The future of practice science: challenges and opportunities for neurosurgery

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Outcomes-directed approaches to quality improvement have been adopted by diverse industries and are increasingly the focus of government-mandated reforms to health care education and delivery. The authors identify and review current reform initiatives originating from agencies regulating and funding graduate medical education and health care delivery. These reforms use outcomes-based methodologies and incorporate principles of lifelong learning and patient centeredness.

Important new initiatives include the Accreditation Council for Graduate Medical Education Milestones; the pending adoption by the American Board of Neurological Surgery of new requirements for Maintenance of Certification that are in part outcomes based; initiation by health care systems and consortia of public reporting of patient outcomes data; institution by the Centers for Medicare & Medicaid Services of requirements for comparative effectiveness research and the physician quality reporting system; and linking of health care reimbursement in part to patient outcomes data and quality measures. Opportunities exist to coordinate and unify patient outcomes measurement throughout neurosurgical training and practice, enabling effective patient-centered improvements in care delivery as well as efficient compliance with regulatory mandates. Coordination will likely require the development of a new science of practice based in the daily clinical environment and utilizing clinical data registries. A generation of outcomes science and quality experts within neurosurgery should be trained to facilitate attainment of these goals.

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Modern informatics and the wide availability of specialist information on the World Wide Web now challenge this aspect of professional identity. At the same time, the ubiquity and power of computing allow the collection and analysis of massive quantities of distributed data and provide a new way in which professionals may define themselves: through detailed analysis of the outcomes of their professional activity. During the 20th century, distinct educational institutions, accrediting organizations, peer-reviewed publications, and professional societies defined each medical specialty. In the 21st century, the collection and analysis of practice data using shared mechanisms and platforms will add to these important shared and defining professional activities. The core attribute of professionalism in medicine and surgery has always been the promotion of the patient’s interests above those of the practitioner. Careful, accurate measurement and transparent public

Abbreviations used in this paper: ABMS = American Board of Medical Specialties; ABNS = American Board of Neurological Surgery; ACGME = Accreditation Council for Graduate Medical Education; CER = comparative effectiveness research; CMS = Centers for Medicare and Medicaid Services; EMR = electronic medical record; IT = information technology; MOC = maintenance of certification; NPA = NeuroPoint Alliance; N2QOD = Neurosurgery Quality and Outcomes Database; PQRS = Physician Quality Reporting System; RCT = randomized controlled trial.
sharing of outcomes, by promoting the interests of patients, will further define professionalism and distinguish individual professional groups in the modern era.

It is strongly in the interest of the neurosurgical profession, therefore, to collect and define our own practice data. The creation of practice data platforms, in a practical sense, will do as much in the future to define the boundaries of distinct professional subgroups as training programs and journals do in the present day.

The NeuroPoint Alliance (NPA) was founded precisely to provide data platforms for national registry participation by all neurological surgeons in the US. Although its first registry projects, the NeuroPoint–Spinal Disorders (NeuroPoint-SD) and the National Neurosurgery Quality and Outcomes Database (N’QOD), have focused solely on spinal neurosurgery, the intention of both the N’QOD and the broader efforts of NPA are to serve as the principal practice science infrastructure for each area of neurosurgical subspecialty practice. To successfully pursue this strategy, it is necessary for NPA to align its systems with the educational and regulatory imperatives that currently govern and define neurosurgery as a distinct profession.

Changes in medical and surgical professionalism resemble and reflect larger trends in society and parallel changes in other health care organizations and regulators.

Milestones, Lifelong Learning

The Accreditation Council for Graduate Medical Education (ACGME) is charged with oversight of medical and surgical residency and fellowship training programs in the US. In July 2002, the ACGME introduced the “Outcomes Project,” notable for the introduction of 6 core competencies: professionalism, communications and interpersonal skills, systems-based practice, practice-based learning and improvement, medical knowledge, and patient care.1

The ACGME Outcomes Project envisioned the creation by individual programs and institutions of relevant and valid tools to assess the knowledge, skills, and attitudes necessary for competence in professional practice. For the most part, these assessments did not emerge.14,37 As public focus on safety intensified, the ACGME in 2011 announced additional measures to improve safety and quality and to validate educational outcomes.

First, standards for duty hour limitation and supervision in the clinical training environment were strengthened.1 Second, a renewed effort was made to create an assessment system based on the achievements of individual trainees qualifying them for independent practice. This outcomes-based approach will soon replace the traditional system, which has previously focused on certifying appropriate training environments while delegating the assessment of individual trainees to the postgraduate board certification process.

This outcomes-based methodology will incorporate minimum operative case volumes in each major area of neurosurgical practice, assessment of skills competency, formative knowledge assessments, and other more specific measures of training progress. The Society of Neurological Surgeons (comprising residency program directors, department chairs, and other educational leaders) has created national junior resident courses comprising instruction and evaluation in key elements of the ACGME core competencies.31,32 The ACGME neurological surgery milestones will specifically evaluate various skills and competencies related to safety, quality, and the use of patient outcomes methodologies in lifelong learning.

Maintenance of Certification

The American Board of Medical Specialties (ABMS) (http://www.abms.org/About_ABMS/member_boards.aspx) regulates the activities of 24 member boards, including the American Board of Neurological Surgery (ABNS),7 that award board certification in and set policy for 145 specialty and subspecialty areas of medical and surgical practice (http://www.abms.org/Maintenance_of_Certification/ABMS_MOC.aspx). In 2000, partly in response to governmental and societal pressure for improvements in quality and safety, the ABMS introduced a new program of continuous professional development, reflecting the goals and methodology of lifelong learning. Termined “maintenance of certification (MOC),” this program is based on the same 6 core professional competencies adopted by the ACGME. Thus, the principal regulatory agencies for certification of residency training environment and independent practice certification, recognizing their interrelated missions, have adopted a formal system and language for lifelong learning.

Maintenance of certification replaced recertification programs, which were limited to periodic assessment of professional standing (such as licensure and privileges) and reexamination of cognitive expertise (by a traditional written knowledge examination). By contrast, MOC is principally focused on an ongoing assessment of practice competency. The MOC program in neurological surgery, for example, includes requirements for evidence of lifelong learning and self-assessment, as well as evaluation of performance in practice. The ABNS MOC requirement for performance in practice currently includes indirect evidence about clinical outcomes, using a patient survey of communication skills and extremely limited, self-reported outcomes information from a sequential series of 10 surgical cases.14 It is likely that the MOC program will evolve toward a continuous process of outcomes assessment, documentation, analysis, and feedback. It is expected that this process will also serve as the mechanism for maintenance of licensure and qualification for performance- and quality-based reimbursement. Having one system, which will meet multiple reporting requirements with a single episode of data entry, is a strategic goal of NPA.

Effective measurement and analysis of patient-centered, relevant, and risk-adjusted neurosurgical outcomes has the potential to provide, for the first time, a completely direct methodology for the oversight of practice certification using parameters that are meaningful to patients and are inseparable from safety and quality. Previous certification methodologies offer at best indirect, and in many cases notoriously inaccurate, measures of professional effectiveness (such as professional standing or reputation).31 By basing certification decisions in part on legitimate
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and accurate outcomes data, certifying organizations will provide the public with information to which even industry “insiders” seeking personal care (for example, fellow physicians) have traditionally had imperfect access.

Public Reporting

Initial phases of public reporting have led to disension and often confusion, particularly among the patients who are supposed to benefit from the liberal availability of quality information. Data derived from administrative (billing) databases that are inaccurately coded, are not risk adjusted, and are often arbitrary in their definitions can produce information that is either unhelpful or frankly misleading.19

The goal of producing patient-centered information is best described as presenting accurate, correctly analyzed, and transparently summarized data about a particular care decision (for example, choice of procedure, surgeon, or facility) that a highly knowledgeable and expert individual would wish to have if they themselves were the patient. Currently, a patient considering undergoing a lumbar instrumented fusion for spondylolisthesis will most likely have access to relatively fragmented and largely tangential information about surgical complications only (such as deep venous thrombosis/pulmonary embolism and surgical site infection). Publicly available data could point a patient toward a center with low neurosurgical volumes and undefined outcomes, but low publicly reported deep venous thrombosis/pulmonary embolism and surgical site infection rates as a statistical artifact of volume and risk considerations. In some cases, patients may be directed away from the highest-quality providers who are publically profiled based on their treatment of patients with extensive medical comorbidity or other risk factors. In fact, crude quality analyses often conflate low risk with high-quality practice. Often, no public data are currently available about the quality of the neurosurgical intervention itself and its long-term outcomes.

The public has responded very positively to the availability of specific data on outcomes from coronary artery bypass and other cardiac surgical interventions, via the Society for Thoracic Surgery Database.33 The experience of thoracic surgeons during the creation and adoption of their database is both a testament to the complexity of this type of undertaking and the ultimate power of its success. Patient-centered information on real-life medical decisions will define realistic expectations, aid effective and efficient decision making, and empower both patients and surgeons.

Physician Quality Reporting System

Neurosurgeons will be required to report PQRS measures effective in 2013 or sustain penalties by 2015. The PQRS measures that are relevant to neurosurgeons include perioperative measures (antibiotic prophylaxis and venous thromboembolism prophylaxis), but will now also include the evaluation and management of low back pain. Neurosurgeons will be required to either submit practice data, probably for 10–30 unique Medicare Part B patients, or will be required to submit a 50% sample via claims (for the entire year) or an 80% sample via a registry (for 6 months). Although the specific details of the requirements may change as the new health care legislation is implemented, neurosurgeons must be prepared to report data regarding process and outcome for the evaluation and treatment of low back pain and other conditions seen commonly in neurosurgical practice. Presently, organized neurosurgery is working with CMS to develop novel measures groups that will allow for meaningful reporting of neurosurgical outcomes to the PQRS program. The organizational infrastructure of the National Neurosurgery Quality and Outcomes Database (N’QOD) registry in the future will meet all standards for the reporting of PQRS measures.

Policy-Purchaser Collaboration

Accountable care organizations represent a group of physicians, hospitals, and other health care providers that take responsibility for a defined population of patients.5 The fundamental concept is that third party payers (including the government’s CMS) will pay for quality as opposed to quantity of health care services.13,21,39 In addition to improving access of patients to health care, a major goal is to give physicians and hospitals an incentive to provide high-quality care at reduced cost. Across the nation, payers and providers are seeking partnerships to develop infrastructure for measuring performance. One of the key aspects of performance is patient-reported outcome. Current administrative databases, including the national inpatient sample, do not contain patient-reported outcomes data, which are essential to consider when assessing the quality of most neurosurgical and, particularly, spinal treatments.

In addition, it is important when measuring economic and other outcomes that registries record data that can be accessed by multiple stakeholders. Third party payers, patients, and the government have different and equally valid reasons to access data regarding the effectiveness of spinal surgery, for example. Physicians are uniquely qualified to generate, organize, and interpret these data both for society and for quality improvement purposes in this country. The NPA has engaged with numerous health care service purchasers to assure that the design of N’QOD and other neurosurgical registries are and will continue to be compatible with the interests of these important stakeholders for outcomes data collection and analysis.

Comparative Effectiveness Research Consortium

The American Recovery and Reinvestment Act of 2009 allocated 1.1 billion dollars for new comparative effectiveness research in the US (http://www.recovery.gov/About/Pages/The_Act.aspx). Both the NIH and the Agency for Healthcare Research and Quality (AHRQ) have requested meaningful proposals to develop infrastructure for CER and specific proposals for actual CER studies. The Institute of Medicine defines CER as “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of health care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy
matters to make informed decisions that improve health care at both the individual and population levels.

This component of the new health care legislation implies a multitude of changes and promotes an urgent need to define the safety, effectiveness, and cost of medical interventions. To succeed in this environment will require the development of valid methodologies that permit comparison of safety, effectiveness, and cost for individual interventions. During development, the N2QOD registry project will be used to compare valid treatment options in specific populations. One of the potential enormous benefits of the N2QOD effort is its design by neurosurgeons to produce valuable data specifically about neurosurgery. It will be critical for the scientific leadership of N2QOD to continually evaluate and deploy disease-based modules that permit true comparative effectiveness evaluations. In fact, the N2QOD infrastructure meets all requirements for the newly formed Patient-Centered Research Outcomes Institute, which is actively funding new comparative effectiveness research.

**Practice Science**

One of the ultimate goals of the N2QOD mission is to advance the science of neurosurgical practice. Most clinical scientists agree that the ideal randomized controlled trial (RCT) represents the gold standard for determining whether an intervention is superior, equivalent, or inferior to another treatment modality. The ideal RCT is accepted as gold standard because it reduces the errors from bias, confounding, and chance that can plague clinical research. However, many surgical RCTs are unmasked, lack equipoise, may be invalidated by high cross-over rates, require a carefully defined study population, which might not actually represent the majority of patients treated in actual US practice, and involve practitioners whose surgical skills may not accurately represent those of US surgeons. In addition, RCTs are expensive and labor intensive and often take many years to complete. As neurosurgical techniques evolve, the results of RCTs might not be relevant because the techniques studied may have changed by the time the results of the RCT are available.

For these reasons, we now look to scientific registries as an alternative to RCTs. Successful registries have the power to provide useful data on the actual practice of neurosurgery in the US. Collecting prospective data on patient characteristics, processes of care, and patient centered outcomes; analyzing these data; and feeding them back to individual surgeons is a powerful tool for quality improvement. This iterative process can be used to refine surgical indications, determine best practices, and recognize new beneficial innovations in surgical care. Application of this kind of outcomes-based quality improvement algorithm has significant advantages over the process-based algorithm that presently predominates.

Nevertheless, outcomes registries also face a unique set of legitimate challenges and questions, such as obtaining appropriate follow-up of patient-reported outcomes data. The Spine Tango Registry in Europe, for example, reported a 33% rate of follow-up after collecting data from 6000 patients. Despite problems with missing data, the Spine Tango Registry served as one model for the provision of quality improvement information through real-time access to individual site data in addition to aggregate dataset outcomes. The Spine Tango Registry has also been effective in risk-adjusted benchmarking, assessing complications data, and in documenting the overall effectiveness of surgery for common spinal conditions such as lumbar spinal stenosis. Incorporating these lessons, the N2QOD project has focused significant attention on database auditing and on obtaining high-quality long-term follow-up data. In addition, the N2QOD project is taking place within the context of massive new national incentives for outcomes tracking and research that reflect a consensus in favor of outcomes methodologies and a highly conducive environment for their implementation.

The initial effort of the N2QOD has been focused on lumbar spinal disorders. Neurological surgery desperately needs a scientific enterprise that will enable various specialists to develop disease-based modules. For example, the AANS-CNS Joint Cerebrovascular Section recently reviewed the results of the extracranial-intracranial (EC-IC) bypass versus medical therapy trials and concluded that specific patient populations with hemispheric ischemia might benefit from surgery even though the results of RCTs suggest otherwise. The group identified several aspects of the trial design, including assumptions regarding the effectiveness of medical therapy, which limited their ability to determine the effectiveness of bypass surgery. In addition, they pointed out that the nature of the study population, which excluded acutely symptomatic patients, might have limited the power of trials such as the recently completed Carotid Occlusion Surgery Study (COSO) to detect a benefit from EC-IC bypass in selected patients. By contrast, a registry module to study the effectiveness of this procedure would permit centers with a low perioperative complication rate to demonstrate whether careful patient selection results in effective outcomes following bypass surgery for appropriate subsets of patients. This type of approach would presumably enable other sites to duplicate their results in a fashion that could be continually assessed and recorded using the registry module.

While the N2QOD initiative has already demonstrated the ability to collect high-quality outcomes data with over 90% follow-up at 3 months, there are many steps that the registry must take in order to make it relevant to all practice sites and sizes. For example, once validation of the auditing system has been accomplished, it will be important to develop simpler essential datasets based on the more comprehensive current set that will permit acquisition of data at smaller practice sites without a requirement for individual personnel wholly dedicated to data collection and Web-based data entry. Streamlined data collection among large numbers of additional smaller sites, analyzed in the context of complete data sets from the larger dedicated centers, will add significantly to the volume and breadth of information about neurosurgical practice outcomes across the spectrum of US neurosurgical practice. Although high-quality data management and auditing are key to the success of the overall effort and will always require significant personnel and financial resources, it will nevertheless become important to reduce the burden of data collection.
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for neurosurgeons in practice and to make the quality improvement power and regulatory benefits of participation available as widely as possible.

**Informatics Infrastructure for the Future of Practice Science**

Historically, each new clinical trial, registry, and outcomes reporting effort has been paired with an information infrastructure to coordinate, collect, and protect data. Information technologies (IT) have more recently been leveraged to allow for direct data capture from subjects via the Web, and training and communication between study coordinators and consortium members. However, in most cases, an IT infrastructure is custom designed and implemented on a case-by-case basis, consuming an increasing share of the costs of conducting research.

Lessons learned from both prior bioinformatics efforts and best practices from software design and business management were implemented to provide the NQOD with an IT infrastructure capable of collecting and protecting the desired data, communicating within the corporate structure of the consortium, and providing training and resources to participating members. A conscious decision was made to use the services of experienced and proven partners, outsourcing nearly all of the IT infrastructure. The Research Electronic Data Capture (REDCap) Consortium is a Web-based platform used by over 450 members in over 45,000 projects across 49 countries to provide for secure capture and exchange of protected health care information for research. The REDCap platform allowed the NQOD to focus on defining data and capturing outcomes of interest without spending a significant amount of time designing and implementing a standards-compliant platform.

In a similar fashion, cloud-based IT services are used for handling the day-to-day communications necessary to conduct the business of the consortium, providing training and support to members of the NQOD registry, and securely distributing reports (after removal of protected health information) to members (http://www.project-redcap.org). The REDCap platform is highly scalable as the NPA adds participating sites to the registry and guarantees 99.9% uptime with archiving of all communications related to the project. Finally, cloud-based project management services have been selected to coordinate the vast numbers of volunteers working in parallel on the NQOD and future modules of the NPA. This type of outsourced IT platform may serve as a model for future consortia.

**Future Directions**

Today, there is little question that we need to collect patient-reported outcomes and economic data to monitor the cost-effectiveness of neurosurgical interventions. The NQOD will eventually leverage electronic medical record (EMR) technologies to enable automatic data capture, which will ultimately reduce the labor costs associated with data entry. As our medical culture evolves, the completion of patient-reported outcomes instruments using wireless devices will become possible and EMR systems should be able to extract and save these data for continuous quality assessment. Regardless of the specific technology used to streamline patient-centered data collection, these novel methods must first be carefully compared with data derived using existing validated methodologies and resulting national benchmarks. Without such comparisons, the accuracy of newer and more efficient EMR and patient portal tools cannot be established. The NPA is moving forward to fund and implement research projects designed to address this critical issue. Finally, outcomes databases should be transparent and capable of integration into related administrative and claims databases. Once we understand how to collect outcomes data from the vast majority of US practices and to combine outcomes with related economic data, it should be possible to very accurately compare the cost-effectiveness and utility of different neurosurgical interventions in the US.

Although the drive for patient-reported outcomes data is by definition patient centered, it must take place with recognition of the financial and practical realities of modern medical and surgical practice. Much has already been written about the unintended consequence of EMR adoption to distract physicians from interaction with the patient during the clinical encounter. Registry participation and other improvements related to lifelong learning and quality should therefore be maximally efficient, both financially and in terms of patient and physician effort. One way to accomplish this is to design outcomes registries explicitly to simultaneously fulfill various regulatory and payment incentives and imperatives. In the ideal setting, patient data collection platforms should support outcomes analysis and quality improvement, public and governmental reporting, maintenance of certification, patient-centered decision making, and even (through use during training) of outcomes and quality education for young physicians. This goal may only be achieved in small steps, negotiating with each stakeholder and making necessary data platform modifications in a flexible manner over time to keep up with the changing contour of the regulatory landscape. This strategy will also require a degree of goal-oriented, flexible cooperation between governmental and regulatory stakeholders and neurosurgeons, reflecting the unprecedented nature of the current transition in health care delivery systems.

**Continuum of Neurosurgical Practice**

Neurosurgeons today accurately perceive that external societal forces are in the process of profoundly altering the practice of our profession. In the traditional professional paradigm, dictation of imperatives from without is entirely a threat. In the face of tidal societal change, however, it is inevitable that definitions of professionalism, itself, must be revised.

The parochial and defensive aspects of professional privilege, including its exclusive “guild” culture that attempts to protect value by creating artificial barriers and protected knowledge, are unlikely to survive in the infor-
during training, benefiting both their education and the mal quality improvement in the live clinical environment case collection for the ACGME should closely corre­and platforms. Ideally, the platforms used for residency secure to case and disease management outcomes processes. Thus, residency training should incorporate direct expo­and leadership Society of Neurological Surgeons, which curriculum of national courses promulgated by the educationalism embody such efforts and priorities, as does the cur­riculum of the profession. Our generation faces the real question of whether neurological surgery will shatter into technique­our profession. Our generation faces the real question of whether neurological surgery will shatter into technique­oriented fragments that anneal with other similar technical practitioners to form new specialties defined, for ex­ample, by the common use of intravascular catheters or skeletal instrumentation.

Conversely, the philosophical underpinnings of pro­fessionalism suggest that we should instead reinvigorate our traditional, patient-centered concern with the natural history and pathophysiology of human diseases, bringing to bear any skill, perspective, or technology that is ef­fective for the treatment of individual patients. Our suc­cess will be measured, literally, through the tracking and analysis of disease-focused outcomes.

The extent to which we collect and analyze these data together will, in a practical sense, go a long way toward de­fining the future community of neurological surgery. Most importantly, neurological surgery will remain a profession dedicated to the diagnosis, treatment, and alleviation of nervous system disease in patients, rather than one defined by a particular technology, activity, or economic structure.

Another laudatory aspect of professionalism, which should survive in the future, is the value of lifelong learn­ing. Thus, it is incumbent upon neurosurgical organiza­tions and educational leaders to create an environment of patient-centered care, self-analysis, and continuous qual­ity improvement that are the essence of routine clinical practice throughout our profession, from the time of entry until retirement.7,40

This approach requires both explicit and implicit learning. The professional attributes that form the vision and mission of the profession should be explicitly taught and reflected through mentorship by our educators. These attributes should be evaluated and made a precondition of progression toward independent practice. Indeed, the ACGME neurological surgery milestones for profes­sionalism embody such efforts and priorities, as does the cur­riculum of national courses promulgated by the education and leadership Society of Neurological Surgeons, which is responsible for residency curriculum.9,32

In addition, the skills and experience necessary to effectively collect and analyze practice data must be ex­plicitly taught to trainees. Adult learners (including post­graduate resident trainees) benefit most from training that closely approximates their future practice environment.4 Thus, residency training should incorporate direct ex­posure to case and disease management outcomes processes and platforms. Ideally, the platforms used for residency case collection for the ACGME should closely corre­spond or be identical to those used in practice. Residents should be taught basic statistical skills and engage in for­mal quality improvement in the live clinical environment during training, benefiting both their education and the excellence of medical care at academic health centers. Finally, the sophistication required to promulgate patient outcome and quality improvement methodologies widely across the specialty, to systematically teach these skills to new generations of practitioners, and to contrib­ute novel advances in theory and methodology all re­quire the creation of a new sphere of professional activity within neurosurgery. Our national organizations should fund and support the recruitment and training of young neurosurgeons as intentionally trained specialists in out­comes science, quality improvement, bioinformatics, and neurosurgical education. We should also recognize and promote such individuals on par with the value of sur­geons who develop novel technical and surgical expertise. Ultimately, a modern view of professionalism within neurosurgery will recast the “threats” and “mandates” that appear to externally impact our specialty. Neurosur­geons may choose and adapt methods developed by other professions that are of tested and proven effectiveness and have been adopted broadly within the modern infor­mation age. Neurological surgeons should avoid a false choice between loss of control and access to powerful disciplinary knowledge, systems practice, safety, and eff­fectiveness improvements that have transformed modern society and economic systems around us.

Disclosure

Drs. Selden, Ghogawala, Harbaugh, and Asher are members of the Board of Directors of NeuroPoint Alliance. Drs. Harbaugh and Asher are members of the Board of Directors of the American Association of Neurological Surgeons. Drs. Selden and Ghogawala are members of the Board of Directors of the Congress of Neurological Surgeons. Dr. Selden is the Chair of the Committee on Resident Education of the Society of Neurological Surgeons. Drs. McGirt and Litvack are principals of the NeuroPoint Alliance project, the National Neurosurgery Quality and Outcomes Database. Dr. McGirt receives non–study related support from DuPuy Spine. Dr. Asher owns stock in Hyperbranch Medical Technology and serves as a consultant for Medtronic and Stryker.

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