Prospectus

Spinal Phantom Development

(Technical Topic)

The Analysis of the Adoption of Medical Device Technology in the United States of America

(STS Topic)

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Introduction

Learning a new clinical device is a challenge for any practitioner. In the case of spinal anesthesia injection, clinicians physically manipulate a patient's back to find the injection point. Currently, obstetric neuraxial analgesia shows a 12% failure rate with an overall catheter replacement rate of 7.1% with 1.9% experiencing multiple replacements (Pan, Bogard, & Owen, 2004). Since epidurals are primarily given during active labor, the time at which the patient is experiencing regular and intense contractions, any time spent relocating the catheter equates to more patient pain. Rivanna Medical, a local Charlottesville designer, manufacturer, and distributer of medical technologies, manufactures a handheld ultrasound device, named the Accuro, to increase precision during injection point identification. The adjustment from manual search to technology-assisted search, an entirely new procedure, requires a training device known as a lumbar spinal phantom to allow doctors to practice before using it on patients. Contemporary commercial spinal phantoms do not have the ability to self-heal, leading to unfavorable outcomes that limit clinician's time, money, and energy. The development of a novel lumbar spinal phantom to complement Rivanna Medical's Accuro device, the aim of technical project, will deliver superior performance when training clinicians to administer spinal anesthesia, ultimately innovating medical technologies. However, a technical solution alone is insufficient to adopt novel medical device technology because it does not fully address the social aspects, such as the medical institutions' modes of control and patient feedback that consequently affect the integration of medical devices.

Currently, the United States remains the largest medical device market in the world with a market size around $156 billion ("Medical Technology Industry Spotlight | SelectUSA.gov," n.d.). The medical technology industry consists of articles, instruments, and machines that are used

in the prevention diagnosis or treatment of illness or for detecting, measuring, restoring, or modifying the structure or function of the body for some health purpose. The process for introducing a medical device to the market requires an understanding of the classification, premarket preparation and submission to the Food and Drug Administration (FDA) who regulate the sale of medical device products in the U.S. and monitors the safety of all regulated medical products. There exist five steps for approval. First, the device must be classified. Class is based on the risk to the patient or user, intended use, and indications for use. Class I devices pose the lowest risk and are subject to general controls. Class II devices illustrate moderate risk and will require special controls in addition to general one. Class III, or high-risk devices require premarket approval. The second step is the identification of the correct premarket submission. Submissions include the 510(k) Premarket Notification, Premarket Approval Application (PMA), Humanitarian Device Exemption (HDE), and the De Novo Evaluation of Automatic Class III Designation. The third step, or preparation for premarket submission, includes collecting design controls, non-clinical testing, clinical evidence, and collecting any other information that must be included in the premarket submission. Next, the submission takes place for the FDA to conduct an administrative review to determine if the submission is sufficiently complete. Finally, the device's establishment must be registered after the premarket approval is granted ("Bringing Medical Devices to Market in the U.S.," n.d.). The FDA utilizes post-market surveillance to monitor performance of medical devices after they enter the market, specifically focusing on device safety and effectiveness. Even with FDA approval and a position in the medical device market, society's successful adoption of a novel medical device design is dependent on the advantage of its superior technology and the dynamic relationship between medical professionals, manufacturers, regulators, and patients.

To resolve this issue, a solution that considers both technical and social factors is necessary to address the evolution of medical technology and to highlight the way in which advanced medical devices are accepted and integrated in the United States.

Technical Component

Many clinical advancements in recent years have come from new devices or techniques which doctor adopt in order to improve patient outcomes. Learning a new clinical device or technique is a challenge for any practitioner, and Rivanna Medical's handheld ultrasound device, the Accuro, is no exception. The technique that the device replaces is the physical manipulation of a patient's spine in order to find an appropriate injection point. The jump from manual search to technology-assisted search is an entirely new procedure, requiring a training device to allow doctors to practice before conducting Accuro-guided spinal injections on patients. The objective of the technical project is to complete the formulation, testing, and commercialization of a training device to function as complement to Rivanna Medical's ultrasound device.

Due to the location and the nature of the procedure, the training device needs to be a lumbar spinal phantom. A phantom is an artificial device that mimics human tissue for the purpose of imaging and clinical transition ("What are Imaging Phantoms? | NIST," n.d.). In order to allow doctors to progress from the injection point search to removing the needle, the technical project will create an in-house lumbar spinal phantom for Rivanna Medical.

Currently, Rivanna Medical packages their device with a commercially available spinal phantom. However, this commercial phantom and other contemporary commercial spinal phantoms have specific issues which limit their usage with Rivanna's Accuro device. The first is the phantom's inability to self-heal. Self-healing is defined as a material's ability to automatically form new bonds when old bonds are broken due to some injury of the material,

without human intervention. The lack of self-healing in current phantoms cause unfavorable outcomes. First, the phantom accumulates needle tracks as multiple clinicians practice the procedure multiple times on the device. This is a problem because as the phantom is used, the accumulating needle tracks could interfere with the Accuro's spinal identification algorithms. The potentially mistargeted algorithms could discourage clinicians from using the device as they perceive it to be ineffective at identifying the correct injection location. The accumulation of needle tracks also limits the longevity of the phantoms, as they will have to be replaced when tracks consistently interfere with device training. Also, many phantoms have water in their chemical bond structure, which leads to a phantom to dry out over time, limiting their longevity further.

The problems with currently available commercial phantoms demonstrate the need to develop an improved, customized phantom for Rivanna Medical. The technical project will focus on the development of a novel design for a lumbar spinal phantom. This new phantom will focus on self-healing, which will be achieved through the use of a two-part polyurethane with a "filler" of terphenyl added. Polyurethane has been shown to be a promising material for self-healing applications due to its inherent "shape memory" property, which allows it to be close to the injured area, and then reform the broken bonds (Menon, Madras, & Bose, 2019). Additionally, the terphenyl has been shown to act as a hydrocarbon filler for polyurethane chains, creating bonds between the chains (United States Patent No. US6858680B2, 2005). From the combination of the two-part polyurethane and the filler, the phantom can heal at room temperature, thus qualifying it as self-healing. The two-part polyurethane does not require exposure to air to cure, thus it does not incorporate water in its chemical bond structure. This

prevents the "drying out" effect seen in current phantoms over time due to loss of air tightness or other such breaches of water vapor into the phantom (Pogue & Patterson, 2006) .

Tests will be conducted to assess the success of the spinal phantom. The self-healing properties will be assessed quantitatively and qualitatively through the use of a time-lapse camera to observe the needle-damaged area and self-healing performance over the course of 24 hours. Additionally, the ultrasonic properties will be tested quantitatively through the use of a clinical ultrasound device to compare observed distances to actual distances. The data will be used to compute the speed of sound through the phantom, which will be compared to the speed of sound through human tissue. Overall, these tests will assess the novel aspects of the phantom.

Ultimately, the goal of the technical project is the completion of the formulation, testing and commercialization of a novel lumbar spinal phantom, providing Rivanna Medical with an in-house product to complement their Accuro ultrasound device. Furthermore, the completion of the technical project will improve the longevity of spinal phantoms to be utilized by clinicians, ultimately delivering superior performance when training to administer spinal anesthesia.

STS Component

The medical device industry is an innovative and dynamic business sector ("Medical Device Industry—An overview | ScienceDirect Topics," n.d.). Developing an enormous number of products ranging from surgical gloves to artificial joints, the medical device industry plays a crucial role in developing medical technologies that can improve human health (Bergsland, Elle, & Fosse, 2014). Specifically, the device market in the United States has a relatively small number of large, diversified companies and a larger number of small companies that are mainly engaged in research and development of new devices for a focused therapeutic area. The medical industry is distinctive for its tendencies to make frequent, incremental changes to its device

products in addition to its extensive ties with physicians. All medical devices on the market are regulated by the FDA, however, the market dynamics for medical devices can vary based on device technology. Markets for conventional devices such as surgical gloves are more competitive as companies compete heavily on price and need high sales volume in order to be profitable. In contrast, markets for advanced products are more difficult to enter and are less competitive, allowing device companies to charge higher prices and earn substantial profits ("WHO | Medical Devices," n.d.). While medical professionals and the FDA still hold essential positions as users and approvers of innovative clinical methods, other participants in society's adoption process of medical devices are important. These participants include patients, health economists, government officials, insurers, and regulators, all of whom are increasingly important in identifying demands for advancing technologies as well as which devices should be integrated and adopted into mainstream health care.

To analyze the introduction of medical devices in the United States, the Theory of Technological Determinism could be applied to determine the factors that drive the FDA and medical professionals to approve and regulate medical devices in the U.S. market. Technology determinism assumes that a society's technology determines the development of its social structure and views ("Technological Determinism," n.d.). Ultimately, the theory of technological determinism will allow the reader to understand that while the purpose for engaging in biomedical innovation is imperative to introduce novel medical devices to the market, it can lead to an imbalance in power and differentiating views in healthcare. This imbalance can be described as an extreme "information asymmetry" between physician and patient which gives clinical professionals unlimited power to determine the demand for novel techniques. Specifically, factors such as clinical evidence and superior technology will be explored as

factors leading to decisions by medical professionals and the FDA. Additional factors included the quality of the device, the efficiency of the delivery, the cost of the device, the class of the device, and the sources of prestige, status, and distinction surrounding the device will be analyzed to identify potential factors impacting human interaction with a novel medical device and potential factors driving its introduction into the health care system.

To analyze the adoption of medical devices in the U.S. market, the Theory of Co-production of Science and Social Order could be used to understand the dynamic relationship between the interactions of medical devices with stakeholders, particularly medical professionals, patients, manufacturers, and regulators. Co-production of Science and Social Order focuses on the mutual constitution of technoscience and social order ("Co-production of Science and Social Order—Stswiki," 2015). This theory will allow the reader to understand the relationship between medical innovation and society, specifically the impact of a device's acceptance into health care and the impact of society on furthering medical innovation. Specifically, the analysis of patient feedback, government regulations, medical modes of control, disparities in health care opportunities, and geographic locations will be analyzed to identify potential patterns leading to the adoption or rejection of medical devices in the United States and how the society drives further development of medical technology. Thus, the introduction and adoption of medical devices into mainstream health care should be explored to understand the impact of medical device technology and society's impact on medical innovation in the United States.

Conclusion

By examining the introduction and acceptance of medical devices the United States through the lens of the Theory of Technological Determinism and the Theory of Co-production

of Science and Social Order, the understanding of society's acceptance and rejection of medical devices may be understood. The technical component will aim to develop a novel lumbar spinal phantom to improve the longevity of spinal clients and delivery superior technical performance. Additionally, the STS component will aim to uncover the social factors that allow the introduction and adoption of novel medical technology as a mainstream health solution. The combination of the technical and STS components will develop a formulation of necessary technical and social qualities to encourage medical innovation for the discovery and development of novel therapies that save and extend lives.

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