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

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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.

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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 neurosurgical 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
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.\(^6\) 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.\(^1\) 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,\(^5\) 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.\(^9\)

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-
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 risks, 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.1 Most major industries have used the systematic collection of data from experience to inform total quality improvement for decades.2 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 developments.
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 reorganize 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 reconstituted 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, Crockroft, and Adelson completed their director terms, and Drs. Mitchell 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 NQOD 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 NQOD 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 NQOD 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 NQOD 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 byproduct of rich data sources such as large clinical registries. As such, it is probable that future secondary objectives of the NQOD 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.

The NQOD 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). 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 NQOD 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 NQOD activation will generate over 1 million independent data elements a year.

The infrastructure of the NQOD 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.

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. A. L. Asher et al.
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 5 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 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 participants’ 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 N’QOD 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 N’QOD, 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 N’QOD project and is detailed in another paper in this issue of Neurosurgical Focus.

The N’QOD Business Committee is currently chaired by Ms. Mary Cloninger and Mr. Todd Barnes. The committee includes business representatives from all active N’QOD sites, along with the N’QOD senior leadership and NPA administrative staff, including NPA counsel. The Business Committee is responsible for developing the business model for the N’QOD, examining alternative revenue sources to support registry activities, defining participating site definitions, and modifying contracts based on certain local regulations or state laws. The N’QOD 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 N’QOD 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 N’QOD 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 N’QOD scientific lead and principal investigator. Ms. Joan Gottesman serves as the N’QOD 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 N’QOD 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. 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 N’QOD 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 N’QOD

In brief, any practice group performing the index surgical procedures (for the lumbar module, lumbar spinal operative care) is eligible to participate in N’QOD. 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 N’QOD 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 N’QOD site’s IRB has imposed a requirement for research-related informed consent. Once the business associate and data use agreements between the
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 N’QOD as a quality-improvement charter prior to enrolling into the N’QOD program. Full details related to N’QOD participation are available for interested practices, the public, and other stakeholders on the NPA/N’QOD websites.

Once an N’QOD 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 N’QOD 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 N’QOD 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 N’QOD 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 N’QOD 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 N’QOD 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 N’QOD 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 N’QOD modules are developed.

Although the full capabilities of the registry will take time to develop, N’QOD 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. N’QOD 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 N’QOD practice sites.

N’QOD 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 N’QOD 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 N’QOD 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” N’QOD 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 neuro oncology 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 wide-
spread implementation of practice science techniques).

Leaders of NPA and N'QOD are working with a va-
riety of stakeholders in and outside of our specialty to
develop strategies to minimize clinical data collection
burdens on individual surgeons and groups. Such strate-
gies 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 stake-
holders such as the American Board of Medical Special-
ties, which is actively promoting clinical registry devel-
opment, 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 clinici-
an effectiveness. Current “real-world data” on costs are
largely limited to administrative databases. N'QOD's
electronic infrastructure, data flow processes, and target-
ed data elements have been designed with the capability
to facilitate future collaboration and shared resourcing
with other emerging registry efforts and existing ad-
ministrative 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 N'QOD 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 harmoniz-
ing related data collection efforts and facilitating commu-
nication and cooperation between specialty groups that
treat similar medical and surgical disorders. Such coordi-
nation will be essential to allow for valid outcome com-
parisons between various quality efforts and will require
the development of common processes and data com-
patibility across specialties. The NPA aims to share its
processes, methods, data definitions, and quality-control
infrastructure with other physician stakeholders to en-
courage 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 medi-
cal 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 re-
garding current N'QOD infrastructure and early lessons
learned from the initial N'QOD experience. As a result of
this and other recent stakeholder interactions, a key NPA
strategic objective is for neurosurgery’s N’QOD data to be
compatible with orthopedic, physical medicine and reha-
bilitation, and interventional radiology registry data.

In addition to the development of common data lan-
guages for shared clinical activities, other mechanisms
exist to facilitate cooperative quality care efforts. Over
the past 3 years, the NPA has assembled and operation-
ialized a multiorganizational process of data collection,
storage, quality control, analytics, and audit-based data
validation. Partnerships have been forged with propri-
etary owners of various outcomes instruments, coordi-
nating centers, academic institutions, electronic tool kits,
and Web designers. The resulting versatile, multifaceted
N’QOD 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 N’QOD modules con-
sistent 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 por-
tals with a shared electronic and scientific infrastructure
(for example, REDCap data collection system, compat-
ible data sets, shared data coordinating, analytics, quality
control, and reporting center).

In summary, the NPA, through its N’QOD 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 collec-
tion and analysis, particularly in multidiscipline areas
such as spine surgery. Although no single effort can ad-
dress all of our practice science needs, there are signifi-
cant advantages to embracing a common specialty-based
program.

First and foremost, the commitment of our neuro-
surgical 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 qual-
ity measures and performance standards.

At the practice level, it is imperative that we work co-
operatively to promote the streamlining of data reporting
and collection responsibilities. As mentioned previously,
organized neurosurgery is working to adapt the N’QOD
platform to help individual surgeons fulfill a variety of
practice data requirements, including maintenance of cer-
ficitation, maintenance of licensing, PBLI, and the CMS
PQRS.

The widespread adoption of a national data collec-
tion system will dramatically increase opportunities for
practice-based education and scientific collaboration within our specialty. Comprehensive Web-based services will link all members of the N$^2$QOD 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 N$^2$QOD effort; each creates distinctive opportunities for our specialty.

The N$^2$QOD 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 N$^2$QOD—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 neurosurgical 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 neurological 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.

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