THE SOCIAL DEVELOPMENT, USE, AND WASTE OF MEDICAL DEVICES

A Research Paper submitted to the Department of Engineering and Society
In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science in Biomedical Engineering

By

Julia Donlon

March 27, 2020

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.

ADVISOR
Catherine D. Baritaud, Department of Engineering and Society

More than 30 million adults in the U.S. are currently suffering from Osteoarthritis (OA) (Centers for Disease Control and Prevention (CDC), 2019c). Of that population, 80% of the cases involve arthritis of the knee (Wallace et al., 2017). An estimated 90% of patients experiencing pain associated with OA are also diagnosed with knee effusions: a buildup of fluid within the knee joint (Maricar et al., 2016). Additionally, knee effusions can result from trauma or other chronic diseases (Mayo Clinic, 2018). To remove the discomfort accompanying an effusion, physicians will extract the fluid into a syringe by a procedure referred to as arthrocentesis. This cumbersome procedure requires the doctor to maneuver the fluid with one hand, while simultaneously aspirating the fluid into a syringe. For the technical portion of this project, the developmental process of a medical device will be discussed. This medical device has been designed and constructed to attach to a syringe to make the joint fluid extraction of arthrocentesis accessible by one hand, allowing the other hand to manipulate the fluid within the knee. The device has been modeled using computer-aided design (CAD) softwares and 3D-printed to assemble a complete prototype. Device efficacy is to be tested by mimicking arthrocentesis with aspiration of fluid from an artificial knee joint. Overall, the creation of this device aims to improve arthrocentesis for patients and physicians.

Aside from the clinical benefits of medical device creation, there are unintended consequences to their use. Disregarding the syringes disposed of during hospital procedures, such as arthrocentesis, at-home needle injections alone contribute to “over 13 million needles and syringes" discarded in landfills every day (Gold, 2011, para. 2). Moreso, plastic waste is estimated to contribute to 25% of all healthcare facility refuse (Gibbens, 2019). Regardless of public knowledge regarding the devastation of excess garbage production and plastic use, the

medical field continues to contribute to and exacerbate the problem: “the health, environmental and social costs of the production of these consumables is something that doesn’t get costed” (Glauser et al., 2016, para. 33). To discover why, a socio-technological analysis will be applied to the field of medical devices. More specifically, through the use of Pinch and Bijker theory of the Social Construction of Technology (SCOT), a framework will be developed to understand the motivations and individuals that influence medical device creation and use (Pinch & Bijker, 1984). This Science, Technology and Society (STS) topic of the social construction of medical device design is tightly-coupled to the technical topic, which presents the mechanics of creating a specific medical device. While the technical topic answers how a medical device is developed, the STS topic will answer why.

THE MOTIVATION: MEDICAL WASTE IN THE U.S.

Health is one of the most personal and unique traits to each individual human. It is something that will dictate our daily lives forever, as made evident by the global health crisis of 2020. As an answer to the upkeep and restoration of our health, we have medicine. Leaps and bounds have been made in modern medicine, but with that advancement have come unintended consequences, such as bacterial resistances and massive waste production. We frequently criticize non-medical industries for contributing to the bulk of our landfills. Although medical waste can be essential, it is no small contribution, as mentioned previously. The amount of medical waste is considerable, and so is the alarming lack of statistics to track that waste data. As of 2016, there is "no organization…[that] tracks how much medical trash the United States produces," but as of 30 years ago, the 1990 estimate was "two million tons a year" (Chen, 2010, para. 3). With growing waste production and a growing life expectancy, there has only been an increase in medical care and waste.

Major contributors to the copious amounts of waste are surgical wrappings and medical devices. Current device designs are being dictated by risks that emerge when medical devices are reprocessed: "due to patient safety, cost and convenience, more and more clinical instruments and supplies are being marked as 'single use' and thrown out" (Glauser et al., 2016, para. 4). The rise of single-use devices has come from the need to maintain sterility for the patient the device is being used on, as well as eliminating contamination risks for the next patient the device will be used on. Additionally, the upfront cost of single-use devices is noticeably less than that of a multi-use device (Barbella, 2019). Hospitals, designers, and policymakers have taken a utilitarian stance for how to solve the problem of healthcare contamination: a cost-benefit analysis of which

factors to consider over others (Martin & Schinzinger, 2010). Rather than prioritize the development of improved sterilization protocols, single-use devices are preferred due to the ease-of-use and perceived decreased risk for the patient.

Why Address Medical Waste?

Throughout the process of developing the technical portion of this portfolio, there has been pressure to make a knee aspirator medical device that is single-use, primarily supported by ease-of-use for physicians performing arthrocentesis. The initial reaction to this request sparked confusion and desire to investigate the environmental side-effects of single-use medical devices, as investigated in the previous section. With further research, the desire shifted to understand not just what happens after a medical device is discarded, but to learn about why a device takes a disposable form in the first place. Single-use medical devices and environmental considerations for medical waste will serve as examples and motivations through which the remainder of this thesis is driven. These ideas will be used to serve as a starting point to consider the broader picture of the social interaction between people, their concerns, and medical devices.

IDENTIFYING CONCERNS AND PREFERENCES

The waste associated with healthcare products is noticeable but derives from concerns for providing clean and cheap medical care. These concerns and desires are held by both those producing and using the products. To form a more comprehensive idea as to why medical devices take their form, the major overarching design concerns, alluded to previously, will be briefly analyzed below. While there are many reasons and considerations for a product's final design, the issues recognized in this thesis are safety and economic concerns, as well as personal preferences, as depicted in Figure 1 on the following page.

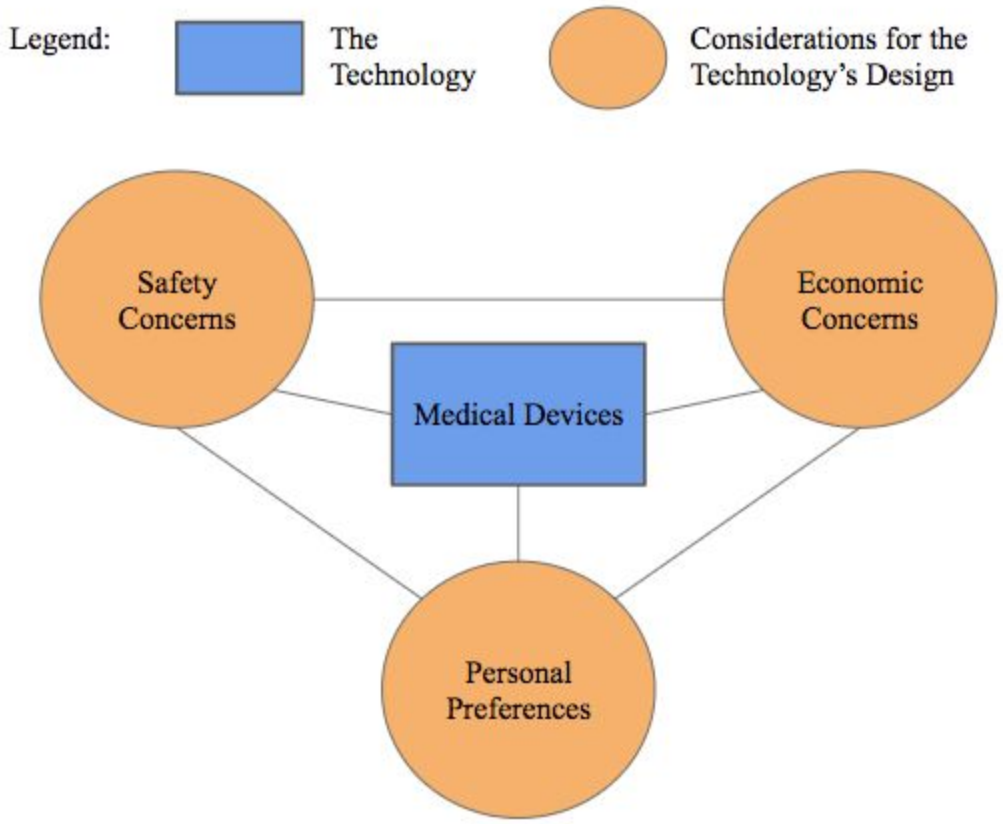

Figure 1: The Considerations that Shape Medical Device Design. A diagram representing the concerns and preferences that are relevant to the creation and eventual use of medical devices. All of these considerations are connected to the technology, and are also interrelated, as depicted by the lines between all diagram components. The interconnectedness between considerations represents how one concern or preference can not be viewed independently of the other considerations pertaining to the technology (Created by Donlon, 2020).

These reasons and considerations will be cross-examined to briefly discuss reasoning behind choosing single-use versus reusable medical devices. In addition, the importance of each of these topics will also be addressed, as well as the interconnectedness between the topics and how they shape medical device design and use overall.

Safety Concerns

For a medical device to be used in a clinical setting, it must be either single-use, or be able to be reprocessed or sterilized. As mentioned, the major concerns with sterilization of medical devices comes from a fear of cross-contamination or infection from a previous patient. These worries are well-founded, however the Centers for Disease Control and Prevention believe that sterilization methods have significantly mitigated this risk: "while the use of inadequately sterilized critical items represents a high risk of transmitting pathogens, documented transmission of pathogens associated with an inadequately sterilized critical item is exceedingly rare" (CDC, 2019b, para. 2). Additionally, the U.S. Food and Drug Administration has made efforts to reduce adverse effects of sterilization and improve protocols (U.S. Food and Drug Administration (FDA), 2019). Even so, single-use devices are still prevalent.

Single-use devices do not have to be sterilized after use, so the safety concerns of removing all contaminants are alleviated. Beginning in the 1970's, health regulatory agencies began to explore options of reusing previously marked "single use" devices (CDC, 2019a, para. 1). There is even an FDA protocol for how to determine if a single-use device can be reused or not (FDA, 2000). Progress and considerations have been made for creating multiple uses for and producing less waste from medical devices. These transitions are not simple, however, and even the topic of "reuse of single-use devices involves regulatory, ethical, medical, legal and economic issues and has been extremely controversial" (CDC, 2019a, para. 1).

Economic Concerns

The cost of any product will always be a controversial topic. Many individuals in the healthcare field are interested in the idea of single-use medical devices because they are initially

cheaper in the short-run (Barbella, 2019). For a single-use device, the materials are only required to be strong enough for one operation or procedure. These materials are commonly plastic. The longer-lasting materials required of multi-use devices are generally more expensive, such as metals. Based on a 2013 estimate, "U.S. hospitals on average spent $3.8 million on supply expenses," with about 60% of those expenses covering "medical supplies" (Health Management, Policy & Innovation, 2017, para. 2-3). These are not minor costs to consider, so the single-use versus reusable decision is crucial for a hospital's budget.

Although reusable hospital equipment is more expensive outright, in the long-run it is expected that the cost of multi-use medical devices are cheaper, as they do not have to be replaced as frequently (Glauser et al., 2016). The longevity of multi-use devices is enticing, however there is still the necessary cleaning required to ensure sterilization. The environmental impacts of sterilization versus disposal of medical devices is a criticized issue, especially when taking into account the amount of water usage and excess CO_2 emissions associated with sterilization efforts (McGain et al., 2017). Overall, this ongoing debate shows that economic data can not be considered independently of other information.

Personal Preference

Beyond comparing quantitative measures for choosing single-use versus multi-use devices, there is also the necessary consideration for personal preference. Physicians, patients, engineers, and all others involved in the design and function of a medical device have a different opinion on what the best form of the device could be.

Health care professionals want a device that is easy to use and does not interfere in any patient procedures. Patients want a medical device that will effectively aid in providing a

treatment for their ailments, while also not incurring any additional risks. Regulation agencies, such as the FDA, want to make sure that the device meets all necessary safety regulations. Additionally, the needs of the environment and subsequent public safety preferences for proper medical waste treatment, in terms of microbial infection and waste disposal, must also be considered. Each of these preferences can promote and condemn both single-use and reusable devices, which is where safety and economic concerns must also be examined.

What These Concerns and Preferences Mean

The outline of safety, economic and personal concerns is discussed to acknowledge several of the key influences that will drive decision making for a technology; specifically medical devices. These influences serve as a basis through which to identify the serious contradictory and controversial considerations that go into creating life-saving technology. Not only is there more than one piece of information to consider, but there are many individuals, groups, and ideas that are affected by the concerns discussed before, as well as concerns beyond those presented in this thesis. Now that the problems with medical device design have been addressed, the remainder of this thesis will explore the social context of those affected by these problems.

HOW WILL EVERYONE'S NEEDS BE CONSIDERED?

As discussed, there is no single reason for why a medical device is rendered in its final material or form. More importantly, there is no single person or group that influences the design criteria and subsequent functionality. So the question must be asked: how are the plethora of needs of all influencers considered in the design and purpose of medical devices?

In order to answer this question, an analysis will be presented to identify the different participants that influence and are affected by the creation of medical devices. For a medical device to pass through the complicated healthcare system in this country, "innovators [must] recognize and try to work with the complex interests of the different players" (Herzlinger, 2006, para. 13). This analysis will be framed using Pinch and Bijker's theory, the Social Construction of Technology (Pinch & Bijker, 1984). The SCOT framework will be employed to express collaboration and consideration of social groups interacting with medical technology, and to review the current flow of decision making and the potential improvements.

Introduction to the Social Construction of Technology

A more inclusive expression of the technological diffusion of medical devices requires a broader social context. The Social Construction of Technology (SCOT) theory identifies the development of an innovation in terms of economic, regulatory, and cultural influences, with particular emphasis on the human involvement in technological creation (Johnson, 2005, p. 1793-94). To understand why a technology or "artefact" interacts with its environment using SCOT, "we have to specify first the relevant social groups and second, the problem(s), each group experiences with respect to that artefact" (Bijker et al., 1984, p. 43).

In terms of social groups, this does not necessarily have to refer to people. These groups can also be things or ideas. For the purpose of this thesis, the relevant groups in medical device design are the engineers or designers, patients, healthcare professionals, regulatory committees, as well as university members, indicated in Figure 2 on the following page. While each social group has varied concerns and problems regarding the technology at hand, there are still overlaps amongst these groups and a shared influence on the technological function.

The importance of a SCOT framework is to identify the many individuals and concerns that shape a technology. There is no single group which develops a technology, and thus no single issue to address during technological creation or use. Thus, the answer to the research question requires interconnectedness amongst all groups. The connection between all relevant

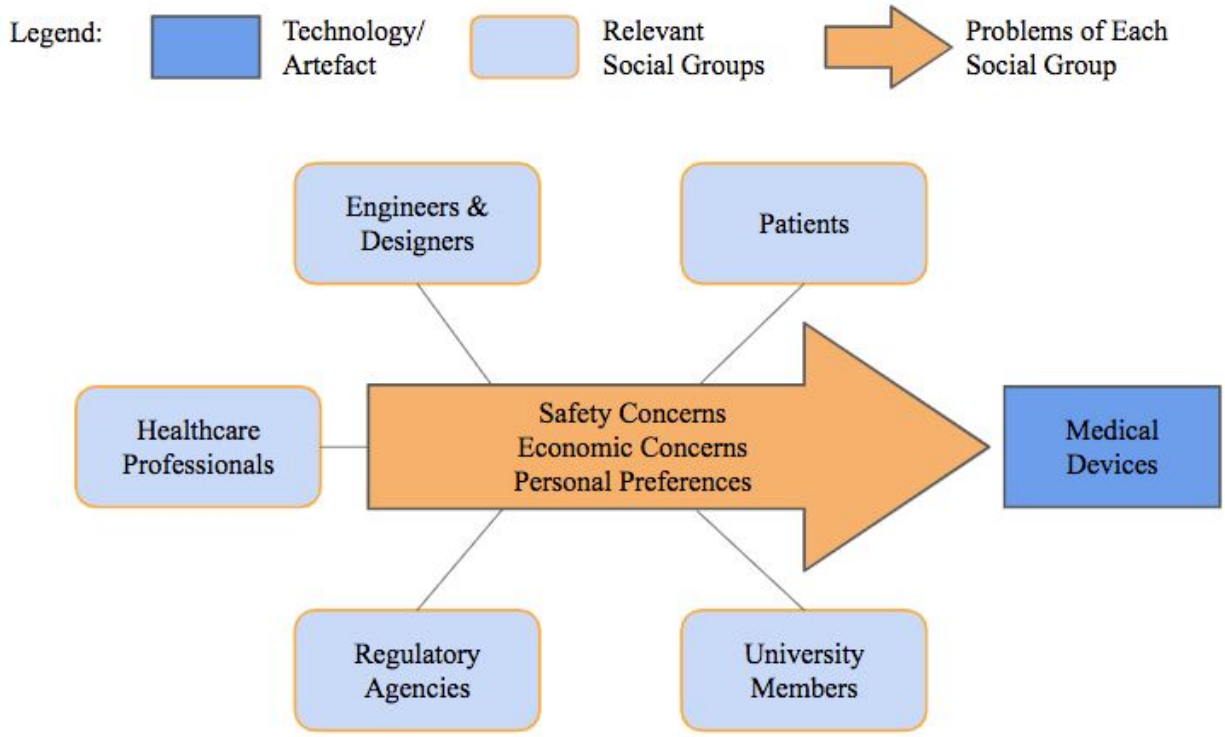

Figure 2: Social Construction of Medical Device Design. A framework depicting the relevant social groups and their respective problems and desires, which collectively develop medical device design. The use of an arrow in this framework expresses the social influence shaping a technology. While medical devices are the end result, all groups have equal and important stakes in the creation, use, and waste of the devices (Created by Donlon, 2020).

social groups is depicted by the shared influence they have in expressing concerns and preferences directed at how a medical device is created and used, rendered by the arrow in Figure 2 above. The influence and potential furtherance of the relevant social groups and their objectives regarding medical devices will be analyzed next.

COMMUNICATION, EDUCATION, AND UNDERSTANDING

To reduce the waste produced from healthcare treatments while still keeping paramount patient safety, there must be connection between and consideration for all people, groups, ideas, and entities connected to medical devices. Incentives and impacts of technological distribution can be viewed in terms of the "perception" of different "social groups" (Bijker et al., 1970, p. 41). An outline of these proposed considerations for and by those influencing a device's function will be described below. These considerations are discussed with the aim of presenting a greater understanding for the social groups relevant to the medical device design process.

Patients

Regardless of who is manipulating a medical device, the end-goal is always to create a device that positively affects the patient. Because the patients are the ones receiving the care, considerations for single-use versus multi-use devices must address the potential risks for contamination and biohazard on all sides. If a device is re-sterilized, patients may be exposed to a worse infection or acquire a new disease. These risks appear from improper sterilization efforts, or potentially unidentifiable contamination. If a single-use plastic device is used, the patient might also be exposed to harms from harsh plastic chemicals, causing a completely new health problem (Glauser et al., 2016).

While a patient has the opportunity to choose the type of at-home medical device they are using, mentioned later in the *Case Study of Engineering, Business, and Medicine: SmileDirectClub* section, this discussion between single-use and multi-use is rarely his or her choice in a hospital. During a medical procedure, a patient must relinquish personal choice at the discretion of his or her medical staff. There are clear reasons why this is in the patient's best

interest, however there is a lack of individual patient autonomy through this process. They are not asked which tool will be used on them, nor are they given a list of potential device options beforehand.

It is not necessarily the solution to have patients design their own medical devices, because they are not proficient in the technological or physiological insight held by physicians and engineers. However, the key change for patient influence must come from open consent and understanding beyond just which procedure is being performed, but also what is being used to perform it (Martin & Schinzinger, 2010, p. 50). Not every patient will desire such extensive knowledge on the different devices used in regards to his or her health, however all patients do care about and have the right to medical treatment that will lead to an improved health outcome. By providing patients with full disclosure, they have the opportunity to question and actively participate in their own health care.

Engineers and Designers

When designing a medical device that will be used by a patient it is important to keep forefront "patient awareness and safety" (Barbella, 2019, para. 49). Engineers are rarely in direct communication with the end users of their products. Even so, the device designers must apply empathy and compassion for patients in the design process. The device is not only required to be functional, but should consider the vulnerable state of patients during procedures or at-home healthcare treatments. Patients have the right to maintain integrity and comfort through any interaction with a medical device. It is thus the duty of designers to uphold this integrity through design considerations, and in return maintain the "awareness and safety" of the patient (Barbella, 2019, para. 49). Insufficient patient understanding, coupled with poor engineering and business

practices, can cause a collection of moral dilemmas and poor medical care, as described below in the real-world example of the company, SmileDirectClub.

Case Study of Engineering, Business, and Medicine: SmileDirectClub

Two *New York Times* reporters, Erin Griffith and Peter Eavis, address the ramifications of ethically questionable business practices of the at-home teeth straightening brand SmileDirectClub (SDC), in the 2020 article, "*This Company Says It Will Fix Your Smile. It May Shush You if It Doesn't*." (Griffith & Eavis, 2020). One of the major ethical issues addressed in this article is SDC's business model: "In lieu of having dentists review patient dental records or perform any sort of patient exam … before prescribing orthodontic treatment, SmileDirectClub instead requires customers to self-report their dental condition" (American Dental Association, 2019, para. 9). These unsafe medical practices expose a larger issue at the clash of medicine, business, and economics. Griffith and Eavis hint at a challenging healthcare dilemma: providing affordable products to the masses versus using more expensive materials and superb professional opinion. Even SDC users have acknowledged that "given the cost, [they were] not expecting perfection" (Griffith & Eavis, 2020, para. 25). But consumers should not have to sacrifice health care due to cost. While a company's primary incentive is to boost revenue, it is also that company's moral duty to provide all product users with honest customer testimonies regardless of impact on profit. Particularly in regards to one's health, it becomes imperative to follow set procedures for how to provide safe care and products to customers. Emphasized by the many accounts of worsened dental health following SDC product use, the lack of professional orthodontic examination can be a "dangerous" practice (Griffith & Eavis, 2020, para. 19). While

this article outlines the story of one specific medical device, these cautions and principles can be applied to all healthcare products.

It is important for the engineers to have respect for the research and potential improvements that can maintain both patient and environmental safety. Considerations for consequences must be put at the same priority level as considerations for functionality of a device: an "engineer [is] to view his or her specialized activities in a project as part of a larger whole having a social impact—an impact that may involve a variety of unintended effects" (Martin & Schinzinger, 2010, p. 87-88). Design consequences result from the use of cheap materials for single-use devices, or faulty engineering practices, such as those of SmileDirectClub, or from potential risks caused by growing environmentally-induced health problems associated with irresponsible waste disposal.

In short, engineers and designers of medical devices have far-reaching responsibilities. An engineer has a "professional duty… to hold paramount the safety, health, and welfare of those affected by engineering projects" (Martin & Schinzinger, 2010, p. 87). Additionally, they have a professional responsibility to help encourage economic growth for their company. Moral dilemmas can transpire between these two seemingly contradictory views. However, "money matters, and it matters morally" because "safety, environmental protection, convenience, and money… [are] relevant" to all forms of technological "development" (Martin & Schinzinger, 2010, p. 30). The values of safety, usability, affordability and environmental care are held by most users of any technology, and become essential to some of the biggest users of medical devices: hospitals.

Healthcare Professionals

One of the most obvious users of medical devices are physicians. They have a demand for functional instruments that will improve their own performance, and in return provide improved patient care. However, doctors are not the only ones involved in the care, health, and safety of patients at a hospital. Design considerations must also include the nurses, cleaning staff, technicians, and any other person using or maintaining the medical device. In this sense, the needs of all hospital staff members shape the use and need of a medical device. Single- versus multi-use medical devices will change the amount of time needed to clean an operating room, or the flow of surgical instrument supply in a hospital. These types of changes can seem obvious or insignificant, but they impact more than just the mechanics of a procedure. High demand for both sterilization of reusable supplies plus organization and distribution of single-use instruments significantly alters productivity and staffing in a hospital, an example of which can be seen by the need for volunteer staff at the University of Virginia hospital (Madison House Medical Services, 2019).

Staffing requirements and device choices will have direct impact on the economic concerns impacting healthcare facilities. Coupled with these economic considerations are the issues of personal preferences. A doctor's preference has an important influence on what a hospital will purchase. These doctor-chosen devices are referred to as "physician preference items" (Burns et al., 2018, para. 2). Beyond caring for the success rates of the technology in question, doctors state "device design", "ease of use", and "longevity" as some of the most important factors to consider when choosing the device type (Burns et al., 2018, para. 28). Hospitals are the ones who purchase devices that fit these criteria. These criteria should thus be

directly communicated from physicians to engineers or manufacturers. An additional consideration with increased physician influence in device design, however, is the risk of conflict of interest in device or industry preference (Citron, 2012).

Doctors can help influence device design in terms of shape ergonomics, and also in terms of material choice and disposal. Many hospital employees are in fact frustrated with the ongoing waste accumulated from single-use devices, and packaging of devices in particular (Glauser et al., 2016). Though these product users have identified concerns, they are not necessarily informing those who could help create change. Hospitals do not have to view themselves as individual units, as the communication of desires shared amongst multiple hospitals can improve device design: "though it may be difficult for one small organization to convince a manufacturer to change, hospitals can get together to pressure manufacturers to reduce packaging" (Glauser et al., 2016, para. 28).

Manufacturers

The current function of a device manufacturer is to take design specifications and visions, and bring that idea to life. For the most part, these groups serve as middlemen between the innovator and user. But a manufacturer does not have to simply be the person who produces the device. They should have input in the design, particularly on the material side, because they are the ones closest to the actual configuration of the device. Additionally, manufacturers have legal obligations to ensure the utmost safety of a product (Martin & Schinzinger, 2010, p. 38). As a so-called middleman, a manufacturer is in the unique place in device development to be able to communicate concerns of both designers and users to produce the best and safest medical device.

It is critical to consider that environmental safety is not only applicable to the waste accumulation from actual discarded device material, but also the harm of transporting the many devices and tools that come from overseas, as well as chemical pollution generated from sterilization procedures (Glauser et al., 2016). Addressing the waste problem that begins early on in the device production process can open the discussion for considering decreased distance between creation and end-user locations. In fact, it may be more cost-effective and environmentally-friendly to "keep manufacturing closer to end-users" (Barbella, 2019, para, 42). In this sense, closer interactions throughout the production process could keep paramount safety, cost, and a decreased environmental footprint. Among these considerations, manufacturers must also interact with specific industry standards and guidelines.

Regulatory Bodies

When it comes to industry standards in biomedical engineering, and specifically medical device production, the U.S. Food and Drug Administration (FDA) has chief influence. Regulations presented by the FDA are not to merely create guidelines for designers, engineers, and manufacturers, but can be used to promote innovation and safety. Broader considerations, however, can be made by regulatory organizations and lawmakers to look beyond the safety of the patient inside the hospital. These regulations should consider the health effects of waste disposal processes for the general public. As mentioned earlier, these considerations are beginning to be made by addressing concerns of increased single-use device production and potential for improved sterilization protocols (FDA, 2019).

There are debates, however, over the effectiveness of certain governing bodies, especially the FDA. While all involved desire the same safety and proper functionality of devices, debates

emerge over the "subjective factors [that] have led to strict government oversight and evolving regulation" (Citron, 2012, p. 310). Greater communication can occur between the engineers and designers, regulatory committees, environmental sustainability organizations, and even just amongst hospital staff, to produce products that promote safety and human well-being before, during, and after the device is used (Aljabre, 2002). Additionally, consistency of standards and communication is key to providing the best possible health products and care. Industry standard consistencies will also help to set clear precedents for those next to enter into the world of medical technologies.

University Members

At the beginning stages of biomedical research are those most recently entering the field: students. Students should be encouraged by professors to explore medical device design processes outside of the current norm. The next generation of student engineers, and those going into health care, have grown up in a world of climate change, recycling, and banning of plastic straws. The word sustainability is regularly uttered throughout many public debates and discussions in recent times. This new generation of students will have the expertise of a traditional technological background, with an increasing preference towards sustainability and efficiency.

In addition to a more eco-friendly approach to medical care, other relevant cultural concerns must also influence medical device design. To ensure all necessary groups and experiences are included, universities must hold diversity and inclusion as a high priority in all settings. The goal of this thesis is to identify the necessary groups and ideas that will influence and are influenced by medical device design. No human is untouched by some form of medicine.

This means that each individual will have different preferences, safety concerns, and economic strategies for creating the best medical practices. Universities must honor and celebrate "cultural diversity and [respect] legitimate differences among individuals and groups" (Martin and Schinzinger, 2010, p. 234). These changes are beginning to be made, as can be noted by the University of Virginia's 2020 Biomedical Engineering class of over 50% women. By continually making education more accessible to minorities and underrepresented groups, a ripple effect will be witnessed in the medical device world that includes more and more necessary groups, to produce better medical technology everyday.

A SOCIAL PROGNOSIS

This thesis was inspired by an observation of unnecessary wastefulness in the medical field. Specifically, the seemingly unnecessary push towards the creation of a single-use medical device for a knee aspirator technology that would easily be reusable. An analysis of considerations for single-use versus reusable medical devices was used as an example of one specific topic to consider in device design. The example was used to better illustrate why medical waste is growing, as well as to show how one decision in biomedical design is related to many more issues. The remarks and facts presented in this thesis are not to be seen as a solution to the problem of medical waste. Rather, this thesis should serve as an outline and framework through which to consider the complexity and potentially contradictory views that produce medical devices in the forms and functions they take. By addressing overarching concerns, groups, and ideas surrounding medical devices, a broader connection of people and thoughts is hoped to have come from this paper.

Overall, connection between relevant social groups does not necessarily equate to every group constantly interacting directly with one another. Instead, each group is to be informed of the decisions that are going into the technological process, as ultimately, each group's decision is affecting the others'. The Social Construction of Technology is a powerful framework through which the connection and incentives or perspectives of all groups can be implemented and respected to better the creation of a technology. Improved understanding, with open communication and collaboration among those affected by a particular product will allow for an increased chance of considering all necessary consequences in device design, and ideally, a reduction in unnecessary waste.

An Additional Note: Coronavirus

Throughout the development of this thesis, there has been global concern and discussion on the topic of single-use medical devices. On March 11, 2020 the novel respiratory virus sweeping the globe, coronavirus disease 2019 (COVID-19), was officially declared a pandemic by the World Health Organization (WHO) (WHO, 2020). The virus has left healthcare systems of cities, states, and countries nearly crippled with overcrowding and resource strain. Because of the aggressively infectious nature of COVID-19, single-use respiratory aids, such as respirator masks worn by healthcare professionals and infected patients, have been suggested to become reusable medical devices (Letzter, 2020).

This new reusable label has not come without serious debate. Once again, the needs and concerns of different social groups have such extreme impacts on the function of medical devices. Politicians and biomedical researchers and physicians are attacking the problem from different expertises, creating more confusion and distress on the matter (Bruer & Hilk, 2020). If

these devices are reused, other hospitalized patients may be put at risk of contracting COVID-19, or cross-contamination between COVID-19 patients might also occur. One Los Angeles area medical technician was cited as saying that healthcare workers "are [now] being asked to wear items 'for hours on end, even beyond manufacturers' recommendations'" (Karlamangla, 2020, para. 13). What is worse, the Centers for Disease Control and Prevention (CDC), one of the leading regulatory agencies for COVID-19 awareness, are changing the standards of the reuse of single-use devices almost daily (Billman, 2020).

Because the coronavirus outbreak has occurred so rapidly, there are still many unknowns and changing concerns surrounding the virus. This additional note is meant to provide a recent and real-world example involving the decision between single-use versus reusable medical devices, particularly to accentuate the contradictory and complex problems of each relevant social group in medical devices associated with coronavirus. The social construction of medical devices is not something that is merely written about, but is experienced by everyone, even right now.

WORKS CITED

Aljabre, S. (2002). Hospital generated waste: A plan for its proper management. *Journal of Family & Community Medicine*, *9*(2), 61–65. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3430187/

American Dental Association (ADA). (2019, October). *ADA sets record straight on status of petition to FDA regarding SmileDirectClub*. Retrieved from https://www.ada.org/en/publications/ada-news/2019-archive/october/ada-sets-record-straight-on-status-of-petition-to-fda-regarding-smiledirectclub

Barbella, M. (2019, April 3). *Once or again? Single-use products are gaining attention*. Retrieved from https://www.mpo-mag.com/issues/2019-04-01/view_features/once-or-again-single-use-products-are-gaining-attention/

Bijker, W., Bönig, J., & van Oost, E. (1970). The social construction of technological artefacts. In J. Woodforde (Ed.), *The story of the bicycle* (p. 39-51). London, England: Routledge & Kegan Paul.

Bijker, W., Bönig, J., & van Oost, E. (1984). The social construction of technological artefacts. *Zeitschrift für Wissenschaftsforschung*, 2(3), 39-52.

Billman, J. (2020, March 26). Duke researchers find way to decontaminate and reuse N95 masks, possibly alleviating critical shortfall. *INDY Week*. Retrieved from https://indyweek.com/

Bruer, W., & Hilk, M. (2020, March 21). Despite federal guidelines, Trump suggests "sanitizing" and reusing medical masks. *CNN*. Retrieved from https://www.cnn.com/2020/03/21/politics/trump-sanitize-medical-masks/index.html

Burns, L., Housman, M., Booth, R., & Koenig, A. (2018). Physician preference items: What factors matter to surgeons? Does the vendor matter? *Medical Devices (Auckland, N.Z.)*, *11*, 39–49. https://doi.org/10.2147/MDER.S151647

Centers for Disease Control and Prevention (2019a, April 4). *Guideline for Disinfection and Sterilization in Healthcare Facilities: Reuse of Single-Use Medical Devices.* Retrieved from https://www.cdc.gov/infectioncontrol/guidelines/disinfection/reuse-of-devices.html

Centers for Disease Control and Prevention (2019b, April 4). *Guideline for Disinfection and Sterilization in Healthcare Facilities: Sterilization*. Retrieved from https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/index.html

Centers for Disease Control and Prevention. (2019c, January 10). *Osteoarthritis (OA)*. Retrieved from https://www.cdc.gov/arthritis/basics/osteoarthritis.htm

Chen, I. (2010, July 5). In a world of throwaways, making a dent in medical waste. *The New York Times*. Retrieved from https://www.nytimes.com/

Citron, P. (2012). Ethics considerations for medical device R&D. *Progress in Cardiovascular Diseases*, *55*(3), 307–315. https://doi.org/10.1016/j.pcad.2012.08.004

Donlon, J. (2020). *The Considerations that Shape Medical Device Design.* [Figure 1]. *STS Research Paper: The Social Development, Use, and Waste of Medical Devices* (Unpublished undergraduate thesis). School of Engineering and Applied Science, University of Virginia. Charlottesville, VA.

Donlon, J. (2020). *Social Construction of Medical Device Design.* [Figure 2]. *STS Research Paper: The Social Development, Use, and Waste of Medical Devices* (Unpublished undergraduate thesis). School of Engineering and Applied Science, University of Virginia. Charlottesville, VA.

Gibbens, S. (2019, October 4). Can medical care exist without plastic?. *National Geographic*. Retrieved from https://www.nationalgeographic.com/

Glauser, W., Petch, J., & Pendharkar, S. (2016, August 18). Are disposable hospital supplies trashing the environment?. *Healthy Debate*. Retrieved from https://healthydebate.ca/2016/08/topic/hospital-medical-waste

Gold, K. (2011). Analysis: The impact of needle, syringe, and lancet disposal on the community. *Journal of Diabetes Science and Technology*, *5*(4), 848–850. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3192588/

Griffith, E., & Eavis, P. (2020, January 21). This company says it will fix your smile. It may shush you if it doesn't. *The New York Times*. Retrieved from https://www.nytimes.com/

Health Management, Policy & Innovation. (2017, September 9). *How Much Do U.S. Hospitals Spend on Medical Supplies?*. Retrieved from https://hmpi.org/2017/09/09/how-much-do-u-s-hospitals-spend-on-medical-supplies/

Johnson, D. (2005). Social construction of technology. In *Encyclopedia of Science, Technology, and Ethics* (Vol. 1, p. 1791–1795). Detroit, MI: Macmillan

Karlamangla, S. (2020, March 25). There are no masks left in L.A. County's emergency stockpile. *Los Angeles Times*. Retrieved from https://www.latimes.com/

Letzter, R. (2020, March 24). Doctors scramble for best practices on reusing medical masks during shortage. *Livescience*. Retrieved from https://www.livescience.com/sanitizing-medical-masks-for-reuse-coronavirus.html

Madison House Medical Services. (2019). *Volunteer handbook 2019-2020* [Brochure]. Retrieved from https://static1.squarespace.com/static/55ab1302e4b0ea19042e75fa/t/5d69696cfbbeca0001129ec2/1567189357741/Medical+Services+2019-2020+Unit+Handbook.pdf

Maricar, N., Callaghan, M., Parkes, M., Felson, D., & O′Neill, T. (2016). Clinical assessment of effusion in knee osteoarthritis—A systematic review. *Seminars in Arthritis and Rheumatism*, *45*(5), 556–563. https://doi.org/10.1016/j.semarthrit.2015.10.004

Martin, M., & Schinzinger, R. (2010). *Introduction to engineering ethics* (2nd ed.). New York, NY: McGraw-Hill Higher Education.

Mayo Clinic. (2018, April 21). *Swollen knee—Symptoms and causes*. Retrieved from https://www.mayoclinic.org/diseases-conditions/swollen-knee/symptoms-causes/syc-20378129

McGain, F., Story, D., Lim, T., & McAlister, S. (2017). Financial and environmental costs of reusable and single-use anaesthetic equipment. *British Journal of Anaesthesia, 118*(6), 862–869. https://doi.org/10.1093/bja/aex098

Pinch, T., & Bijker, W. (1984). The social construction of facts and artefacts: Or how the sociology of science and the sociology of technology might benefit each other. *Social Studies of Science*, *14*(3), 399-441.

U.S. Food and Drug Administration (2000, February 2). *Reprocessing and reuse of single-use devices: Review prioritization scheme*. Retrieved from https://www.fda.gov/media/71761/download

U.S. Food and Drug Administration (2019, November 26). *Ethylene oxide sterilization for medical devices.* Retrieved from http://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices

Wallace, I., Worthington, S., Felson, D., Jurmain, R., Wren, K., Maijanen, H., Woods, R., & Lieberman, D. (2017). Knee osteoarthritis has doubled in prevalence since the mid-20th century. *Proceedings of the National Academy of Sciences of the United States of America*, *114*(35), 9332–9336. https://doi.org/10.1073/pnas.1703856114

World Health Organization. (2020, March 11). *WHO Director-General's opening remarks at the media briefing on COVID-19—11 March 2020*. Retrieved from https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020

BIBLIOGRAPHY

Akbarnia, H., & Zahn, E. (2019). Knee arthrocentesis. In *StatPearls* [Internet]. Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK470229/

AliExpress. (n.d.). *Plastic pipette tips box import 96 vents for 200ul chemical biological laboratory pipette tip cartridge for 200ul lengthened*. Retrieved from https://www.aliexpress.com/item/32529478504.html

Aljabre, S. (2002). Hospital generated waste: A plan for its proper management. *Journal of Family & Community Medicine*, *9*(2), 61–65. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3430187/

American Dental Association (ADA). (2019, October). *ADA sets record straight on status of petition to FDA regarding SmileDirectClub*. Retrieved from https://www.ada.org/en/publications/ada-news/2019-archive/october/ada-sets-record-straight-on-status-of-petition-to-fda-regarding-smiledirectclub

Arthritis Foundation (n.d.). *Osteoarthritis symptoms*. Retrieved from https://www.arthritis.org/about-arthritis/types/osteoarthritis/symptoms.php

Autodesk Knowledge Network. (2014, July 30). *How a caulk gun works*. Retrieved from https://knowledge.autodesk.com/support/inventor-products/getting-started/caas/CloudHelp/cloudhelp/2015/ENU/Inventor-Tutorial/files/GUID-D30E25A6-DD90-4B54-93EB-7DD0DEAED93E-htm.html

Barbella, M. (2019, April 3). *Once or again? Single-use products are gaining attention*. Retrieved from https://www.mpo-mag.com/issues/2019-04-01/view_features/once-or-again-single-use-products-are-gaining-attention/

Bijker, W., Bönig, J., & van Oost, E. (1970). The social construction of technological artefacts. In J. Woodforde (Ed.), *The story of the bicycle* (p. 39-51). London, England: Routledge & Kegan Paul.

Bijker, W., Bönig, J., & van Oost, E. (1984). The social construction of technological artefacts. *Zeitschrift für Wissenschaftsforschung*, 2(3), 39-52.

Billman, J. (2020, March 26). Duke researchers find way to decontaminate and reuse N95 masks, possibly alleviating critical shortfall. *INDY Week*. Retrieved from https://indyweek.com/

Bruer, W., & Hilk, M. (2020, March 21). Despite federal guidelines, Trump suggests "sanitizing" and reusing medical masks. *CNN*. Retrieved from https://www.cnn.com/2020/03/21/politics/trump-sanitize-medical-masks/index.html

Burns, L., Housman, M., Booth, R., & Koenig, A. (2018). Physician preference items: What factors matter to surgeons? Does the vendor matter? *Medical Devices (Auckland, N.Z.)*, *11*, 39–49. https://doi.org/10.2147/MDER.S151647

Centers for Disease Control and Prevention (2019a, April 4). *Guideline for Disinfection and Sterilization in Healthcare Facilities: Reuse of Single-Use Medical Devices.* Retrieved from https://www.cdc.gov/infectioncontrol/guidelines/disinfection/reuse-of-devices.html

Centers for Disease Control and Prevention (2019b, April 4). *Guideline for Disinfection and Sterilization in Healthcare Facilities: Sterilization*. Retrieved from https://www.cdc.gov /infectioncontrol/guidelines/disinfection/sterilization/index.html

Centers for Disease Control and Prevention. (2019c, January 10). *Osteoarthritis (OA)*. Retrieved from https://www.cdc.gov/arthritis/basics/osteoarthritis.htm

Chen, I. (2010, July 5). In a world of throwaways, making a dent in medical waste. *The New York Times*. Retrieved from https://www.nytimes.com/

Citron, P. (2012). Ethics considerations for medical device R&D. *Progress in Cardiovascular Diseases*, *55*(3), 307–315. https://doi.org/10.1016/j.pcad.2012.08.004

Demoulin, L., Kesteloot, K., & Penninckx, F. (1996). A cost comparison of disposable vs reusable instruments in laparoscopic cholecystectomy. *Surgical Endoscopy*, *10*(5), 520 –525. https://doi.org/10.1007/BF00188399

Donlon, J. (2019). *The social context of medical devices* (Prospectus). University of Virginia, Charlottesville, VA.

Donlon, J. (2020). *The Considerations that Shape Medical Device Design.* [Figure 1]. *STS Research Paper: The Social Development, Use, and Waste of Medical Devices* (Unpublished undergraduate thesis). School of Engineering and Applied Science, University of Virginia. Charlottesville, VA.

Donlon, J. (2020). *Social Construction of Medical Device Design.* [Figure 2]. *STS Research Paper: The Social Development, Use, and Waste of Medical Devices* (Unpublished undergraduate thesis). School of Engineering and Applied Science, University of Virginia. Charlottesville, VA.

Erin Griffith. (n.d.). *Bio*. Retrieved from http://www.eringriffith.com/bio

Eustice, C. (2019, August 28). *Arthrocentesis or joint aspiration*. Retrieved from Verywell Health website: https://www.verywellhealth.com/arthrocentesis-what-you-should-know -2552134

Gibbens, S. (2019, October 4). Can medical care exist without plastic?. *National Geographic*. Retrieved from https://www.nationalgeographic.com/

Glauser, W., Petch, J., & Pendharkar, S. (2016, August 18). Are disposable hospital supplies trashing the environment?. *Healthy Debate*. Retrieved from https://healthydebate.ca/2016/08/topic/hospital-medical-waste

Gold, K. (2011). Analysis: The impact of needle, syringe, and lancet disposal on the community. *Journal of Diabetes Science and Technology*, *5*(4), 848–850. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3192588/

Griffith, E., & Eavis, P. (2020, January 21). This company says it will fix your smile. It may shush you if it doesn't. *The New York Times*. Retrieved from https://www.nytimes.com/

Gupte, C., & St Mart, J. (2013). The acute swollen knee: Diagnosis and management. *Journal of the Royal Society of Medicine*, *106*(7), 259–268. https://doi.org/10.1177/0141076813482831

Haseler, L., Sibbitt, R., Sibbitt, W., Michael, A., Gasparovic, C., & Bankhurst, A. (2011). Syringe and needle size, syringe type, vacuum generation, and needle control in aspiration procedures. *Cardiovascular and Interventional Radiology*, *34*(3), 590–600. https://doi.org/10.1007/s00270-010-0011-z

Health Management, Policy & Innovation. (2017, September 9). *How Much Do U.S. Hospitals Spend on Medical Supplies?*. Retrieved from https://hmpi.org/2017/09/09/how-much-do-u-s-hospitals-spend-on-medical-supplies/

Herzlinger, R. (2006, May 1). Why innovation in health care is so hard. *Harvard Business Review*. Retrieved from https://hbr.org/2006/05/why-innovation-in-health-care-is-so-hard

Innomed. (n.d.). *Gray syringe assist with ergonomic handle* [Fact sheet]. Retrieved from http://www.innomed.net/PDFsInnomed/InnoGraySyringeAssist.pdf

Johnson, D. (2005). Social construction of technology. In *Encyclopedia of Science, Technology, and Ethics* (Vol. 1, p. 1791–1795). Detroit, MI: Macmillan

Karlamangla, S. (2020, March 25). There are no masks left in L.A. County's emergency stockpile. *Los Angeles Times*. Retrieved from https://www.latimes.com/

Letzter, R. (2020, March 24). Doctors scramble for best practices on reusing medical masks during shortage. *Livescience*. Retrieved from https://www.livescience.com/sanitizing-medical-masks-for-reuse-coronavirus.html

Lindsey, D. (2018). *Mechanical device compatible with a syringe to perform single handed knee aspiration* (Technical Report). University of Virginia, Charlottesville, VA.

Madison House Medical Services. (2019). *Volunteer handbook 2019-2020* [Brochure]. Retrieved from https://static1.squarespace.com/static/55ab1302e4b0ea19042e75fa/t/5d69696cfbbeca0001129ec2/1567189357741/Medical+Services+2019-2020+Unit+Handbook.pdf

Maricar, N., Callaghan, M., Parkes, M., Felson, D., & O′Neill, T. (2016). Clinical assessment of effusion in knee osteoarthritis—A systematic review. *Seminars in Arthritis and Rheumatism*, *45*(5), 556–563. https://doi.org/10.1016/j.semarthrit.2015.10.004

Martin, M., & Schinzinger, R. (2010). *Introduction to engineering ethics* (2nd ed.). New York, NY: McGraw-Hill Higher Education.

Mayo Clinic. (2018, April 21). *Swollen knee—Symptoms and causes*. Retrieved from https://www.mayoclinic.org/diseases-conditions/swollen-knee/symptoms-causes/syc-20378129

McGain, F., Story, D., Lim, T., & McAlister, S. (2017). Financial and environmental costs of reusable and single-use anaesthetic equipment. *British Journal of Anaesthesia, 118*(6), 862–869. https://doi.org/10.1093/bja/aex098

The New York Times. (n.d.). *Peter Eavis*. Retrieved from https://www.nytimes.com/by/peter-eavis

Pinch, T., & Bijker, W. (1984). The social construction of facts and artefacts: Or how the sociology of science and the sociology of technology might benefit each other. *Social Studies of Science*, *14*(3), 399-441.

Practicon. (n.d.). *6-1/2" X 10" EnviroPouch reusable cassette sterilization pouch*. Retrieved from https://www.practicon.com/6-1-2-x-10-enviropouch-reusable-cassette-sterilization-pouch/p/7037413

Ragan, G. (2007). Innovative recycling options for biomedical research facilities. *Chemical Health & Safety*, *14*(6), 17–20. https://doi.org/10.1016/j.jchas.2006.12.001

SmileDirectClub. (n.d.). *Affordable teeth straightening aligners.* Retrieved from https://smiledirectclub.com/pricing/

Solberg, K. (2009). Trade in medical waste causes deaths in India. *The Lancet*, *373*(9669), 1067. https://doi.org/10.1016/S0140-6736(09)60632-2

Tom Vanderbilt. (n.d.). *About The Author*. Retrieved from https://tomvanderbilt.com/about/

U.S. Food and Drug Administration (2000, February 2). *Reprocessing and reuse of single-use devices: Review prioritization scheme*. Retrieved from https://www.fda.gov/media/71761/download

U.S. Food and Drug Administration (2018, September, 27). *Reprocessing of reusable medical devices: Information for manufacturers*. Retrieved from https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/reprocessing-reusable-medical-devices-information-manufacturers

U.S. Food and Drug Administration (2019, November 26). *Ethylene oxide sterilization for medical devices*. Retrieved from http://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices

Vanderbilt, T. (2019, February 4). *"*Reverse innovation" could save lives. Why aren't we embracing it?. *The New Yorker*. Retrieved from https://www.newyorker.com/

Wallace, I., Worthington, S., Felson, D., Jurmain, R., Wren, K., Maijanen, H., Woods, R., & Lieberman, D. (2017). Knee osteoarthritis has doubled in prevalence since the mid-20th century. *Proceedings of the National Academy of Sciences of the United States of America*, *114*(35), 9332–9336. https://doi.org/10.1073/pnas.1703856114

Williams, P. (1997). Physician reimbursement mechanisms as social constraints: An historical critique of Douglass North's theory of institutional evolution. *Politics and the Life Sciences*, *16*(2), 289–298. Retrieved from https://www.jstor.org/stable/4236367

World Health Organization. (2018, February, 8). *Health-care waste*. Retrieved from https://www.who.int/en/news-room/fact-sheets/detail/health-care-waste

World Health Organization. (2020, March 11). *WHO Director-General's opening remarks at the media briefing on COVID-19—11 March 2020*. Retrieved from https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020