Clinical and Economic Workshop Fall 2008

ACMEGS

AMERICAN CLINICAL MEG SOCIETY

Athinoula A. Martinos Center for Biomedical Imaging

Massachusetts General Hospital

November 6 - 7, 2008
Boston, MA

ACMEGS **American Clinical MEG Society November 6 – 7, 2008 in Boston, MA**

Welcome to Boston! On the behalf of the Organizing Committee, I hope that you enjoy your visit to the Athinoula A. Martinos Center for Biomedical Imaging.

This is the 2nd 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 workshop 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 head trauma, schizophrenia diagnosis and stratification, and motor mapping in Parkinson's disease. Drs. Timothy Roberts and Jeff Lewine will expand on these topics on the first morning.

We also welcome Robert Knowlton as the first 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.

I also wish to welcome our new Executive Director of ACMEGS, Michael Longacre.

Please enjoy the conference and dinner.

Sincerely,

Steven M. Stufflebeam, 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
Roland Lee, University of California San Diego, San Diego CA
Steven Stufflebeam, Mass. General Hospital, Boston MA

PROGRAM

Thursday, November 6, 2008

9:00 am **Arrival / Breakfast Reception (Provided)**

10:30 am **ACMEGS Presidential Address**
Welcome
Current Membership
Plans for 2008/9 and beyond

10:45 am **Clinical Research (Steve Stufflebeam)**
How to write a clinical MEG article that even an insurance company can understand. **Jeffrey Lewine** (Chicago)
ISACM 2009 in Athens **Tim Roberts** (Philadelphia)

12:00 pm **Lunch (Provided)**

1:00 pm **Business Meeting (Michael Funke)**
Proposals & Discussion
- Mission Statement
- Benefit Statement
- Membership Fee Structure
- Annual Meeting 2009

2:00 pm **Towards Clinical Standards and Certification (Anto Bagic)**
Necessity, Process, Issues and Outlook
Forming of ACMEG task-force groups

Dinner (Provided) 6 pm - late

Friday, November 7, 2008

9:00 am **Breakfast (Provided)**

9:30 am **John-Gates-Lecture**
Robert Knowlton (Birmingham, AL)

10:15 am **MEG Economics Bootcamp (Michael Longacre)**
Medicare Update 2009
National MEG Services Analysis
Private Reimbursement Strategies Roundtable
ACMEGS Evaluation Projects
Open Discussion

Noon **Lunch (Provided)**

1:00 pm **Meeting Adjourn**

Steven Stufflebeam

ACMEGS Presidential Address

Steven Stufflebeam, M.D.
Director of Clinical Magnetoencephalography
Associate Professor of Radiology, Massachusetts General Hospital

ACMEGS

American Clinical Magnetoencephalography Society

Philadelphia, PA, USA Dec 2, 2007

Desired Future of MEG

Current Situation	*Desired Situation*
1. 20+ active clinical MEG sites in US	1. Thriving MEG centers in all hospital centers
2. Some carriers pay others don't; con't to evolve	2. All carriers reimbursing
3. Major MEG vendor suspended manufacturing	3. Thriving MEG Vendors, innovating
? Restart	

History of ACMEGS

- APC Panel Meeting, August 2005
- CMS Meeting Sept 2005 on proposed MEG reimbursements for 2006
- Need a vehicle to meet with CMS as physicians' organization
  - Work with all vendors yet operate independent of vendors
- Educate members and insurance carriers
- Trade organization: NP 510c(6) tax status to allow for political activity
  - Incorporated April 25, 2006

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 we have over 30 paid members from 16 sites in the United States
  - Equal representation from all manufacturers
- We wish to have at least one member from each site in the US

Clinical MEG

- Present clinical MEG reimbursement:
  - CMS has recently reduced reimbursement
  - Private insurance reimbursement is uneven
- We wish to achieve fair reimbursement for clinical MEG from gov't and private carriers
- *Strategy*: Organize through ACMEGS

ACMEGS 2000

- Immediate plan ACMEGS going to do next?
  - Create a public statement from ACMEGS regarding the current status of clinical MEG
    - Website (www.acmegs.org)
    - ? Published in a clinical journal
  - Have an informational meeting with CMS
  - Anonymous data base of all cases of member sites
  - Standards and QA for clinical MEG

How to write a clinical MEG article that even an insurance company can understand

Jeffrey Lewine, Ph.D.
Alexian Brothers Center for Brain Research, Elk Grove Village, IL
Executive Director

ALEXIAN ADVANCED MEDICINE

Alexian Neurosciences Institute

Clinical MEG

Where are we now?
Where do we need to go?
How do we get there?

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

ALEXIAN BROTHERS HOSPITAL NETWORK

Alexian Brothers Medical Center
St. Alexius Medical Center
Alexian Brothers Behavioral Health Hospital
Alexian Rehabilitation 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.

Bad News – Good News

- The Bad News First
- There are two very influential Technology Assessments that consider MEG to be investigational – BCBS [2003], Hayes [updated in 2005].
- There is a 2007 report from the Medical Advisory Secretariat to the Ministry of Health and Long-Term Care for Ontario which also suggests MEG to be mostly investigational.
- There is a recent meta-analysis by Lau et al., 2008 which concludes MEG to be investigational.
- Most of the major private insurance companies have negative MEG policies: Most BCBS chapters, United HealthCare, Aetna, and Cigna, and most have updated their policy within the last year.
- The demise of VSM contributes to a growing impression that MEG is a technology that has not found, and never will find, its clinical foundation.

Bad News – Good News

- And now some Good News
- We have CPT-codes, and medicare reimbursement levels are not unreasonable but we have to be careful here with respect to billing practices.
- There continue to be US sales to influential clinical sites.
- There are some positive MEG policies – TriCare, BCBS Kansas, High Point
- Most insurance companies will ultimately approve a MEG examination if you are persistent and jump through all of the hoops. Every company has medical directors you can appeal to, and most provide for independent outside medical review.

Where do we need to go?

- We have to work together to convince insurance companies that even initial denial of MEG is to their detriment – it costs them money to go to outside medical review!
- We need to do research that is geared towards addressing technology assessment concerns.
- We need to become much better at how we present our data in publications and what conclusions we draw.
- If we do these things, reimbursement will ultimately become routine.
- Finally we need to develop some new, real clinical applications fast!

How do we get there?

- Dealing with insurance companies:
  - Our attitude has to be that all of the key data to support the clinical utility of MEG is already available. As a community we should still be planning multisite trials and better clinical studies, but don't say this in print, and don't say it to a medical director.
  - As a community we need to share reimbursment information and strategies, including strategies for cultivating support from local carriers [invite local directors to the site], drafts of appeal letters, and lists of who has paid for what type of studies. Also, maintaining records of contacts is key. We need to identify resources for maintaining a data base. A major strategy is to make the appeal process such a pain that you give up – be persistent.
  - There are two arguments used for denying MEG [1] the procedure is investigational and [2] inadequate medical necessity. The 2nd issue is patient specific, but the first is only partially so. If you know that a company has paid, even once, for a presurgical mapping in a patient with a frontal tumor, they are hard pressed to continue to argue that the procedure is investigational in cases like this. Don't be shy about calling these guys out to the mat on an issue like this.

How do we get there?

- Better Research – Understand the Technology Assessment Process
- TEC Assessment Criteria:
  - Regulatory Approval
  - Scientific evidence must permit conclusions concerning the effect of the technology on health outcomes
  - The technology must improve net health outcomes
  - The technology must be as beneficial as any established alternatives
  - The improvement must be attainable outside of investigational settings
  - Demonstrate that the method is of diagnostic and/or prognostic value
  - Demonstrate that the method is valid with respect to a gold standard
  - Demonstrate the resultant data alters health outcomes in a positive manner
  - Demonstrate that the method is cost effective

How do we get there?

- Studies must have > 20 subjects
- Prospective studies are better than retrospective studies
- Multisite is better than a single site.
- Studies should be blinded
- Comparison to gold standard – be very careful here – consider for example using the agreement between the location of MEG spikes and ECoG as a standard for epilepsy. If the outcome is that the patient is seizure free, this makes perfect sense. However, for a patient with a poor clinical outcome, the concordance with the ECoG is a comparison point, but a discordant result does not imply an MEG failure.
- OUTCOME, OUTCOME, OUTCOME

How do we get there?

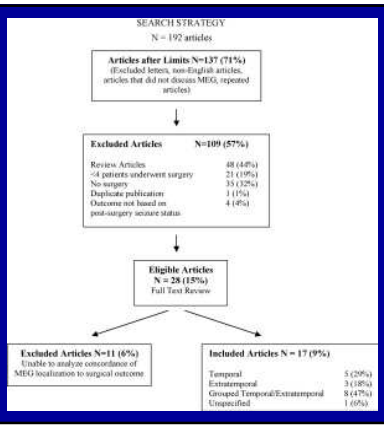
- Be thoughtful in writing manuscripts:
- Insurance companies want to see terms like sensitivity and specificity, positive and negative predictive value, and most importantly impact on outcome.
- Also, steer away from statements like – the available clinical data is not adequate to demonstrate utility so we did this study…, more research is needed.
- Good Examples:
  - Knowlton et al., 2008
  - Sutherling et al., 2008

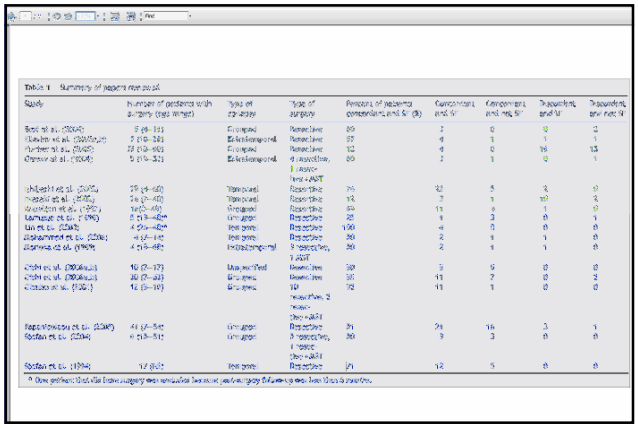
Some Additional Short Term Help!

- Recommendations from ACMEGS – we need to have this, but impact is likely to be small on private payors.
- We need to push AAN to complete its hopefully favorable technology review. An alternative might be a more general non-evidence based statement.
- A Support letter from the Directors of Comprehensive Epilepsy Programs
  We need to provide the expert opinions and make certain that an outside reviewer would be hard pressed to argue the technology to be investigational.
- A meta-analysis of existent epilepsy and presurgical data that is explicitly geared towards reviewing the technology. We need to take this into our own hands.

Lau et al., 2008, Epilepsy Research

- There is insufficient evidence in the current literature to support the relationship between the use of MEG in surgical planning and seizure free outcome after epilepsy surgery.



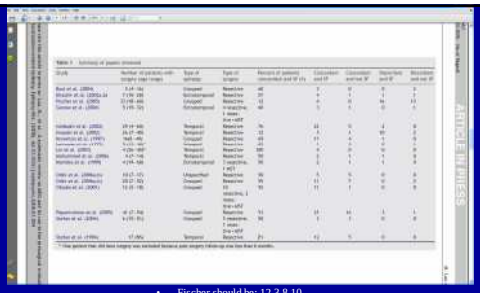


Problems

- Using the Lau numbers, MEG is NOT a significant predictor of outcome

But

THE NUMBERS ARE WRONG!!!



- Fischer should be: 12,3,8,10
- Iwasaki should be: 7,1,6,2
- Knowlton should be: 10,3,0,1
- Lamuso should be: 1,1,0,3
- Oshi should be: 10,5,1,4
- Otsubo should be: 6,0,5,1
- Papanicolaou should be: 18,11,6,6

- Fixing these numbers makes MEG significant at p<0.01

New Meta-analysis

Article	# Concordant Seizure-free	# Concordant Not seizure-free	# Discordant-Seizure-free	# Discordant Not Seizure-free	Total # of subject
Bast et al., 2004	3	0	0	2	5
Eliashev et al., 2002	4	1	1	1	7
Fernandez et al., 2004*	10	0	8	2	20
Fischer et al., 2005	12	3	8	10	33
Genow et al., 2004	3	1	0	1	5
Guggisberg et al., 2008	6	4	7	6	23
Ishibashi et al., 2002	22	5	2	0	29
Iwaski et al., 2002	7	1	6	2	16
Knowlton et al., 1997	10	3	0	1	14
Knowlton et al., 2008a,b	23	7	7	12	49
Lamuso et al., 1999	1	1	0	3	5
Leijten et al., 2003	3	2	0	1	6
Lin et al., 2003	4	0	0	0	4
Mamalek et al., 2002	9	2	2	2	15
Manoharan et al., 2007**	30	13	2	1	46
Mohamed et al., 2006	2	1	1	0	4
Mohamed et al., 2007a	2	2	0	1	5
Mohamed et al., 2007b	9	3	0	1	13
Oishi et al 2006	9	5	1	4	19
Otsubo et al., 2001	6	0	5	1	12
Pataraia et al., 2004	26	21	6	12	65
RamachandranNair et al., 2007	6	3	3	10	22
Smith et al., 2003***	18	8	9	16	51
Stefan et al., 2004	3	3	0	0	6
Stefan et al., 1994	12	5	0	0	17
Wheless et al., 1999***	11	4	7	7	29
POOLED DATA	251	98	75	96	520

When MEG identified zones of epileptogenicity are not included in the surgical resection zone, seizure free outcomes are achieved less than 45% of the time.

When MEG zones are included in the resection, seizure free outcomes are seen in 72% of cases.

This indicates a highly significant and positive benefit for including MEG information in the surgical treatment plan:

Chi-square = 37.26 p<0.001
Sensitivity = 0.77
Specificity = 0.49
Positive predictive value = 0.717
Negative predictive value = 0.559
 # needed to treat = 3.62

Future applications of clinical MEG

Tim Roberts, Ph.D.
Vice Chair of Research, Department of Radiology at Children's Hospital of Philadelphia
Professor of Radiology at the University of Pennsylvania School of Medicine

Tim Roberts

(MEG) Biomarkers of Autism

Timothy P.L. Roberts

Susan Levy, Michael Gandal, Sarah Khan, J. Chris Edgar, Deborah Zarnow, Erin Simon Schwartz

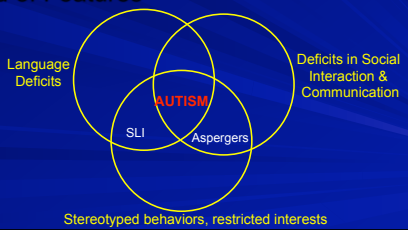
The Children's Hospital of Philadelphia
A pediatric healthcare network

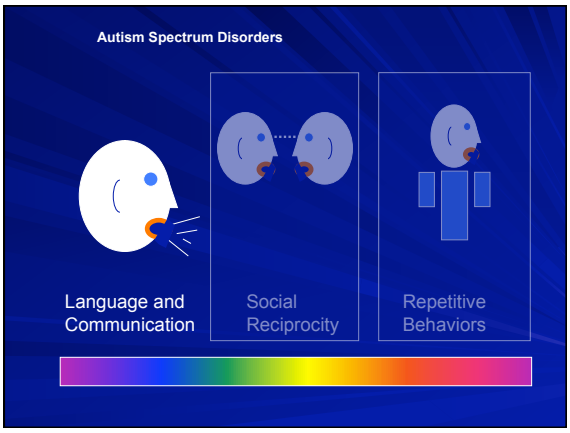
Electrophysiological Signatures of Autism Spectrum Disorders

- Roles:
  - Characterization / more specific diagnosis
  - Identify target neural systems for intervention
  - Stratify patients for intervention
  - Objectively evaluate therapy
  - Bridge to experimental (animal) models
- Hypothesis:
  - A disorder of neural communication will be revealed in **temporal** and **oscillatory** shifts, rather than spatial organization alone – these can form imaging biomarkers

Autism Spectrum (ASD)

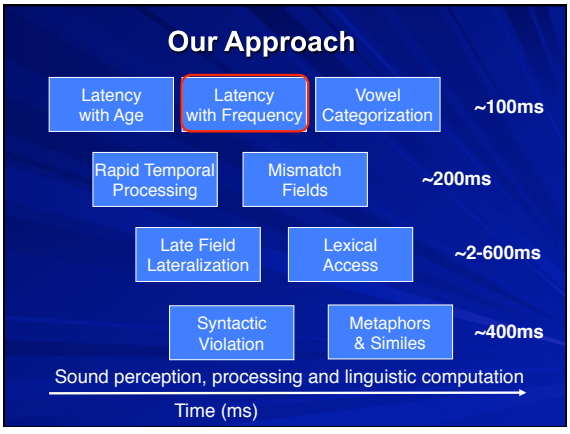
- Neurodevelopmental disorder, 65-90% heritable, ~1 in 150 children [CDC, 2007]
- Triad of Features





Language Impairment in Autism

- Language delay: one of earliest indicators of ASD
- Language processing can be modeled using auditory evoked potentials/fields (AEP/AEF)
- Our strategy: use AEF to characterize bottom-up building blocks of language processing, compare ASD vs typically developing children



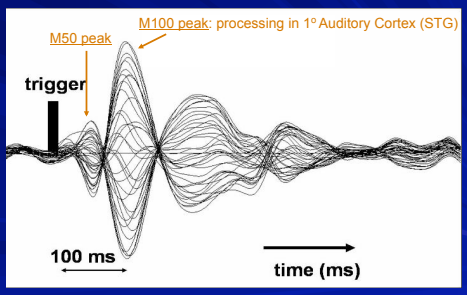
Methods

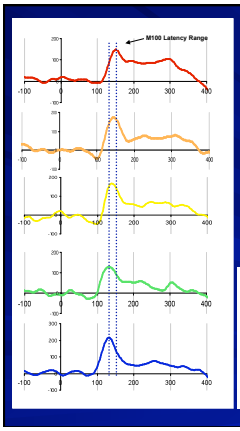
100Hz
200Hz
300Hz
500Hz
1000Hz

Subjects (age 6-15)

- **Autistic children (n = 21)**
- **Typically developing children (n = 19)**

Auditory electrophysiological signature

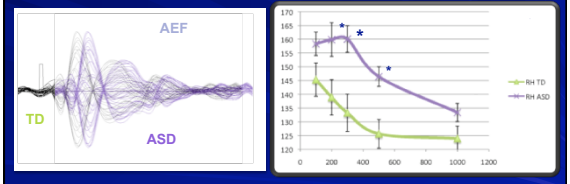




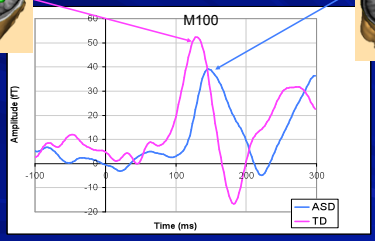
- Changes in tone frequency modulate M100 latency, but not amplitude
- Is this affected in Autism?

100Hz
200Hz
300Hz
500Hz
1000Hz

A (Bio)-marker for Autism:
Delayed Response in Auditory Evoked Field:
A symptom of impaired CONNECTIVITY

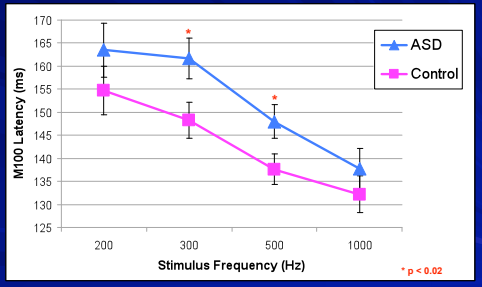


Results

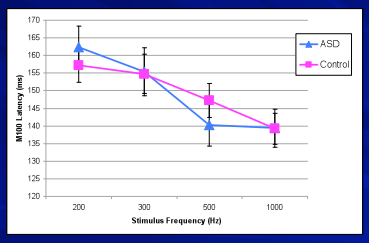


Robust delay in M100 peak in autistic subjects

Right Hemisphere

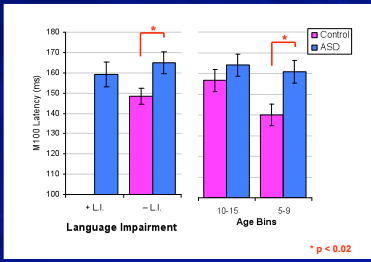


Left Hemisphere

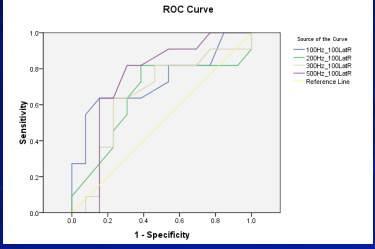


- No significant difference in LH
- Also no difference in M100 amplitude in left or right hemispheres

Subgroup Analysis



Implications: A Biomarker for ASD?



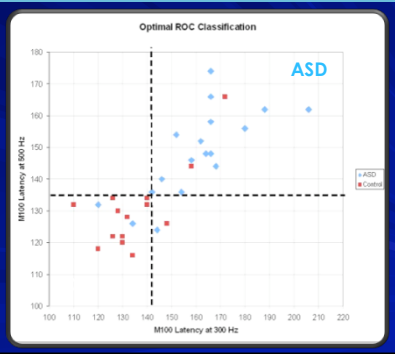
500 Hz Stimulus

-Sensitivity 82%

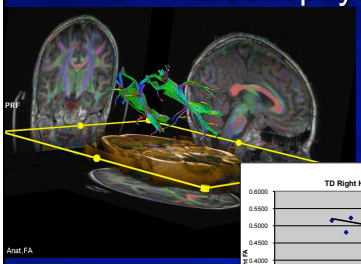
-Specificity 70%

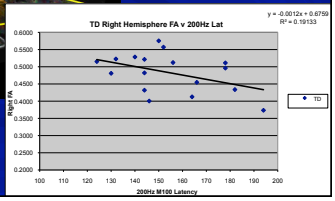
(p<0.05)

A (Bio)-marker for Autism: Delayed Response in Auditory Evoked Field: A symptom of impaired CONNECTIVITY



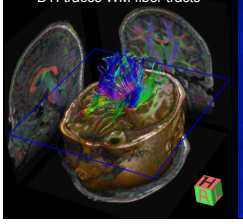
DTI / Electrophysiology

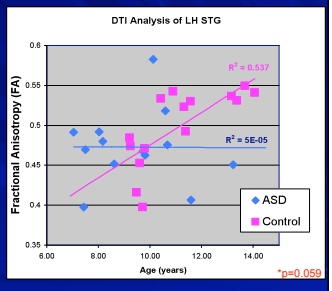




Future directions: Altered myelination in ASD?

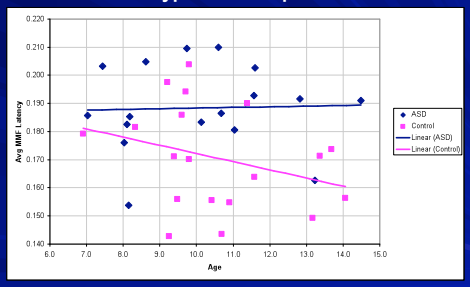
DTI traces WM fiber tracts





Mismatch Field Latency

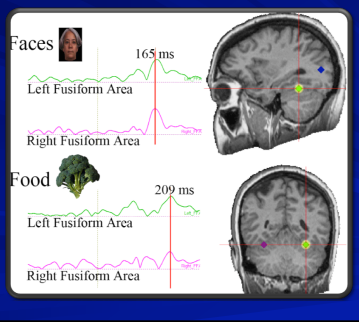
Shortens with Typical Development – Not in ASD



Sens: 88%
Spec: 74%
(p=0.001)

Mirrors Myelination Differences Shown by DTI

Temporal Signatures in Other Domains: Face Processing as a (Bio)-marker for Socialization ?



"Faces" are processed faster than "Objects" in typical development - resolvable with MEG

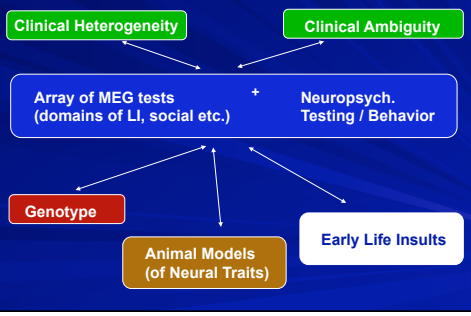
Conclusion

- Systematic ~20% **delay in M100 latency** in Autism
  - Specific to right hemisphere
  - Specific to 300 Hz and 500 Hz stimuli → '/u/' and '/a/' sounds
  - Specific to ASD, not a confound of age or language impairment
  - Marker of delayed/dysfunctional language processing
- ASD Biomarker?
  - 80+% sensitivity and 70% specificity
  - Can improve using LDA and multiple factors (e.g. M100 & MMF)
- Future Directions
  - Impaired myelination? Follow up with DTI

Electrophysiological Signatures of Autism Spectrum Disorders – Timing Matters

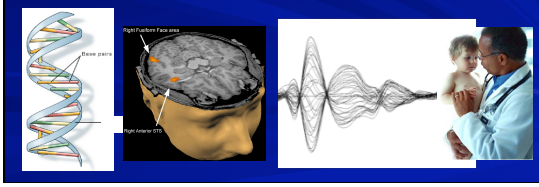
- Roles:
  - Characterization / more specific diagnosis (early predictor?)
  - Identify target neural systems for intervention
  - Stratify patients for intervention
  - Objectively evaluate therapy
  - Bridge to experimental (animal) models
  - Essentially BIOMARKERS of ASD
- Working Concept:
  - Spatial, temporal and spectral parameters might combine to yield desired sensitivity and specificity for neural impairments underlying ASD – 5D endophenotypes / biomarkers

Role of Electrophysiological Endophenotypes



Imagining the Future

1) Genetics Screening at birth (or before)
   - Profile of genetic risk factors
   - Prediction of risk based on sum of all factors
2) Enrollment in monitoring program during the risk period (first 6-24 months)
   - Biomarkers (Brain Growth, Electrophysiological Signatures)
   - Behavioral markers (lack of social communication)
3) Prophylactic interventions (behavioral, environmental triggers, pharmaceuticals)



CHOP MEG Lab

J Christopher Edgar, PhD

Sarah Khan
Mike Gandal
Katelyn Cannon
Tina Ahmadinejad
Gwen Schmidt
Michael Rey
Justin Monroe

Erin Schwartz, MD
Deborah Zarnow, MD
Susan E. Levy, MD
Lisa Blaskey, PhD
Sarah Woldoff, PhD
John Dell, RT
Ralph Magee, RT

Funding

NIH R01-DC00871
Nancy Lurie Marks Family Fdn
Christina & Jeffrey Lurie
Autism Speaks
HRSA
Samueli Institute
Commonwealth of PA

ISACM 2009

- September 3-6th 2009
- Athens, Greece
- Thurs-Sat Meeting
- Roundtable format
- Sunday – optional cultural tours

ACMEGS Business Meeting

Michael Funke, M.D., Ph.D.
Assitant Professor, Department of Neurology
University of Utah, Salt Lake City, UT

Michael Funke

ACMEGS MISSION STATEMENT

With the goal of improving clinical outcomes, the American Clinical MEG Society strives to make high quality healthcare available and affordable for patients with epilepsy and other neurological conditions across the country.

ACMEGS is a non-profit 501c6 trade association with a membership of more than 20 specialized clinical MEG centers in the United States. Founded in 2006 by physician-leaders committed to setting a national agenda for quality epilepsy care, ACMEGS educates public and private policymakers and regulators about appropriate patient care standards, reimbursement and medical services policies. ACMEGS is designed to complement, not compete with, the efforts of existing scientific and charitable epilepsy organizations.

Objectives

The primary objectives of ACMEGS are to support physicians and administrators in the operation of their clinical MEG centers.

We do this by:

- Linking patients, admininstrators, and referring clinicians with providers of specialized care.
- Connecting clinical MEG center members with each other for information sharing.
- Educating members and other organizations about ever-changing rules, governmental regulations and payor reimbursement issues that affect the success of specialized MEG care in the United States.
- Initiating positive changes in public and private reimbursement policies, coding and legislation and regulations that govern how specialized MEG care is delivered. Advocating for improved reimbursement for all MEG services, hospital outpatient

payments, inpatient hospital care, new technologies in both the public and private realms.

- Collaborating with the American Clinical Neurophysiology Society (ACNS), the National Association of Epilepsy Centers (NAES), the American Academy of Neurology (AAN), the American College of Radiology, the American Epilepsy Society (AES) and the Epilepsy Foundation (EF) on matters affecting epilepsy care by identifying areas and projects of mutual interest.

- Working with other organizations to bring new applications of MEG technology to improve the health of patients.

ACMEGS maintains solid working relationships with public and private organizations whose activities directly and indirectly affect access to high quality patient care. For example, organizations like the U.S. Department of Health and Human Services, the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention's (CDC's) epilepsy program, Joint Commission on Accreditation of Health Care Organization (JCAHCO), and Health Resources and Services Administration (HRSA).

ACMEGS MEMBERSHIP FEE SCHEDULE

MEG Center Membership

Annual MEG center membership dues are $2000. Membership is available to clinical MEG programs active in the diagnosis and treatment of epilepsy regardless of size or scope. Membership includes the Medical Director (and/or Co-medical Director) and the Program Administrator (person with budgetary authority for the epilepsy program). All centers that applied for membership are invoiced.

Individual Membership

Annual individual membership dues are $50 per individual. Professionals affiliated with a clinical MEG or epilepsy center member in good standing may belong as individual members. Associate membership rate is $50/year for technologists and affiliated professionals. All individual members are invoiced.

Billing Cycle

Annual memberships are effective January 1 through December 31 of each year. Centers are invoiced for the following year no later than November. Dues are payable by January 31st of each year.

BENEFITS OF ACMEGS MEMBERSHIP

In the healthcare environment of today ACMEGS membership has value.

- ACMEGS organizes and sponsors a yearly clinical and economic workshop that highlights recent changes in the finances of a new or growing clinical MEG site.

- Create a clinical MEG community, both online and in the real world.

- ACMEGS acts as the united voice of clinical MEG centers and maintains a national focus in the areas of clinical guidelines, government regulation and third party reimbursement.

- ACMEGS is continually seeking opportunities to promote the specialized services of MEG centers, and to improve coverage and payment for services in both the public and private insurance arenas. Acting on behalf of clinical MEG centers, the ACMEGS directs efforts in the establishment of CPT codes and relative values, Medicare coverage policies, and public health programs to encourage early intervention, accurate diagnosis and comprehensive treatment for patients.

- ACMEGS maintains relationships with key government, scientific and charitable organizations and decision makers on matters affecting patient care.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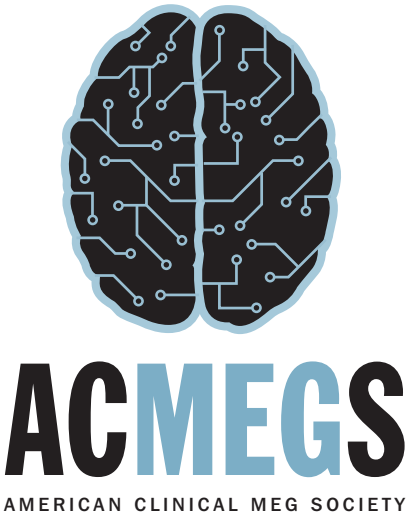
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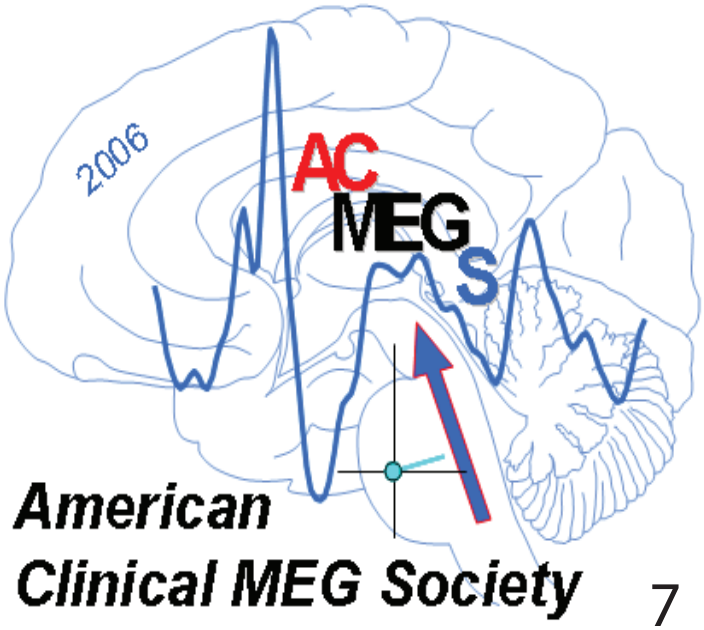

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ACMEGS

AMERICAN CLINICAL MEG SOCIETY

8

Towards Clinical Standards and Certification

Anto Bagic, M.D., M.sc.
Assistant Professor, Neurology & Neurosurgery Chief, Epilepsy Division Director
University of Pittsburgh Medical Center, Pittsburgh, PA

Anto Bagic

John Gates Lecture

Robert Knowlton, M.D., M.S.P.H.
Associate Professor of Neurology, Division of Epilepsy, Director MEG Laboratory
University of Alabama, Birmingham, AL

Robert Knowlton

Role of MSI in Epilepsy Surgery

American Clinical MEG Society
John Gates Lecture 2008

Robert C. Knowlton, MD, MSPH

Goal of MSI in Epilepsy

Noninvasive 3D localization of abnormal and normal cerebral function.

Epileptiform and non-epileptiform disturbances of cerebral activity.

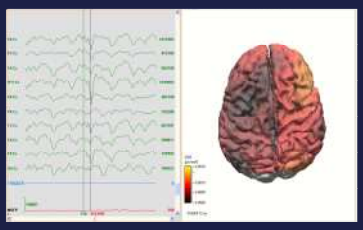
Cortical function / brain mapping.

Limitations

- Mathematical models used to compute source localization make many assumptions about the source(s) that may or may not be valid.
- Magnetic fields from some deep sources cannot be detected at the scalp.
- Resources to implement MEG technology and analysis labor are both expensive.

Spike Source Localization

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

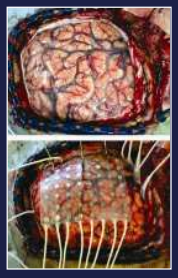


Technical and Clinical Validation

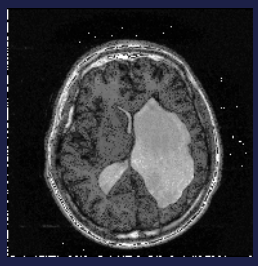
- Implanted dipoles.
- Simultaneous MEG and ICEEG.
- Colocalization with epileptogenic lesions (MRI).
- Colocalization with functional epilepsy imaging (PET, ictal SPECT, MRSI).
- Correlation with ICEEG and surgery outcome.

Epilepsy Surgery

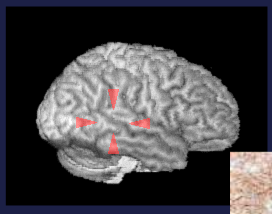
The Problem

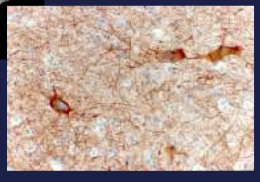


Non-localizing MRI

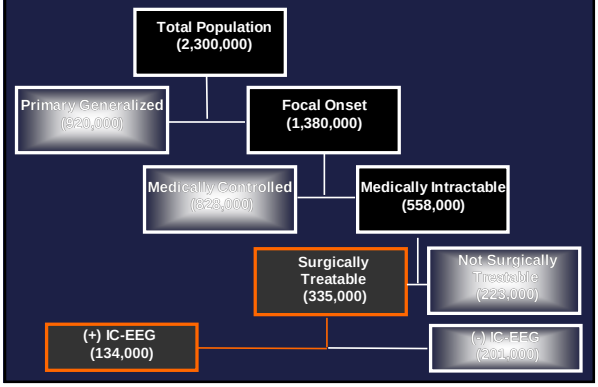


Value ?





Epilepsy Prevalence - U.S.



Epilepsy Neurophysiology

Non-invasive

Seizure monitoring (VEEG)

Source localization (EEG and MEG)

EEG/fMRI

Invasive

ICEEG

SEEG

Wada

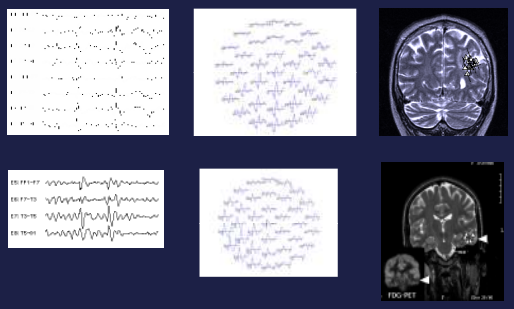
MEG in Epilepsy Validation

- Direct:
  - Implanted dipoles by special intracranial electrodes implanted for epilepsy surgery localization
  - Simultaneous ICEEG-MEG recordings

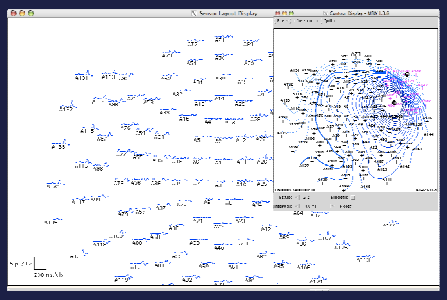
MEG in Epilepsy Validation

- Indirect:
  - Colocalization with epileptogenic lesions (MRI and histopathology)
  - Colocalization with functional imaging: PET, ictal SPECT, MRS
  - Correlation with subsequent ICEEG recordings and surgery outcomes

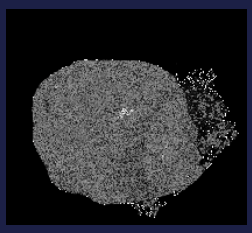
MEG colocalization with lesions

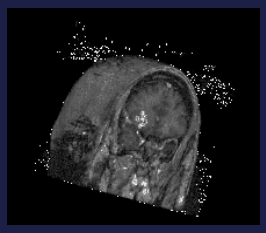


MEG

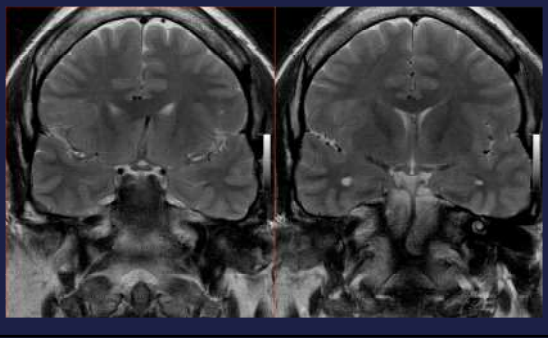


MSI

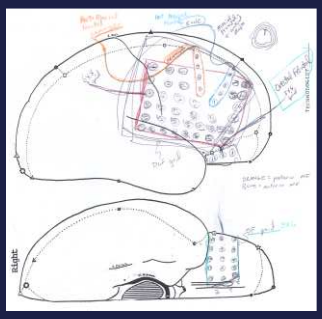




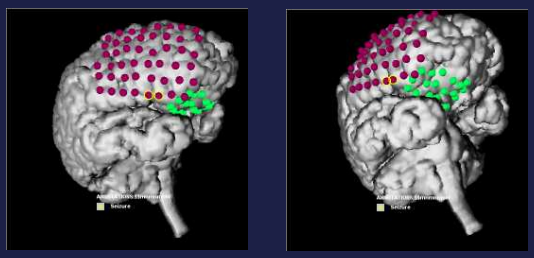
MRI



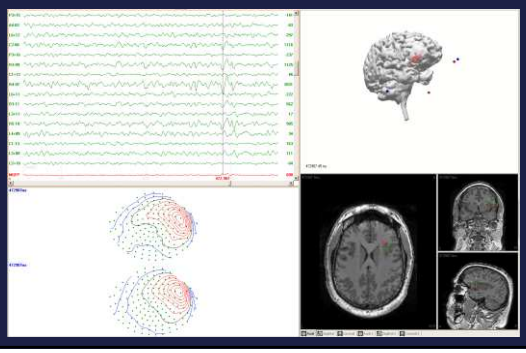
Intracranial EEG (ICEEG)



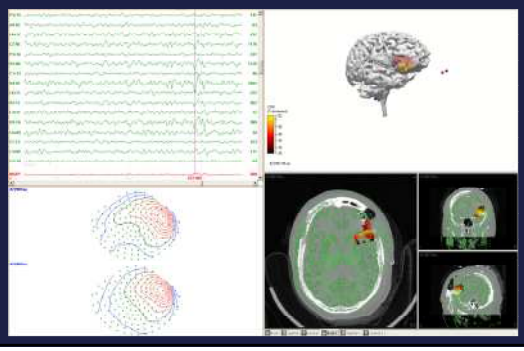
Grid View and Preoperative Imaging



MSI: Dipole Modeling



MSI: Extended Source



ICEEG Patients from Cohort

Patients n=77
mean age=27 (range 1-62)
female=49%

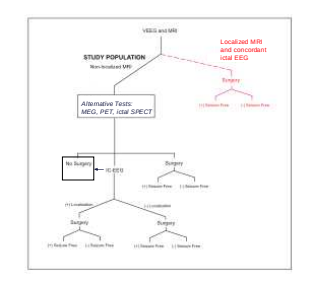
VEEG CLASS
ExTLE=33 (43%)
MTLE=30(39%)
LTLE=9 (12%)

MRI CLASS
Normal=33 (43%)
Lesions=7 (9%)
Ambiguous=37 (48%)

Prospective MSI and multimodality imaging study

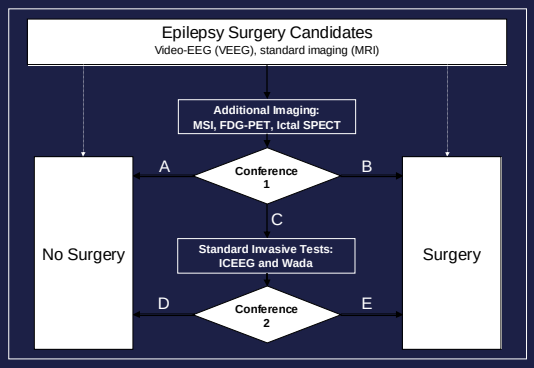
- Patient Selection began in 2001:
  1. Surgical candidates following scalp VEEG monitoring
  2. MRI non-localizing, normal, ambiguous –ultimately excluded patients with unilateral hippocampal sclerosis or focal *epileptogenic* lesion and concordant ictal EEG.

Study Design Overview



AIMS

1. To determine sensitivity, specificity and predictive values of MEG with respect to ICEEG and surgical localization
2. Compare degree of localization agreement (redundancy versus complementary role) between MEG, PET, and ictal SPECT.



Methods: MEG

- *Whole head* magnetometer (148 channels)– 40 minutes of spontaneous cerebral activity typically during sleep with or without clonidine (for enhancement of spikes).
- Simultaneous recording of EEG (10-20 system with additional electrodes FT9 & FT10).
- Single ECD model for source localization

Methods: FDG-PET and ictal SPECT

- Interictal FDG-PET scans with modern high-resolution camera–visual analysis versus SPM
- Ictal SPECT (HMPAO) with brain dedicated triple head camera–visual analysis, subtraction, and SPM
- With and without coregistration to MRI

Methods: ICEEG

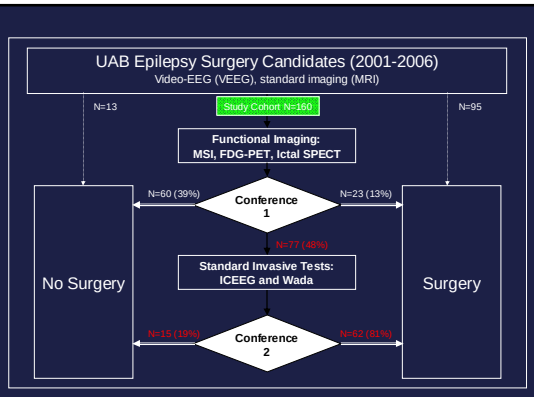
- ExTLE: subdural grid and strip electrodes with coverage over the hypothesized location* of the epileptogenic zone
- MTLE: bilateral subtemporal epidural or subdural strip electrodes (+/- hippocampal depth electrodes)
- LTLE: subtemporal strip and lateral temporal grid electrodes.

* Coverage of hypothetical seizure localization based on electro-clinical-anatomic data and other imaging, not MEG

Methods: ICEEG

- MSI data provided after an initial ICEEG coverage plan was designed.
- Only additional electrodes to cover region(s) indicated by MSI that were not included in original plan (no change to original sampling).

Comparison of localization



ICEEG Cohort (n=77): Epilepsy category by MRI class

	MTLE	LTLE	ExTLE	NL
MRI class				
Normal	14 (50)	2 (22)	14 (45)	1 (25)
Abnormal				
large, ambiguous, multiple	7 (25)	3 (33)	11 (35)	1 (25)
questionable	5 (18)	3 (33)	3 (10)	1 (25)
localized	2 (7)	1 (11)	3 (10)	1 (25)
Total	**28**	**9**	**31**	**4**

MTLE=mesial temporal lobe epilepsy, LTLE=lateral temporal lobe epilepsy, ExTLE=extratemporal lobe epilepsy
NL=non-localized

MSI–ICEEG Classification

VEEG	MEG/MSI			ICEEG		
	Localized	*NL*	*Negative*[*]	*Localized*	*NL*	*Negative*[§]
ExTLE	20	9	4	22	9	2
MTLE	17	5	8	20	8	2
LTLE	7	0	2	8	1	0
NL	4	0	1	4	0	1
Total	48	14	15	54	18	5

[*] no spikes captured during MSI recording session
[§] no seizures captured during ICEEG recording session (minimum 5 days)

Localization Concordance

	ICEEG	
MSI	+	-
concordant +	32	7
-	19	14
discordant +	5	κ=0.2518 [0.039,0.4646]

Localization Concordance

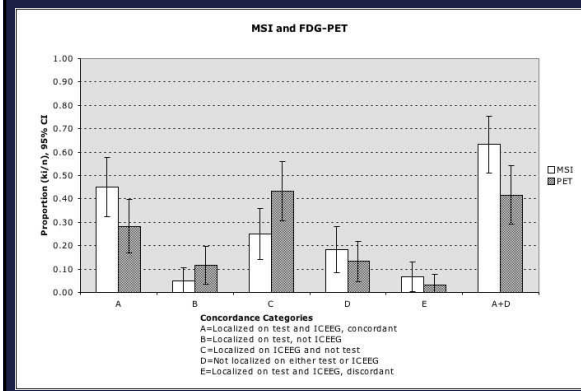
	ICEEG	
MSI	+	-
concordant +	32	7
-	8	10
discordant +	5	κ=0.3818 [0.124,0.6396]

Non-diagnostic MSI (no spikes) excluded

MSI localization in comparison to ICEEG

	MSI *n=77*	MSI *n=72*	MSI *n=58**
Sensitivity	62.7% (54.4, 69.6)	62.7% (48.1,75.5)	80.0% (63.9, 90.4)
Specificity	66.7% (46.3, 82.3)	75.0% (47.4,91.7)	69.2% (38.9, 89.6)
PPV	82.1% (71.1, 91.0)	88.9% (78.0, 96.4)	88.9% (73.0, 96.4)
NPV	42.4% (42.4, 29.5)	38.7% (22.4, 57.7)	52.9% (28.5, 76.1)
Discordant cases, n	5	5	5

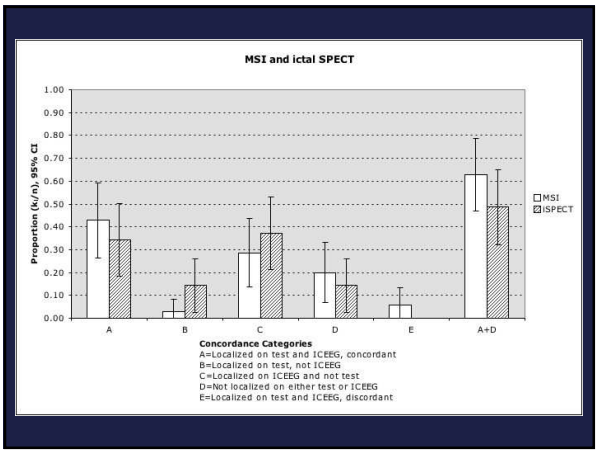
non-diagnostic ICEEG (no seizures) cases excluded
* both non-diagnostic ICEEG and MSI (no spikes) cases removed



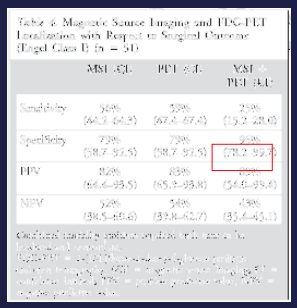
MSI and PET localization in comparison to ICEEG

n=60	MSI	PET	MSI or PET	MSI and PET
Sensitivity	64.3% (55.6, 69.4)	39.5% (31.4, 47.4)	80.0% (73.0, 87.4)	15.6% (8.7, 19.2)
Specificity	78.6 % (52.4, 94.0)	53.3% (30.0, 76.0)	40.0% (19.0, 62.1)	86.7% (66.1, 97.6)
PPV	90.0% (77.8, 97.2)	70.8% (52.2, 85.0)	80.0% (73.0, 87.4)	77.8% (43.6, 96.0)
NPV	42.3% (28.2, 50.6)	23.5% (13.2, 33.5)	40.0% (19.0, 62.1)	25.5% (19.5, 28.7)
Discordant cases, n	4	2	0	0

non-diagnostic ICEEG (no seizures) cases excluded



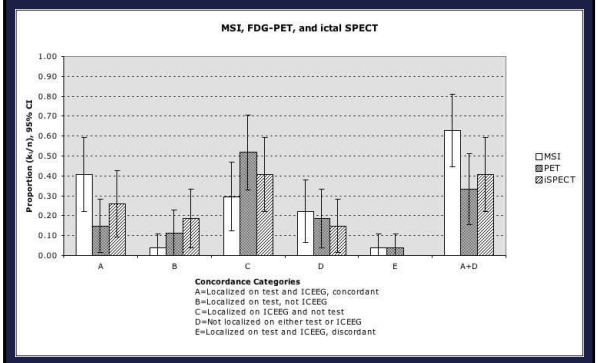
MSI and FDG-PET



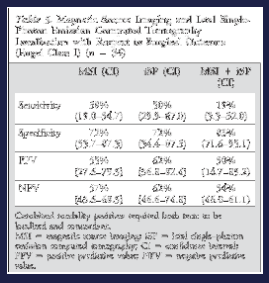
MSI and ictal SPECT in comparison to ICEEG

n=35	MSI	iSPECT	MSI or iSPECT	MSI and iSPECT
Sensitivity	60.0% (48.4, 63.8)	48.0% (36.9, 59.1)	80% (70.0, 90.2)	24.0% (13.1, 27.8)
Specificity	87.5% (51.1, 99.3)	50.0% (22.3, 77.7)	40% (15.1, 65.7)	90.0% (62.8, 99.5)
PPV	93.8% (75.6, 99.7)	70.6% (54.3, 86.9)	76.9% (67.3, 86.8)	85.7% (46.8, 99.2)
NPV	41.2% (24.1, 46.7)	27.8% (12.4, 43.2)	44.4% (16.8, 73.0)	32.1% (22.4, 35.5)
Discordant cases, n	2	0	0	0

non-diagnostic ICEEG (no seizures) cases excluded



MSI and iSPECT



MSI, PET, and ictal SPECT localization in comparison to ICEEG

n=27	MSI	PET	iSPECT
Sensitivity	57.9% (43.6, 62.9)	22.2% (9.5, 33.9)	38.9% (25.5, 53.8)
Specificity	85.7% (47.0, 99.2)	62.5% (33.9, 88.7)	44.4% (17.7, 74.3)
PPV	91.7% (69.1, 99.6)	57.1% (24.5, 87.1)	58.3% (38.3, 80.7)
NPV	42.9% (23.5, 49.6)	26.3% (14.3, 37.4)	26.7% (10.6, 44.6)
Discordant cases, n	1	1	0

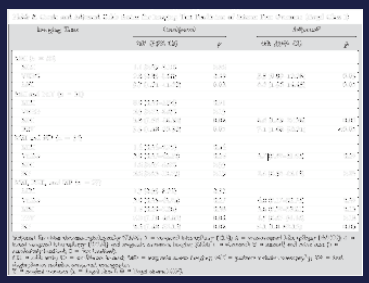
non-diagnostic ICEEG (no seizures) cases excluded

MSI, PET, and ictal SPECT localization in comparison to ICEEG: combined imaging

n=27	PET or iSP	PET and iSP	MSI or PET or iSP	MSI and PET and iSP
Sensitivity	44.4% (31.0, 59.3)	22.2% (9.2, 33.9)	72.2% (63.2, 86.4)	5.6% (0.3, 10.8)
Specificity	44.4% (17.5, 74.2)	66.7% (40.6, 90.1)	22.2% (4.2, 50.5)	88.9% (78.4, 99.4)
PPV	61.5% (42.9, 82.2)	57.1% (23.6, 87.2)	65.0% (56.9, 77.7)	50.0% (2.7, 97.3)
NPV	28.6% (11.2, 47.7)	30.0% (18.3, 40.5)	28.6% (5.3, 65.0)	32.0% (28.2, 35.8)

non-diagnostic ICEEG (no seizures) cases excluded

Prediction of Outcome



MSI Effect on ICEEG

- 18 of 77 cases[†] (23%)–MSI modified coverage
- In 44% percent (95% CI: 24.5, 66.3) seizures involved the additional ICEEG electrodes indicated by MSI.

[†] two of the 18 patients did not have surgery
- One case with seizures likely arising from MSI indicated OF region still insufficiently sampled.
- Second case with left posterior *lateral* TLE that overlapped with receptive language.

MSI Effect on ICEEG

- Conversely 10 of 18 cases–seizures did not include additional electrode coverage
  - Over interpretation of scattered spikes
  - Poor spatial resolution of ECD model in certain spike types

MSI Effect on ICEEG (Surgery population, n=62)

- No significant difference in seizure-free outcome between groups (n=16 MSI (+) ICEEG versus n=48 MSI (-) ICEEG.
- Seizure-free outcome correlated with highly localized MSI in both groups.

Conclusions

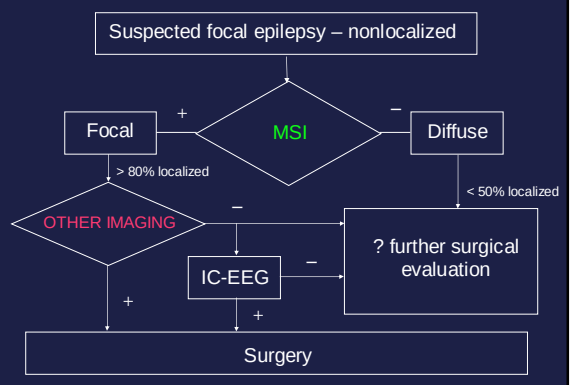
- MSI has a high positive predictive value for seizures localized with ICEEG.
- Diagnostic gain may be achieved with addition of either PET or ictal SPECT to MSI.
- *Conclusively localized* MSI studies have clinical value predicting seizure-free outcome in surgery candidates who typically require ICEEG.

Conclusions

- MSI spike localization increases the chance that the seizure onset zone is sampled when patients undergo ICEEG.

Role of MSI in Epilepsy Surgery

1) Patient selection
2) Improving ICEEG localization yield and accuracy
3) Aiding non-invasive tests such that an increased proportion of patients may avoid ICEEG



Adapted from Mamelak et al. 2002, *J Neurosurg*

Gaps in our knowledge and what is needed

1. Accurate characterization of true sources from intracranial measures
2. Further understanding of propagation versus volume conduction with regard to true sources
3. Automated high-resolution segmentation of tissue types used in models
4. Clinical testing and validation of source models

Major Question

How do we overcome the difficulties of employing multi-step complex computational methods such that requirements† for clinical use can be met?

† reliable, reproducible, accurate, easy to use, and, of course, not too costly

Michael Longacre
Executive Director, ACMEGS

Michael Longacre

American Clinical MEG Society
Boston 2008 Meeting

MEG Reimbursement Overview

Michael Longacre
Executive Director
ACMEGS

American Clinical MEG Society
Boston 2008 Meeting

Michael Longacre's Introduction:

Michael's 30-year plus experience spans the spectrum of healthcare markets from pharmaceuticals, diagnostics, medical devices and patient- physician Internet connectivity. He has held senior level reimbursement and managed care, as well as sales and marketing, positions for a number of healthcare start-up companies. Most recently, he managed his own consulting firm, specializing in assisting companies in development and execution of their reimbursement strategies. Prior to that, he was VP of Sales and Marketing with Inpharma, a start-up biopharmaceutical company, and Director of Reimbursement and Managed Care with Inovise, where he successfully obtained a CPT code for an innovative cardiology product. He has also held senior reimbursement and managed care positions with R2 Technology, BIEX and Cytyc. His extensive experience includes obtaining CPT codes, influencing reimbursement rates and coverage, and representing clients as a lobbyist at both the state and national level. Michael is a recognized expert in reimbursement and managed care and has numerous speaking engagements, articles and direct quotes in trade publications to his credit. Mike graduated from California State University in Los Angeles with a BS in Biology.

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Reimbursement Overview

1. Payer Review
2. Medicare HOPPS and RBRVS
3. Chargemaster Project
4. Reimbursement 101 – Quick Review
5. Future Projects

Payor Headlines

April 2008
Expose' shows insurers have reason to gloat
Issue: "Blanket denials are first line of defense"
Diagnostic Imaging
February 13, 2008
UnitedHealth unit charged with fraud
Issue: Defective and manipulated data base
Market Watch
July 11, 2008
Report: Payors putting squeeze on imaging overuse
Issue: Expansion of accreditation/certification
AuntMinnie.com

Payor Headlines

July 13, 2008
Doctors-insurers confrontation heats up
Issue: Jump in denied claims, administrative costs up 118% last ten years ($453)
Dallas Morning News
July 15, 2008
GAO report on overutilization draws industry ire
Issue: Preauthorization to reduce studies
AuntMinnie.com
July 21, 2008
Rating Insurers will help fix inefficient claims system
Issue: Claims payments are late and inaccurate, correct 62% to 82%
Amednews.com

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"So what's the point?"

We need to be more organized and act as a group to influence payers on behalf of the patients we serve.

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Medicare Review

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2009 RBRVS (Professional Fee Only)

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

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2008 Medicare HOPPS Analysis

95965

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

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CY 2009 HOPPS and RBRVS Totals

Code	APC $	RBRVS $	Total $
95965	$3803.23	$424.07	$4,227.30
95966	$952.38	$210.72	$1,163.13
95967	$952.38	$180.35	$1,132.73

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Chargemaster Project

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Chargemaster Project

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.

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"Reimbursement 101: Working with Vendors to Make your Facility Competitive"

Reimbursement Model

Responsibilities

Vendor/ACMEGS	Provider
Code	Submit Claims
Values	Appeal Denials
Reimbursement Support	Influence Regional Payors
Reimbursement Tool Kit	Maintain Chargemaster
Marketing Tool Kit	Appropriate Coding
Advocacy Support	Collect Payor Information
Collect Coding & Payor Data	Community Marketing
Distribute Payor Data	Communicate Payor Activity

Codes

CPT I Code: The preferred code, it comes with corresponding values recommended by the AMA (RUC)

CPT III Code: This code is intended to be utilized as a tracking code and does not have recommended values via the RUC. This can be overcome by obtaining the publication of non-Medicare RBRVS.

HCPCS Code: This is a Medicare specific code not always recognized by private payors

Alternative CPT I Code: An existing procedure similar to the technology

Unlisted CPT I Code: This is also referred to as a "miscellaneous" code

Published Values

RBRVS: Values published by Medicare Part B which are utilized by approximately 70% of all payors

Non-Medicare RBRVS: RBRVS values for non-Medicare covered services

APC: Hospital Out-patient Perspective Payment Medicare reimbursement (Medicare Part A).

Relative Values for Physicians: A proprietary, physician based values which enables doctors to defend and negotiate fees

Ingenix RVUs: Values determined by matrix of RVP, PCHS, ??

Advocacy

National

- Communicate benefits of technology to appropriate advocacy group(s)

Regional

- Coordinate communications with providers to maximize potential benefits

Payor Reporting

Review Payor reimbursement data from Explanation of Benefits (EOBs)

Compile and distribute appropriate data to providers

- Primarily “who’s paying and who’s not”
  - This becomes very helpful regionally in the attempt to influence local payors

Reimbursement Model

Responsibilities

Vendor/ACMEGS	Provider
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Values	Appeal Denials
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Marketing Tool Kit	Appropriate Coding
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Collect Coding & Payor Data	Community Marketing
Distribute Payor Data	Communicate Payor Activity

ACMEG Future Projects

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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

Discussion

Discussion
Questions
Comments
Feedback

CMS-1404-P Medians 2009 HOPPS Proposed Rule

HCPCS Code	Short Description	SI	APC	Payment Rate	Single Frequency	Total Frequency	Minimum Cost	Maximum Cost	Mean Cost	"True" Median Cost	CV
95965	Meg, spontaneo	S	0067	3664.34	31	33	663.02	4787.76	2609.27	2632.33	57.04
95966	Meg, evoked, si	S	0065	995.33	24	28	183.17	2591.31	1348.99	1060.26	64.177
95967	Meg, evoked, ea	S	0065	995.33	9	15	120.01	1699.12	1116.26	1699.12	64.2

APC	SI	Payment Rate	Single Frequency	Total Frequency	Minimum Cost	Maximum Cost	Mean Cost	"True" Median Cost	CMS Adjusted Median of Total Cost	CV
0067	S	3664.34	5107	5889	131.34	25328.88	4509.41	3657.89		69.338

FINAL OPPS PAYMENT BY HCPCS CODE FOR CY 2009

HCPCS Code	Short Desc.	CI	SI	APC	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
95965	Meg, spontaneous		S	0067	57.5732	$3,803.23		$760.65
95966	Meg, evoked, single		S	0065	14.4171	$952.38		$190.48
95967	Meg, evoked, each addÆl		S	0065	14.4171	$952.38		$190.48

MEG 2009 RBRVS												
Code	**Description**	**Mod**	**Physician Work RVUs**	**2009 Transitional Facility RVUs**	**F-I Facility PE RVUs**	**2009 Transitional Facility RVU**	**Mal-Practice RVUs**	**Total**	**2009 Dollars**	**APC**		**Total (Global) APC + 26**
95965		00										**$4,227.30**
95965		TC								0067	$3,803.23	
95965		26	7.99	2.86	2.66	2.86	0.46	11.31	$424.07			
95966		00										**$1,163.13**
95866		TC								0065	$952.38	
95966		26	3.99	1.44	1.35	1.44	0.19	5.62	$210.72			
95967		00										**$1,132.73**
95967		TC										
95967		26	3.49	1.16	1.14	1.16	0.16	4.81	$180.35	0065	$952.38	
2009 Conversion Factor		37.495										

AKNOWLEDGMENT

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

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

	clarity of the information presented	relevance 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
Anto Bagic	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
Michael Longacre	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: _____