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Ethical Considerations in Neurosurgery

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Congress of Neurological Surgeons

EDITOR'S NOTE

Ellen L. Air
2022-23 Co-Editor

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2022-23 Co-Editor

As neurosurgeons, we are tasked with the tremendous responsibility of performing complex surgical procedures and making decisions that impact the lives of our patients. With this responsibility comes the need to navigate ethical considerations. In this issue of *Congress Quarterly*, we explore some of the most pressing ethical issues in neurosurgery and how we can address them.

The articles in this issue cover various topics, from conflicts of interest to bringing new innovations bedside, to providing equitable care in the US and abroad. As healthcare providers, we must ensure that we are not influenced by any external factors that may compromise our ability to make the best decisions for our patients. Parag Patil discusses identifying and mitigating conflicts of interest to ensure our patients receive the best care possible. One dimension of conflict of interest is how the current fee-for-service model influences medical decision making. Stephen Bergin and Khoi Than examine the perverse incentives in spine surgery. They argue that the current reimbursement system incentivizes spine surgeons to perform unnecessary procedures, and suggest systemic changes to ensure surgeons are incentivized to provide optimal patient care.

Core to our work as neurosurgeons is bringing forward new therapies and surgical approaches, yet this also presents unique challenges. Francis X. Shen, et al. focus on using advanced neurotechnology and informed consent in neurosurgery. This article highlights the importance of obtaining informed consent from patients, and explores ways to ensure that patients clearly understand the risks and benefits of these new technologies.

While off-label use of drugs is relatively common, using off-label surgical procedures raises different ethical considerations. Robert Gross explores the use of off-label surgery as a means of discovery and discusses ways to balance its potential benefits with the need to protect our patients from harm.

Adnan Siddiqi and Ammad Baig examine the use of industry funding for research, as well as the potential concerns it raises about potential bias. Dr. Siddiqi discusses ways to ensure that industry funding does not compromise the integrity of our research.

Gabriel Lázaro-Muñoz, al. discuss the key takeaways from the Harvard Medical School Center for Bioethics Neurotech Justice Summit. This article highlights the importance of addressing issues of equity and justice in developing and using new neurotechnologies. Mark Pacult and Michael Lawton discuss how insurance companies affect access to care through prior authorization and narrow coverage networks. As healthcare providers, we must ensure that our patients have access to the care they need, regardless of their insurance coverage. The authors suggest ways to advocate for our patients and work with insurance companies to ensure that our patients receive the best care possible.

Gail Rosseau examines the ethical considerations and challenges of medical service trips in global neurosurgery, which can provide much-needed care to underserved populations but also raise concerns about cultural sensitivity, sustainability, and the potential for harm. The author suggests ways to approach medical service trips thoughtfully and ethically.

Finally, Hussam Abou-Al-Shaar, and Douglas Kondziolka, examine research integrity in neurosurgery. Research is an integral part of advancing the field of neurosurgery, and the authors emphasize the importance of adhering to ethical standards in research and ensuring that research is conducted with integrity and transparency. We hope you find this issue thought-provoking and informative.

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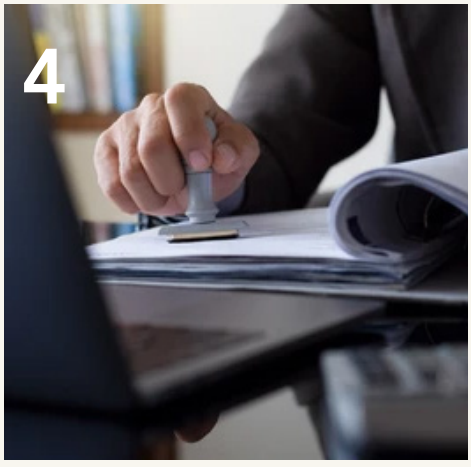

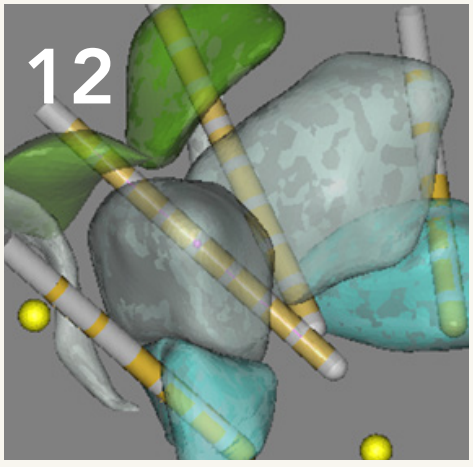

PRESIDENT'S MESSAGE

Elad I. Levy, MD, MBA
President, Congress of
Neurological Surgeons

In concert with our neurosurgical colleagues around the world, we are formulating approaches to the new professional challenges we face in this still uncharted post-pandemic world. While we strive to improve treatment for life-altering neurological conditions, we must also be sharply attuned to their harmonious interface with global ethical codes of conduct, yet to be composed. The difficult decisions each of us struggles with during a complicated case are exacerbated by the imperative of balancing surgical choices with ethical concerns. This issue of *Congress Quarterly* explores diverse ethical dilemmas and considerations of our specialty.

As we work to bring the most practical and relevant educational content to our members, the CNS is committed to helping our members address critical ethical topics impacting their practice. The CNS endeavors to be a resource for disseminating the best ethical practices for neurosurgical education and comportment. These efforts focus educating trainees on surgical indications, promoting equitable health care access through the CNS DEI committee, transparency with industry partnerships, and proposing our best treatment approaches through the CNS Guidelines initiatives.

Congratulations to Drs. Ellen Air and Clemens Schirmer for curating this critically important issue of *Congress Quarterly*. I hope you will find it as instructive as I did, and that you will utilize this issue as a springboard for further consequential dialogue. I also invite you to join us for the CNS Leadership Institute programs, our complications courses, and our other noteworthy programs, where we address prominent ethical questions through small group discussions, contemporary research, and foundational case studies.

I am especially looking forward to welcoming you to Washington DC this fall for our 2023 CNS Annual Meeting, themed ***Imagine, Innovate, and Inspire***. Our scientific program focuses on timely topics critical to leading researchers and clinicians, and our engaging list of keynote presenters are sure to stimulate you to ***Imagine, Innovate, and Inspire***.

As always, I welcome your comments and suggestions on these topics as well as others impacting your neurosurgical practice. Your ideas and thoughtful suggestions help calibrate the CNS to best assist you in navigating practice challenges, while maintaining acute focus on patient care. I encourage you to share your feedback at any time by contacting the CNS Headquarters office, or reaching out to one of the officers.

In conclusion, it is my hope that you find this issue of *Congress Quarterly* both informative and enjoyable.

Sincerely,

Elad I. Levy, MD, MBA

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Parag G. Patil, MD PhD

Conflicts of Interest in the Complex Health Care Environment

Conflicts of interest (COI) are a major concern in neurosurgery, especially in today's complex and high-stakes health care environment. Though the traditional focus has been on the financial conflicts of individual practitioners directly engaged in patient care, the COI landscape is far more nuanced. The asymmetry in power dynamics between neurosurgeons and the institutions that employ them, the purchases of medical practices and insurance companies by tech and drugstore giants, and large insurance conglomerates' involvement in the supply of patient-care data to researchers all represent complex situations where the potential for COI may significantly impact quality and access to medical care.

As a broad definition, COI potentially arises whenever health care professionals, organizations, or other entities have competing interests that could interfere with the ability to make or to execute unbiased patient-care decisions. While COI can arise in any situation in which competing interests, loyalties, or obligations are possible, the challenges of such conflicts in the health care context are particularly acute. Hidden or unmanaged conflicts lead to ethical and legal issues, damage public trust, diminish access to novel therapies, and negatively impact patient care. This article discusses multiple forms of conflict of interest arising at individual and institutional levels, as well as traditional means to mitigate the adverse impact of these potential conflicts. The goal here is to highlight, for the neurosurgical community, ways in which traditional thinking about COI may fail to capture the vast and largely hidden landscape of potential conflict that exists all around us.

Financial Conflicts of Individual Providers

The traditional focus of COI policy is financial. Financial COI potentially occur when individual financial interests influence clinical or research decisions. For example, a neurosurgeon who has a financial stake in a medical device company may improperly favor or recommend the use of that company's products over similarly effective but competing alternatives. This traditional narrative carries several implicit (though potentially valid) underlying assumptions. In some instances, however, these assumptions presume wrongdoing where there is none, thereby falsely impugning the professionalism and integrity of the practitioner. Some commonly held assumptions are:

- **The patient is vulnerable.** There is little doubt that, outside of exceptional circumstances, the provider holds a position of power and influence over the patient. Patients may not be able to critically evaluate their provider's recommendations or seek alternative providers in a timely fashion. The existence of such vulnerability, however, by no means implies a provider's willingness to exploit it.
- **Private financial interests interfere with professional responsibilities.** A prima facie assumption of the example above is that the industry relationship will cause the neurosurgeon to detrimentally select one product over another for the patient. But what if the neurosurgeon has partnered with that company precisely due to the superiority of its products and a mission-driven professional desire to move the field forward? For myriad reasons, one must not proceed under an assumption that all financial conflicts are harmful or unethical.
- **Decisions based on private financial interests are detrimental to patients.** This may seem self-evident; however, most institutions reward neurosurgeons financially based on clinical productivity. Providers regularly, but not always, resist a strong incentive to provide unhelpful surgical care over more conservative therapies. Institutional conditions of employment are rarely disclosed to patients, even though productivity-based incentives often far outweigh any potential industry-to-physician enticements.

To mitigate the potentially adverse effects of financial conflict, institutions commonly adopt broad disclosure requirements. Universities, private health care corporations, and government agencies routinely require disclosures of potential financial COI. The *Physician Payments Sunshine Act of 2010* and the *Open Payments Program* websites further provide unprecedented access to information on industry-based payments to physicians. Such information allows comparison among practitioners and documents the identities of drug and medical device companies that provide funding to a named provider. However, again, the existence of a financial relationship does not imply professional impropriety. The reality is far more nuanced.

Other Forms of Potential Conflict Among Individual Providers

Financial COI are far from the only conflicts that potentially affect physician judgements and actions:

- **Personal Conflicts of Interest:** Personal COI can arise when a medical professional's personal relationship with a patient or

another individual interferes with their professional judgment. For example, a doctor treating a friend may feel compelled to prescribe a treatment they would not normally prescribe in the absence of the personal relationship.

- **Intellectual Conflicts of Interest:** Intellectual COI occur when a medical professional has a stake in a particular intellectual viewpoint, research area or treatment. For example, an expert in tumor vaccines may experience unrecognized confirmation bias and favor treatments employing similar strategies.
- **Conflicts of Loyalty:** Conflicts of loyalty arise when a medical professional has conflicting obligations to multiple parties, such as a patient and an employer. For example, a doctor who is employed by one university may feel pressure to refer internally, despite greater confidence in a provider at an outside facility.
- **Conflicts of Responsibility:** Conflicts of responsibility occur when a medical professional has conflicting responsibilities to multiple patients or stakeholders. For example, a doctor who has limited access to the operating room may be "encouraged" by an employer to prioritize a "VIP" patient over another patient, leading to an ethical dilemma.

Neurosurgeons in practice experience such hidden, non-financial conflicts on a regular basis. Ultimately, the management of such unstated and unrecognized conflicts relies upon self-awareness, personal and professional ethics, and a willingness to act (or not to act) on principle. Such hidden conflicts may be potent, and when choosing to act in a patient's interests over an employer's, may carry heavy retributive consequences for the provider.

Conflict of Interest Disclosure and Mitigation

In the best-case scenario, COI would be managed under conditions of transparency, with governance by clear and comprehensive policies and procedures. Education of patients and providers would ensure that policies were understood, and full compliance was achieved. Several factors make this optimal scenario unlikely in today's complex health care environment.

Health care institutions author policies defining and enforcing COI practices for their employees. However, since conflict of interest is conceptually difficult to define, policy-based management is challenging. Policies often seek to regulate not only clear COI, where detrimental action has been taken, but also "potential" conflicts where the likelihood of a negative outcome is less clear. Some policies go further to include "possible" conflicts that exist "either in actuality or in appearance." The challenges of determining the threshold of possibility or of defining conflict in terms of "appearance" begs the question of the identity of the observer or the means to define or to verify an apparent conflict. Furthermore, when the scope of the policy, includes outcomes such as potential impacts on judgement (which appear identical to judgement errors), bias (which may appear the same as an unbiased shift in direction), or undefined "matters of interest" to the institution, challenges arise. Often, institutions define potential COI in a manner that allows the institution maximal flexibility and power over employed providers, while circumventing institutional scrutiny.

While some health care organizations may establish so-called "independent" oversight committees to review and to mitigate potential conflicts of interest, such committees are rarely truly independent, as committee members are selected by and often employed by the institution. Hence, in certain institutions an influential employee, such as the CEO, may be allowed greater license to maintain financial or other conflicts than rank-and-file providers.

Institutional Conflicts of Interest

Conflicts of interest also manifest at an institutional level. Here neurosurgeons and perhaps the entire field of neurosurgery may occupy a relatively vulnerable position, like patients. Health care institutions have vast financial resources, broad legal expertise, and extensive organizational support. Neurosurgeons may be pressured to take on more patients than they can reasonably handle, leading to burnout, stress, and reduced quality of care. Health care institutions may also use their power to limit the autonomy of individual practitioners through restrictive employment contracts and policies that limit practitioners' willingness to speak out on issues of patient safety or institutional misconduct for fear of repercussions. In extreme situations, the power imbalance between doctors and health care institutions may result in bullying, harassment, and discrimination. Doctors who speak out or challenge institutional policies may face retaliation or be ostracized from their workplace. In the commercial realm, health care institutions may prioritize profit over patient care, requiring providers to choose between offering what they see as the best care for each patient or meeting the goals of the institution that employs them. Just as individual neurosurgeons are held accountable to patients through COI policies, there is growing awareness that institutions must similarly be held accountable to providers and patients.

In conclusion, in today's complex health care environment, the commercial conflicts of individual providers represent only the most visible danger in a minefield that is traversed with most every patient encounter. As institutions capture greater influence in the doctor-patient relationship, it is critical that we scrutinize not only our own conflicts but also those that exist in the broader ecosystem of Neurosurgery.

Ian Stevens Ilona Cenolli, MBE Robert J. Kim Jasmine A. Kwasa, PhD

Advanced Neurotechnology and Informed Consent in Neurosurgery: Ethical and Legal Perspectives

The Challenge of Informed Consent in Neurosurgery

Obtaining informed consent is a legal and ethical requirement for all neurosurgical procedures. At the heart of informed consent is a "meeting of the minds" between the neurosurgeon and patient.[1] As surgical procedures and consent discussions have become more complex, there is a concern that this added complexity will reduce patient comprehension of the information being communicated. For example, when patients scheduled for deep brain stimulation (DBS) device implantation were interviewed, they reported a lack of retention and comprehension of the procedure despite the utilization of properly trained research coordinators relying on a standardized protocol.[2] These findings are consistent with earlier studies showing participants' difficulty recollecting discussions about post-trial care in experimental DBS trials.[3]

The challenge of informed consent is likely to become even more complex with the advent of advanced neurotechnologies that may utilize artificial intelligence (AI), such as Responsive Neurostimulation (RNS) for treatment-resistant epilepsy.[4] When advanced neurotechnology enter the clinic, it will remain the neurosurgeon's ethical and legal responsibility to communicate effectively with patients about the advanced neurotech device and the procedure to implant it.[5]

Legal and Ethical Foundations

United States courts have long recognized a patient's right to self-determination.[6] In a landmark 1914 case, Judge Cardozo held that "[e]very human being of adult years and sound mind has a right to determine what shall be done with [their] own body..."[7] Healthcare providers can be exposed to liability if they withhold information pertinent to the patient making an educated and informed choice.[5] This legal liability is typically grounded in the tort claims of battery and negligence. Ethically, an obligation for informed consent is founded in the principle of respect for autonomy.[8] The Congress of Neurological Surgeons Code of Ethics includes this principle of "respect for autonomy,"[9] and it is a core biomedical ethics principle as well. At a minimum, an ethical informed consent process should include discussion of the diagnosis, the surgical treatment along with its risks and benefits, as well as the alternative options, including doing nothing.[8]

While there is agreement that promoting patient autonomy by obtaining meaningful informed consent is necessary, there is significant confusion about what is legally required. While variances exist between jurisdictions, generally there are three legal standards used in the U.S., and these standards vary in the type and level of information that must be provided to the patient. These standards are: (1) what a reasonable physician would provide; (2) what a reasonable person would want to hear; and (3) the subjective standard test: what this particular patient would need to understand in order to make an educated decision.[8] In more than half of the U.S. the reasonable physician standard is used, but there is significant variation because these standards leave room for interpretation and may differ between jurisdictions applying them.[5,6] For instance, a patient's preferred level of understanding before proceeding with a procedure can depend on their values.[8] Neurosurgeons should be sensitive to the reality that what a patient desires from the consent process will depend on the patient's cultural background, preferred learning modality, and level of trust in the medical establishment. In particular, trust in the medical establishment may be eroded in marginalized populations and communities of color.[10,11]

Additional guidance and requirements from the Federal Policy for the Protection of Human Subjects (the "Common Rule") are applicable if the neurosurgery is part of research that is federally funded, federally conducted, or conducted by an institution that renders a broad Federalwide Assurance (45 C.F.R. Part 46).[12,13] Food and Drug Administration (FDA) informed consent requirements (21 C.F.R. § 50.20) may also be applicable. The Common Rule states that the informed consent process "must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized


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representative's understanding of the reasons why one might or might not want to participate."[13]

Informed Consent and Liability with Procedures Involving Advanced Neurotechnologies

Where informed consent does not conform to legal requirements, a remedy available to patients is a medical malpractice suit. Neurosurgeons are familiar with this possibility, as neurosurgery is a specialty that is among the most likely to be a defendant in medical malpractice suits.[14] Informed consent is not infrequently one of the pillars of a neurosurgery malpractice claim. A recent review found that in neurosurgery malpractice litigation, informed consent is raised in 8% to 43% of the cases.[15] When informed consent is litigated, at issue will be the duty to disclose all risks and alternatives, and whether a breach of this duty to disclose caused the harm.[6]

The ever-growing complexity of neurotechnologies with semi-autonomous functionalities, like RNS, will make it more difficult for a neurosurgeon to (1) fully understand the technology, and then (2) effectively communicate "all risks" of the implanted device during the informed consent process.

Fully understanding how new therapeutic and diagnostic neurotechnologies work is not necessarily in the purview of the neurosurgeons implanting them. While neurosurgeons will surely have a high level of familiarity with the devices, given the intricate engineering required for device fabrication "[n]o single neurosurgeon can master all these domains, as talented as [they] may be."[16] Yet the key defendant in malpractice claims will often be the neurosurgeon,[5,17] and there will be a need to become familiar with issues such as potential algorithmic bias and data privacy related to the implantable device.

Given the coming advances in implantable neurotechnologies that utilize AI, especially those with "black box" algorithms whose underlying mechanisms are poorly understood, we see a need for revisiting the standard of care as it relates to informed consent. Prior legal scholarship in AI shares these medical liability concerns and highlights the asymmetry in information between what we want a patient to know and what we can actually tell the patient due to an algorithm's "dynamic inscrutability."[18]

One additional possibility would be to consider an expansion of products liability claims in this space. In general, the warning defect doctrine holds that the distributor of a product remains liable for a party's injuries if the purchaser is not adequately warned about the product's risks.[6] Scrutiny could be given to the warnings provided to the surgical team by the manufacturer. Other alternative frameworks are possible, as is improving training for providers on the complexities of these technologies.[17]

Toward New Standards for New Technologies

Legal standards strike a balance between respecting the patient's autonomy to make an educated decision about a procedure, and recognizing that neurosurgeons cannot and should not be required to share with patients every detail of a complicated procedure and technology. Legal standards have shifted in the past, and they will need to be revised again in light of new neurotechnologies on the horizon.

Now is the time to begin a dialogue with a diverse range of stakeholders, including patients, community members, device manufacturers, neurosurgeons, insurers, and regulatory authorities along with neuroethics and neurolaw experts.[19] Central to the success of this collaborative process will be the inclusion of individuals at the historical margins of society due to their race, language, religion, and other identifiers. These patients' providers may leave them misinformed disproportionately, whether intentionally or not, and they may face other biases embedded in the neurotechnologies themselves.[10,11]

Meeting of the minds in informed consent requires a joint effort by neurosurgeons and patients. The process for defining informed consent standards in the wake of advancing neurotechnologies should similarly be grounded in deep and lasting engagement between clinicians, patients, researchers, and manufacturers.[20,21]

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Mark A. Pacult, MD

Michael T. Lawton, MD

How Insurance Companies Affect Access to Care through Prior Authorization and Narrow Networks of Coverage

As early as one hundred years ago, the cost of medical care was largely the responsibility of the patient. Physicians, commonly applying a sliding scale fee system, were bound by ethical and fiduciary duties to the patient, though few regulations existed to define the scope of medical care. The rise of third-party insurance, which began formally in this country during the Great Depression, fundamentally altered this relationship. Insurance companies have utilized tools such as prior authorization and the limiting of physician networks throughout history to mitigate risk and reduce costs. Delineating the historical roots of these mechanisms paves the way for a deeper understanding of how decisions about medical care are influenced and constrained by third party insurers and how physicians will contend with these challenges in the years to come.

Historical Background

Early forms of third-party insurance were primarily employer-offered during the latter years of the Industrial Revolution; the manufacturing sector was necessarily interested in the physical health of its employees and frequently offered subscription-based health insurance which covered anything from funeral costs to sick days.[2] The employer-based definition of group was solidified after World War II when, competing in a thinned labor pool, employers began subsidizing health benefits as recruitment enticements.[3] Hospitals, too, began underwriting insurance during these early years. During the Great Depression, when many hospitals saw declining revenues due to shrinking incomes, they began offering prospective subscription services as means to raise dependable revenue streams. This was the well-known origin of the Blue Cross insurance company.[1]

Physicians combated these trends for various reasons. In general, organized physician groups opposed initial subscription-based health plans as either restrictive to patient choice and thus bad for business, or else as limiting their autonomy to provide medical care.[2] In response to hospital-offered insurance, which frequently restricted patient care to the offering hospital, physicians in California formed the California Physicians' Service, a precursor to the eventual Blue Shield.[3] State and local medical societies frequently expelled physicians who went to work for employers and in-house physicians; their opposition was grounded in both ethics and economics: such plans limited patient choice, but they also threatened the existing sliding-scale fee service that many independent physicians used at the time.[2, 3]

These newly-formed third-party payors faced two accepted challenges specific to the insurance industry which persist in today's environment; these challenges pre-empted the use of cost-controlling measures such as prior authorization and limited networks. These mechanisms evolved as direct responses to mitigate two types of risk inherent in insuring against health events that are important to understand from a physician's perspective.

Moral Hazard

The first is what is defined as moral hazard, which refers to the risk a party assumes by depending on the moral (or healthy) behavior of the other party. Depending on such behavior is itself risky due to the tendency of individuals to behave recklessly if losses are covered by insurance. For example, an individual may be more prone to drive a sports car recklessly with the knowledge that it is insured, just as an individual may be more prone to utilize healthcare resources with the knowledge that he or she is insured.

Prior authorization emerged as one way third-party payors can mitigate the risk associated with moral hazard. Its earliest forms were retroactive, and they took many guises. In the 19th century, sickness funds, which were voluntary contributions made by industrial workers to emergency funds, were regulated through visits of fellow fund members and delayed disbursal.[3] As early as the 1960s, Blue Cross plans had programs to determine whether hospital stays were medically necessary and whether length of stay was appropriate for certain conditions. Early forms of surgical second opinion review programs also emerged during this time.[1]

The entry of government into the health insurance space in the 1960s with the creation of Medicare and Medicaid honed the blade of utilization review. With the expansion of healthcare insurance to groups not typically covered under private, employer-based schemes, a supply and demand mismatch ensued, leading to rising costs and enormous healthcare consumption on the part of this newly

insured class of Americans. Various forms of review were codified around this time, the most well-known being the establishment of "professional standards review organizations" (PSROs).[1]

In its current-day form, prior authorization necessitates enormous resources on the part of physician practices and undoubtedly affects patient access to care. While over 80% of neurosurgery services are approved after prior authorization, 82% of neurosurgeons report that the process causes patients to abandon treatments at least sometimes.[4] Although data from a health insurance trade organization reports that 98% of prior authorization is intended to "promote evidence-based care" and that 100% of prior authorization programs incorporate "peer-reviewed evidence-based studies," surveys of physicians indicate that 30% of prior authorization criteria are "rarely" evidence-based.[5, 6] Such reviews are frequently performed by physicians or assistants outside of the specialty in question who lack specific knowledge about why a physician might order a particular test or procedure. Furthermore, a recent report found that Medicare advantage plans frequently deny care that should be covered under standard Medicare rules by utilizing their own opaque clinical criteria.[13]

Adverse Selection

Adverse selection is another risk that insurance companies must mitigate. This concept refers to the fact that sicker people are more likely to purchase health insurance than healthy people. For example, a plan offering comprehensive coverage for a premium of $X may be a bargain for certain individuals with high health needs, but the premium may exceed the health expenditures of a healthier individual. Such plans may be filled with sicker enrollees, thus skewing economies for insurers. As a result, insurance companies have devised mechanisms such as narrowing coverage networks to protect against the risks of adverse selection that undoubtedly affect patient access to care.

A narrow network is a limited group of providers and facilities that a patient may utilize under a certain plan. Such plans lower costs to insurers for three main reasons: first, they are comprised of individuals who may have lower health needs, second, they are able to negotiate lower prices with providers as a result, and third, they are able to select lower-cost providers or hospitals as part of the plan over higher-cost facilities. Studies show that the bulk of savings from such plans comes from decreased healthcare resource utilization on the part of enrollees of such plans.[7]

The impact of narrow networks on access to neurosurgical care has been examined in several geographic areas. In Arizona, for example, one study found that, despite containing neurosurgical facilities, 9 of 10 counties do not have in-network neurosurgeons listed as covered under a plan.[8] A similar examination in the state of Louisiana found a high proportion of neurosurgeon-deficient plans in populous counties (despite those counties having practicing neurosurgeons).[9] As the authors of this last study discuss, the ideal scenario of such plans is when enrollees do not require healthcare, insurers do not have to disburse payments, and providers provide care to only those covered under a plan. However, an unintended consequence, particularly relevant in neurosurgery (where need for care is unpredictable and urgent), occurs when an individual is out of network. In such cases, the individual may either pay higher costs to see an out of network provider or seek care in an emergency room. Although studying these utilization trends may be an area for new research, early data in specialties such as ophthalmology indicates that emergency room utilization actually increased following passage of the ACA.[10] Recently passed federal legislation, the "No Surprises Act," limits patient contribution to out of network medical bills and may harbinger push-back on the part of insurance companies on out-of-network medical costs.

Conclusion

Reform efforts in these arenas are not novel; rather, they exist within a continuum of historical tension between physicians, insurance agencies, and hospital systems. Modern reform efforts, including CMS proposals, focus on streamlining prior authorization in electronic format and eliminating delays in responses. Reform of network adequacy is largely dictated by states, and few national standards exist.[11] CMS has proposed time and distance maximums for enrollees on federally-managed health exchanges for each specialty beginning in 2023. For example, for neurosurgery, in a large metro county, enrollees would be guaranteed to have in-network access to a neurosurgeon within 30 minutes of travel time or 15 miles.[12] However, standards for other metrics, such as minimum provider-to-enrollee number, do not currently exist for the federal marketplace.

Organized neurosurgery and physician's advocacy groups are critical in contending with these roadblocks to care. Opportunities for reform specific to neurosurgery exist beyond streamlining the submission process, namely: requiring transparency in both the clinical criteria used for prior authorization cases and the rationale for denials, requiring that reviews be adjudicated by providers within the questioned specialty, and enabling objective oversight of criteria and rationale used for such decisions. Neurosurgeons must continue to ask research questions that examine the ethics and economics of such policies and their impact on quality of, access to, and cost of care. Focusing the research light on such topics may reaffirm how dire the need for reform truly is and reveal new ways forward.

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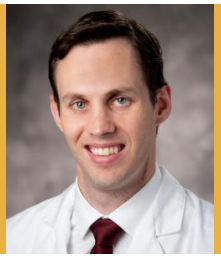

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Perverse Incentives in Spine Surgery

It is a complex and evolving challenge to perfectly align financial incentives with optimal patient care. A perverse incentive is an incentive that results in unintended and undesirable results contrary to the intentions of the incentive. This perspective highlights perverse incentives within spinal care that can arise within the relative value unit (RVU)-based payment system.

Despite the movement toward value-based care with alternative payment models, the fee-for-service (FFS) RVU-based method remains a dominant payment method for many spine surgeons.[1] The value of the RVU is meant to reflect the complexity and training required to perform the service. Despite this goal, several studies have shown that the RVU does not proportionally compensate spinal surgeons for the added time, effort, and skill for more complex operations.[2] The perverse incentive of the FFS RVU is that the volume-based incentive can inappropriately incentivize surgeons to choose higher-billing or unnecessary surgeries. One of the more prominent examples of spine surgery coming under scrutiny for perverse incentives is the role of fusion in symptomatic lumbar degeneration.

From 1990 to 2001, there was a 220% increase in the number of lumbar fusion surgeries performed.[3,4] Many articles, both in popular press and spine-specific journals, highlighted the increase in lumbar fusion over simpler decompression surgeries, with the claim that many fusion surgeries were inappropriately performed for the financial benefit of the physician.[5] However, other publications challenged the assertion that spine surgeons have an undue financial incentive to recommend a combined decompression and instrumented fusion procedure over an isolated decompression, especially when considering the greater time, effort, and risk characteristic of the more complex fusion operation.[6]

In addition to influencing the type of spine surgery selected, the RVU-based system influences the selection of spinal grafts. For instance, during an anterior cervical discectomy and fusion (ACDF) surgery a structural autograft, structural allograft, or a synthetic cage may be used to promote fusion across the disc space, but each pays the surgeon a different rate assigned through the work RVU (wRVU). To illustrate, as of 2022 the CPT code for a synthetic interbody cage (22853) has a significantly higher reimbursement rate than that for a structural allograft (20931), with a wRVU of 4.25 versus 1.81, respectively, even though there is no added work to using one over the other. This economic incentive is compounded when a multi-level procedure is done, as the structural allograft can only be coded once per surgery whereas each individual synthetic cage can be coded for each level. Therefore, in a three-level ACDF, the difference in wRVUs is approximately 12.

Polyetheretherketone (PEEK)-based interbodies are among the most commonly used synthetic interbodies[7], despite studies calling into question the efficacy of PEEK-based arthrodesis for ACDFs over structural allograft.[8, 9] PEEK-based interbodies are also more expensive than structural allograft. One group found that the average cost of an ACDF with a PEEK cage was $18,314 compared to $12,539 when structural allograft was used.[10] A cost-effectiveness study that looked at cost per quality adjusted life year (QALY)—where the lower the cost/QALY, the more cost-effective the intervention—found that the cost/QALY of ACDFs done with PEEK was $3,220 compared to $2,358 for structural allograft.[10] Taking into consideration that the ACDF procedure one of the most common procedures performed by neurosurgeons and orthopedic spine surgeons, this example illustrates an important perverse incentive within spinal surgery that impacts surgeon decision-making and patient care.

The high RVU for spinal operations has also attracted non-spine surgeons to perform procedures on the spine. A number of non-surgeon clinicians—including interventional radiologists, anesthesiologists, and physiatrists—now perform minimally invasive arthrodesis procedures that alter the biomechanics of the spine. One such therapy is the interspinous process fixation device which, despite initial promotion as safe and effective, now has more long-term data suggesting less impressive clinical results and a higher rate of failure than initially reported.[11] This raises concerns about patient safety and quality of care, as these non-surgeon clinicians are not required to undergo training in spinal biomechanics or in the broad spectrum of spinal fusion and instrumentation techniques.[12] In response, nine major neurosurgical and orthopedic societies unanimously endorsed a position statement in 2021 recommending "arthrodesis or any other intervention that alters the biomechanics of the spine should not be performed by practitioners in other

fields outside of specialty-trained neurosurgery or orthopedic spinal surgeons."[12] Future legal changes may attempt to curb this practice of arthrodesis by non-surgeons. For instance, in 2022 the state of Louisiana proposed a bill, HB941, which "provides requirements and limitations to certain procedures performed on the spine, specifically that no physician shall perform or bill for a decompression, fusion, or instrumentation procedure on the lumbar, thoracic, or cervical spine unless he is credentialed as an orthopedic surgeon or neurosurgeon at facility at which he performs the procedure."[13]

Despite these actions, however, the perverse incentive for physicians and non-physician providers to perform unnecessary spinal procedures will likely persist in the FFS RVU-based system. Capitation and bundled payment systems are among several value-based, alternative payment methods proposed to replace the RVU system, and a common belief is value-based payment methods will control costs and improve patient care. However, these systems also contain perverse incentives for providers.[14] For instance, while value-based systems reduce incentives to deliver care of unproven value, these systems do not by themselves create incentives for the delivery of care of proven value. Further, within a value-based system, unintended consequences include causing physicians to avoid certain patients (including the very sick, the poor, or the uneducated) who can lower their scores on the value-based outcome measurements. Additionally, surgeons who are motivated to achieve target rates for health care interventions may discount their own clinical judgement or patient preference, resulting in inappropriate treatment for patients.[15] Reimbursement penalties from the Centers for Medicare & Medicaid Services Physician Quality Reporting System (CMS PQRS) were implemented in 2018, and performance measurements for quality will continue to become more widespread. Spine surgeons should be involved with professional surgical societies to prioritize developing appropriate quality measures and reporting systems that minimize the impact of perverse incentives on patient care.

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Robert E. Gross, MD, PhD

Off-label Surgery as a Means of Discovery

I often perform off-label surgery and I always discover something as a result. I discover first and foremost, whether it helped the patient, but discover new knowledge in the process. I will here build the ethical case for the use of data derived from off-label uses of approved devices, procedures, or drugs for discovery of new knowledge.

Under the principles of beneficence, nonmaleficence, respect for autonomy, and justice, all research with human subjects requires approval from an Institutional Review Board (IRB). We tacitly assume this to include all experiments performed involving patients, but does it? Is there ever a justification to perform an experiment with a patient that is not subsumed under the rubric of human research?

The New Oxford American dictionary defines *experiment* as:

- a scientific procedure undertaken to make a discovery, test a hypothesis, or demonstrate a known fact: I have tested this by *experiment* | *laboratory* ***experiments*** *on guinea pigs.*

It would clearly be unethical to subject a patient to a scientific procedure defined as such, without their signing an IRB-approved consent form for participation in research. But the definition goes on to include the following:

- a course of action tentatively adopted without being sure of the outcome: the farm is an ongoing experiment in sustainable living.

Whenever we as surgeons perform a surgery, we are in fact performing an experiment, according to that definition, in that we can't predict the outcome to a complete degree of certainty.

Thus, in a real sense all of our actions are small experiments, even when approved by regulatory bodies. Is it "discovery" when we learn something from seemingly idiosyncratic results of standard-of-care actions? When this happens, we label the patient "interesting." Put enough interesting patients together—perhaps write up a series—and the answer is yes. It is easy to agree that discovery of this sort, approved retrospectively by an IRB, is ethical.

> I have long said that worse than being a patient is being an "interesting" patient, and the only thing worse than that is being an "instructive" patient. Our patients rarely want to be in the position of teaching us doctors something we did not already know!

In the field of epilepsy surgery, when planning an intracranial monitoring surgery, we go so far as to frame hypotheses of where we think the epileptogenic zone could be prior to performing the stereo-EEG "experiment". The surgery is, in deed and in fact, an experiment, as we certainly "are not sure of the outcome."

The aforementioned describes experimentation in the course of approved practice. Occasionally, however, when deciding on the best therapeutic approach to a particular patient, we determine that going beyond "approved" practice, as determined by RCTs and/or standard-of-care practices, has the highest benefit-to-risk ratio for that patient. The autonomy to make such decisions is granted to us by the system in which we practice if they are ultimately defensible. Some patients' needs fall outside the "standard of care", a normalized approach to treatment that covers most patients--but not all. These are instances in which the outcomes of our actions are less predictable, due to sparse pretest data, than those that have been subjected to higher degrees of a *priori* experimentation. However, they do in fact fall on the continuum of legitimate physicians' and surgeons' actions. Like any therapeutic (or diagnostic) decision, they come with a degree of uncertainty and thus fulfill the definition of an experiment.

Given the spare data set informing results of off-label therapeutics, we are significantly more likely to learn something by observing the results. The motivation to perform the surgery is, first and foremost, to treat the patient. Still, we "discover" new knowledge from the result. These patients, go beyond being interesting to become 'instructive.' With that discovery in hand, we may well seek—indeed are obligated—to disseminate this new knowledge through publication. We may even put together a retrospective series of similar patients, all of whose surgeries were motivated to provide the best benefit-to-risk ratio of available options. A series of discoveries is more useful and reliable than a single one, albeit less than a larger, prospective, controlled series. It is ethical discovery nevertheless and often the best we can do. It is hardly feasible to carry out a prospective randomized double blind controlled trial on all potential surgical interventions. Thus, we are always operating (pun intended) with "sparse knowledge." Making the best imputation from what we know in the service of our patients is ethical; not to do so would be unethical. Discovery of new knowledge as the result of this individualized off-label experimentation is, therefore, ethical. To forgo something that might help, even in the absence of high pretest probability just because it may result in discovery of new knowledge is unethical.

Case illustrations from my own practice:

- **Deep brain stimulation for Tourette Syndrome.** We have done several DBSs for Tourette Syndrome over the years, off-label in terms of indication as well as, in some cases, target (centromedian nucleus). I recently replaced the neurostimulator of one of our patients whose life was altered by the implantation of bilateral globus pallidus and centromedian nucleus leads. This and other patients were contributed to a registry that was recently published reporting the results of off-label treatment in 185 patients.[1]
- **Deep brain stimulation for generalized epilepsies.** DBS of the anterior nucleus of thalamus (ANT) was approved in 2018 for the treatment of drug-resistant focal seizures,[2] but a large remaining unmet need is the treatment of generalized epilepsies. Published series dating to 1987 support the effectiveness of a different target—centromedian nucleus; neither the indication nor the target is FDA-approved. To address this unmet need we have been performing off-label CM DBS for generalized epilepsies since 2018 on a case-by-case basis and collected the retrospective data into a recently published paper, including analyzing the location/outcome relationship.[3]
- **Novel targets for brain stimulation for epilepsy.** Patients with ostensibly non-limbic focal epilepsy may be less likely to respond to ANT DBS. For that reason, we (and others) have been intrigued by novel targets that may better engage those epileptic networks, such as pulvinar for posterior quadrant epilepsies and mediodorsal nucleus for motor epilepsies.[4] However, since ANT is approved for focal epilepsy and not known to be ineffective for those circuits, and since the effectiveness of novel targets is not yet known, in five patients we have implanted both bilateral ANT and novel targets, using a new 4-channel neurostimulator device which is not formally approved for epilepsy indications (**Figure 1**). This allows for both the standard-of-care approach and a novel and exploratory one, on a case-by-case basis, based on the patient's epileptic network as defined during stereoEEG intracranial monitoring (Yang et al., submitted). Interestingly, while pulvinar is not FDA approved as a target for DBS, which is only approved for ANT, it is covered within the indications for use for responsive neurostimulation (RNS, Neuropace) which includes thalamus not-otherwise-specified, even though there were no pulvinar or indeed thalamic implanted leads in the pivotal pre-market approval RCT for RNS.[5]

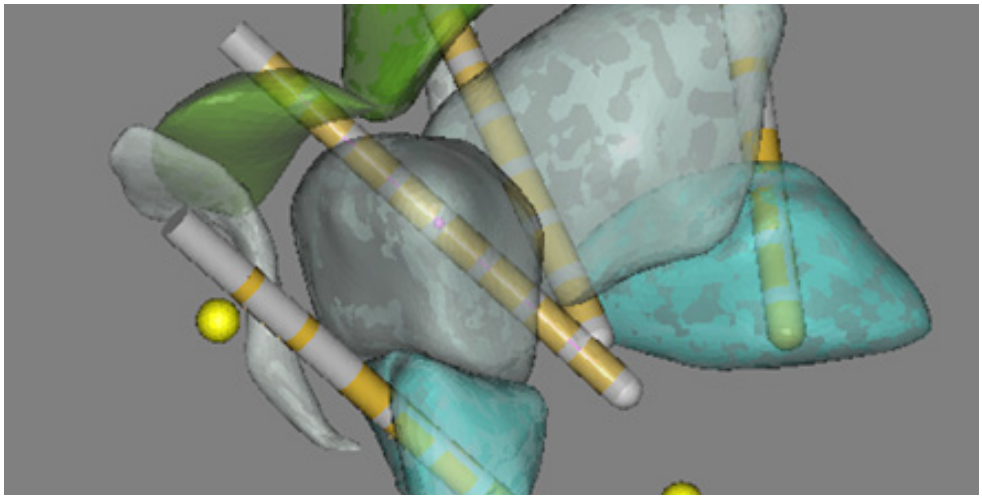

Figure 1: *ANT, MD AND CM DBS – 3D reconstruction showing bilateral DBS leads targeting the anterior nucleus of thalamus (anterior) and mediodorsal nucleus with an 8-contact lead (BSC Vercise-DBS-2201, Boston Scientific), and bilateral leads targeting the centromedian nucleus with segmented leads (BSC Vercise Cartesia Directional Lead, Boston Scientific). They were connected to a 4-channel internal pulse generator (Vercise Genus R32, Boston Scientific). Anterior is towards the upper left; the two yellow dots are the anterior and posterior commissures.*

These approaches are all, in my opinion, in the best interest of the patient, but in every instance we discuss all options and their approval status with the patient and their family. Through this approach we stand to discover much about the how best to treat each patient but also about the circuitry underlying various types of movement disorders, epilepsy and other disorders. Filling both the treatment gap and a knowledge gap become possible, helping both the individual patient, our first ethical obligation, and the community, our second ethical obligation.

The duality between treating the patient and discovery were highlighted to me during fellowship training when one of our patients about to undergo thalamic DBS for a novel indication – essential myoclonus – asked my mentor: "I have a question: are you doing this because you care about making me better, or because you are just interested in whether it will work?" The hesitation before his answer was the answer.

References

(Continued on page 32)

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Conflicts of Interest and Ethics in Neurosurgery

Ideally, we want a doctor to treat their patient solely on the merits of the case and their best abilities. Any interaction we have with a commercial or governmental agency with grants, work for hire, or even a cup of coffee, results in our profession and institutions quickly identifying that as a conflict. Additionally, any conflict is automatically presumed to harm the patient regardless of evidence. Some of the best clinicians are practitioners, innovators, investigators, entrepreneurs, and educators. So being a patient advocate and seeking the best and the brightest, finding someone genuinely talented with no conflicts is truly rare. Another factor to consider: the United States is the bastion of free market, entrepreneurship, and enterprise. How do we legitimately exclude the key players who physically do the work of neurosurgery from bettering their trade? Neurosurgeons are not and likely will never be passive recipients of technology. So how do we square this circle of conflict avoidance and free enterprise? Alex Bernstein, a father of interventional neuroradiology, said once, "no conflict, no interest." The central role of the physician inventor or trialist remains as accurate today as 50 years ago. In our opinion, the focus must be on conflict management, not avoidance. The best way to do that in a free market with free will exercised by patients is through a robust disclosure process at all levels of interaction.

Decision-making in neurosurgery is complex— to begin with, and made ever more challenging for novel procedures where complication rates and outcomes are not well-known, and personal experiences and biases often guide decision-making. As a result, this leaves room for conflicts of interest to influence decisions on procedures and the use of medical devices, which, if not managed appropriately, can erode patient and peer trust in health care providers. Furthermore, neurosurgery often needs to clarify the distinction between clinical care, innovation, and research. While institutional oversight is required for formal clinical research with novel devices, there needs to be more oversight for clinical care involving innovative procedures, which tend to gradually deviate from traditional indications and practice. Yet it is this aspect of clinical care which is the lifeblood of innovation and progress. That said, it is also prone to misuse or even abuse. The process which leads to landmark innovations and progress almost always begins in the operating room with a neurosurgeon trying to solve a complex problem and possibly doing not what is the standard of care but employing ingenuity and skill to create a novel solution.

In the United States, a state licensing body issues a medical license to a physician, but the physician's actual procedural privileges are granted and delineated by the institution where the physician provides care. Variability in institutional oversight exists among organizations. ith Aacademic programs tend to have stricter controls through processes such as formal morbidity and mortality conferences. Alternatively, other institutions activate with most institutions activate triggers of review only upon a slew of adverse outcomes.

Moreover, physicians, like all human beings and other professions, can be influenced by direct (e.g., financial gain) and indirect (e.g., relationships with colleagues and industry) incentives, which can sway surgical decision-making and the use of devices. It should be noted that there are few professions beyond clergy and medicine where greater emphasis is placed on ethics and morality. It would be naïve to assume that physicians cannot succumb to perverse incentives. However, since human frailty is unpredictable and possibly ubiquitous, it is of greater value to consider mechanisms that allow for the lifeblood of medicine and science, which is innovation and investigation, without being compromised by graft and greed.

It is paramount to acknowledge that during patient care, neurosurgeons are sometimes faced with situations where their judgment can be influenced by their self-interest, whether financial or non-financial. These conflicts can arise from various sources, including prestige, research grants, employment opportunities, consulting, and ownership interests in medical device companies. The repercussions of conflicts of interest in neurosurgery can be profound. Patients may be subjected to suboptimal care if a neurosurgeon's judgment is colored by self-interest, whether financial or non-financial. Moreover, conflicts of interest can damage patients' trust in their health care providers.

Conflict of interest is carefully scrutinized in professions such as health care, where strict guardrails have been developed to govern acceptable behavior. The question arises whether physicians should have any conflicts of interest in the first place? The logical answer in the United States is that physicians should be able to contribute to their field of expertise based on their ability to innovate in their work environment. Otherwise, it would be an egregious violation of their right to pursue free enterprise. However, this right has to be balanced with the primary concern of protecting the patient from any potential harm caused by a physician's self-benefit.

Today, neurosurgeons routinely derive income through performing procedures. Thus, there is an unavoidable interest in operating. As we move towards value-based models, these conflicts could be better managed than simple fees for service. However, in this article we are dealing with disputes beyond the essential medical conflict, namely additional incentives such as reputational or financial gains because of the specific selection of one methodology over another during treatment decisions.

The goal should not be conflict avoidance but conflict management. The existence of potential conflicts should not prevent physicians from participating in clinical research or practice. However, guidelines and oversight mechanisms must be created and followed. One essential tool available is routine and rigorous financial disclosure. While the government has created a central database under the Sunshine regulations, which lists all physicians' financial payments from the medical industry, this platform is neither easily accessible nor navigable by patients. It is our opinion that all neurosurgeons should also share their financial disclosures with all patients they treat as a matter of routine when patients are introduced to their practice. Typically, these disclosures are limited to review during participation in research studies but not provided to patients in routine practice. We advocate that a standard disclosure form should be shared with all patients and available on various easily accessible online platforms. While this is not possible during life-threatening emergencies, it can be done during formal follow-up. Similarly, at least an annual disclosure should be provided to all institutions where the neurosurgeon practices so that Medical Affairs or similar departments are informed cognizant, and able to provide adequate institutional oversight.

In addition to these steps, several broader initiatives can help minimize conflicts of interest in neurosurgery. Practical guidelines from neurosurgical societies should emphasize the importance of a collaborative and properly structured relationship between neurosurgeons and commercial interests, which can benefit patient care through technical innovation, research trials, and education. The collaboration ensures that patients receive optimal surgical outcomes and that neurosurgeons remain up-to-date with the latest technology in surgical care. The guidelines can clarify the proper relationships between neurosurgeons and commercial interests and avoid improper inducements or incentives. Additionally, medical journals require authors to disclose their financial and non-financial interests, which can help readers evaluate the validity of the research.In terms of research, most Institutional Review Boards have become excellent at identifying conflicts and managing them. Firstly, they require the relevant conflict for a research study to be listed on the patient consent prominently and under its own heading. Secondly, they require a conflict management plan that routinely involves a review of all enrollments by a separately experienced non-conflicted neurosurgeon to ensure appropriate registration. Finally, while it is acceptable to enroll patients, those with significant financial conflict (ownership) can participate in the clinical trial but should defer leadership of the trial to independent physicians with non-material conflicts limited to compensation for their time and effort according to fair market value.

It is paramount that neurosurgeons be transparent about their financial and non-financial interests to all their patients, peers, payors, and institutions of practice. Disclosure creates transparency, allows patients to make informed decisions about their care, and ensures that neurosurgeons are held accountable for their actions. While patients can choose another physician if they do not trust their current one, they are usually impressed with the innovation and seldom make this decision.

In conclusion, our key concept is that the neurosurgeon should disclose conflicts to all patients and all individuals engaged in a physician's work environment. In clinical research, financial interests require greater restrictions than clinical practice, and physicians should not lead studies with material conflicts. These guidelines ensure patients are informed and protected from potential harm caused by conflicts of interest.






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"Neurotech Justice" in the Clinic:

Key Takeaways from the Harvard Medical School Center for Bioethics Neurotech Justice Summit

Introduction

Neurotechnologies, including neuroimaging, wearable, and implantable neuro-stimulatory devices, are rapidly evolving, spurring ethical questions about their potential to create more harm than good in society.[1–3] As part of the Dana Foundation Center for Neuroscience and Society planning grant, an interdisciplinary team of lawyers, clinicians, ethicists, and "Dana Planning Grant Next Generation Leaders"[4] held the inaugural Neurotech Justice Summit on January 24, 2023, sponsored by the Dana Foundation and the Harvard Medical School (HMS) Center for Bioethics. The application of ethics to neurotechnology, which we term "neurotech justice," is important to define and pursue in clinical settings. Here, we share discussions from sessions and present strategies for how neurosurgeons can pursue neurotech justice.

How Do We Define "Neurotech Justice"?

Next Generation Leaders identified and presented four essential elements of neurotech justice: socio-ecological, distributive, transformative, and restorative.

Socio-ecological Justice

Socio-ecological models analyze health-outcomes at individual, interpersonal, community, and socioeconomic levels.[5,6] We adapt these models to neurotechnology applications. On individual levels, these frameworks prioritize notions inspired by neurorights, which encompasses mental privacy, agency, and personal identity.[3] Interpersonal considerations include building trust within the intertwined relationships of patients, caregivers, surgeons, and industry representatives.[7] Inclusion of demographically diverse patient populations perspectives on neurotechnologies will create nuanced community perspectives.[6] Systemically, policies must price neurotechnologies affordably.[7]

Distributive Justice

Neurotechnology use is limited by varied insurance coverage decisions that generate inequitable treatment options.[8,9] Research highlights higher rates of Medicaid-use among African-American patients with Parkinson's Disease as a potential mediator for their lower access to deep brain stimulation.[10] Burdensome out-of-pocket costs and insurance gaps unfairly allocate neurotechnologies.[11] Just distributions of neurotechnologies will meet increasing device demands, in financially inclusive ways, as diagnoses of neurologic and psychiatric conditions rise.[12]

Clinical access to neurotechnologies is influenced by federal and state governments, insurance companies, and physician-specialty groups that create guidelines on their uses for diagnosis, prognosis, treatment, insurance coverage and reimbursement.[8–10] Guidelines must account for drivers of health inequities--racism, sexism, classism, ableism, xenophobia, and homophobia--to enforce practices that consciously and proactively meet all patients' needs.

Transformative & Restorative Justice

Transformative and restorative practices are community-based efforts to prioritize healing and accountability for harms.[13,14] Indigenous, Black and Brown, immigrant, poor, disabled, queer, transgender, and sex-work communities pioneered these to build safe spaces within structurally-violent systems.[15,16] In health care, approaches should respond to current and historical medical injustices to improve neurotechnology development and distribution."

Patients' realities of pain, decreased functions, and diminished consciousness are compounded by harms that occur when their identity intersects multiple marginalized groups. Restoration requires acknowledgement and care about the structural and interpersonal harms patients experience and tangible efforts to repair harms.[17] Transformative approaches require thoughtful broadscale interventions for the needs of patients, families, and communities harmed by unjust development, distribution, and applications of neurotechnologies.[17]

Neurotech Justice In the Clinic

Later in the Neurotech Justice Summit, panelists discussed a case study presented by an HMS bioethicist and neurosurgeon:

An adult patient with severe traumatic brain injury (sTBI) caused by a subdural hematoma showed cognitive-motor dissociation (CMD) on an fMRI, eliciting a guarded but positive prognosis from the surgeon. Post-rehabilitation, the patient exhibits the cognitive functionality of a child, which the family remains disappointed with.

The clinical case study introduced ethical questions regarding uses of neuroimaging to enhance prognostic capabilities, potential outcomes, and protection of patient


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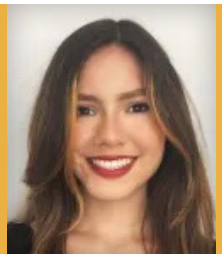
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neurorights. We discussed the meanings of "minimally acceptable outcomes" versus "favorable outcomes."[18] Because TBI recovery can take many years, transparent communication between surgeons, patients, and caregivers is necessary to evaluate how "minimally acceptable outcomes" change throughout recovery.[18] Further, we considered neuroimaging uses for more comprehensive prognostication of disorders of consciousness, and how access to such technologies supports accurate prognoses and timely decision-making.[19] The panelists characterized neurotechnology as a potential instrument of justice, and highlighted using fMRI as a communication tool among patients in minimally conscious states.[20,21] This productive session scratches the surface of expansive ethical considerations regarding patient-physician communication, technology access, and the protection of mental integrity with neurotechnologies.

How Can Neurosurgeons Advance Neurotech Justice?

In the Clinic

Research shows that neurotechnologies (e.g., EEG, fNIRS, cerebral oximetry) perpetuate phenotypic, racial, ethnic, and cultural biases, because they are not developed with diverse populations, limiting their usability and efficacy in marginalized groups.[22] Neurosurgeons must recognize these biases and restructure clinical trials to ensure developing neurotechnologies are widely applicable. Furthermore, neurosurgery teams must build trust with vulnerable patient populations to ensure every patient is respected and has agency to join fair clinical trials.

Neurosurgeons must acknowledge their underlying biases that could prevent prompt recommendations of potentially beneficial neurotechnological interventions to patients. Neurosurgeons often face difficult decisions in suboptimal conditions, e.g., urgency, emotional distress, and fatigue.[23] Time constraints and information gaps can cloud surgeons' ability to make comprehensive judgements about patient values and clinical circumstances to prevent patient harm.

To address these biases, surgeons need diverse and effective teams and should consider implementing innovative care delivery models to fill information gaps. Establishing a diverse work environment where everyone safely shares opinions about patient-care decisions ensures patients' needs are prioritized, and options are explored for the patient's benefit. Neurosurgeons should solicit team members' opinions, rectify non-inclusive team dynamics, and implement relevant aids (e.g. predictive analytics, surgical risk calculators,[24] ethics consultations, and relevant models of care delivery,[25–27] like integrated care pathways[28]) to make comprehensive decisions

Communication

Neurosurgery teams face numerous barriers to effectively communicate with patients and caregivers and to understand patient values and outcomes.[29,30] Improving communication with patients/caregivers amidst complex and urgent circumstances requires teams to embrace radical transparency: prioritize sharing emerging patient information and ensure an understanding of all recommended treatment options. Additionally, language/cultural discordance and physicians' individual judgements prevent necessary discussions of diagnoses, prognosis, and treatment options in timely and culturally sensitive manners.[31] Neurosurgeons must be trained to engage with patients from different backgrounds and to integrate medical/cultural interpreters into patient-care.[32–34]

Neurosurgeons are situated to engage with insurance representatives, neurotechnology companies, and medical administration and should similarly lead with radical transparency during meetings. Discussion must be continually held regarding insurance barriers, device pricing, insurance reimbursement, and administrative workloads that prevent neurosurgery teams from providing quality care to all patients.[35–39]

Open conversation on neurotech justice should extend beyond academia to interpersonal engagement to understand the perspectives of patients, families, and communities on neurotechnologies. Recommended works for discussion include the memoir All That Moves Us by pediatric neurosurgeon Jay Wellons, MD, MSPH,[40] Healing by psychiatrist Thomas Insel, MD,[41] The Battle For Your Brain by legal ethicist Nita Farahany, JD, PhD,[42] and the mini-documentary centering patient experiences with implantable neurotechnology, Seizing Hope: High Tech Journeys in Pediatric Epilepsy.[43]

Advocacy

Advocacy can begin with interdisciplinary discourse at professional gatherings and journals, like the Summit and this *Congress Quarterly's* theme. This may require collaborative large-group meetings, small-group negotiations, research to measure harms, and long-term efforts devoting funding, personnel, and time to rectify distribution and outcome disparities. Such clinical conversations and policy developments must involve patients and caregivers.

Conclusion

Ensuring all patients can comfortably access necessary neurotechnological interventions pushes society towards achieving neurotech justice. These are long-term commitments to minimize biased development and distribution of neurotechnologies. Nevertheless, engaging now reduces the potential for future harm to patients and communities.

References

(Continued on page 31)

Ethical Considerations and Challenges of Medical Service Trips in Global Neurosurgery

The History of Global Neurosurgery:

Historically associated with "mission trips," short-term medical service trips (MSTs) are defined as volunteer providers traveling for a finite period of time to provide medical care.[1] Early MSTs, were sponsored by the Catholic Church, lacked personnel with medical training, and provided care at new religiously-affiliated healthcare installations.[2]

Throughout the 20th Century, the formation of organizations including the League of Nations, the World Health Organization (WHO) and the Peace Corps led to a transition from religious to governmental MSTs.

In 2008, Partners in Health co-founders Drs. Paul Farmer and Jim Young Kim highlighted a need for incorporating comprehensive surgical services into global health efforts and deemed surgery the "neglected stepchild of global public health."[3] Soon after, the WHO passed Resolution 68.15, calling for the "strengthening of emergency and essential surgical care and anesthesia as a component of universal health coverage."[5] Global neurosurgery's expansion in recent decades has attempted to bridge this gap for neurosurgical patients. Herein, we review the ethical considerations of global neurosurgery MSTs and how MSTs can contribute to the WHO Building Blocks of Health Systems and the UN Sustainable Development Goals (SDGs).[6-8]

Ethical Considerations in Global Neurosurgery:

Current global neurosurgical efforts can be divided into four categories: MSTs, educational initiatives, training programs, and health systems strengthening, each with its own ethical considerations.

MSTs

Neurosurgical MSTs encompass both smaller, individual teams and larger, institutional efforts. One example of an MST is Mission:Brain, founded in 2011, by Drs. Alfredo Quiñones-Hinojosa and Michael Lawton with over 50 existing partnerships in Mexico and the Philippines.[9] Institutional MSTs, such as those at Vanderbilt University and Weill Cornell Medicine comprise the majority of present-day MSTs.[10,11]

Ethical considerations regarding MSTs are often classified as "venue-related" or "visitor-related."[4] Lack of long-term sustainability is the most often cited venue-related ethical pitfall of MSTs.[12-14] Furthermore, MSTs may perpetuate a cycle of medical and psychological dependency.[15] Visitor-related ethical concerns include lack of multidisciplinary care, providing second-line care due to resource and time limitations, and working with misaligned intentions.[16-18] Misaligned intentions include self-serving purposes, institutional publicity, or even the "white man's burden" to help those in low- and middle-income countries (LMICs) - risking a new age of colonialism.[12,13, 16, 18]

Educational Initiatives and Training Programs

Educational initiatives emphasize knowledge building through "skills transfer, teaching, and providing educational materials."[8] Through their International Visiting Scholars and Clinical Observership Program, Barrow Neurological Institute has welcomed learners worldwide for over two decades to participate in observerships, allowing for vital knowledge transfer.[19] Established in 2022, Barrow Global seeks to expand upon this solid international educational experience.[19]

Training initiatives involve a "formalized process…to increase the number of neurosurgeons or neurosurgery-capable professionals in the country."[8] Short-term training can either be directed at local neurosurgeons or entry-level providers/general surgeons, known as "task-shifting".[20,21] Since 2009, Duke Global Neurosurgery and Neurology (DGNN) has led a sustainable in-country training program in Uganda.[22] Eight Ugandan neurosurgeons have been trained since the program's inception, and DGNN aims to train 50 neurosurgeons by 2030.[23]

Educational initiatives and training programs raise several ethical questions. Regarding educational content, the global neurosurgical community must consider personal, institutional, and financial conflicts of interest. Creating a standardized neurosurgical curriculum may be one way to avoid educational conflicts of interest.[8] In high-income country (HIC) training programs, "brain drain" — the departure of highly specialized neurosurgeons from LMICs to HICs — is a constant ethical consideration, which successful training programs in LMICs can help to limit.[8,16,24]


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Health Systems Strengthening

Health systems strengthening refers to deliberate efforts at reframing global neurosurgery to incorporate "the entire healthcare continuum."[8] The Global Neurosurgery Initiative (GNI) at the Program in Global Surgery and Social Changes (PGSCC) and DGNN are key thought leaders in exploring how to prioritize access to surgical care against other immediate health system needs.[8,25]

Sustainable Practices Moving Forward:

Most MSTs are unlikely to achieve the ultimate goal of global neurosurgery: ensuring access to neurosurgical care for all who need it. Advances in global health equity have been driven principally by the UN SDGs, specifically SDG #3 which aims to "ensure healthy lives and promote well-being for all at all ages."[26] Thus, to advance global health equity most directly, a permanent shift in what it means "to do" global neurosurgery is required: from MSTs to thoughtfully designed interventions aligned with the SDGs. Below are four illustrative examples, using the WHO Building Blocks for Health Systems as a template.[27]

Service Delivery, Technology Dissemination

In the early 2000s, Dr. Benjamin Warf of CURE Uganda established a treatment center for children with hydrocephalus. Two obstacles they faced were the high cost and failure rate of shunts.[28,29] In addition to reducing shunt surgery costs, Warf and colleagues pioneered the endoscopic third ventriculostomy with choroid plexus cauterization (ETV-CPC) technique to reduce the overall necessity for shunts.[28,29] Today, the ETV-CPC technique is widely practiced across the globe.[30] Thus, in addition to providing care, CURE Uganda is also a renowned surgical training site for neurosurgeons globally.

Healthcare Workforce & Global Health Leadership and Governance

The World Federation of Neurological Societies (WFNS) Training Centers & Fellowships are helping to expand the global neurosurgical workforce, affecting five continents in 18 countries.[31] The first center was established in Rabat, Morocco in 2002, and has trained more than 60 neurosurgeons, more than 60% of whom have returned to their home countries.[31]

As a member of the G4 Alliance, the WFNS Foundation provides input to the WHO on policy issues regarding public health and neurosurgical disease. Through participation in policymaking, neurosurgeons have affected change in the treatment and prevention of neurological conditions worldwide.[32] An additional example of effective advocacy in global neurosurgery is the Global Alliance for the Prevention of Spina Bifida F (GAPSBiF), formed by the G4 Alliance and the International Society of Pediatric Neurosurgeons (ISPN). GAPSBiF aims to promote global folate fortification in an effort to decrease neural tube defects.[33]

Information dissemination

The International Student Surgical Network (InciSioN) has established a worldwide network of trainees who collaborate to advance surgical research and access, using their collective voice to amplify critical issues facing patients and trainees in global surgery.[34] InciSioN has built a successful peer mentorship program which recruits and nurtures the next generation of neurosurgeons through research and clinical skill development.[34]

Financing Global Neurosurgery

In 2015, Shrime and colleagues published an analysis in the Lancet Global Health that modeled the global burden of catastrophic expenditures of surgery, which disproportionately affects LMICs.[35] The 2015 Lancet Commission on Global Surgery resolved that by 2030 households should have "100% protection against impoverishment from out-of-pocket payments for surgical and anesthesia care," which spurred the field of global neurosurgery to understand and mitigate the burden of catastrophic expenditures.[36] For example, Ferraris et al. published policy recommendations to protect patients and health systems from suffering catastrophic costs as a result of neurosurgical pathologies.[37] In recent years there has been a notable rise of research within the United States on outcomes disparities in neurosurgery.[38-40] This research, in combination with the targeted policy efforts described above, are needed to meet the global burden of neurosurgical disease.

Final Thoughts for a Sustainable Global Neurosurgery Future

Neurosurgery has been one of the most active specialties in mobilizing to address the needs for access to high quality neurosurgical care and surgical education. As illustrated, MSTs can meaningfully contribute to patient care, but efforts in global neurosurgery must align with greater global health efforts to promote sustainable development. This must be a core responsibility of each individual neurosurgeon. We all don't need to travel, but must all support efforts to make essential neurosurgical care available to everyone, everywhere.

References

(Continued on page 33)

Hussam Abou-Al-Shaar, MD

Douglas Kondziolka, MD, MSc

Research Integrity in Neurosurgery

Research integrity is a critical element in academic publishing, fundamental to fostering an optimal research environment.[1] The increased reporting of research misconduct, academic fraud, and plagiarism has shed light on the importance of research ethics and integrity among the global scientific research community including neurosurgery. Therefore, understanding the essential components of research integrity is vital to avoiding scientific malpractice.

Research integrity in the United States was emphasized on a governmental level by the establishment of the Office of Scientific Integrity in 1989, which later integrated with the Office of Research Integrity in 1992.[2] Various other governments and funding agencies across the globe have also put together guidelines, such as the Declaration of Helsinki, in order to establish rigorous international guidelines, policies, regulations, and principles for conducting research according to ethical standards and avoiding questionable research practices.

Conducting research with high integrity relies on multiple facets. The authors should focus on producing high quality research, rather than on mere quantity. The neurosurgical literature, like that of other disciplines, has witnessed a "research fever" and a spike in research output, increasing expectations for higher publication volume among residency applicants in recent years.[3] Authors should be encouraged to conduct high quality research that has the potential to alter current practices, enhance the understanding of disease processes, or challenge long-standing dogmas.

Researchers should be educated on appropriate research methods and responsible conduct; helpful resources and materials should be available to researchers and students in every academic and research institution.[4] Additionally, mentors should emphasize the importance of research integrity and act as role models to their mentees by adopting appropriate research practices and promoting awareness of ethical problems and their solutions.[5] Beyond that, research integrity includes the novelty and the originality of research output and the declaration of any potential conflicts of interest relating to authorship.

Research authorship should be monitored and authorship guidelines should be adhered to. Many journals have set clear descriptions of authorship criteria including but not limited to "(1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; and (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be published" among others.[4] Additionally, some journals require the authors to include a description of each author's contribution.[6] Principle investigators should therefore monitor these processes and ensure that all listed authors have contributed significantly to the work. This is essential, especially with the increased utilization of artificial intelligence (AI) programs and research engines that can generate entire manuscripts or sections of articles. Although this is beyond the scope of this article and has been discussed extensively in multiple editorials, in *Neurosurgery*[7] and others,[8–10] use of AI programs for the production of research articles is questionable and does not warrant authorship, as the AI software cannot adhere to journal guidelines around original work or assume accountability and responsibility for the research content. Numerous errors and plagiarism have been linked to such programs as well making their use even more problematic.[10] We utilize ithenticate software to evaluate all articles for similarities to other works. Sometimes this requires a significant rewrite. Occasionally, an error can occur and be published, usually related to data analysis. When this is detected after publication and we are notified, we publish an erratum and correction.

Authors are frequently involved in the review process for articles submitted to journals in their area of interest. Research integrity violations have been widely reported in the review process, and multiple papers have been retracted due to faulty review processes and fake peer review issues.[11] The review process should be strict and the reviewers and editors have the responsibility to ensure a

thorough and comprehensive assessment of the submitted content to avoid plagiarism, fabrication of published scientific information, and research misconduct.[4]

Finally, institutional supervision and auditing processes should be established in academic institutions and research centers to ensure the accuracy and the quality of the data before publication.[12] Academic and research institutions should promote and facilitate research integrity among their researchers. Research integrity and responsible conduct of research workshops and courses should be offered by institutions to promote the optimal research climate.[13] Violations of research integrity should be handled seriously with appropriate disciplinary actions.

Above all, researchers and the research community should remember the significant impact and importance of their research message on the daily practice and care of patients. Such impact should be honored by ensuring the highest academic standards and research integrity across scientific research. We at **Neurosurgery Publications** are proud to have a world class editorial board, advisory panel, committed publisher and staff that focus on research quality and integrity. <

DECLARATIONS: Dr Kondziolka receives research support from Brainlab and purchased direct stock in Chiefy.

> ABOVE ALL, RESEARCHERS AND THE RESEARCH COMMUNITY SHOULD REMEMBER THE SIGNIFICANT IMPACT AND IMPORTANCE OF THEIR RESEARCH MESSAGE ON THE DAILY PRACTICE AND CARE OF PATIENTS. SUCH IMPACT SHOULD BE HONORED BY ENSURING THE HIGHEST ACADEMIC STANDARDS AND RESEARCH INTEGRITY ACROSS SCIENTIFIC RESEARCH. <

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FOUNDATION UPDATE

Are you a CNSF Donor? Then You Are a Neurosurgeon's Hero!

Dear Colleagues,

Spring is the time for the CNS Foundation's annual Application Award cycle. (To view 2023 calendar for Awards and Scholarships please visit foundation.cns.org/awards). What difference do these awards make to neurosurgery? Our awardees say it best. On the following page, we share the words of four of our 2022 award recipients. Do you remember starting out as a neurosurgeon? Was your faith to continue this demanding work ever challenged? Have you ever received a gift that replenished you for years afterwards?

Now, imagine being the patient of someone who received an award to learn more. Perhaps you were an awardee once. How did that feel?

The awards at the CNS Foundation are created to feed the education and creative ideas of our fellow neurosurgeons. Please see below the recently announced winners of 2023 awards for Diversity, Equity, and Inclusion. Thank you both Medtronic and Stryker for your generous support of these important awards.

Thank you for your gifts. We as doctors constantly give back to our patients. Through your gifts to the CNS Foundation, you can give back to your colleagues, brothers, and sisters in arms. I invite you to hear the joy in each of the letters that follow.

Sincerely,
Martina Stippler, MD
Chair, The CNS Foundation

CONGRATULATIONS

2023 WINNERS OF DIVERSITY, EQUITY, AND INCLUSION AWARDS

DEI Scholar Award

Graciously funded by **Medtronic**

Jacob Greenberg	*Washington University School of Medicine*
Nicholas Laskay	*University of Alabama at Birmingham*
William Ashley	*Sinai Hospital of Baltimore*

DEI Think Tank

Graciously funded by **Medtronic**

Matthew Anderson	*Brown University*
Sonia Eden	*Semmes Murphey Clinic and UTHSC*
Damirez Fosset	*Howard University*
Tessa Harland	*Albany Medical College*
Cleresa Roberts	*UVA Health*

DEI Pilot Project

Graciously funded by **Stryker**

Alexandra Giantini Larsen	*NY Presbyterian Hospital–Weill Cornell Medical Center*
Alankrita Raghavan	*Duke University*

DEI Impact Project

Graciously funded by **Stryker**

Rory Goodwin	*Duke University*

Smruti K. Patel, MD: 2022 Future Women Leaders in Neurosurgery Scholar Winner

Funded by donors to the DEI: FWLN Scholar Fund

"The Leaders Course that I was able to attend as a result of the Women Leaders in Neurosurgery Scholarship from the CNS Foundation…helped cultivate and hone skills and strategies to be successful and productive. I was so impressed with how well organized and how much great knowledge I gained from attending. In addition to being the youngest surgeon at the course, I was also one of a handful of women...One of the best parts of the course was meeting all of the participants and engaging in real, meaningful conversations with them about the hurdles of leadership but also of the rewards that these roles afford. I've made some great friends in other surgical disciplines through attending this course whom I plan to keep in touch throughout my career. Most importantly, I very quickly was able to use what I learned and apply it to my newly appointed leadership roles."

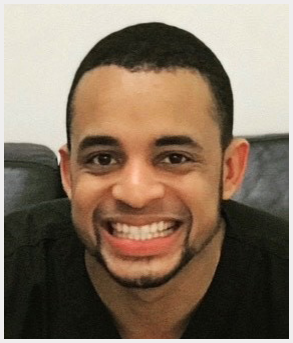
Clara Martin, MD, (Argentina): 2022 Cerebrovascular Visitorship

Funded by Penumbra

"An incredible experience of intense learning visitorship in cerebrovascular neurosurgery at Emory University Hospital thanks to a CNS Foundation award. Hosted by Dr. Brian Howard and Dr. C. Michael Cawley and the outstanding team. In a two-week period, I observed 24 cases between endovascular and open cerebrovascular surgeries, as they are dual trained neurosurgeons. Very grateful for this amazing experience!"

Franly Vasquez, MD, (Dominican Republic): 2022 Neurotrauma and Critical Care Visitorship

Funded by the Joint Section on Neurotrauma and Critical Care



"For those who, like me, are doing residencies in a national reference trauma hospital, and doing rotations in the only other two trauma centers in the country, neurotrauma is something especially painful.

My country leads the world in deaths from traffic accidents, 67 people per hundred thousand inhabitants lose their lives every year and it is an expense in health. That is why I am so grateful for the opportunity that the CNS Foundation has given me to increase my knowledge of neurotrauma so that I can serve my nation."

Chrystal Calderon, MD (Trinidad Tobago): 2022 MGH Harvard 6-month Observership

Funded by donors to the CNS Foundation

"I want to express my gratitude to the CNS Foundation for my experience in this international observership program over the last 6 months in Boston. This was truly an exceptional opportunity to broaden my neurosurgical purview. Kee Park welcomed me into the Global Surgery program, sharing eye-opening and impactful information and research on Global Surgery. Brian Nahed and Myron Rolle facilitated my transition to neurosurgery clinical service at MGH. I can go on and on about the cases observed and the excitement in participating in different approaches and utilizing all the resources possible. Thank you seems insufficient for the role that this program has played in my neurosurgery residency program."

To make a donation to the CNS Foundation, please visit foundation.cns.org/donate.

To inquire about making legacy gifts, please contact CNS Foundation Director, **Courtney Johnson**.

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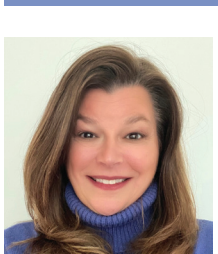
INSIDE THE CNS

Washington Committee Report



Katie O. Orrico, Esq

Washington Committee Sets 2023 Legislative & Regulatory Agenda

The Congress of Neurological Surgeons (CNS) and the American Association of Neurological Surgeons (AANS) released their 2023 Legislative & Regulatory Agenda, including health policy action items the neurosurgical societies plan to advance with Congress and the Biden Administration. Organized neurosurgery aims to:

- **Protect patients' timely access to care** by reforming prior authorization and repealing Medicare's appropriate use criteria program for advanced diagnostic imaging;
- **Support quality resident training and education** by increasing the number of Medicare-funded residency positions and preserving the ability of surgeons to maximize education and training opportunities within the profession's current regulatory structures;
- **Champion fair reimbursement** by improving the Medicare physician payment system — including providing an annual inflationary payment update and improving the value-based care programs — following the clear language of the *No Surprises Act* and implementing a fair process for resolving provider and health plan payment disputes, permanently expanding telehealth flexibilities and closing the gap in payments between Medicaid and private insurers to reduce access to care disparities;
- **Improve competition in the health care system** by increasing scrutiny of hospital and other health care consolidation, removing restrictions on physician ownership of hospitals and other ancillary services, establishing network adequacy standards and broadening health insurance coverage options;
- **Fix the broken medical liability system** by adopting proven reforms that are in place in California and Texas and other innovative solutions;
- **Alleviate the burdens of electronic health records** (EHRs) by achieving interoperability, preventing data blocking, reducing unnecessary data entry and improving the functionality of EHR systems to enhance, not hinder, the delivery of medical care; and
- **Continue progress with medical innovation** by prioritizing funding for the National Institutes of Health, pioneering medical technology and life-saving therapies by streamlining the Food and Drug Administration's approval processes and expanding Medicare coverage of new technology.

In a press release announcing the advocacy agenda, **Russell R. Lonser**, MD, chair of the Washington Committee, stated, "The AANS and the CNS will continue to encourage policymakers to work together to find bipartisan solutions for our nation's top health care issues to ensure that our patients have timely access to high-quality, equitable neurosurgical care. We look forward to working with Congress and the Biden Administration to advance sound health care policy for the betterment of our patients and profession."

Click here for the policy agenda and here to read the press release.

CNS and AANS Comment on Prior Authorization Reform Proposals

On Dec. 6, 2022, the Centers for Medicare & Medicaid Services (CMS) issued a **proposed rule** requiring Medicare Advantage plans and other public health insurers to implement automated prior authorization systems. Subsequently, on Dec. 14, 2022, CMS issued another **proposed rule** to improve prior authorization in the Medicare Advantage program. Taken together, the proposed rules would:

- Require insurers to adopt electronic prior authorization;
- Reduce care delays and improve patient outcomes by ensuring that health plans respond to prior authorization requests within specific timeframes (72 hours for urgent requests and seven days for standard requests);
- Mandate that prior authorization approvals remain valid for a patient's entire course of treatment;
- Require coverage determinations to be reviewed by professionals with relevant expertise;
- Support efforts (e.g., gold cards) to waive or modify prior authorization requirements based on provider performance; and
- Compel health plans to publicly report the use of prior authorization, including information on delays and denials.

The CNS and the AANS responded to the proposal by joining several coalition letters.

- Click **here** and **here** for the Regulatory Relief Coalition (RRC) letters;
- Click **here** and **here** to read the Alliance of Specialty Medicine letters; and
- Click **here** for the AMA-led letter from nearly 120 organizations.

Washington Committee chair **Russell R. Lonser**, MD, stated in an RRC **press release**, "It's long past the time for CMS to hold health plans accountable for unconscionable delays and denials of care. Clearly, CMS listened to patients and providers when developing this rule, which will help eliminate care delays, patient harms and practice hassles that contribute to physician burnout, and is a huge step in the right direction."

Court Rules in Favor of Physicians in Lawsuit Challenging No Surprises Act

In a win for physicians and hospitals, for the second time in less than two years, a federal court in Texas has rejected the Biden Administration's attempt to rewrite the independent-dispute resolution process that Congress created in the **No Surprises Act** (NSA). The NSA bans surprise medical bills for out-of-network care and establishes a process for resolving payment disputes between health plans and providers.

Unfortunately, the **final rule** implementing the law continued to give preference to the qualifying payment amount (QPA) — or median in-network rate — which unfairly favors insurers when settling out-of-network payment disputes. In contrast to the final rule, the NSA requires arbiters to consider several factors equally — not just median in-network rates — including the physician's training and experience, the severity of the patient's medical condition, prior contracting history, health plan market share and other relevant information.

According to the court, the final rule "continues to place a thumb on the scale for the QPA by requiring arbitrators to begin with the QPA and then imposing restrictions on the non-QPA factors that appear nowhere in the statute." In sending parts of the regulations back to the agencies, the court ruled that "rather than instructing arbitrators to consider all the factors pursuant to the Act, the Final Rule requires arbitrators to consider the QPA first and then restricts how they may consider information relating to the non-QPA factors."

On Oct. 19, the CNS and the AANS spearheaded a physician-led **amicus brief**, along with the Physician Advocacy Institute, supporting the Texas Medical Association's (TMA) **lawsuit** challenging these rules. The Biden Administration has until early April to appeal the decision.

Neurosurgery Urges Congress to Hold Hearings on Medicare Physician Payment Reform

On Jan. 23, the CNS and the AANS joined more than 100 national medical associations urging Congress to hold Congressional hearings and work with all stakeholders to explore long-term payment solutions to reform the Medicare physician payment system. The letter points out that Medicare physician payments have declined by 22% over the past 20 years, given that the Medicare fee schedule lacks an annual inflationary update. The absence of an annual inflationary update, combined with statutory budget neutrality requirements, results in ongoing cuts to neurosurgical payments.

Click **here** to read the letter.

CNS and AANS Endorse Cerebral Cavernous Malformations Legislation

Once again, the CNS and the AANS endorsed the Cerebral Cavernous Malformations Clinical Awareness, Research and Education (CCM-CARE) Act. Sponsored by Sens. **Ben Ray Luján** (D-N.M.) and **Martin Heinrich** (D-N.M.), the bill would expand National Institutes of Health (NIH) research related to cerebral cavernous malformations. The legislation directs the NIH director to:

- Conduct basic, clinical and translational research on CCM;
- Support multi-site clinical drug trials for cavernous angioma; and
- Integrate CCM within existing clinical research networks.

The bill also directs the U.S. Department of Health and Human Services secretary to establish a CCM education and information program to expand training programs for clinicians and scientists.

The sponsors' press release featured Washington Committee chair **Russell R. Lonser**, MD, who stated:

> Cerebral cavernous malformations can lead to seizures, stroke and death. As neurosurgeons who treat patients with this disease, we appreciate the leadership of Senators Luján and Heinrich in sponsoring the Cerebral Cavernous Malformations Clinical Awareness, Research and Education Act to help expand research and treatment options for patients with this rare but devastating medical condition.

On March 1, the *Los Alamos Daily Post* posted an article about the bill, including Dr. Lonser's quote.

CNS and AANS Join Alliance in Urging CMS to Ensure Network Adequacy Standards

On Dec. 21, 2022, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that includes provisions related to network adequacy standards. The proposal would require all Affordable Care Act exchange plans to comply with existing standards for network adequacy, including those that have not used a provider network. Unfortunately, the CNS and the AANS believe that the existing network adequacy standards fail to ensure robust access to specialty and subspecialty medical care. In commenting on the proposal, the groups urged CMS to take the necessary steps to address the problem of narrow and restrictive provider networks.

Click here to read the Alliance of Specialty Medicine letter.

Neurosurgery Recommends that CMS Expand Carotid Artery Stenting Coverage

On Feb. 7, the CNS, AANS and the Cerebrovascular Section sent a letter to CMS urging the agency to update its National Coverage Determination for Carotid Artery Stenting (CAS). In 2009, the CNS and the AANS disagreed with proposals to expand coverage for CAS to asymptomatic patients based on the available evidence at that time. However, as noted in the letter, since then, multiple randomized controlled trials have been published, physicians from several different specialties have amassed extensive real-world experience and data have been collected as part of national registries. Therefore, neurosurgery now urges CMS to revisit the coverage for CAS.

Click here to read the letter.

AANS and CNS Urge CMS to Ban Step Therapy in Medicare

On Feb. 13, the CNS and the AANS sent a letter to the CMS asking the agency to reinstate the step therapy prohibition in the Medicare Advantage program. In the letter, the groups requested that the agency prohibit step therapy for Part B drugs as specified in the original Sept. 17, 2012, memo, "Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services." Step therapy, also known as "fail first," is utilized by health plans to determine coverage and requires that patients fail on an insurer's preferred medication before the therapy prescribed by their health care provider is covered.

Click here to read the letter.

CNS and AANS Urge Congress to Address Medical Student Debt

Reps. **Brian Babin**, DDS, (R-Texas) and **Chrissy Houlahan** (D-Pa.) in the U.S. House of Representatives and Sens. **Jacky Rosen** (D-Nev.) and **John Boozman**, OD, (R-Ark.) in the U.S. Senate, have introduced legislation to address physician student loan debt. The bipartisan Resident Education Deferred Interest (REDI) Act (H.R. 1202/S. 704) would allow borrowers to qualify for interest-free deferment on their student loans while serving in a medical internship or residency program. The CNS and the AANS endorsed the REDI act, joining more than 40 organizations in thanking the bill's sponsors for introducing this critical legislation.

Click here to read the House letter and here for the Senate letter.

HHS to End COVID-19 Public Health Emergency Declaration

On Feb. 9, the U.S. Department of Health and Human Services (HHS) announced its plans to end the COVID-19 public health emergency (PHE) on May 11. The administration will transition away from various pandemic policies and flexibilities over the next few months. Click here and here for more information and guidance to help neurosurgical practices prepare and plan for the end of the PHE.

IMAGES IN NEUROSURGERY

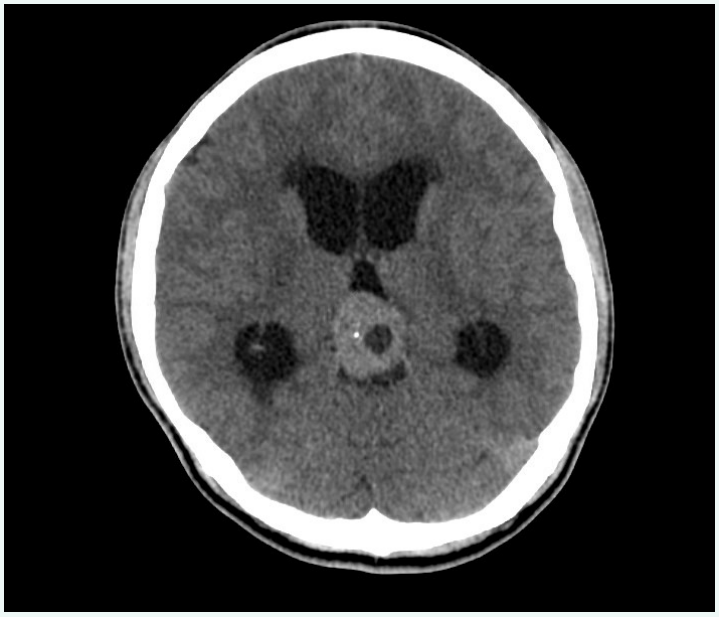


Figure 1: CT of the head without contrast demonstrates a hyperdense mass with calcification in the pineal region with hydrocephalus.

Pineal Germinoma

A 21-year old male presented to the emergency room with headaches, difficulty ambulating and upward gaze palsy. CT of the head demonstrated a hyperdense mass with calcification in the pineal region with hydrocephalus (**Figure 1**). MRI of the brain with and without contrast showed a heterogeneously enhancing tumor in the pineal region with hydrocephalus (**Figure 2**). The patient underwent endoscopic third ventriculostomy as well as endoscopic biopsy of the pineal region mass. The mass was avascular and soft, tan-white in appearance. CSF alkaline phosphatase and human chorionic gonadotropin were elevated. The biopsy resulted as pineal germinoma and the patient was treated with radiation therapy. 14-month follow-up MRI demonstrated resolution of ventriculomegaly and absence of pineal germinoma (**Figure 3**). Pineal germinomas are the most common tumors of the pineal region and account for approximately 80% of all intracranial germ cell tumors. These tumors are radiosensitive, present in younger patients < 20 years of age, and have a male predominance.

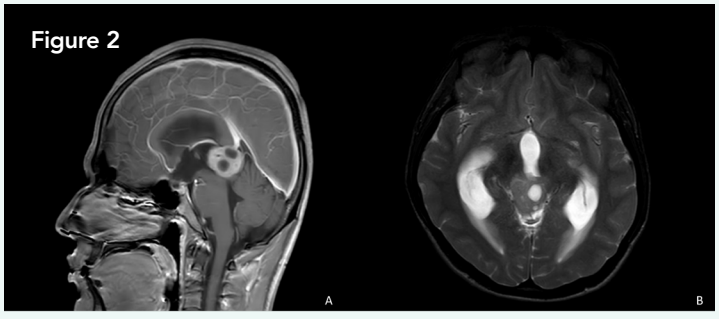


Figure 2: MRI of the brain T1 with contrast sagittal section demonstrates heterogeneously enhancing tumor in the pineal region (A). Axial T2 MRI demonstrates pineal region mass with hydrocephalus (B).

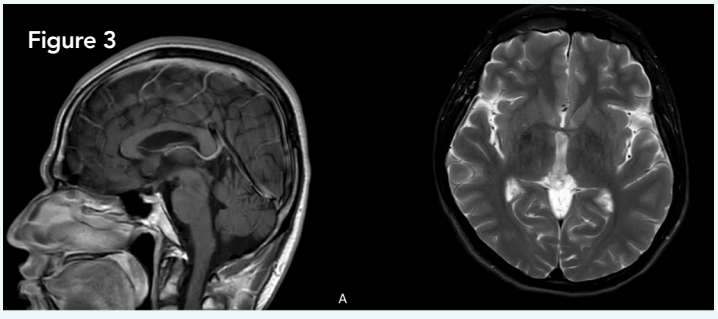


Figure 3: 14-month follow-up MRI T1 with contrast subsequent to radiation therapy demonstrates absence of pineal germinoma (A). Axial T2 MRI demonstrates resolution of hydrocephalus (B).

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