Opinion: Role of Modern Neurosurgeon in Medical Device Development

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The field of neurosurgery is deeply integrated with, and highly dependent on, medical device development to facilitate surgical technical success and improvements in patient outcomes. As such, neurosurgeons are uniquely positioned at the interface of technologic breakthrough and clinical medicine to adopt and translate academic innovations into real-world solutions affecting patient care. Over the years, collaboration among neurosurgeons, translational researchers, and members of the medical device industry has stimulated the development of groundbreaking neurosurgical devices, improving neurosurgical care worldwide.

Neurosurgeons are vital to the medical device innovation process. Although a minority of neurosurgeons have disclosed patent protection over a medical device,[1] all surgeons use devices of varying technologic complexity throughout their daily clinical practice, from elemental electrocautery to advanced intraoperative augmented reality platforms. This practical clinical experience is fundamental for medical device development, making clinician feedback a basic tenet of device innovation. Neurosurgeons, in particular, have essential background knowledge of normal anatomy and physiology and further understand how pathologic changes can distort the expected. Perhaps more importantly, as tactile practitioners, surgeons know how a medical device should interact with tissue and can offer invaluable feedback on early-stage device ergonomics. Given that this knowledge is accumulated and refined over decades of training, neurosurgeons are uniquely posed to leverage their experience for the benefit of medical device development and, ultimately, for improvements in patient care.

To affect medical device development, however, requires a basic understanding of the classic biodesign engineering process.[2] In general, once a clinical need is openly defined and market research identifies a potential gap, ideation and innovation begin. This is initially a divergent process, through which many potential solutions are identified and loosely designed. Then, by incorporating feedback between clinicians and engineers, these solutions are optimized in a converging process to bring about narrowly defined conceptual prototypes. Once a final prototype is engineered, individual device components are defined and iterated to enhance device efficiency. This is an ongoing process that lasts though clinical trial and implementation and requires constant feedback between user (surgeon) and engineer (**Figure 1**). The biodesign model considers many practical aspects of medical device development including material selection, manufacture, sterilization, packaging, and distribution. Concurrently, device innovators must also pursue intellectual property protection and clinical regulatory clearance (see **Table 1** for an overview of device classification in the United States). Given its inherent, necessary complexity, medical device development is an expensive, time-consuming process; survey data of medical device companies suggest costs of up to $31 million and 31 months spent before U.S. Food and Drug Administration 510(k) approval of class II devices and up to $94 million and 54 months spent before U.S. Food and Drug Administration premarket approval of high-risk, class III devices.[3]

The neurosurgical device industry, encompassing devices for open surgical, endovascular, neurostimulation, and neurointensive care purposes, generated over $3.8 billion in revenue in 2016 and is projected to grow to $5.6 billion annually by 2023.[4] Given this, it is important to consider who are the targeted consumers of these medical devices: hospitals or practices that make the direct purchase from manufacturer, surgeons who use the device in the clinical setting, or patients who ultimately benefit from device implementation. At a fundamental level, medical devices are designed to improve patient outcomes; however, the ultimate consumers of medical device technology are the surgeons. Consider the patient's perspective: he or she does not decide which brand of deep brain stimulation electrode to have implanted for Parkinson tremor. Rather, the patient inherently trusts the surgeon's experience to dictate device selection. As the surgeon, therefore, a decision should be empirically made using evidence-based, rather than emotional, standards. Often, if clinical outcomes between similar (competitor) devices are equivocal, ergonomic factors such as surgeon comfort and ease of device use are major decision characteristics. Given these observations, several important considerations should be inferred. First, on behalf of their patients, surgeons should perform due diligence for all medical devices used including indications, intended uses, risks, and alternatives. Second, as the targeted consumers of novel medical device technology, surgeons should be skeptical of medical device sales tactics and rely on empiric evidence rather than emotional reactivity for clinical use decision making. Lastly, if novel device data truly suggest equipoise with a predicate device, ergonomic factors can and should be used to make decisions regarding device adoption and implementation.

The relationship between surgeon and industry is fundamental in driving the development of neurosurgical devices. Whereas manufacturers rely on surgeons to define clinical needs, provide device feedback, and perform clinical research, surgeons depend on medical device corporations to push novel innovations through academic, regulatory, and legal hurdles. These interdependencies are the basis of a lucrative mutual relationship: according to analysis of Physician Payments Sunshine Act data, medical drug and device manufacturers paid over $99 million to neurosurgeons in 2015 alone.[5] Three quarters of this amount comes in the form of royalties and licensing, suggesting that neurosurgeons are highly influential in medical device innovation, feedback, and commercialization.

Neurosurgeons have the privilege to innovate medical devices and ultimately bridge the divide between concept and reality. As

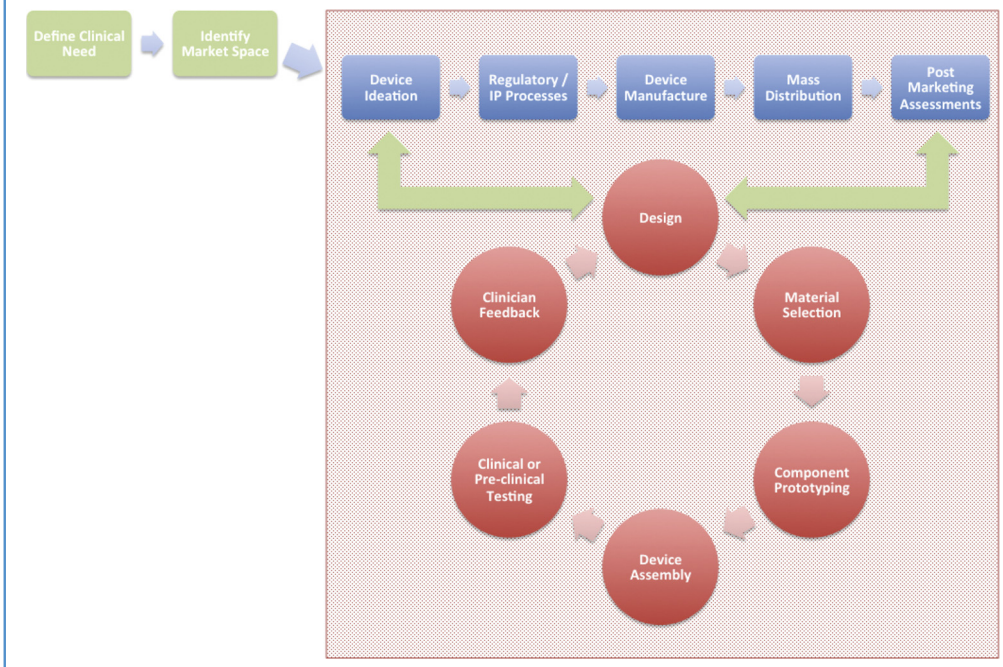

Figure 1. Schematic representation of the medical device development process. Once a clinical need and an open market opportunity have been identified, the innovative process begins. The biodesign process uses an iterative, cyclical, and feedback-driven mechanism, compiling input from both conceptual designers and practicing clinicians. This process occurs contemporaneously with other logistical device development requirements, such as regulatory approval, intellectual property protection, and mass manufacture and distribution. After device distribution, postmarket assessments of safety and efficacy are also essential for device improvement.

practitioners in the surgical arena, it is the surgeons who understand how and when to implement medical devices in order to affect patient outcomes. Further, they can intuit ergonomic characteristics that can lead to more widespread clinical adoption. Lastly, given the relatively small neurosurgical community, a device's commercial success may depend on the support of a small cohort of decisive clinical researchers and outspoken activists. Thus as influencers of medical device design and development, neurosurgeons have a distinct duty to participate in this process on behalf of their patients. Given their unique background knowledge, tactile clinical experience, and close industry relationships, neurosurgeons can advocate for medical device improvement at any stage, from idea conception to prototype iteration to postmarket safety evaluation. And, ultimately, at each stage of this device innovation lifecycle, the patients' best interests should be considered paramount.

Table 1. General Overview of U.S. Food and Drug Administration Medical Device Classification

Class	Risk	Example	Approval	Evidence
I	Low	Gauze head bandage	None	None
II	Moderate	Surgical retractor	510(k)	Substantial equivalence with predicate device
III	High	Implanted neurostimulator electrode	PMA	Primary scientific evidence
HDE	N/A	Deep brain stimulation for obsessive compulsive disorder	HDE	N/A

HDE, Humanitarian device exemption; PMA, premarket approval.

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