THESIS PROJECT PORTFOLIO

Designing a Double-Barreled Syringe Device for Ultrasound-Guided Musculoskeletal Injections

(Technical Report)

Sterilization vs. Sustainability: Determinants of the Lifespan of Medical Devices

(STS Research Paper)

An Undergraduate Thesis

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TABLE OF CONTENTS

My thesis portfolio consists of a technical project paper and a sociotechnical research paper. My technical paper describes my group's work on our Fourth Year Capstone Project under the guidance of our advisor, Dr. Jeremy Kent, M.D. of UVA Family Medicine and UVA Athletics. We were tasked with designing a double-barreled syringe device to aid in ultrasound-guided musculoskeletal injections for athletic injuries. We iterated through several design concepts, and ultimately manufactured a prototype for a device that met the majority of our design requirements. One of these requirements was that the device would be disposable after single-use in a clinical setting. Many medical devices are single-use to preserve sterility and prevent infection among patients. My sociotechnical research paper investigates the utilization of single-use and reused devices in medical settings. The lifecycle of medical devices is regulated by the Food and Drug Administration (FDA), which affects how medical device companies manufacture their devices and establish indicated use directions for hospitals and clinicians. With patient safety at the forefront of medical decisions, environmental effects and cost are also important factors to consider when developing and using medical devices. My sociotechnical research paper explores the key participants involved in medical device use, manufacturing, and regulation, and highlights recycling solutions to preserve sterility, cost, and the environment.

In order to design a double-barreled syringe device, my group needed to understand the current processes and user needs for an improved design. This process of ultrasound-guided injections involves drawing up and injecting two disparate solutions (a local anesthetic and a steroid), while also holding an ultrasound probe. Currently, Dr. Kent and other clinicians draw up each solution into two different syringes and inject the anesthetic into the patient after attaching a needle. Then, the needle remains inside the patient, while the anesthetic syringe is swapped out

for the steroid syringe. This is very challenging for clinicians to perform, as they may only use one hand to operate the syringe while the other hand is occupied with the ultrasound probe. The current injection method causes significant discomfort for patients, and procedural inefficiency for clinicians. With the help of Dr. Kent, we determined design specifications for ergonomic factors, leakage, and intermixing. Our group developed a device to interface with existing syringes that allows solutions to be drawn up or injected from one syringe, while blocking the other. This device uses a rotating rod design, which was 3D printed using a combination of flexible resins and hard plastic resins. Overall, the device was able to meet the ergonomic design specifications, perform with minimal leakage, and achieve no intermixing of solutions.

Because medical devices, such as syringes, interface with patients, they attract microorganisms that may form biofilms on the surface of the device depending on the level of interaction between the device and human tissue. For this reason, many medical devices are single-use, especially those used internally within patients. In order to combat the environmental and financial costs of using a new device for each patient, some hospitals and medical device manufacturers are developing reuse strategies. The FDA has responded to these efforts by categorizing devices based on their level of contamination and establishing guidelines for the level of sterilization needed to reuse the device in order to provide the best care to patients. For critical devices that require the highest level of sterilization, medical device manufacturers have also considered repurposing strategies that involve recycling the device for a different application. Looking forward, in order to maintain patient safety, along with sustainability and low cost, it is essential that medical devices are classified accurately based on their material properties and use in patients in order to determine the action that can be taken after use.

Working on designing the double-barreled syringe device for my capstone project allowed me to view medical devices through the lens of a clinician and medical device manufacturing company. I am very appreciative for the opportunity to work with Dr. Kent on this project, which aided in my understanding of the clinician perspective in my thesis paper. Additionally, I used literature to better understand medical waste and potential solutions to preserve the environment, while also preventing contamination across patients. Based on the FDA's guidelines, a device such as the double-barreled syringe device could likely be reused after disinfecting, as long as a new needle was used for each patient. The device designed by my capstone group was successful in terms of meeting the needed design requirements to achieve a more comfortable and efficient device for ultrasound-guided injections. This device was intended for single-use only, however, if manufactured using more durable and antimicrobial materials, it could be developed into a reusable device to reduce cost and environmental effects using the strategies discussed in the research paper. My research paper may serve as a resource for clinicians, hospital administration, and medical device companies looking to limit the waste caused by single-use medical devices as well as cost to patients.

I would like to acknowledge Dr. Kent for his help and guidance throughout my capstone project. I am thankful for Dr. Barker, Dr. Allen, Noah Perry, and Vignesh Valaboju for all of their help throughout the technical portion of my thesis. I would also like to thank Professor Norton and Professor Wayland for their insight and support in developing my research for the sociotechnical research paper.