DESIGNING A DOUBLE-BARRELED SYRINGE DEVICE FOR ULTRASOUND-GUIDED MUSCULOSKELETAL INJECTIONS

STERILIZATION VS. SUSTAINABILITY: DETERMINANTS OF THE LIFESPAN OF MEDICAL DEVICES

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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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General Research Problem

How can novel devices be used to improve the outcomes of medical procedures?

Medical devices serve as fundamental components of healthcare around the world. With medical devices, clinicians diagnose, treat, and rehabilitate patients (PAHO, 2019). Safe and effective medical devices are not merely well suited to the particular procedure. They also cause the clinician no unnecessary discomfort (which can impair accuracy). Though devices are reliably sterile, they must not needlessly exacerbate the medical waste problem. Innovations in medical device design may also save time, space, materials, or costs.

Designing a Novel Double-Barreled Syringe Device

How can a syringe be redesigned to improve efficiency in ultrasound-guided musculoskeletal injections?

The capstone project to investigate this technical research problem is advised by Dr. Jeremy Kent of UVA Family Medicine and the Athletics Department. The team of four biomedical engineering students will develop a functional double-barreled syringe to be used to draw and inject solutions during ultrasound-guided musculoskeletal injections. Current protocol for this procedure involves the clinician drawing up one solution in a standard syringe, injecting the solution into the patient, removing the syringe, and then repeating these steps with a secondary solution and syringe. This procedure is painful for patients, and can be awkward and uncomfortable for the clinician to perform. By developing a double-barreled syringe, clinicians would be able to inject multiple solutions into a patient with only one injection site, thus reducing patient discomfort and improving procedural efficiency. The device is required to maintain separation between the solutions so they do not intermix. Additionally, the device must

deliver the appropriate amount of solution to the patient via injection, and therefore, cannot leak. The desired project outcome will be a working and clinician-approved 3D-printed syringe device.

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

In the U.S., how do healthcare professionals, hospitals, FDA, and advocacies compete to influence the standards governing the reuse, disposal, and recycling of medical materials?

Medical devices must be sterilized. The U.S. Food and Drug Administration (FDA) issues standards governing sterilization procedures, such as its Sterilization Process Controls. Hospital administrations must manage patient care within FDA standards. Participants include the University of Virginia (UVA) Health System, the American College of Obstetricians and Gynecologists (ACOG), the Alliance of Nurses for Healthy Environments (ANHE), PVC MedAlliance, Practice Greenhealth, and the Northcoast Environmental Center. To prevent contamination, 5 billion pounds of medical waste go to U.S. landfills each year (Wisniewski et al., 2020). Sterilization is a safe but expensive alternative.

Sterilization requirements vary by device and use. “Critical items” come in contact with sterile tissue, “semicritical items” come in contact with mucous membranes, and “noncritical items” contact only intact skin. Respectively, critical, semicritical, and noncritical items require sterilization, high-level disinfection, and low-level disinfection after use in a medical setting (FDA, 2018). FDA requires point-of-use processing, thorough cleaning, and disinfection or sterilization of all reused medical devices (FDA, 2015).

Many hospitals, such as the UVA Hospital, follow only limited sustainability procedures and seek more recycling and reuse to reduce waste and costs (UVA Health, n.d.). Yet reuse can

be risky. Because hospitals "face medical malpractice lawsuits when patients contract infections" in the clinic, any reused devices or materials must be properly identified and sterilized (Ottaviano, 2019). Third-party medical device repurposing services can reduce the risk of costly lawsuits, but they are expensive. UVA Hospital therefore employs some FDA-compliant in-house reuse techniques.

The UVA Hospital developed the Medical Equipment Recovery of Clean Inventory (MERCI) Program in 2007 to limit waste by promoting safe reuse of sterile equipment. According to Trena Berg, RN, who leads the MERCI Program, "70 percent of what we get goes back into the system. The hospital is the first priority but the rest we cannot use" (Stover, 2012). To save money, the hospital seeks to optimize reuse within the UVA Health System. To comply with FDA standards, however, the hospital must re-sterilize medical devices that have been opened even if they have not been used. Yet the hospital can reuse such devices in the non-clinical medical training of medical and nursing students. According to Berg, within the hospital "some products are re-sterilized, but in many cases, U.S. manufacturers won't stand behind re-sterilized products or the FDA won't allow those products to be reused" (Stover, 2012). The MERCI Program seeks users for these devices, typically among hospitals abroad that are not subject to FDA regulations or comparable standards.

Clinicians and patients often oppose reuse policies. Many clinicians choose single-use plastics for procedural ease and to save time. Devices that will be used again must be handled with care and organized for sterilization and storage. Clinicians prefer to know when they are given a device that has been sterilized and repurposed so they can plan their procedure accordingly (ACOG, 2012). Some clinicians are willing to compromise procedural efficiency to reduce waste. ANHE works to "provide [their] patients, communities, families and children with

a safe and healthy future" (ANHE, 2017). ANHE represents nurses who consider the climate emergency a public health crisis that "threatens cardiac and respiratory health" and that may affect food and water supplies (ANHE, 2017). It is committed to reducing medical waste.

Advocacy groups such as Practice Greenhealth are promoting sustainability in healthcare by aiding health systems in reducing their total waste volume. Third-party medical device reprocessors such as Practice Greenhealth prepare plastic devices for safe reuse. According to Kaeleigh Sheehan of Practice Greenhealth, health systems "can't continue to landfill and incinerate without considering the ripple effects" (Healey and Sheehan, 2020).

Environmental advocacies have also demanded that hospitals reduce medical waste. The Northcoast Environmental Center claims that "contrary to what the plastics industry says, single-use isn't safer" for medical procedures (Griffith, 2020). Responding to the surge in medical waste from the COVID-19 pandemic, it contends that the plastics industry is taking advantage of the public's fear of the virus to promote its product. Plastics industry groups, such as the PVCMed Alliance, claim that "COVID-19 has highlighted the crucial role played by single-use plastic medical devices in the prevention and control of infection in hospitals" (Sparrow, 2021). PVCMed Alliance, based in Europe, is a member of the European Council of Vinyl Manufacturers. On behalf of medical plastics companies, this trade association promotes single-use medical devices as necessities to prevent the spread of disease. Instead of reuse policies, PVCMed Alliance favors development of more recyclable plastics, such as recyclable polyvinyl chloride (PVC). Though PVC has been controversial for its toxicity and poor recyclability, PVCMed Alliance defends the plastic, arguing that it has "undergone strict regulatory review by many government and independent health agencies around the world"

(PVCMedAlliance, n.d.). PVCMed Alliance contends that recyclable, single-use PVC can safely reduce waste, and uses this claim to deter reuse policies.

In collaboration with ANHE, researchers have studied medical waste's implications for greenhouse gas emissions (Kleber & Cohen, 2020). Device sorting, equipment nurses, and other techniques affect waste volumes. Kleber and Cohen (2020) argue that since nurses manage medical devices, they can serve as environmental liaisons in hospitals and clinics.

In a study of the effects of FDA, clinicians, and patients on device reuse, reprocessing, repair, repurposing, and recycling, MacNeill et al. (2020) found that multi-use medical devices may improve healthcare and associated costs (MacNeill et al., 2020). Whatever becomes the preferred method of medical device use and disposal, to best serve patients it must neither compromise sterilization nor unduly inconvenience personnel.

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