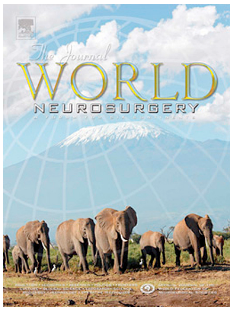
Accepted Manuscript



Neurosurgery: Expanding Relevance in the Evolution of Medicine?

Charles Y. Liu, MD, PhD

PII: S1878-8750(14)00995-4

DOI: 10.1016/j.wneu.2014.10.001

Reference: WNEU 2575

To appear in: *World Neurosurgery*

Neurosurgery: Expanding Relevance in the Evolution of Medicine?

The field of neurosurgery has enjoyed an enviable position among medical specialties over the past decades. In most parts of the world, including North America, virtually all neurosurgeons have been able to expect to fulfill fundamental material needs quite quickly after training. In addition, most have been able to function autonomously, with modest oversight from colleagues, other medical practitioners, and administrators. Finally, neurosurgeons have felt comfortable with the general importance of the specialty in the medical realm. Over the past decade, tremendous changes are evident across the medical landscape globally. Perhaps the one remaining constant may be the severity and dramatic nature of the diseases that neurosurgery treats, preserving the potential for neurosurgeons to singularly change the life course of select patients. However, is this enough to maintain neurosurgery's importance, particularly when many of these changes directly undermine factors that have contributed to its success?

The success of neurosurgery has been predicated upon several key factors, but tremendous change evident in each. First, much of medicine's initial understanding of the nervous system was based primarily on anatomy. Among the medical specialties of the clinical neurosciences of neurosurgery, neurology, and psychology, ours is uniquely grounded in such consideration. In the past decades, the fundamental knowledge of the nervous system is increasing at all levels of resolution, including subcellular, single neuron, neural circuits and populations of neurons, functional brain regions, and ultimately behavior. The primary conversation is rapidly shifting from anatomy to underlying genomic and proteomic features of diseases. Furthermore, integrated function is being studied by functional MRI, as well as electrical and magnetic source imaging, leading to efforts to directly improve neurological function as the primary goal of treatment. While this shift in focus has not entirely disenfranchised considerations of anatomy, neurosurgery's voice in the dialogue has most definitely been joined by that of many other disciplines, even related to traditionally "neurosurgical" diseases. Perhaps even more importantly, the increasing knowledge of the nervous system diseases and potential to treat functional disorders is now poised to dramatically shift the entire attention of the clinical neuroscience world. Consider for example the direct and indirect costs associated with Alzheimer's disease as the world's population ages, autism, depression, post-traumatic stress disorder that costs the lives of multiple American veterans a day, and the increasing focus on mild traumatic brain best highlighted by recent discussions on American football. What role will neurosurgery play in the treatment of these diseases?

For a large part of its evolution, neurosurgery has been successful in controlling the treatment of specific disease entities, leaving the bulk of other diseases to neurologist and psychiatrists. This has had the effect of minimizing competition from other disciplines for patients, as well as reducing unfavorable and unsympathetic oversight. However, dramatic changes are evident in how physicians are organized to treat diseases. In contrast to the traditional paradigm of individual physicians treating patients, many disease entities are now being treated by multidisciplinary teams of specialists. In many modern centers, patients with neurovascular diseases are managed by the cerebrovascular and stroke services that comprise of neurosurgeons, neurologists, intensivists, and radiologists. Epilepsy and functional neurosurgery programs are organized in much the same way, as are neuro-oncology programs. In other cases, non-neurosurgeons can now offer competing treatments for our patients. Orthopedic surgeons have competed for spine patients for decades, but this phenomenon is also evident in endovascular, where neurologists now comprise a large percentage of new trainees in neurointerventional techniques. In profound ways, developments in stereotactic radiosurgery have changed the flow of brain tumor patients, with modern frameless methods allowing radiation oncologists to treat patients without neurosurgical input, using technology originally developed by neurosurgeons. In many hospitals, the flow of patients in the neuro ICU has also shifted, with neurocritical care neurologists playing a central role in hospital transfers. Perhaps most importantly, the electronic health records that are becoming required in the United States are making the individual and composite outcomes of neurosurgeons transparent for evaluation, with far-reaching implications. While many of these forces contribute to improve the care of neurological patients and thus should be celebrated by physicians worldwide, they nonetheless combine to undermine the autonomy enjoyed by neurosurgery.

Traditionally, neurosurgery has been important to the business of medicine in ways that belies the size of our specialty. Most of our diagnostic studies are costly. Many of our patients require ICU care. The mere availability of neurosurgical services is indispensable for the success of other medical specialties in the care of trauma patients. Furthermore, our surgeries are very much driven by technology, resulting in tremendous opportunity for intellectual-properties focused business development. Certainly in North America and in many other parts of the world, this financial relevance has held neurosurgery in good stead. Even this is poised to change. Consider spine surgery, for example, where intellectual-property driven development has had a major financial effect on neurosurgery. Indeed, the development of spinal instrumentation and techniques in collaboration with industry is viewed by many as one of the success stories in our field. As many of these patents expire, hospitals are now engaging in major supply-chain control efforts, where generic products may have almost all the features of brand-name products for far less cost, at least in the eyes of hospital administration. Endovascular neurosurgery has also experienced similar influences and may ultimately need to address the same considerations. Perhaps even more importantly, what is the role of neurosurgery in capitated healthcare delivery models, where our impact may have greater immediate relevance in discussions related to cost? Will we continue to enjoy the unmitigated support of hospitals, health systems, and the medical economy?

To face the challenges inherent to our discipline, neurosurgery has relied upon the incomparable esprit-de-corps that holds together neurosurgeons world-wide. This is reflected in the sheer number of neurosurgical societies, organizations, and associations in the world. The selection process to gain entry into the field as well as the arduous and lengthy training programs all serve to create a unique bond and kinship in neurosurgeons globally. This has created a most cohesive medical fraternity, with virtually all neurosurgeons proud to consider themselves a member of this elite group. However, the past decade has witnessed a transformation in the nature of neurosurgery residency training in the United States. Many countries in Western Europe experienced these changes even earlier. Resident work-hour regulations have required the increased reliance on physician extenders, and the sense of ownership of patients is arguably less among current residents. While residency training governing bodies have reacted very effectively to these new considerations, and residency education is perhaps more structured and effective than ever, there is nevertheless a philosophical and generational gap that exists between neurosurgeons trained prior to these regulations and those trained under contemporary circumstances. In modern practice in the United States, more and more neurosurgeons are working as hospital employees, a development that may further erode our personal equity ownership of our activities.

While all of these developments seem to bode poorly for neurosurgery's future, these winds of change may ultimately represent tremendous opportunity. Most in leadership positions in our discipline recognize the plateau that has characterized the state of neurosurgery following the amazingly productive period catalyzed by the operating microscope and advanced imaging. These two developments have combined to enable the establishment of modern microsurgery and minimally invasive techniques found ubiquitously in the world. Without a doubt, neurosurgery continues to attract singularly talented young doctors, the lifeblood of any discipline and the envy of virtually all of the other medical specialties. In addition, the training and practice of neurosurgery by its very nature endows the neurosurgeon with skills to conquer unique challenges with discipline and creativity. In this consideration, our core strength is shifting from our technical abilities to our intellectual and personal qualities. Recognizing this with appropriate shifts in emphasis, the field of neurosurgery may find even greater relevance in the new landscape of medicine.

The key to this escalation of relevance, of course, lies in the direction and choices we make. For example, as the conversation surrounding clinical neurosciences shifts from anatomy to function, neurosurgery has played a singular role historically in the restoration of function. The correlation of function to anatomy has truly been one of our greatest contributions to the world. Even today, the gold standard for identifying functional regions in the nervous system continues to be direct electrophysiological recordings, and neurosurgeons are the only physicians that are in position to perform such recordings in human beings. The application of an external force to improve nervous system function through neuromodulation is uniquely neurosurgical. Indeed, the targets and indications for neuromodulation are increasing rapidly in the cerebral cortex, deep brain structures, as well as in the spinal cord and peripheral nervous system. Unlike many neurosurgical procedures, neuromodulation treatments are all driven by Class I data generated by clinical trials and successfully traversing the regulatory process. However, conventional thinking must be challenged to overcome clear bottlenecks to widespread acceptance of concepts with demonstrated value. For example, if we are to adhere to the strict definition of neuromodulation to require application of electrical forces through an invasive electrode, we would miss the potential of noninvasive strategies for neuromodulation offered by transcranial magnetic stimulation, or focused ultrasound. There is no doubt that the invasive nature of current strategies poses a significant barrier with regard to patient choice, as well as to the future development of neuromodulation concepts, particularly in the harsh regulatory environment of medical devices. Importantly, neurosurgeons must embrace a much broader definition of what is considered neurosurgery, with scope to include the application of any external influence to the nervous system for therapeutic effect, however delivered.

Neurosurgery can indeed play an increased role the evolution of clinical neurosciences, particularly as transformative technologies are developed to restore neurological function as a primary goal of treatment, and strategies are developed to address the overwhelming burden of neurological disease that fall outside the traditional scope of neurosurgery. From genesis of concept to widespread utility in treating patients, a well-defined progression is necessary that can perhaps be considered to fall into three successive phases. The first phase requires a new idea or discovery to be generated, typically in the laboratories of our universities or in the minds of transformative thinkers in the non-academic sector. Ideally, the neurosurgeon plays a significant role in the development of the concept in collaboration with scientists and engineers to contribute the important perspective of patient need and indication. Proof of concept involves the sequential progression from in-vitro studies to engineering a prototype for in-vivo demonstrations in an animal model, in some cases, non-human primates, a highly expensive proposition made even less palatable due to the absense of plans for ultimately treating the non-human primate. Successful demonstration in non-human primates does not obviate the necessity of similar studies in human beings, where even greater costs and regulation are expected. One way for neurosurgery to contribute to this bottleneck may be to take advantage of sequential “early-into-humans” opportunities presented in the course of our standard-of-care treatment of patients. An example may be the use of electrode grids for invasive EEG monitoring in epilepsy surgery for electrocorticograpy based brain machine interface studies. In this way, no additional risk is undertaken by the patient other than in the standard-of-care treatment of epilepsy. With strict oversight of the process in the interest of patient safety, this may allow for the sequential, low-risk development of concepts directly in humans in a process that cannot proceed without the neurosurgeon.

The second phase after a human prototype is developed requires a large-scale clinical trial and navigating the regulatory process. In this phase, partnerships between academic, government, and private sector entities are critical, where the combined expertise and resources of each may be synergized. Typically, over $200 million and over a decade time may be necessary to bring a prototype to FDA approval in the United States. Clearly, a transparent collaboration that engenders society’s trust is necessary to overcome this daunting barrier.

The final phase to bring a new transformative technology or treatment to patients requires effective engagement of the disparate health systems found in the United States and all over the world. For neurosurgeons to have influence in this process, it is necessary for our direct participation in the administrative structures of public and private sector health systems, as well as in government and industry. The heterogeneity of advanced care is grossly evident in public and private sector hospitals, urban and rural environments, as well as academic and community centers. The ultimate impact of any transformative technology depends entirely on its widespread deployment and availability, an arena that requires influence by neurosurgeons in the political and administrative realm.

In sum, despite the tremendous changes that characterize the evolution of medicine world-wide, neurosurgery remains well-positioned to flourish with ever-increasing relevance. However, the field itself must evolve as well, in ways that may seem counterintuitive to conventional considerations.

Charles Y. Liu, MD, PhD
Apuzzo Professorship for Advanced Neurosurgery
Professor of Neurosurgery, Neurology, and Biomedical Engineering
Director, USC Neurorestoration Center
Surgical Director, USC Comprehensive Epilepsy Center
Keck School of Medicine and Viterbi School of Engineering
University of Southern California
And
Chairman, Department of Neurosurgery and Orthopedic Surgery
Associate Chief Medical Officer
Rancho Los Amigos National Rehabilitation Center
And
Visiting Associate
Division of Biology and Biological Engineering
California Institute of Technology

ACCEPTED MANUSCRIPT