Turning a New Page in Clinical Magnetoencephalography: Practicing According to the First Clinical Practice Guidelines

BACKGROUND AND PRIOR ART

Magnetoencephalography (MEG) has been in existence for four decades (Cohen, 1968, 1972), and now, a large body of literature exists (Bagić et al., 2009), including well-designed studies demonstrating its clinical value (Knowlton et al., 2008*a*, 2008*b*, 2009; Sutherling et al, 2008). Clearly, MEG is no longer a "new technology," and it is a propitious time to promulgate 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 MEG laboratories are adhering to good practice, a desire for systematic comparison across laboratories and in multicenter studies that demand consistent practices, and some minimal standards that both laboratory directors and payers can point to. It also is in keeping with the tradition of the American Clinical Neurophysiology Society, which for the past several decades has formulated and revised Clinical Practice Guidelines (CPGs) on a variety of neurophysiologic diagnostic tests (see http://www.acns.org/guidelines.cfm for a listing).

Other bodies will dictate what good practice is if we do not. Society and regulatory bodies want to ensure competency, and medical practitioners expect leadership toward quality (Clavien et al., 2005; Nahrwold, 2010). 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. The very existence of voluntarily produced and expertly reviewed guidelines demonstrates a level of professionalism and maturity that establishes a baseline of clinical credibility.

Clinical Practice Guidelines have been a reality in the medical profession for decades (e.g., Schorow and Carpenter, 1971; Talley et al., 1990; Wiebe, 2010; http://www.acns.org/guidelines.cfm). Yet, actual penetration of these guidelines into clinical practice varies (Haneef et al., 2010; Wiebe, 2010). To move toward excellence in MEG, as in all areas of clinical medicine, we must first obtain a clear picture of the current practices and the roles of the people practicing. Hence, the process of establishing the American Clinical Magnetoencephalography Society's (ACMEGS) first CPGs started with an assessment of the state of clinical MEG in the United States (Bagić, 2011). This survey was conducted in 2008 and included 90% of MEG centers providing clinical services at that time. Of course, not all individuals practicing clinical MEG from each participating center responded, and the field has dramatically grown even further in the past three years. Despite these and other limitations, this survey is the first systematic attempt to recount the prevailing clinical MEG practice in the United States, and it provides several important points to consider (Bagić, 2011).

The survey revealed a diversity of organizational structures and a large variability in daily practice. In more than a quarter of the surveyed centers, clinical reports of epilepsy MEG studies are signed by nonneurologists, two of whom were nonphysicians. Another remarkable finding was that the turnaround time from test to report ranged from 0.5 to 30 days, and this reporting time variability was not related to volume. These results demonstrate not only numerical variability but also suggest fundamental differences in practice and raise important questions. Should those of us struggling to complete our analysis and reports within even several days or a week be embarrassed that we cannot complete them within a day? Should we attempt to massively streamline our practice? And on the flip side, is there any reason why reports should take up to 30 days to send out in any clinical MEG center?

Integration into the overall clinical neurophysiology community is crucially important. Considering the complementary nature of MEG and EEG techniques (Barkley and Baumgartner, 2003, Ebersole and Ebersole 2010), it was reassuring to find that all centers claimed to be using EEG collected simultaneously with MEG in some way, but it remains concerning that EEG is used variably in study processing and interpretation. Some centers use EEG only to define the time slice of the MEG signal for dipole modeling, while rare centers also engage in EEG source localization. Although only a small point, the fact that the number of averaged responses used for mapping a particular modality ranged across centers by a factor of 19 is further illustrative of a wide variability in practice—or is a high number of averages an indication of fundamentally low signal quality?

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Does an expertise in EEG, with its accompanying understanding of clinical neurophysiology, convey an automatic readiness to interpret MEGs, or is it irrelevant? Both of these opposing positions were endorsed by some survey participants. Nevertheless, it is clear to the more experienced clinical magnetoencephalographers that having an MD/DO and/or PhD degree, having pursued a residency in neurology, neurosurgery, or radiology, or even an Accreditation Council for Graduate Medical Education-approved fellowship is insufficient per se. Respondents were more declaratively united on the need for some kind of standardized training and an assurance of a certain amount of "experience" in analyzing and interpreting MEGs, than on the specifics. Most medical professionals would agree that five years in the field (after training) represents a significant experience (McCray et al., 2008). However, in this survey, "experience" was purely chronologically based and varied widely, depending on the institution, with some busy magnetoencephalographers reading more clinical MEGs in an average month than some in the less busy laboratories see in five years (Bagić, 2011).

The survey demonstrated that both physicians and nonphysicians recognize the need for clinical MEG standards. Generally, 81% of the surveyed participants displayed a positive attitude by welcoming an "appropriate form of standardized training WITH certification" or believing that it "would improve the quality of patient care and help propel clinical MEG." One eighth of the respondents thought that clinical MEG standards already existed, and some even believed that "everybody in the field knows the standards." Yet either way, one out of five respondents still believed that "standards would not change what they do" (Bagić, 2011). It has been suggested that practitioners are far more likely to change their behavior if there is direct interaction between the subject matter experts and the practitioners (Akbari et al., 2008). For clinical MEG, still very much a growing field, this presents a great opportunity.

So, the process of defining the first CPGs for MEG began. There are some initial philosophical questions that our group attempted to grapple with to create some context for our guidelines. These questions, and some brief summaries of our answers, are included below.

PHILOSOPHICAL QUESTIONS

1. *Who is the target audience? Current practitioners of the MEG art? Trainees and those who educate them? Administrators and department chairman at hospitals considering establishing an MEG laboratory (center)? Payers? Referring physicians?*
   The guidelines are not meant to be a comprehensive how-to manual for MEG. They are aimed at those already trained in MEG who are responsible for ensuring that their laboratory is conducting high-quality studies that are considered the standard of practice. The guidelines are meant to answer the specific questions that ensure some level of uniformity across laboratories. Just as with any other clinical test, reporting style differs from one MEG center to another. Physicians referring patients to MEG laboratories have sometimes found that the reports they receive back are impenetrable or do not answer the clinical question for which the patient was sent to the laboratory. Hence, there is a need to ensure that the test results are understandable and meet their expectations.

2. *Are these guidelines meant to be "minimal standards" or "best practices"?*
   The ACMEGS was formed, in part, to advocate for best practices in MEG so that high-quality clinical answers are delivered, and hence, MEG testing becomes even more valuable in clinical care. Therefore, even though the guidelines are not meant to establish a legal "standard of care," they are designed to point us in the direction of excellent standards of practice—not just 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 these initial guidelines are living documents that, with more maturity in the field, will eventually evolve into "best practices."

3. *How detailed should the guidelines be?*
   Guidelines developed at this stage of MEG must navigate a fine line between being so restrictive as to stifle innovations and improvements versus being so vague that they are simply impractical platitudes. However, there is no point in establishing guidelines that are too broad lest they leave new users with no guidance at all. While there are many laboratories that are quite comfortable and confident with their work product, others, especially those just starting up, are hungry for some relatively specific starting points. Hence, the level of detail included in these guidelines was meant to offer the minimal practical guidance desired by the MEG community. The specifically recommended settings may not cover every single clinical circumstance encountered, but they are meant to serve as excellent starting points, which have been verified in practice.

4. *Shall we include only Center for Medical Services-approved clinical studies, or provide more general guidance that can be extrapolated to the conduct of research studies?*
These guidelines concentrate on the essential elements but do not dictate which services should be provided. Educational and research endeavors, by ACMEGS as well as by other organizations and universities, will provide the foundation for extending MEG studies into many realms of investigation. However, the guidelines focus on established areas where it is known that MEG works well. Magnetoencephalography's strength, and the primary reason for referral of patients to the MEG laboratory, is in *localization*. It is on the capability for localization that the guidelines focus, rather than on typical normal/abnormal decisions that depend on a normative database (as in traditional evoked potential studies). Although there are some promising applications for MEG that may someday become commonplace in clinical practice, these guidelines are meant to focus on the two established indications for MEG: localization of epileptic foci and presurgical functional brain mapping in patients with operable lesions.

5. *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?*
Because of the relatively high cost and comparative adolescence of magnetoencephalograph manufacturing, MEG recording systems are not commodities, and MEG analysis packages are not uniform. We chose to restrict ourselves to whole-head systems because these certainly are the standard for clinical use, but we expect that more advanced specifications, such as acceptable noise performance or adequate analog-to-digital converter resolution, will continue to evolve. Given the enormous capital costs of MEG apparatus, it is not reasonable to expect replacement or upgrade frequently.

INTENT AND PRACTICAL APPLICATION OF THE GUIDELINES

The main thrust of the CPGs development effort was to provide guidance that will help to improve the consistency and quality of the clinical application of MEG. The CPGs included in this journal are purposely not called "standards" but rather "guidelines." Guidelines are just that: they are meant to be helpful not dictatorial; they are meant as a starting point not a full prescription. Because these Guidelines are essentially a consensus starting point, there will be many laboratories, especially the better established ones, doing things slightly differently. The important thing is for laboratories to be *aware* that there are guidelines and to use them to make sure that they are at least living up to the basics of the Guidelines. It is by pushing the envelope outside of established practice that modern medicine innovates, either to improve accuracy and quality or to improve efficiency and cost. The Guidelines will probably be of most help to laboratories that do not know exactly what to do for each type of test and want to start from a known place.

It is not surprising in the translation of a basic research technology into a clinical diagnostic technique that the backgrounds and career orientations of those involved in MEG to date have been quite inhomogeneous. In this regard, the field of MEG today is quite similar to where the field of EEG was in the 1950s, because EEG and evoked potentials emerged from research laboratories into clinical practice. At that time, many of the world's experts were research scientists without medical training, as exemplified by the career of Peter Kellaway, PhD, to cite just one example (Mizrahi and Pedley, 2004). The Guidelines recognize these differences and are meant to help pull the MEG community together for clinical purposes. Clinical Practice Guideline 4 (Bagić et al., 2011) deserves special mention because some may view it as an attempt at de facto credentialing. While it is possible that credentialing of personnel and accreditation of laboratories will be considered in the future, the field is young and the contributions of a variety of neuroscientists are critical to continued nurturing of the field. It is anticipated that laboratories will reexamine their procedures as a result of these guidelines, but it is not expected that any individuals currently involved in the acquisition or processing of magnetoencephalograms will suddenly be excluded from these activities. On the contrary, this document points up the scarcity of good training programs in MEG and may help to bring together the ideas for a body of knowledge that should be part of the curricula in some fellowships or included in certain examinations. Clinical Practice Guideline 4 was built around the concept that these CPGs establish (1) best practices in 2011 where possible, (2) a need for and challenge to the MEG community to get training in place, and (3) a recognition of the important role of nonphysician MEG scientists and excellent technologists. Should there come a time when certification and/or laboratory accreditation is considered, there will doubtless be a period of grandfathering and other transitional measures required. At that time, an appropriate degree of sensitivity should be demonstrated toward experienced practitioners and their diverse routes to clinical practice, according to well-established approaches that have already been applied in other medical specialties.

There is no intent within these documents to disenfranchise anyone. Rather, they should encourage all of us to advance to the next level. They are intended for everyone in the field and those who intend to come into it. They clearly raise the bar for all of us, that is, they represent—purposely—a considerable challenge for each and every member of the community. Judicious implementation of the CPGs should be supplemented with and facilitated by structured comprehensive educational activity covering MEG from basic science to best practices. These CPGs provide a set of practical recommendations that should help laboratories and clinicians to practice clinical MEG more uniformly and consistently, with all the direct and fringe benefits of such a new reality.

RESULTS OF A TEAM EFFORT

After more than two years of work, the ACMEGS 10-member CPG Committee defined four final documents: CPG 1: Recording and Analysis of Spontaneous Cerebral Activity (Bagić, Knowlton, Rose and Ebersole, 2011a); CPG 2: Presurgical Functional Brain Mapping Using MEG Evoked Fields (Burgess, Funke, Bowyer, Lewine, Kirsch and Bagić, 2011); CPG 3: MEG–EEG Reporting (Bagić, Knowlton, Rose and Ebersole, 2011b); and CPG 4: Qualifications of MEG–EEG Personnel (Bagić, Barkley, Rose and Ebersole, 2011). Each of these documents was authored by specific task forces (subcommittees), with the role of each member as indicated on the respective document. All final versions were approved unanimously by the ACMEGS Board, and we are particularly pleased that they were also endorsed by the American Clinical Neurophysiology Society Council.

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