REFINEMENT OF AN ULTRAVIOLET FILTER TO PREVENT BLOODSTREAM INFECTIONS

(Technical Paper)

INVESTIGATING DISPARITIES RELATED TO HEALTHCARE ASSOCIATED INFECTIONS AND ACCESS TO MEDICAL DEVICES

(STS Paper)

A **Thesis Prospectus** submitted to the

Faculty of the School of Engineering and Applied Science

University of Virginia | Charlottesville, Virginia

In partial fulfillment of the requirements of the degree

Bachelor of Science, School of Engineering

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Fall, 2024

Department of Biomedical Engineering

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

Every year the United States healthcare system is burdened anywhere between $28.4 to $45 billion dollars to due to treatment of healthcare associated infections (Gidey et al., 2023). Patients receiving treatment at a hospital may have their condition worsened by acquiring a healthcare associated infection, which can lead to prolonged hospital stays, additional treatments, severe complications, and even death. A healthcare associated infection (HAI) is an infection that develops during or shortly after receiving medical care. Caused by bacteria, viruses, or fungi, these infections have the potential to affect the bloodstream, lungs, skin, urinary, or digestive tracts, and occur in a variety of clinical settings, including hospitals, clinics, nursing homes, and during homecare. HAIs are the most common adverse events in healthcare that negatively impact patient safety, with 1 in 31 hospital patients suffering from HAI on a given day. Survival rate and treatment success depends on many factors, namely the severity of the infection, but it is estimated that of patients with an HAI, 1 in 10 will die due to the infection (CDC, 2024).

One specific type of HAI is a central line-associated bloodstream infection (CLABSI), which accounts for 15% of all HAIs. These infections occur when bacteria enter a patient's central line and, consequentially, the bloodstream, which provides an avenue for the infection to rapidly spread throughout the body (Haddadin et al., 2024). A central line, also commonly referred to as a central venous catheter (CVC), is a long, flexible tube that is inserted into a vein near the heart used to deliver medication and fluids, draw or deliver blood, and monitor a patient's venous pressure and blood oxygen

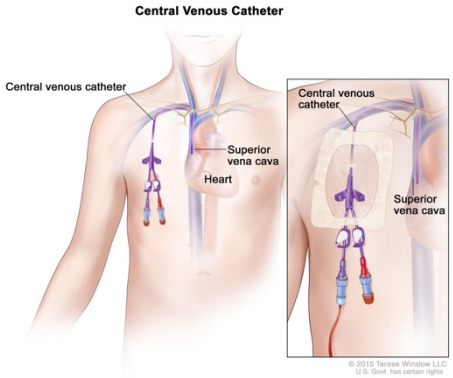

Figure 1. Diagram depicting the location of the most common insertion point for central lines.

levels. These devices accompany a variety of medical situations, including, but not limited to, surgery, cancer treatments involving chemotherapy, and dialysis treatments. There are over 5 million central lines inserted annually in the United States (Ault & Rosen, 2003).

Central line-associated bloodstream infections have a mortality rate of 12% to 25%, depending on the bacteria that caused the infection. An estimated 250,000 to 500,000 cases occur annually in the United States, with each infection costing an average of $48,000. Overall, CLABSI itself burdens the United States healthcare system with an additional $300 million to $1 billion per year (Toor et al., n.d.). Currently, a device does not exist that has the capacity to attach to a central line and eradicate infections that may be present in the fluids directly entering a patient's bloodstream. Prevention of these infections largely revolves around strict hygiene procedures that often fail (Collins, 2008). However, creation of such a device that is affordable, safe, and tested across diverse demographic groups would drastically reduce the costs of infection treatment for both hospitals and patients while ensuring efficacy, inclusivity, and equitable performance for all potential users.

Technical Topic

Eradication of infection-causing microorganisms via ultraviolet (UV) light has been in existence since the late 1800s, with primary applications focused on eliminating harmful germs and microbes from air and water (Enwemeka et al., 2021). In recent years, especially following the COVID-19 pandemic, UV light has gained attention as a mechanism for eliminating infections in clinical settings. One promising clinical application is to prevent CLABSI by eliminating bacteria from fluids that enter a patient's body via a central line. Current preventions of CLABSI largely revolve around adherence to strict hygiene procedures, which still carry a high probability of failure. Even despite proper sterilization efforts, these infections persist,

highlighting the need for a solution that reduces dependence on human factors and can consistently ensure patient safety.

Approximately 50% of CLABSI are classified as “intraluminal” infections, which means that bacteria were inadvertently injected into the patient following a breach in sterility. These infections can theoretically be eliminated by using UV light to irradiate all fluids and medications that enter a patient using a device attached to the central line. Dr. Thiele of the UVA Health Department of Anesthesiology has been developing a prototype of a device that attaches to the central line that includes a commercial off-the-shelf (COTS) mini-UV unit from AquaSense and a custom 3D printed cartridge. Preliminary testing conducted by Dr. Thiele and his team revealed that 10 seconds of UV light exposure caused a 4log reduction in the amount of *Staphylococcus aureus* (*S.* aureus) and *Escherichia coli* (*E. coli*) bacteria present, as seen in Figure 2.

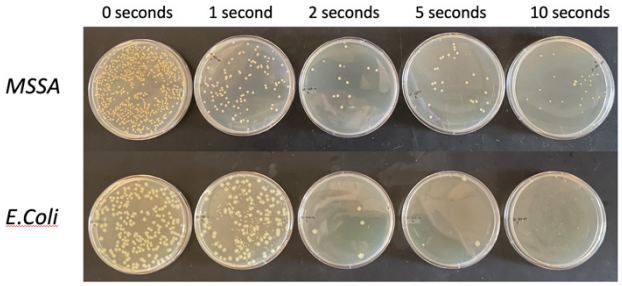

Figure 2. Preliminary tests performed by Dr. Thiele and his team to test the effects of UV light exposure on *S. aureus* (top) and *E. coli* (bottom) bacteria. Testing revealed a 4log reduction in number of bacteria after 10 seconds.

Additionally, no degradation was observed in medications commonly used with central lines after prolonged UV light exposure. However, the current prototype of the device, shown in Figure 3, requires further refinement to meet the practical demands of clinical use. The device must be made smaller to

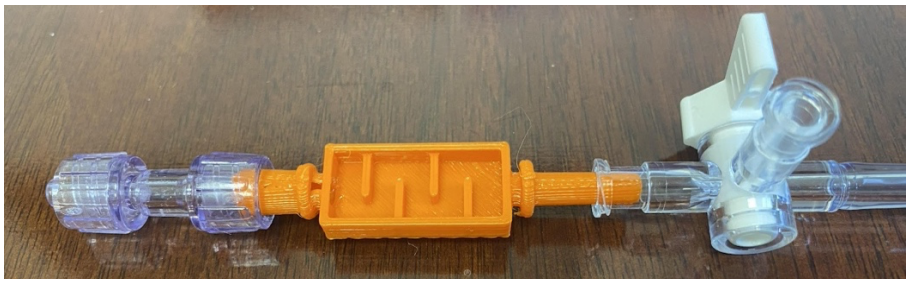

Figure 3. Dr. Thiele’s initial prototype of the device. The custom 3D printed cartridge is in orange and is shown housed in the central line. UV light and power supply are not shown.

ensure ergonomic suitability for ICU nurses, and a power supply must be implemented that does not interfere with intravenous tubing or poses a risk of overheating and harming patients.

This technical project will span both semesters of the BME Capstone course. Under Dr. Thiele's guidance, my Capstone group and I seek to accomplish three aims that will lead to the refined device. The first one is to improve the device's overall ergonomics so it can be easily used by an ICU nurse or other clinicians. This requires decreasing the size of the device to roughly the size of an AA battery. To better fit into the clinical workflow of the hospital, we plan to implement a Luer lock system, allowing for easy attachment and removal from the central line tubing without disrupting the flow of medications and fluid into the patient. The new cartridge will feature two disposable components along with reusable housing to reduce waste. The power supply of the device will be integrated either into the central line tubing itself, or securely attached to the outside, to minimize extra wires and tubes that could be mistaken with those connected to the patient. A basic rendering of potential design elements is shown in Figure 4.

Once there is a refined prototype of the device, testing will be done to ensure that it is as effective as Dr. Thiele's original design in reducing the bacterial contamination of fluids. These tests will be performed on S. aureus and E. coli bacteria, as Dr. Thiele's tests were, as well as *Pseudomonas aeruginosa* and coagulase-negative Staphylococcus bacteria, which have been shown to cause CLABSI. This

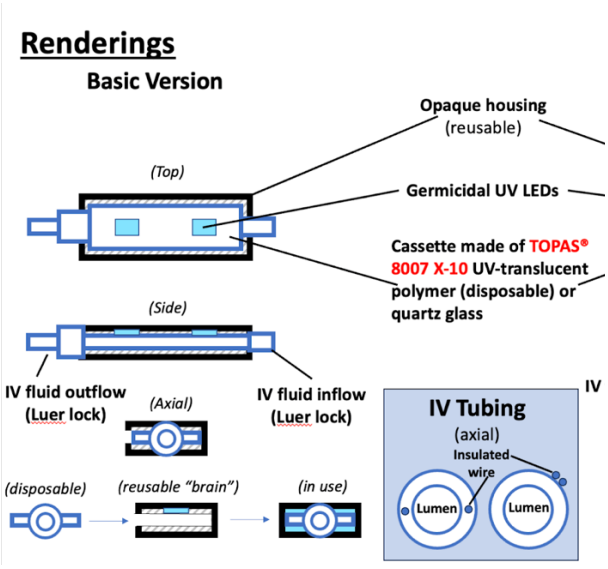

Figure 4. Basic rendering of potential design elements to include in the refined prototype.

will be achieved by passing a fluid containing cultured bacteria through the prototype, collecting and re-culturing it, and then quantifying the remaining bacterial load in terms of colony forming units (CFUs). The degradation of common medications will also be investigated.

The last aim is for the device to have the ability to be mass produced. This must be taken into consideration at all parts of the design process because the method of manufacturing will determine the type of material able to be used and major components of the overall design. The ability to be mass produced will greatly increase the appeal of the device to hospitals and other medical facilities because it will likely result in a lower cost per unit.

STS Topic

Healthcare-associated infections (HAIs), including central line-associated bloodstream infections (CLABSI), are a significant problem in clinical settings, that often lead to high rates of morbidity and mortality, along with significantly increased healthcare costs. These infections are often preventable, but disparities in their prevalence and in access to infection-preventing medical devices persist. Lower-resource facilities and communities with historically marginalized populations face higher rates of HAIs, a fact that underscores how social and economic factors can influence patient outcomes and access to essential medical technologies. This project examines the development and distribution of a novel medical device designed to prevent CLABSI by using UV light to filter fluids administered through central lines. The primary focus is to address disparities in HAI rates, specifically CLABSI and explore how equal access to this device could improve patient safety and reduce healthcare inequities.

The primary stakeholders in this research include patients, healthcare providers, device manufacturers, and hospital administrators. Patients, especially those in lower-resource settings, have a vested interest in access to affordable infection-prevention technology, as this can directly

impact their risk of developing HAIs. Healthcare providers, particularly ICU nurses and clinical staff, are directly affected by the design and usability of such devices, as they need tools that are both effective and ergonomically suitable within high-demand environments. Hospital administrators have a financial interest in reducing HAIs, as these infections can lead to extended hospital stays and increased costs, which are often not fully reimbursed by insurers. The physical artifacts in this project are the medical devices themselves, particularly the prototype of the device. Nonphysical artifacts include infection-control protocols, healthcare policies, and ethical considerations surrounding device access and affordability. Infection-control protocols, such as strict hygiene practices, are essential but often fall short, and this device aims reduce such reliance on human factors.

Inequities exist both in prevention and treatment of healthcare associated infections. Most hospitals and other care facilities do not focus on assessing disparities in the rates of occurrence of healthcare associated infections, so there is limited data on this topic. A 2011 study found that among patients hospitalized with cardiovascular disease, pneumonia, and major surgery, Asian and Hispanic patients had significantly higher rates of healthcare associated infections when compared to white non-Hispanic patients (Bakullari et al., 2014). Specifically related to central line-associated bloodstream infections, a study published in 2022 found that when compared to non-Hispanic White patients, the rates of CLABSI were significantly higher in non-Hispanic Black patients and Hispanic patients (Gettler et al., 2022). Another study analyzed over 8000 outcomes of hospitalized patients who required central lines from 2012 to 2018 found that Black patients and patients who speak a language other than English experienced higher rates of CLABSI even after accounting for known risk factors. The authors of the study believe that

systemic racism and other forms of bias play a role in inequitable hospital care for hospital acquired infections (McGrath et al., 2023).

Additionally, there are disparities present related to access and design of medical devices. Pre-market testing of medical devices often lacks adequate representation of certain populations, including racial and ethnic minorities, women, older adults, children, rural communities, and low-income patients (Kadakia et al., 2023). The majority of medical devices are classified as having low or moderate risk by the FDA, which is likely what this refined device would be classified as, and therefore are not required to undergo premarket clinical testing, which would allow for the opportunity to detect any potential population-specific differences in performance. High-risk medical devices undergo premarket testing, but often the manufacturers of such devices do not report information about the race, ethnicity, or gender of participants, and even limit enrollment in testing trials to certain age groups. Access to the benefits of medical devices can be further hindered by factors such as geographic region, insurance coverage restrictions, out of pocket costs, bias, and structural racism (Kadakia et al., 2023).

This research focuses on addressing disparities in access to infection-preventing medical devices, which contribute to unequal healthcare outcomes. Patients in lower-resourced settings face higher risks of healthcare-associated infections, as they often lack access to effective preventive technologies available in more affluent facilities. Ensuring that infection-prevention devices are affordable and accessible across healthcare environments can reduce these disparities, improve patient safety, and foster a more equitable healthcare system where patient outcomes are not determined by socioeconomic factors or other structural biases.

Conclusion

Developing a medical device that incorporates UV light to filter fluids entering a patient's body via a central line holds a significant promise in reducing the incidence of central line-associated bloodstream infections (CLABSI). By lowering infection rates, this device aims to enhance patient outcomes, alleviate the healthcare burden of treating CLABSI, and promote safer, more effective care across clinical settings. Our goal is to create a safe, efficient, and cost-effective device accessible to hospitals of all sizes and resource levels, ensuring that no facility is restricted from preventing these infections due to financial constraints or geographic limitations. This approach not only addresses current inequities in medical device access, but also tackles disparities in healthcare-associated infection rates, which disproportionately affect underserved populations and demographics. By balancing innovative technology with ethical and responsible design, the benefits of this device can be made universally available, thereby contributing to a more equitable healthcare system and improving the standard of care for all patients.

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