Prospectus

Self-Healing Lumbar Spinal Phantom for Clinician Training
(Technical Topic)

How the Adoption of a New Medical Device Highlights Previous Biases in Treatment
(STS Topic)

By

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Prospectus Introduction: Socio-Technical Research Problem

Clinical spinal injections are used for one of two purposes: diagnosis of the locus of pain or therapeutic delivery of treatment to alleviate pain. The location and depth of the spinal injection depends on the condition being treated. Because of this variance in delivery metrics, these injections are usually guided by imaging techniques such as x-rays or a Computer Tomography (CT) scan (Park, 2018). However, the radiation associated with x-ray and CT imaging modalities prohibits their use for needle placement guidance on pregnant women generally and in obstetric procedures. Thus, physicians manually palpate the spine in order to identify a proper injection point. Palpation involves a clinician using his or her fingers to externally identify anatomical structures in a person's body. Although this technique is used widely, it has limitations. This technique has demonstrated failure rates, back pain complication rates, and needle relocation rates as high as 12%, 20%, and 7.1%, respectively (Arendt & Segal, 2008) ("Clinical value," n.d.). Relocating the needle causes pain for the patient due to the additional injection required and, if the injection is for anesthetic purposes, causes more total pain due to a further delay in receiving pain relief. The technical solution for this problem involves creating a training device to retrain physicians and anesthesiologists to conduct ultrasound-guided injections. The novel training device, which can be imagined as a "spine-in-a-box," will allow doctors to conduct the entire injection procedure from scanning the spine to injecting and withdrawing the needle. Then the device will heal itself, without human intervention, through the use of self-healing bonds. The training device will also mimic the acoustic properties of human tissue properties and be customized to the specifications of Rivanna Medical's handheld ultrasound guidance device, the Accuro.

However, the technical solution is necessary but not sufficient to resolve the broader socio-technical problem of the adoption of a new medical device to replace a long-standing treatment approach. For the Accuro, since pregnant women represent a significant cohort of the Accuro's target market, the social aspect of the problem includes issues of sexism and bias in medicine. The status quo of manual search was maintained through a combination of ignorance and disregard for the excess pain associated with this injection guidance procedure, likely due to the bias in treatment of pain for female patients (Samulowitz, Gremyr, Eriksson, & Hensing, 2018). Contemplating these social aspects using Langdon Winner's Theory of Technological Politics provides a more complete understanding of how medical device adoption can be affected by existing biases against certain patient populations within medicine.

To address the problem of adoption of a new medical device that improves the standard of care, a solution that is both technical and social in nature is necessary. This combination will provide physicians with a novel and innovative training device that is customized to the Accuro while also exploring the manner in which a new medical device collides with and exposes biases in medical treatment.

Technical Research Problem

Many clinical advancements in recent years have come from new devices or techniques which doctors 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 Accuro allows for ultrasound-assisted identification of a proper spinal injection point using anatomy-tracking algorithms which fit anatomical structures onto the ultrasound readout. The device shows the ultrasound readout with spinal anatomy graphics superimposed, allowing a clinician to mark the appropriate injection point and proceed with

confidence. The Accuro replaces palpation, or physical manipulation of a patient's spine to find an appropriate injection point. The jump from manual search to technology-assisted search requires a training device to allow doctors to practice with the Accuro before conducting the new procedure on patients.

Currently, Rivanna packages its device with a commercially available lumbar spinal phantom. A phantom is an artificial device that mimics human tissue and other anatomical structures for the purposes of imaging and clinical training (Materese, 2018). The phantom currently packaged with the Accuro is suitable to practice any lumbar spinal injection site identification and injection procedure.

However, there are several problems with using the current commercial phantom. The first is that the phantom does not self-heal its tissue layer. Self-healing is defined as a material's ability to form new bonds when old bonds are broken due to some injury of the material without human intervention (Woodford, 2019). The lack of self-healing in the current phantom causes 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 mistargeting algorithms, malfunctioning due to external circumstances, could discourage clinicians from using the device as they may 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 the tracks consistently interfere with device training. Other currently available phantoms that have some healing ability require heat to reform the broken bonds. This means that a clinician must put the phantom in an oven to heal. This does not qualify as self-healing because it requires a user's action to heal effectively,

taking up the medical staff's time. This healing process is also cumbersome, requiring additional, expensive equipment that may not be readily available, and thus is not preferable. Also, many phantoms have water in their chemical bond structure, which leads a phantom to dry out over time, limiting their longevity further (Pogue & Patterson, 2006). The limitations of current phantoms lead to extra expenditures in equipment, increasing the cost burden of technology in healthcare. As a result, new technologies are less likely to be adopted and trained.

The solution to the technical problem of device adoption is to design a customized lumbar spinal phantom for use with Rivanna Medical's Accuro. The problems with currently available commercial phantoms demonstrate the need to develop an innovative, improved phantom. This new phantom will focus on self-healing, which will be quantitatively and qualitatively measured through the use of a time-lapse camera. Additionally, the speed of sound through the tissue will be tested and compared to the current phantom and known human tissue values. Overall, these tests will assess the novel aspects of the phantom and allow for characterization of the final product as innovative.

STS Research Problem

Medical devices are becoming more prominent worldwide as a large, aging population requires more care and new, innovative approaches to therapy and diagnosis (Depenbrok, 2019). One such device is the Accuro, manufactured by Rivanna Medical. Traditionally, imaging guidance methods such as x-rays or CT scans were used to guide practitioners, but the radiation associated with these imaging modalities prohibits their use for procedures on pregnant women (Park, 2018). Thus, physicians use manual palpation of the spine in order to identify a proper injection point. The Accuro is attempting to replace this technique through the use of ultrasound imaging, which is safe for pregnant women and fetuses. The Accuro utilizes algorithms to

analyze the raw ultrasound data, identify underlying spinal topography, and indicate whether a certain place along the spine is appropriate for injection. The doctor or anesthesiologist can then use a grooved attachment on the front of the device to imprint the patient, connect the imprints to mark the injection point, and inject the patient.

The technical aspects of the Accuro are well characterized, but the device also influences the social and political arenas. As the advantages of ultrasound-guided spinal injections for procedures on pregnant women become more apparent, more physicians are being asked to learn the new device. However, physicians are traditionally resistant to changes in their techniques, especially when the changes are mindset shifts, such as transitioning from physically locating an injection point to using a technological device to scan for an injection point (Shryock, 2018). However, to attribute the lag in adoption of new medical devices only to human psychology is to ignore the influence of sexism and other biases on physician decisions. Since the Accuro is primarily designed for use when the patient cannot safely receive radiative imaging options, pregnant women are a target patient population. This patient population is inherently female, increasingly racially diverse, and increasingly obese ("Births, by mother's race/ethnicity," n.d.) (Steele, 2018). These demographic groups have been shown to be vulnerable to clinician bias (Hoffman, Trawalter, Axt, & Oliver, 2016) (Phelan et al., 2015) (Samulowitz et al., 2018). Due to the inherently female patient population, the group is susceptible to clinician gender bias with regard to pain treatment, which is particularly relevant in considering the adoption of a device that can likely relieve pain for patients (Samulowitz et al., 2018).

To continue to think that the Accuro is only a technical device, is to discount how it demonstrates sexism and gender bias in the medical profession. To analyze the social aspects of the device, I will use Langdon Winner's Theory of Technological Politics to provide a more

complete understanding of how medical devices expose long standing biases in medicine. Technological politics concerns the inherent political dimension of technology, whether intended or unintended, which alter the power dynamics between groups of people depending on their demographics (Winner, 1980). Specifically, the example of the Accuro will be analyzed through the lens of Technological Politics in order to show how a medical device can highlight underreported biases in treatment of various patient groups.

Conclusion

This paper looks to present the technical and social solutions to the problem of the manual spinal injection procedure by creating a training device for doctors to learn a new technology while also questioning why the current procedure remained popular despite its flaws. The technical project will produce a new, improved, and customized lumbar spinal phantom that can be used as a practice device for doctors learning a new technology. The innovation of this phantom focuses around its ability to self-heal, which will make it more customized to the specific training case and increase its longevity. The STS research paper will use Technological Politics to explore the adoption of the Accuro, the device for which the training device is being created. The analysis will illuminate how a medical device innovation can highlight silent biases and discrimination in the treatment of certain patient groups. The analysis will also highlight the political implications of a device that was likely not designed to challenge preexisting gender, racial, and weight biases in medicine.

The technical project will help resolve the socio-technical problem of doctors adapting to new technology by allowing them to practice the new technique using a product designed to mimic the human patient. The findings of the STS paper will elucidate the politics between groups that influence the adoption of the new technology.

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References

Arendt, K., & Segal, S. (2008). Why epidurals do not always work. *Reviews in Obstetrics and Gynecology*, *1*(2), 49–55.

Births, by mother's race/ethnicity. (n.d.). *Kidsdata.org*. Retrieved October 30, 2019, from https://www.kidsdata.org/topic/31/births-race/table#fmt=146&loc=1&tf=84,46,8,3,13&ch=7,11,8,507,9,73,74&sortColumnId=0&sortType=asc

Clinical value. (n.d.). . Retrieved October 20, 2019, from https://rivannamedical.com/clinical-value/

Depenbrok, S. (2019, April 30). Analysts say medical devices are on the rise. *Machine Design*. Retrieved October 29, 2019, from https://www.machinedesign.com/medical/analysts-say-medical-devices-are-rise

Hoffman, K. M., Trawalter, S., Axt, J. R., & Oliver, M. N. (2016). Racial bias in pain assessment and treatment recommendations, and false beliefs about biological differences between blacks and whites. *Proceedings of the National Academy of Sciences of the United States of America*, *113*(16), 4296–4301.

Materese, R. (2018, April 19). What are imaging phantoms? *NIST*. Retrieved October 21, 2019, from https://www.nist.gov/topics/physics/what-are-imaging-phantoms

Park, D. K. (2018, August). Spinal injections. *OrthoInfo*. Retrieved October 20, 2019, from https://www.orthoinfo.org/en/treatment/spinal-injections/

Phelan, S. M., Burgess, D. J., Yeazel, M. W., Hellerstedt, W. L., Griffin, J. M., & van Ryn, M. (2015). Impact of weight bias and stigma on quality of care and outcomes for patients

with obesity. *Obesity Reviews: An Official Journal of the International Association for the Study of Obesity*, *16*(4), 319–326.

Pogue, B. W., & Patterson, M. S. (2006). Review of tissue simulating phantoms for optical spectroscopy, imaging and dosimetry. *Journal of Biomedical Optics*, *11*(4), 041102.

Samulowitz, A., Gremyr, I., Eriksson, E., & Hensing, G. (2018). "Brave men" and "emotional women": A theory-guided literature review on gender bias in health care and gendered norms towards patients with chronic pain. *Pain Research & Management*, *2018*. Retrieved October 30, 2019, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5845507/

Shryock, T. (2018, May 24). Why it's so hard for doctors to change. *Medical Economics*. Retrieved October 29, 2019, from https://www.medicaleconomics.com/article/why-it%E2%80%99s-so-hard-doctors-change

Steele, M. F. (2018). More U.S. women obese before pregnancy. *WebMD*. Retrieved October 29, 2019, from https://www.webmd.com/baby/news/20180104/more-us-women-obese-before-pregnancy

Winner, L. (1980). Do artifacts have politics? *Daedalus*, *109*(1,), 121–136.

Woodford, C. (2019, March 23). How do self-healing materials work? *Explain that Stuff*. Retrieved October 29, 2019, from http://www.explainthatstuff.com/self-healing-materials.html