A Duty Ethics Analysis of the Use of Reprocessed Medical Devices by Physicians

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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

Healthcare facilities are the second leading contributor to waste in the United States producing more than 40 billion pounds of waste annually (Kwakye et al., 2011). This waste is not only a problem environmentally, polluting bodies of water and contributing to greenhouse house emissions, but also economically, costing an average of $790 per ton to dispose (Windfeld & Brooks, 2015). Operating rooms and labor-delivery suites specifically produce about 70% of all medical waste in hospitals, the majority of which is single-use medical products (Albert & Rothkopf, 2015; Conrardy et al., 2010). Consequently, many studies have identified reducing the single-use waste produced by physicians as a key strategy for improving the fiscal and environmental impact of medical waste on hospitals.

However, many hospitals and physicians are reluctant to adopt new strategies or technologies that reduce waste production due to ethical concerns surrounding patient care. For example, one solution which has emerged to decrease single-use device waste is the reprocessing of single-use devices. This process allows hospitals to reuse many products labelled as "single-use", significantly reducing their costs and waste production. However, many physicians have ethical concerns about using reprocessed single-use devices. As a result, many physicians report feeling uncomfortable about using reprocessed devices, and single-use disposable products continue to be predominant throughout the medical industry, further augmenting the economic and environmental costs of healthcare (Grantcharov et al., 2019).

I believe that viewing the use of reprocessed medical devices through a duty ethics framework may shed light on this morally ambiguous practice. Specifically, I plan to use the American Medical Association's (AMA) Nine Principles of Medical Ethics to explore the ethics of reprocessed single-use products by assessing its alignment with physician's ethical duties as

outlined by the AMA's nine key principles. By doing this, I hope to provide an ethical framework through which physicians may evaluate future technological developments that aid hospitals in reducing their waste.

Background

Reprocessing refers to a "detailed, multi-step process to clean and then disinfect" a medical device after being opened or used in a clinical setting (Dunn, 2002; Health, 2019). The practice of reprocessing single-use devices began in the 1970s, but has remained controversial throughout the medical industry due to the regulatory, ethical, medical, legal, and economic challenges involved in reusing a device labelled as "single-use". (*Single-Use Devices | CDC*, 2019). According to the Center for Disease Control and Prevention (CDC), approximately 20-30% of all hospitals in the United States reported reusing at least one single-use medical device. These devices are regulated by the Food and Drug Administrator (FDA), and hospitals and third-party reprocessors are subject to the same FDA regulation as device manufacturers (Health, 2019). The FDA currently allows for 79 devices, ranging from surgical knives, to catheters, to elastic bandages, to be reprocessed and reused for surgery. (Grantcharov et al., 2019).

Physicians have an influential role in determining what technology is implemented within a hospital. Physicians request equipment from hospitals, initiate new product trials and evaluations, and make decisions about what equipment should be used to diagnose and treat patients (Dunn, 2002). Consequently, physicians have the ultimate say over whether reprocessed medical devices, and other similar technologies, are used.

Literature Review

Many scientific articles published within medical and public health journals explore the technical and safety challenges of reprocessed single-use devices. These articles often analyze the sterility, durability, and economics of specific reprocessed single-use devices in order to determine the viability of reprocessing them. Many studies have demonstrated the safety and cost-efficiency of reprocessing common disposable devices, such as heart catheters, and found that they pose no additional risk compared to single-use devices (Chen, 2010; Collier, 2011; Dunn, 2002; Lee et al., 2007). However, certain scholars still resist the use of single-use devices by citing their potential for harm to patients and the insufficiency of studies proving their safety. For example, in a hearing before the Committee on Oversight and Investigations in the U.S. House of Representatives, opponents of reprocessed single-use devices claimed that "the possibility exists that injuries associated with the use of reused single-use devices occur more frequently than reported because current methods of patient surveillance are, in general, lacking" and a as a result, single-use devices should not be reused until the risks are better understood. (Feigel, 2000). Due to this controversy, evaluating the ethics of reprocessed device use is very difficult, and many scholars avoid "picking a side" in the debate.

In *The ethics of reusing single-use devices,* Roger Collier presents a broad analysis of the various ethical considerations surrounding the reuse of single-use products. Collier begins his essay by discussing the issue of patient consent when using reprocessed single-use devices. Collier argues that on one hand, patient consent may not be needed if hospitals have policies to ensure reused devices are as safe and effective as new ones. However, on the other hand, Collier states that not acquiring patient consent could be seen as "hidden rationing" and does not respect patient autonomy while exposing patients to a higher risk of infection. He then approaches the

use of reprocessed single-use devices from a financial and utilitarian point of view, and states that not reusing devices that can be reprocessed is unethical if it can be safely used again and save a hospital money. However, as with the issue of patient consent, Collier points out that the fiscal burden incurred by hospitals if patients suffer harm after using a reprocessed device may outweigh the cost-savings of reprocessing. Collier also analyzes reprocessed devices from an environmental view, and states that their use may be ethical due to their positive environmental impact. Collier concludes by saying that the issue is "complicated" and that the true solution may be designing products that are meant to be reused long term (Collier, 2011). Thus, Collier avoids passing any definitive judgement on the ethics of using reprocessed single use products.

An independent study by the Association of periOperative Registered Nurses (AORN) titled *Reprocessing Single-Use Devices - The Ethical Dilemma* also explores the complex ethical questions surrounding this issue. Similar to Collier, this essay identifies multiple ethical concerns with reprocessed single-use devices such as: patient consent, patient safety, patient populations on which reprocessed devices will be used, and patient charging (Dunn, 2002). The essay takes a multi-faceted approach to analyzing these ethical concerns and presents multiple perspectives and arguments. However, like Collier's article, the essay avoids making any definitive moral judgement, and instead suggests that the subject should continue to be investigated.

Subsequently, although current literature exploring this ethical dilemma contains arguments both for and against the use of reprocessed disposable devices, it does not provide the physician with a framework to evaluate this moral quagmire. In addition, no current literature has directly applied tenets of medical ethics as a means of framing this problem. This paper will attempt to evaluate physician use of reprocessed single-use devices by using a duty ethics framework in order to address this void in the literature. This will provide a sample framework

through which physicians may better evaluate the use of future medical technologies or processes, focusing on cost-savings and sustainability.

Conceptual Framework

The ethics of using reprocessed single-use medical devices can be analyzed using a duty ethics framework. Duty ethics, or deontological ethics, is an ethical theory that uses rules or principles to distinguish right from wrong (University of Texas at Austin, 2020). According to duty ethics, actions are morally acceptable "if it is in agreement with a moral rule that is applicable in itself, independent of the consequences of that action" (van de Poel & Royakkers, 2011). Conversely, actions that contradict a set moral rule are morally unacceptable and should be avoided.

A clear example of deontological ethics can be seen in many religious texts, including the Ten Commandments found in the books of Exodus and Deuteronomy in the Old Testament (Kerns, 2013). The Ten Commandments lay out rules that followers have a duty to observe including "honor your father and mother", and "you shall not murder" (Harn, 2007). Regardless of the situation, these rules are unchanging and actions that violate these principles are considered amoral. Thus, unlike other ethical frameworks, duty ethics avoids questions of subjectivity and theoretical consequences by focusing on the nature of the action rather than the results.

Duty ethics, in the form of medical codes, have been common in medicine throughout history. For example, one of the oldest known examples of a medical code, The Hippocratic Oath, is based on deontological ethics. In the Hippocratic Oath, physicians swear a duty to uphold specific ethical standards that are considered the essential to be a moral physician

(Veatch, 2000). Actions that uphold these ethical standards are considered moral, whereas actions that violate the oath are considered immoral. Versions of this code, as well as other medical codes continue to be used within the medical profession, showing the relevance of deontological ethics to modern medicine (Crawshaw, 1994).

In order to apply duty ethics to a physician's use of reprocessed single-use devices, a specific set of independent rules that encapsulate a physician's ethical ideals are needed. Accordingly, I will be using the American Medical Association's (AMA) Nine Principles of Medical Ethics as the basis for determining whether or not a physician's actions are ethical. These principles are the basis of the AMA's Code of Medical Ethics, and provide ethical guidance to physicians regardless of specialty (*AMA Principles of Medical Ethics*, 2020). These principals are as follows:

The Nine Principles of Medical Ethics

I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.

II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.

III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.

IV. A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.

V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.

VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.

VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.

VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.

IX. A physician shall support access to medical care for all people.

Figure 1: American Medical Association's Nine Principles of Medical Ethics

According to the AMA, these principles define the basis of "honorable behavior" that physicians have a duty to follow. Actions that violate these principles are considered unethical.

In this paper, I will argue that reprocessed single-use devices are ethical due to the fact that their use aligns with the AMA's Nine Principles of Medical Ethics. I will do this by examining ways in which the use of reprocessed devices complies with the Principles of Medical Ethics, and therefore ethical behavior, with a specific emphasis on how it compares to the continued use of single-use devices.

Analysis

Three specific principles of the AMA's Nine Principles of Medical Ethics can be used to examine the use of reprocessed medical devices: principle V, VII, and IX. These principles are most relevant to a physician's use of medical technology in comparison to the other principles, which mainly focus on a physician's relationships with patients and the law. They are as follows:

Medical Ethical Principles to be Used in Analysis

V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.

VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.

IX. A physician shall support access to medical care for all people.

Figure 2: American Medical Association's Medical Ethics Principles Applied in Analysis

Compliance with these principles are essential for ethical behavior, as they form the basis from which the entire Code of Medical Ethics is formed. As a result, actions that uphold these principles can be deemed ethical and actions that refute these principles can be deemed unethical. The following section will examine each of the aforementioned principles as they relate to reprocessed single-use devices in order to assess their morality.

Principle V: Commitment to Scientific Knowledge

The use of reprocessed medical devices can be viewed as morally just due to its accordance with Principle V of the AMA Nine Principle of Medical Ethics. This principle states: "A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated." In essence, this states that an action which applies or advances scientific knowledge is ethical, so long as it does not cause harm to the patient (*AMA Principles of Medical Ethics*, n.d.).

Many scientific studies have explored the benefits of implementing reprocessed single use devices. In a study conducted by Unger & Landis, the environmental, human health, and economic impacts of reprocessed medical devices was evaluated at Phoenix Baptist Hospital in Phoenix, Arizona. This study performed a full life cycle assessment of reprocessed medical devices, allowing the researchers to examine their full effects in comparison to disposable devices. The study found that reprocessed devices are beneficial from both a global warming and human health perspective, and have a significant financial benefit to the hospital (Unger & Landis, 2016). This study evidences scientific knowledge that proves the effectiveness of reprocessed medical devices. In the context of Principle V, the use of reprocessed devices is therefore ethical because it is a direct application of scientific knowledge.

Several scientific studies and investigations have also found reprocessed devices to be safe. According to guidelines published by the CDC, "investigators have demonstrated it is safe to reuse disposable medical device, such as cardiac electrodes", and there are no known additional risks to using a reprocessed single-use device if sterilized correctly (*Single-Use Devices | CDC*, 2019). These guidelines also detail the regulatory steps that hospitals must undergo with the FDA in order to use reprocessed single-use devices These regulatory steps include the submission of a 510(k) which must "provide scientific evidence that the [reused] device is safe and effective for its intended use" (*Single-Use Devices | CDC*, 2019). Consequently, the CDC's guidelines indicate that scientific investigations have proven the safety of reprocessed single-use devices, and that hospitals must undergo scientific scrutiny before reprocessing single-use devices. This evidence is supported by a report presented to the U.S. House of Representatives Committee on Oversight and Investigation where the director of the Food and Drug Administration stated that no published scientific data has implicated reprocessed

devices in increased health risks in the United States (Feigel, 2000). Thus, there is established scientific knowledge from governmental institutions that support the safety of reprocessed medical devices, further supporting the idea that the use of these devices is ethically justified in relation to Principle V.

It should be noted that the evidence presented is only considering physicians and studies within the United States. Internationally, scientific studies have found that reprocessed single-use devices pose a public health risk due to improper or unvalidated reprocessing techniques (Collier, 2011). Accordingly, this analysis only considers published literature from the United States, where reprocessed medical devices are subject to more stringent regulation, and healthcare institutions can be held accountable to the sterilization standards needed to prevent patient harm.

Principle VII: Contribute to the Betterment of Public Health

The use of reprocessed medical devices by physicians can also be considered ethical when examining it in relation to Principle VII of the AMA's Nine Principles of Medical Ethics. According to Principle VII : "A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health." (*AMA Principles of Medical Ethics*, 2020). Consequently, this principle states that physicians have an ethical duty to take actions that improve public health.

As mentioned earlier, several studies have demonstrated the direct human health benefits of reprocessed single use devices. In the study conducted by Unger & Landis., the amount of PM10 emitted during the lifetime of a reprocessed medical device was lower than that of disposable devices (Unger & Landis, 2016). PM10 is a common air pollutant associated with

many respiratory and cardio-vascular diseases and has been found to decrease lung function (Gilmour et al., 1996). Accordingly, by using reprocessed devices, physicians can actively improve public health by decreasing the air pollution emitted by hospital waste. Thus, these direct human health benefits make reprocessed devices ethically acceptable according to Principle VII.

The use of reprocessed medical devices compliance with Principle VII is further supported by the massive effects that climate change is projected to have on public health. According to the International Panel on Climate Change (IPCC), climate change is the greatest threat to global health in the 21st century. From temperature extremes and degraded air quality to increases in vector-borne illnesses and malnutrition, climate change is poised to have an enormous impact on human health around the globe (*AR5 Climate Change 2013: The Physical Science Basis—IPCC*, 2013; *COP24 Special report*, 2018). Many studies have demonstrated the link between climate-change and human health, and the World Health Organization (WHO) projects that climate change will lead to 250,000 additional deaths between 2030 and 2050, and cost the healthcare industry 2-4 billion USD per year by 2030 (*Climate change*, n.d.).

In order to avoid the most disastrous effects of climate change, emissions must be cut considerably, especially in the healthcare industry (Rogelj et al., 2018). To put healthcare emissions into perspective: the aviation industry, a notoriously polluting industry, produces about 3% of the United States' national greenhouse gas emissions while the healthcare industry produces about 8% (*Fact Sheet: The Growth in Greenhouse Gas Emissions from Commercial Aviation | White Papers | EESI*, n.d.; *WHO | Climate impacts*, n.d.). According to the Association of Medical Device Reprocessors, reprocessing common single-use devices would allow hospitals to divert over 50,000 pounds of medical waste per a year from greenhouse gas

emitting incinerators and landfills (AMDR, 2020a). Furthermore, the lifetime analysis conducted by Unger et al. found a slight decrease in greenhouse gas emissions when reprocessing was performed (Unger & Landis, 2016). Consequently, the use of reprocessed devices is an effective measure for reducing healthcare's carbon footprint and mitigating climate change. This mitigation contributes to improving the global public health, thereby aligning with Principle VII.

Acknowledgement & Response

Thus far, I have argued that the use of reprocessed medical devices is beneficial to public health due to its lower PM10 and greenhouse gas emission rates per use, and is therefore in agreement with Principle VII. However, many of the ethical objections to the use of reprocessed single use devices stem from the potential health hazards posed by these devices if reprocessed incorrectly. For example, in the AORN independent study the authors question whether the potential risks of cross-contamination, infection, and device malfunction associated with reprocessed devices is worth the economic and environmental benefits when a safer alternative is available in disposable products (Dunn, 2002). Furthermore, some studies indicate that even when effectively disinfected, reusable devices may still carry microorganisms that increase the risk of contracting non-resistant or nosocomial organisms and viruses (Heeg et al., 2001). Subsequently, opponents of reprocessed single-use devices may point out that despite the environmental benefits (and consequent public health benefits) of this technology, reprocessed single use devices still present a risk to public health and are therefore unethical according to Principle VII.

To these criticisms I would respond that the risks associated with reprocessed medical devices are potential and contingent upon human error or dishonesty. As previously stated, reprocessed single-use devices are regulated by the FDA the same way as disposable devices

(Health, 2019). Accordingly, reprocessed devices must undergo the same scrutiny as regulated devices and therefore meet the same safety standards.

In addition, whereas the public health risks associated with reprocessed devices are contingent upon improper manufacturing or regulation, the public health risks of climate change are well documented, known, and inevitable unless action is taken. Accordingly, from a utilitarian point of view, it would be more beneficial for the healthcare industry to address a known problem that affects the entire global population, than a potential risk that relies upon human negligence. Furthermore, according to the IPCC, action must be taken immediately to mitigate the worst effects of climate change (*2019—IPCC*, 2019). The reprocessing of single-use devices is an actionable, proven technique that many hospitals already employ. Accordingly, by refusing to use these devices and proliferating single-use devices, physicians are actively causing harm to public health. Thus, even when considering the potential risks reprocessed devices pose, their use can still be seen as ethical through the lens of Principle VII.

Principle IX: Support Access to Medical Care

The last Principle of Medical Ethics which can be used to analyze the ethics of using reprocessed single use devices is Principle IX. This principle states: "A physician shall support access to medical care for all people." According to the U.S. Office of Disease Prevention and Health Promotion, one the largest barriers towards accessing healthcare in the U.S. is the high cost of care (*Access to Health Services*, 2020). For example, one study found that 13.7% of diabetics with coronary heart disease did not follow through with their recommended treatment plan due to the cost of medical care (Parikh et al., 2014). Consequently, cost is a defining factor in determining the accessibility of healthcare within the United States. As a result, actions that

help reduce the cost of healthcare are moral according to Principle IX, as a reduction in cost leads to a greater accessibility of healthcare.

The reprocessing of single-use devices has the potential to cut medical equipment costs significantly. Data from the Association of Medical Device Reprocessors found that hospitals can reduce the cost of single-use medical devices by up to 50% through reprocessing (AMDR, 2020b). This could greatly reduce the cost of medical procedures performed in hospitals, as equipment costs are a driving factor in the high cost of many procedures (Pauly & Burns, 2008). For example, a new heart catheter, a device commonly used in many cardiovascular procedures, can cost over $5000. (Rao, 2014). As a result, hospital charges for an inpatient cardiac catheterization procedure, which covers the cost of medical devices used during the procedure, can average $38,500. In comparison, professional fees, which covers the actual labor done by a cardiologist, only average $7,700 (Rao, 2014). However, by reprocessing heart catheters, hospitals can reduce the total amount of money spent on catheters by as much as 30%. (Thording, 2017). Thus, reprocessing heart catheters alone would save cardiovascular units thousands of dollars per a year in operating costs. This reduction could translate directly to cost-savings for patients, thereby increasing the overall accessibility of care, supporting Principle IX.

Conclusion

Reprocessed single-use medical devices are an environmentally friendly and cost-effective alternative to single-use devices. However, due to ethical concerns, many hospitals and physicians have been unsure about how to embrace this technology. Although further studies looking into the efficacy and safety of reprocessed medical devices will undoubtedly shape ethical discussions around their use, based on current research and a duty ethics framework, the

use of these devices by physicians can be viewed as ethical due to their alignment with three of AMA's Nine Principles of Medical Ethics. The framework used in this analysis may serve as an example through which physicians may examine the ethics of future technologies which aim to reduce medical costs and the environmental impacts of the healthcare industry.

As climate change, public health, and the cost of healthcare continue to evolve, the nature of these ethical conversations are likely to change. For instance, as the effects of climate change take develop, factors such as hospital greenhouse gas emissions may increase in importance in comparison to patient risk. Conversely, the development of a deadly, contagious pathogen (such as COVID-19) may cause hospitals to reprioritize efforts that reduce the risk of exposure, such as by adopting single-use devices. As a result, physicians should constantly question the ethical implications of their practices in order to do the most good in an ever-changing world.

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