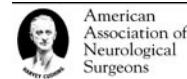


Neurotrauma & Critical Care NEWS



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AANS/CNS Section on Neurotrauma & Critical Care

Editor:

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In This Issue...

2, 5

In Focus

Two Views: Balancing Active Clinical Research Programs With Clinical Practice

Clinical Research in Private Practice, 2

Academic Research in the HIPAA Era, 5

3

Position Statement on Reconciling On-Call Responsibilities With EMTALA Requirements

Useful CPT 2003 Codes

4

Membership Application

6

Section Leadership

Chairman's Message



Donald Marion, MD, FACS

interspecies differences that limit valid comparisons. With few exceptions, the most relevant clinical research programs in neurotrauma are directed by neurosurgeons. Through our daily clinical experience, we see which problems most directly cause adverse outcomes for our patients and glean practical potential solutions to those problems.

Numerous members of the Trauma Section have succeeded in balancing busy neurosurgical practices with incredible research productivity. We have helped to define the numerous molecular and physiologic mechanisms of secondary brain injury in humans through microdialysis and cerebrospinal fluid studies and systematic imaging studies of cerebral blood flow and metabolism. We have critically assessed the use of more than a dozen novel pharmacological agents intended to limit secondary brain injury and improve outcomes after traumatic brain injury (TBI).

While none of these studies has found improved outcomes as a result of a particular drug, they have clarified the appropriate design of future studies. For example, we now know that TBI trials must account for the influence of gender and that a new treatment may benefit patients with focal contusions but not those with diffuse injuries. Advances in neurotrauma research could be greatly accelerated if more neurosurgeons were involved, particularly in multicenter trials. However, many neurosurgeons do not consider conducting research because of increasing pressures to expand their clinical volume as reimbursement continues to fall.

For this issue of the newsletter, we invited two senior colleagues to relate their experience with bal-

ancing active clinical research programs and clinical practice. Despite very different backgrounds, both exemplify the true academic neurosurgeon. Bill Welch, MD, trained for a career in academic neurosurgery, and completed fellowships in both neuro-oncology and spine surgery before joining the faculty at the University of Pittsburgh and developing a successful academic spine program. He directs clinical research projects funded both by the National Institutes of Health and private industry. Dom Esposito, MD, began his career in private practice. He came to academics only after he could no longer resist direct involvement in developing better treatments for patients with TBI. After years of private practice, he joined the faculty at the University of Mississippi and quickly developed a well-funded and productive TBI research program.

National Neurotrauma Society Meets Nov. 6-7

The National Neurotrauma Society provides an excellent forum for collaboration between neurosurgeons and basic neuroscientists interested in neurotrauma research. Virtually all clinical and basic science investigators currently conducting brain and spinal cord injury research are members and regularly attend the annual meeting. Ross Bullock, MD, the past chair of the Trauma Section, also was a recent president of the Neurotrauma Society. The section strongly supports this organization, and we encourage you to attend its 2003 annual meeting in Biloxi, Miss., on Nov. 6 and 7.

Acknowledgements

The Trauma Section wishes to thank Sam Hasenbusch, MD, and the other members of the Coding and Reimbursement Committee for their work in pushing through the new Current Procedural Terminology codes for traumatic brain injury. In CPT 2003, you will find new codes for decompressive craniectomy (61322) and decompressive lobectomy for intractable intracranial hypertension (61323). We encourage you and your billing staff to review these codes and use them as appropriate.

Clinical Research in Private Practice

Domenic P. Esposito, MD, FACS, and John H. McVicker, MD, FACS

Despite the tremendous volume of clinical material handled by private practice neurosurgeons in this country, very little clinical research is actually performed in this setting. This is particularly true for neurosurgical practices serving community hospitals.

This article will attempt to analyze some of the reasons for this phenomenon and propose some potential solutions.

The reasons why clinical research is seldom performed in the private practice setting are fairly self-evident. Obviously the priorities for the maintenance of a private practice are different from those found in a university environment. There is no such thing as “protected time” in private practice, which would allow the clinician to dedicate a portion of his or her week to activities such as grant writing, data collection and data analysis. Most neurosurgeons work well over 40 hours per week and the time that they have at their disposal after their hours of work is seldom dedicated to research activities. In addition, there are some significant medicolegal issues to be considered, as well as the new Health Information Portability and Accountability Act (HIPAA) regulations and governmental constraints that would make even the interested practitioner somewhat leery to embark on these endeavors, particularly without competent research personnel to help get the research structured for compliance. Lastly and probably most importantly, in a private practice setting there is a lack of the support personnel, such as clinical research coordinators and technical assistants, to assist with the performance of clinical research activities. In many cases, the individuals who do spend time in the clinical research arena have to bear a substantial portion of the cost of these studies from their office overhead.

Given the above issues, why do we feel that clinical research should be performed in the private practice environment?

Why Be a Private Practitioner and Clinical Researcher?

First and most importantly, there is a wealth of clinical material that is handled in the private practice environment. In fact, in the arenas of certain issues—simple and complex spine surgery, carotid endarterectomy, peripheral nerve surgery, and critical care neurosurgery—the number of cases performed in the private practice setting often far exceeds the same number of similar cases performed in the university environment.

Secondly, particularly in light of the new requirements for residency training, many individuals who are coming out of neurosurgical programs have had anywhere between six and nine years of surgical and neurosurgical training, and often during their training they have been exposed to both basic science and clinical research projects. The era of the neurosurgeons who trained in three or four years and perhaps had little exposure to a research environment is quickly drawing to a close, as these individuals no longer practice. It seems a waste of hard work and time on the part of the young neurosurgeons and their teachers that following the completion of residency these skills are never used again. It also seems somewhat

ironic that this shift toward better-trained scientist-neurosurgeons has occurred over the same time period that research in many settings, both academic and private, has become technically and economically more difficult.

Those individuals slated for careers in private practice seldom or never become involved in research activity and academic activity in general. Many individuals feel that once they have chosen a private practice environment, they will likely continue in that vein for the rest of their professional careers. But by abandoning all connection with academic medicine and any form of clinical research, these individuals could be forsaking professional opportunities that they may find appealing during the latter portion of their clinical careers.

Encouragement for the Private Practitioner

How can private practitioners be encouraged to participate in clinical research? One solution lies with our academic institutions. Academic institutions should reach out to private practitioners and try to keep them involved in academic endeavors. Often an academic institution will be able to provide some of the support materials necessary to allow the private practitioner to participate in clinical research projects. In addition, a private practitioner, particularly the young private practitioner, needs to have a spirit of volunteerism to pursue these endeavors. Perhaps in medium- and large-size private-practice groups one individual could be given the resources and time to coordinate the academic activities for the group.

But to flesh out the “town-gown” alliance we need to go beyond the spirit of volunteerism and collegiality. There is great practical benefit to both a private practice and an academic institution when they develop a research partnership. The wealth of clinical material alluded to above is unavailable to the academic institution doing research unless such a partnership is present. Data collection can be undertaken by university personnel working in or with the private practice as long as the duties are clearly outlined and do not violate Federal Trade Commission regulations. This type of affiliation is the only practical way for otherwise unaffiliated individuals in private practice to undertake clinical research unless they are independently wealthy or have extraordinarily understanding partners.

Build the Right Environment

Another option, given the right environment and a critical mass of like-minded physicians within a supportive community, is building a nonprofit institute that supports the personnel required to write grants, develop funding, collect and analyze data, and recruit or accrue patients under the direction of the physicians. Such institutes typically function in other ways as well, such as educating the community about neurological disease, holding outreach clinics, applying careful outcomes measures, and providing interdisciplinary

continued on page 6

AANS/CNS Section on Neurotrauma and Critical Care Position Statement on Reconciling On-Call Responsibilities With EMTALA Requirements

Background

For more than one year, the AANS/CNS Section on Neurotrauma and Critical Care has been grappling with the complex issue of on-call physicians' responsibilities for delivering neurotrauma services. After much discussion, the Trauma Section's Executive Committee has identified the following issues, among others, that represent the crux of the dilemma facing each neurotrauma service that aims to implement reasonable on-call physician policies:

- Ensuring the greatest degree of safety for the patient suffering traumatic injury to the brain or spinal cord;
- Endorsing the caveat that the neurosurgical specialist provides the best care needed by the neurotrauma patient;
- Reconciling the inherent conflict of EMTALA's policy that physicians are not required to be on call at all times with the law's requirement that hospitals must maintain the on-call list in a manner that "best meets the needs of the hospital's patients"; and
- Matching the limited number of neurosurgeons with the total number of hospitals requiring on-call coverage, while at the same time acknowledging that there are simply more hospitals than neurosurgeons available to provide continuous neurotrauma services.

Consensus Opinion

Multiple factors within various geographic regions (including location, available neurosurgical work force versus nonparticipatory work force, proximity to other neurosurgical centers, and typical elective and neurotrauma workload) inevitably conflict with the EMTALA guidelines established to protect the patient, the neurosurgeon and the institution. Each institution and its neurosurgeons should therefore specify these provisions contractually when they address the unique requirements of the area to ensure compliance with EMTALA. Ultimately, only the individual neurosurgeon can determine the limits of his or her ability to provide continued coverage. Hospitals should not force or coerce neurosurgeons to provide continuous on-call coverage when it is impossible or unreasonable for neurosurgeons to do so.

To best meet the needs of patients, in advance and prior to crisis, the neurosurgeons and the institutions must negotiate contingency plans and inter-hospital transfer agreements for periods of non-coverage (whether due to fatigue, simultaneous coverage, vacation, or limited number of neurosurgeons in the area or available to the institution).

Rationale

Recognizing that it is unavoidable that an individual neurosurgeon might be required to be on call simultaneously at more than one institution because of the lopsided ratio of individual neurosurgeons relative to institutions requiring neurosurgical coverage, recent EMTALA guidelines now permit simultaneous on-call

coverage. These guidelines further acknowledge that EMTALA does not require institutions to have continuous neurotrauma availability. However, the guidelines require, among other things, that hospitals have "policies and procedures to follow when an on-call physician is simultaneously on call at another hospital and is not available to respond. Hospital policies may include, but are not limited to procedures for back-up on-call physicians or the implementation of an appropriate EMTALA transfer..." EMTALA guidelines further permit on-call physicians to schedule elective surgery while on call, although these same guidelines also state that hospitals may prohibit this practice. It is therefore incumbent on the neurosurgeon and the institution(s) to address all of these issues in writing to avoid any uncertainties with their respective EMTALA obligations.

EMTALA is the Emergency Medical Treatment and Labor Act. EMTALA and the issue of on-call requirements have been addressed in previous issues of Neurotrauma and Critical Care News, available at www.neurosurgery.org/trauma/newsletter.

Did You Know?

Potentially useful codes from CPT 2003, including new additions (*):

- 99050 Services requested after office hours in addition to basic service
- 99052 Services requested between 10:00 PM and 8:00 AM in addition to basic service
- 99054 Services requested on Sundays and holidays in addition to basic service
- 99056 Services provided at request of patient in a location other than physician's office which are normally provided in the office
- 99058 Office services provided on an emergency basis
- *61322 Craniectomy or craniotomy, decompressive, with or without duraplasty, for treatment of intracranial hypertension, without evacuation of associated intraparenchymal hematoma; without lobectomy
- *61323 With lobectomy
- *61316 Incision and subcutaneous placement of cranial bone graft



American Association of Neurological Surgeons

Application for Membership

AANS/CNS Section on Neurotrauma and Critical Care



Eligibility: Members of the AANS and/or CNS who are actively interested in Neurotrauma.
Note: Adjunct Membership is available to non-neurosurgeons who are not members of the AANS or CNS. Please contact 847-378-0500 for an Adjunct Membership application.

I. Biographical:

- (A) Name: _____
- (B) Home Address: _____
- (C) Office Address: _____

- Phone: _____ Fax: _____
- (D) E-Mail: _____

II. Category of Membership Requested:

- Active Associate International Resident*
- * Membership dues are waived for applicants currently enrolled in a neurosurgical residency program.

III. Membership, Certification and Practice:

- (A) Are you certified by the American Board of Neurological Surgery? Yes No
- (B) For Resident Applicants-Expected Residency Completion Date (month/year) _____
- (C) Are you a member of
 - 1. The American Medical Association? Yes No
 - 2. A Local or Regional Medical Society? Yes No
 - 3. A State or Provincial Medical Society? Yes No
 - Name: _____
 - 4. American Association of Neurological Surgeons? Yes No
 - 5. Congress of Neurological Surgeons? Yes No

- (D) I would like to support  with my donation of
 - \$10.00 (Recommended) Other amount \$ _____

Signature of Applicant

Date

**Please return completed application with your membership fee of \$50 and any donations to:
 AANS/CNS Section on Neurotrauma and Critical Care
 Dept. 77-7550
 Chicago, Illinois 60678-7550**

Academic Research in the HIPAA Era

William C. Welch, MD, FACS, FICS, and Patricia Karausky, RN

Physicians clearly are living in interesting times, especially those who are active in academic pursuits. In the past, physicians could pose a question, perform a limited retrospective study and derive an answer with the expectation of publication in a peer-reviewed journal. Scientific expectations are much higher today. Current study proposals require considerations of funding (costs cannot be offloaded to insurance companies), institutional review board (IRB) approval, patient counseling and consent, extensive data collection, and interpretation and generation of a work documenting the methods of study and conclusions. Should the study involve the investigation of a new device or drug, a Food and Drug Administration (FDA) audit reasonably can be expected. Studies funded by the National Institutes of Health require safety review committee meetings in addition to the above requirements. Most journals expect that studies will be randomized and have an adequate follow-up period.

HIPAA Hampers Research

With the advent of the Health Information Portability and Accountability Act (HIPAA) rules, yet another layer of difficulty has been applied to research endeavors. Under the guise of protecting human subjects' rights, two of the most important pieces of research have been negatively affected. Research regarding the collection and analysis of medical records information will be required to undergo a process of de-identification of data by an "honest broker" before it can ever reach the office of the clinical investigator.

This process often can result in data that is not useful due to the vigorous cleansing process of the 18 items that will assure complete de-identification of the subject. These identifiers include dates directly related to an individual, including discharge date and date of birth; device identifiers; and any number, characteristic or code or other unique identifier. Another option to fulfill this regulation would be to request that the IRB grant a waiver of consent. To satisfy the regulatory criteria, the requirements for a waiver include proof that the research could not be practicably conducted without a waiver and without access to the personal health information (PHI). Additional assurances include: protection of improper use of identifiers, plans to destroy the information at the earliest opportunity, and written assurance that the PHI will not be reused or disclosed improperly. A waiver of authorization will not be easily obtained. Lastly, to preemptively get permission from potential subjects who come to the clinic for use of their PHI in research, each department could develop a research registry. But while development of a registry may be an answer for future research, such registries would be bulky and slow to develop. In addition, what we are to do about the vast pool of retrospective data that could be accessed for research purposes remains an open question.

The second area of research adversely affected by the HIPAA privacy rules comes with the identification and recruitment of subjects. It is no longer permissible to be recommended to a study by

the physician and to consequently be seen by the co-coordinator. Now, potential subjects must sign an authorization for the sharing of PHI with the study team. While this is a reasonably benign process, it involves one more barrier to recruitment. The study team can no longer perform routine recruitment activities such as accessing patient visit lists, reviewing a chart or calling a potential subject at the direction of the physician, without violating the HIPAA laws.

And So It Comes to This...

And so it comes to this for potential subjects. At the front desk of a clinic they are asked to go through the registration process and sign as guarantors. They are given a research registry consent to read and sign for future studies. After being seen by the physician and determined to be potential candidates for a study, they are asked to sign an authorization for the sharing of their PHI and, lastly, they are asked to sign a 10- to 20-page consent form to enroll in the study.

One of the hallmark attributes of informed consent is that the manner and the context in which the information is presented are as important as the information itself. Have we not done a great disservice to the consent process by reducing the comprehension level of the subject through the plethora of documents requiring signatures? Does our fervor for privatizing research subjects' PHI, ultimately result in harm to the very people we are protecting? As the Belmont Report so succinctly states: Respect for Persons, Justice and Beneficence. Can't that be enough guidance for the ethical practitioner?

A Silver Lining?

Despite these difficulties, researchers have continued to perform research and will continue to do so. A significant effect of the daunting HIPAA regulations is that they force the researcher to ask a well-defined question, develop a plan of execution, and see the process through to the end. One may require financial support from a granting source to obtain the resources to perform the study. Thus, the proposal is scrutinized by the granting source(s), the IRB(s), and potentially by the FDA. Each of these institutions may make a positive contribution to the development of the project. As the difficulty and cost of research continues to escalate, one hopes that the quality of the finished product will increase, as well.

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Clinical Research *continued from page 2*

clinical care coordination and administrative support, in addition to organizing the research activities. As such an institute takes root, it attracts bright and energetic young physicians with an inclination toward research who, for whatever reason, are not interested in pursuing a purely academic career. Although creating it is no easy task, such a research institute may be an ideal way to bring research to the community.

In addition, much research is supported in “the private sector” by pharmaceutical or device companies. Although this arrangement is seldom as satisfying as basic “bench work” or clinical research that springs from one’s own grant-writing efforts, it clearly allows the private practice surgeon to participate in research at some level while the fiscal burden for performing it is relieved.

There are a number of private practice neurosurgeons who participate in academic activities, and certainly these individuals are to be commended for wearing more than one hat. We do feel very strongly, however, that there is wealth of clinical material that is not being collected and documented for research studies.

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John McVicker, MD, FACS, is a member-at-large of the AANS/CNS Section on Neurotrauma and Critical Care Executive Committee and past chair of the CSNS Neurotrauma Committee.