

The National Neurosurgery Quality and Outcomes Database and NeuroPoint Alliance: rationale, development, and implementation

ANTHONY L. ASHER, M.D.,^{1,2} PAUL C. MCCORMICK, M.D., M.P.H.,³
NATHAN R. SELDEN, M.D., PH.D.,⁴ ZOHER GHOGAWALA, M.D.,^{5,6}
AND MATTHEW J. MCGIRT, M.D.⁷

¹Carolina Neurosurgery & Spine Associates; ²Department of Neurological Surgery, Carolinas Medical Center, Charlotte, North Carolina; ³Department of Neurological Surgery, Columbia University College of Physicians and Surgeons, New York, New York; ⁴Department of Neurological Surgery, Oregon Health & Science University, Portland, Oregon; ⁵Wallace Trials Center, Greenwich Hospital, Greenwich, Connecticut; ⁶Department of Neurosurgery, Lahey Clinic Medical Center, Burlington, Massachusetts; and ⁷Department of Neurological Surgery, Vanderbilt University Medical Center, Nashville, Tennessee

Patient care data will soon inform all areas of health care decision making and will define clinical performance. Organized neurosurgery believes that prospective, systematic tracking of practice patterns and patient outcomes will allow neurosurgeons to improve the quality and efficiency and, ultimately, the value of care. In support of this mission, the American Association of Neurological Surgeons, in cooperation with a broad coalition of other neurosurgical societies including the Congress of Neurological Surgeons, Society of Neurological Surgeons, and American Board of Neurological Surgery, created the NeuroPoint Alliance (NPA), a not-for-profit corporation, in 2008. The NPA coordinates a variety of national projects involving the acquisition, analysis, and reporting of clinical data from neurosurgical practice using online technologies. It was designed to meet the health care quality and related research needs of individual neurosurgeons and neurosurgical practices, national organizations, health care plans, biomedical industry, and government agencies. To meet the growing need for tools to measure and promote high-quality care, NPA collaborated with several national stakeholders to create an unprecedented program: the National Neurosurgery Quality and Outcomes Database (N²QOD). This resource will allow any US neurosurgeon, practice group, or hospital system to contribute to and access aggregate quality and outcomes data through a centralized, nationally coordinated clinical registry. This paper describes the practical and scientific justifications for a national neurosurgical registry; the conceptualization, design, development, and implementation of the N²QOD; and the likely role of prospective, cooperative clinical data collection systems in evolving systems of neurosurgical training, continuing education, research, public reporting, and maintenance of certification.
(<http://thejns.org/doi/abs/10.3171/2012.10.FOCUS12311>)

KEY WORDS • National Neurosurgery Quality and Outcomes Database •
N²QOD • quality • value • health care reform •
NeuroPoint Alliance • clinical registry

THE National Neurosurgery Quality and Outcomes Database (N²QOD) is a prospective clinical registry designed to address the need for high-quality outcome data related to care of patients with neurosur-

gical disorders. This project description is intended to outline the evolution of the registry and, more broadly, the evolution of practice science methodologies over the past several years. It also attempts to describe the role of this clinical registry in the context of a rapidly changing health care landscape, which is increasingly mandating that clinicians participate in the routine collection, analysis, and application of clinical data related to the safety, quality, and value of care.

Health Care Reform and the Emerging Requirement for Quality Data

Over the past several decades, the biomedical community has successfully used scientific methodologies to

Abbreviations used in this paper: AANS = American Association of Neurological Surgeons; ABNS = American Board of Neurological Surgery; CMS = Centers for Medicare and Medicaid Services; CNS = Congress of Neurological Surgeons; HIPAA = Health Insurance Portability and Accountability Act; IRB = institutional review board; N²QOD = National Neurosurgery Quality and Outcomes Database; NeuroPoint-SD = NeuroPoint–Spinal Disorders; NPA = NeuroPoint Alliance; PBLI = practice-based learning and improvement; PBLN = Practice Based Learning Network; PQRS = Physician Quality Reporting System; SNS = Society of Neurological Surgeons; STS = Society of Thoracic Surgeons; VIMPH = Vanderbilt Institute for Medicine and Public Health.

fuel dramatic progress in the practice of medicine, to the benefit of patients and the groups that serve them, including physicians and biotechnology industry. Most of this progress has been related to the development of countless new devices and procedures designed to diagnose and treat human illness. This same community has, however, largely failed to apply scientific principles to routine analyses of the relative effectiveness and value of those medical interventions in everyday practice. The past emphasis on technological innovation has profound implications in the present, for it is now clear to all health care stakeholders that we have built a medical system that is technologically sophisticated, yet economically unsustainable and often incapable of self-assessment and improvement.

Health care reform has been a topic of debate and concern for decades in America, but the tipping point in public acceptance for substantial change can perhaps be traced to the period around the beginning of this century. During that period, 2 influential reports issued by the Institute of Medicine raised concerns about the quality and safety of medical care in the US, emphasizing the need for performance and outcome measurements focused on improvement of care and greater accountability.^{4,6} Soon thereafter, a number of oversight organizations (such as the American Council for Continuing Medical Education [www.acme.org], the American Council for Graduate Medical Education [www.acgme.org/acgmeweb], and medical boards) modified their certification processes to incorporate some of these recommendations. Additionally, government agencies such as the Department of Health and Human Services initiated small pilot programs designed to promote high-quality health care.¹¹ Despite these incremental regulatory changes, general medical and surgical practices remained largely unchanged with respect to the routine integration of techniques designed to promote high-quality patient care.

Concurrently, opinion polls consistently identified rising health care costs as one of the public's chief concerns. Over the next several years, constant media attention to the issues of cost, safety, and quality of medical care gave rise to widespread expectation among the American public of greater physician accountability and optimization of care. The financial crisis of 2007, in combination with disturbing economic projections that suggested health care expenditures could potentially exceed 20% of the gross domestic product within another decade,^{5,9} bolstered arguments by many stakeholders and mostly Democratic politicians in favor of dramatic health care reform. The subsequent passage of the Patient Protection and Affordable Care Act dramatically (and probably permanently) shifted the focus of attention toward quality and cost in health care delivery.¹⁰

Today, numerous statutory changes to the Medicare and Medicaid programs, enacted in 2009 and aimed at making all health care professionals directly accountable for their outcomes as well as the overall value of care, are being actuated. In the private sector, numerous stakeholders are rushing forward to define their own health care performance standards (<http://www.bcbs.com/why-bcbs/blue-distinction/>, <http://www.uhc.com>). In many instances these programs lack an accurate level of clinical data

to support true quality improvement, are being developed with minimal physician input, and are being implemented in ways that serve various stakeholders' own interests in the current resource-limited environment.

In summary, the need for data that can be used to objectively improve quality of care and intelligently inform the allocation of increasingly scarce health care resources lies at the heart of the ongoing national debate regarding health care reform and is driving the largest transformation of health care processes in modern history.

Defining Requirements for Quality Data Collection

In the past, administrative, claims-based data sets have been used to provide insight into health care costs and outcomes. However, the claims system was developed primarily for reimbursement purposes. Claims databases capture information about the types of medical services provided but include limited information about clinical diagnosis. Strengths of administrative data sources include their large size and their comprehensive coverage of a patient's entire health care experience. The major disadvantage of administrative databases is their lack of accurate or detailed clinical information that is often required to support health care quality improvement. Despite the fact that specific methods do not yet exist for determining the quality and value of most neurosurgical services, many coverage and access decisions are already being made using large global administrative data sets, with no risk adjustment; these data sets poorly reflect the clinical and economic realities of caring for individual patients.

Physicians understand that meaningful efforts designed to improve the quality of care must be driven by clinical experts. High-quality clinical data are essential to the promotion of the best medical care. Fortunately, federal agencies and even many private payers are still open to advice on what are the best benchmarks for performance and quality in neurological surgery. If we want to continue to provide the best and most essential services for patients with spine and other neurosurgical disorders, we must provide leadership in the emerging quality of care paradigm.

The gold standard for medical evidence has been the randomized clinical trial, which is still useful for answering a number of important surgical issues. Such studies are nevertheless often difficult to perform due to ethical challenges, such as patient and surgeon preferences and the controversial use of placebos and blinding, as well as cost and time. In addition, the general applicability of data from randomized clinical trials is often compromised by patient crossover between treatment groups and strict eligibility criteria. Moreover, findings of efficacy in controlled research settings may not translate into effectiveness in the real-world delivery of health services.

Although the American Association of Neurological Surgeons (AANS) and other medical organizations continue to support the use of randomized controlled trials to address specific clinical and scientific questions, there is a growing belief that traditional scientific methods are inadequate to address the challenges we now face, raising the question of what other mechanisms can produce high-

The National Neurosurgery Quality and Outcomes Database

quality data most relevant to the safety, effectiveness, and cost of various therapeutic interventions.

Those who purchase and consume health care services and products commonly request information relevant to 3 questions: 1) What is the probability that a procedure will produce measurable beneficial effects, with acceptable risk, in specific groups of patients? 2) If a procedure has the potential to produce beneficial effects, which physicians possess the capability to successfully perform that procedure, and what techniques do they employ? 3) What is the fundamental nature of the potential benefits (to the individual, society, or both; economic, noneconomic, or both)?

Currently available in neurosurgery are modest amounts of data related to Question 1, very limited data related to Question 2, and virtually no data relevant to Question 3.

Answering Question 1 requires the collection of risk-adjusted patient-centered outcomes data from all practice settings to develop true national benchmarks for performance. Question 2 cannot be answered without the contribution of representative clinical data from all surgeons in a particular specialty. Addressing Question 3 requires the engagement of all relevant stakeholders and the development of broad consensus regarding the intended effect of specific procedures.

Surgeons are currently faced with both individual and collective national quality mandates. Individual surgeons will be held increasingly responsible for the quality of health care they provide and will face constant pressures to analyze and improve methods of care. Surgeons will require support for the collection of data demonstrating the value of that care, as well as national performance standards that facilitate local quality improvement. Large national surgeon groups will be responsible for the development of intelligent systems to collect data from clinical practice and the development of quality standards relevant to all practice settings. These unique, interdependent clinical and scientific responsibilities suggest the need for an entirely new method of science based in clinical practice, in other words, a “science of practice.” In contrast to traditional frameworks for scientific advance, which were dominated by relatively few clinician scientists, this new paradigm will necessarily involve all practitioners (along with other stakeholders) in a continuous, comprehensive system to define, measure, and promote quality of care.

Meeting the Health Care Quality Challenge—the Evolution of Practice Science in Neurosurgery

Every day, the information surgeons need to improve care is generated in actual practice, but goes largely uncollected, remains unanalyzed, and is therefore not available to improve subsequent care. The cycle of data collection, analysis, and application to practice is grounded in some of the most powerful currents in modern society. For example, the combination of data from experience with traditional educational methods has become a central feature of modern learning science and has been shown to powerfully influence behavior and promote deep conceptual understanding, particularly in mature or adult learners, such as physicians and surgeons.² Most

major industries have used the systematic collection of data from experience to inform total quality improvement for decades.⁷ In fact, medicine is one of the few industries that do not routinely apply these methods. That deficiency can and must change. Most importantly, the use and generation of novel information has become the major transforming influence and currency in our “knowledge society.” Those who control essential data and who use data to generate new knowledge and facilitate improvement will be able to adapt, effect change, and prosper. In this regard, the science of practice is not simply a response to abstract or irrelevant external requirements but an opportunity to survive and indeed thrive amid the increasing competition and demands of the informatics age.

For many years, visionaries within the neurosurgical community have recognized the need to develop a national competency in the science of neurosurgical practice. The beginning of a coherent national effort in practice science can be traced to 1997, when the leadership of the AANS and Congress of Neurological Surgeons (CNS) addressed the extraordinary challenge of harnessing our collective ability to use patient care data to measurably improve the quality of neurosurgical care and more efficiently allocate health care resources, through the formation of a Joint Outcomes Committee, led by Dr. Robert Harbaugh.

The AANS/CNS Outcomes Committee was charged with developing the infrastructure necessary to perform reliable outcome analyses, including studies related to the comparative effectiveness of surgical procedures and other therapies as well as evaluations of the costs and benefits of new technologies. The Outcomes Strategic Subcommittee conceived and developed the infrastructure for outcome studies related to the treatment of a variety of neurosurgical disorders. The infrastructural components included specific outcome methodologies, information technologies (including an online reporting system linked to the NEUROSURGERY://ON-CALL national website), and educational materials for the neurosurgical community. Starting in 1998, a pilot study of the treatment of patients with intracranial aneurysms was initiated in several academic institutions and private practice groups. This time-limited study successfully completed accrual in 2000 and was followed by other analyses, including a multicenter study of patients with carotid stenosis. The Joint Outcomes Committee became an important proof of principle for the practicability and utility of a larger, sustained national outcomes program in neurosurgery.

From 2001 through 2006, various programs to advance neurosurgical practice science were reviewed and discussed among the leadership of organized neurosurgery. Early advocates for these programs included Dr. Harbaugh, Dr. Daniel Resnick, and Dr. Paul McCormick, among several others. In March 2005, the Quality Improvement Workgroup was established within the AANS/CNS Washington Committee to respond to the development of quality-related programs across the public and private sectors. A senior manager for quality improvement was established within the Washington Committee offices in 2006 to support the work of the Quality Improvement Workgroup and promote quality-improvement

efforts throughout neurosurgery. Strategic conversations during this period focused on the health care quality needs of various national stakeholders along with the practical and scientific realities of developing a national network for practice data collection, including sustainable business models, health information technology systems, and methodological constructs.

In early 2007, the presidents of the CNS and AANS, Dr. Anthony Asher and Dr. James Bean, respectively, developed a joint task force to examine the development of a specialty-wide effort to promote quality of care and outcomes science initiatives. Physician members of that initial group included Dr. Douglas Kondziolka, Dr. Nathan Selden, Dr. Joel MacDonald, Dr. Christopher Wolfla, Dr. Hunt Batjer, Dr. Ashwini Sharan, Dr. Jon Robertson, and Dr. Fred Barker, in addition to Drs. Asher, Bean, Harbaugh, and McCormick. Ms. Katie Orrico and Ms. Rachel Groman from the AANS/CNS Washington Committee, AANS and CNS counsel, along with the executive directors of the AANS and CNS, Mr. Tom Marshall and Ms. Laurie Behncke, respectively, also played substantial roles in the group's deliberations.

An important early development in the joint discussions occurred when the Neurosurgery Executives' Resource Value and Education Society (NERVES), under the leadership of Mary Cloninger, M.B.A., commissioned a survey of NERVES member sites, which indicated a strong desire among practice sites around the country for the development of a cooperative system to track and report the outcomes of neurosurgical care along with a willingness to help fund such an effort. This enabled the development of a sustainable budget model for a proposed national practice data collection system.

In late 2008, on the basis of joint task force discussions, the AANS and CNS formed a cooperative venture intended to address the health care quality and related research needs of a broad range of health care stakeholders including individual neurosurgeons, neurosurgical practices, national organizations, health care plans, biomedical industry, and government agencies: the NeuroPoint Alliance (NPA). The initial members of the NPA Board of Directors were Dr. Robert Harbaugh (president), Dr. Paul McCormick, Dr. Chris Wolfla, Dr. Anthony Asher, Dr. Ashwini Sharan, Mr. Ron Engelbreit, Mr. Tom Marshall, and Ms. Laurie Behncke. The NPA, a not-for-profit 501(c)(3) corporation, was specifically created to coordinate a variety of national projects involving the acquisition, analysis, and reporting of clinical data from neurosurgical practice, using online technologies. Such projects include outcomes research (particularly comparative effectiveness research) and universal data reporting requirements, including maintenance of certification, maintenance of licensure, and the PQRS, in addition to local and national quality-improvement efforts. One of the earliest efforts of NPA was to develop a cooperative relationship with Outcome Sciences, a Boston health care technology corporation that was contracted to help coordinate the practice data component of maintenance of certification for the American Board of Neurological Surgery (ABNS).

By late 2009, the NPA Board of Directors, including representatives from the AANS and CNS, decided to reor-

ganize the governance structure of the corporation. At that time, the AANS assumed the primary leadership role in the newly reconstituted NPA Board of Directors as well as in funding the activities of the organization and in the creation of the administrative infrastructure for the reconfigured corporation. The newly reconstituted board was composed of representatives appointed by the AANS Board of Directors, with unofficial CNS representation. From late 2009 to October 2011, the NPA directors included Dr. Paul McCormick, Dr. Anthony Asher, Dr. Robert Harbaugh, Dr. Anil Nanda, Dr. David Adelson, and Dr. Kevin Crockoft. Dr. McCormick served as NPA president for the majority of this period. In October 2011, further restructuring allowed for the formal participation of a broad coalition of neurosurgical societies in NPA, including the AANS, CNS, Society of Neurological Surgeons (SNS), specialty sections participating in ongoing NPA projects, and the ABNS. At that time, voting members officially representing the ABNS (Dr. Matthew Howard), SNS (Dr. Alan Friedman), and CNS (Dr. Zoher Ghogawala) were added to the NPA board. Drs. Nanda, Crockoft, and Adelson completed their director terms, and Drs. Mitchel Berger, Joseph Cheng, and Nathan Selden were appointed to the board. Drs. Harbaugh, Asher, and McCormick were reappointed directors at that time.

A critically important event in the evolution of the NPA came in October 2010, when the AANS Executive Committee, under the leadership of then-president Dr. James Rutka, decided to dedicate significant resources to the support of NPA projects and administration. At that point, the activities of the NPA were adopted as a major strategic initiative of the AANS.

Additionally in 2010, the NPA's first research project, NeuroPoint-Spinal Disorders (SD), under the leadership of Dr. Zoher Ghogawala, was initiated. Dr. Asher, Dr. Resnick, and Dr. Christopher Shaffrey served as coinvestigators on this project, which was jointly supported by the AANS-CNS Joint Section for Disorders of the Spine and Peripheral Nerves (Joint Spine Section), NPA, and the Wallace Foundation. The aim of NeuroPoint-SD was to create an alliance of tertiary and community-based spine surgeons with a simple Web-based infrastructure to collect outcome data for common lumbar spine procedures in actual practice using a spinal disorder patient registry. This project, which was recently completed, demonstrated the ability of a cooperative group of surgeons to collect 1-year patient-reported outcome data and achieve follow-up in 80% of patients enrolled. This pilot project was a significant success and provided foundational tools for the creation of a larger national clinical registry.

Concurrent with the development of NeuroPoint-SD, the NPA leadership examined a variety of mechanisms to facilitate the widespread adoption of outcome and practice science techniques into clinical practice. After much due diligence, the NPA determined that patient registries were the most logical and practical mechanism to achieve this objective. Patient care registries are cost-effective, easily scaled to accommodate numerous users, and can rapidly and efficiently yield vast amounts of high-quality clinical data. Registries document care in real-world environments, without the artificial constraints of narrow

The National Neurosurgery Quality and Outcomes Database

eligibility criteria used in controlled trials. Registry data can therefore be readily generalized to a wide range of practice situations. In part for these reasons, health care policy makers, purchasers, and payers are increasingly demanding their use.

The Society of Thoracic Surgeons (STS) National Database has dramatically shown the power of national practice data collection programs (<http://www.sts.org/national-database>). This well-established database is used by 95% of all US thoracic surgery practices and is unquestionably the most successful surgical registry in existence. The STS has used its database to define its own measures of quality and performance, 23 of which have been endorsed by the National Quality Forum. As a direct result, they've reduced the likelihood of thoracic surgeons being forced to comply with arbitrary performance standards created by outside stakeholders. For each of these measures, the STS has developed risk-adjusted national and regional benchmarks for the safety and quality of their procedures. Individual surgeons and practice groups have the tools to analyze their own morbidity and clinical outcomes in real time and compare these data with the national benchmarks. This allows surgeons to determine which areas of their practice should be targeted for quality improvement. It also allows them to satisfy public reporting requirements and develop practice-specific quality and efficiency data to support claims made to public and private payers.

The STS has used aggregate national efficacy data to inform discussions with the Relative Value Scale Update Committee, private payers, and large purchasers of care. In doing so, they have successfully protected patient access to surgical care and have defended the value of their procedures. The STS has developed sophisticated risk models to determine subgroups of patients most likely to benefit from specific therapies. Finally, and perhaps most importantly, the STS registry has been used to advance scientific discovery and improve patient care. For example, the STS database helped establish the superiority of internal thoracic artery bypass grafting and made this method standard care in thoracic surgery. Therefore, one of the most significant advances in cardiac surgical outcomes was not the exclusive creation of a small group of academic clinical scientists, but rather the product of a dedicated and diverse community of surgeons from all practice settings.

As early adopters of practice science methodologies, thoracic surgeons effectively demonstrated the value and safety of their care, increased public trust in their science, and provided other surgical specialties with a roadmap for pursuing their own quality-improvement efforts. Although the great variety and complexity of illnesses neurosurgeons treat creates unique requirements for practice data collection and analysis, the STS experience provides a useful roadmap as we seek to promote the practical adoption of practice science methodologies in our own specialty.

The National Neurosurgery Quality and Outcomes Database

The NeuroPoint Alliance shares with the public a

sense of urgency and responsibility to meet the challenges of creating a sustainable health care system. From 2010 through 2012 our organization therefore developed, in conjunction with relevant national stakeholders, a centralized and nationally coordinated effort to allow individual neurosurgeons and practice groups to measure and analyze practice patterns and outcomes. This unprecedented health care quality program, the N²QOD, will allow any US neurosurgeon, practice group, or hospital system to contribute to and access national aggregate quality and outcome data. The N²QOD is primarily designed to serve as a continuous national clinical registry for neurosurgical procedures and practice patterns along the lines of the very successful STS database.

The primary goals of this program are 1) to establish risk-adjusted national benchmarks for both the safety and effectiveness of neurosurgical procedures, 2) to allow practice groups and hospitals to analyze their individual morbidity and clinical outcomes in real time, 3) to generate both quality and efficiency data to support claims made to public and private payers and objectively demonstrate the value of care to other stakeholders, 4) to demonstrate the comparative effectiveness of neurosurgical and spine procedures, 5) to develop sophisticated "risk models" to determine which subpopulations of patients are most likely to benefit from specific surgical interventions, and 6) to facilitate essential multicenter trials and other cooperative clinical studies.

The N²QOD is one of the most comprehensive national outcomes registries yet constructed. Its scalable format will ultimately allow for the collection of clinical, demographic, and quality-of-life data from all neurosurgical patients. Its longitudinal structure will allow for the determination of the sustainability of treatment effects. The inclusion of patient-reported outcomes will allow for the collection and analysis of essential efficacy data not available in the medical record. Groups and even individual surgeons will be able to compare their performance against robust, risk-adjusted national standards (thus facilitating the development of new care initiatives). By combining quality and cost data neurosurgeons will, for the first time, be in a position to define the relative value of various forms of care. Through the N²QOD, the neurosurgical community will be able to assess the factors and variables that correlate with individual treatment outcomes. That information will allow surgeons to reduce uncertainty at the individual patient level and select for surgery only those patients whose profiles and variables predict favorable outcomes. Finally, we will gain the capacity to compare the relative effectiveness, safety, and value of various approaches to care.

The health information technology partner for this project was understood to be a critical component in its ultimate success. Telephone and electronic communications were exchanged with approximately 6 health information technology companies over a 6-month period; the list of potential partners was ultimately narrowed to 3. Site visits were subsequently conducted with representatives of MedAssurant (subsequently Inovalon, Inc.), Outcome Sciences, Inc. (subsequently acquired by Quintiles), and the Vanderbilt Institute for Medicine and Pub-

lic Health (VIMPH). At the conclusion of this extensive evaluation process, the NPA board determined to partner with VIMPH for management of the collection and analysis of standardized data across neurosurgical practices.

The strategic partnership with VIMPH was formalized in February 2012. The VIMPH is a nationally recognized leader in the field of health services research and quality improvement, with advisory positions and funding from the Agency for Healthcare Research and Quality, the National Institutes of Health (NIH), the Institute of Medicine, and Centers for Medicare and Medicaid Services (CMS). The VIMPH was chosen by the NPA from a short list of leading national public health institutes because of its recognized expertise and experience facilitating multicenter quality improvement and health services research initiatives. Among many other services, VIMPH provides independent, third-party, continuous quality control for N²QOD and will conduct site audits to ensure the validity and reliability of collected data. These features are critical to the development of trust within and outside the project with respect to our reports and findings. The REDCap software platform (<http://project-redcap.org>), developed by an informatics core at Vanderbilt University with ongoing support from NIH grants, is one of the most powerful, cost-effective, and versatile clinical data capture systems yet created and will be used by N²QOD sites for data collection.

The purpose and design of this registry is to track quality of surgical care for the most common neurosurgical procedures as well as provide practice groups and hospitals with an immediate infrastructure for analyzing and reporting the quality of their neurosurgical care. The N²QOD will serve as a national network of practicing neurosurgeons (and, where applicable, other related specialists including multidiscipline spine surgeons) with the primary aim of providing surgeons with a dynamic quality assessment and reporting infrastructure.

In brief, the registry will function as follows: participating N²QOD practice sites will collect personal health information and other data related to the standard care of patients undergoing specified types of neurosurgical procedures at their facilities each week. These data will be collected from the medical record, pre- and postoperative validated survey assessment procedures, and interviews. The data will be entered into a HIPAA-compliant, Web-based portal (the REDCap database) and transmitted to the institution serving as the registry (VIMPH) for analysis. Among other activities, VIMPH will use these data to 1) establish new national practice benchmarks for the quality of surgical procedures and 2) provide reports to the practice sites detailing the (risk-adjusted) quality of their services compared with the national benchmarks. The NPA will provide oversight for the entire project. Data transfer and data use will be governed by business associate agreements between the sites, NPA, and VIMPH.

Although the primary focus of this program is quality improvement, the NPA acknowledges that the creation of “generalizable knowledge” has been, in the past, a by-product of rich data sources such as large clinical registries. As such, it is probable that future secondary objec-

tives of the N²QOD could include research focused on ways of improving patient outcomes and resulting public health. A review of such activities and their regulatory implications is provided in another paper in this issue of *Neurosurgical Focus*.³

The N²QOD project will be developed in stages. Subspecialty-specific “modules” will encompass every subspecialty practice area in neurosurgery, including all common neurosurgical diagnoses and procedures, both cranial and spinal. The NPA’s initial registry effort focuses on lumbar spine disorders, given the pressing need expressed by many groups around the country for outcome data in this practice area and the high percentage of spine procedures that make up neurosurgical practice (approximately 65% of aggregate cases based on the 2006 AANS procedural statistics survey).¹ This need has been particularly acute in states such as North Carolina, where insurers are already restricting access to spine surgery based on their own flawed interpretations of clinical evidence.

In late February 2012, the N²QOD lumbar spine module was piloted in 5 academic centers. This program has rapidly expanded, and as of September 2012, 23 programs across the country, representing both academic and community settings, are entering data into the program. A total of 37 sites have achieved complete institutional review, and the NPA is activating new sites weekly. To date, 1504 patients have been enrolled. It is estimated that the 45 sites that are either already participating or are in various stages of N²QOD activation will generate over 1 million independent data elements a year. The infrastructure of the N²QOD has been designed to greatly expand the number of participating sites over time. A detailed methodological outline of the project and justification for the scientific structure of the database as a surgical registry are described in a separate paper in this issue of *Neurosurgical Focus*.⁸

Registry Administration and Leadership

The first full-time NPA administrator was hired in March 2011. As of this writing, Ms. Irene Zyung is the current NPA administrator. The deputy executive director of the AANS, Ms. Kathleen Craig, has provided substantial senior administrative support since NPA’s inception.

Dr. Paul McCormick made the promotion of practice science and the development of the NPA a central focus of his AANS presidency from April 2011 to April 2012. Since April 2012, Dr. Mitchel Berger, current AANS president, and Dr. William Couldwell, AANS president-elect, have continued to make the NPA a strategic priority. The late Dr. Christopher Getch, recent past CNS president, initiated a process within the CNS Executive Committee in 2011 to develop material support for the NPA and its projects. That process was brought to completion by Dr. Christopher Wolfla during his CNS presidency.

The NPA Board of Directors is presently made up of 6 directors from the AANS, and one each from the CNS, SNS, and ABNS. The 2011–2012 NPA directors are Dr. Mitchel Berger (president), Dr. Anthony Asher (vice-president), Dr. Robert Harbaugh (treasurer), Dr. Joseph S. Cheng (secretary), Dr. Paul McCormick, Dr. Nathan Selden, Dr.

The National Neurosurgery Quality and Outcomes Database

Zoher Ghogawala (CNS), Dr. Allan Friedman (SNS), and Dr. Matthew Howard (ABNS). The NPA currently supervises, as described previously, time-limited research projects, data collection for the practice data component of maintenance of certification, and the N²QOD. Leadership of the AANS/CNS Washington Committee and Quality Improvement Workgroup serve as liaison to the NPA board.

The N²QOD senior leadership includes a director and vice-director, currently Dr. Anthony Asher and Dr. Matthew McGirt, respectively. The N²QOD has 3 major subcommittees: the Scientific Committee, the Business Committee, and the Operations Committee. The functions of each committee are described below. Chairs of the 3 major subcommittees, along with the N²QOD leadership, comprise the N²QOD Executive Committee. The Executive Committee is involved in higher-level decision making and reports directly to the NPA board of directors.

The N²QOD Scientific Committee is currently chaired by Dr. Matthew McGirt and Dr. Nathan Selden. Dr. Zoher Ghogawala, and Dr. Steven Kalkanis are co-vice-chairmen. The Scientific Committee is responsible for a broad variety of scientific projects and oversight, including new project development, development of scientific methodologies, grant development and submission, and data validity. This committee is also primarily responsible for setting priorities for new module development. After new module concepts are vetted within the scientific committee, they are forwarded to the N²QOD Executive Committee and ultimately the NPA Board of Directors for final approval. Current Scientific Committee subcommittees include the Data Use, Access, and Publications Subcommittee; the Patient Protections Subcommittee; and the Data Validity and Quality Control Subcommittee. Multiple neurosurgical subspecialties are represented on the scientific committee, which also includes epidemiologists, quality scientists, and biostatisticians.

The development of the N²QOD lumbar spine module provides an example of the processes used by the Scientific Committee. In January 2011, the NPA board decided to proceed with the development of a registry module that would allow for the collection of risk-adjusted outcome data from patients undergoing common lumbar spine surgeries. A preliminary set of variables was suggested by the Scientific Committee. Over the next several months, this preliminary module was discussed and vetted among a broad group of experts and stakeholders that included representatives from the AANS/CNS Joint Spine Section, the AANS/CNS Washington Committee's Quality Improvement Workgroup, the AANS/CNS Special Spine Task Force, the North American Spine Society, the Scoliosis Research Society, and clinical outcomes scientists. A revised data set was presented to the N²QOD Executive Committee and NPA Board of Directors for approval in June 2011. This data set subsequently underwent final modification after review by statisticians and quality researchers at VIMPH in August 2011. A finalized module was distributed to practice sites in the fall of 2011. Since that time, the lumbar module has undergone several minor revisions by the Scientific Committee and VIMPH based on continuous observation of its use in clinical

practice. The Scientific Committee has used similar processes in the development of a cervical spine module and a condensed "essential" lumbar spine module (described in following sections). These modules are presently undergoing final review by the NPA Board of Directors.

The Scientific Committee working in conjunction with the Operations Committee (see below) helped facilitate contracts with EuroQol and MAPI Research Trust, the developers and proprietary holders of the outcomes instruments EQ-5D and ODI, respectively, allowing N²QOD's measurement of physical disability and health-related quality of life. Those agreements and partnerships have established an ongoing collaboration between NPA and EuroQOL and MAPI Research Trust to study the use of these instruments in the context of a large, longitudinal registry and the modification of the instruments to allow for use in phone interviews and online patient-initiated data entry.

The N²QOD Operations Committee is currently chaired by Dr. J Mocco and Dr. John Wilson. Dr. Neil Malholtra and Dr. Zach Litvack are co-vice-chairmen. Dr. Litvack also serves as the N²QOD information technologies coordinator. The Operations Committee is the largest N²QOD committee, and serves as a representative and interactive forum, with surgeon members from all active N²QOD practices, along with the leadership of the other N²QOD committees and representatives from VIMPH and the AANS/CNS Washington Committee. The Operations Committee is charged with oversight of the daily operations of the registry. Ongoing site feedback is critical to the functioning of the committee and keeps site needs at the center of registry development and revision. The activities of the Operations Committee include registry implementation (including site recruitment, initiation, and contract execution); oversight of data coordinators; solicitation of feedback from participating institutions; development of N²QOD content and deliverables, marketing, education, and stakeholder outreach; and, when necessary, database revision in cooperation with the N²QOD Scientific Committee. Notable activities of the Operations Committee over the past year have included the development of NPA and N²QOD branding, the development of the NPA/N²QOD website and participant intranet, development of numerous educational offerings on practice science, and development and revision of N²QOD user manuals and data collection guidelines (<http://www.neuropoint.org> and <http://www.neuropoint.org/NPA%20N2QOD.html>).

Stakeholder outreach has been undertaken with great energy over the past 2 years, and has included numerous meetings with representatives of multiple private insurance companies, CMS, the Agency for Healthcare Research and Quality, the National Quality Forum, the Patient Centered Outcomes Research Institute, patient advocacy groups, and purchasers of health care services. The Operations Committee has also facilitated outreach within the medical community, including conferences with the American Medical Association and the developers of other large registries such as those of the American College of Surgeons National Surgical Quality Improvement Program, or NSQIP, and the STS (STS Database). The committee, in conjunction with the leadership of the

AANS/CNS Quality Improvement Workgroup (under the leadership of Dr. Jack Knightly and Dr. John Ratliff), recently completed extensive interactions with CMS regarding potential incorporation of N²QOD data elements into the neurosurgery-specific PQRS group measures. The Operations Committee's most significant stakeholder outreach occurred over a 9-month period and involved numerous meetings and communications with the US Department of Health and Human Services' Office for Human Research Protections and Office for Civil Rights regarding the regulatory implications of the N²QOD, specifically the elements of the registry that require direct patient contact, collection of personal health information, and long-term follow-up. The interactions with these agencies ultimately led to a multistakeholder meeting at the White House in August 2011, followed by the delivery of written guidance from the Office for Human Research Protections. That guidance greatly facilitated local review and implementation of the N²QOD project and is detailed in another paper in this issue of *Neurosurgical Focus*.³

The N²QOD Business Committee is currently chaired by Ms. Mary Cloninger and Mr. Todd Barnes. The committee includes business representatives from all active N²QOD sites, along with the N²QOD senior leadership and NPA administrative staff, including NPA counsel. The Business Committee is responsible for developing the business model for the N²QOD, examining alternative revenue sources to support registry activities, defining participating site definitions, and modifying contracts based on certain local regulations or state laws. The N²QOD business model presently calls for a shared contribution from the primary registry sponsor (NPA/AANS) and the practice sites. The NPA, through the Business Committee, is developing a strategy to have the majority of costs for the local conduct of the registry assumed by institutions (as opposed to practice groups) as part of their general processes of quality control. The STS has already developed a precedent for this type of ongoing support. The major costs of N²QOD participation are the yearly subscription fee (currently \$13,000 per site, which includes registry deliverables along with database access) and any costs associated with on-site data collection and entry. The present subscription fee will allow sites access to the current lumbar spine module, along with the cervical module, due for release in the first quarter of 2013. These direct and indirect costs are very comparable or favorable compared with costs that have been acceptable and sustainable to STS practice and hospital members over decades.

The Vanderbilt Coordination Center for the N²QOD resides within the VIMPH. Dr. Robert Dittus, director of the VIMPH, provides ongoing support to NPA and the registry team. Dr. Ted Speroff serves as the N²QOD scientific lead and principal investigator. Ms. Joan Gottesman serves as the N²QOD project manager. Dr. Frank Harrell and Ms. Sharon Phillips from the Vanderbilt Department of Biostatistics serve as principal biostatistician and database designer, respectively, for the neurosurgery registry project. The VIMPH and Vanderbilt University biostatistics teams are charged with the development of

methodologies for the conduct of the registry (in conjunction with the N²QOD Scientific Committee), data collection processes, analysis and reporting, quality control, and data coordinator supervision. A detailed description of the role of VIMPH and the specific methodologies employed in the database is described in another paper in this issue of *Neurosurgical Focus*.⁸ Of note, the VIMPH team has recently spearheaded an innovative program called the Practice Based Learning Network (PBLN). The PBLN is composed of data coordinators and clinicians from all participating N²QOD sites. It is designed to promote a learning culture within the registry, foster cooperation and communication among sites, and allow all participants to benefit from the collective experience of the group. Recent cooperative efforts have focused on development and review of user manuals as well as on recommendations to ensure appropriate patient enrollment, adherence to prescribed sampling methodologies and inclusion/exclusion criteria, and accurate and complete data collection. The VIMPH team is currently finalizing its recommendations for electronic and on-site data and source material audits.

Note that the NPA aims more broadly to serve the clinical research needs of the neurosurgery community by offering services of project management and data coordination for a variety of prospective research projects. In 2011, the NPA and Vanderbilt University signed a memorandum of understanding that Vanderbilt University and the NPA would partner to serve as an academic research organization to assist in the planning, oversight, and management of clinical trials or prospective comparative effectiveness research on an ad hoc basis. In this model, any prospective research study that the NPA plans to manage could be submitted to Dr. Gordon Bernard (director of the Vanderbilt Institute for Clinical and Translational Research) or his specified associate for joint review and potential collaboration for project management and coordination. If NPA and Vanderbilt decide to partner in the management of a particular research study, the personnel, data collection tools, and analytics required for project management and oversight would be provided the Vanderbilt Institute for Clinical and Translational Research.

Participating in N²QOD

In brief, any practice group performing the index surgical procedures (for the lumbar module, lumbar spinal operative care) is eligible to participate in N²QOD. Practice groups are then given data use agreements and business associate agreements that their practice group or hospital system can formally execute (the details and purpose of the data use and business associate agreements are described on the NPA website). In addition, an N²QOD project description that describes the proper use of protected health information, operational protocols, patient interaction, and reporting methods will be made available to sites for submission to their hospital's quality improvement office or IRB. As of September 2012, no participating N²QOD site's IRB has imposed a requirement for research-related informed consent. Once the business associate and data use agreements between the

The National Neurosurgery Quality and Outcomes Database

site and NPA have been executed, a site must either provide documentation of the IRB letter of approval (with designation as nonresearch IRB exempt, research with waiver of consent, research with verbal consent, or research with written consent) or a letter from the hospital's administration or quality office granting permission to participate in N²QOD as a quality-improvement charter prior to enrolling into the N²QOD program. Full details related to N²QOD participation are available for interested practices, the public, and other stakeholders on the NPA/N²QOD websites.

Once an N²QOD site is established, it must identify a surgeon representative, the site's primary data coordinator, and the group's business representative. The surgeon representatives are expected to provide oversight to the data extractor and help to resolve data quality issues. The data coordinator/extractor serves as the main contact person throughout registry participation and will be responsible for case selection and Web-based data entry. The business representatives are the primary contacts for all contracts with the NPA. The surgeon representative(s) and data coordinator(s) will be required to complete human subjects training to ensure best practices in ethics, privacy, confidentiality, and data security.

Once contact information for a site's 3 primary representatives has been obtained by NPA, the site is formally registered as a user of the N²QOD Web portal and a protected website login name and password are issued by NPA and REDCap and provided to the data coordinator(s) and the clinical representative. Data coordinators are able to interact with the Vanderbilt N²QOD Coordination Center through a variety of communication vehicles including Skype, email, and telephone. All site coordinators will undergo detailed orientation regarding data collection, patient screening and selection, database methods, and quality control before data entry can begin.

Immediate-Term and Long-Term Goals

Our many clinical, scientific, and economic goals will not be attained immediately. Although the N²QOD launch was preceded by years of due diligence and preparation and the conceptualization of this project was based on solid outcomes science theory, only empirical methods and practical experience will allow for the optimization of our techniques. It is essential that all N²QOD participants understand that we have embarked on a collective, iterative learning experience that will result in the development of a powerful tool to improve patient outcomes and demonstrate the value of care.

The immediate objectives of the N²QOD are to 1) to implement a functionally operational national database; 2) to use pilot-year data to empirically refine methodologies to maximize data representativeness, accuracy, and collection techniques; 3) to intelligently expand the number of participating sites; and 4) to determine national performance benchmarks trusted by outside health care stakeholders (via a high degree of quality control, data integrity oversight, and auditing validation).

The determinations listed above will require the measurement of variation around our main end points from a national sample, along with analyses of other database

characteristics such as the proportion of cases entered into the N²QOD database versus total cases performed. Without the acquisition of preliminary data from multiple centers representing a variety of practice settings, we cannot power the statistical models necessary to determine critical program standards such as the optimal number of captured cases per site or per surgeon, nor can we optimize data collection paradigms. Even when standards are established for data assessment, those standards will require regular modification as new sites are added, variables are revised, and new N²QOD modules are developed.

Although the full capabilities of the registry will take time to develop, N²QOD users will immediately gain valuable experience in the routine collection of outcomes and other clinical data, an activity that is clearly the future of clinical practice. N²QOD centers in the early phases of this project will receive regular feedback on their data collection techniques and baseline patient characteristics. Within the next few months, we anticipate being able to forward preliminary outcomes data to the initial N²QOD practice sites.

N²QOD sites will receive reports generated by an independent third party health information technology vendor (VIMPH) allowing the demonstration of their center's safety and effectiveness of care along with crude, unadjusted national norms. As the size of the registry grows, risk-adjusted modeling, accounting for clinical variables that have true influence on outcome, will generate performance norms unique to each practice based on their unique patient and disease population. This will allow true performance measurement that does not unfairly profile practices that take on more risk. Such society-backed and validated reports may in the future be providers' only insurance against inaccurate public reporting from non-disease-specific administrative reports. Furthermore, by simply participating in N²QOD in the first years, practice centers may qualify for maintenance of certification, PQRS, and even insurance credentialing and reimbursement (see following). Additionally, the current and incoming N²QOD sites will develop the data foundation upon which all of our national benchmarks and methodological determinations will be initially based. Through their leadership, the "founding" N²QOD sites will help define a culture of systematic prospective data collection and self-assessment and establish these practices as integral components of the practice of neurosurgery.

The NPA looks forward to the maturation of a variety of new initiatives over the next few years. A cervical spine module will be released in 2013 and modules in cerebrovascular disease and neurooncology are in development. An "Essentials" program is being developed to create modules with abridged variable sets for use in situations where data collection resources are limited. It is likely that the Essentials platforms (being developed in multiple subspecialty areas) will be modified for potential application to programs focused on individual (as opposed to group) performance measurement, such as PQRS and maintenance of certification (see below). Support is also being coordinated for the development of research projects including comparative effectiveness trials and database integration with electronic medical records

(the latter effort being essential to facilitating the widespread implementation of practice science techniques).

Leaders of NPA and N²QOD are working with a variety of stakeholders in and outside of our specialty to develop strategies to minimize clinical data collection burdens on individual surgeons and groups. Such strategies could include extension of registry participation to programs such as PQRS, maintenance of certification, maintenance of licensure, and residency training. At a minimum, the NPA will work with the coordinators of those programs to promote the standardization of data elements and requirements among various efforts. These initiatives are consistent with the activities of other stakeholders such as the American Board of Medical Specialties, which is actively promoting clinical registry development, interoperability, and “alignment” with other data collection programs, most notably PQRS.

Defining the value of various medical interventions is a critical goal of virtually all health care stakeholders. Value analyses require cost data in the context of clinical effectiveness. Current “real-world data” on costs are largely limited to administrative databases. N²QOD’s electronic infrastructure, data flow processes, and targeted data elements have been designed with the capability to facilitate future collaboration and shared resourcing with other emerging registry efforts and existing administrative data sets. Universal patient identifiers such as social security number and date of birth are collected as a component of personal health information, allowing potential linkage to any payer or government database containing cost and resource utilization data. In this way, the NPA aims to make N²QOD a vehicle to allow payers and purchasers of care to move from cost-based to value-based analyses, through collaboration and the provision of the missing clinical numerator of the “value equation.”

The NPA understands the importance of harmonizing related data collection efforts and facilitating communication and cooperation between specialty groups that treat similar medical and surgical disorders. Such coordination will be essential to allow for valid outcome comparisons between various quality efforts and will require the development of common processes and data compatibility across specialties. The NPA aims to share its processes, methods, data definitions, and quality-control infrastructure with other physician stakeholders to encourage the development of a “common language” among various data collection efforts and facilitate the creation of a network of interconnected national registries.

Spinal disorders represent a critically important area of clinical overlap between neurosurgery and other medical specialties. At recent roundtable discussions between NPA, multiple specialty societies, and the Patient-Centered Outcomes Research Institute, hosted by the Partnership to Improve Patient Care in Washington, DC, in June 2012, interest was expressed by nonsurgical spine societies regarding current N²QOD infrastructure and early lessons learned from the initial N²QOD experience. As a result of this and other recent stakeholder interactions, a key NPA strategic objective is for neurosurgery’s N²QOD data to be compatible with orthopedic, physical medicine and rehabilitation, and interventional radiology registry data.

In addition to the development of common data languages for shared clinical activities, other mechanisms exist to facilitate cooperative quality care efforts. Over the past 3 years, the NPA has assembled and operationalized a multiorganizational process of data collection, storage, quality control, analytics, and audit-based data validation. Partnerships have been forged with proprietary owners of various outcomes instruments, coordinating centers, academic institutions, electronic tool kits, and Web designers. The resulting versatile, multifaceted N²QOD Web-portal technology can be configured to meet the needs of any specialty group, disease state, or treatment of interest. Related specialties that prefer to not develop independent registry programs could therefore choose to enter data into existing N²QOD modules consistent with their own quality objectives. Alternatively, related physician groups could modify existing modules to suit their particular needs or even use our developed tool kits to allow for the design of specialty-specific portals with a shared electronic and scientific infrastructure (for example, REDCap data collection system, compatible data sets, shared data coordinating, analytics, quality control, and reporting center).

In summary, the NPA, through its N²QOD program, is committed to facilitating cooperative multispecialty quality efforts and comparative effectiveness research initiatives to help drive a sustainable best-evidence health care system.

The Logic for a Common Program

It is likely that neurosurgeons will be presented with a variety of options with respect to practice data collection and analysis, particularly in multidiscipline areas such as spine surgery. Although no single effort can address all of our practice science needs, there are significant advantages to embracing a common specialty-based program.

First and foremost, the commitment of our neurosurgical societies to this registry ensures a sustainable and trustworthy system, fundamentally dedicated to the optimization of patient-centered care. A truly national registry that links providers, practices, and organized neurosurgery together will provide the scientific power and legitimacy we need to affect public opinion and to positively influence payers, policy makers, and hospitals. Already, major health care purchasers and payers are concentrating their attention on nationally coordinated quality and outcomes projects, particularly those that have achieved specialty-wide consensus regarding quality measures and performance standards.

At the practice level, it is imperative that we work cooperatively to promote the streamlining of data reporting and collection responsibilities. As mentioned previously, organized neurosurgery is working to adapt the N²QOD platform to help individual surgeons fulfill a variety of practice data requirements, including maintenance of certification, maintenance of licensing, PBLI, and the CMS PQRS.

The widespread adoption of a national data collection system will dramatically increase opportunities for

The National Neurosurgery Quality and Outcomes Database

practice-based education and scientific collaboration within our specialty. Comprehensive Web-based services will link all members of the N²QOD community and will soon include programs to facilitate individual learning, the sharing of clinical experience, and cooperative knowledge generation. Our infrastructure is designed to support essential multicenter trials and other cooperative clinical studies similar to NPA's first cooperative research project, NeuroPoint-SD.

Finally, by rallying around a common effort, we will be far more likely to produce the fundamental shifts in neurosurgical culture necessary to embed quality improvement in the fabric of daily practice. Simply put, all neurosurgeons need to make the development of national competence in practice science a top educational and academic priority. Already, our national societies are developing targeted support to encourage scholarship and research in outcomes research. They are encouraging our training programs to promote expertise in outcomes theory and develop leaders to advance practice science in neurosurgery and throughout medicine. The NPA has initiated development of educational programs to broadly advance knowledge in outcomes science.

Summary

The ultimate status and implementation details of the Affordable Care Act will not change the inevitable demand for an outcomes- and value-based approach to medical care. The quality and outcomes movements predate health care reform legislation, are strongly supported by both private and governmental payers, are of intense interest to the public, and are now a permanent societal fixture.

All major health care stakeholders now agree that data related to the safety, efficacy, and value of health care must inform decisions related to the use of limited health care resources. Society is increasingly concerned that we lack credible information regarding the safety and value of our procedures; and in many areas our data are, at best, incomplete. Now is the time for us to provide leadership in the emerging health care quality paradigm. Failure to act will ensure that our patients will not have access to essential therapies. Our performance will be graded solely by meaningless metrics. New technologies will go undeveloped. We must define and collect the data that justify our practices—before others collect and analyze irrelevant data for us.

Systematic, prospective data collection and self-assessment are becoming integral components of clinical practice in many medical specialties. Although some national groups have suggested universal, short-term methods to measure health care performance, meaningful clinical assessment techniques must be tailored to specific disease states and therapeutic approaches. In that regard it is essential that neurosurgeons respond to the medical needs of society with solutions that we as clinical experts devise and implement. The unique needs of our patients mandate the creation of a versatile outcomes evaluation system that is relevant to all practice settings and the wide spectrum of neurosurgical disorders. It is

particularly important that neurosurgeons have the means to assess risk-adjusted measures of the value and durability of treatment responses, understand their patients' perspectives with respect to clinical outcomes, and compare the relative effectiveness of various therapeutic interventions. Each of these capabilities has been incorporated into the design of the N²QOD effort; each creates distinctive opportunities for our specialty.

The N²QOD will allow neurosurgeons to meet the challenges of creating a sustainable health care system. Although the clinical, practical, and scientific potential of this project is tremendous, it is essential for all participating groups to realize that continuous evolution is an inherent and inescapable characteristic of any registry design. The full potential of the N²QOD—and the methods of practice science—will only be realized over time.

Our specialty is now engaged in an unprecedented cooperative effort that aims to create a new integrative culture of neurosurgical practice. Every day, evidence emerges from actual practice in favor of the imperative to improve care and shape the future of neurological surgery. Our new scientific and economic potential resides in our daily activities. If all neurosurgeons embrace elements of practice science, including national registry clinical data collection, as essential components of modern neurosurgical practice and choose to collaborate in our collective future, we will meet the challenges of creating a sustainable health care system. We will also define the relevance of neurosurgical practice within the broader realm of medicine, surgery, and modern society.

Disclosure

Dr. Selden is a member of the NPA Board of Directors and the SNS Executive Council. Dr. Asher, Dr. McCormick, and Dr. Ghogawala are members of the NPA Board of Directors. Dr. McCormick and Dr. Asher are members of the AANS Board of Directors.

Author contributions to the study and manuscript preparation include the following. Conception and design: Asher. Acquisition of data: Asher. Analysis and interpretation of data: Asher, McCormick, Ghogawala, McGirt. Drafting the article: Asher, McGirt. Critically revising the article: Asher. Reviewed submitted version of manuscript: Asher, Ghogawala, Selden. Approved the final version of the manuscript on behalf of all authors: Asher. Administrative/technical/material support: Asher. Study supervision: Asher.

Acknowledgments

The AANS, NPA, and N²QOD leadership would like to thank the numerous individuals, many of whom were mentioned here, who contributed to the design and development of practice science theory and methods, including the N²QOD, over the past several years. Their dedication is testimony to the spirit of innovation and service that sustains our remarkable specialty.

References

1. American Association of Neurological Surgeons: **National Neurosurgical Procedural Statistics, 2006 Survey**. Rolling Meadows, IL: AANS, 2008
2. Asher A, Kondziolka D, Selden NR: Addressing deficiencies in American healthcare education: a call for informed instructional design. **Neurosurgery** 65:223–230, 2009
3. Asher AL, McGirt MJ, Glassman SD, Groman R, Resnick DK, Mehrlich M, et al: Regulatory considerations for prospec-

- tive patient care registries: lessons learned from the National Neurosurgery Quality and Outcomes Database. **Neurosurg Focus** 34(1):E5, 2013
4. Committee of Quality of Health Care in America: **Crossing the Quality Chasm: A New Health System for the 21st Century**. Washington, DC: National Academy Press, 2001
5. Keenan SP, Cuckler GA, Sisko AM, Madison AJ, Smith SD, Lizonitz JM, et al: National health expenditure projections: modest annual growth until coverage expands and economic growth accelerates. **Health Aff (Millwood)** 31:1600–1612, 2012
6. Kohn LT, Corrigan J, Donalson MS (eds): **To Err is Human: Building a Safer Health System**. Washington, DC: National Academies Press, 1999
7. Linskey ME: The total quality movement: A paradigm shift in leadership and management philosophy for neurological surgery and health care in general, in Linskey ME, Rutigliano MJ (eds): **Concepts in Neurosurgery: Quality & Cost in Neurological Surgery**. Baltimore: Lippincott Williams & Wilkins, Vol 10, 2001, pp 3–31
8. McGirt MJ, Speroff T, Dittus RS, Harrell FE Jr, Asher AL: The National Neurosurgery Quality and Outcomes Database (N²QOD): general overview and pilot-year project description. **Neurosurg Focus** 34(1):E6, 2013
9. Orszag P, Ellis P: The challenge of rising health care costs—a view from the Congressional Budget Office. **N Engl J Med** 357:1793–1795, 2007
10. Patient Protection and Affordable Care Act of 2010, Pub Law 111–148, 124 Stat. 127, Sec. 6301 (March 23, 2010) (<http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>) [Accessed October 30, 2012]
11. Thorpe JH, Weiser C: Medicare Quality Measurement and Reporting Programs. **HealthReformGPS**. February 9, 2011 (<http://healthreformgps.org/resources/medicare-quality-measurement-and-reporting-programs>) [Accessed October 25, 2012]

Manuscript submitted September 18, 2012.

Accepted October 11, 2012.

Please include this information when citing this paper: DOI: 10.3171/2012.10.FOCUS12311.

Address correspondence to: Anthony L. Asher, M.D., Carolina Neurosurgery & Spine Associates, 225 Baldwin Road, Charlotte, North Carolina 28204. email: asher@cnsa.com.