)
 - Somatosensory stimulus amplitude should be individualized, based on exceeding the motor threshold (i.e. should produce a clearly visible twitch).
 - Stimulation electrode impedance should be 5 K Ω or less
 - Stimulus frequency should not be higher than 5/sec even if multiple stimulation sites are used (like both median and both tibial nerves in randomized fashion, patient comfort)
- Mechanical stimulation
 - Tactile stimulation does not produce results which are as reliable as electrical stimulation
 - Devices include air puffs, pressurized bellows (sometimes incorporated into specialized gloves), and other electrically triggered devices. However they may be advantageous in infants and toddlers or in patients with impaired cognition.

Recording (based on electrical stimulation)

- Bandpass 0.03 – 200 Hz with a digitization rate of at least 600 Hz. A bandpass extending up to 300 Hz with a digitization rate of at least 1000 Hz is preferred to facilitate post-processing of the raw data.

- Recording the raw data should be mandatory, real-time average optional. Averaging off-line after data collection permits noise reduction processing and manual or automatic artifact rejection.
- Epoch duration -50 ms to 250 ms. Additional pre-stimulus baseline (e.g. back to -100 ms) may be useful for off-set correction.
- Stimulus channel indicators: raw data should indicate stimulation triggers accordingly labeled and one should be able to deselect undesirable trials or channels
- Jitter less than 10 microseconds
- Head position measurement should be carried out prior to each ensemble or data block. Use of continuous head position tracking is preferred where available.
- Two replications mandatory.

Averaging (based on electrical stimulation)

- Optional real-time averaging can be helpful in order to obtain an estimate of the SNR.
- Recording of the raw data should be mandatory, and the analysis system must permit post-hoc averaging
- The analysis system must permit inspection of raw data
- 200 - 500 trials per stimulus location are required in order to acquire an adequate number of acceptable repetitions (usually at least 200).
- Off-line averaging after data acquisition permits elimination of artifact-containing traces and judicious selection of bandpass filtering (typically 4-9 hz to 100 hz).
- During source analysis computations, the location of the N20m and or P35m peaks should be fitted and their quality assessed by the localization difference within a single ensemble (usually no more than 2-3 mm).
- Ensemble replications should differ from each other by less than 5 mm for N20m and P35m localizations.

Motor evoked fields

Indications

- Localization of primary motor cortex in situations with rather large abnormalities (cystic encephalomalacia, polymicrogyria etc., or smaller caliber abnormalities, space demanding processes in vicinity of the expected central region).

Activity

- Motor functions evaluated and timing fiducial
 - finger tapping, self paced, light-beam interruption
 - finger tapping, cued (visually, auditory) light-beam interruption,
 - repeated contractions with EMG onset as time mark for averaging
 - isometric contraction, simultaneous EMG

Recording

- Bandpass 0.03 – 200 Hz with a digitization rate of at least 600 Hz. A bandpass extending up to 300 hz with a digitization rate of at least 1000 Hz is preferred to facilitate post-processing of the raw data.

- Recording the raw data should be mandatory, real-time average optional. Averaging off-line after data collection permits noise reduction processing and manual or automatic artifact rejection.
- Epoch duration
 - finger tapping, self paced, -100 ms to 250 ms
 - finger tapping, cued (visually, auditory), -100 ms to 250 ms
 - repeated contractions with EMG, -100 ms to 300 ms
 - isometric contraction, 240 s of isometric contraction (with short interruptions permitted)
- Stimulus channel indicators, raw data should indicate stimulation triggers accordingly labeled
- Head position measurement should be carried out prior to each ensemble or data block. Use of continuous head position tracking is preferred where available.
- The arousal state of the subject must be checked as it is important for execution of test
- No silent counting, it eliminates the Bereitschafts-potential
- Two replications mandatory

Averaging

- Optional real-time averaging can be helpful in order to obtain an estimate of the SNR
- Recording the raw data should be mandatory, and the analysis system must permit post-hoc averaging
- The analysis system must permit inspection of raw data
- Off-line averaging after data acquisition permits elimination of artifact-containing traces and judicious selection of bandpass filtering (typically 1-25 Hz for finger-tapping tasks).
- Required averages
 - finger tapping, self paced, 100 each left and right
 - finger tapping, cued, 50 each left and right
 - repeated contractions with EMG, 100 each left and right
 - isometric contraction, calculating cortico-muscular coherence
- Source analysis computations
 - finger tapping, pre-motor field approximately 30 ms before movement onset
 - finger tapping, pre-motor field approximately 30 ms before movement onset
 - repeated contractions with EMG, pre-motor field approximately 30 ms before movement onset
 - isometric contraction, coherence peak at 20 Hz
- Habituation and boredom often limit the replications of a motor task that can be done by a subject.

Auditory evoked fields

Indications

- Localization of primary auditory cortex on the superior temporal gyrus

- Assessment of hearing in children
- In contrast to electrical auditory evoked potentials, the early latency signals (BAEP) are not well recorded by MEG.

Stimulation

- Tones, typically 1000 Hz, presented monaurally
- Parameters 80 dB SPL, 25-500 ms duration, 1 s ISI, Jitter less than 100 microseconds
- Contralateral white noise masking at 40 - 50 dB

Recording

- Bandpass 0.03 – 200 Hz with a digitization rate of at least 600 Hz. A bandpass extending up to 300 Hz with a digitization rate of at least 1000 Hz is preferred to facilitate post-processing of the raw data.
- Recording the raw data should be mandatory, real-time average optional. Averaging off-line after data collection permits noise reduction processing and manual or automatic artifact rejection.
- Epoch duration -200 ms to 1000 ms.
- Stimulus channel indicators: raw data should indicate stimulation triggers accordingly labeled and one should be able to deselect undesirable trials or channels
- Head position measurement should be carried out prior to each ensemble or data block. Use of continuous head position tracking is preferred where available.
- Patient must be awake.
- Two replications per ear mandatory.

Averaging

- Optional real-time averaging can be helpful in order to obtain an estimate of the SNR.
- Recording of the raw data should be mandatory, and the analysis system must permit post-hoc averaging
- The analysis system must permit inspection of raw data
- Include 100 trials per average.
- Off-line averaging after data acquisition permits elimination of artifact-containing traces and judicious selection of bandpass filtering (as narrow as 1-30 Hz)
- Localize the N100m component of the AEF

Visual evoked fields

Stimulation

- Typically generated using specialized computer connected with image shown on a back-projection screen.
- In order to eliminate partial-visual-field effects, computer graphics output cards and projectors must be specially chosen for fast response.
- In order to eliminate timing errors or jitter (due to uncertainty of timing from computer, raster refresh rate, etc), a timing synch pulse (either from the stimulus

PC or from an independent indicator such as a photocell) must be recorded by the MEG system that is accurate to within 1 msec.

- Place screen at 100 cm from cornea.
- A fixation point should be provided.
- Contrast, luminance, should be adjusted as for conventional scalp VEP
- Check size and field size should be governed according to conventional scalp VEP guidelines

Recording

- Bandpass 0.03 – 200 Hz with a digitization rate of at least 600 Hz. A bandpass extending up to 300 Hz with a digitization rate of at least 1000 Hz is preferred to facilitate post-processing of the raw data.
- Recording the raw data should be mandatory, real-time average optional. Averaging off-line after data collection permits noise reduction processing and manual or automatic artifact rejection.
- Epoch duration -50 ms to 250 ms. Additional pre-stimulus baseline (e.g. back to -100 ms) may be useful for off-set correction.
- Stimulus channel indicators: raw data should indicate stimulation triggers accordingly labeled and one should be able to deselect undesirable trials or channels
- Jitter less than 50 microseconds
- Head position measurement should be carried out prior to each ensemble or data block. Use of continuous head position tracking is preferred where available.
- Two replications mandatory.

Averaging

- Optional real-time averaging can be helpful in order to obtain an estimate of the SNR.
- Recording of the raw data should be mandatory, and the analysis system must permit post-hoc averaging
- The analysis system must permit inspection of raw data
- 100 trials per average.
- Off-line averaging after data acquisition permits elimination of artifact-containing traces and judicious selection of bandpass filtering (typically 4-9 Hz to 100 Hz).
- During source analysis computations, the location of the N100m.
- Ensemble replications should differ from each other by less than 5 mm for the localization of the N100m.

Interpretation of MEG Evoked Fields

- The primary sensory responses, with latencies similar to scalp EPs, should be identified. The application of MEG-compatible scalp electrodes and simultaneous recording of the scalp EP helps with the identification of the MEG components.
- When careful elimination of individual artifact-containing traces (either automatically or manually) does not produce an adequate average, off-line noise-reduction techniques or more restrictive band-pass filtering can improve the localization.

- These major components should be localized and co-registered with the patient's own MRI. Several source localization techniques exist and may be applied --- as with other MEG signals. The single equivalent current dipole is an adequate model for MEG evoked fields.
- MRI image volumes with a 1mm slice thickness (e.g. MPRAGE or similar) are required for adequate localization. Skin to skin MRI head coverage is necessary for proper co-registration.
- Head position determination and proper coregistration require digitization of head coils, landmarks, and at least 50 additional points distributed over the head.
- Reports should include the following:
 - Patient identification
 - facility name, laboratory name, address
 - test date, test identification number, procedure name
 - requesting physician's name, interpreting physician's name
 - patient name, age, gender
 - Clinical information
 - What is the clinical question
 - Findings that could influence test, patient behavior, sedation
 - Technical data
 - Standard lab settings, stim parameters
 - Volume conductor model, source model, coordinate transformation
 - Results
 - Number of averages, reproducibility
 - Numerical values, pictures
 - Description
 - Deviation from normal location, as well as unusual waveforms etc..
 - Interpretation:
 - Impression normal vs. abnormal
 - Clinical correlation
 - Pictures:
 - Sources/MSI with waveforms that appear to be normal, alone or in combination with other relevant sources (like motor and posterior frontal epileptogenic cluster)
 - For non-primary sensory responses (motor, language), and very abnormal looking signals of primary sensory responses the graphical presentation of waveform should be considered part of the clinical documentation/report

ACMEGS BUSINESS MEETING

1. Financial Report Anto Bagic
2. Mission Statement Michael Funke
3. Position Statement Anto Bagic
4. New Business
 - Webpage
 - Annual Meeting 2010
 - Other

1. Financial Report



ACMEGS
AMERICAN CLINICAL MEG SOCIETY

Financial Report
January – December 2008

Ordinary Income/Expenses


Income

• Conference Registration Fees	\$2,200.00
• Grants	\$21,992.00
• Membership Dues	\$1050.00
• Interest Income	\$0.37

Expenses


• Bank Service Charges	\$136.64
• Consulting	\$5,000.00
• Meals and Entertainment	\$296.49
• Meals for ACMEGS Conf.	\$1,707.15
• Miscellaneous	\$178.25
• Supplies	\$462.45
• Travel	\$2,340.22

Net Income **\$15,121.17**



Current Balance (05/12)

\$20,089.38



Received Membership Dues 2009

- Institutional memberships at \$2,000: 4 \$8,000.00
- "Institutional membership" at \$100: 1 \$100.00
- Individual memberships:
 - Members 4 \$350.00
 - Associate Members 2 \$100.00

Total ***\$8,550.00***



2. Mission Statement

AMERICAN CLINICAL MEG SOCIETY

Mission Statement

ACMEGS strives to ensure that all individuals living in the United States who have neurological conditions receive the highest quality health care by offering magnetoencephalography that is affordable and accepted by insurance providers.

American Clinical MEG Society is a non-profit 501(c)(6) trade association that includes the membership of 21 clinical magnetoencephalography (MEG) facilities in the United States. Founded in 2006 by physicians committed to setting a national standard for high quality care of patients with epilepsy, ACMEGS now advocates for all individuals with neurological conditions who would benefit from MEG by educating policymakers and regulators about current and recommended standards of care, financial reimbursement, and health care provider regulations.

OBJECTIVES

The primary objective of ACMEGS is to support MEG service providers with facility and business operations. This objective is met with the following actions:

- Gathering MEG clinical service providers together for an annual symposium.
- Networking patients, physicians, and health care administrators with MEG providers.
- Acquainting clinical MEG providers with each other for information sharing.
- Educating ACMEGS members and other organizations about varying rules, regulations, and reimbursement matters that affect the success of MEG facilities in the United States.
- Initiating modification of public and private reimbursement policies, coding, legislation, and regulations that govern MEG and the delivery of high quality health care.
- Advocating for improved reimbursement of MEG services, outpatient fees, inpatient care, and technology in both public and private realms.
- Collaborating with American Clinical Neurophysiology Society (ACNS), National Association of Epilepsy Centers (NAES), American Academy of Neurology (AAN), American College of Radiology, American Epilepsy Society (AES), and Epilepsy Foundation (EF) on matters affecting patient care.
- Working with other organizations on new applications of MEG to improve the health of all patients who would could benefit from this technology.

To the benefit of our members, ACMEGS sustains a solid working relationship with public and private organizations that affect access of individuals to MEG and high quality health care: United States Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC) epilepsy program, Joint Commission on Accreditation of Health Care Organization (JCAHCO), and Health Resources and Services Administration (HRSA).

3. Position Statement

ACMEGS Position Statement

The Value of MEG/MSI in Non-Invasive Presurgical Evaluation of Patients with Medically Intractable Localization-Related Epilepsy

The American Clinical MEG Society (ACMEGS) is a professional society of physicians and other professionals with doctoral degrees “involved in clinical use of magnetoencephalography (MEG), electroencephalography (EEG), magnetic resonance imaging (MRI) or computerized axial tomography (CAT)” [ACMEGS, Inc, Bylaws, 2006]. The ACMEGS is primarily focused on advancing clinical applications of MEG, while representing all American MEG centers and individual professionals concerned with clinical MEG. Currently, our membership is comprised of over 50 individual and/or collective members, including the most prominent investigators who have made cardinal contributions to the development of the clinical MEG. A significant proportion of the four-thousand plus, peer-reviewed, MEDLINE publications on “magnetoencephalography” has been authored by members of the American MEG community, including the most sophisticated clinical MEG studies designed and published internationally (Knowlton et al., 2008a, Knowlton et al., 2008b; Sutherling et al., 2008).

Magnetoencephalography (MEG) / Magnetic Source Imaging (MSI) is a modern and powerful technology for studying brain function directly and non-invasively by analyzing magnetic fields induced by synchronized neuronal activity that are recorded outside of the skull (Cohen, 1968; Cohen, 1972; *Rev.* Hamalainen et al., 1993; Okada et al., 1984; Okada et al., 1999). Routinely, MEG can attain a temporal resolution of less than a millisecond and, under optimal circumstances, spatial resolution of several millimeters (Brenner et al., 1975; Hamalainen et al., 1993; Hari et al., 1988; Okada et al., 1984; Okada et al., 1999; Romani et al., 1982). Over the last forty years, MEG instruments have evolved from a single channel portable system to the modern whole head systems with more than 300 channels that are housed in multilayered shielded rooms (MSR)(*Rev.* Hamalainen et al., 1993; *Rev.* Barkley and Baumgartner, 2003). It is now accepted that MEG/MSI can provide clinicians with accurate and critical information regarding the location of important cerebral sources, such as epileptic foci (Ebersole, 1997; Fischer et al., 2005; Iwasaki et al., 2002; Kirsch et al., 2007a; Knake et al., 2006; Knowlton, 2004; Knowlton et al., 2006; Knowlton, 2008; Knowlton et al., 2008a, Knowlton et al. 2008b; Lin et al., 2003; Mamelak et al., 2002; Mohamed et al., 2007; Oishi et al., 2006;; Papanicolaou et al., 2005; Patariaia et al., 2004; RamachandranNair et al., 2007; Rodin et al., 2004; Smith et al., 2000; Stefan et al., 2003; Sutherling et al., 2008; Verrotti et al., 2003), sensory-motor cortex (Alberstone et al., 2000; Brenner et al. 1978; Castillo et al., 2004; Ganslandt et al., 2004; Kirsch et al., 2007b; Korvenoja et al., 2006; Nakasato and Yoshimoto, 2000; Oishi et al., 2003; Okada et al., 1984; Pang et al., 2008), visual (Alberstone et al., 2000; Brenner et al., 1975; Ganslandt et al., 2004; Grover et al., 2006; Nakasato et al., 1996; Nakasato and

Yoshimoto, 2000), auditory (Alberstone et al., 2000; Godey et al., 2001; Nakasato and Yoshimoto, 2000; Romani et al., 1982) and language cortex (Bowyer et al., 2004; Bowyer et al., 2005; Flagg et al., 2005; Ganslandt et al., 2004; Grummich et al., 2006; Hirata et al., 2004; Kamada et al., 2003; Merrifield et al., 2007; Papanicolaou et al., 2004; Papanicolaou et al., 2006; Salmelin, 2007) MEG/MSI findings may be displayed on a patient's MRI or combined with other imaging modalities to form multimodal neuronavigational maps that can be used directly in stereotactic neuronavigation systems during surgery (Duffner et al., 2003; Firsching et al., 2002; Ganslandt et al., 1999; Kamada et al., 2003; Kamada et al., 2007; Nimsky et al., 1999; Rezai et al., 1995; Rezai et al., 1996; Rezai et al., 1997; Ochi and Otsubo, 2008).

Nearly three million Americans are afflicted with epilepsy (Hauser and Hesdorffer, 1990). About thirty percent suffer from seizures that are refractory to medications despite the twenty antiepileptic drugs (AEDs) that are currently available (Brodie, 2005; Kwan and Brodie, 2000). These patients are responsible for eighty percent of the \$12.5 billion annual cost of epilepsy to society (Begley et al., 2001). A significant minority of these epilepsy patients have localization-related or focal epilepsy that may be amenable to surgical therapy (Engel 2003, 2008). Thus, competent estimates indicate that 100,000 to 200,000 patients with uncontrolled epilepsy may be surgical candidates (Engel and Shewmon, 1993; Engel 2003). Epilepsy surgery has been proven to be superior to medical treatment in patients with temporal lobe epilepsy in a randomized controlled trial (Wiebe et al., 2001; Engel et al., 2003; Engel, 2008), and a recent analysis revealed that "the combination of surgery with medical treatment is four times as likely as medical treatment alone to achieve freedom from seizures" (Schmidt and Stavem, 2009). Furthermore, long-term follow up studies showed that many patients that underwent resective brain surgery remain seizure-free (Spencer and Huh, 2008; Téllez-Zenteno et al., 2005, Téllez-Zenteno et al., 2006; Téllez-Zenteno et al., 2007), and that, "in carefully selected patients, epilepsy surgery can control seizures, improve quality of life and reduce costs of medical care" (Kuzniecky and Devinsky, 2007). However, for multiple reasons, epilepsy surgery, the only potential cure for epilepsy (Engel, 2003, 2008; Spencer and Huh, 2008; Wiebe et al., 2001), is offered to only 2-3% of potential surgical candidates (Engel, 2003).

The critical and often rate-limiting factor in epilepsy surgery is functional localization of the epileptic focus that may not be adequately supplied by traditional diagnostic investigations, including EEG, video-EEG (v-EEG) monitoring, MRI, and in some cases PET and SPECT scans (Barkley and Baumgartner, 2003; Engel, 2003; Engel, 2008; Knowlton et al., 2006; Kuzniecky and Devinsky, 2007; Langfitt and Wiebe, 2008; Papanicolaou et al., 2005; Stefan et al., 2003; Wheless et al., 1999). All too frequently these studies fail to identify clearly the seizure focus (Barkley and Baumgartner, 2003; Knowlton et al., 2006; Knowlton, 2008; Knowlton et al., 2008a, Knowlton et al., 2008b; Papanicolaou et al., 2005; Rodin et al., 2004; Stefan et al., 2003; Sutherling et al., 2008). Alternatively, the identified focus is complex, ambiguous, or closely positioned to the eloquent cortices, making surgery dangerous (Barkley and Baumgartner, 2003; Knowlton et al., 2006; Knowlton, 2008; Knowlton et al., 2008a, Knowlton et al., 2008b; Rodin et al., 2004; Stefan et al., 2003; Sutherling et al., 2008). Clinicians uniformly agree that

additional and non-redundant localizing information, preferably acquired non-invasively, are necessary for making clinical decisions in these situations (Barkley and Baumgartner, 2003; Knowlton et al., 2006; Knowlton, 2008; Knowlton et al., 2008a, Knowlton et al., 2008b; Stefan et al., 2003; Sutherling et al., 2008).

The ability of MEG/MSI to fill this diagnostic gap has been demonstrated in numerous published studies (Assaf et al., 2004; Fischer et al., 2005; Iwasaki et al., 2002; Kirsch et al., 2007; Knake et al., 2006; Knowlton et al., 2006; Knowlton, 2008; Knowlton et al., 2008a, 2008b; Lin et al., 2003; Mamelak et al., 2002; Mohamed et al., 2007; Oishi et al., 2006;; Papanicolaou et al., 2005; Patariaia et al., 2004; RamachandranNair et al., 2007; Rodin et al., 2004; Smith et al., 2000; Stefan et al., 2003; Sutherling et al., 2008; Verrotti et al., 2003). In fact, almost seven hundred peer-reviewed MEDLINE publications on “magnetoencephalography” are devoted to “epilepsy”. These have established that MEG/MSI may locate epileptogenic foci, not otherwise identifiable or localizable, in up to thirty percent of patients (Stefan et al., 2003; Sutherling et al., 2008) and clarify the spatial relationships of these foci to eloquent cortices non-invasively (Castillo et al., 2004; Papanicolaou et al., 2004; Papanicolaou et al., 2005; Patariaia et al., 2004). Two recent and meticulously designed studies have proven the usefulness and predictive value of MEG (Knowlton et al., 2008a, Knowlton et al., 2008b). Additionally, the first prospective and blinded study of MEG/MSI demonstrated that non-redundant information that positively affected clinical decision making and proved to be beneficial for the outcome was obtained in thirty-three percent of patients (Sutherling et al., 2008).

The highest standards of clinical care include sound judgment and rational utilization of resources. Therefore, it is inappropriate to use an expensive study, if a more cost effective one provides clinically adequate results. Thus, it is only when traditional EEG studies (routine laboratory, ambulatory and video-EEG long-term monitoring) fail to deliver sufficient localizing information for planning a direct surgical intervention or invasive monitoring that MEG is indicated (Knake et al. 2006; Knowlton, 2008; Knowlton et al., 2008a, Knowlton et al., 2008b; RamachandranNair et al., 2007; Sutherling et al., 2008). Based on the current published evidence (*A few selected examples*: Knake et al. 2006, Knowlton et al., 2006; Knowlton et al., 2008a, Knowlton et al., 2008b; RamachandranNair et al., 2007; Stefan et al., 2003; Sutherling et al., 2008), the ACMEGS supports the routine use of MEG/MSI in presurgical epilepsy evaluations because it can improve noninvasive evaluation that is ordinarily much cheaper and safer than invasive studies (Barkley and Baumgartner, 2003; Knowlton, 2008), and because it can enhance the yield of invasive studies by directing the placement of grids, strips and depth electrodes (Knowlton et al., 2008a, Knowlton et al., 2008b; RamachandranNair et al., 2007; Sutherling et al., 2008). Overall, these may reduce costs and improve the accuracy of epilepsy evaluations, thus making surgery a more appealing treatment option (Barkley and Baumgartner, 2003; Knowlton et al., 2006; Knowlton, 2008; Knowlton et al., 2008a, Knowlton et al., 2008b; Papanicolaou et al., 2005; RamachandranNair et al., 2007; Stefan et al., 2003; Sutherling et al., 2008).

Based on all available published evidence, the ACMEGS considers the current state of MEG/MSI technology to be completely mature for routine use in presurgical

evaluations of patients with epilepsy. The ACMEGS also supports the widely accepted and scientifically supported position that MEG and EEG are complementary modalities that yield the best results when combined. Consequently, the debate about superiority among these two complementary modalities is clinically irrelevant for the acceptance of MEG as a routine clinical test. The ACMEGS does, however, encourage further comparative studies that may lead to new advancements in electro-magnetic neuroimaging.

ACMEGS Position

Therefore, after considering the entire body of published evidence (MEDLINE search for “epilepsy” and “magnetoencephalography” gleaned 665 hits; accessed on April 20, 2009) and appreciating the publication of a milestone Class I study (Sutherling et al., 2008), the ACMEGS acknowledges that sufficient credible evidence has been published to support a Position Statement regarding the value of MEG in the presurgical evaluation of patients with medically intractable localization-related epilepsy. Accordingly, the following principles regarding the routine use of MEG/MSI are proposed.

The ACMEGS supports:

1. The routine clinical use of MEG/MSI in obtaining non-invasive, non-redundant localizing information in presurgical evaluation of patients with medically-intractable localization-related epilepsy.
2. The determination of MEG/MSI indications for an individual patient by an epileptologist or a clinical team associated with a National Association of Epilepsy Centers (NAEC)-designated epilepsy center.
3. The routine use of MEG/MSI only when traditional EEG methods and MRI are implemented and provide insufficient localizing information.
4. The progressive movement of insurers toward complete coverage for MEG/MSI. It is in the best interest of patients to have appropriate and timely access to the best possible care. This includes MEG/MSI, as well as previously established diagnostic tests.
5. Uses for MEG/MSI indicated by accepted standards of clinical judgment and care and the rational utilization of resources without further restrictions.
6. Further systematic clinical research that seeks to establish other clinical indications for MEG/MSI.

The ACMEGS invites and encourages other medical societies and organizations including but not limited to the American Clinical Neurophysiology Society (ACNS), American Academy of Neurology (AAN) and American Epilepsy Society (AES) to support this statement and/or adopt complementary position statements. The ACMEGS intends to enhance the practice of clinical MEG/MSI further by developing practice parameters.

References:

1. Alberstone CD, Skirboll SL, Benzel EC, et al. Magnetic source imaging and brain surgery: presurgical and intraoperative planning in 26 patients. *J Neurosurg* 2000;92(1):79-90.
2. Assaf BA, Karkar KM, Laxer KD, et al. Magnetoencephalography source localization and surgical outcome in temporal lobe epilepsy. *Clin Neurophysiol* 2004;115(9):2066-76.
3. Barkley GL, Baumgartner C. MEG and EEG in epilepsy. *J Clin Neurophysiol* 2003;20(3):163-78.
4. Baumgartner C, Pataria E, Lindinger G, Deecke L. Magnetoencephalography in focal epilepsy. *Epilepsia* 2000;41 Suppl 3:S39-47.
5. Begley CE, Famulari M, Annegers JF, et al. The cost of epilepsy in the United States: an estimate from population-based clinical and survey data. *Epilepsia* 2000;41:342-351.
6. Bowyer SM, Moran JE, Mason KM, et al. MEG localization of language-specific cortex utilizing MR-FOCUSS. *Neurology* 2004;62(12):2247-55.
7. Bowyer SM, Moran JE, Weiland BJ, et al. Language laterality determined by MEG mapping with MR-FOCUSS. *Epilepsy Behav* 2005;6(2):235-41.
8. Brenner D, Williamson SJ, Kaufman L. Visually evoked magnetic fields of the human brain. *Science* 1975;190(4213):480-2.
9. Brodie MJ. Diagnosing and predicting refractory epilepsy. *Acta Neurol Scand Suppl* 2005;181:36-9.
10. Castillo EM, Simos PG, Wheless JW, et al. Integrating sensory and motor mapping in a comprehensive MEG protocol: clinical validity and replicability. *Neuroimage* 2004;21(3):973-83.
11. Cohen D. Magnetoencephalography: evidence of magnetic fields produced by alpha rhythm currents. *Science* 1968;161:784-6.
12. Cohen D. Magnetoencephalography: detection of the brain's electrical activity with a superconducting magnetometer. *Science* 1972;175(22):664-6.
13. Duffner F, Freudenstein D, Schiffbauer H, et al. Combining MEG and MRI with neuronavigation for treatment of an epileptiform spike focus in the precentral region: a technical case report. *Surg Neurol* 2003;59(1):40-5.
14. Ebersole JS. Magnetoencephalography/magnetic source imaging in the assessment of patients with epilepsy. *Epilepsia* 1997;38:S1-5.
15. Engel J Jr. A Greater Role for Surgical Treatment of Epilepsy: Why and When? *Epilepsy Curr* 2003;3(2):37-40.
16. Engel J Jr. Surgical treatment for epilepsy: too little, too late? *JAMA* 2008;300(21):2548-50.
17. Engel J Jr, Shewmon DA. Overview: who should be considered a surgical candidate? In:
18. Engel J Jr, ed. *Surgical Treatment of the Epilepsies*. 2nd ed. New York: Raven Press, 1993:23-34.
19. Engel J Jr, Wiebe S, French J, et al. Practice parameter: temporal lobe and localized neocortical resections for epilepsy. *Epilepsia* 2003;44(6):741-51.

20. Firsching R, Bondar I, Heinze HJ, et al. Practicability of magnetoencephalography-guided neuronavigation. *Neurosurg Rev* 2002;25(1-2):73-8.
21. Fischer MJ, Scheler G, Stefan H. Utilization of magnetoencephalography results to obtain favourable outcomes in epilepsy surgery. *Brain* 2005;128(Pt 1):153-7.
22. Flagg EJ, Cardy JE, Roberts W, Roberts TP. Language lateralization development in children with autism: insights from the late field magnetoencephalogram. *Neurosci Lett* 2005;386(2):82-7.
23. Ganslandt O, Fahlbusch R, Nimsky C, et al. Functional neuronavigation with magnetoencephalography: outcome in 50 patients with lesions around the motor cortex. *J Neurosurg* 1999;91(1):73-9.
24. Ganslandt O, Buchfelder M, Hastreiter P, Grummich P, Fahlbusch R, Nimsky C. Magnetic source imaging supports clinical decision making in glioma patients. *Clin Neurol Neurosurg* 2004;107(1):20-6.
25. Godey B, Schwartz D, de Graaf JB, Chauvel P, Liégeois-Chauvel C. Neuromagnetic source localization of auditory evoked fields and intracerebral evoked potentials: a comparison of data in the same patients. *Clin Neurophysiol* 2001;112(10):1850-9.
26. Grover KM, Bowyer SM, Rock J, et al. Retrospective review of MEG visual evoked hemifield responses prior to resection of temporo-parieto-occipital lesions. *J Neurooncol* 2006;77(2):161-6.
27. Grummich P, Nimsky C, Pauli E, Buchfelder M, Ganslandt O. Combining fMRI and MEG increases the reliability of presurgical language localization: a clinical study on the difference between and congruence of both modalities. *Neuroimage* 2006;32(4):1793-803.
28. Hamalainen M, Hari R, Ilmoniemi RJ, Knuutila J, and Lounasmaa OV. Magnetoencephalography - theory, instrumentation, and applications to noninvasive studies of the working humans brain. *Rev Mod Phys* 1993;65:413-197.
29. Hari R, Joutsiniemi SL, Sarvas J. Spatial resolution of neuromagnetic records: theoretical calculations in a spherical model. *Electroencephalogr Clin Neurophysiol* 1988;71(1):64-72.
30. Hauser WA, Hesdorffer DC. *Epilepsy: Frequency, Causes and Consequences*. New York: Demos Press, 1990.
31. Hirata M, Kato A, Taniguchi M, et al. Determination of language dominance with synthetic aperture magnetometry: comparison with the Wada test. *Neuroimage* 2004;23(1):46-53.
32. Iwasaki M, Nakasato N, Shamoto H, et al. Surgical implications of neuromagnetic spike localization in temporal lobe epilepsy. *Epilepsia* 2002;43(4):415-24.
33. Jannin P, Morandi X, Fleig OJ, et al. Integration of sulcal and functional information for multimodal neuronavigation. *J Neurosurg* 2002;96(4):713-23.
34. Kamada K, Houkin K, Takeuchi F, et al. Visualization of the eloquent motor system by integration of MEG, functional, and anisotropic diffusion-weighted MRI in functional neuronavigation. *Surg Neurol* 2003;59(5):352-61.

35. Kamada K, Todo T, Masutani Y, et al. Visualization of the frontotemporal language fibers by tractography combined with functional magnetic resonance imaging and magnetoencephalography. *J Neurosurg* 2007;106(1):90-8.
36. Kamada K, Sawamura Y, Takeuchi F, et al. Expressive and receptive language areas determined by a non-invasive reliable method using functional magnetic resonance imaging and magnetoencephalography. *Neurosurgery* 2007;60(2):296-305.
37. Kirsch HE, Mantle M, Nagarajan SS. Concordance between routine interictal magnetoencephalography and simultaneous scalp electroencephalography in a sample of patients with epilepsy. *J Clin Neurophysiol* 2007a;24(3):215-31.
38. Kirsch HE, Zhu Z, Honma S, Findlay A, Berger MS, Nagarajan SS. Predicting the location of mouth motor cortex in patients with brain tumors by using somatosensory evoked field measurements. *J Neurosurg* 2007b;107(3):481-7.
39. Knake S, Halgren E, Shiraishi H, et al. The value of multichannel MEG and EEG in the presurgical evaluation of 70 epilepsy patients. *Epilepsy Res* 2006;69(1):80-6.
40. Knowlton RC, Elgavish R, Howell J, et al. Magnetic source imaging versus intracranial electroencephalogram in epilepsy surgery: a prospective study. *Ann Neurol* 2006;59(5):835-42.
41. Knowlton RC, Elgavish RA, Limdi N, et al. Functional imaging: I. Relative predictive value of intracranial electroencephalography. *Ann Neurol* 2008a;64(1):25-34.
42. Knowlton RC, Elgavish RA, Bartolucci A, et al. Functional imaging: II. Prediction of epilepsy surgery outcome. *Ann Neurol* 2008b;64(1):35-41.
43. Knowlton RC. Can magnetoencephalography aid epilepsy surgery? *Epilepsy Curr* 2008;8(1):1-5.
44. Korvenoja A, Kirveskari E, Aronen HJ, et al. Sensorimotor cortex localization: comparison of magnetoencephalography, functional MR imaging, and intraoperative cortical mapping. *Radiology* 2006;241(1):213-22.
45. Kuzniecky R, Devinsky O. Surgery Insight: surgical management of epilepsy. *Nat Clin Pract Neurol* 2007;3(12):673-81.
46. Kwan P, Brodie MJ. Early identification of refractory epilepsy. *N Engl J Med* 2000;342(5):314-9.
47. Langfitt JT, Wiebe S. Early surgical treatment for epilepsy. *Curr Opin Neurol* 2008;21(2):179-83.
48. Lee D, Sawrie SM, Simos PG, Killen J, Knowlton RC. Reliability of language mapping with magnetic source imaging in epilepsy surgery candidates. *Epilepsy Behav* 2006;8(4):742-9.
49. Lin YY, Shih YH, Hsieh JC, et al. Magnetoencephalographic yield of interictal spikes in temporal lobe epilepsy. Comparison with scalp EEG recordings. *Neuroimage* 2003;19(3):1115-26.
50. Mamelak AN, Lopez N, Akhtari M, Sutherling WW. Magnetoencephalography-directed surgery in patients with neocortical epilepsy. *J Neurosurg* 2002;97(4):865-73.

51. Merrifield WS, Simos PG, Papanicolaou AC, Philpott LM, Sutherling WW. Hemispheric language dominance in magnetoencephalography: sensitivity, specificity, and data reduction techniques. *Epilepsy Behav* 2007;10(1):120-8.
52. Mohamed IS, Otsubo H, Ochi A, et al. Utility of magnetoencephalography in the evaluation of recurrent seizures after epilepsy surgery. *Epilepsia* 2007;48(11):2150-9.
53. Nakasato N, Seki K, Fujita S, et al. Clinical application of visual evoked fields using an MRI-linked whole head MEG system. *Front Med Biol Eng*. 1996;7(4):275-83.
54. Nakasato N, Yoshimoto T. Somatosensory, auditory, and visual evoked magnetic fields in patients with brain diseases. *J Clin Neurophysiol* 2000;17(2):201-11.
55. Nimsky C, Ganslandt O, Kober H, et al. Integration of functional magnetic resonance imaging supported by magnetoencephalography in functional neuronavigation. *Neurosurgery* 1999;44(6):1249-55.
56. Oishi M, Fukuda M, Kameyama S, Kawaguchi T, Masuda H, Tanaka R. Magnetoencephalographic representation of the sensorimotor hand area in cases of intracerebral tumour. *J Neurol Neurosurg Psychiatry* 2003;74(12):1649-54.
57. Ochi A, Otsubo H. Magnetoencephalography-guided epilepsy surgery for children with intractable focal epilepsy: SickKids experience. *Int J Psychophysiol* 2008;68(2):104-10.
58. Oishi M, Kameyama S, Masuda H, et al. Single and multiple clusters of magnetoencephalographic dipoles in neocortical epilepsy: significance in characterizing the epileptogenic zone. *Epilepsia* 2006;47(2):355-64.
59. Okada YC, Lahteenmäki A, Xu C. Experimental analysis of distortion of magnetoencephalography signals by the skull. *Clin Neurophysiol* 1999;110(2):230-8.
60. Okada YC, Tanenbaum R, Williamson SJ, Kaufman L. Somatotopic organization of the human somatosensory cortex revealed by neuromagnetic measurements. *Exp Brain Res* 1984;56(2):197-205.
61. Pang EW, Drake JM, Otsubo H, et al. Intraoperative confirmation of hand motor area identified preoperatively by magnetoencephalography. *Pediatr Neurosurg* 2008;44(4):313-7.
62. Papanicolaou AC, Patariaia E, Billingsley-Marshall R, et al. Toward the substitution of invasive electroencephalography in epilepsy surgery. *J Clin Neurophysiol* 2005;22(4):231-7.
63. Papanicolaou AC, Simos PG, Castillo EM, et al. Magnetocephalography: a noninvasive alternative to the Wada procedure. *J Neurosurg* 2004;100(5):867-76.
64. Papanicolaou AC, Pazo-Alvarez P, Castillo EM, et al. Functional neuroimaging with MEG: normative language profiles. *Neuroimage* 2006;33(1):326-42.
65. Patariaia E, Simos PG, Castillo EM, et al. Does magnetoencephalography add to scalp video-EEG as a diagnostic tool in epilepsy surgery? *Neurology* 2004;62(6):943-8.
66. RamachandranNair R, Otsubo H, Shroff MM, et al. MEG predicts outcome following surgery for intractable epilepsy in children with normal or nonfocal MRI findings. *Epilepsia* 2007;48(1):149-57.

67. Rezai AR, Hund M, Kronberg E, et al. Introduction of magnetoencephalography to stereotactic techniques. *Stereotact Funct Neurosurg* 1995;65(1-4):37-41.
68. Rezai AR, Hund M, Kronberg E, et al. The interactive use of magnetoencephalography in stereotactic image-guided neurosurgery. *Neurosurgery* 1996;39(1):92-102.
69. Rezai AR, Mogilner AY, Cappell J, Hund M, Llinás RR, Kelly PJ. Integration of functional brain mapping in image-guided neurosurgery. *Acta Neurochir Suppl* 1997;68:85-9.
70. Rodin E, Funke M, Berg P, Matsuo F. Magnetoencephalographic spikes not detected by conventional electroencephalography. *Clin Neurophysiol* 2004;115(9):2041-7.
71. Romani GL, Williamson SJ, Kaufman L. Tonotopic organization of the human auditory cortex. *Science* 1982;216(4552):1339-40.
72. Salmelin R. Clinical neurophysiology of language: the MEG approach. *Clin Neurophysiol* 2007;118(2):237-54.
73. Schmidt D, Stavem K. Long-term seizure outcome of surgery versus no surgery for drug-resistant partial epilepsy: A review of controlled studies. *Epilepsia* 2009 Feb 21. [Epub ahead of print], PMID: 19243421.
74. Smith JR, King DW, Park YD, Lee MR, Lee GP, Jenkins PD. Magnetic source imaging guidance of gamma knife radiosurgery for the treatment of epilepsy. *J Neurosurg* 2000;93 (S3):136-40.
75. Spencer S, Huh L. Outcomes of epilepsy surgery in adults and children. *Lancet Neurol*. 2008;7(6):525-37.
76. Stefan H, Hummel C, Scheler G, et al. Magnetic brain source imaging of focal epileptic activity: a synopsis of 455 cases. *Brain* 2003;126(Pt 11):2396-405.
77. Sutherling WW, Mamelak AN, Thyerlei D, et al. Influence of magnetic source imaging for planning intracranial EEG in epilepsy. *Neurology* 2008;71(13):990-6.
78. Téllez-Zenteno JF, Dhar R, Wiebe S. Long-term seizure outcomes following epilepsy surgery: a systematic review and meta-analysis. *Brain* 2005;128(Pt 5):1188-98.
79. Téllez-Zenteno JF, Dhar R, Hernandez-Ronquillo L, Wiebe S. Long-term outcomes in epilepsy surgery: antiepileptic drugs, mortality, cognitive and psychosocial aspects. *Brain* 2007;130(Pt 2):334-45.
80. Téllez-Zenteno JF, Wiebe S. Long-term seizure and psychosocial outcomes of epilepsy surgery. *Curr Treat Options Neurol* 2008;10(4):253-9.
81. Verrotti A, Pizzella V, Madonna L, et al. Magnetoencephalographic and electroencephalographic evaluation in patients with cryptogenetic partial epilepsy. *Neurophysiol Clin* 2003;33(4):174-9.
82. Wheless JW, Willmore LJ, Breier JJ, et al. A comparison of magnetoencephalography, MRI, and V-EEG in patients evaluated for epilepsy surgery. *Epilepsia* 1999;40(7):931-41.
83. Wiebe S, Blume WT, Girvin JP, Eliasziw M; Effectiveness and Efficiency of Surgery for Temporal Lobe Epilepsy Study Group. A randomized, controlled trial of surgery for temporal-lobe epilepsy. *N Engl J Med* 2001;345(5):311-8.
84. Williamson SJ, Lü ZL, Karon D, Kaufman L. Advantages and limitations of magnetic source imaging. *Brain Topogr* 1991;4(2):169-80.

4. New Business

Notes

Notes

Andy Dean

**Overcoming Coverage Denials & Strategies to Maximize
Reimbursement**

Andy Dean

Program Coordinator


Department of Neurology, University of Alabama at Birmingham, Birmingham AL



Enhancing the MEG Laboratory Clinical Revenue Cycle

Andy Dean
 Program Coordinator
 UAB Magnetoencephalography Lab
 May 2009


REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK



Clinical Billing & Reimbursement How to Maximize Reimbursement & Overcome Coverage Denials

- **Clinical Billing Overview**
 - Areas to focus for maximum reimbursement
- **Revenue Cycle Overview**
 - Authorizations / Pre-Determinations
 - (Prior Service Review vs. Pre-Certification)
- **Denial Management**
- **Questions and Answers**

A. Dean REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK 05/14/2009



The Clinical Revenue Cycle

- **What is the revenue cycle?**
 - Begins with appointment scheduling and ends with payment resulting in zero balance due
- **Revenue Cycle Measures**
 - Days in Accounts Receivable
 - Collection percentages
 - Amount of Accounts Receivable outstanding >120 days
 - Charge posting log
 - Denial percentages


A. Dean REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK 05/14/2009



Signs Of Poor Controls / Performance

- ✖ Excessive Credit Balances
- ✖ Patients Complain: Insurance paid, yet "I'm being billed!"
 - ✖ (Patients need to be advised when the lab is not a participating provider with their carrier.)
- ✖ Poor Claim Review Process
- ✖ Processing Backlog > One Week


A. Dean REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK 05/14/2009



Challenges of MEG Clinical Billing

- Challenges:
 - Medical policies against MEG technology
 - Operational inefficiencies
 - Insurance underpayments
 - Self-pay and uninsured patients
 - Billing errors
 - Barriers to success
 - Resistance to change from physicians' office staff




A. Dean REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK 05/14/2009



MEG Clinical Environment

- Major Insurance Carriers
 - United Healthcare
 - Humana
 - Cigna
 - Aetna
- Medicare Advantage Plans
 - EPOs/HMOs, POS, PPO, FFS
- Standard Medicare Part B
- Medicaid (few states cover MEG)




A. Dean REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK 05/14/2009

Factors Affecting MEG Reimbursement

- Setting (inpatient scans versus outpatient)
- In-Network vs. Out-of Network (participation in insurer's plan)
 - GAP Exceptions / Non-Par Authorizations
 - Balance-billing (percentage which patient is billed)
- The Insurance Plan (EPO/HMO, POS, PPO, FFS, HSA)
 - Why/How does this have an impact?
- Self-Funded Plans vs. Fully-Insured Plans (affecting pre-determinations & patient leverage)

A. Dean
REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK
05/14/2009

Settings / Facilities & Billing Impact




Inpatient Billing

- Billed through DRGs & ICD
- DRGs determine compensation for Medicare
 - No additional compensation for MEG
- Authorizations can be included in in-patient stay
- MEG can still be denied as uncovered benefit

Outpatient Billing


- Billed through CPT codes / ICD 9
- Almost all insurance requires pre-determination (other than Standard Medicare Part B)
- More revenue obtained through pre-determination than to pursue appeals after claim denial
- Third-party billing frequently doesn't pursue denials with insurers

A. Dean
REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK
05/14/2009

Why Is The MEG Lab Revenue Cycle Important?

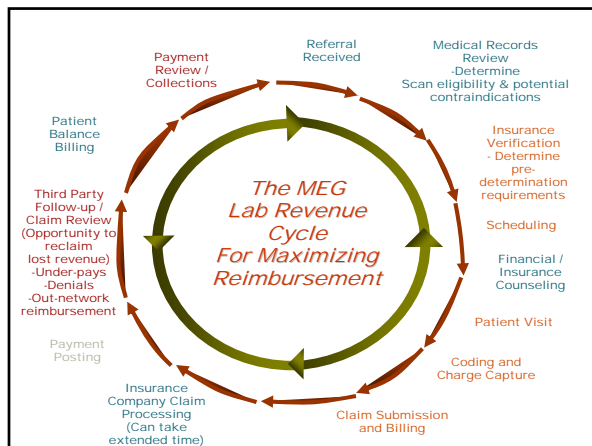
Why is it different from other lab and clinic settings?



"If you have always done it that way, it is probably wrong."

--Charles Kettering

A. Dean
REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK
05/14/2009



Signs Of Poor Lab Revenue Performance

- ✖ High Number Of Rejected Claims
- ✖ High Volume Of Patient Calls
- ✖ High Accounts Receivable
- ✖ High Amount Of \$ or Number of Claims Assigned To Collection Agency

Where to focus:

- ✓ Pre-Arrival & Insurance Verification
- ✓ Pre-Determinations & Prior Authorizations
- ✓ Payment Review & Claim Denial Appeals

A. Dean
REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK
05/14/2009

Guiding Principles for a Successful Lab Revenue Cycle

- ✓ Maximize Payment
- ✓ Do So In Shortest Possible Time
- ✓ Do So Efficiently and Cost Effectively
- ✓ Minimize Negative Patient Experience
- ✓ Focus on:
 - Pre-Registration & Insurance Review Prior to Appointment
 - Prior Determinations
 - Out-of-Network Approvals / GAP Exceptions
 - Billing Systems (ensure you have access)
 - Claim Review – reading EOBs/PRA's
 - Watch improper use of contractual adjustments

A. Dean
REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK
05/14/2009








Pre-Arrival, Insurance Verification, & Prior Determinations

- ✓ **Pre-Registering the MEG patient: Recommendations**
- ✓ Have an information packet and website with insurance information and billing practices included
- ✓ **Insurance/ Benefits Verification**
 - ✓ Ensure the information you received on the referral or in your billing system is current, up-to-date, and accurate
- ✓ Pre-Determinations (HMO, POS, PPO, FFS, HSA etc.)
- ✓ Inform Patient of Insurance Participation, non-Participation, advise them they made need to be involved in billing resolution if claim is unpaid

Very important: Make sure nurses and referring physicians (internal to your facility) are as familiar as possible with your insurance issues so that patients are not misled or misinformed about their insurance coverage and MEG. Simply tell them, "Most insurance will not cover, but we will check and pursue it."




A. Dean REDUCING COSTS IMPROVING QUALITY & SAFETY MANAGING RISK 05/14/2009

Requesting Pre-Determinations & Appealing Pre-Service Denials

- ✓ Some insurers allow medical providers to initiate pre-determinations over the telephone; however, it is frequently easier to submit the request via facsimile / in writing. Many insurers now have a dedicate fax line or address for processing prior determinations (aka pre-service reviews). These are claims made in advance of a particular service, and medical records are usually submitted for consideration.
- ✓ Each insurer has their own process, forms, and timelines for completing this procedure. It is important to have this information before you submit the initial "Pre-D" to the insurer so that you can advise patients what to expect.



A. Dean REDUCING COSTS IMPROVING QUALITY & SAFETY MANAGING RISK 05/14/2009






Self-Insured/Funded vs. Fully-Insured Health Insurance Plans

- ❑ This is not something you can tell by looking at a patient's insurance card.
- ❑ Sometimes, the patient will know, but it frequently requires calling the patient's insurance carrier to determine this information.
- ❑ Self-funded plans are more likely when the patient's employer is large and multi-state.
- ❑ Self-funded plans are actually paid by the employer; insurance "premiums" are actually just paid into a fund out of which employee healthcare costs are paid, and insurance carriers are the 3rd-party administrator of the plan. Actual plan policies are determined by the employer.
- ❑ Fully-insured plans are those where the insurance company pays claims itself and "premiums" paid by employers and employees go to the insurance company.


A. Dean REDUCING COSTS IMPROVING QUALITY & SAFETY MANAGING RISK 05/14/2009



Medicare Advantage Plans & How They Can Affect Reimbursement

- Coverage under a Medicare Advantage Plan replaces a patient's existing (Standard Medicare) coverage. With Medicare Advantage plans, some patients can reduce their out-of-pocket costs (like deductibles, co-insurance, and co-pays to very small amounts, but there are significant issues to consider with seeing these patients.
- One of the biggest issues with these Medicare Advantage plans is that not all of them pay for MEG scans. Only the MEG Private-Pay Fee-for-Service plan always pays for an MEG scan.
- Type of Medicare Advantage Plans
- Medicare HMO Plans covers care received through a network of approved physicians and hospitals that coordinate patient care. In most cases, care received from non-participating (out-of-network) providers, neither Medicare nor the Medicare Advantage HMO plan will pay for the costs, regardless of its medical necessity.


A. Dean
 REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK
 05/14/2009



More Medicare Advantage Plan Types

- Medicare POS Plans
- Medicare Point-of-Service plans are a type of HMO plan that allow the use of non-plan or non-preferred providers, but their services usually cost patients more, i.e., a greater co-insurance percentage. For example, paying 30% to 40% of the allowed amount, PLUS balance billing if the participating provider is not in-network with the plan.
- Medicare PPO Plans
- Medicare Preferred Provider Organization (PPO) plans allow patients to choose between in-network and out-of-network provider. These plans usually provide reimbursement for all covered benefits, as long as they are medically necessary. For services received outside of the network, patients generally have both higher co-pay and co-insurance costs.


A. Dean
 REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK
 05/14/2009



Medicare Advantage Plan Types

- Medicare Private Fee-for-Service Plans


A. Dean
 REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK
 05/14/2009



Denial Management & Payment Review

- **Decide how to correct, critical thinking**
 - Is the denial something that can be corrected?
 - If so, what steps should be taken
- **Create “common denials” & action spreadsheet**
 - By Payer
 - CPT/HCPCS Code, denial code, action to take
 - Accessible on the network to all billers
- ❖ **“Actual vs. Expected” Reimbursement or “Contract Management”**


A. Dean REDUCING COSTS IMPROVING QUALITY & SAFETY MANAGING RISK 05/14/2009



Common Areas of Potential Claim Denial & Underpayment

- ✗ **No one watching for claim payment; over-reliance on external or 3rd-party claims office:** Claims are rejected by automated systems which deny certain codes as “always investigational” or “always uncovered benefit”, even when you have a pre-determination or prior approval (aka Claim Edits)
- ✗ **Failure to appeal claim denial within the allowed timeframe** (different insurers and even different plans have different timeframes)
- ✗ **Being paid as out-of-network when you could receive in-network compensation**

A. Dean REDUCING COSTS IMPROVING QUALITY & SAFETY MANAGING RISK 05/14/2009



Insurance Payment Review

- § **Standard UC Policies on Handling/ Accounting for Money**
- § Insurance companies focus on speed and efficiency, as do most 3rd-party billing operations
- § **Electronic Remittances – Review EOBs/PRA**s
- § **Multiple Payors in Most Cases** (Primary, Secondary, Patient)
- § **Contractual Allowances**
- § **Line Item Posting – review EOB/PRA for mistakes;** need to see the actual EOB, not just your internal payment posting system
- § **Balance Billing**

A. Dean REDUCING COSTS IMPROVING QUALITY & SAFETY MANAGING RISK 05/14/2009

Claim

Code	Description	Billed Fee*
95965	MEG – Epilepsy Localization	\$4000*
95819	EEG	\$1000*
TOTAL		\$5000*

Payor Remittance / PRA or EOB

Contractual Allowance	Discount or Dis-Allowed Amount	Patient Liability	Payor Payment	TOTAL
\$2000	\$2000	\$100	\$1900	\$4000
\$100	\$900	0.00	\$100	\$1000
\$2100	\$2900	\$100	\$2000	\$5000

*These are not actual figures but are random selections to allow for example-based calculations and samples.

Steps to Reduce Claim Denial & Underpayment on MEG Claims

- Establish relationship/liaison with your billing department
- Request weekly reports of denials if you do not have immediate workflow access (Monthly is too long to wait, given timeframes required by some insurers)
- Verify the patient's insurance information & determine what pre-determination / certification requirements are necessary immediately when referral is received
- Obtain automatic monthly PAB (Payments, Adjustments, Balance) reports for lab that show individual claim activity by insurer
- Make sure that someone in lab has access to electronic/scanned version of EOBs (Explanation of Benefits) so that these can be reviewed
- Increase the probability of payment: follow-up on claims which were denied - ALWAYS appeal. Many rejections are automatic.
- Provide/request as much lead-time with patient referrals as possible
- Have a financial policy that explains options when insurance denies coverage

A. Dean
REDUCING COSTS | IMPROVING QUALITY & SAFETY | MANAGING RISK
05/14/2009

Questions ?

Andy Dean
aadean@uabmc.edu

Michael Longacre


MEG Economic Environment

Michael Longacre
Executive Director, ACMEGS
Becton, Dickinson and Company, Associate Director
Global Reimbursement and Healthcare Economics, Yamhill OR

American Clinical MEG Society
Salt Lake City 2009 Meeting

MEG Reimbursement Overview

Michael Longacre
Executive Director
ACMEGS


HEALTHCARE
MARKET STRATEGIES, INC.

REIMBURSEMENT • MARKETING • SALES

American Clinical MEG Society
Salt Lake City 2009 Meeting

Reimbursement Overview

- Medicare; Six Simple Steps
- Commercial Payer Strategy
- Reimbursement Discussion
- Future Projects

HEALTHCARE
MARKET STRATEGIES, INC.

REIMBURSEMENT • MARKETING • SALES

American Clinical MEG Society
Medicare Cost Report

Medicare Cost Report


HEALTHCARE
MARKET STRATEGIES, INC.

REIMBURSEMENT • MARKETING • SALES

American Clinical MEG Society
Medicare Cost Report

Medicare Cost Report

1. Contact Dir of reimbursement or Cost reporting
2. Inquire about which line the MEG costs are captured
3. Are MEG costs bundled in with other procedures; for example EEG line 54?
4. If yes, submit a request/appeal to Medicare Administrator Contractor
5. Ensure that the MEG CPT codes are correctly captured on the claim.
6. Contact Patient Accounting, (Billing and Financial Services) and confirm that the appropriate MEG CPT codes are being captured by charge entry and the chargemaster for submission on the 837 file that goes to Medicare.




REIMBURSEMENT • MARKETING • SALES

MEG Reimbursement
Medicare Cost Report

Results

Who has made the appropriate inquiries?
Results?

Who needs more time?
When can we expect completion?




REIMBURSEMENT • MARKETING • SALES

MEG Reimbursement
Medicare Cost Report

CMS 2010 Strategy

- We anticipate further reductions in HOPPS payment for 2010
- ACMEGS will request that CMS freeze current reimbursement
- Documented results from the Six Simple Steps program will be utilized in support of the freeze.



REIMBURSEMENT • MARKETING • SALES

MEG Reimbursement Payer Strategy

Point I

MEG is a diagnostic tool used primarily to identify the epileptogenic zone in patients with intractable epilepsy. I feel it is important to note that MEG is not ordered by a single physician but by a committee of health professionals that often include epileptologists, neurosurgeons, neuroradiologists, neuropsychologists, nuclear medicine, etc.



REIMBURSEMENT • MARKETING • SALES

MEG Reimbursement Payer Strategy

Point II

For most payers, MEG utilization represents a very small patient sample. Based on the prevalence of neurosurgeries for epilepsy, we have calculated that approximately 52 MEGs would be performed annually on Aetna's members. (One would fully expect Regence's MEG utilization to be considerably less.)

1. 174 neurosurgeries for epilepsy would result in 52 MEGs.
2. Amortized over Aetna's total membership 52 MEGs per year represents a Per Member Per Year (PMPY) of 0.012 (using CMS rates)
3. CMS reported a total of 33 MEG procedures for epilepsy in 2007



REIMBURSEMENT • MARKETING • SALES

MEG Reimbursement Payer Strategy

Point III

Recently, BlueShield of California reviewed MEG. The opportunity presented by BlueShield of CA resulted in a published coverage policy. This is yet one example of numerous payers who have chosen to publish positive coverage decisions for MEG; CMS, TriCare, Highmark, and a number of Medicaid, North Carolina, Utah, Idaho. We have also documented a considerable number of payers (close to 200) who are reimbursing for MEG without a published policy.




REIMBURSEMENT • MARKETING • SALES

MEG Reimbursement
Clinical Papers

Influence of magnetic source imaging for planning intracranial EEG in epilepsy: W. W. Sutherling, A. N. Mamelak, D. Thyrelei, T. Maleeva, Y. Minazad, L. Philpott and N. Lopez. *Neurology* 2008; 71: 990-996

The Sutherling paper was published in the fall of 2008 and is considered a Class 1 paper by the ANN. It found that MSI provided non-redundant information in 33% of patients. In those who have undergone surgery to date, MSI added useful information that changed treatment in 6 (9%), without increasing complications. MSI has benefited 21% who have gone to surgery.




REIMBURSEMENT • MARKETING • SALES

MEG Reimbursement
Clinical Papers

Functional Imaging: II. Prediction of Epilepsy Surgery Outcome: R. C. Knowlton, R. A. Elgavish, A. Bartolucci, B. Ojha, N. Limdi, J. Blount, J. G. Burneo, L. Ver Hoef, L. Paige, E. Faught, P. B. Kankirawatana, K. Riley, and R. Kuzniecky. *Ann Neurol*. 2008 Jul;64(1):35-41

The goal of this study was to establish the predictive and prognostic value of MSI, FDG-PET, and ictal SPECT as measured by seizure-free outcome after epilepsy surgery. This work was part of a prospective observation study of epilepsy surgery candidates not sufficiently localized with scalp electroencephalography and magnetic resonance imaging. Of 160 patients enrolled, 62 completed intracranial electroencephalography seizure monitoring and subsequent surgical resection. Sixty-one percent resulted in an Engel I seizure-free outcome. MSI, FDG-PET, and ictal SPECT each have clinical value in predicting seizure-free surgical outcome in epilepsy surgery candidates who typically require intracranial electroencephalography.




REIMBURSEMENT • MARKETING • SALES

MEG Reimbursement
Clinical Papers

MEG Predicts Outcome Following Surgery for Intractable Epilepsy in Children with Normal or Nonfocal MRI Findings: Rajesh RamachandranNair, Hiroshi Otsubo, Manohar M. Shroff, Ayako Ochi, Shelly K. Weiss, James T. Rutka, and O. Carter Snead. *Epilepsia*. 48(1):149-157, 2007

Twenty-two children with normal MRI findings underwent surgery for intractable epilepsy following extraoperative intracranial EEG. 17 children (77%) had a good postsurgical outcome (defined as Engel class IIIA or better), which included eight (36%) seizure-free children. Surgery for intractable epilepsy in children with normal MRI findings provided good postsurgical outcomes in the majority of our patients. As well, restricted ictal onset zone predicted postoperative seizure freedom. Postoperative seizure freedom was less likely to occur in children with bilateral MEG dipole clusters or only scattered dipoles, multiple seizure types and incomplete resection of the proposed epileptogenic zone. Seizure freedom was most likely to occur when there was concordance between EEG and MEG localization and least likely to occur when these results were divergent.



REIMBURSEMENT • MARKETING • SALES

MEG Reimbursement Clinical Papers

The value of multichannel MEG and EEG in the presurgical evaluation of 70 epilepsy patients: S. Knake, E. Haigren, H. Shiraishi, K. Hara, H.M. Hamer, P.E. Grant, V.A. Carr, D. Foxe, S. Camposano, E. Busa, T. Witzel, M.S. Hamalainen, S.P. Ahlfors, E.B. Bromfield, P.M. Black, B.F. Bourgeois, A.J. Cole, G.R. Cosgrove, B.A. Dworetzky, J.R. Madsen, P.G. Larsson, D.L. Schomer, E.A. Thiele, A.M. Dale, B.R. Rosen, S.M. Stufflebeam. *Epilepsy Research April, 69(1)2006: 80-86*

Seventy patients were prospectively evaluated by simultaneously recorded MEG/EEG. All patients were surgical candidates or were considered for invasive EEG monitoring and had undergone an extensive presurgical evaluation at a tertiary epilepsy center. In 67 patients, the overall sensitivity to detect interictal epileptiform discharges (IED) was 72% (48/67 patients) for MEG and 61% for EEG (41/67 patients) analyzing the raw data. In 13% (9/67 patients), MEG-only IED were recorded, whereas in 3% (2/67 patients) EEG-only IED were recorded. The combined sensitivity was 75% (50/67 patients).



REIMBURSEMENT • MARKETING • SALES

ACMEG Future Projects

ACMEGS Potential Future Projects

- Monitor success of chargemaster program
- Web based reimbursement informational site
- Analysis of actual reimbursement from payers
- Referring physician marketing materials
- Member site reimbursement training
- Patient education via advocacy groups



REIMBURSEMENT • MARKETING • SALES

Discussion

Discussion
Questions
Comments
Feedback



REIMBURSEMENT • MARKETING • SALES

**American Clinical MEG Society
Boston 2008 Meeting**

Medicare Review



REIMBURSEMENT • MARKETING • SALES

**American Clinical MEG Society
Boston 2008 Meeting**

2009 RBRVS (Professional Fee Only)

Code	Total RVU	Dollars
95965	11.31	\$424.07
95966	5.62	\$210.72
95967	4.81	\$180.35



REIMBURSEMENT • MARKETING • SALES

**American Clinical MEG Society
Boston 2008 Meeting**

2008 Medicare HOPPS Analysis

95965

- Total Frequency: 33 Claims
- "True" Median Cost: \$2632.33
- CY 2009 Final Payment: \$3,803.23
- ❑ APC 0067



REIMBURSEMENT • MARKETING • SALES

**American Clinical MEG Society
Boston 2008 Meeting**

CY 2009 HOPPS and RBRVS Totals

<u>Code</u>	<u>APC \$</u>	<u>RBRVS \$</u>	<u>Total \$</u>
95965	\$3803.23	\$424.07	\$4,227.30
95966	\$952.38	\$210.72	\$1,163.13
95967	\$952.38	\$180.35	\$1,132.73



HEALTHCARE
MARKET STRATEGIES, INC.

REIMBURSEMENT • MARKETING • SALES

Robert Knowlton

John Gates Lecture 2009

Robert Knowlton, M.D., M.S.P.H.

Associate Professor of Neurology, Division of Epilepsy, Director MEG Laboratory
Department of Neurology, University of Alabama at Birmingham, Birmingham AL

Epilepsy Surgery: Clinical Utility of MEG Spike Source Localization

American Clinical MEG Society
John Gates Lecture 2009

Robert Knowlton, MD, MSPH
University of Alabama at Birmingham

How to determine the clinical utility of MSI in Epilepsy Surgery

- Epilepsy surgery clinical context—stakes are uniquely high and impact is profound
- Impact of a test (MSI) must account for and distinguish between two important effects:
 - Diagnostic value on patient selection
 - Localization information on cure rate
- Randomized comparisons of medical tests vs. decision analysis and cost effectiveness

BC/BS 2008 TEC Assessment: Effecting Patient Selection

...examining the diagnostic characteristics of MEG
..., sensitivities and specificities were well below 90%, indicating the likelihood of both false-positive and false-negative studies. Predictive values based on these sensitivities and specificities mean that MEG can neither rule in nor rule out a positive intra-cranial EEG, meaning that MEG cannot be used as a **triage** test before intra-cranial EEG to avoid the potential morbidity in a subset of patients.

<https://www.bcbsal.org/providers/policies/final/338.pdf>

BC/BS 2008 TEC Assessment: Effecting Outcome

...results are consistent with an association between resection of the MEG-defined region and surgical cure, but that it is an imperfect predictor of surgical success. However, it does not address the question as to whether MEG contributed original information to improve the probability of cure.

<https://www.bcbstai.org/providers/policies/final/338.pdf>

BC/BS 2008 TEC Assessment: Overall Effects

MEG would be considered useful if, when compared to not using MEG, it improved patient outcomes. Such improvement in outcomes would include more patients being rendered seizure-free, use of a less invasive and morbid diagnostic workup, and increased surgical success rates. This is a complicated array of outcomes that has not thoroughly been evaluated in a comprehensive manner.

<https://www.bcbstai.org/providers/policies/final/338.pdf>

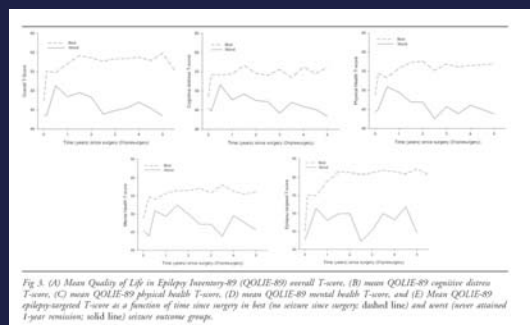
Test Effects

- 1) Selection
 - Diagnostic Value
- 2) Outcome
 - Treatment Value
- 3) Cost

Impact of Epilepsy Surgery: Seizure Freedom



Impact of Epilepsy Surgery—QOLIE: Spencer et al. 2007



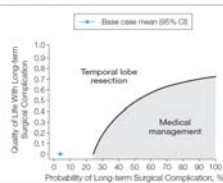
Impact of Epilepsy Surgery

JAMA®
 Online article and related content current as of December 2, 2008.
Epilepsy Surgery for Pharmacoresistant Temporal Lobe Epilepsy: A Decision Analysis
 Hyunmi Choi, Randall L. Sell, Leslie Lenert, et al.
 JAMA. 2008;300(21):2497-2505 (doi:10.1001/jama.2008.771)
<http://jama.ama-assn.org/cgi/content/full/300/21/2497>

Effect on **life expectancy** and quality of life compared to medical management

Impact of Epilepsy Surgery: Choi et al. JAMA 2008

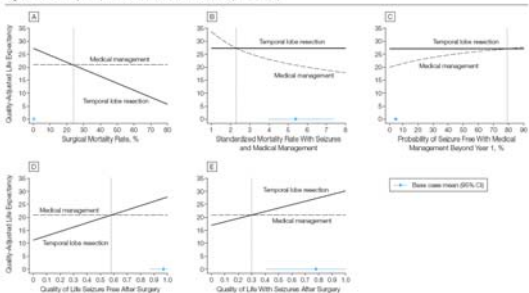
Figure 4. Probability of Long-term Complication After Surgery and the Quality of Life With a Long-term Surgical Complication



The line represents threshold values, so that for combinations of values above the line, surgery is preferred and for those below the line, medical management is preferred. Even if the quality of life with a long-term complication were 0, the probability of a long-term complication would have to exceed 24% (baseline 4%, 95% confidence interval [CI], 2%-6%) for medical management to be preferred.

Impact of Epilepsy Surgery: Choi et al. JAMA 2008

Figure 3. Sensitivity Analysis of Resection vs Pharmacotherapy for Epilepsy

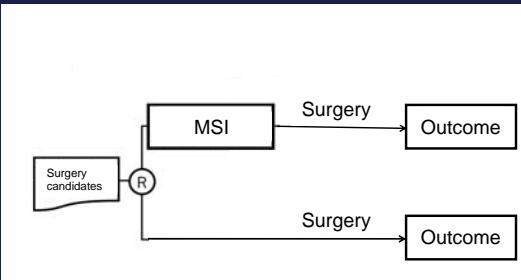


BC/BS 2008 TEC Assessment

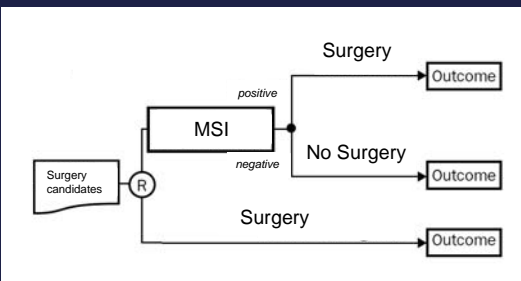
Ideally, a randomized trial comparing the outcomes of patients who receive MEG as part of their diagnostic workup compared to patients who do not receive MEG could determine whether MEG improves patient outcomes.

<https://www.bctsaal.org/providers/policies/inal/338.pdf>

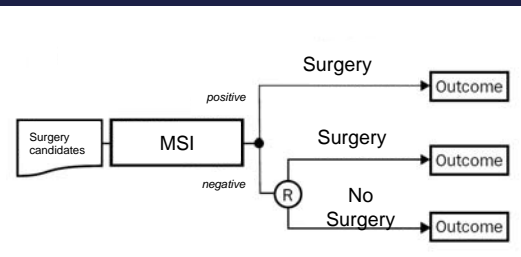
Randomized Comparison of MSI



Randomized Comparison of MSI

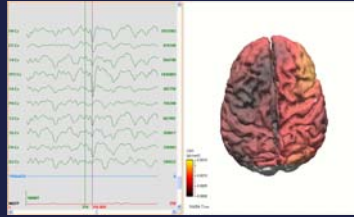


Randomized Comparison of MSI

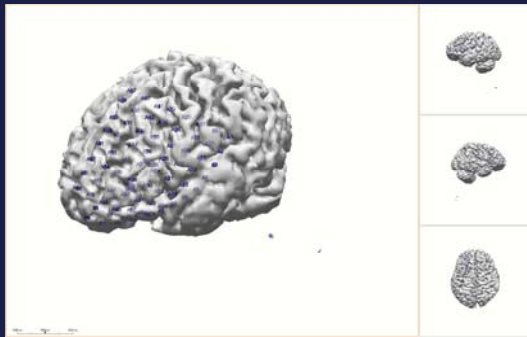


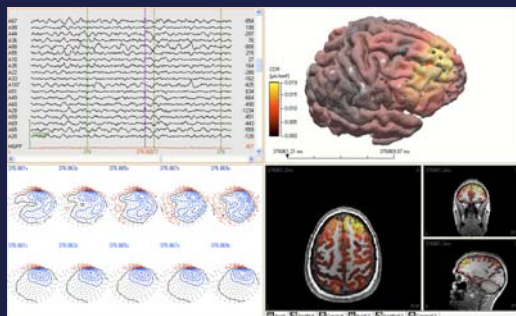
Spike Source Localization

- Validity
 - Technical
 - Statistical
 - Clinical
- Value
 - Clinical
 - Economical



The Problem





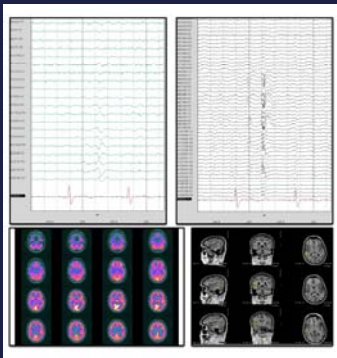
ICEEG findings in additional electrodes

N=18	Percentage of cases with involvement in additional ICEEG electrode coverage indicated by MSI (95% CI)	
	YES	NO
Seizures	39% (16.4 - 61.4)	61% (38.5 - 83.6)
Spikes	88% (65.9 - 98.1)	11% (1.8 - 34.1)

Effect on Outcome via Accurate Electrode Placement

Table 2. Localization Results and Effect on Intracarotid Electrophysiology and Surgery in Cases with Magnetic Source Imaging-Modified Electrode Coverage

Case No.	Age	Onset	VEEG Class	MBI Class	MSI Score	Seizure Onset Involves Added Electrodes	ICEEG Class	Effect on Surgery	Outcome
040	23	18	MTLE	Normal	3	Yes	Multifocal	No	III
051	9	7	LITLE	Localized	5	No	Localized	No	II
058	28	20	LITLE	NL	5	Yes	Localized	Yes	I
062	48	41	MTLE	NL	5	No	Localized	No	I
070	25	12	ExTLE	Normal	3	Yes	NL	Yes	NS ^a
083	54	38	ExTLE	NL	3	No	Localized	No	IV
091	17	7	ExTLE	Normal	3	No	Multifocal	No	III
092	41	5	NL	Normal	4	Yes	Localized	Yes	NS ^b
098	27	19	MTLE	Normal	3	No	NL	No	I
107	41	4	MTLE	NL	3	No	Localized	No	I
120	2	1	ExTLE	NL	5	Yes	Localized	Yes	II
123	27	11	ExTLE	Localized	4	Yes	Localized	Yes	I
129	10	5	ExTLE	Normal	4	No	Localized	No	II
133	5	2	ExTLE	Normal	4	No	Localized	No	I
142	13	1	ExTLE	Normal	4	No	Localized	No	IV
148	53	6	LITLE	NL	5	No	Localized	No	I
153	22	2	LITLE	Normal	5	Yes	Localized	Yes	I
155	17	1	MTLE	Normal	5	No	Localized	No	I



Example Case, no. 153. Patient who would have likely had only evaluation for anterior temporal localization without MSI. All aspects of case were supportive of right anterior medial temporal lobe epilepsy except that MRI was normal. Scalp EEG (top left)—both interictal and ictal findings—and FDG-PET (bottom left) were consistent with anterior temporal localization. Analysis of MEG (top right) revealed that nearly all spike source estimates (bottom right) were tightly clustered in the posterior peri-sylvian region where typical spontaneous seizures were recorded with ICEEG that would not have included this region without MSI.

Effect on Surgery Decision-Making Sutherland et al. 2008

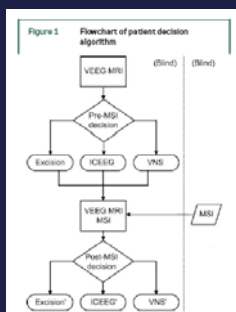


Table 2: Pre- and post-MSI decisions in three main categories

	Pre-MSI	Post-MSI
ICEEG	45	47
Surgery without ICEEG*	13	7
Vagal nerve stimulation	0	12

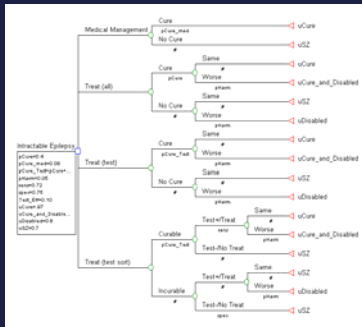
Effects on ICEEG and surgery

- Modify ICEEG electrode coverage
 - Add
 - Decrease
- Change from ICEEG to no surgery
- No surgery to ICEEG
- ICEEG (second stage modification)

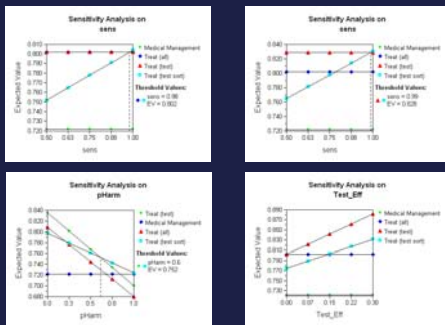
Utility of MSI in Epilepsy Surgery

- 1) Patient selection
- 2) Improving ICEEG localization yield and accuracy --> increase cure rate
- 3) Aiding other non-invasive tests such that an increased proportion of patients may avoid ICEEG
- 4) Decrease costs

Test Effect Decision Analysis



Sensitivity Analysis



Impact of Epilepsy Surgery: Cost Effectiveness in Test Utility

The Cost-Effective Use of ^{18}F -FDG PET in the Presurgical Evaluation of Medically Refractory Focal Epilepsy

Terence J. O'Brien¹, Ken Miles², Robert Ware³, Mark J. Cook⁴, David S. Burns⁵, and Rodney J. Hicks³

¹Departments of Medicine, Surgery, and Neurology, Royal Melbourne Hospital, University of Melbourne, Parkville, Victoria, Australia; ²Brighton and Sussex Medical School, University of Sussex, Brighton, United Kingdom; ³Centre for Molecular Imaging, Peter MacCallum Cancer Institute, Victoria, Australia; and ⁴Centre for Clinical Neuroscience and Neurological Research, St. Vincent's Hospital, Melbourne, Australia

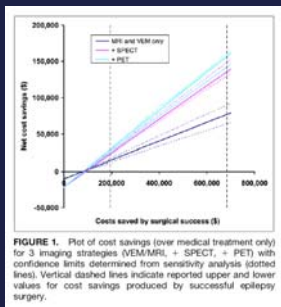
Cost Effectiveness of *test* on indeterminate VEEG/MRI: O'Brien et al. 2008

TABLE 1
Parameters Used in Decision Tree Modeling

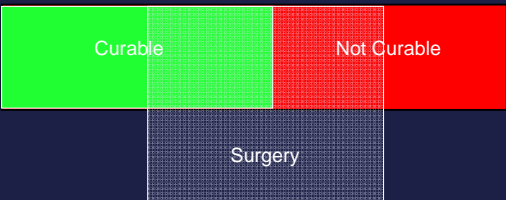
Parameter	Baseline value	Limit for sensitivity analysis	
		Lower	Upper
Prevalence of class I/II outcomes	0.267	0.202	0.332
Sensitivity of VEEG/MRI for class I/II outcomes	1.0	0.845	1.0
Specificity of VEEG/MRI for class I/II outcomes	0.705	0.581	0.804
Proportion of VEEG/MRI indeterminate	0.523	0.449	0.597
Prevalence of class I/II outcomes if VEEG/MRI indeterminate	0.278	0.196	0.378
Sensitivity of PET for class I/II outcomes if VEEG/MRI indeterminate	0.96	0.805	0.993
Specificity of PET for class I/II outcomes if VEEG/MRI indeterminate	0.246	0.158	0.363
Sensitivity of total SPECT for class I/II outcomes if VEEG/MRI indeterminate	0.783*	0.664*	0.869*
Specificity of total SPECT for class I/II outcomes if VEEG/MRI indeterminate	0.471*	0.262*	0.691*
Cost of VEEG	\$4,110	NA	NA
Cost of MRI	\$600	NA	NA
Cost of total SPECT	\$5,310	NA	NA
Cost of PET	\$918	NA	NA
Cost of surgery	\$25,691	NA	NA
Cost savings after class I/II outcome	\$440,000	\$0	\$700,000

*Data are based on Won et al. (26).
NA = not applied.

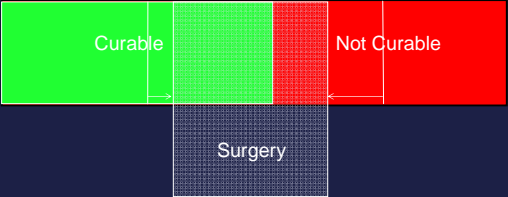
Cost Effectiveness in Test Utility: O'Brien et al. 2008



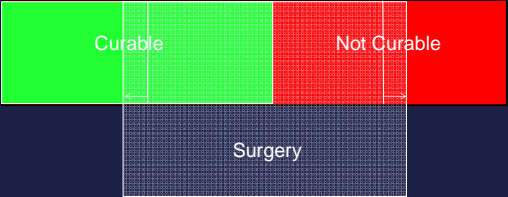
Effecting Surgical Outcomes?



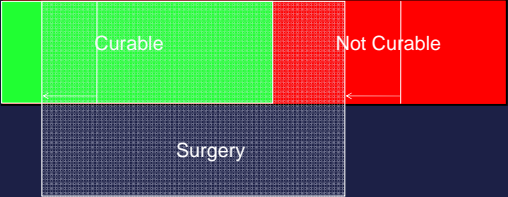
Effecting Surgical Outcomes?



Effecting Surgical Outcomes?



Effecting Surgical Outcomes



What is needed to show MSI utility?

- 1) MSI must effect an improvement in *net seizure-free* outcome (around 10-15%).
- 2) If MSI cannot sufficiently effect the total cure rate, then cost effectiveness will have to be demonstrated to make up for deficiencies in sensitivity and specificity needed for a test-sort role.

ACKNOWLEDGMENT

Grateful acknowledgment is made to the following organizations for their generous support of this workshop in the form of unrestricted educational grants.



University Health Care
Clinical Neurosciences Center



E L E K T A



A - N - T

EVALUATION

Please identify yourself: ☐ Neurologist ☐ Neurosurgeon
 ☐ Radiologist ☐ Technologist
 ☐ Other _____

Please rate the effectiveness using the following scale:
 1 = poor 2 = below average 3 = average 4 = above average 5 = excellent

	<u>clarity</u> of the information presented	<u>relevance</u> of the information to your clinical practice	objectivity, balance & scientific rigor
Jeff Lewine	① ② ③ ④ ⑤	① ② ③ ④ ⑤	① ② ③ ④ ⑤
Sylvain Baillet	① ② ③ ④ ⑤	① ② ③ ④ ⑤	① ② ③ ④ ⑤
Anto Bagic	① ② ③ ④ ⑤	① ② ③ ④ ⑤	① ② ③ ④ ⑤
Susan Bowyer	① ② ③ ④ ⑤	① ② ③ ④ ⑤	① ② ③ ④ ⑤
Richard Burgess	① ② ③ ④ ⑤	① ② ③ ④ ⑤	① ② ③ ④ ⑤
Michael Longacre	① ② ③ ④ ⑤	① ② ③ ④ ⑤	① ② ③ ④ ⑤
Andy Dean	① ② ③ ④ ⑤	① ② ③ ④ ⑤	① ② ③ ④ ⑤
Robert Knowlton	① ② ③ ④ ⑤	① ② ③ ④ ⑤	① ② ③ ④ ⑤

Rate your overall satisfaction with the opportunity to network with colleagues.	① ② ③ ④ ⑤
Rate your overall satisfaction with the quality of this conference/workshop.	① ② ③ ④ ⑤
Please rate your satisfaction with the organization of the conference/workshop.	① ② ③ ④ ⑤
How would you rate the cost of registration versus what you personally got out of the conference?	① ② ③ ④ ⑤

What other topics should ACMEGS address in future conferences?

- 1) _____
- 2) _____
- 3) _____

Additional comments? _____

Did you perceive commercial bias in any of the presentations? ☐ No ☐ Yes

Explain: _____

ACMEGS BYLAWS

**BYLAWS
OF
AMERICAN CLINICAL MAGNETOENCEPHALOGRAPHY SOCIETY, INC.,
A NON-PROFIT CORPORATION**

**ARTICLE I
ORGANIZATION**

1.1 The name and charitable purposes of the organization shall be as set forth in its Articles of Organization. In addition to the charitable purposes as set forth in the Articles of Organization, the organization may work cooperatively with other national and international magnetoencephalography (MEG), neurology, neurosurgery, and radiology organizations in determining how best to meet the clinical needs of MEG sites within the United States. These Bylaws, the powers of the organization and of its directors and officers, shall be subject to the Articles of Organization as in effect from time to time. The principal office of the organization in the Commonwealth of Massachusetts shall initially be located at the place set forth in the Articles of Organization.

1.2 The organization may have a seal which shall be in such form as the Board of Directors may, from time to time, adopt or amend.

1.3 The organization may at its pleasure by a vote of the Members (as hereinafter defined) change its name.

1.4 The pronoun "he" or "his," when appropriate, shall be construed to mean also "she" or "her" and the word "chairman" shall be construed to include a female.

**ARTICLE II
MEMBERSHIP**

2.1 Membership in this organization shall be open to those who support the purpose statement of the organization as set forth in the Articles of Organization and meet the qualifications set forth in Section 2.2. Continuing membership is contingent upon being up-to-date on membership dues which shall be paid annually on or before September 1st of each year.

2.2 There shall be two (2) classes of membership in the organization; namely, a Member class and an Associate Member class.

- a. "Members" shall include those individuals involved in the clinical use of magnetoencephalography (MEG) alone or in combination with electroencephalograms (EEGs), magnetic resonance imaging (MRI) or computerized axial tomography (CAT) scans and possessing a medical degree (M.D.), a Ph.D. in one of the aforementioned fields, or some equal equivalent degree. Each Member shall have one vote per person at all annual and special meetings of the members.
- b. "Associate Members" shall include clinicians, or their clinical assistants, involved with the use of magnetoencephalography (MEG) alone or in combination with electroencephalograms (EEGs), magnetic resonance imaging (MRI) or

computerized axial tomography (CAT) scan equipment and students with an interest in any of those fields. There are no voting rights for Associate Members.

Individuals wishing to join the membership of this organization for either class of membership shall apply for admission and be nominated by two (2) existing members of the member class for which membership is sought; provided, however, that those individuals identified as directors in the Articles of Organization as originally filed with the Massachusetts Clerk of the Commonwealth shall be automatically admitted into the Member class of this organization without further application. The Membership Committee shall review and recommend either admission or denial into the membership of this organization for each application submitted, after which the entire Board of Directors shall vote to accept or reject the Membership Committee's recommendation. The vote of the Board of Directors shall be final.

2.3 The dues for each membership class shall be reviewed and set annually by the Board and any proposed changes shall be voted on at the annual membership meeting.

2.4 Only those members who are current on their membership dues and are in the Members class shall be eligible to vote at any annual or special meetings of the membership.

ARTICLE III **MEMBERSHIP MEETINGS**

3.1 The first annual membership meeting of this organization shall be held on August 26, 2006 and thereafter shall be held on such date as determined by vote of the membership at the prior year's annual membership meeting.

3.2 The Clerk shall cause to be mailed to every member in good standing at its address as it appears in the membership roll book in this organization a notice telling the time and place of such annual meeting.

3.3 Meetings of the membership may be held at such time and place, within or without the Commonwealth of Massachusetts, as shall be stated in the notice of the meeting or in a duly executed waiver of notice thereof. Notices of meetings shall be sent to all members at their addresses as they appear in the membership roll book at least ten (10) days before the scheduled date set for such meeting. If mailed, notice is given when deposited in the United States mail, postage prepaid, directed to the member at such member's address as it appears on the records of the organization. Without limiting the manner by which notice otherwise may be given effectively to members, any notice to members given by the organization shall be effective if given by a form of electronic transmission consented to by the member to whom the notice is given. Any such consent shall be revocable by the member by written notice to the organization. Any such consent shall be deemed revoked if (1) the organization is unable to deliver by electronic transmission two consecutive notices given by the organization in accordance with such consent and (2) such inability becomes known to the Clerk or an Assistant Clerk of the organization, or other person responsible for the giving of notice; provided, however, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action.

3.4 The presence of not less than a majority of the Members class shall constitute a quorum and shall be necessary to conduct the business of this organization; but a lesser percentage may adjourn the meeting for a period of not more than four (4) weeks from the date scheduled

by these Bylaws and the Clerk shall cause a notice of this scheduled meeting to be sent to all those members who were not present at the meeting originally called. A quorum as herein before set forth shall be required at any adjourned meeting.

3.5 Special meetings of the members may be called by the President when he deems it for the best interest of the organization. Such notice shall state the reasons that such meeting has been called, the business to be transacted at such meeting and by whom it was called. At the request of a majority of the members of the Board of Directors or a majority of the Members class, the President shall cause a special meeting to be called but such request must be made in writing at least ten (10) days before the requested scheduled date.

3.6 No other business but that specified in the notice may be transacted at such special meeting without the unanimous consent of all present at such meeting.

ARTICLE IV

VOTING

4.1 When a quorum is present at any meeting, the vote of a majority of the Members class present in person or represented by proxy shall decide any question brought before such meeting, unless the question is one upon which by express provision of the statutes or of the Articles of Organization a different vote is required in which case such express provision shall govern and control the decision of such question.

4.2 Unless otherwise provided in the Articles of Organization or these Bylaws, each member of the Members class shall at every meeting of the membership be entitled to one (1) vote in person or by proxy, but no proxy shall be voted on after three (3) years from its date, unless the proxy provides for a longer period.

4.3 Unless otherwise provide in the Articles of Organization, any action required to be taken at any annual or special meeting of the membership of the organization, or any action which may be taken at any annual or special meeting of such members, may be taken without a meeting, without prior notice and without a vote, if a consent in writing, setting forth the action so taken, shall be signed by the members of the Members class having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which such members of the Members class were present and voted. Prompt notice of the taking of the action without a meeting by less than unanimous written consent shall be given to those members who have not consented in writing.

ARTICLE V

BOARD OF DIRECTORS

5.1 The business of this organization shall be managed by a Board of Directors consisting of the President, Clerk, Treasurer and two (2) at-large members, all of whom shall be Members. The initial directors shall be appointed by the sole incorporator. Thereafter, the directors shall be elected at the annual meeting of the membership in accordance with these Bylaws. Each director elected shall hold office until his successor is elected and qualified.

5.2 The at-large directors shall serve for a term of two (2) years. There shall be no limits on the number of terms an at-large director may consecutively serve. The terms of the at-large

directors shall be staggered with their initial terms as set forth in the Articles of Organization as originally filed with the Massachusetts Secretary of the Commonwealth.

5.3 Any Assistant Treasurer(s) chosen by the directors in accordance with Section 6.1 of these Bylaws shall be an ex-officio member of the Board of Directors.

5.4 The Board of Directors shall have the control and management of the affairs and business of this organization. Such Board of Directors shall only act in the name of the organization when it shall be regularly convened by its chairman after due notice to all the directors of such meeting.

5.5 A majority of the members of the Board of Directors shall constitute a quorum and the meetings of the Board of Directors shall be held regularly as such dates and times as the Board of Directors may determine, but no less than quarterly. The Board of Directors may hold meetings, both regular and special, either within or without the Commonwealth of Massachusetts.

5.6 Each director shall have one (1) vote and such voting may not be done by proxy.

5.7 Special meetings of the Board may be called by the President on five (5) days' notice to each director by mail or forty-eight (48) hours notice to each director either personally or by electronic means of communications, including electronic mail and facsimile transmission; special meetings shall be called by the President or Clerk in like manner and on like notice on the written request of one (1) director.

5.8 Unless otherwise restricted by the Articles of Organization or these Bylaws, any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting, if all members of the Board or committee, as the case may be, consent thereto in writing, and the writing or writings are filed with the minutes or proceedings of the Board or committee.

5.9 Unless otherwise restricted by the Articles of Organization or these Bylaws, members of the Board of Directors, or any committee designated by the Board of Directors, may participate in a meeting of the Board of Directors, or any committee, by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

5.10 Unless otherwise restricted by the Articles of Organization or these Bylaws, any director may be removed, with or without cause, by a majority of the members entitled to vote on such directorship. Any director may resign at any time by giving written notice of resignation to the Board of Directors, to the President or to the Clerk. Any such resignation shall take effect upon receipt of such notice or at any later time specified therein. Unless otherwise specified in the notice, the acceptance of a resignation shall not be necessary to make the resignation effective.

5.11 Vacancies in the Board of Directors shall be filled by the members entitled to vote on such directorship. Each director chosen to fill a vacancy on the Board of Directors shall hold office until the next annual election of directors and until his successor shall be elected and qualified.

ARTICLE VI

OFFICERS

6.1 The officers of the organization shall be chosen by the Board of Directors and shall be a President, a Clerk and a Treasurer, all of whom shall be Members. The Board of Directors may also choose one or more Assistant Clerks and Assistant Treasurers. Any number of offices may be held by the same person, unless the Articles of Organization or these Bylaws otherwise provide.

6.2 The Board of Directors at its first meeting after each annual meeting of the membership shall choose a President, a Clerk and a Treasurer from those members of the Board of Directors, and may elect one or more Assistant Clerks and Assistant Treasurers as the Board of Directors shall deem to be in the organization's best interests.

6.3 The Board of Directors may appoint such other officers and agents as it shall deem necessary who shall hold their offices for such terms and shall exercise such powers and perform such duties as shall be determined from time to time by the Board.

6.4 No officer shall for reason of his office be entitled to receive any salary or compensation, but nothing herein shall be construed to prevent an officer or director for receiving any compensation from the organization for duties other than as a director or officer.

6.5 The officers of the organization shall hold office until their successors are chosen and qualify. Any vacancy occurring in any office of the organization shall be filled by the Board of Directors. Any officer elected or appointed by the Board of Directors may be removed at any time by the affirmative vote of a majority of the Board of Directors. Any officer may resign at any time by giving written notice of resignation to the Board of Directors, to the President or to the Clerk. Any such resignation shall take effect upon receipt of such notice or at any later time specified therein. Unless otherwise specified in the notice, the acceptance of a resignation shall not be necessary to make the resignation effective.

6.6 The President shall be the chief executive officer of the organization, shall have general and active management of the business of the organization and shall see that all orders and resolutions of the Board of Directors are carried into effect. The President shall preside at all meetings of the membership and of the Board of Directors at which he is present. The President shall have all powers and duties usually incident to the office of the President except as specifically limited by a resolution of the Board of Directors. The President shall have such other powers and perform such other duties as may be assigned to him from time to time by the Board of Directors.

6.7 The Clerk shall attend all meetings of the Board of Directors and all meetings of the membership and record all the proceedings of the meetings of the organization and of the Board of Directors in a book to be kept for that purpose and shall perform like duties for the standing committees when required. He shall give, or cause to be given, notice of all meetings of the membership and special meetings of the Board of Directors, and shall perform such other duties as may be prescribed by the Board of Directors or President, under whose supervision he shall be. He shall have custody of the corporate seal of the organization and he, or an Assistant Clerk, shall have authority to affix the same to any instrument requiring it and when so affixed, it may be attested by his signature or by the signature of such Assistant Clerk. The Board of Directors may give general authority to any other officer to affix the seal of the organization and to attest the affixing by his signature.

6.8 The Assistant Clerk, or if there be more than one, the Assistant Clerks in the order determined by the Board of Directors (or if there be no such determination, then in order of their election) shall, in the absence of the Clerk or in the event of his inability or refusal to act, perform the duties and exercise the powers of the Clerk and shall perform such other duties and have such other powers as the Board of Directors may from time to time prescribe.

6.9 The Treasurer shall have the custody of the corporate funds and shall keep full and accurate accounts of receipts and disbursements in books belonging to the organization and shall deposit all monies and other valuable effects in the name and to the credit of the organization in such depositories as may be designated by the Board of Directors. He shall disburse the funds of the organization as may be ordered by the Board of Directors, taking proper vouchers for such disbursements, and shall render to the President and the Board of Directors, at its regular meetings, or when the Board of Directors so requires, an account of all his transactions as Treasurer and of the financial condition of the organization. He shall exercise all duties incident to the office of Treasurer.

6.10 The Assistant Treasurer, or if there shall be more than one, the Assistant Treasurers in the order determined by the Board of Directors (or if there be no such determination, then in the order of their election) shall, in the absence of the Treasurer or in the event of his inability or refusal to act, perform the duties and exercise the powers of the Treasurer and shall perform such other duties and have such other powers as the Board of Directors may from time to time prescribe.

ARTICLE VII

COMMITTEES

7.1 The Board of Directors may create committees as needed, such as executive, audit, and public relations. There shall be one standing committee – the Membership Committee. Except for members of the Membership Committee, membership in any committee created by the Board of Directors may contain such numbers of Members and Associate Members as the Board of Directors may reasonably determine.

7.2 No less than three (3) directors of the Board of Directors shall be appointed by the Board of Directors and shall serve as the members of the Membership Committee.

7.3 The Membership Committee shall have responsibility for reviewing applications for admission and making recommendations with respect such applications to the full Board of Directors.

ARTICLE VIII

GENERAL PROVISIONS

CHECKS

8.1 All checks or demands for money and notes of the organization shall be signed by such officer or officers or such other person or persons as the Board of Directors may from time to time designate.

FISCAL YEAR

8.2 The fiscal year of the organization shall be fixed by resolution of the Board of Directors.

BOOKS AND RECORDS

8.3 The books of the organization shall be kept at such place as the Board of Directors shall designate by resolution.

ARTICLE IX INDEMNIFICATION; LIMITATION ON LIABILITY

9.1 Each director and officer of the organization shall be indemnified to the fullest extent now or hereafter permitted by law in connection with any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he is or was a director or officer of the organization or is or was serving at the request of the organization as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise. Without limiting the generality of the foregoing, the organization shall indemnify each person within the scope of the foregoing to the extent to which it is given the power to do so by Section 8.56 of the Massachusetts Business Corporations Act of the Commonwealth of Massachusetts as in effect on the effective date of these Bylaws or as thereafter amended. To the extent permitted by applicable law, the organization shall have power to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the organization, or is or was serving at the request of the organization as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against any liability asserted against him and incurred by him in any such capacity or arising out of his status as such whether or not the organization would have the power to indemnify him against such liability under applicable law.

9.2 A director of the organization shall not be personally liable to the organization or its members for monetary damages for breach of fiduciary duty as a director except for liability (i) for any breach of the director's duty of loyalty to the organization or its members, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 8.56 of the Massachusetts Business Corporations Act of the Commonwealth of Massachusetts, as the same exists or hereafter may be amended, or (iv) for any transaction from which the director derived an improper personal benefit. If the Massachusetts Business Corporations Act hereafter amended to authorize the further elimination or limitation of the liability of directors, then the liability of a director of the organization, in addition to the limitation on personal liability provided herein, shall be limited to the fullest extent permitted by the amended Massachusetts Business Corporations Act. Any repeal or modification of this Article IX by the members of the organization shall be prospective only, and shall not adversely affect any limitation on the personal liability of a director of the organization existing at the time of such repeal or modification.

ARTICLE X AMENDMENTS

10.1 These Bylaws may be altered, amended, repealed or added to by an affirmative vote of not less than a majority of the members entitled to vote thereon.