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

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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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Introduction

On average, each bed in a hospital produces more than 29 pounds of waste per day (Practice Greenhealth, 2020). Due to safety restrictions, healthcare facilities participate in limited recycling and reuse programs, resulting in over five billion pounds of medical waste being added to landfills each year (HERC, 2015). Technology has been developed to turn hazardous medical waste into sterile waste that can be recycled or reused, however this poses economic impacts to hospitals and clinicians. In 2020, the U.S. spent $4.1 trillion on healthcare, approximately 5% of which came from medical device costs (CMS, 2020). The costs of healthcare with respect to sustainability may be viewed as a double-edged sword. One on side, disposing of medical devices after only one use can be economically wasteful. On the other side, investing in sterilization technology may cause a significant increase in healthcare costs.

Patients and clinicians have also responded to reuse efforts with uncertainty over its safety in comparison to single-use devices. Finding a middle-ground between discarding all medical materials and reusing supplies where appropriate will be essential for patient safety and environmental preservation. This paper will study various reuse strategies for medical devices in order to understand whether or not they pose a safety threat to patients. Actor Network Theory will be used to analyze the relationships between the Food and Drug Administration (FDA), medical device companies, microorganisms, patients, hospitals, insurance companies, and physicians. This analysis may inform regulations regarding the reuse of medical devices to reduce waste accumulated by single-use medical devices while also prioritizing human health.

History of Medical Device Life Cycle

As medicine has advanced over the past 100 years and hospitals have become more sterile, medical waste has increased significantly. The transition to single-use plastics did not originally begin as an effort to improve hygiene, but rather a push by clinicians for procedural convenience. Beginning in the 1970s, items such as syringes, blood bags, and tubing transitioned into single-use devices in hospitals in the United States. By the 1990s the list of single-use devices expanded and became common practice in most developed countries. It was found during this time that using new medical devices for each patient decreased contamination and improved overall health and hygiene in the hospital. Now in the 21st century, these single-use devices have proven to contribute negatively to environmental waste (Figure 1) (Hodges, 2017).

Because of increased environmental awareness, healthcare facilities have attempted various methods to maintain the high standard of health brought by the single-use devices, while also decreasing environmental impact. The primary strategies for recycling and reuse of medical materials are manufacturing devices with degradable materials, sterilizing devices in-hospital, separating materials after use, and utilizing third-party recycling (WasteCare Corporation, n.d.). These sterilization processes may be costly, however, which is not sustainable for patients to be able to afford.

The medical device life cycle is regulated by the FDA, and any type of device reuse or sterilization is subject to FDA oversight as well. The FDA classifies medical devices according to their safety for reuse and recycling. Items that are considered "critical" come in contact with sterile tissue, whereas "semicritical" items come in contact with mucous membranes, and "noncritical items" contact only intact skin. Respectively, these critical, semicritical, and noncritical items require sterilization, high-level disinfection, and low-level disinfection after use in a medical

setting (Health, 2019). Because of the time and resources it takes to perform these cleaning processes, many devices used in medical settings are single-use.

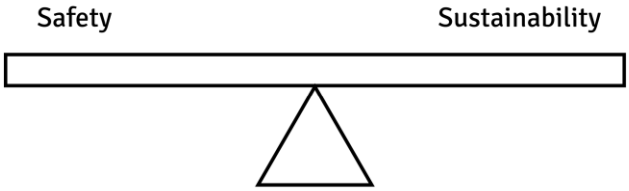

Figure 1. A balance must be struck between safety and sustainability for the future of medical devices. In order for medical devices to be effective, they must satisfy safety requirements and protect public health. However, sustainability must also be considered in order to preserve the environment, which is currently being negatively impacted by medical waste (Johner Institute, n.d.).

Actor Network Theory

Medical device use and reuse involves many human and nonhuman actors that contribute to the strategies employed in healthcare. The actors all contribute to the behavior of one another, with the FDA serving as a primary actor due to their legally-determined regulatory role. Within the lens of Actor Network Theory, this role is known as interessement where negotiations occur with other actors to determine the roles they play within the network (Figure 2) (Latour, 1996).

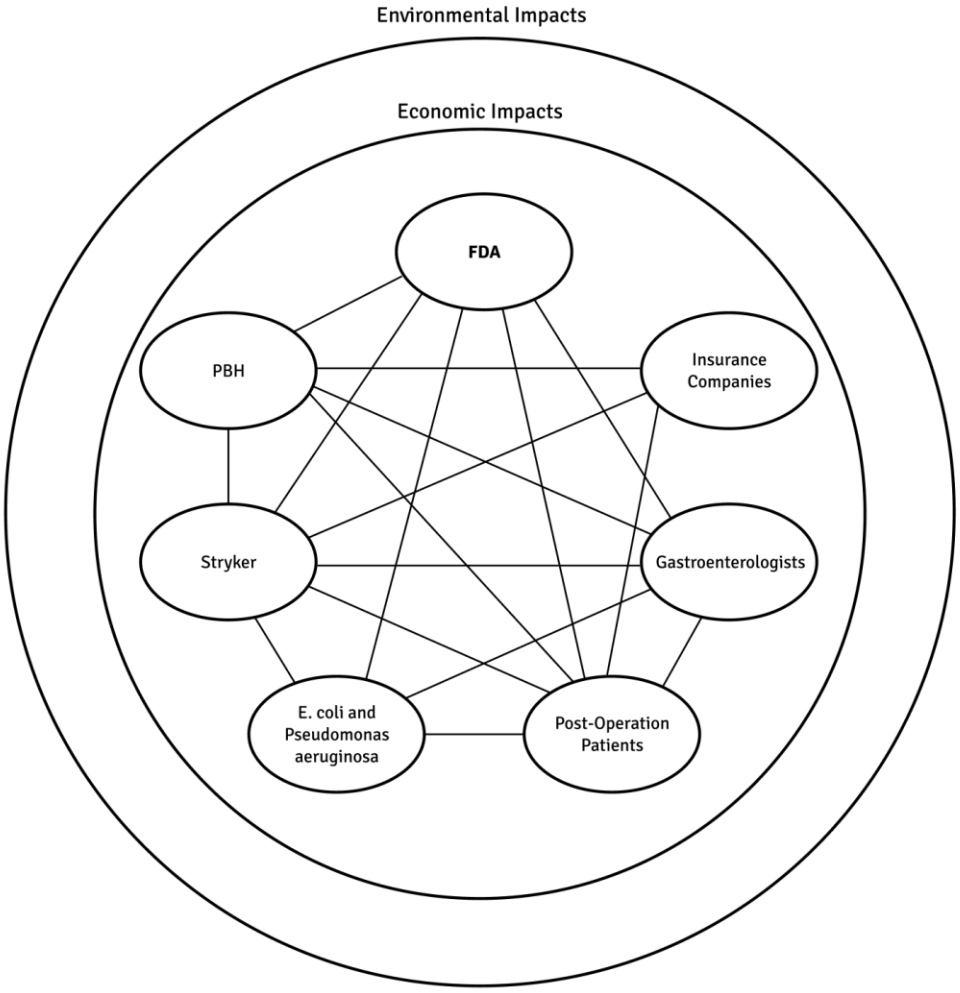

Figure 2. This figure demonstrates the relationships between the actors involved in medical device use and reuse. The FDA's position at the top of the network is due to its interessement. The FDA serves as the regulatory body overseeing the use of medical devices, so healthcare providers, patients, and device companies are all influenced by its regulations. The FDA is influenced by its goal to keep patients safe and limit contamination. All of these internal relationships must also consider the economic and environmental impacts of their actions. Reusing medical devices reduces the amount of waste involved in the healthcare system, but depending on the device and the materials required for successful reuse, financial considerations could change positively or negatively.

The FDA oversees sterilization in medical care in order to enhance the health and well-being of all Americans. As a government agency, the FDA imposes regulations to keep patients safe. These regulations often need to be adjusted based on new scientific information, as well as

political and social factors. Because the FDA seeks to regulate clinicians, hospitals, medical device companies, and others, their role is largely based on interessement. The behavior of all other actors changes with rules imposed by the FDA, who may be prompted to make changes in regulations based on instability among the actor system. The FDA has successfully achieved enrollment if the other actors accept the regulations.

Medical device companies design and manufacture the devices being used on patients by clinicians in healthcare facilities. These companies must undergo FDA regulations in order for their device to be commercialized, and it must be useful to the patients and clinicians in order for it to be successful in making a profit. These devices can improve the lives of patients, but also negatively impact the environment in the case of single-use devices. The medical device companies must aim to reduce contaminants on their devices, as high rates of contamination make the device unusable by patients. Microorganism contaminants mobilize the companies to implement material adjustments and quality assurance in order to keep patients safe. Most companies also need pushback from the public in order to mobilize with respect to environmental impacts.

The microorganisms that contaminate medical devices require the FDA to make regulations which the hospitals, clinicians, and medical device companies must act upon because they may infect patients. Their durability on the device surface affects how the regulations manifest (i.e. simple cleaning, disinfection, full sterilization). Microorganisms such as bacteria, viruses, and fungi may contaminate medical devices that have been in contact with humans. These pathogens form “biofilms” on medical devices when groups of bacteria colonize on the device’s surface. Prior to the 1980s, medical devices were made with only metal, glass, or rubber, which are easily sanitized. Since then, medical devices made with plastics, intricate designs, and flexible properties

have been used more frequently, as they are more effective for procedural outcomes. Medical devices are made to be biocompatible, meaning they are manufactured using materials and chemical properties that will not harm patients' tissues or the healthy bacteria in their bodies. This also means these intricate plastic devices serve as suitable environments for microorganisms to create a biofilm, which can cause infection if the pathogens interact with another human (Josephs-Spaulding & Singh, 2021). These infections pose health risks to patients, as well as the clinicians interacting with the devices. The most common type of microorganism contaminating medical devices is Staphylococcus epidermidis. This type of infection results from implantation of medical devices such as cardiac and orthopedic devices. Nearly 20% of patients with implanted cardiac devices are infected with the bacteria, which can cause skin irritation, pain, and possibly life-threatening sepsis (Lee & Anjum, 2022). Because of these risks, medical device companies must work to make their devices resistant to harmful microorganisms or find drugs to combat infections. This has become increasingly difficult in the past several decades, as multidrug-resistant (MDR) bacteria have emerged. Microorganisms evolve after being exposed to antibiotics if the entire biofilm or colony is not eliminated, creating resistance to future drug use (Josephs-Spaulding & Singh, 2021). Therefore, the microorganisms themselves change in response to the actions made by medical device companies and their device properties, along with physicians and their drug prescriptions for patients.

The public is divided into supporters of single-use devices and opponents of single-use devices in the medical device industry. The supporters value sterility and hygiene in medical settings, while the opponents value reducing waste. Since members of the public receive medical care, they are directly impacted by the devices being used for their care, along with the microorganisms that may contaminate the devices. These actors indirectly influence the FDA's

regulations via advocacy groups and legislators. As patients, the public is also impacted by the decisions the FDA makes in regard to devices.

Hospitals serve the public by employing clinicians and purchasing medical devices to provide healthcare to those who are sick. The hospital administration focuses largely on cost to their organization and to the patients deciding to receive care at the facility. They must provide valuable care to the patients in order to be successful, while also adhering to FDA and other regulations for safety. This success is largely measured by profit and patient outcomes. Patients pay hospitals out of pocket or via insurance companies for quality care. Health insurance companies and Medicare place pressure on hospitals to decrease the costs of care, including the cost of medical devices used on patients (Carey, n.d.). On the other hand, hospitals must pay clinicians and medical device companies. They may choose which of these actors to pay based on their adherence to regulations and public support. Hospitals may be liable for infections caused by unclean medical devices, which may hurt them financially, legally, and among public opinion.

While clinicians are also members of the public, their primary role in the network is to use medical devices on patients, while preventing contamination. They must adhere to the guidelines set by the hospital (based on FDA regulations), and are experts in using medical devices. Clinicians value procedural efficiency, so it is often preferred for them to use single-use devices, rather than spend time cleaning devices. As members of the public, however, many clinicians are willing to take extra steps in order to preserve the environment and protect their patients' pockets.

Methods

Two cases will be explored to demonstrate the relationship between devices' impacts on patients, as well as the environment. These cases show the role played by actors, such as the FDA, hospital administrations, and manufacturing companies, along with how they impact the lifecycle of medical devices. Sustainability in both an environmental and financial sense is essential to preserve public health. Actor Network Theory describes the interconnectivity between the healthcare actors and how all of their actions contribute to the environment and the economy.

Case 1: Duodenoscope Repurposing Case

Duodenoscopes are flexible, lighted tubes used to visualize the abdominal anatomy during endoscopic retrograde cholangiopancreatography (ERCP). ERCPs consist of inserting an endoscope down the throat and into the pancreas and bile ducts. Dye is injected so the ducts can be visualized via X-ray, and any strictures, blockages, or abnormal cells can be found. Based on this imaging, gastroenterologists can diagnose and treat conditions such as gallstones, inflamed gallbladders, bile duct blockages, pancreatitis, and pancreatic cancer (*ERCP*, n.d.). Approximately 500,000 ERCPs are performed each year, and the procedure can be life-saving for many patients. Because of the complex technology embedded in duodenoscopes and the harmful waste caused by discarding them, these devices have typically been reused and used in multiple patients. Motivation for reusing this device also came from attempts to limit costs. The device manufacturers supported the reuse of their duodenoscopes and developed standardized cleaning and disinfection instructions for healthcare providers to follow. This protocol involved using automated endoscope reprocessors (AERs). After many patients experienced bacterial infections following ERCP procedures, the

Center for Disease Control (CDC) contacted the FDA about the potential for a relationship between the infections and duodenoscope reuse (FDA, 2021).

The FDA has worked with medical device manufacturers to develop a safer repurposing strategy for duodenoscopes. This involved conducting a study to understand the cause and prevalence of duodenoscope-transmitted infections. It was found that approximately 3% of patients experience contamination by "high concern organisms" such as *E. coli* and *Pseudomonas aeruginosa* (FDA, 2019). These organisms are resistant to many drugs, making them very dangerous for patients, requiring the FDA to take action in this case. Warning letters were sent to the three primary duodenoscope manufacturers, Fujifilm Medical Systems USA, Inc, Olympus Medical Systems Corporation, and Pentax of America to stress the importance of fully sterilizing these devices. In conjunction with the CDC and the American Society for Microbiology, the FDA released voluntary standardized protocols and safety communications to device manufacturers and gastroenterologists involved in the use and reprocessing of duodenoscopes. These updated procedures included performing microbiological culturing, sterilization, use of a liquid chemical sterilant processing system, and repeat high-level disinfection in addition to the original AER procedure.

This case highlighted the difference between disinfection and sterilization. Disinfection reduces or eliminates harmful microorganisms from the device, whereas sterilization is the process of killing all microorganisms. It was determined that disinfection was insufficient for the duodenoscopes due to the high-risk bacteria remaining on the devices. This caused the FDA to take the reuse requirements a step beyond disinfection and now they require full sterilization on reused duodenoscopes. Some companies, such as Boston Scientific, have released single-use devices to eliminate the possibility of infection by cross-patient contamination. The FDA is

engaged in research and communication with stakeholders and multi-use device manufacturers to further specify the repurposing requirements for duodenoscopes, and this situation has led to investigations into the proper way to reuse other medical devices (Figure 3).

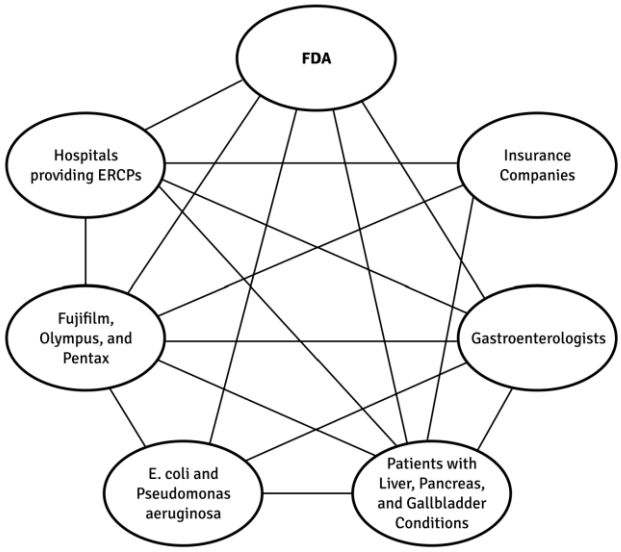

Figure 3. This figure demonstrates the network of actors involved in the reuse of duodenoscopes. The key medical device companies involved in manufacturing duodenoscopes are Fujifilm, Olympus, and Pentax. These devices are used by gastroenterologists, who have historically reused these devices after disinfecting them. Because the disinfection methods were inadequate, patients contracted bacterial infections, which has resulted in a push for single-use duodenoscopes.

Case 2: Deep Vein Thrombosis Sleeve

Phoenix Baptist Hospital (PBH) in Arizona has led a study on medical device reprocessing and its impacts on healthcare costs and environmental impact. Many hospitals, such as PBH, use deep vein thrombosis (DVT) sleeves to prevent blood clots and improve circulation in patients. This device uses an inflatable compression mechanism to move blood throughout the patients' limbs after surgeries. Patients often experience long periods of physical inactivity during and after surgical procedures, causing poor circulation. Patients are susceptible to severe blood clots, or

pulmonary embolism, following surgeries as a result of poor circulation, so DVT sleeves are potentially life-saving devices. Medical device companies, such as Stryker, manufacture DVT sleeves with the potential for reprocessing, and the PBH study analyzed the inputs of this reprocessing and their effects on safety, cost, and the environment (Unger & Landis, 2016).

Stryker describes three distinct steps in the reprocessing timeline: decontamination and cleaning, performance testing and inspection, and quality assurance. The used DVT sleeves are pre-treated with cleaning agents to remove visible soil and then receive a high level disinfection or ethylene oxide exposure. Then devices are inspected for debris, contamination and overall integrity, and are performance tested to simulate clinical application. Those devices that cannot withstand the pressure of the performance test are discarded and unable to be reused. Stryker recommends that healthcare providers conduct daily monitoring on the devices to ensure they are meeting performance standards. These devices are also subject to random sampling and testing for quality assurance by Stryker (Stryker, n.d.). Because the sleeves are considered "noncritical" devices, the FDA does not require strict sterilization protocols. If the devices were found to pose a threat to patients, the FDA would need to develop a regulation plan for the reuse of DVT sleeves.

After taking into account the chemicals, water, electricity, and other inputs required to perform this standard of processing, the PBH found that reprocessing DVT sleeves was more beneficial than discarding the device after one use in regard to its effect on climate change and cost, while also providing the same care to the patients. However, purchasing the required inputs for this type of reprocessing (i.e. chemicals, electricity) can be costly for hospitals if they do not already have these materials. Even with positive results for patient and environmental safety, hospitals and healthcare providers may be unwilling to compromise cost for sustainability. Therefore, it is essential to optimize the amount of inputs being used so that the cost does not

exceed that of single use devices. The study also proposed an alternative solution to the reprocessing techniques: changing the material of the DVT sleeve from woven cotton to degradable natural fiber. This could potentially allow the device to be single-use, while still preserving the environment (Unger & Landis, 2016). Future studies would need to be conducted to determine whether material adjustment would outweigh the environmental impacts of disposal, while also keeping costs down and remaining functional for patients (Figure 4).

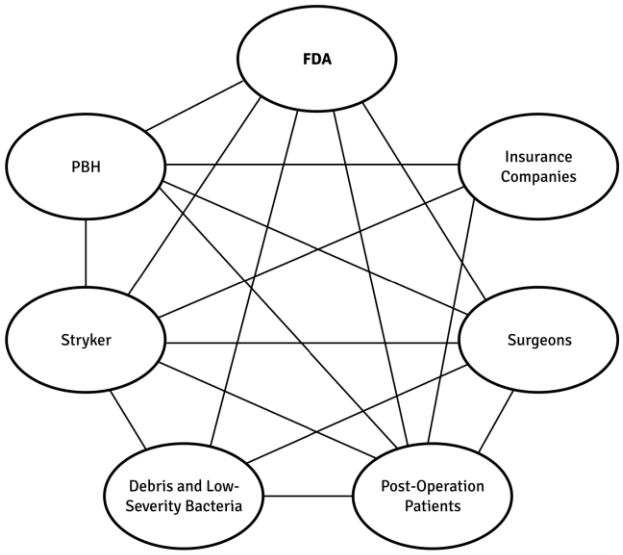

Figure 4. This diagram depicts the Phoenix Baptist Hospital's (PBH) approach to reusing deep vein thrombosis (DVT) sleeves made by Stryker. These devices only interact with patients' skin, and therefore are not prone to attracting high-risk bacteria. This has allowed the DVT sleeves to be reused without strict sterilization guidance from the FDA.

Discussion

The cases of repurposing duodenoscopes and DVT sleeves highlight the breadth of medical devices and their varied susceptibility to cause infections. Noncritical devices such as DVT sleeves have been reused without causing harm to patients. These devices are not prone to leading to infection, and therefore may undergo a quick disinfection process before being reused. DVT

sleeves are very common devices, so implementing the strategies used in the Phoenix Baptist Hospital case may result in significant cutbacks of cost and waste. Many semi-critical devices, such as duodenoscopes, are complicated to manufacture, so it may be tempting to reuse the devices for the sake of reducing cost. However, more long-term complications may arise from their close interaction with human tissue, which may become more expensive than simply using a single-use scope. If patients contract infections, they may require in-patient care, antibiotics, and/or further procedures, thus drastically increasing the amount of hospital resources used. While it is not feasible to reuse duodenoscopes for the same purpose, there has been discussion throughout the medical field to repurpose critical and semi-critical devices for a noncritical purpose. This may pose a promising solution to limiting waste and cost while also preserving the health of patients.

Conclusion

In order to move forward with attempts to limit medical waste and cost, recycling and reuse methods will need to be refined and specified for certain types of devices. The solution to balancing safety and sterility is not a "one size fits all" solution, as medical devices contact different levels of patient tissue/fluids and may retain different levels of bacteria, as seen in the duodenoscope and DVT sleeve cases. The International Federation of Infection Control has proposed five questions to help guide medical device reprocessing: Is the device functional? Can it be cleaned? Is it sterile? Is it cost effective? Who can take responsibility?. As medical device reprocessing advances, FDA requirements will need to be updated with consideration for these questions, especially policy regarding who is responsible when things go wrong. These changes may disrupt current healthcare workflow, however it is essential to protect both patients and the environment.

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